

***REHABILITATION OF PATIENTS AGED OVER 65 YEARS
AFTER TOTAL HIP REPLACEMENT***

BASED ON PATIENTS' HEALTH STATUS

PH.D. THESIS

BRITTA HØRDAM



FACULTY OF HEALTH SCIENCES

UNIVERSITY OF AARHUS, DENMARK, 2007

Supervisors

Kjeld Søballe, MD, DMSc

Department of Orthopaedics

Aarhus University Hospital, Denmark

Svend Sabroe, MD, DMSc

Department of Clinical Epidemiology

University of Aarhus, Denmark

Preben U. Pedersen, Ph.D, Associate Professor

Department of Nursing Science

University of Aarhus, Denmark

Evaluation Committee

Kristian Stengaard-Pedersen, MD, DMSc

Department of Rheumatology

Aarhus University Hospital, Denmark

Marianne Schroll, MD, Professor Emerita

Klostervang 16, st.

4000 Roskilde, Denmark

Yrsa Andersen Hundrup, MN, Ph.D., Project coordinator

The Danish Nurse Cohort Study

Research Center for Prevention and Health

Department 84/85, Glostrup University Hospital, Denmark

Correspondence

Britta Hørdam, RN, MSc in Nursing, Ph.D-student

Department of Orthopaedics

Aarhus University Hospital, Denmark

Phone: +45 22214383 Fax: + 45 56147921

E-mail: bhoerdam@mail.dk

Table of contents

Rehabilitation of patients aged over 65 years after total hip replacement	1
Based on patients' health status	1
Ph.D.Thesis	1
Britta Hørdam	1
Faculty of Health Sciences	1
University of Aarhus, Denmark, 2007	1

Preface

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

I am deeply indebted to a number of persons who made this work possible.

First of all, I want to express my sincere gratitude to my supervisors Kjeld Søballe, Svend Sabroe, Preben U. Pedersen and Steen Mejdahl for their valuable and skilful guidance, discussion and support in the field of orthopaedic surgery.

I am especially grateful to my supervisor Kjeld Søballe for believing in me, continuously providing constructive ideas and support for my research and focus on the importance of nursing research as a part of the total field of research in orthopaedics.

I am also grateful to Svend Sabroe for being available with useful advice for data analyses, inspiring discussions, invaluable help and stimulating enthusiasm.

I am much obliged to Preen U. Pedersen for being helpful, stimulating talks, valuable input and encouragement to complete my research, demonstrating the importance of interdisciplinary collaboration within clinical orthopaedic practice.

I want to thank Steen Mejdahl and Jette Gram for being helpful, supportive and seeing the importance of interdisciplinary collaboration in orthopaedic clinical practice.

Furthermore, I want to thank my colleagues in the orthopaedic research unit for a creative, stimulating and supportive work environment during my research period.

For financial support, I would like to thank: Health Insurance Foundation in Denmark.

November 2007

Britta Hørdam

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+ after total hip-replacement
2. Hordam B, Pedersen PU, Mejdahl S, Sabroe S, Soballe K.
Intervention by telephone interviews improves health status of patients aged over 65 years after total hip replacement: a randomised clinical trial.
3. Hordam B, Pedersen PU, Keiding H, Soballe K.
Health-related quality of life of patients over 65 years after total hip replacement.

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 the development of specific rehabilitation and intervention in patients aged over 65 years after total hip replacement (THR) based on health status.

The project consists of 3 studies, first a description of patients' health status after THR, followed by a randomized clinical trial by using telephone interview and counseling postoperatively, and to test improvement in patients' health status after THR. Finally, to test the effect of nursing intervention by providing a measurement of patients' health related quality of life was carried out.

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+, 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 domains of health status after surgery.

In study 2 the aim was to study the effect during the first 9 months on health status of intervention by telephone interviews 2 and 10 weeks after the operation. Method: A randomised clinical trial of 180 patients aged over 65 years 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 over 65 years 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 over the age of 65 receiving conventional treatment after THA with patients having conventional treatment 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 over 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 tværsnitsundersøgelse, 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. Tværsnitsundersøgelsen 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 individuelle og specifikke tiltag baseret på patienternes helbredsstatus.

English summary

Each year an increasing number of total hip replacements are performed, especially in elderly men and women over 65 years of age because of osteoarthritis. It is well established that patients gain improved walking function and reduction of pain. By way of introduction, this research has described in a cross-sectional study 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 of intervention by telephone interview and advice from 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.

Additional research would be relevant in relation to intervention and follow-up over a longer period, with both telephone interviews and individual and specific interventions based the health status of patients.

1. Introduction

In Denmark with a population of 5 million people, approximately 20% of the population are over the age of 65 years, and the annual incidence of THR among patients aged 65+ is about 5000 (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 prognoses, the number of elderly will increase to 847.000 by the year 2020, i.e., 20 % of the total population (2). In the EU member states, over 190.000 THR's are performed every year. In the Nordic countries some 50000 THR's are carried out annually (3).

Because OA is the most frequent disease in people over the age of 65 years, the number of older patients that will need 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 far as aetiology, medical science has more or less shown what can provoke OA. None of these factors are, however, the direct cause of the arthritis, but accepted 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, uric arthritis, psoriasis 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 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 customs 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 placed in five 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 hospital, which also can include some of the private hospitals. 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 (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 then consists of the artificial ball, the stem and finally the socket. In 1925 the history of total hip replacement began in the USA, in Boston Massachusetts thanks to Marius Smith-Petersen, who invented an arthroplasty first of glass, which is a very fragile material, but later he used others materials including steel and plastic. During this period Frederisck R.Thomsen from New York and Austin T. Moore from South Carolina each independently developed a hemiarthroplasty, with which the acetabulum was not replaced. 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 THR is tremendous pain and reduced walking ability caused osteoarthritis (OA) especially among men and women aged over 65 years (1,5,7-9).

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

OA is the most frequent disease among people over 65 years of age.

The most common, and very effective, treatment is surgery with 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 do 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 described that patients more or less live the life they did before surgery and do not adapt to new possibilities of living (9, 11, 12).

For some persons, this type of surgery may not benefit the overall quality of life, as their health status does not improve accordingly

As a consequence, clinical effectiveness and the economic investment in health care from society must be considered simultaneously to derive 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 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 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 health care society-economic to evaluate its patient-related benefit in comparison to other treatments, which already underwent 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 need for 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 total hip replacement (13-15). Such a study has not yet been done in Denmark. A search of 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 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, focusing on pain and physical function, in which 96 patients answered a questionnaire 1 week preoperatively and 1 week and again 6 months postoperatively, 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, but were only satisfied with the surgery itself (24).

After THR, up to 98% of the patients experience pain relief (9,11,12, 17-28) and up to 80% of patients improve their walking ability, but only 33% of the patients reported 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 adapt to other new ways of living (19, 26, 27) 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 (12, 26-29) 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 (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).

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 (9, 26-29), and for this reason regarding the health status of patients research is needed.

By using questionnaire SF-36 it is possible 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 3 studies, first a description of patients' health status after THR that is followed by a randomized clinical trial by using telephone interview and counseling postoperatively. The objective is to test improvement in patients' health status after THR. Finally, to test the effect of nursing intervention by providing 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 the development of specific rehabilitation and intervention in patients aged over 65 years after THR based on health status.

2. Aims of thesis

Aims:

1. Study 1
 - a. To describe health status of patients with OA aged over 65 years following 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 over 65 years by using telephone interviews 2 and 10 weeks after surgery.
3. Study 3
 - a. To measure the difference in health-related quality of life between the intervention and the control group preoperatively and at follow-up 9 months after THR.

3. Material and methods

3.1 Study-population

Study 1

Patients over 65 years from five different counties in Denmark, who had had a THA within the last 12 months, were invited to participate in the study. As shown in table 1, a total of 314 patients from the hospitals' catchments areas who underwent THR from January 2000 to January 2001 were 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.

Table 1:

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	

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 over 65 years 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 2).

Among the dropout patients the mean age was 76.5 years and 31.5% were men v, mean age was 74.9 years (P=0.270) and 34.8% were 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 of 65 to 88 years. Characteristic of patients were similar at baseline in both the intervention and the control group (table 2).

Table 2:

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

3.2 Methodological considerations

Study 1

A cross-sectional study was carried out to describe health status of patients with OA aged over 65 years 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 SF-36 manual (34). All patients who had been consecutively admitted for THR were mailed an introduction letter together with a questionnaire containing a number and a prepaid return envelope. In the questionnaire they were asked to give demographic data and assess their health status. Patients' who had not responded within two 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 their surgery.

Figure 1:

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

Eight dimensions of health and well-being:

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

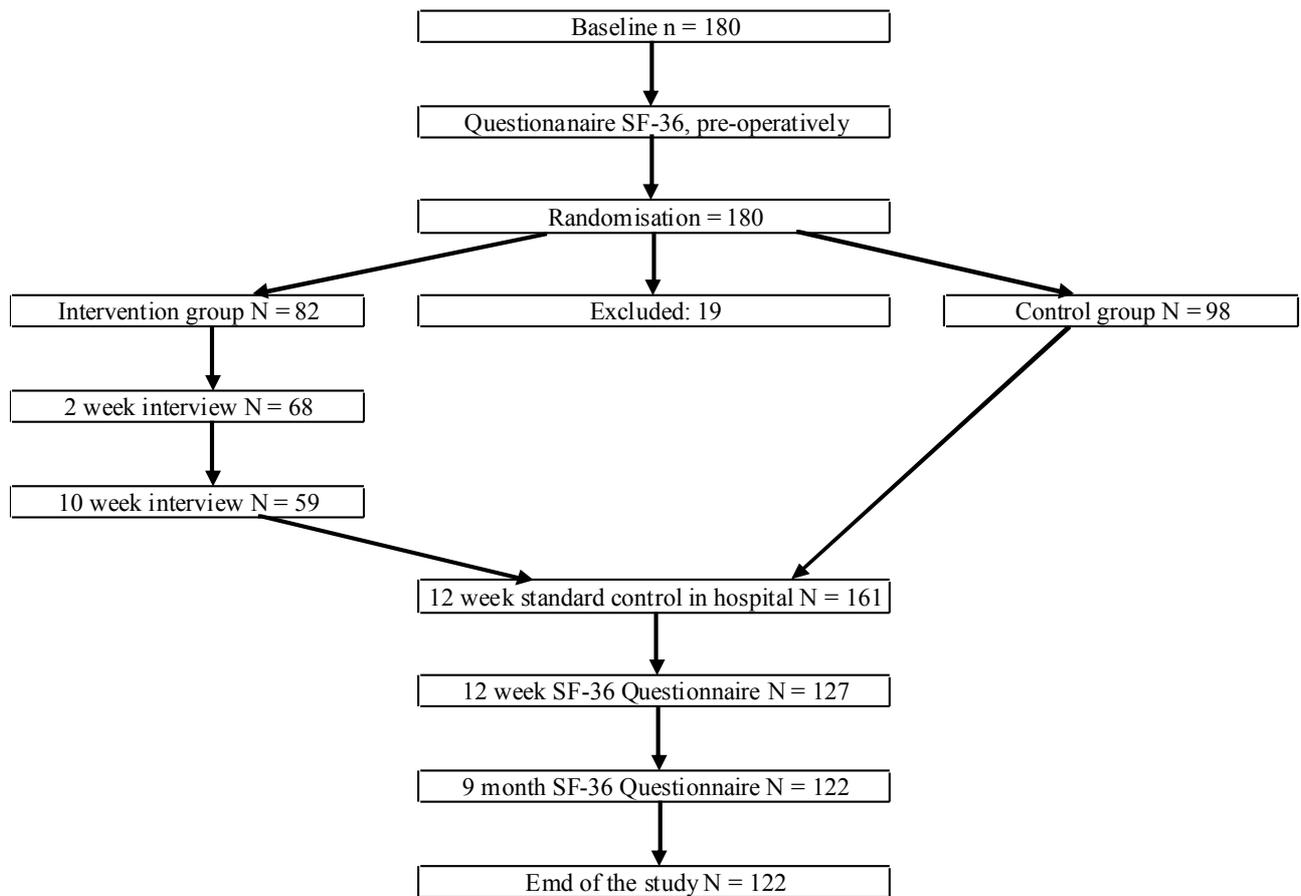
Study 2

Randomisation:

A randomized clinical trial was carried out between January 2005 and May 2007. All consecutive patients 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 program, 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.

Figure 2:

Flow chart:



Methods:

Patients received a mailed questionnaire 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 currently situations and need for further support and counseling 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 the 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. 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 counseling 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). 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 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 over 65 years after THR was measured. 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. 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 method described by Braizer (15). All patients received the standard treatment of the hospital. The intervention group had phone-monitoring consisting of support and advices 2 and 10 weeks after surgery. The phone 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). 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 Braizer (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 twice. Had the patients still not returned the questionnaire after the reminders 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 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 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 Braizer (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 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. 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+ after total hip-replacement (THR).

In this cross-sectional study, patients aged of 65-95 years were enrolled from hospitals in five different counties in Denmark. More that 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 reviled a significant difference in six out of eight health dimensions 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=(found variation of the group averages)/(expected variation of the group averages)

	F	P
Dysfunction		
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
General Health		
General health perception (GH)	5.619	0.000
Vitality (VT)	5.221	0.000
Mental health (ME)	3.295	0.012

Physical dysfunction:

Table 4 shows the scores from men and women divided into two age groups (65-74 and 75+). Overall women had a significantly lower RP and SF score 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 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 ($P= 0.007$).

Table 4:

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

Age	Men		p	Women		p
	65-74 n=63	75 n=42		65-74 n=91	75 n=86	
Dysfunction						
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
General Health						
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

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.

Table 5: Odds ratios for having a score of self-rated health above the population's 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)	1.53(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.

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 randomized 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 26.5% were men ($P = 0.173$), 75.8% were living alone ($P = 0.030$), and 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 intervention group eight patients dropped out. These patients had significantly lower scores at baseline within the dimension of BP ($P = 0.032$).

Table 6

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	.000	55.7	.000	32.0	51.6	.000	52.8	.000
RP	14.7	30.3	.011	38.5	.000	13.3	24.1	.064	38.9	.000
BP	30.6	56.6	.000	64.3	.000	31.5	53.7	.000	57.4	.000
GH	55.1	61.5	.526	61.5	.630	52.8	61.6	.000	60.6	.007
VT	41.5	64.9	.000	59.1	.000	41.2	52.9	.000	56.3	.000
SF	61.3	75.6	.002	77.7	.000	60.3	74.3	.007	76.7	.006
RE	34.8	45.0	.605	50.9	.114	38.0	41.6	.858	48.3	.190
MH	64.5	72.0	.073	75.9	.002	63.5	72.9	.000	74.4	.000

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		P-value
	Intervention	Control		Intervention	Control	
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	2.5-4.8		1.6-9.9	4.5-7.4	
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 from preoperative to 3 and 9 months after surgery in the control and intervention group.

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 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=.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 three months postoperatively. The patients that dropped-out had a QALY of .3734 (.1874) vs .5516 (.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 over 75 years had significantly lower health status than women aged 65 to 74. Women aged 75+ 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 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 (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 as only 4-8% of patients scored 100 on at least one scale.

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 sex 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 depressions 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. Hence, it 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 therefore show, that the patients' activities of daily living and self-care ability were compromised and that a rehabilitation programme aimed at improving these dimensions could be needed.

However, intervention research is needed before such a programme 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.

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

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 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.

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 with THR. Moreover, there is 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 with possibilities for nurses to purposefully guide patients in reaching their optimal health-related quality of life.

One way could be planning specific rehabilitation and intervention preoperatively based on health status, knowing from study 1, that 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 (75+) had significantly lower health status than women aged 65-74 years. Women aged 75+ had generally the lowest score of health status.

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 for development of patients' health status.

Identification of patients at risk of having a low health status would improve the total outcome of surgery. 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 patients' possibilities for a higher score.

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 telephone interviews after surgery increase patient health status during the first 3 months after THR compared with conventional treatment.

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 effect.

8. References

1. Danish Hip Arthroplasty Registry 2005. Annual report. Available from URL.:<http://www.dhr.dk>; 2005.
2. Danmarks Statistik. www.statistikbanken.dk 2004
3. Health Statistic in the Nordic Countries 2004. Received 20th December 2006; from <http://www.finlex.fi>.
4. Ministry of Interior and health. Health Care in Denmark .2003; available from: URL.: <http://www.im.dk/Index/publikationer.asp?s=5&n=3&o=2&t=5>).
5. The Danish Rheumatism Association. www.gigtforeningen.dk Researchresults; 2005.
6. Regeringen. Sund hele livet – de nationale mål og strategier for folkesundheden 2002 – 2010. København, Indenrigs- og Sundhedsministeriet; 2002.
7. Pedersen A.B. Studies based on the Danish Hip Arthroplasty Registry. Ph.D.-thesis, University of Aarhus, Denmark 2006.
8. Iversen L, Kristensen TS, Holstein BE, Due P. Medicinsk sociologi. Munksgaard Danmark; 2002.
9. Croft P, Lewis M, Wynn Jones C, Coggon D, Cooper C. Health status in patients awaiting hip replacement for osteoarthritis. *Rheumatology* 2000; 41:1001-7.
10. Bjerne JB, Thunedborg K, Kristensen TS, Modvig J, Bech P. The Danish SF-36 Health.Survey: Translation and Preliminary Validity Studies. *J Clin Epidemiol* 1998; 51(11): 991-9.
11. Holmberg Sv. Life Expectancy After Total Hip Arthroplasty. *The Journal of Arthroplasty* 1992;7 (2):183-187.
12. Lieberman JR, Dorey F, Shekelle P, Schumacher L, Kilgus DJ, Thomas BJ, Finerman GA. Outcome after total hip artroplasty. Comparison of a traditional Disease-specific and a quality-of-life measurement I: *Journal of Artroplasty*, 1997;12(6):639-45.

13. Pedersen K.M, Wittrup-Jensen K., Brooks R., Gudex C.: Værdisætning af sundhed. Syddansk Universitetsforlag. Odense 2006.
14. Drummond M., McGuire A.(ed): Economic evaluation in health care. Oxford University Press, Oxford. 2006.
15. Brazier J et al. Deriving a preference-based single index from the UK SF-36 Health Survey, J Clin Epidemiol 1998;51:1115-1128.
16. Visuri T, Honkanan R. The Influence of Total Hip Replacement on Selected Activities of Daily Living and on the Use of Domestic Aid. Scand J Rehab Med 1978;10:221-225.
17. Rissanen P, Aro S, Sintonen H, Slätis P, Paavolainen P. Quality of life and functional ability in hip and knee replacement: A Prospective Study. I: Quality-Of-Life-Research 1996;5(1): 56-64.
18. Jacobsson S-A, Rehnberg C, Djerf K. Risks, Benefits and Economic Consequences of Total Hip Arthroplasty in an Aged Population. Scand J Soc Med 1991;19(1):72-78.
19. Södermann P, Malchau H, Herberts P. Outcome after total hip arthroplasty. Acta Orthop Scand 2000;71(4):354-359.
20. Wiklund I, Romanus B. A Comparison of Quality of Life Before and After Arthroplasty in Patients Who Had Arthrosis of the Hip Joint. The Journal of Bone and Joint Surgery 1991; 73A(5):765-770.
21. Munk S, Pedersen KM, Helmer-Hansen HB. Hoftesmerter og fysisk helbredsstatus før og efter total hoftealloplastik. I:Ugeskrift for Læger 1988;150 (5); 281-283.
22. Moiniche S, Hansen BL, Dahl SE, Berg J, Kehlet H. Patientaktivitet og indlæggelsestid efter hoftealloplastik med balanceret smertebehandling og tidlig mobilisation. Ugeskrift For Læger 1992; 21: 1495-1499.
23. Hansen LN, Overgaard S, Knudsen HM, Mossing N. Alders- og kønsspecifik incidens af primær total hoftealloplastik i Sønderjyllands Amt. I: Ugeskrift for læger 1993;155(36): 2777- 2799.

24. Hindso K, Nicolajsen K, Carlsen AW. Kvalitetssikring af patientinformation – før knæ- og hoftealloplastik. I: Ugeskrift for læger 1994; 156(31):4470-4474.
25. Ragab A. Validity of self-assessment outcome questionnaires: patient-physician discrepancy in outcome interpretation. *Bio med Sci Instrum* 2003;(39):579-84.
26. Mahomad NN, Liang MH, Cook EF, Daltroy LH, Fortin PR, Fossel AH, Katz JN. The importance of patient expectation in predicting functional outcomes after total joint arthroplasty. *J Rheumatol* 2002;29(6):1273-9.
27. Smith C. Total Hip Replacement. I: *Nursing Times* 1989; 85:(46): 15-21,28-31.
28. Lyndell J Brodie, Rodney M. Sloman. Changes in Health Status and Elderly Patients Following Total Hip Replacement Surgery, *Gerontological Nursing* 1998;24(3):5-12.
29. Ackermann IN, Severely compromised quality of life in women and those of lower socioeconomic status waiting for joint replacement surgery. *Arthritis & Rheumatism* 2005;5: 563-68.
30. Hirvonen J, Health-related quality of life in patients waiting for major joint replacement. A comparison between patients and population controls. *Health and Quality of Life Outcomes* 2006; 4:3 doi: 10.1186/1477-7525-4-3.
31. Bachmeier CJM, et al. A comparison of outcomes in osteoarthritis patients undergoing total hip and knee replacement surgery. *Osteoarthritis Cartilage* 2001;9:137-46.
32. Nilsson A-K, Age and waiting time as predictors of outcome after total hip replacement for osteoarthritis. *Rheumatology* 2002;41:1261-67.
33. Bjorner J, Kristensen TS, Orth-Gomer K, Tibblin G, Sullivan M, Westerholm P. Self-Rated Health, a useful concept in research, prevention and clinical medicine. Swedish Council For Planning Of Research. Uppsala 1996.
34. Bjorner J, Damgaard M, Watt T, Bech P, Kristensen T, Modvig J, Thuneborg K.: Dansk Manual til SF-36, Lif. København 1997.

35. Gandek B, Ware JE Jr. Translating Health Status Questionnaires and evaluating their quality: The IQOLA Project Approach. I: J Clin Epidemiology 1998;51(11):913-923.
36. Ware JE, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). Medical Care 1992;30(6):473-83.
37. Nielsen T, Kreiner S, SPSS Introduktion til databehandling og statistisk analyse. Jurist- og Økonomforbundets Forlag, 2003; 2 udgave, 1 oplag.
38. Savage LS. Telephone Monitoring After Early Discharge For Cardiac Surgery Patients. I: American Journal of Critical Care 1999;8(3):154-160.
39. Ostendorf M, Stel HF van, Buskens E, Schrijvers AJP, Marting LN, Verbout AJ, Dhert WJA. Patient-reported outcome in total hip replacement. I: The Journal of Bone & Joint Surgery 2004;(86-B):801-808.
40. Sjolund H, Wiklund I, Caidahl K, Hartford M, Karlsson T, Herlitz J. Improvement in quality of life differs between women and men after coronary artery bypass grafting. I: J Intern Med 1999;245:445-54.
41. Barnason S, Zimmerman L, Anderson A, Mohr-Burt S, Nieveen J. Functional status outcomes of patients with a coronary artery bypass graft over time. I: Heart Lung 2000;29:33-46.
42. Vaccarino V, Lin ZQ, Kasl SV, Mattera JA, Abrahamson JL, Krumholz HM. Gender differences in recovery after coronary artery bypass surgery. I: Journal of American Collegium of Cardiology 2003;41:307-14.
43. Westin L, Carlsson R, Erhardt L, Cantor-Graae E, McNeil T. Differences in quality of life in men and women with ischemic heart disease. I: Scand Cardiovasc J 1999;33:160-5.
44. Czajkowski S, Terrin M, Lindquist R, Hoogwerf B, Dupuis G, Shumaker SA, Gray JR, Herd JA, Tret-Jacobson D, Zyzanski S, Knatterud GL. Comparison of postoperative characteristic of men and women undergo coronary artery bypass grafting (The post coronary artery bypass graft CABG biobehavioral study). I: Am J Cardiol 1997;79:1017-24.

45. Hoogwerf B, Dupuis G, Shumaker SA, Gray JR, Herd JA, Tret-Jacobson D, Zyzanski S, Knatterud GL. Comparison of postoperative characteristic of men and women undergoing coronary artery bypass grafting (The post coronary artery bypass graft CABG biobehavioral study). I: Am J Cardiol 1997;79:1017-24.
46. Garbuz D. S. Et al.: Patients' Outcome After Total Hip Arthroplasty.I: The Journal of Arthroplasty 2006;21(7):998-100.

9. Figures & tables

List of figures:

Figure 1: Health dimensions in SF-36 reflecting dysfunction and general health (page 24).

Figure 2: Flow-chart of study-population in the randomized clinical trial (page 26).

List of tables:

Table 1: Study population of study 1 – a cross-sectional study (page 22).

Table 2: Study population of studies 2 and 3 in a randomised clinical trial (page 23).

Table 3: A one-way analysis of variance of differences between scores from the five participating hospitals (study 1) (page 32).

Table 4: Mean score of self-rated health in two age groups stratified by gender (study 1) (page 34).

Table 5: Odd ratios for having a self-rated health score above populations means (study 1) (page 35).

Table 6: Health status of patients in the intervention and control groups at baseline and at 3 and 9 months after total hip replacement (study 2) (page 37).

Table 7: Differences in health status between intervention and control patients from baseline to 3 and 9 months after total hip replacement (study 2) (page 38).

Table 8: Development in health-related quality of life from preoperative to 9 months after surgery in the control and intervention groups (study 3) (page 39).

10. APPENDIX

Original papers

1. A cross-sectional study of health status in Danish patients aged 65+ after total hip-replacement.
2. Intervention by telephone interviews improves health status of patients aged 65+ after total hip replacement: a randomised clinical trial.
3. Health-related quality of life of patients over 65 years after total hip replacement (THR).