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Johanna Hirvonen

Effect of Waiting Time on Health Outcomes and Service Utilization

A Prospective Randomized Study on Patients Admitted to Hospital for Hip or Knee Replacement

STAKES

National Research and Development Centre
for Welfare and Health

Research Report 170

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Abstract

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Although the principle of equal access to medically justified treatment has been promoted by official health policies in many Western health care systems, practices do not completely meet policy targets. Waiting times for elective surgery vary between patient groups and regions, and growing problems in the availability of services threaten equal access to treatment. Waiting times have come to the attention of decision-makers, and several policy initiatives have been introduced to ensure the availability of care within a reasonable time. In Finland, for example, the treatment guarantee came into force in 2005. However, no consensus exists on optimal waiting time for different patient groups.

The purpose of this multi-centre randomized controlled trial was to analyse health-related quality of life, pain and physical function in total hip or knee replacement patients during the waiting time and to evaluate whether the waiting time is associated with patients' health outcomes at admission. This study also assessed whether the length of waiting time is associated with social and health services utilization in patients awaiting total hip or knee replacement. In addition, patients' health-related quality of life was compared with that of the general population.

Consecutive patients with a need for a primary total hip or knee replacement due to osteoarthritis were placed on the waiting list between August 2002 and November 2003. Patients were randomly assigned to a short waiting time ($\leq$ 3 months) or a non-fixed waiting time (waiting time not fixed in advance, instead the patient followed the hospitals' routine practice).

Patients' health-related quality of life was measured upon being placed on the waiting list and again at hospital admission using the generic 15D instrument. Pain and physical function were evaluated using the self-report Harris Hip Score for hip patients and a scale modified from the Knee Society Clinical Rating System for knee patients. Utilization measures were the use of home health care, rehabilitation and social services, physician visits and inpatient care.

Health and social services use was low in both waiting time groups. The most common services used while waiting were rehabilitation services and informal care, including unpaid care provided by relatives, neighbours and volunteers. Although patients suffered from clear restrictions in usual activities and physical functioning, they seemed primarily to lean on informal care and personal networks instead of professional care.

While longer waiting time did not result in poorer health-related quality of life at admission and use of services during the waiting time was similar to that at the time of placement on the list, there is likely to be higher costs of waiting by people who wait longer simply because they are using services for a longer period. In economic terms, this would represent a negative impact of waiting.

Only a few reports have been published of the health-related quality of life of patients awaiting total hip or knee replacement. These findings demonstrate that, in addition to physical dimensions of health, patients suffered from restrictions in psychological well-being such as depression, distress and reduced vitality. This raises the question of how to support patients who suffer from psychological distress during the waiting time and how to develop strategies to improve patients' initiatives to reduce symptoms and the burden of waiting.

Key words: waiting time, total hip replacement, total knee replacement, health-related quality of life, randomized controlled trial, outcome assessment, social service, utilization of health services

Summary in Finnish

Johanna Hirvonen. Effect of Waiting Time on Health Outcomes and Service Utilization. A Prospective Randomized Study on Patients Admitted to Hospital for Hip or Knee Replacement [Hoitoon jonottamisen vaikutukset terveydentilaan ja palveluiden käyttöön lonkan ja polven tekonivelleikkauspotilailla: prospektiivinen, satunnaistettu tutkimus]. STAKES, Research Report 170. Helsinki 2007. ISBN 978-951-33-2032-4

Pitkittyneet jonotusajat kiireettömään hoitoon, alueelliset erot jonotusajoissa ja hoidon saatavuuteen liittyvät ongelmat ovat herättäneet niin Suomessa kuin monissa muissa länsimaissa päätöksentekijät etsimään keinoja hoidon saatavuuden parantamiseksi ja jonotusaikojen lyhentämiseksi. Tästä osoituksena muun muassa Suomessa vuonna 2005 voimaan tulleet kiireettömän hoidon järjestämisen enimmäisajat. Perustelut harjoitettavalle jonopolitiikalle näyttävät kansainvälisesti katsoen varsin samansuuntaisilta: pidentyneet jonotusajat asettavat kansalaiset keskenään eriarvoiseen asemaan, vievät pohjaa terveydenhuollon tasa-arvotavoitteelta sekä synnyttävät ja lisäävät kustannuksia terveyshaittojen vaikeutuessa. Tästä huolimatta tutkittua tietoa jonotusajan yhteydestä potilaan terveydentilaan on saatavilla vain vähän.

Tämän satunnaistetun, monikeskustutkimuksen tavoitteena oli tarkastella lonkan ja polven primaariin tekonivelleikkaukseen jonottavien potilaiden terveyteen liittyvää elämänlaatua, kipua ja liikkumista leikkaukseen jonottamisen aikana sekä arvioida jonotusajan vaikutuksia terveyteen ja sosiaali- ja terveyspalvelujen käyttöön. Lisäksi potilaiden terveyteen liittyvää elämänlaatua verrattiin vastaavanikäiseen suomalaisväestöön.

Potilaat rekrytoitiin tutkimukseen elokuun 2002 ja marraskuun 2003 välisenä aikana. Jonoon laiton yhteydessä potilaat satunnaistettiin koe- ja kontrolliryhmään: 1) nopeasti hoitoon pääsevät (short waiting time), jotka jonottivat toimenpiteeseen korkeintaan kolme kuukautta ja 2) normaalisti hoitoon pääsevät (non-fixed waiting time), jotka pääsivät leikkaukseen sairaalan normaalin käytännön mukaisessa ajassa.

Potilaiden terveyteen liittyvää elämänlaatua mitattiin jonoon laiton yhteydessä sekä sairaalaan saavuttaessa. Mittarina käytettiin suomalaista terveyteen liittyvää 15D-elämänlaatumittaria. Kipua ja liikkumista mitattiin sairausspesifeillä modifioiduilla Harris Hip Score ja Knee Score -mittareilla. Palvelujen käyttöä mitattiin tutkimusta varten laaditulla kyselyllä, joka sisälsi tiedot potilaan käyttämistä kotiin saatavista terveyspalveluista, kuntoutuspalveluista, kotihoidon tukipalveluista, lääkärikäynneistä sekä vuodeosastohoidosta.

Tutkimustulosten mukaan pidempään jonottaneiden terveyteen liittyvä elämänlaatu ei ollut sairaalaan saavuttaessa nopeasti hoitoon päässeitä huonompi.

Siitä huolimatta, että potilaiden terveydentilassa ei tapahtunut muutosta jonotusaikana, leikkaukseen jonottavien potilaiden terveyteen liittyvä elämänlaatu oli huomattavasti vastaavanikäistä vertailuväestöä huonompi. Fyysisten ulottuvuuksien lisäksi potilaat kärsivät masennuksesta, ahdistuneisuudesta sekä uupumuksesta, väsymyksestä ja voimattomuudesta.

Sosiaali- ja terveyspalvelujen käyttö oli jonotusaikana vähäistä eikä jonotusaika ollut yhteydessä palvelujen käyttöön. Palveluista eniten käytettiin kuntoutuspalveluita sekä omaisten tarjoamaa epävirallista kotiapua. Hoitoon pääsyä odottaessaan potilaat turvautuivat vain harvoin ammatilliseen hoitoon ja hoivaan. Sen sijaan potilaat pyrkivät selviytymään tavanomaisista toiminnoistaan läheisten tarjoaman avun turvin turvautumatta julkisiin tai yksityisiin sosiaali- ja terveyspalveluihin.

Tulevaisuudessa jonotusajan vaikutuksia tulisi tarkastella myös muissa potilasryhmissä. Vertailutietoa on mahdollista hyödyntää kehitettäessä jononhallinnan käytäntöjä sekä potilaan kunnon ja elämäntilanteen huomioon ottavia vertailevia, geneerisiä elämänlaatumittareita optimaalisen hoitoajankohdan määrittelemiseksi.

Avainsanat: jonotusaika, lonkan tekonivelleikkaus, polven tekonivelleikkaus, terveyteen liittyvä elämänlaatu, satunnaistettu tutkimus, sosiaalipalveluiden käyttö, terveyspalveluiden käyttö

Summary in Swedish

Johanna Hirvonen. Effect of Waiting Time on Health Outcomes and Service Utilization. A Prospective Randomized Study on Patients Admitted to Hospital for Hip or Knee Replacement [Väntetidens inverkan på hälsotillståndet och användningen av tjänster. En prospektiv och randomiserad undersökning bland höft- och knäprotespatienter]. STAKES, Research Report 170. Helsinki 2007. ISBN 978-951-33-2032-4

De allt längre väntetiderna till icke-brådskande vård, de regionala skillnaderna i väntetiderna samt problemen beträffande tillgången till vård har väckt beslutsfattarna i såväl Finland som i många andra västländer att söka metoder för att förbättra vårdtillgängligheten och förkorta väntetiderna. En bekräftelse på detta är bl.a. de maximitider för ordnande av icke-brådskande vård som trädde i kraft i Finland år 2005. Motiveringarna för den köpolitik som tillämpas verkar internationellt sett vara tämligen likriktade: de allt längre väntetiderna försätter medborgarna sinsemellan i en ojämlik ställning, undergräver hälsovårdens målsättningar avseende jämlikhet samt ger upphov till mer kostnader i och med att de hälsomässiga nackdelarna ökar. Trots detta finns det endast mycket lite undersökta fakta om sambandet mellan väntetiden och patientens hälsotillstånd.

Syftet med denna randomiserade multicenterundersökning är att studera den hälsorelaterade livskvaliteten, smärtförnimmelserna och rörligheten under tiden i operationskön bland patienter i kö för primär ledprotesoperation i höft- och knäled samt att uppskatta väntetidens inverkan på hälsan och användningen av hälso- och socialtjänster. Dessuom jämfördes patienternas hälsorelaterade livskvalitet med den finska befolkningen i motsvarande ålder.

Patienterna rekryterades till undersökningen mellan augusti 2002 och november 2003. I samband med att patienterna ställdes i kö, indelades de randomiserat i en test- eller kontrollgrupp: 1) patienter som får vård snabbt (short waiting time), vilka köade högst tre månader för åtgärden och 2) patienter som får vård i normal ordning (non-fixed waiting time), vilka opererades inom ramen för sjukhusets normala tidtabell.

Patienternas hälsorelaterade livskvalitet mättes i samband med att de ställdes i kö samt när de togs in på sjukhus. Som mätare användes den i Finland utvecklade 15D-metoden för mätning av livskvaliteten. Smärtförnimmelserna och rörligheten mättes med sjukdomsspecifika modifierade Harris Hip Score och Knee Score-mätare. Användningen av tjänster mättes med en enkät som utarbetats för undersökningen och som innehöll uppgifter om vilka hälsovårdstjänster i hemmet, rehabiliteringstjänster, stödtjänster inom hemvården, läkarbesök samt vård på bäddavdelning som patienten använt.

Enligt undersökningsresultaten var den hälsorelaterade livskvaliteten bland dem som köat längre inte sämre när de togs in på sjukhuset än bland dem som fått vård snabbt. Trots att det inte inträffat någon förändring i patienternas hälsotillstånd under tiden i kö, var den hälsorelaterade livskvaliteten bland dem som köade till en operation betydligt sämre än bland jämförelsebefolkningen i motsvarande ålder. Utöver de fysiska dimensionerna led patienterna av depression, ångest samt utmattning, trötthet och kraftlöshet.

Användningen av social- och hälsovårdstjänster var under tiden i kö ringa och väntetiden hade inget samband med tjänsternas användning. Av tjänsterna användes mest rehabiliteringstjänster samt inofficiell hemhjälp av de anhöriga. I väntan på vård tydde sig patienterna endast sällan till yrkesmässig behandling och omvårdnad. Däremot försökte patienterna reda sig i sina normala sysslor med hjälp av sina närstående utan att anlita offentliga eller privata social- och hälsovårdstjänster.

I framtiden borde inverkan av väntetiden granskas också inom andra patientgrupper. Jämförelsematerialet kan utnyttjas vid utvecklandet av praxis för köhantering samt jämförande, generiska mätare av livskvaliteten som beaktar patientens kondition och livssituation för att fastställa den optimala behandlingstidpunkten.

Nyckelord: väntetid, ledprotesoperation i höftled, ledprotesoperation i knäled, hälsorelaterad livskvalitet, randomiserad undersökning, användning av socialtjänster, användning av hälsovårdstjänster

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II Hirvonen Johanna, Blom Marja, Tuominen Ulla, Seitsalo Seppo, Lehto Matti, Paavolainen Pekka, Hietaniemi Kalevi, Rissanen Pekka, Sintonen Harri. Evaluating waiting time effect on health outcomes at admission: a prospective randomized study on patients with osteoarthritis of the knee joint. *Journal of Evaluation in Clinical Practice* 2007; 13:728-733.

III Hirvonen Johanna, Blom Marja, Tuominen Ulla, Seitsalo Seppo, Lehto Matti, Paavolainen Pekka, Hietaniemi Kalevi, Rissanen Pekka, Sintonen Harri. Is longer waiting time associated with health and social services utilization before treatment? A randomized study. *Journal of Health Services Research & Policy* 2007; 12:209-214.

IV Hirvonen Johanna, Blom Marja, Tuominen Ulla, Seitsalo Seppo, Lehto Matti, Paavolainen Pekka, Hietaniemi Kalevi, Rissanen Pekka, Sintonen Harri. The effect of waiting time on health-related quality of life, pain and physical function in patients awaiting primary total hip replacement: A randomized controlled trial. (Submitted).

Abbreviations

ADL	Activities of daily living
AQoL	Assessment of Quality of Life
BMI	Body mass index
CEA	Cost-effectiveness analysis
CI	Confidence interval
CUA	Cost utility analysis
EQ-5D	EuroQol (5 dimensions)
GHQ	General Health Questionnaire
GP	General practitioner
HADS	Hospital Anxiety and Depression Scale
HHS	Harris Hip Score
HRQoL	Health-Related Quality of Life
HUCH	Helsinki University Central Hospital
HUI	Health Utility Index
ITT ANALYSIS	Intention-to-treat analysis
MAUS	Multi attribute utility scale
NHP	Nottingham Health Profile
NIH	U.S. National Institutes of Health
NOMESCO	Nordic Medico-Statistical Committee
OA	Osteoarthritis
OECD	Organisation for Economic Co-operation and Development
OHS	Oxford Hip Score
PP ANALYSIS	Per protocol analysis
PRO	Patient-reported outcome
QOL	Quality of life
QWB	Quality of Well-Being Scale
SF-36	Medical Outcomes Study 36-item short-form health survey
STAKES	National Research and Development Centre for Welfare and Health
THA	Total hip arthroplasty
TKA	Total knee arthroplasty
THR	Total hip replacement
TKR	Total knee replacement
WHO	World Health Organization
WOMAC	Western Ontario and McMaster Universities Osteoarthritis Index
WT	Waiting time

1 Introduction

Since the beginning of the 21st century, equal access to treatment has been a key performance indicator of medical care in Finland. Many Western countries that monitor and record waiting times (e.g. Australia, Canada, Denmark, Finland, Ireland, Italy, Netherlands, New Zealand, Norway, Spain, Sweden, United Kingdom) have reported that timely access to treatment has become "*a significant health policy concern*" (Siciliani & Hurst 2003). As the population ages, the prevalence of slowly progressive diseases, such as osteoarthritis (OA) of the hip or knee joint, is likely to increase. This in turn may lead to a greater demand for elective treatment – total hip and knee replacements, among other things. For example, in Finland between 1987 and 2002, the number of total hip replacements (THR) rose on average by 5% annually, and the number of total knee replacements (TKR) by 12% (Mikkola et al. 2005).

The rationale for policies to reduce waiting times seems to be similar in systems with relatively long waiting times; delayed access to medical care may threaten equal access to treatment and impose a variety of costs such as welfare losses during the period, more severe treatment due to delayed waiting, work absenteeism, income losses, increased medication and service utilization (Hamilton et al. 1996, Martin & Smith 1999). These are, however, more politically legitimated arguments behind health care reforms than the main conclusions of scientific studies. No consensus exists on optimal waiting time (WT) for different patient groups.

The results of empirical studies evaluating the effects of WT on health status are ambiguous. Some studies have shown that the length of WT is not associated with health status, whereas other studies have reported the opposite results. Inconsistency in empirical findings is partly explained by differences in study design, instruments (disease-specific or generic), sample size and follow-up period.

Although many Western countries, such as Canada, New Zealand, Australia and Norway, have pioneered monitoring and priority scoring systems for waiting times, to my knowledge, none of these countries has randomly allocated patients with OA of the hip or knee joint to different waiting groups, prospectively following the groups and evaluating the effects of waiting on health status and/or service utilization. Due to the lack of randomized trials, more studies on the effects of increased waiting durations are needed. Therefore, a project was launched to examine the effect of WT on Health-Related Quality of Life (HRQoL), pain, physical function and social and health service utilization among patients awaiting primary THR or TKR. Major joint replacement was chosen as the surgical procedure for this study because OA is one of the most prevalent chronic diseases causing long-term physical disability, especially among older people, and thus, joint replacement surgery has become a commonly performed orthopaedic procedure for patients with advanced OA.

Sections 3–6 form the literature review of this study. In these sections, the main concepts and background of the WT phenomenon and the measurement of health outcomes in patients awaiting major joint replacement are discussed. In section 3, the main approaches to WT are outlined. To be able to answer the question of the health outcome of a certain intervention, the measurement should be based on a wide understanding of the concept of health. Thus, in section 4, HRQoL is first conceptualized and then HRQoL measurement is discussed. Section 5 deals with service utilization, i.e. how service utilization is conceptualized and what is already known about social and health service utilization in the elderly and in patients with joint replacement surgery. Section 6 covers definition of the main concepts concerning THR and TKR. The aims of the study are presented in section 7, and materials and methods in section 8. The results section (section 9) first describes patients' HRQoL at the time of placement on the waiting list, comparing it with the HRQoL of the general population. Next, the results of a randomized trial are presented, including comparison of HRQoL, disease-specific pain and function and service utilization between the randomized groups. Finally, in sections 10 and 11, study results, strengths and limitations are discussed, practical implications and possible future challenges are suggested and conclusions are drawn.

2 STUDY CONTEXT

This study evaluates the health outcomes of waiting. At the time of the study, a major reform was instigated in the Finnish health care system; from the beginning of March 2005, time-frames for access to non-emergency treatment were set. Thus, public interest and a wide political concern about growing problems in the availability of public health services underlie the questions on the effects of waiting (arrow 1 in Figure 1). Further, the results of this study are of clinical relevance when searching for tools to manage waiting lists in major joint replacements at hospital level and to improve clinical decision-making. The results have a political relevance when searching for improved ways to allocate health resources and to develop recommendations and criteria for assessing health care needs (arrow 2 in Figure 1).

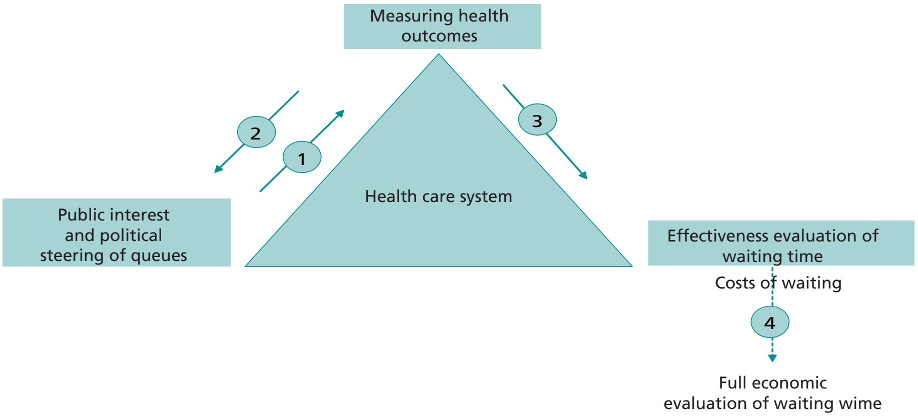

FIGURE 1. Context of the study

Economic evaluations of health care, such as cost-effectiveness analysis (CEA), and cost-utility analysis (CUA), compare “alternative courses of action in terms of both costs and consequences” (Drummond et al. 1987). Although a large amount of biomedical indicators, generic quality-of life instruments and disease-specific scales have been developed to measure health outcomes, economists tend to favour standardized measures known as multi-attribute utility scales (MAUS)[1], which attach a pre-existing set of preference or utility weights to patient-assessed status on specific dimensions (Drummond & Davies 1991, Brazier & Deverill 1998). Full economic evaluations of WT require that both costs (arrow 4 in Figure 1) and

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[1] E.g. Quality of Well-Being Scale (QWB), Rosser´s disability/distress scale, the Health Utility Index II and III (HUI-II, HUI-III), EuroQoL (EQ-5D), 15D

outcomes (arrow 3 in Figure 1) of waiting are identified and compared between two or more alternatives. This study focuses on the identification and comparison of outcomes (arrow 3 in Figure 1) between two alternatives, and thus, the evaluation is termed an effectiveness evaluation of waiting instead of a full economic evaluation, which is not done in this study.

3 WAITING FOR SURGICAL PROCEDURES

3.1 Concept of waiting

When analysing WT phenomenon, some main concepts need clarification. First of all, WT should be distinguished from the waiting list. Patients needing an appointment to a hospital are recorded and monitored using the waiting list (HOPE 2004). Waiting list data can be used to facilitate waiting list (or queue) management and direct policy initiatives (e.g. activity-based funding for hospitals) between regions, hospitals or surgical procedures. By contrast, WT for a service is a series of periods for which duration is estimated, fixed or non-fixed (random). Depending on the recording system, WT may include the different combinations of time periods presented in Figure 2. The time between primary care consultation and specialist assessment at an outpatient clinic is called outpatient waiting (WT2 in Figure 2), as distinct from inpatient waiting (WT4 in Figure 2), which refers to the time between treatment decision (placement on the waiting list) and admission for an elective procedure (Siciliani & Hurst 2003). This study focuses on inpatient waiting.

A major weakness of empirical studies that have examined whether sustained waiting times prolong pain and complicate physical function and normal activities has been that they have usually evaluated patients from the time that a patient was placed on the waiting list to the date of surgery, instead of following patient's paths to care and waiting periods, from the first contact with a primary care practitioner to surgery (the so-called Path-to-Care Approach, see Sanmartin 2003). The total time a patient waits for treatment comprises, however, more periods than outpatient and inpatient waiting, including first contact with health care professionals, time between first contact and primary care consultation (WT1 in Figure 2) and establishing whether treatment is required (WT3 in Figure 2, including diagnostic tests [WT2a + WT3a] and referrals to other specialists to be carried out before a decision). Ideally, the whole path to care, from initial referral to the specialist, should be monitored (HOPE 2001). In prospective studies, it is, however, difficult to collect WT data through the chain of decisions and actions from first contact with primary care practitioner to treatment. Evaluating the whole path of the care process seems to be methodologically difficult for the reason that at the first contact, there is no confidence regarding the clinical need for surgical treatment.

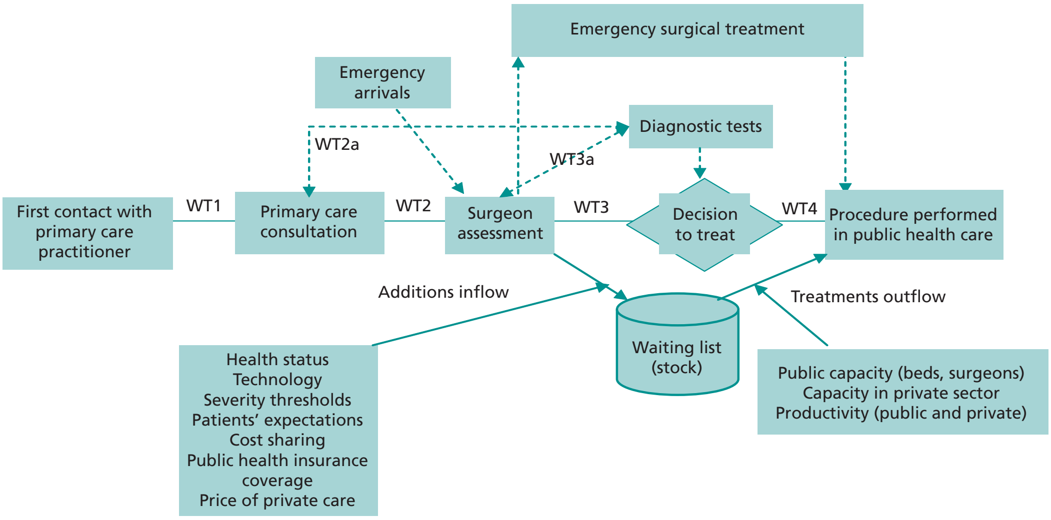


FIGURE 2. Waiting periods and likely determinants of waiting (adopted from Sanmartin 2003, Siciliani & Hurst 2003, HOPE 2004)

Besides identifying different time periods, we should define a patient's status on the list, when reporting waiting times. HOPE´s Working Party on Management of Waiting List (HOPE 2001) has the following means for separating patients on the list: 1) active patients who are ready for surgery, and 2) suspended patients who have been placed on the list, but who are not available for surgery. There are several reasons for suspended waiting. Some patients may want to postpone surgery that inconveniently arrives too soon, some are not clinically ready for surgery and some may have difficult personal circumstances. It is highly dependent on the waiting list policy whether a suspended patient is removed from the list. For example, in Australia, where monitoring and reporting of waiting times for elective treatment have been systematically developed for years, suspended patients are removed from the list.

Problems with measuring waiting times for non-emergency surgery are related to the lack of standardized methods for recording these times. One recording method is to cross-sectionally measure on a given day the waiting times for those on the list (= monitoring waiting list). The problem with this measurement method is that patients who will not be treated in the future (suspended patients) are included in the study population (HOPE 2004). Alternatively, patients can be prospectively followed until admission, but a weakness with this approach is inconsistency in defining time period; whether to follow a patient from a general practitioner (GP) referral to a specialist consultation, from a GP consultation to admission or from a specialist consultation to admission. The third main method is to use retrospective data on waiting times (= monitoring WT), which may serve as a tool for managers to plan, organize and compare the units (HOPE 2004). The problem with retrospective data is that it does not benefit patients on the list, whose major interest is to know the remaining time for treatment (HOPE 2004).

3.2 Recording of waiting times for surgical procedures in Finland

The availability of reliable and valid data on waiting times and waiting lists is an essential part of developing actions for shortening waiting times and managing waiting lists. In Finland, measurement of waiting times is based on retrospective recording of inpatient waiting. Waiting times are reported at the regional and hospital levels to give surgery-, procedure- and speciality-specific information. Waiting times for elective surgery have been monitored since the 1960s, when the Hospital League published the national report on waiting times for surgery (Lahtinen & Maamies 1971). After that, waiting times for elective surgery have been regularly reported (Ministry of Social Affairs and Health 1988, Alanko et al. 1992, Kekomäki et al. 1995, Järvelin & Linna 2004).

Today, the National Research and Development Centre for Welfare and Health (STAKES) collects nationwide data on WT and access to care. Health care units are obliged to publish bi-annual raw WT figures and STAKES, in turn, produces follow-up data. Besides national monitoring of waiting times, Finland has also been a partner in international comparison studies of waiting list management. An international non-profit association, the Standing Committee of the Hospitals of the European Union, measured and compared waiting lists in four European countries between 1997 and 2004 (HOPE 1998, 2001, 2004). The comparison showed that differences exist between the countries in data collection and definition of WT. For example, Finland and Sweden retrospectively follow elective waiting times, whereas Ireland and Spain measure waiting times for the patients on the list (HOPE 2004).

In Finland, waiting times for elective surgery have been on the rise since the last decade. In 2004, the median WT for elective surgery (including inpatient and day surgery) was 60 days (mean 133 days) (STAKES 2005). Cataract operations and hip and knee replacements have traditionally been the surgical procedures with the longest WT. Especially in patients awaiting primary knee replacement, the growth in WT has been enormous (Table 1). Figure 3 shows the median WT and period of care in Finland for nine common elective surgeries. The figures have been calculated from the statistical analyses carried out by STAKES. The waiting times for primary knee and hip replacements and cataract operations were the longest. Especially in patients awaiting primary hip or knee replacement, the median waiting times have increased since the beginning of 2000.

In addition to an increase in median waiting times, regional differences in waiting times have been typical in the Finnish health care system. For example, in 2004, the shortest median WT for elective surgery was 76 days (Etelä-Savo) and the longest 171 days (Pohjois-Savo), when comparing the 20 hospital districts (Table 2).

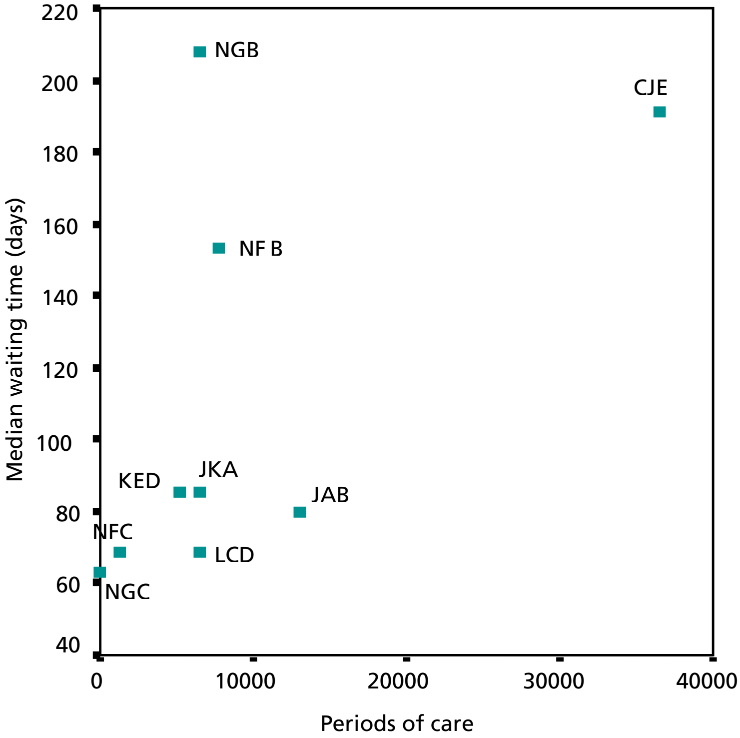
In relation to some countries, waiting times for elective surgery in Finland have been long. According to an Organisation for Economic Co-operation and Development (OECD) comparative analysis of 20 OECD countries, 12 countries reported at the beginning of the 21st century that waiting times are a serious health policy concern. When comparing 10 surgical procedures, Finland and the United Kingdom followed by Denmark, Norway, Australia and Canada were the countries with the longest waiting times (Siciliani & Hurst 2003).

TABLE 1. Median waiting times (days) in Finland according to nine surgical procedures between 2001 and 2004

Surgical procedure	**NOMESCO[c] classification**	**2001**	**2002**	**2003**	**2004**
Cataract operation[a]	CJE	198	182	199	190
Primary prosthetic replacement of knee joint[b]	NGB	186	197	205	210
Primary prosthetic replacement of hip joint[b]	NFB	138	149	155	153
Operations of gallbladder	JKA	92	97	92	81
Secondary prosthetic replacement of hip joint	NFC	82	83	80	77
Total excision of uterus	LCD	78	90	91	78
Repair of inguinal hernia	JAB	76	77	94	80
Secondary prosthetic replacement of knee joint	NGC	65	85	88	76
Partial excision of prostate	KED	47	48	56	81

Source: STAKES 2002, 2003, 2004b, 2005.

[a] Extracapsular cataract operations using phakoemulsification technique.
[b] Total and partial.
[c] Nordic Medico-Statistical Committee.



CJE	Cataract operationa
NGB	Primary prosthetic replacement of knee joint
NFB	Primary prosthetic replacement of hip joint
JKA	Operations of gallbladder
NFC	Secondary prosthetic replacement of hip joint
LCD	Total excision of uterus
JAB	Repair of inguinal hernia
NGC	Secondary prosthetic replacement of knee joint
KED	Partial excision of prostate

FIGURE 3. Median waiting time and periods of care in 2004 according to nine surgical procedures in Finland

TABLE 2. Waiting time variations for surgical procedures between hospital districts 1996-2004 in Finland

Hospital district	**Average waiting time (days) for surgical procedures[a]**									
	1996	**1997**	**1998**	**1999**	**2000**	**2001**	**2002**	**2003**	**2004**	**1996–2004**
Etelä-Karjala	84	78	73	85	85	72	83	86	79	**80**
Etelä-Pohjanmaa	129	127	139	136	107	117	114	110	102	**121**
Etelä-Savo	67	102	108	95	95	99	99	93	76	**92**
HUS	113	116	114	118	119	125	130	125	135	**122**
Itä-Savo	96	89	92	101	103	109	119	163	149	**113**
Kainuu	100	102	119	122	126	121	121	113	93	**115**
Kanta-Häme	112	111	110	106	95	108	132	159	134	**119**
Keski-Pohjanmaa	81	80	102	108	101	109	120	129	108	**108**
Keski-Suomi	125	141	133	117	118	115	146	172	151	**137**
Kymenlaakso	111	121	114	111	91	95	98	95	99	**104**
Lappi	125	103	101	94	106	125	146	135	105	**115**
Länsi-Pohja	105	87	91	104	111	115	133	138	121	**114**
Pirkanmaa	114	122	129	126	119	123	120	135	145	**126**
Pohjois-Karjala	134	140	153	190	178	174	173	181	170	**166**
Pohjois-Pohjanmaa	95	86	93	106	116	130	163	168	128	**123**
Pohjois-Savo	121	146	150	132	180	158	175	200	171	**164**
Päijät-Häme	139	145	134	128	126	154	152	149	151	**142**
Satakunta	111	115	117	101	93	89	111	130	132	**110**
Vaasa	159	144	129	134	136	120	120	110	115	**130**
Varsinais-Suomi	104	112	103	93	83	79	85	80	85	**91**
Whole country	113	117	116	117	115	118	127	131	131	**121**

[a] Classified according to the international classification system ICD-10.

Source: STAKES 2006.

4 MEASUREMENT OF HEALTH-RELATED QUALITY OF LIFE (HRQoL)

4.1 Growing interest in measuring HRQoL

The interest in developing standardized health measurement instruments in health economics research, epidemiological studies and clinical practice has grown within the last 20 years. The reasons for the growing interest are numerous. Firstly, the goal of health care is not only to prolong life, but also to contribute to well-being. The rising burden of chronic diseases forces societies to find more effective ways to improve citizens' health using strict budgeting and cost control (Bowden & Fox-Rushby 2003). Secondly, such international forums as electronic communication and international academic journals and societies have enabled global dissemination of knowledge. At the same time, the desire to assess the impact of health interventions widely beyond the specific disease has been on the increase. The third reason is economic. National political planning and international organizations need evidence of the impact of interventions for resource allocation. (Bowden & Fox-Rushby 2003.)

Adding the terms quality of life (QoL) and HRQoL to the evaluation of medical treatment has extended the biomedical concept of health and statistical presentation of societal welfare more towards global functioning, well-being, QoL (Jenkinson 1995) and perceived health (Hunt 1997). The concepts HRQoL and QoL have been linked to various disciplines: medical and nursing sciences, sociology, psychology, economics, philosophy, history and even geography (Farquahar 1995). Empirical clinical studies and economic evaluations have adopted a narrow approach to QoL by emphasizing those aspects of life that are associated with health status and affected by disease or treatment (Fayers & Machin 2000).

Presenting health outcomes, that is, condensing behaviour variation, social interactions and values into a profile or single index score serves decision-making on health resource allocation, which in turn presents the motives related to the need to legitimate cost-effective resource allocation and decisions on resources and cutbacks. Further, the rise of individual values, patients' increasing demands and growing public expectations and knowledge about health affairs have been presented as a partial explanation for a growing interest in QoL within a new economic and political milieu (Rogerson 1995).

4.2 Generic and disease-specific measures

The increased application of HRQoL instruments has given rise to arguments about what is being measured, why particular domains are being measured, whether the effects are due to the intervention evaluated (internal validity) and whether they can be generalized to other settings (external validity) (Shortell & Richardson 1978). The aspects of life examined may vary from study to study, encompassing physical, mental and social function. HRQoL forms just one of many components of peoples' well-being, living conditions, satisfaction and subjective perceptions of a good life.

Numerous QoL measures have attempted to formally combine aspects of well-being, life satisfaction and an individual's ability to perform everyday roles and tasks. Social scientists have tried to draw a picture of this broad concept (QoL) by incorporating the components of material resources or needs and subjective constructions of happiness, life satisfaction, well-being and QoL. In this kind of social indicators research (Bowling & Brazier 1995), health is just one of many aspects measuring QoL. In epidemiological trials and economic evaluations, QoL refers to more restricted area of people's well-being: indicators which focus on people's perceptions of their current health status. Economists have attempted to avoid theoretical narrowness in the conceptualization of HRQoL by emphasising interest in measuring the value placed on health rather than in measuring health per se (Brazier et al. 1999).

In effectiveness evaluations of health care and in economics, a commonly used approach is a standardized health measurement questionnaire administered to a patient or a third party (e.g. physician) (Brazier & Deverill 1998). Measurement instruments can be either generic or disease-specific, covering a variety of physical, psychological and social dimensions.

Several generic[2] and disease-specific[3] measurement instruments have been introduced to assess the HRQoL of patients awaiting and undergoing THR or TKR. Generic measures may be utilized 1) to evaluate the aspects of health status across diseases and interventions and 2) to give detailed information on the dimensions, which can be affected by means of health care. Generic measures, or, as Elinson (1978) stated, "sociomedical indicators of health", are powerful in comparative study settings (Williams & Kind 1992), when HRQoL is evaluated between patients and a general population, between test and control groups or when a disease or injury has been treated by different methods. Disease-specific measures focus on the specific disorder (Bombardier et al. 1995). For example, in patients with OA of the hip or knee joint, the primary dimensions of interest are function and pain

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[2] E.g. 15D, Medical Outcomes Study Short Form 36 (SF-36), Nottingham Health Profile (NHP), Sickness Impact Profile, Health Assessment Questionnaire

[3] E.g. Western Ontario and McMaster University Osteoarthritis Index (WOMAC), Knee Society Clinical Rating System, Harris Hip Score (HHS), Charnley modified D'Aubigne-Postel, Murray's 12-item score, Johansson's score

(Martin et al. 2000). The disease-specific dimensions of range of motion, muscle strength, stability, deformity and contracture are also widely assessed (Brinker et al. 1997).

The simultaneous use of both generic and disease-specific instruments as outcome measures allows a more global assessment of HRQoL than if the measures were utilized separately (Lieberman et al. 1997). The American Academy of Orthopaedic Surgeons and the Société Internationale de Chirurgie Orthopédique et de Traumatologie have recommended that an assessment of clinical complications, a physical examination of the hip, radiographic studies and an assessment of patient well-being (pain, gait, activities of daily living, overall satisfaction) should be included in all studies of outcome of hip arthroplasty (Söderman & Malchau 2001). Further, Laupacis et al. (1993) emphasized that a disease-specific measure should be included in all outcome studies of total hip arthroplasty (THA).

Patient-reported outcome (PRO) measures are commonly used in clinical assessment of OA (Mahomed et al. 2001). Utilizing PRO measures has reduced the influence of “proxy” assessments made by observers like physicians. Formal evaluations by independent physicians or nurses are preferred in health outcome measurements usually only if the patient is unable to produce an autonomous and coherent response, e.g. when he/she is very young, old, severely ill or mentally impaired (Fayers & Machin 2000).

4.3 Psychometric assessment of HRQoL instrument

The spectrum of psychometric properties indicating the performance of HRQoL measurement instruments is wide. Useful generic measures include validity, reliability, feasibility and sensitivity (Sintonen 1994a).

Validity refers to the extent to which the instrument measures what it is intended to measure. Content validity examines the extent to which a measure represents all aspects of a given outcome variable of interest (Shortell & Richardson 1978). The question of content validity is fundamental when conceptualizing HRQoL, that is, how dimensions of HRQoL included in the measure will be defined and who will judge these dimensions. Several conceptual definitions have been formulated when developing measurement instruments. In the World Health Organization’s (WHO) QoL assessment project, QoL was defined as “individuals´ perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns” (WHOQOL Group 1998). This definition refers to a broad conceptualization of physical, psychological and social aspects of an individual’s life and living environment. Besides self-perceived qualitative aspects of life, attention has also been paid to quantity of life.

Patrick and Erickson (1993) have combined qualitative aspects with quantity of life by defining HRQoL as “the value assigned to duration of life as modified by the impairments, functional states, perceptions and social opportunities that are influenced by disease, injury, treatment or policy.”

When examining an abstract phenomenon that is not well-defined, testing construct validity becomes relevant (Brazier et al. 1999). Construct validity refers to the assessment of whether a measure really measures the underlying theoretical construct it is assumed to measure. A measure with “high” construct validity has a theoretical background that is supposed to be reflected in a particular measure. Essential to construct validity is to find conceptual definitions for the use of topics and theoretical judgements for their integration with external criteria (McDowell & Newell 1996). Then, on the basis of a theoretical understanding of the components and content of the condition, it is possible to formulate hypotheses.

Construct validity can be divided into convergent and discriminate validity. To show convergent validity, two different measures of assessing the same concept should be correlated with each other, whereas discriminate validity provides evidence that two different methods using two different measures do not correlate with each other (Shortell & Richardson 1978).

Criterion validity is based on a comparison between the instrument and some future or current criteria. Concurrent validity as a form of criterion validity involves the correlation of one measure with another at the same point in time, whereas predictive validity involves different measures at different points in time (Shortell & Richardson 1978). In predictive validity, the comparison is made between the instrument and some future behaviour that the instrument validly predicts.

Shortell and Richardson (1978) have defined reliability “as the extent to which the same measure gives the same results on repeated applications.” In measures based on questionnaires, surveys or tests, retest reliability refers to consistent and reproducible measures over time, whereas congruence reliability may be assessed at the same point in time by, for example, comparing responses to short and long questionnaire forms or comparing identical questions (Shortell & Richardson 1978). Without reliability, valid measures cannot be attained.

An instrument must be understandable and acceptable to the patient. A questionnaire is feasible if the burden of filling it out is small or reasonable (Sintonen 1994a). For respondents, this means brief, understandable and unambiguous questions. Low response and completion rates represent problems in the feasibility of an instrument.

Sensitivity is a measure of the association between the change in the observed score and the change in the true value of the construct (Bowling 1995). Sensitivity involves two aspects: the ability to distinguish between individuals and groups in different health states cross-sectionally (discrimination power) and to detect changes in individuals or groups over time (responsiveness to change) (Sintonen 1994a).

4.4 Effect of waiting time on HRQoL of patients awaiting total hip or knee replacement

This literature review summarizes recent studies concerning the outcomes of WT on THR and TKR patients' HRQoL. A review of the literature published up to July 2006 was carried out using the PubMed to search the Medline database. The terms "waiting + THR", "waiting + TKR", "waiting + hip", "waiting + knee", "waiting + joint replacement", "waiting time + quality of life" and "waiting + HRQoL" were searched in the database. Table 3 summarizes the previous studies.

The SF-36 and the NHP have been utilized most often in studies of HRQoL among patients awaiting hip or knee replacement (Martin et al. 2000). The HHS has been shown to be the most widely used hip questionnaire (Mahomed et al. 2001, Söderman & Malchau 2001). In this study, 8 of the 13 studies reviewed (Table 3) used both generic and disease-specific measures when analysing health outcomes. The SF-36 was the most often utilized generic (5/13 studies) and WOMAC (6/13 studies) the most often utilized disease-specific measure.

TABLE 3. Summary of empirical studies on the effects of waiting time in patients undergoing total hip or knee replacement

Authors, year, country	Study design	Participants	Measurement points	Measurement instrument(s)	Main results
Williams et al., 1997, Canada	Prospective observational study	209 patients awaiting and undergoing THR or TKR	1) preoperative interview 2) approximately one year after first interview	SF-36, WOMAC	Relief of pain and functional improvements were reported after surgery, but waiting times were unrelated to the severity of pain or disability reported before surgery.
Derrett et al., 1999, New Zealand	Cross-sectional study	47 awaiting THR or TKR	preoperative interview	SF-36, Lequesne Index of Severity for Hip and Knee Disease, modified Harris pain scale	Although the majority reported severe symptoms and poor quality of life, neither general quality of life nor condition-specific health worsened with duration of wait.
Brownlow et al., 2001, Great Britain	Cross-sectional study	95 patients awaiting THR	preoperative assessment	SF-36, d'Aubigne and Postel hip scoring system, GHQ, HADS	Those waiting longest were no worse on any of the outcome measures and their mental health was better.

Table 3 continues

Table 3 continues

Authors, year, country	Study design	Participants	Measurement points	Measurement instrument(s)	Main results
Kelly et al., 2001, Australia	Prospective study	313 patients awaiting THR or TKR	1) at the time of placement on waiting list 2) before surgery	WOMAC, SF-36	Minimal change in pain and physical and psychosocial function during the waiting time. Waiting time did not have an impact on the amount of pain and dysfunction experienced.
Hajat et al., 2002, Great Britain	Prospective cohort study	7151 patients awaiting and undergoing THR	1) before operation 2) three months after surgery 3) 12 months after surgery	OHS	Those patients who started with a worse OHS before the operation tended to remain worse after the operation. The length of waiting was associated with poorer outcomes 12 months later.
Mahon et al., 2002, Canada	Prospective, observational cohort study	99 patients awaiting and undergoing THR	1) time of referral 2) three months from baseline 3) every six months thereafter 4) three months after surgery	WOMAC, 6-Minute Walk, HUI 3, SF-36, HHS, State-Trait Anxiety Inventory	No significant differences in HRQoL or mobility seen post-operatively between patients with short waits and those with long waits. Patients who underwent the procedure within 6 months after realized greater gains in HRQOL and mobility after surgery than patients waiting more than 6 months. Clinically important losses in HRQOL and mobility occurred in patients waiting more than 6 months.
Nilsdotter & Lohmander, 2002, Sweden	Prospective study	124 patients awaiting and undergoing THR	1) at the time of placement on waiting list 2) preoperatively 3) three months post-operatively 4) six months post-operatively 5) 12 months post-operatively	SF-36, WOMAC	No differences present in preoperative status or post-operative outcome between patients who had been on the waiting list more or less than three months.
Kili et al., 2003, Great Britain	Retrospective study	167 patients awaiting THR	1) at the time of placement on waiting list 2) two weeks prior to surgery	HHS	The HHS decreased preoperatively compared with baseline. Decrease in score correlated with time on the waiting list.
Fitzpatrick et al., 2004, Great Britain	Retrospective study	6700 patients awaiting THR	preoperatively	OHS	No association present between pain and physical function and time on the surgical waiting list.

Table 3 continues

Table 3 continues

Authors, year, country	Study design	Participants	Measurement points	Measurement instrument(s)	Main results
Ostendorf et al., 2004, Netherlands	Prospective cohort study	161 patients awaiting THR	1) at the time of placement on waiting list 2) preoperatively 3) three months after surgery 4) 12 months after surgery	OHS, WOMAC, SF-36, EuroQol	Disease-specific scores showed a significant deterioration during waiting time. No direct effect of waiting time on post-operative outcomes was found.
Chakravarty et al., 2005, Great Britain	Prospective study	125 patients awaiting and undergoing THR	1) addition to surgical waiting list 2) preoperative assessment 3) six months post-operative	Modified HHS	Not all patients deteriorate while waiting; some remain stable or improve
Fielden et al., 2005, New Zealand	Prospective cohort study	153 awaiting and undergoing THR	1) monthly from enrolment preoperatively 2) six months post-operative	WOMAC, EQ-5D	Longer waiting led to poorer physical function preoperatively.
Garbuz et al., 2006, Canada	Prospective study	201 patients awaiting and undergoing primary THR	1) preoperative surgical consultation 2) one year post-operative	WOMAC	Expedited access resulted in better function 12 months after surgery.

EQ-5D, EuroQoL; GHQ, General Health Questionnaire; HADS, Hospital Anxiety and Depression Scale; HHS, Harris Hip Score; HUI, Health Utility Index; OHS, Oxford Hip Score; SF-36, Medical Outcomes Study 36-item short-form health survey; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

Although there are a number of QoL assessments of patients who have undergone THR or TKR, few have examined the change in HRQoL that occurs while waiting for surgery. Studies have mostly focused on the outcomes of surgery, reported improvement in physical function, vitality and mental health and reduction in pain and shown that total knee arthroplasty (TKA) and THA are beneficial and effective treatments (McGuigan et al. 1995, Rissanen 1996, Brander et al. 1997, March et al. 1999, Bachmeier et al. 2001, Chiu et al. 2001, Salmon et al. 2001). However, interest in examining the relationship between health status and time spent waiting for surgery has been on the increase since the beginning of 2000. Studies have evaluated the effects of waiting on HRQoL, attempted to determine the optimal WT, compared the HRQoL of patients with that of the general population and explored differences in WT according to social, geographical and health care system factors (Fitzpatrick et al. 2004). Despite this, knowledge about the effects of WT on HRQoL remains inconsistent.

Some studies have found that the length of wait for THR and TKR is not associated with poorer HRQoL. In 1999, Derrett et al. stated in a cross-sectional study (n=47) that neither the scores of the generic SF-36 Health Survey nor the condition-specific Harris pain scale scores worsened with duration of wait. Kelly et al. (2001) subsequently reported in a prospective study, comprising 313 patients awaiting major joint arthroplasty, that WT did not have a negative impact on amount of pain and dysfunction experienced (measured by the generic SF-36 and the disease-specific WOMAC instruments). In a prospective study, Nilsdotter and Lohmander (2002) examined the relationship between WT and post-operative outcome (measured using SF-36 and WOMAC) in 56 OA patients assigned to THR. According to their results, health status did not differ between those waiting more than three months and those waiting less than three months. However, some studies have reported a poorer health status with increased WT as shown below.

Kili et al. (2003) investigated changes in disease-specific HHS between the time of listing for THR and immediately preoperatively (n=167) and found that orthopaedic condition in hip patients did not become stable or improve with time; instead, time on the waiting list was associated with increased pain and disability. Hajat et al. (2002) measured in a prospective study hip-related pain and disability and compared private and public operations. Disease-specific measurement showed that longer waiting was associated with greater disability in both the public and the private sector. The worst score measured by the Oxford Hip Score (OHS) was among those waiting more than 12 months (Hajat et al. 2002).

Studies on the relation between WT and HRQoL have mainly reported changes in pain, physical function and HRQoL. Brownlow et al. (2001) have, however, in a cross-sectional study assessed disability (d'Aubigne and Postel hip scoring system), aspects of social function (SF-36 scale) and mental well-being (GHQ and HADS) of THR patients. They found no evidence that mental health, social function or physical disability was worse among those waiting longest. Even though no association between time spent on the waiting list and worse physical or mental function was observed, patients awaiting surgery suffered serious pain and immobility.

Mahon et al. (2002) have attempted to define an optimal WT, after which HRQoL is substantially reduced. In a prospective study, they followed HRQoL (SF-36, HUI 3) and mobility (6-Minute Walk, WOMAC, HHS) in 99 patients awaiting THA and found no association between WT and post-operative HRQoL and mobility. Six months seemed to be a critical WT, after which patients experienced clinically significant declines in health status. The study was based on an observational design instead of randomization, and thus, the data provided some indication but did not prove a causal relation between HRQoL, mobility and WT.

Further, some studies (Fortin et al. 2002, Ostendorf et al. 2004) have shown that patients in a later phase of disease do not achieve the same level of outcome as those with better preoperative function, justifying paying attention to changes in HRQoL while waiting.

In Finland, the impact of WT on health outcomes and costs among THR and TKR patients has been investigated by health economists (Blom-Lange 1998, Blom-

Lange et al. 2002). Previous results were, however, not based on a randomized study design, and thus, patients with more severe symptoms may have had surgery more quickly than those with less severe symptoms and longer WT.

In conclusion, previous studies have shown that changes in HRQoL while waiting for THR or TKR are ambiguous. Inconsistency in empirical results is partly explained by differences in study settings, measures (disease-specific or generic), sample size and follow-up period. As the studies have not been based on a random allocation of patients, estimates of the effects of waiting on HRQoL may have been biased. Further, several studies have been cross-sectional in design, and thus, the results should be carefully interpreted. Even though HRQoL may remain stable during waiting, the excess burden is large compared with the general population and seems to be constant throughout WT.

5 SOCIAL AND HEALTH SERVICES UTILIZATION

5.1 Definition of social and health care services

A main pillar of the Finnish social and health care system has traditionally been the wide public service network. One way to define social and health services is through legislation. Citizens' basic rights and liberties are included in the Constitution of Finland. According to the law, "…Those who cannot obtain the means necessary for a life of dignity have the right to receive indispensable subsistence and care. Everyone shall be guaranteed by an Act the right to basic subsistence in the event of unemployment, illness, and disability and during old age as well as at the birth of a child or the loss of a provider." (Constitution of Finland 731/1999, 19§).

According to the Social Welfare Act (710/1982), "…social welfare means social services, social assistance, social allowance and related measures intended to promote and maintain the social security and functional ability of the individual, the family and the community." Of the social services, home help services[4], housing services[5], institutional care[6] and support services (e.g. meals on wheels, cleaning, laundry services, bathing and transportation services) are central for elderly people (Rissanen 1999, Vaarama et al. 2004).

A characteristic of the Finnish health care system is the responsibility of the municipalities in the provision and financing of social and health services. The aim of national health policy is "to extend people's active and healthy life, ensure the best possible quality of life for all, and reduce differences in health between different sectors of the population" (Ministry of Social Affairs and Health 2004). Concerning the arrangement of health services, the Primary Health Care Act (66/1972) and the Act on Specialized Medical Care (1062/1989) are key. Primary health care is mainly organized within municipal health centres or provided jointly with other local authorities, while municipal federations (hospital districts) are responsible for specialized medical care. Public health care financing has, from 1980 to 2000, undergone a change towards growth in local responsibility. The responsibility of local authorities has increased, whereas the state contribution to financing has decreased (STAKES 2004a). Further, the increase in private services may force the responsibilities of citizens, state and municipalities to be redefined and new

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[4] "Performance of or assistance with functions and activities related to housing, personal care and attendance, child care and upbringing, and other conventional functions and activities in normal daily life" (Social Welfare Act 710/1982, 20§).

[5] "The provision of service housing and supported accommodation" (Social Welfare Act 710/1982, 22§).

[6] "The provision of treatment, upkeep and rehabilitation in a social welfare unit providing continuous care" (Social Welfare Act 710/1982, 24§).

co-operative public-private mix models, such as outsourcing, public utilities and municipal enterprises, to be created.

Researchers of social policy have also attempted to define social and health care services. A problem of international comparative studies has been difficulty in finding commensurable definitions of the concepts “social service” and “health service” between countries. Several characteristics make a distinction between the concepts: whether to categorize the services into social care services or health care services (e.g. care of elderly people), to make a distinction between public and private providers or to regard informal care as a social care service (Anttonen & Sipilä 1996). Orloff (1993) and O’Connor (1993) have emphasized that social services can be understood as services that support personal autonomy and independence. By this definition, non-voluntary interventions, commercial care and non-professional care cannot be regarded as social care services. Finnish researchers Anttonen and Sipilä (1996) emphasize in their study on European social care services the importance of making a separation between social services and social care services. They have used social services as a synonym for the British concept of personal social services, which refer to social services as “services concerned with needs and difficulties which inhibit the individual’s maximum social functioning…” (Sainsbury 1977). An American counterpart to the term is “human social service” (Kahn & Kamerman 1977). On the other hand, social care services refer to organized – and often publicly funded – non-commercial and universal services that people need and utilize on a voluntary basis (Anttonen & Sipilä 1996).

5.2 Social and health services utilization among elderly Finnish people

Patients undergoing THR or TKR tend to be older. In 2004, the mean ages of Finnish THR[7] and TKR[7] patients were 71 and 69 years, respectively (Stakes 2005). Thus, when analysing service utilization in these patient groups, it is generally important to have a picture of utilization patterns in an ageing population. When reviewing the utilization of social and health services in Finland, the development seems twofold; the rights of citizens to public services have within recent years widened, but at the same time local authorities have contended with growing duties and strict budgeting and cost control (Lehto 2003).

The average age of Finns is on the rise, which will increase demand for social and health services for the aged. However, several studies have shown that the use of social and health services among aging people is not totally related to need (Laukkanen et al. 1992, Raatikainen 1992, Koskinen et al. 2002, Vaarama et al.

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[7] Primary prosthetic replacement of hip or knee joint, NOMESCO classification.

2004). In Finland, Rissanen (1999) has reviewed empirical studies on social and health service utilization among Finnish elderly people. According to the review, previous studies have shown that services are directed to the oldest. Mikkanen (1988) found that more than half of the people aged over 80 years used home help services. According to Valvanne et al. (1991), the need of support for daily activities doubled between individuals aged 80 and 85 years. However, Virjo (1996) found in the middle of 1990s that 18% of people 75 years or older did not use any social or health services.

In a longitudinal study, Vaarama et al. (2004) revealed that the number of customers (aged 65 or over) in home help services has declined by almost 33% between 1990 and 2002, whereas the use of support services and non-professional care has increased. At the same time, intensified service housing has become more utilised as compared with old people's homes and long-term care in health centre wards (Vaarama et al. 2004). Of the support services, meals on wheels, laundry services, cleaning and transportation have been most often utilized (Vaarama 1992, Karjalainen & Kivelä 1995).

On the basis of literature (Mikkanen 1988, Winblad 1988, Anttila 1989), Rissanen (1999) found that about one-third of the elderly utilized home nursing services in 1988-1990. Vaarama et al. (2004) followed the use of home nursing services from the middle of the 1990s until the beginning of the 21st century and observed that in 2001, almost 7% of people 65 years or older and 12% of people 75 years or older used either home help services or home nursing services. Now, at the beginning of the 21st century, home help and home nursing services are more selectively allocated to the oldest and those in the poorest condition (Vaarama et al. 2004).

5.3 Service utilization in patients with joint replacement surgery: an empirical approach

Numerous empirical studies have assessed health and social services utilization in different subgroups (e.g. by age, gender, diagnostic group, socio-economic status, ethnicity, education and health status). However, little is known about the extent to which patients awaiting and undergoing THR or TKR use social and health services.

In a prospective Scottish study (Orbell et al. 1998), 107 consecutive patients with primary hip or knee replacement were interviewed preoperatively, three and nine months after surgery. Service utilization included non-professional care[8]

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[8] Non-professional care was measured by asking about the amount of time non-professional supporters spent caring for the patient and if anyone helped the patient with shopping, transportation, finances, laundry, legal matters, housework, preparing meals, nursing tasks, dressing/undressing, bathing, toileting, going to bed/getting up, eating and household repairs.

and community care service[9]. Patients reported increases in the utilization of professional and non-professional care at both follow-up measurements compared with preoperative use of services. McMurray et al. (2002) in Australia investigated health service use following THR. They found that most patients were satisfied with the services used after surgery; general practitioners were seen most often, nursing visits occurred in weeks 1 and 2 and specialist visits in weeks 8 and 12 post-operatively. Quan et al. (2002) in a Canadian retrospective cohort study assessed the use of home care in patients awaiting cholecystectomy, discectomy, hysterectomy, THR or TKR. Utilization was measured one year before and immediately after the procedure. The length of waiting was not associated with greater health service use, and thus, length of waiting was not a proxy for utilization. In 1992, Rigge (1994) interviewed 50 orthopaedic patients who had been on the waiting list for at least two years. The use of social services was dispersed both before and after surgery, and those who had undergone surgery or were persistent enough received the most help to make daily living more comfortable.

5.4 Predicting service utilization

A modified version of the Behavioural Model of Health Service Utilization developed by Andersen (1995) was applied in this study when assessing the use of social and health services in patients awaiting THR or TKR (see section 9.2.5). A further understanding of the factors contributing to prediction of service utilization is necessary, particularly regarding utilization patterns of patients with OA of the hip or knee joint.

Andersen's model of service utilization has been widely used to predict the use of social and health services in such groups as diabetic patients (Fakiri et al. 2003) and persons with dementia (Toseland et al. 2002). According to Andersen (1995), utilization of health services is affected by individual determinants, such as need and income, and is also highly influenced by environmental and provider-related (i.e. contextual) factors. The main elements of the model are described in more detail below.

Phase 1 of Andersen's model contained three categories: 1) predisposing factors that are classified into demographic (age, gender), social structure (education, occupation, ethnicity) and attitudinal-belief variables (attitudes, values and knowledge about health and health services), 2) enabling factors that are classified into family resources (e.g. income, health insurance, regular source of care, travel and waiting times) and characteristics of the community (e.g. availability of personnel and facilities) and 3) need factors (perceived and evaluated health or illness). Concerning need factors, several studies have shown that perceived health is an important determinant of health service utilization in adult populations of the

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[9] Home help, district nurse, meals on wheels, laundry services, day centre attendance.

Western world (Hulka & Wheat 1985, Hornbrook & Goodman 1995, Miilunpalo et al. 1997, Nelson et al. 1998).

Andersen's phase 1 model was highly criticized and later revised. In the second phase, health care system factors were included in the model (Andersen 1995). Health care system variables – national health policy, resources and their organization – enlarged the model. Further, personal health behaviour and health outcomes were included in the model. The final model, the phase 4 model, is a synthesis of variables developed in previous phases. The model integrates environmental, individual and provider-related variables with individual's health behaviour and health outcomes (Andersen 1995).

Environmental factors refer to characteristics of the health care delivery system (policies, resources, organization and financial arrangements), external environment (economic climate, relative wealth, politics, level of stress and violence and prevailing norms of society) and community-level enabling variables (attributes of the community where utilization occurs) (Andersen & Davidson 1996). Environmental variables when measured at the population level serve as a pragmatic tool to examine the influence of health policies on service utilization. Like environmental variables, provider-related variables measure the context of utilization and include provider characteristics (e.g. physician's gender, age, education and specialty) and patient-related factors that may be influenced by providers (e.g. regular source of care) (Phillips et al. 1998).

6 TOTAL HIP AND KNEE REPLACEMENT: MAIN CONCEPTS

6.1 Definition of Osteoarthritis (OA)

Osteoarthritis (OA, sometimes referred to as osteoarthrosis or degenerative joint disease, see Hinton et al. 2002) is a chronic joint disease that mostly affects the cartilage. Some theories emphasize the role of mechanical factors in the pathophysiology of OA, whereas other studies have investigated the role of biochemical processes (Pagura et al. 2003). In any case, the interaction between mechanical and biochemical factors leads to changes in the composition and mechanical properties of cartilage (Hinton et al. 2002). Healthy cartilage allows bones to glide over one another, but in cases of OA, the surface layer of cartilage breaks down and wears away. As a result, the underlying bone becomes compressed, irregular and bony outgrowths (spurs) may form. Instead of gliding smoothly, joint surfaces rub against each other. In advanced OA, there is a total loss of the cartilage between the bones of the joints. This results in increased pain and restrictions in physical function (National Institute of Arthritis and Musculosceletal and Skin Diseases 2002).

OA most often occurs at the ends of the fingers, thumbs, knees, hips and spine (Heliövaara 1996) and is divided into primary and secondary OA. The former is related to ageing, whereas the latter is caused by another disease or condition such as obesity, traumatic arthritis, congenital abnormalities, gout, diabetes and other hormone disorders (Arokoski 2002).

6.2 Prevalence of OA

OA is one of the most prevalent chronic diseases causing long-term physical disability, especially among older people, and is ranked second among all diseases that result in restrictions in physical function (Badley 1995, Pagura et al. 2003). The prevalence of arthritis in the US is estimated to rise from 15% (40 million) of the population in 1990 to 18% (59.4 million) in 2020 (Lawrence et al. 1998). In Finland, about 400 000 people are affected by OA of the hip or knee joint. Both men and women are afflicted, but before age 45, the prevalence is higher among males than among females, and after age 45, the situation is the reverse (Arokoski 2002).

6.3 Causes of OA

Understanding of the aetiology of OA is incomplete. There is no single cause of OA, instead OA arises from a combination of factors. The main causes can be categorized as being systemic and local biomechanical factors. Systemic factors, such as age, sex, ethnic background and heredity, expose to risk factors of OA. Local biomechanical factors include obesity, joint injuries, developmental deformities and other biomechanical factors (Arokoski 2002). There is some inconsistency in the risk factors of OA. The prevalence of OA in hip and knee joints correlates strikingly with age for hip and knee joints, whereas the association with body weight or joint injuries is not as strong for hip OA (Table 4).

TABLE 4. Risk factors of OA of the hip and knee joint (Adopted from Arokoski 2002, 63)

Risk factor	Hip	Knee
Age	+	+
Sex	females = males	females > males
Ethnic background	lower incidence in Asians	higher incidence in black people
Obesity	+/-	+
Developmental deformities	+	+/-
Joint injuries	+/-	+
Occupation (farming)	+	+/-

+ = high risk; +/- = little or no evidence.

6.4 Diagnosis of OA

A diagnosis of OA is usually based on a combination of methods such as the patient's medical history, physical examination and radiographs (Hinton et al. 2002). Medical history provides information on symptoms (pain, stiffness, joint function), when and how they occurred and how they have changed over time, on surgeries and other procedures that the patient has had and on the patient's current condition, diseases and medication (National Institute of Arthritis and Musculosceletal and Skin Diseases 2002). In the physical examination, a doctor will check the patient's general health, reflexes, muscle strength and joint function such as bending. Radiographs are needed to confirm a diagnosis, exclude other causes of pain and determine how much joint damage has occurred. Radiographs can show loss of joint cartilage, bone spurs and narrowing of the joint space and may help to make a decision on the timing of surgery (National Institute of Arthritis and Musculosceletal and Skin Diseases 2002). Clinically indicated laboratory tests, such as joint fluid analysis, can be performed to confirm a diagnosis and exclude other diseases or causes of arthritis (Hinton et al. 2002).

6.5 Treatment of OA

The aim of treatment of OA is to improve joint function and reduce pain (Arokoski 2002). OA is a slowly progressive disease. Early in the disease, conservative treatment strategies include exercise, walking aids (e.g. canes and walkers), pain relief medication and physical therapy. There are also several other techniques to relieve pain and stiffness. For example, weight loss can reduce stress on large, weight-bearing joints and limit further injury. Patients may also try acupuncture (Scharf et al. 2006), drink herbal tea, apply warm towels or hot packs or have a warm bath or shower to apply moist heat to the joint. Mud baths, water therapy in a heated pool or whirlpool are also used to relieve pain and stiffness (National Institute of Arthritis and Musculosceletal and Skin Diseases 2002).

For patients with advanced OA of the hip and knee joint, hip and knee replacements have become commonly performed orthopaedic procedures when the pain is severe and not relieved by other methods (Escalante et al. 2000). THR and TKR are surgical procedures to remove the injured or diseased part of the hip or knee joint, replacing it with a new, artificial part known as a prosthesis.

As the population ages, the number of persons suffering from arthritis is increasing, and the demand for THR and TKR is anticipated to grow. In 2003, the number of total primary hip[10] and knee[11] replacements performed in Finland was almost 8800 (169 per 100 000 inhabitants) and 6800 (131 per 100 000 inhabitants), respectively (STAKES 2004b). Between 1987 and 2002, the number of THR operations rose on average by 5% and the TKR operations by 12% annually (Figure 4). Both international and national studies have reported wide geographical variations in the number of replacements, even after adjustment for age and gender (Chassin et al. 1986, Katz et al. 1996, Mikkola et al. 2005). In 2002, the THR rate[12] in Finland was 112 per 100 000 inhabitants, varying from 82 to 143 between hospital districts. In patients undergoing TKR[13], the national average rate was 118 surgeries per 100 00 inhabitants, varying from 73 to 199 (Mikkola et al. 2005).

Numerous studies have shown that total hip and knee replacements are medically effective and cost-effective procedures to relieve pain and improve physical function (Bayley et al. 1995, Bourne 1996, Brander et al. 1997, Rissanen et al. 1997, van Essen et al. 1998, March et al., 1999, O'Connell et al. 2000, Jones et al. 2000, Bachmeier et al. 2001, Chiu et al. 2001, Blom et al. 2006). In addition, the use of generic instruments that encompass not only joint mechanics, pain and

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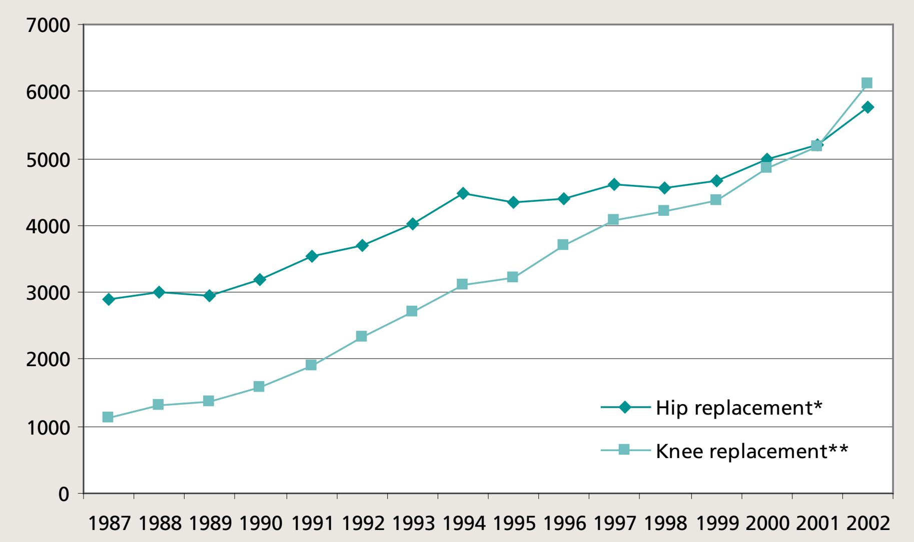
[10] NFB10-NFB99, NOMESCO classification.

[11] NGB10-NGB99, NOMESCO classification.

[12] NFB30-NFB99.

[13] NGB10-NGB99.

physical function, but other dimensions, such as mental health, vitality or social functioning, have become popular and highly utilized in comparisons between efficacious treatments of OA (Lieberman et al. 1997).



* Total replacement (NFB30-90 Nomesco classification).
** Total and partial replacement (NGB10–99).

FIGURE 4. Annual number of total hip and knee replacements in Finland in 1987–2002 (adopted from Mikkola et al. 2005)

7 AIMS OF THE STUDY

The aim of this randomized controlled trial was to elucidate the effects of WT on THR and TKR patients' HRQoL, pain, physical function and utilization of social and health services. In addition, patients' HRQoL was compared with that of the general population. Specific aims of the study were as follows:

1. To compare patients' HRQoL with that of the general population (STUDY I).
2. To analyse HRQoL, pain and function in THR and TKR patients during the waiting time and to evaluate whether waiting time is associated with patients' health outcomes at admission (STUDIES II and IV).
3. To assess whether the length of waiting time is associated with social and health services utilization in patients awaiting THR or TKR (STUDY III).

8 MATERIALS AND METHODS

8.1 Study design

The study is based on a prospective experimental design with three main components: 1) intervention group (patients with short WT), 2) control group (patients with non-fixed WT) and 3) randomization. The study design, known as a pretest-post-test control group design, may be described as follows (Campbell & Stanley 1963, 13):

$$\begin{array}{llll} R & O_1 & X & O_2 \\ R & O_3 & & O_4 \end{array}$$

R indicates random allocation of patients, O_1 and O_2 indicate the pretest-post-test for the treatment group, X indicates intervention for the treatment group and O_3 and O_4 indicate the pretest-post-test for the control group. The effect of intervention X can be measured as the difference between O_2 and O_4.

8.2 Study population

After being informed of the study, 1058 consecutive patients attending preoperative assessment by an orthopaedic surgeon were recruited from three Finnish hospitals (Surgical Hospital, Helsinki University Central Hospital HUCH; HUCH Jorvi Hospital; Coxa Hospital for Joint Replacement) in two hospital districts (Hospital District of Helsinki and Uusimaa and Pirkanmaa Hospital District). Two hospitals were university hospitals providing services for municipalities in the capital area. The third hospital was specialized in endoprosthetic surgery, providing services for municipalities, local and central hospitals, as well as for private patients.

Patients were recruited to the study through regular contact with orthopaedic surgeons and practice staff during four recruitment periods (in Coxa hospital during three recruitment periods) from August 2002 and November 2003. The last patient was admitted to hospital in May 2005. Patients came for an outpatient surgical assessment with a referral from a health centre, a local or central hospital or a private physician. If the patient did not live in the hospital district, a payment agreement given by the home municipality was required.

The inclusion criteria were as follows:

- a need for a primary unilateral or bilateral THR (NFB10-99, NOMESCO classification) or TKR (NGB10-99), as evaluated by the surgeon (excluding rheumatoid arthritis, fractures, haemophilia and deformity)
- an age of 16 years or older
- placement on a waiting list in one of the three research hospitals
- patient willing and mentally able to participate in the study.

A total of 1058 eligible patients were informed about the study and asked to participate (Figure 5). Of these, 225 (21%, 225/1058) were subsequently excluded: 206 refused to participate, 2 were operated on the contralateral side, 2 did not understand Finnish or Swedish, 1 was an inmate of an institution and 14 for some other unknown reason. Only data on patients with a complete set of 15D questionnaires were analysed. A total of 622 patients responded to both two questionnaires.

For each of the 197 patients recruited to the study by the end of May 2003, two population controls matched by age, gender, housing (living alone – living with someone) and place of residence were drawn from the National Population Register using random sampling. Housing was used as a proxy for need of social support and place of residence as a proxy for supply and demand of service utilization. Two controls per patient were selected in case a control subject declined to participate, being replaced in this event with the other control. Of the 197 eligible patients recruited to the study, 30 were excluded because their controls declined to participate. In addition, 6 patients did not complete the baseline and 28 patients did not complete the admission questionnaire and were thus excluded. Thus, the final analysis focused on 133 pairs with complete questionnaires.

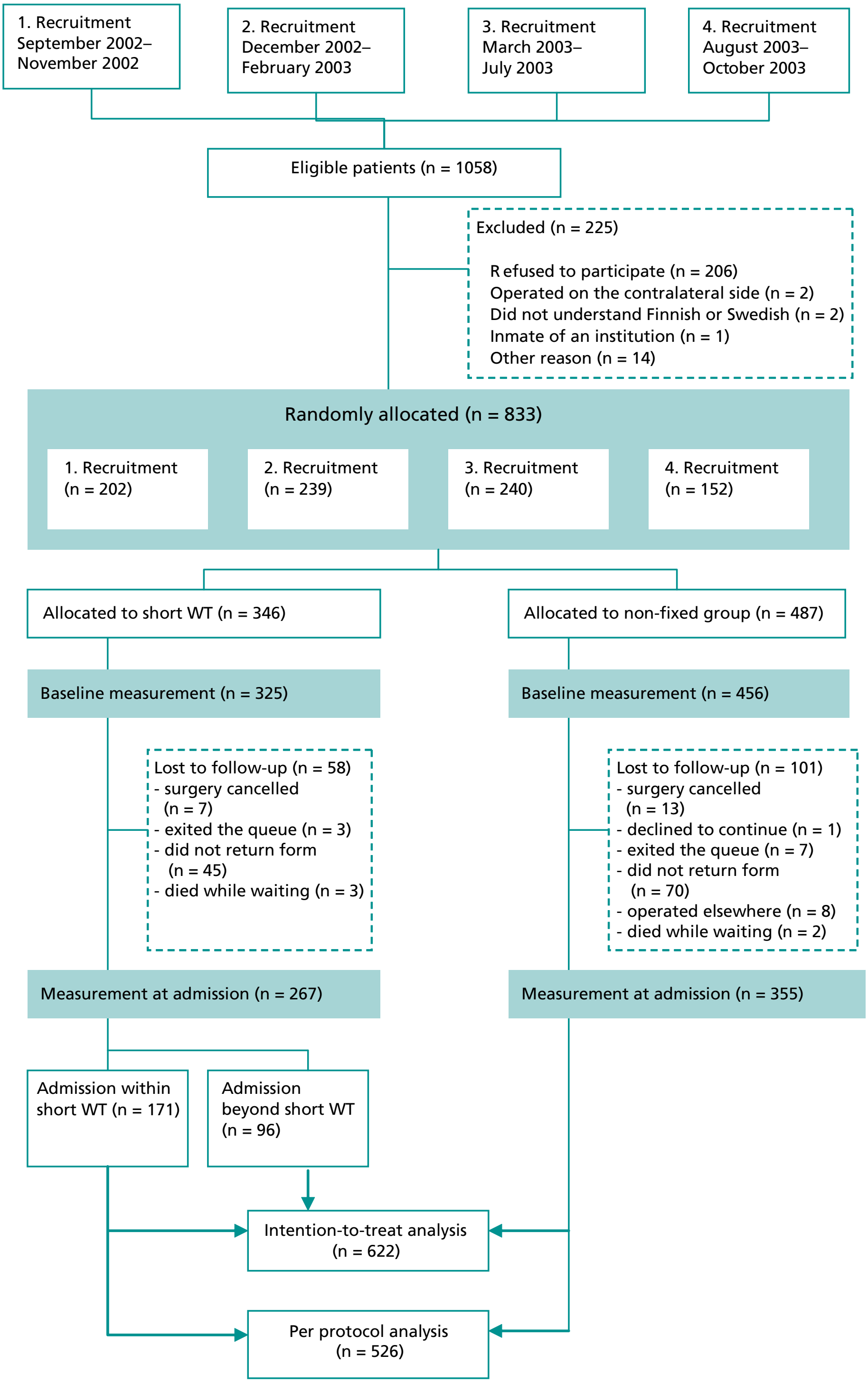


FIGURE 5. Trial profile

8.3 Randomization

WT was defined as a time period between treatment decision and admission for a primary unilateral or bilateral THR or TKR. After being placed on the waiting list according to clinical criteria, patients were randomly assigned to either short (maximum three months[14]) or non-fixed WT (patient received surgery according to the hospitals' routine procedure; from the date he or she was added to the waiting list to the date of surgery).

The number of patients placed on the waiting list varied from one month to another, being specific to each hospital. No advance estimate could therefore be made of the number of patients to be placed on the list. Consequently, the following arrangements were made: 1) the patients randomized into the short WT group could only be operated on every fourth month, and only half of the hospital's one-month surgical capacity could be allocated as short waiting times, so the number of short waiting times was restricted and determined specifically for each hospital, and patients were recruited into the study in three (one hospital) or four (two hospitals) recruitment periods of three months (Table 5); 2) recruitments were made in periods of three months in order to avoid the waiting time for the short WT group exceeding three months; 3) patients in the short WT group were operated on within two weeks after each recruitment period; 4) all eligible patients placed on the waiting list had a chance of being recruited into the study (including the possibility of short WT) by not restricting the size of the non-fixed WT. Thus, the groups were different in size.

The tasks of generating the random sequence and implementing the assignment were separated between researchers and clinical staff. The random allocation sequence was drawn using a computer-generated randomization list. In each hospital, after a patient was placed on the waiting list, the patient's assigned nurse allocated participants to their groups using consecutively numbered, sealed, opaque envelopes. A separate randomization procedure was performed within each hospital. Surgeons were unaware of the assigned intervention. For ethical reasons, double-blinding was not possible.

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[14] WT was limited to three months reflecting the preparatory work of the working group on access to care and waiting list management (Ministry of Social Affairs and Health 2003). According to the working group, medically justified treatment must be provided within three months, or at the very latest, six months.

TABLE 5. Recruitment periods

	Hospital 1*	Hospitals 2 and 3
Recruitment period	-	I recruitment 2.9.–30.11.2002
	I recruitment 1.12.2002–28.2.2003	II recruitment 1.12.2002–28.2.2003
	II recruitment 3.3. –30.5.2003	III recruitment 3.3.–30.5.2003
	III recruitment 18.8.–31.10.2003	IV recruitment 18.8.–31.10.2003
Short WT patients received operation	-	I recruitment 2.–15.12.2002
	I recruitment 3.–16.3.2003	II recruitment 3.–16.3.2003
	II recruitment 2.–15.6.2003	III recruitment 2.–15.6.2003
	III recruitment 3.–16.11.2003	IV recruitment 3.–16.11.2003

* Due to hospital's capacity, only three recruitment periods were needed.

8.4 Outcome measures

8.4.1 Measuring HRQoL with the 15D instrument

In this study, health outcomes refer to the generic HRQoL measure and disease-specific measures assessing hip and knee pain and physical function. Patients' HRQoL was measured by the 15D (Appendix). The 15D is a generic, self-administered and standardised HRQoL instrument consisting of 15 dimensions: moving, seeing, hearing, breathing, sleeping, eating, speech, elimination, usual activities, mental function, discomfort and symptoms, depression, distress, vitality and sexual activity. For each dimension, the respondent must choose one of the five levels best describing his/her current state of health (best level = 1, worst level = 5) (Sintonen 1994a, 2001a).

The single index (15D score) yielding values between 0 (being dead) and 1 (no problems on any dimension) is calculated from the health state descriptive system by using a set of population-based preference or utility weights (Sintonen 1994a). Such a weight for each level of each dimension is obtained by multiplying the value of the level by the importance weight of the dimension at that level (Sintonen 1995). The values of the levels on a 0–1 scale, reflecting the goodness of the levels relative to no problems on the dimension (= 1) and to being dead (= 0), and the importance weights summing up to unity, have been elicited from representative population samples.

8.4.2 Measuring pain and function: modified Harris Hip Score and Knee Society Score

Disease-specific measures were utilized to supplement the generic 15D instrument. Among TKR patients, condition-specific pain and physical function were evaluated using patients´ self-report scales modified from the Knee Society Clinical Rating System (Insall et al. 1989). Functional performances were assessed using walking distance and stair climbing. According to the Knee Society rating system, stair climbing is considered normal if the patient can ascend and descend stairs without holding a railing. Walking distance was expressed in metres and recorded in the categories of unable, housebound, 100–500 m, 1–1.5 km and unlimited. Pain and function calculated by the Knee Society Clinical Rating System are presented as total pain score (0–100 points) and function score (0–100 points). In this study, pain and function were presented as ordinal scale variables (Appendix) instead of a total score because clinical dimensions (range of motion, stability, flexion contracture, extension lag, alignment) could not be measured in a patient self-administered questionnaire, and thus, total score was not possible to calculate.

In THR patients, the patient self-report HHS was used as a disease-specific outcome measure to assess hip pain and function (Mahomed et al. 2001). The self-report HHS consists of pain (0–44 points) and function (0–46 points) subdivided into activities of daily living (ADL, 0–13 points) and gait (0–33 points) (Appendix). The total score ranges from 0 to 90 points, with a high score representing the best health state. Deformity and motion were excluded because these items could not be measured in a patient self-administered questionnaire. The performance of a self-reported HHS is comparable with that of a surgeon-assessed HHS and has been shown to be less burdensome to patients (Mahomed et al. 2001).

8.4.3 Social and health care services utilization

The use of social and health services was assessed using an ad hoc measure based, among other things, on previous studies of service utilization in Finnish populations (Noro et al. 1996, Arinen et al. 1998). Data on service utilization were expressed as the percentage of persons with at least one visit. Participants were asked at baseline and on admission whether they had had home visits from a nurse, chiropodist or physician (public or private) and whether they had used rehabilitation services (public or private) within the last three months due to hip or knee disease (Appendix). Further, patients were asked at baseline and on admission whether they used any support services of home help, including regular or temporary meals on wheels, housework, laundry services, bathing and transportation. Support services were classified into three groups on the basis of the service provider: public support services, private support services and non-professional care provided by a relative, neighbour, voluntary sector or other non-professional provider.

Further, participants were asked at admission whether they had any physician visits in the previous three months (university hospital, central hospital, regional hospital, health centre, private physician, occupational health care visits) for any reason and whether they had been admitted to hospital during this period (inpatient care). The physician consultation rates and inpatient care days are reported only in this summary part of the thesis.

8.5 Measurement points and questionnaires

A self-administered questionnaire accompanied by a prepaid return-addressed envelope was delivered to patients at two specific points in time: 1) at the outpatient clinic, when a patient was placed on the waiting list by the orthopaedic surgeon (baseline), and 2) at hospital admission. Questionnaires were returned to the researchers. Common guidelines for administering the questionnaires were provided in each hospital. The protocol specified that one nurse was assigned to distribute the questionnaire to patients. Swedish-speaking patients obtained the questionnaire in Swedish.

8.6 Data processing and statistical analyses

Frequencies and cross-tabulation were used to detect any inconsistencies in the data, which had been checked in the original questionnaires. The 15D data were originally coded as ordinal numbers (1–5) and replaced afterwards by values of levels produced by the valuation system (Sintonen 2006). Missing values for the 15D dimensions were predicted by regression models, with the responses on the other dimensions and age and gender as explanatory variables (Sintonen 1994a). A missing value was substituted if a minimum of 80% of responses on the dimension was present. Otherwise, missing data were excluded from the analyses.

The sample size estimate was based on the primary outcome variable (15D score). A subgroup of 177 patients provided 80% power and a subgroup of 235 patients 90% power (two-tailed ∀ error 5%) to detect clinically important differences (Δ0.03) in the 15D score between the groups (Sintonen 1994b).

Comparative analyses of baseline socio-demographic and clinical characteristics between patients who completed the questionnaires (baseline and admission) and those lost to follow-up were carried out using either the independent samples t-test or the Chi-squared test depending on the level of measurement.

For the randomized trial, primary analyses were based on the intention-to-treat (ITT) principle and comparisons were between the randomized groups (parallel group design). Group differences in the 15D score, pain, physical function and service utilization were tested by the independent samples t-test or the Chi-squared test depending on the level of measurement. Confidence intervals (CIs) of 95% were calculated for mean differences in outcomes at admission. All differences are presented as short WT minus non-fixed WT.

In a further per-protocol (PP) analysis, short WT patients who were admitted beyond short WT (waiting time > three months) were excluded. In addition, linear regression analysis was used as a supplementary aid to determine the relationship between WT and HRQoL at admission, with WT as an independent variable.

Further, service utilization at admission was analysed by means of logistic regression (using the enter method). Logistic regression models were applied to predict visits to home by nurse, chiropodist or physician, rehabilitation services, support services (regular or temporary meals-on-wheels, housework services, laundry services, bathing services and transportation) and informal care. Each regression model included independent factors according to Andersen's model of utilization (see chapter 5.4) (Andersen 1995):

- Need factor: the baseline HRQoL measured by the 15D
- Predisposing factors: gender, education level
- Enabling factors: home municipality, waiting time.

Two-sided P-values were calculated in all analyses and a value < 5% was regarded as statistically significant. Data analyses were performed using SPSS for Windows, version 12.0.1 (SPSS Inc., Chicago, IL).

8.7 Ethical considerations

All patients provided a written informed consent. The study protocol was approved by the HUCH Surgery Ethics Committee (registration number 134/E6/02). Surgeons were unaware of the assigned intervention. For ethical reasons, double-blinding was not possible. The trial was registered in the U.S. National Institutes of Health (NIH) ClinicalTrials.gov Register (www.clinicaltrials.gov) under trial number NCT00294424.

9 RESULTS

9.1 HRQoL of patients awaiting major joint replacement: comparison between patients and population controls (I)

This analysis was based on a subsample of 133 patients awaiting major joint replacement and belonging to the short WT group in the randomized trial. A sample of controls matched by age, gender, housing and home municipality was drawn from the computerized population register.

The average age of the study population, including both patients and the matched population controls, was 67.6 years (range 36–86 years). Of patients, 73 (55%) were waiting for primary THR and 60 (45%) for primary TKR. The majority (54%, n = 143) of the participants (including patients and population controls) were from the capital area. A total of 75 participants (28%) were from another urban area and 48 (18%) from a rural area.

A comparison between patients and population controls showed that controls more often had a professional education and weighed less than patients. Of patients, 21 (16%) had a normal body mass index (BMI < 25 units) and 112 (84%) were overweight or obese (BMI ≥ 25 units). Of population controls, 45 (34%) had a normal BMI and 86 (66%) were overweight or obese.

At the time the patients were placed on the waiting list, the mean (SD) 15D score was 0.778 (0.091). Among the population controls, the mean (SD) 15D score was 0.883 (0.103). The difference was statistically significant and clinically important (Figure 6). The difference between the groups remained significant and clinically important when patients' HRQoL at admission was compared with the HRQoL among population controls. At baseline, patients had statistically significantly lower scores on the dimensions of moving, sleeping, usual activities, discomfort and symptoms, depression, distress, vitality and sexual activity than population controls.

In patients, the 15D score improved while waiting, but the change was not significant or clinically important (Δ0.008, t = 1.6, P = 0.123, 95% CI 0.002 to 0.019). The patients showed, however, statistically significantly improved mean scores at admission for moving (Δ 0.032, t = 2.2, P = 0.026, 95% CI 0.004 to 0.060), sleeping (Δ 0.042, t = 3.0, P = 0.004, 95% CI 0.014 to 0.071) and discomfort and symptoms (Δ 0.038, t = 2.1, P = 0.041, 95% CI 0.002 to 0.075) compared with the baseline measurement (not shown).

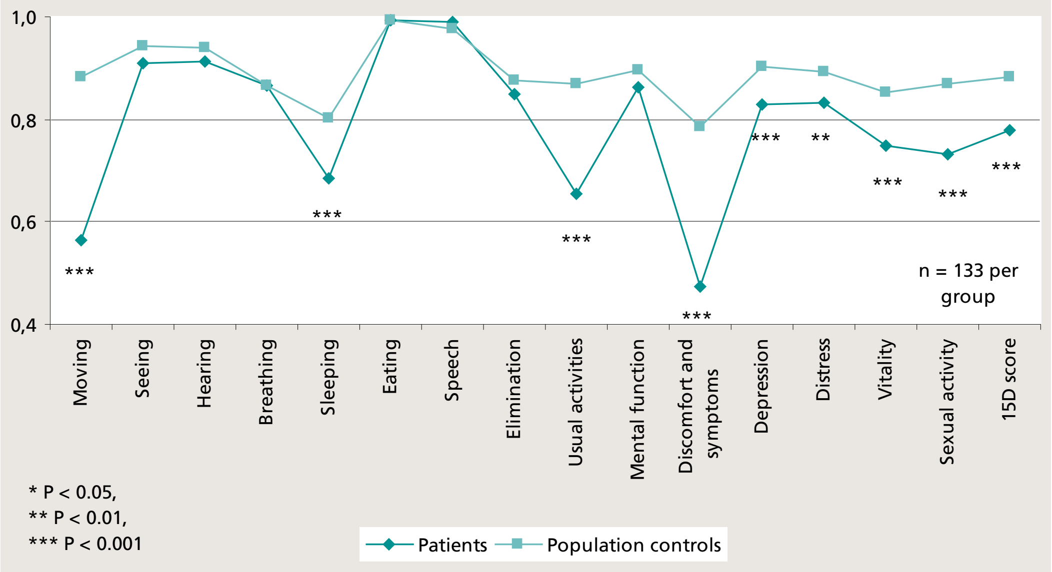

FIGURE 6. Baseline 15D profiles and scores of patients and population controls

9.2 Results of the randomized trial

9.2.1 Baseline characteristics of patients

A comparison of cumulative waiting times between randomized groups shows that in patients with short waiting times the majority (71.2%) were operated on within three months (Figure 7). Nine of the 267 patients (3.4%) waited for more than a year. In patients with non-fixed WT, waiting times were longer and only 52 of 353 patients (14.7%) were operated on within three months. A total of 79 patients (22.3%) waited for more than a year.

The baseline characteristics of patients and subjects lost to follow-up are shown in Table 6.

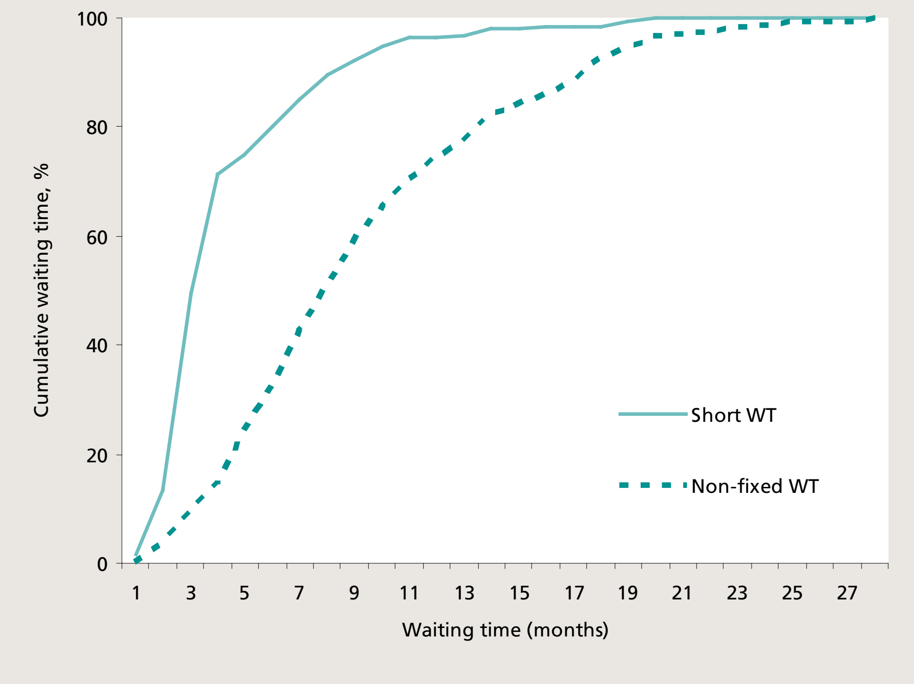

FIGURE 7. Cumulative waiting time curves of randomized groups (total hip and knee replacement)

TABLE 6. Baseline characteristics of respondents and subjects lost to follow-up

Characteristic	Short WT (n = 267)	Non-fixed WT (n = 353–355)[b]	Lost to follow-up (n = 153–159)[b]	P-value[c]
Age, years [mean, (SD)]	66.0 (9.5)	66.7 (9.6)	68.4 (9.9)	0.023
Females [n, (%)]	171 (64.0)	210 (59.2)	101 (63.5)	0.600
Living alone [n, (%)]	88 (33.0)	95 (26.8)	67 (42.1)	0.002
Professional examination, yes [n, (%)]	99 (37.1)	134 (37.9)	51 (32.1)	0.203
Place of residence [n, (%)]				0.002
Capital	138 (51.7)	151 (42.8)	98 (61.6)	
Other urban area	80 (30.0)	121 (34.3)	41 (25.8)	
Rural area	49 (18.4)	81 (22.9)	20 (12.6)	
Joint [n, (%)]				0.008
Hip	140 (52.4)	172 (48.5)	61 (38.4)	
Knee	127 (47.6)	183 (51.5)	98 (61.6)	
BMI[a] [mean, (SD)]	29.3 (4.5)	28.9 (4.5)	28.8 (5.0)	0.568
Co-morbidity, yes [n, (%)]	194 (72.7)	258 (72.7)	124 (78.0)	0.174
Waiting time, days [Median, (range)]	75 (8–600)	222 (7–818)		

[a] Body mass index (kg/m^2).

[b] Number of observations varies due to missing values.

[c] Between patients who completed the questionnaires and those lost to follow-up.

No statistically significant differences (P < 0.05) present in baseline characteristics between randomized groups.

The baseline 15D profile for the whole patient population is shown in Figure 8. Both THR and TKR patients scored lowest for discomfort and symptoms.

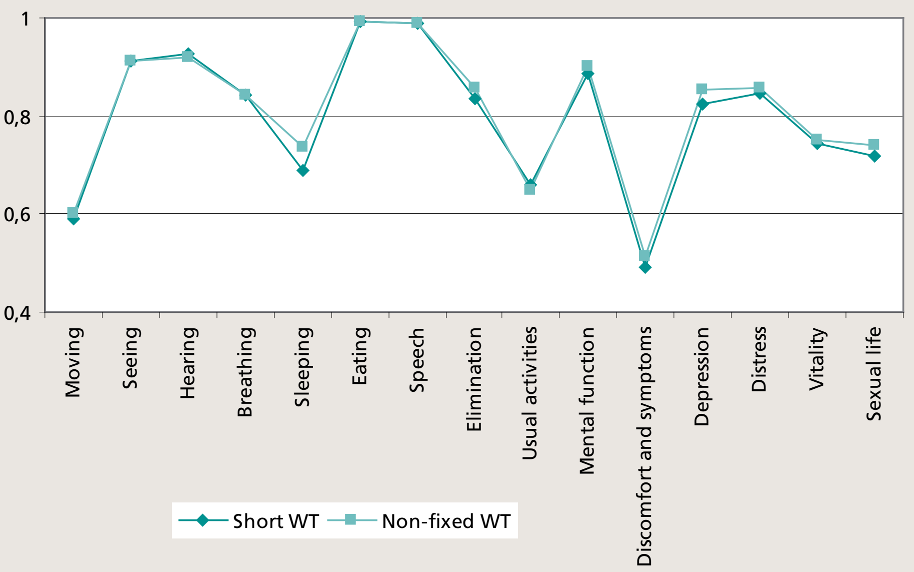

FIGURE 8. Baseline 15D profiles of all patients

9.2.2 Effect of waiting time on HRQoL (intention-to-treat analysis, II, IV)

The 15D profiles of hip and knee patients are shown in Figures 9 and 10. A total of 319 of 622 patients (51.3%) reported poorer HRQoL at admission than at baseline. A further 282 patients (45.3%) reported an improvement in HRQoL while waiting, and the remaining 21 patients (3.4%) reported no change during the WT. In the ITT analysis, a comparison between the randomized groups at admission revealed that no significant or clinically important difference was present in the admission 15D score (Table 7). In the whole patient population (THR + TKR patients), the mean difference between the randomized groups was 0.008 (95% CI -0.007 to 0.022). In THR patients, the mean difference was 0.001 (95% CI -0.002 to 0.021, P = 0.931) and in TKR patients 0.015 (95% CI -0.007 to 0.037, P = 0.170). The differences were, however, not statistically significant or clinically important.

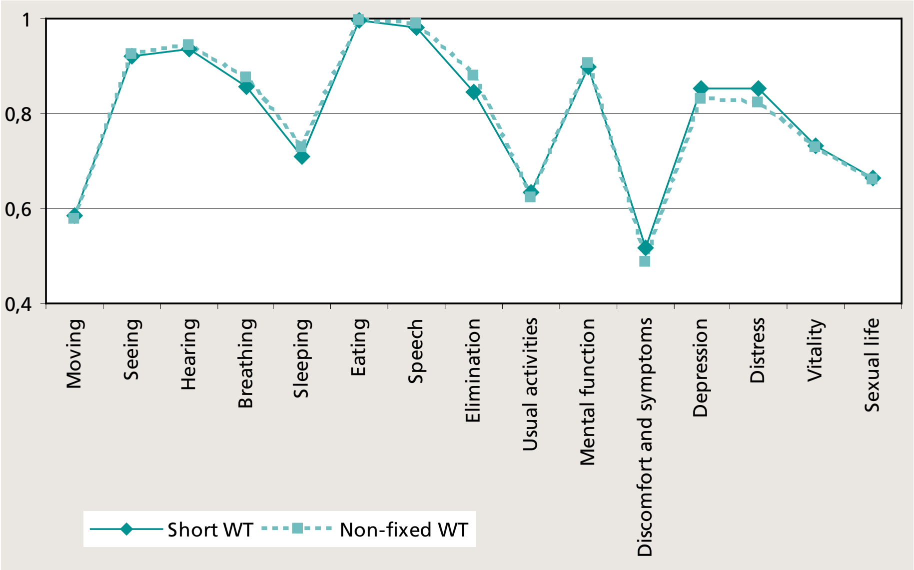

FIGURE 9. Admission 15D profiles of patients undergoing total hip replacement

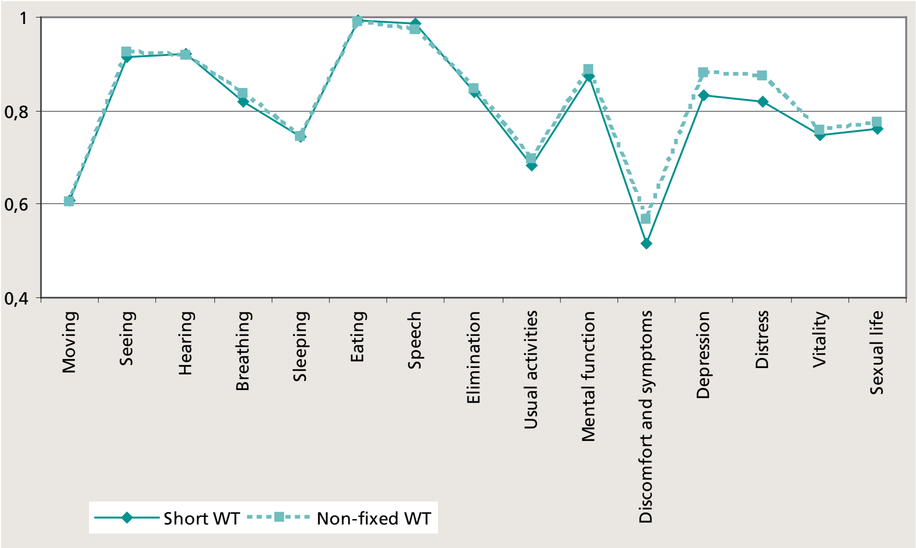

FIGURE 10. Admission 15D profiles of patients undergoing total knee replacement

TABLE 7. Mean 15D scores at admission (intention-to-treat analysis)

Patient group	Mean 15D score (SD)		Mean difference (95% CI)	P-value
	Short WT	Non-fixed WT		
THR + TKR patients	0.785 (0.094)	0.793 (0.093)	0.008 (-0.007 to 0.022)	0.315
THR patients	0.784 (0.089)	0.783 (0.090)	0.001 (-0.002 to 0.021)	0.931
TKR patients	0.787 (0.100)	0.802 (0.094)	0.015 (-0.007 to 0.037)	0.170

9.2.3 Disease-specific outcomes (II, IV)

Self-reported HHS, pain, activities of daily living (ADL) and gait were used as secondary outcome measures. At baseline, there were no statistically significant differences in HHS, pain, ADL and gait between randomized groups. At admission, the mean HHS scores in the short and non-fixed WT groups were 43.5[15] (SD 15.1; range 6 to 90) and 41.9 (SD 14.5; range 2 to 80), respectively. In patients with short WT, the mean (SD) pain score was 17.8[16] (8.0) and in patients with non-fixed WT, 17.1 (8.6). The pain score of HHS at admission ranged from 0 (totally disabled, pain at rest, n = 13, 4.3%) to 44 (no pain, n = 5, 1.6%). A total of 22 patients (7.2%) reported mild pain after unusual activity, 157 (51.5%) reported moderate pain and 101 (33.1%) reported marked or severe pain (Figure 11).

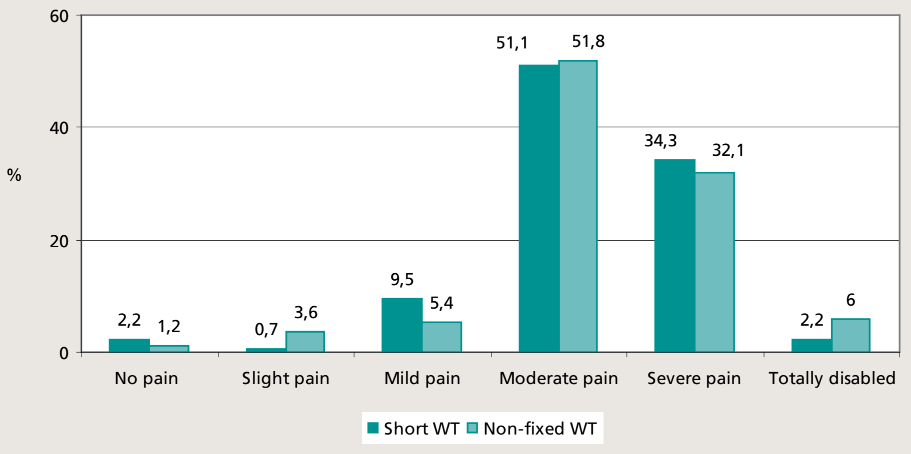

FIGURE 11. Hip pain by randomized group

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[15] Ranging from 0 to 90, worst to best.

[16] Ranging from 0 to 44, worst to best.

With regard to function, the great majority of patients reported limitations in ADL and gait (Table 8). Especially climbing stairs was restricted; only 20 patients (6.5%) were able to climb stairs normally. Furthermore, patients reported problems in walking. A total of 31 patients (10.1%) were able to walk without limits, and the majority (58.3%, 179/307) required support (cane or crutch) to walk comfortably. When comparing the mean scores between two randomized groups at admission, no statistically significant differences in self-reported HHS (Δ1.6, P = 0.359), pain (Δ0.7, P = 0.519), ADL (Δ0.4, P = 0.136) and gait (Δ0.8, P = 0.316) were found.

TABLE 8. Total hip replacement patients' activities of daily living (ADL) and gait at admission by randomized groups

Item	**Short WT[a] (%)**	**Non-fixed WT[b] (%)**
ADL		
Climbing stairs		
Normal	7.2	5.9
Using a railing	39.6	38.5
Step by step, using a railing	51.8	49.7
Unable	1.4	5.9
Sitting		
In ordinary chair for one hour	73.2	64.5
On a higher chair for 0.5 hour	25.4	34.3
Unable to sit	1.4	1.2
Socks		
With ease	13.0	7.1
With difficulty	76.8	78.1
Unable	10.1	14.8
GAIT		
Limp		
None	7.2	5.4
Slight	36.0	28.0
Moderate	43.2	49.4
Severe	13.7	17.3
Support		
None	41.7	41.7
Cane for long walks	10.1	12.5
Cane most of time	13.7	14.9
One crutch	15.1	10.1
Two canes	4.3	5.4
Not able to walk/two crutches	15.1	15.5
Distance walked		
> 1.5 km/unlimited	11.5	8.9
1–1.5 km	23.0	22.5
100–500 m	50.4	52.1
Indoors only	15.1	16.6

[a] n = 138–139.
[b] n = 168–169.

The majority of the TKR patients also experienced moderate to severe pain (73.8% in patients with short, 70.3% in patients with non-fixed WT) at admission (Table 9). Only 4 patients (1.3%) reported no pain. No statistically significant difference was present in the degree of pain between the groups ($\Pi^2 = 3.0$, $P = 0.889$).

At admission, 274 patients (90.7%) reported that their ability to walk was limited, and the majority (n = 241, 79.3%) were able to ascend and descend stairs only with a rail. A total of 22 patients (7.2%) were totally unable to climb stairs at admission. No statistically significant differences were observed in stair climbing ($\Pi^2 = 2.7$, $P = 0.745$) and walking distance ($\Pi^2 = 2.9$, $P = 0.715$) between the groups at admission.

TABLE 9. Total knee replacement patients' self-reported pain and function at admission

Outcome measure	Short WT (%)	Non-fixed WT (%)	P-value
Degree of pain			0.889
None	0.8	1.7	
Mild or occasional	7.1	11.2	
Mild, stairs only	0.8	0.6	
Mild, walking and stairs	17.5	16.2	
Moderate, occasional	40.5	39.1	
Moderate, continual	23.0	22.3	
Severe	10.3	8.9	
Stairs			0.745
Normal up and down	0.8	1.1	
Normal up and down with rail	9.5	8.4	
Up and down with rail	78.6	79.8	
Up with rail, unable down	4.8	2.8	
Unable	6.3	7.9	
Walking distance			0.715
Unlimited	8.0	10.2	
1–1.5 km	25.6	26.6	
100–500 m	51.2	47.5	
Housebound	15.2	14.7	
Unable	0	1.1	
N[a]	125–126	177–179	

[a] Number of observations vary due to missing values.

9.2.4 Further analyses

A PP analysis and regression analysis were performed as supplementary analyses. Concerning THR patients, in the short WT group, those compliant with allocated WT (n = 87) and all patients in the non-fixed WT group (n = 172) were included in the PP analysis. Similar results were obtained in the PP analysis as in the ITT analysis, and WT had no significant effect on the admission 15D score (Δ -0.003).

A linear regression analysis was performed to assess the relationship between WT of THR patients and 15D score at admission; no significant effect was observed ($\beta = -0.0002$, $P = 0.867$, 95% CI -0.002 to 0.002). Similarly, in TKR patients, WT showed no significant effect on the 15D score at admission ($\beta = 0.001$, $P = 0.294$, 95% CI -0.001 to 0.003).

In TKR patients, the PP analysis showed that at admission patients with short WT had significantly lower 15D scores than patients with non-fixed WT (Δ 0.027, 95% CI 0.001 to 0.052, $P = 0.038$).

9.2.5 Health and social services utilization while waiting (III)

In the ITT analysis, within the last three months before admission, the number of home visits from a nurse, chiropodist or physician ranged from 1 to 20 among short WT patients and from 1 to 8 among those with non-fixed WT. Furthermore, 36 short WT (13.5%) and 29 non-fixed WT patients (8.2%) used rehabilitation services during this period. Only seven patients (3%) in the short WT group and two patients (1%) in the non-fixed WT group used rehabilitation services over ten times within this three-month period.

The most commonly used service among patients was informal care (Table 11). Approximately 27% (n = 73) of those with short WT utilized informal care in the last three months before admission as compared with 30% (n = 107) of those with non-fixed WT. The most common provider of the informal care was a relative. Only two patients received support from a neighbour, four from a friend and one from an association. However, the majority of patients in both randomized groups did not utilize any visiting care services, rehabilitation services and home help services.

The results of the ITT analysis showed that patients with short WT significantly more often utilized rehabilitation services ($P = 0.032$) and almost significantly more often visiting care services ($P = 0.054$) than those with non-fixed WT. In the PP analysis, where short WT patients who waited over three months were excluded, no statistically significant differences between the randomized groups were found (Table 11).

TABLE 10. Health and social services utilization at admission (intention-to-treat analysis)

Service	**Short WT (n = 267)**		**Non-fixed WT (n = 355)**		**Difference (95% CI)**	**P-value**
	User (%)	**Non-user (%)**	**User (%)**	**Non-user (%)**		
Visiting care services[a]	7.5	92.5	3.9	96.1	3.6 (-0.1, 7.3)	0.054
Rehabilitation	13.5	86.5	8.2	91.8	5.3 (0.3, 10.3)	0.032
Public support services[b]	2.6	97.4	5.1	94.9	-2.5 (-5.2, 0.2)	0.124
Private support services	6.4	93.6	6.8	93.2	-0.4 (-4.1, 3.3)	0.845
Informal care	27.3	72.7	30.1	69.9	-2.8 (-10.0, 4.4)	0.446

[a] Visits to home from nurse, chiropodist or physician (public or private)

[b] Regular or temporary meals on wheels, cleaning, laundry services, bathing and transportation services

TABLE 11. Health and social services utilization at admission (per protocol analysis)

Service	Short WT (n = 171[a])		Non-fixed WT (n = 355)		Difference (95% CI)	P-value
	User (%)	Non-user (%)	User (%)	Non-user (%)		
Visiting care services	4.1	95.9	3.9	96.1	0.2 (-2.9, 3.3)	0.934
Rehabilitation	13.5	86.5	8.2	91.8	5.3 (0.3, 10.3)	0.057
Public support services	3.5	96.5	5.1	94.9	-1.6 (-4.9, 1.7)	0.421
Private support services	5.8	94.2	6.8	93.2	-1.0 (-5.1, 3.1)	0.690
Informal care	30.4	69.6	30.1	69.9	0.3 (-7.0, 7.6)	0.950

[a] 96 short WT patients admitted beyond three months were excluded.

A total of 497 (79.9%) of 622 patients reported at least one physician visit within the three months before admission (Table 12). There were 47 patients (7.6%) reporting inpatient care days over the previous three months. The number of physician consultations was lower in patients with non-fixed WT than in those with short WT (P = 0.008, 95% CI 0.136 to 0.914). The amount of inpatient care was also lower for patients with non-fixed WT than in those with short WT, but not significantly so.

TABLE 12. Volume of physician visits and inpatient care at hospital admission. A comparison between randomized groups

Service	Short WT	Non-fixed WT	Difference (95% CI)	P-value
Physician visits[a]	2.7	2.2	0.5 (0.136, 0.914)	0.008
Inpatient care[b]	0.5	0.3	0.2 (-0.142, 0.499)	0.273

[a] Average number of physician visits (university hospital, central hospital, regional hospital, health centre, private physician, occupational health care visits) within three months before admission.

[b] Average number of care days within three months before admission.

After adjusting for baseline utilization, WT, gender, home municipality, education and HRQoL, patients with short WT were more likely to use visiting care and rehabilitation services than those in the non-fixed WT group, whereas the patients with non-fixed WT were more likely to use public support services than those with short WT (Table 13). Concerning predisposing factors of utilization, females were more likely to use private support services and informal care than males.

TABLE 13. Logistic regression coefficients for predicting five types of service utilization

	Visiting care services[a]	Rehabilitation[b]	Public support services[c]	Private support services[c]	Informal care[d]
Baseline utilization[e]	1.88**	2.15***	3.62***	3.92***	2.40 ***
Predisposing factors					
Gender	0.51	0.61	0.70	0.99**	0.87*
Professional education	0.34	-0.52	-0.27	-0.41	0.46
Enabling factors					
Waiting time	-0.002	-0.001	0.001	-0.003*	-0.001
Randomized group	-1.07*	-0.67*	1.19**	-0.42	0.13
Home municipality					
rural area	reference	reference	reference	reference	reference
capital area	-0.88	0.49	-0.83	-0.31	0.41
other urban area	-0.19	0.59	-0.82	-0.78	0.19
Need factor					
15D score[f]	0.72	2.15	3.94	-2.92	4.58***

Log odds coefficients. Utilization at admission is an outcome variable coded 0 = user, 1 = non-user. Randomized group coded 0 = non-fixed WT, 1 = short WT. Gender coded 0 = female, 1 = male. Professional education coded 0 = no, 1 = yes.

[a] Visits to home from nurse, chiropodist or physician (public or private)

[b] Public and private rehabilitation services, including physiotherapy and occupational therapy

[c] Regular or temporary meals-on-wheels, housework services, laundry services, bathing services and transportation

[d] Unpaid care provided by relatives, neighbours and volunteers

[e] Coded 0 = user, 1 = non-user

[f] On scale 0-1, worst to best

* Significant at P < 0.05

** Significant at P < 0.01

*** Significant at P < 0.001

9.2.6 Comparison between respondents and individuals lost to follow-up

A comparison between patients who completed the questionnaires (baseline and admission) and those lost to follow-up showed that the latter group was older ($t = 2.3$, $P = 0.023$), more often lived alone ($\Pi^2 = 9.3$, $P = 0.002$) and more often lived in the capital area ($\Pi^2 = 12.2$, $P = 0.002$) than the completers. The 15D profiles for patients and those lost to follow-up are shown in Figures 12 and 13, for THR and TKR patients separately. No significant or clinically important difference was present in the baseline 15D score of those who completed the questionnaires and those lost to follow-up. The proportion of those lost to follow-up was 18% in patients with short WT and 21% in patients with non-fixed WT.

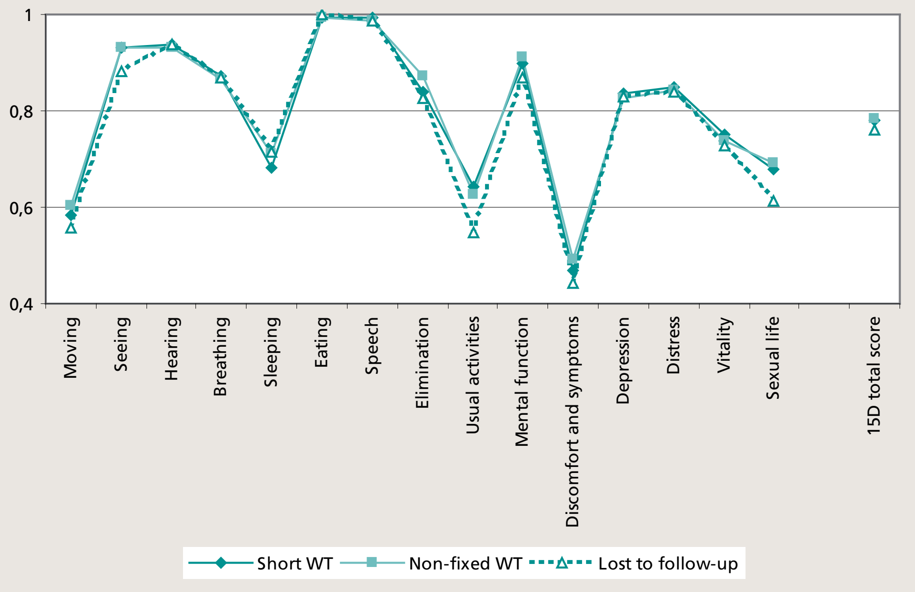

FIGURE 12. Baseline 15D profiles of THR patients and those lost to follow-up

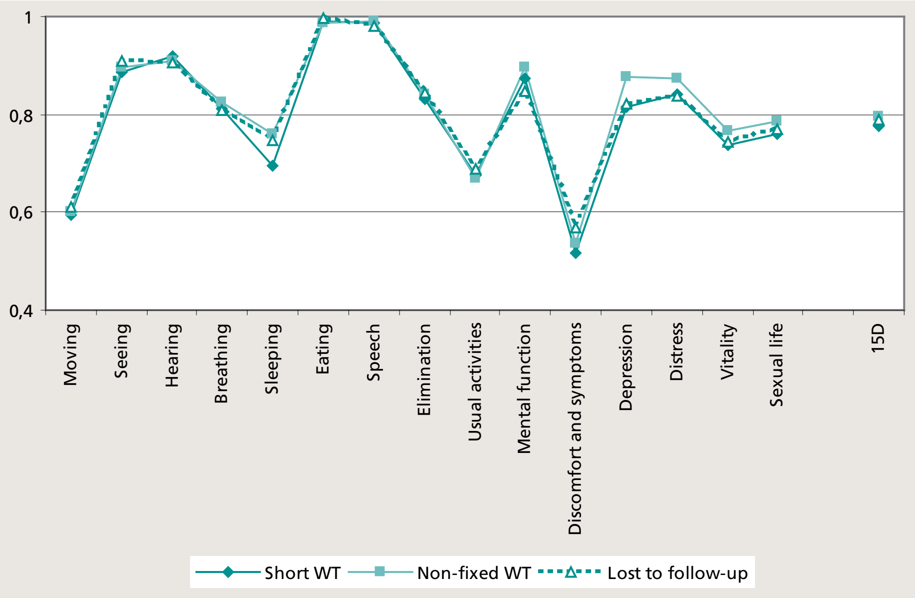

FIGURE 13. Baseline 15D profiles of TKR patients and those lost to follow-up

10 DISCUSSION

10.1 Interpretation of findings

10.1.1 HRQoL of patients placed on the waiting list

Numerous studies have shown that patients awaiting THR or TKR due to OA of the hip or knee joint suffer from pain and reduced physical function (Derrett et al. 1999, Kelly et al. 2001, Croft et al. 2002, Ackerman et al. 2005). The results of this study were consistent with earlier reports. At the time of placement on the waiting list, patients suffered from poor HRQoL and had significantly lower scores in both physical and psychological dimensions than the general population. Patients were significantly worse off on the dimensions of moving, sleeping, usual activities, discomfort and symptoms, depression, distress, vitality and sexual activity than the matched general population. Further, the majority of the patients experienced moderate to severe pain and limitations in function during their wait. Patients had scores comparable with the general population with respect to dimension mental function. In addition to physical functioning, psychological dimensions of health seem to be disease-specific in patients with OA of the hip or knee joint. Pain and functional restrictions together with reductions in psychological functioning, such as depression, distress and decreased vitality, indicate that patients can experience extended morbidity. Similar findings have been reported in an Australian study (Ackerman et al. 2005). These authors emphasized that interventions to address psychological distress and self-efficacy could reduce the burden of disease.

10.1.2 Effects of waiting on HRQoL at admission

According to the ITT analysis, longer waiting did not result in poorer HRQoL at admission. Both the generic 15D instrument and the disease-specific pain and function measures supported the main finding. Patients' overall HRQoL even improved while waiting (excluding THR patients with non-fixed WT), although the improvement was not statistically significant or clinically important.

Thus, these findings corroborate previous studies that have found no association between the length of WT and HRQoL (Williams et al. 1997, Brownlow et al. 1999, Kelly et al. 2001, Nilsdotter & Lohmander 2002). These earlier studies were, however, not based on a randomized design, and thus, patients with more severe symptoms may have had surgery more quickly than those with less severe symptoms.

The results of this study may reflect patients' expectations of the upcoming surgical intervention, which is supposed to relieve the disabling symptoms and to improve function; individuals' ability to tolerate delayed access may therefore increase while waiting. Most patients are placed on the waiting list when symptoms are severe and after making a decision to operate the certainty of treatment and the anticipated relief of pain may have a positive impact on health perceptions. Nilsdotter and Lohmander (2002) have talked about "regression to mean", i.e. with a surgical decision, the patient's health status may improve. It is also possible that patients may have given themselves the most severe rating at baseline and then scored the same at admission, even though the symptoms have worsened (i.e. a ceiling/floor effect, Kelly et al. 2001). Further, an interesting aspect is the association between medication, HRQoL and patients' pain management strategies during the WT.

Although patients' HRQoL did not seem to decrease while waiting and no association between WT and poorer HRQoL at admission was found, this does not affect our general conclusion that patients awaiting major joint replacement due to OA suffer from discomfort and symptoms and have clear problems in moving, usual activities, sleeping, sexual life and some psychological aspects (distress, depression, vitality). While further deterioration in HRQoL was limited after placement on the waiting list, delayed access to surgery imposes a burden of disease.

10.1.3 Service utilization

In analysing service utilization in THR and TKR patients, we found that health and social service utilization while waiting was rather low in both WT groups, and only a minority of patients received visits to their home from professional services. The most common services utilized while waiting were non-professional care and rehabilitation services. Patients with shorter WT were more likely to use rehabilitation and visiting care services at admission than those with non-fixed WT.

There are many different explanations for this. One explanation for the generally low levels of utilization might be that after a decision to treat, a patient may ´hang on` until the surgery using informal care and personal networks instead of professional care. Second, use of services may be low universally in patients awaiting joint replacement. It is also possible that Finnish thresholds for joint replacement are low compared with other countries. This argument is, however, not consistent with studies (Rissanen et al. 1997, Räsänen 2007) that have reported severe pain, limitations in physical function and losses in HRQoL in patients awaiting joint replacement. Alternatively, national eligibility criteria for using supportive health and social care while waiting might be set high. There is some evidence for this theory. The availability of home help services has declined by almost one half since

1990 (Vaarama et al. 2004), as local authorities have implemented strict budget constraints. Further, some studies have identified unmet needs for social and health services among Finnish elderly people (Raatikainen 1992, Rissanen 1999). Elderly people may also be poorly informed about services (Koskinen 1994).

A final explanation might be that the measures of use were flawed. All data were self-reported. Reijneveld (2000) has suggested that self-reports of health care utilization are accurate, whereas Nelson et al. (1998) found that 5% of subjects over-reported and 25% under-reported outpatient consultation rates. The psychometric properties of the utilization measure were, however, considered when developing the questionnaire. The ad hoc service utilization questionnaire was developed after reviewing previous studies of service utilization among Finnish population. The questionnaire included questions on service utilization (yes/no) and rates of utilization. Before data collection, six people (one under and five over 70 years old) tested the questionnaire. They had no difficulties in answering the questions, but some re-phrasing was carried out to ensure a clear and user-friendly questionnaire.

In multinomial regression analysis, service utilization was explained by predisposing and enabling factors. Of the predisposing factors, gender was related to utilization; females were more likely to use private support services and informal care than males. This result is in line with studies on service utilization patterns between the sexes (Hulka & Wheat 1985, Miilunpalo et al. 1997, Nelson et al. 1998). Concerning the need factor, only informal care was explained by patient's HRQoL; patients with better HRQoL were less likely to have informal care at home.

Self-reported utilization is nevertheless prone to recall errors (Lam et al. 2002). Especially elderly people may under- or overestimate the utilization. In this study, a patient self-reported questionnaire instead of register-based data on service utilization was, however, justified because there is no full systematic register on social services utilization, including public and private services and non-professional care.

Data processing showed that the responses were partly incomplete; some patients answered that they had utilized services, but they did not mention the number of visits. The results presented in this study were therefore based on the percentage of people with at least one visit instead of analysing and comparing utilization rates.

10.2 Generalizability

This study focused only on patients with OA of the hip and knee joint, and thus, HRQoL and utilization patterns may be different in other patient groups and health care systems. OA is, however, one of the most prevalent chronic diseases in adults, and as the population ages, it is likely that the demand for major joint replacement will increase – a justification for paying particular attention to the burden of waiting for hip and knee arthroplasty.

In a randomized controlled trial, we found that patients who were excluded from the study before randomization (n = 225) were more often females (71%) than males and older than completers (mean age 70 years vs. 66 years), which may restrict the generalizability of the results to younger THR and TKR patients. On the other hand, the sample was drawn from three large hospitals across two hospital districts, and the sex and age structure of patients were representative of Finnish THR and TKR patients. In 2003, the average age of Finnish patients undergoing THR or TKR was 71 and 69 years, respectively. The majority of patients operated on in Finnish hospitals are females (STAKES 2004b). In this study, the mean age of THR and TKR patients was 66 and 68 years, respectively, and the majority of respondents were females.

Of the 225 excluded patients, 206 had refused to participate. Participating in a study requiring completion of self-administered questionnaires may have been too large a burden for elderly people with a progressive disease. However, because age was not a predictive factor in regression analysis for the 15D at admission, this likely did not lead to a selection bias.

Patients who were lost to follow-up (between first and second measurement) were older, more often from the capital area and more often living alone than those who completed the questionnaires. There was, however, no significant or clinically important difference in baseline HRQoL between those who completed the questionnaires and those lost to follow-up, challenging the argument that those with greater pain and sufferings did not return the second questionnaire.

The median WT for patients with non-fixed WT both in TKR patients (266 days) and in THR patients (194 days) was comparable with the median WT for primary prosthetic replacement of the knee and hip joint in Finland when taking into account marked regional differences. In 2002, the shortest median WT for primary hip replacement was 84 days and the longest 327 days, and in TKR patients 129 days and 574 days when comparing the 20 hospital districts (Mikkola et al. 2005).

Most patients (490/620, 79%) resided in an urban area, which may limit the generalizability of results to rural populations. A study has shown that urban THR patients may differ from rural patients with respect to pain threshold and perceptions of function (Visuri & Honkanen 1982).

10.3 Methodological considerations

This study is part of a larger research project exploring the costs and effects of WT in patients undergoing THR or TKR. The aim of the project was to assess the effects of waiting on health outcomes and service utilization and to analyse the costs and distribution of cost liabilities between WT, period of care and post-operative period (three months and one year after surgery). This study focused on the period between placement on the waiting list and hospital admission. The results of the post-operative measurements will be reported at a later phase of the project.

In this study, the time between placement on the waiting list and hospital admission was measured instead of following patients from GP's consultation to treatment. Ideally, the entire WT from initial referral to the specialist should be monitored (HOPE 2001). OA is a slowly progressive disease, and patients likely have suffered from pain and restrictions in physical function long before GP consultation and may go on waiting for specialist consultation. Ostendorf et al. (2004) have stated that ideally patients should be monitored from the onset of first symptoms. In prospective studies, it is, however, difficult to collect WT data through the care process from primary care consultation to treatment – not to mention from the first symptoms until surgery.

A limitation of the study was that 96 patients in the short WT group waited longer than three months before being operated on. This may have resulted in an underestimation of the WT effect. The primary analysis was, however, based on the ITT principle to address the question of clinical effectiveness and treatment policy and to avoid the bias associated with a non-random loss of participants. The additional analyses – a PP analysis where short WT patients admitted beyond three months were excluded and a regression model with WT as an independent variable – supported the main finding and did not show a significant or clinically important difference in HRQoL between the randomized groups.

Nurses' feedback on the study protocol revealed why 96 patients in the short WT group did not receive the allocated intervention in time. Some patients wanted to postpone surgery that had inconveniently arrived too soon, some were not clinically ready for surgery, randomization had not been clearly adhered to in the hospital or the capacity to carry out surgery within three months was compromised. These explanations relate to current clinical practices in Finnish health care. The nationwide principles of access to health care within a reasonable period came into force in March 2005. Although the "maximum waiting time guarantee" has improved access to treatment, some areas have reported problems in access to care due to hospitals' limited surgical capacity or patients' unwillingness to be treated within the specified time (Hirvonen et al. 2006).

The 15D score at admission was used as an outcome measure. There were three reasons for utilizing total score instead of mean change score (baseline minus admission score). Firstly, utilizing change score is based on the presumption that HRQoL status will change during WT. According to a literature review, the effects of waiting on health status are, however, ambiguous. In this context, the one-sided hypothesis on the effect of waiting as well as utilizing mean change score instead of total score becomes questionable. Secondly, randomization was used to give each patient an equal chance of being assigned to the short WT group. Although randomization does not guarantee a perfect balance between the groups (due to chance), it is used to obviate a systematic difference (bias) between the groups. Randomization ensured that at baseline each group was similar. In studies where comparison groups are not randomized but have a different average baseline status, the mean change score becomes more important. Thirdly, interpreting the results of multivariate analyses becomes more difficult in models with change score as a dependent variable and baseline total score as an independent variable. The problem lies with interpreting the change in expected response (mean change score) per unit increase in the independent variable (baseline total score).

10.4 Internal validity and alternative explanations

In studies that assess the effects of interventions, internal validity is the primary consideration in focusing on causal relationships and possible alternative explanations for the outcome. Campbell and Stanley (1963) have presented eight common threats to internal validity: history, maturation, instability, testing, instrumentation, statistical regression, experimental mortality and selection-maturation interaction. The strength of the pretest-post-test control group design is that it controls the factors that are threats to internal validity. History effect, maturation and testing can be controlled as specific events, or the effects of taking a test upon the scores of a second testing that might have produced a difference in the test group would also produce a difference in the comparison group (Campbell & Stanley 1963).

Instrumentation may become a problem if observers or interviewers are used in collecting measurements. In this study, health outcomes and service utilization were, however, based on fixed instruments – survey questionnaires that were utilised in both test and control groups. The effect of regression was controlled, as consecutive patients with the need for primary hip or knee replacement were recruited to the study. However, patients were recruited from three different hospitals, which may have had an impact on patients' baseline HRQoL, especially if the surgeons and hospitals had applied different criteria for treatment. A comparison of baseline 15D scores showed that there were no differences between the three research hospitals. Thus, the results do not support an argument of a regression effect or a selection bias (data not shown).

A total of 159 patients were lost to follow-up between baseline and admission measurement. Mortality, lost cases and cases with partial data are troublesome. In this study, the primary analysis was based on the ITT principle: all of the test and control group patients who completed both baseline and admission questionnaires, including those in the test group who were admitted beyond short WT, were included in the analysis. This may have resulted in an underestimation of the WT effect, but did avoid a sampling bias. An additional analysis – a PP analysis in which short WT patients admitted beyond short WT were excluded from the analysis, supported the main finding.

10.5 Properties of the HRQoL instrument

The results imply that patients who are placed on the waiting list are those with end-stage arthritis and their function is restricted and they suffer severe pain. Thus, longer WT may not result in poorer HRQoL, pain and function at admission, and patients seem to tolerate moderate waiting. When analysing the results, the properties of measurement instruments must also be taken into account. A problem with utilizing generic HRQoL measures is that the absence of a gold standard approach may render the validity of the measurement instrument as uncertain. The essence of validity is the degree of confidence that can be placed in the inferences drawn from the scores of an instrument in different contexts.

Review of the medical literature shows many measurements of QoL in clinical trials to be inappropriate because of poor conceptualization (Gill & Feinstein 1994). However, theory-driven selection of the domains and items may strengthen an analytical insight into the patient's condition and make the approach to the phenomenon more explicit and conceptual.

The rationale for the choice of the 15D instrument instead of other well-known multi-attribute utility scales pertained to psychometric properties of the instrument and the possibility to produce reference data. The spectrum of psychometric properties indicating the performance of measurement instruments is wide. Researchers have developed a variety of criteria for validation testing: content validity, face validity, construct validity, which is differentiated into convergent and discriminant validity, criterion validity, concurrent validity and predictive validity; and for testing the repeatability of a measurement: multiple-form, internal consistency, test-retest reliability, intra-rater and inter-rater agreement and sensitivity to change. The current terminology for assessing the performance of instruments is variegated and psychometric properties of measurement instruments have been addressed more fully in methodological literature of economic and program evaluation (Shortell & Richardson 1978, Bowling 1995, McDowell & Newell 1996, Brazier et al. 1999, Streiner & Norman 2003).

The 15D instrument has been/is being used in a great number of different patient groups (e.g. patients undergoing hip or knee arthroplasty) to assess outcomes from health care interventions (Rissanen et al. 1996, Sintonen 2006, Räsänen et al. 2007). In most of the important properties, the 15D compares favourably with other similar instruments, such as EQ-5D, HUI3, SF-6D and Assessment of Quality of Life (AQoL) (Sintonen 1994a, 1995, 2001a, 2001b, Stavem 1999, Hawthorne et al. 2001).

The increase in the number of comparative multinational studies has raised concern about the equivalence of the instruments in different cultures. Since the source language of the 15D questionnaire is Finnish and the 15D preference weights have been elicited from representative Finnish population samples, there is no "cultural bias", which may occur when an instrument is used in a different linguistic and cultural context.

10.6 Practical implications

Patients' subjective perceptions, as measured by validated and standardized generic HRQoL instruments, are of clinical relevance when planning and developing recommendations for priority setting in clinical decision-making. The results have a health-political relevance when developing recommendations and criteria for assessing health care needs and arranging the queue in terms of severity.

Within the last ten years, discussion on priority setting has fluctuated from ethical issues to debates over the effectiveness of health services. The challenges of a publicly financed health care system seem to be similar: to find economically and politically legitimate ways of dealing with the problem of limited resources and unlimited demand.

It is easy to think that a fair means of distributing commodities in the private market is to sell goods on the basis of first-in first-out. However, in the public delivery of commodities, the first-in first-out principle is seldom ethically just. In reality, pain, severity and prognosis of the disease, age, general health perceptions, quality of life and personal circumstances vary between patients. Scoring practices tend to be unilaterally and professionally controlled and are based on disease-specific dimensions such as pain, distress and progression of disease. A future challenge is to identify factors that comprehensively predict the need for care. Key questions are how large is the burden of waiting and should it be taken into account when developing scoring practices.

In the literature, some factors predicting health outcomes have already been established. Martin et al. (2000) in a literature review summarized data concerning the outcomes of hip and knee replacement. The authors collected the main prognostic indicators of treatment benefit. According to their review, preoperative pain and function and co-morbidity were the best predictors of health outcomes. BMI, age and OA versus rheumatoid arthritis were weaker predictors, but more significant than living conditions (living alone versus living with someone), gender, ethnicity and education, which they concluded not be considered in the decision to schedule surgery (Martin et al. 2000). MacWilliam et al. (1996) have reported similar findings. They evaluated eight patient risk factors (age, sex, race, marital status, education, co-morbidity, preoperative pain and function) that might predict poor outcome after THR and found preoperative health status to be an important predictor. Lieberman et al. (1997) have, in turn, stated that age, sex and co-morbidity should be considered in multivariate modelling of outcomes.

When developing “risk factors” or “behavioural models” in clinical practice, there are numerous considerations. What are the criteria in priority setting - are they general or specific? How are social and clinical criteria taken into consideration and what kinds of QoL measurements are used to evaluate health status? Who decides on the criteria and what is the relative influence of politicians, medical professionals and health service managers, researchers and the general public in priority setting? A major challenge is obtaining a global view of the patient’s current condition and the burden of waiting when assessing the patient’s need for care.

Continued investigation of the long-term effects and the stability of the effects of WT, as well as the effects of waiting on the demand for medication are becoming increasingly necessary and important. Further, concerning the development of more cost-effective and customer-oriented welfare services, the entire path to care should be taken into account. This is possible in, for example, study settings that retrospectively follow the patient from the first contact with a primary care practitioner to treatment.

11 Conclusions and future suggestions

According to the national guidelines for elective treatment, medically justified treatment must be provided within three months, or, at the very latest, six months. In this respect, the finding that there was no difference in HRQoL, pain and physical function at admission between patients with short WT (median WT three months) and those with non-fixed WT (median WT seven months) may support guidelines for medically justified treatment within six months or even beyond instead of three months. However, although longer WT did not result in poorer HRQoL at admission and use of services was similar during WT as it had been at the time of placement on the waiting list, there is likely to be higher costs of waiting by people who wait longer simply because they use services for a longer period. In economic terms, this represents a negative impact of waiting.

Health and social services use was low in both WT groups. The most common services used while waiting were rehabilitation services and informal care, including unpaid care provided by relatives, neighbours and volunteers. Although patients suffered from clear restrictions in usual activities and physical functioning, they seemed primarily to lean on informal care and personal networks instead of professional care. Patients' closest relatives should be informed about strategies on how to support patients' usual activities during the WT.

Only a few reports exist of the HRQoL of patients awaiting THR or TKR. In addition to physical dimensions of health, patients appear to suffer from restrictions in psychological well-being such as depression, distress and reduced vitality. This raises the questions of how to support patients who suffer from psychological distress during the WT and how to develop strategies to improve patients' initiatives to reduce symptoms and the burden of waiting.

Only patients with OA of the knee or hip joint were followed in this study. OA is, however, one of the most prevalent chronic diseases in adults. As the population ages, the demand for THR and TKR will likely increase. In the future, the effect of waiting should also be assessed in other patient groups. Evidence of the effect of waiting in different patient groups can be used for managing waiting lists at the hospital level, improving clinical decision-making and developing criteria to identify patients who will especially benefit from advanced treatment. Currently, the principle of a maximum of six months' waiting is used in all patient groups. A key issue for the future is how to obtain a global view on the patient's current condition and the burden of waiting in different patient groups when assessing the patient's need for care.

Evidence of the long-term effects and the stability of the effects of WT, as well as the effects of waiting on medication use could provide further information on the burden of waiting for health care resources. A future challenge is determining how to monitor the entire WT from initial referral to specialist care. One way may be to involve patients in the planning of health care and to pioneer patient-centred research and development activities to identify patients' experiences of waiting.

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Appendix

Information collected by questionnaire

1. BACKGROUND VARIABLES

1. Date of placement on the waiting list (dd/mm/yy)
2. Date of filling out the questionnaire (dd/mm/yy)
3. Sex (female/male)
4. Professional education (1 = none, 2 = course(s), 3 = school level education, 4 = college level education, 5 = university degree)
5. Employment status (1 = working, 2 = retired, 3 = at home, 4 = studying, 5 = unemployed)
6. Housing (living alone/living with someone)
7. Weight (kg)
8. Height (cm)
9. Comorbidity (yes/no)

2. SERVICE UTILIZATION

1. Physician visits (university hospital, central hospital, regional hospital, health centre, private physician, occupational health care visits) within the last 3 months
2. Inpatient care (number of care days) within the last 3 months
3. Visits at home within the last 3 months from a nurse, chiropodist or physician (public or private) due to disease (visits/month)
4. Visits at home within the last 3 months from a nurse, chiropodist or physician (public or private), other reason (visits/month)
5. Rehabilitation services within the last 3 months (public or private) due to disease (visits/month)
6. Rehabilitation services within the last 3 months (public or private), other reason (visits/month)
7. Use of regular support services, including private, public or informal meals on wheels, housework, laundry services, bathing and transportation services (visits/month)
8. Use of temporary support services, including private, public or informal meals on wheels, housework, laundry services, bathing and transportation services (visits/month)

3. QUALITY OF LIFE QUESTIONNAIRE (15D©)

Please read through all the alternative responses to each question before placing a cross (x) against the alternative which best describes your present health status. Continue through all 15 questions in this manner, giving only one answer to each.

QUESTION 1. MOVING

1 ( ) I am able to walk normally (without difficulty) indoors, outdoors and on stairs.
2 ( ) I am able to walk without difficulty indoors, but outdoors and/or on stairs I have slight difficulties.
3 ( ) I am able to walk without help indoors (with or without an appliance), but outdoors and/or on stairs only with considerable difficulty or with help from others.
4 ( ) I am able to walk indoors only with help from others.
5 ( ) I am completely bed-ridden and unable to move about.

QUESTION 2. SEEING

1 ( ) I see normally, i.e. I can read newspapers and TV text without difficulty (with or without glasses).
2 ( ) I can read papers and/or TV text with slight difficulty (with or without glasses).
3 ( ) I can read papers and/or TV text with considerable difficulty (with or without glasses).
4 ( ) I cannot read papers or TV text either with glasses or without, but I can see enough to walk about without guidance.
5 ( ) I cannot see enough to walk about without a guide, i.e. I am almost or completely blind.

QUESTION 3. HEARING

1 ( ) I can hear normally, i.e. normal speech (with or without a hearing aid).
2 ( ) I hear normal speech with a little difficulty.
3 ( ) I hear normal speech with considerable difficulty; in conversation I need voices to be louder than normal.
4 ( ) I hear even loud voices poorly; I am almost deaf.
5 ( ) I am completely deaf.

QUESTION 4. BREATHING

1 ( ) I am able to breathe normally, i.e. with no shortness of breath or other breathing difficulty.
2 ( ) I have shortness of breath during heavy work or sports, or when walking briskly on flat ground or slightly uphill.

3 ( ) I have shortness of breath when walking on flat ground at the same speed as others my age.
4 ( ) I get shortness of breath even after light activity, e.g. washing or dressing myself.
5 ( ) I have breathing difficulties almost all the time, even when resting.

QUESTION 5. SLEEPING
1 ( ) I am able to sleep normally, i.e. I have no problems with sleeping.
2 ( ) I have slight problems with sleeping, e.g. difficulty in falling asleep, or sometimes waking at night.
3 ( ) I have moderate problems with sleeping, e.g. disturbed sleep, or feeling I have not slept enough.
4 ( ) I have great problems with sleeping, e.g. having to use sleeping pills often or routinely, or usually waking at night and/or too early in the morning.
5 ( ) I suffer severe sleeplessness, e.g. sleep is almost impossible even with full use of sleeping pills, or staying awake most of the night.

QUESTION 6. EATING
1 ( ) I am able to eat normally, i.e. with no help from others.
2 ( ) I am able to eat by myself with minor difficulty (e.g. slowly, clumsily, shakily, or with special appliances).
3 ( ) I need some help from another person in eating.
4 ( ) I am unable to eat by myself at all, so I must be fed by another person.
5 ( ) I am unable to eat at all, so I am fed either by tube or intravenously.

QUESTION 7. SPEECH
1 ( ) I am able to speak normally, i.e. clearly, audibly and fluently.
2 ( ) I have slight speech difficulties, e.g. occasional fumbling for words, mumbling, or changes of pitch.
3 ( ) I can make myself understood, but my speech is e.g. disjointed, faltering, stuttering or stammering.
4 ( ) Most people have great difficulty understanding my speech.
5 ( ) I can only make myself understood by gestures.

QUESTION 8. ELIMINATION
1 ( ) My bladder and bowel work normally and without problems.
2 ( ) I have slight problems with my bladder and/or bowel function, e.g. difficulties with urination, or loose or hard bowels.
3 ( ) I have marked problems with my bladder and/or bowel function, e.g. occasional ‘accidents’, or severe constipation or diarrhea.
4 ( ) I have serious problems with my bladder and/or bowel function, e.g. routine ‘accidents’, or need of catheterization or enemas.
5 ( ) I have no control over my bladder and/or bowel function.

QUESTION 9. USUAL ACTIVITIES
1 ( ) I am able to perform my usual activities (e.g. employment, studying, housework, free-time activities) without difficulty.
2 ( ) I am able to perform my usual activities slightly less effectively or with minor difficulty.
3 ( ) I am able to perform my usual activities much less effectively, with considerable difficulty, or not completely.
4 ( ) I can only manage a small proportion of my previously usual activities.
5 ( ) I am unable to manage any of my previously usual activities.

QUESTION 10. MENTAL FUNCTION
1 ( ) I am able to think clearly and logically, and my memory functions well
2 ( ) I have slight difficulties in thinking clearly and logically, or my memory sometimes fails me.
3 ( ) I have marked difficulties in thinking clearly and logically, or my memory is somewhat impaired.
4 ( ) I have great difficulties in thinking clearly and logically, or my memory is seriously impaired.
5 ( ) I am permanently confused and disoriented in place and time.

QUESTION 11. DISCOMFORT AND SYMPTOMS
1 ( ) I have no physical discomfort or symptoms, e.g. pain, ache, nausea, itching etc.
2 ( ) I have mild physical discomfort or symptoms, e.g. pain, ache, nausea, itching etc.
3 ( ) I have marked physical discomfort or symptoms, e.g. pain, ache, nausea, itching etc.
4 ( ) I have severe physical discomfort or symptoms, e.g. pain, ache, nausea, itching etc.
5 ( ) I have unbearable physical discomfort or symptoms, e.g. pain, ache, nausea, itching etc.

QUESTION 12. DEPRESSION
1 ( ) I do not feel at all sad, melancholic or depressed.
2 ( ) I feel slightly sad, melancholic or depressed.
3 ( ) I feel moderately sad, melancholic or depressed.
4 ( ) I feel very sad, melancholic or depressed.
5 ( ) I feel extremely sad, melancholic or depressed.

QUESTION 13. DISTRESS
1 ( ) I do not feel at all anxious, stressed or nervous.
2 ( ) I feel slightly anxious, stressed or nervous.

3 ( ) I feel moderately anxious, stressed or nervous.
4 ( ) I feel very anxious, stressed or nervous.
5 ( ) I feel extremely anxious, stressed or nervous.

QUESTION 14. VITALITY
1 ( ) I feel healthy and energetic.
2 ( ) I feel slightly weary, tired or feeble.
3 ( ) I feel moderately weary, tired or feeble.
4 ( ) I feel very weary, tired or feeble, almost exhausted.
5 ( ) I feel extremely weary, tired or feeble, totally exhausted.

QUESTION 15. SEXUAL ACTIVITY
1 ( ) My state of health has no adverse effect on my sexual activity.
2 ( ) My state of health has a slight effect on my sexual activity.
3 ( ) My state of health has a considerable effect on my sexual activity.
4 ( ) My state of health makes sexual activity almost impossible.
5 ( ) My state of health makes sexual activity impossible.

4. MODIFIED DISEASE SPECIFIC MEASURES

THR patients		
Item	**Description**	**Point**
Pain	1 None	44
	2 Slight, occasional	40
	3 Mild pain, rarely with unusual activities	30
	4 Moderate pain, some limitation of ordinary activity	20
	5 Marked pain, limitation of activities	10
	6 Totally disabled, pain in bed	0
Function		
A. Gait	1 None	11
1. Limp	2 Slight	8
	3 Moderate	5
	4 Severe	0
2. Support	1 None	11
	2 Cane for long walks	7
	3 Cane most of the time	5
	4 One crutch	3
	5 Two canes	2
	6 Two crutches	0
	7 Not able to walk	0
3. Distance walked	1 > 1.5 km/unlimited	11
	2 1–1.5 km	8
	3 100–500 m	5
	4 Indoors only	2
	5 Unable	0
B. Activities	1 Normally	4
1. Stairs	2 Normally, using a railing	2
	3 Step by step, using a railing	1
	4 Unable to do stairs	0
2. Shoes and socks	1 With ease	4
	2 With difficulty	3
	3 Unable	0
3. Sitting	1 In ordinary chair one hour	5
	2 On a higher chair for one-half hour	3
	3 Unable to sit	0

TKR patients		
Item	**Description**	**Point**
Pain	1 None	50
	2 Mild and occasional	45
	3 Mild, stairs only	40
	4 Mild, walking and stairs	30
	5 Moderate, occasional	20
	6 Moderate, continual	10
	7 Severe	0
Function		
1. Walking	1 > 1.5 km/unlimited	50
	2 1 –1.5 km	40
	3 100–500 m	20
	4 Indoors only	10
	5 Unable	0
2. Stairs	1 Normal, up & down	50
	2 Normal up, down with rail	40
	3 Up & down with rail	30
	4 Up with rail, unable down	15
	5 Unable	0

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Health-related quality of life in patients waiting for major joint replacement. A comparison between patients and population controls

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Abstract

Background: Several quality-of-life studies in patients awaiting major joint replacement have focused on the outcomes of surgery. Interest in examining patients on the elective waiting list has increased since the beginning of 2000. We assessed health-related quality of life (HRQoL) in patients waiting for total hip (THR) or knee (TKR) replacement in three Finnish hospitals, and compared patients' HRQoL with that of population controls.

Methods: A total of 133 patients awaiting major joint replacement due to osteoarthritis (OA) of the hip or knee joint were prospectively followed from the time the patient was placed on the waiting list to hospital admission. A sample of controls matched by age, gender, housing and home municipality was drawn from the computerised population register. HRQoL was measured by the generic 15D instrument. Differences between patients and the population controls were tested by the independent samples t-test and between the measurement points by the paired samples t-test. A linear regression model was used to explain the variance in the 15D score at admission.

Results: At baseline, 15D scores were significantly different between patients and the population controls. Compared with the population controls, patients were worse off on the dimensions of moving ($P < 0.001$), sleeping ($P < 0.001$), sexual activity ($P < 0.001$), vitality ($P < 0.001$), usual activities ($P < 0.001$) and discomfort and symptoms ($P < 0.001$). Further, psychological factors – depression ($P < 0.001$) and distress ($P = 0.004$) – were worse among patients than population controls. The patients showed statistically significantly improved average scores at admission on the dimensions of moving ($P = 0.026$), sleeping ($P = 0.004$) and discomfort and symptoms ($P = 0.041$), but not in the overall 15D score compared with the baseline. In patients, 15D score at baseline ($P < 0.001$) and body mass index (BMI) ($P = 0.020$) had an independent effect on patients' 15D score at hospital admission.

Conclusion: Although patients' HRQoL did not deteriorate while waiting, a consistently worse HRQoL was observed in patients waiting for major joint replacement compared with population controls.

Background

The OECD Waiting Times project [1] on waiting time variations for elective surgery across OECD country showed waiting times to be "a significant health policy concern" in almost half of all OECD countries. Finland and the United Kingdom were the countries with the highest waiting times.

In Finland, major joint replacements are surgical procedures with high volume and relatively long waiting times. In 2003, almost 8 800 hip replacement patients (169 per 100 000) and 6 800 knee replacement patients (131 per 100 000) were operated in Finnish hospitalss [2]. Between 1987 and 2002, the THR rate rose on average by 5% annually and the TKR rate by 12% [3]. Comparing waiting times among Finnish THR and TKR patients shows significant regional differences and a trend towards longer waiting times within the last ten years. In 2003, for patients with primary THR, the median waiting time was 155 days, and for patients with TKR 205 days [2].

To ensure the availability of care in Finland, the Council of State initiated in 2001 a national project to secure the future of health care. Guidelines for the implementation of a nationwide system for assessing health care needs and for the treatment criteria were prepared by the end of 2003. The national principles of access to hospital treatment within six months or less came into force in March 2005.

Several studies have assessed health-related quality of life (HRQoL) among patients who have undergone major joint replacement and shown that patients experience substantially more pain and restrictions in physical function than the general population [4-6]. Still, relatively few of them have examined the change in HRQoL that occurs while waiting for surgery. Studies have mostly focused on the outcomes of surgery, reported improvements in physical function, vitality and mental health and reductions in pain, or have shown that total knee arthroplasty (TKA) and total hip arthroplasty (THA) are beneficial and effective [7-13]. However, the interest in examining the relationship between HRQoL and time spent waiting for surgery has been on the increase since the beginning of 2000. The results have shown no consistent evidence that HRQoL is worse in patients having to wait longer [14-16]. However, a prospective Canadian study concluded that patients who wait 6 months at the most realize greater gains in HRQoL than those waiting longer [17]. Further, a prospective study of patients waiting for total hip arthroplasty (THA) found that patients in a later phase of disease did not reach the same level after THA as those with better preoperative function [4].

Although the principle of equal access to surgeries and other health services has been promoted by health policy in many western health care systems, practices do not totally equate to policy targets. A common view is that delayed access to care may impose a variety of costs such as welfare losses during the waiting period [18]. Still, evidence of the effect of waiting on patients' health status is mixed.

The purpose of this study is to assess HRQoL in patients awaiting major joint replacement and to compare the HRQoL of patients with that of population controls. The data collected for this analysis is part of long-term follow-up data for patients in a prospective multi-centre study aimed at assessing the costs and effects of waiting.

Methods

Data collecting

Patients were enrolled into this study in three Finnish hospitals (HUCH Surgical Hospital, Helsinki; HUCH Jorvi Hospital, Espoo and Coxa Hospital for Joint Replacement, Tampere) in two hospital districts (Hospital District of Helsinki and Uusimaa and Pirkanmaa Hospital District). Two hospitals provide surgical services for municipalities in the capital area. The third hospital is specialised in endoprosthetic surgery which provides services for municipalities, local and central hospitals, as well as for patients paying the costs themselves.

Patients were recruited into the study through regular contact with the orthopaedic surgeons and practice staff. The *Ad hoc* recruitment began in August 2002 and finished in November 2003.

The inclusion criteria were: need for a primary total joint arthroplasty due to osteoarthritis (OA) of the hip or knee joint (excluding rheumatoid arthritis, fractures, haemophilia and deformity) as evaluated by the hospital surgeon, a patient aged 16 years or older was placed on the waiting list in a research hospital, and the patient was willing and mentally able to participate in the study. Each patient provided a signed informed consent. The study had ethical approval from the Helsinki University Central Hospital (HUCH) Surgery Ethics Committee.

Patients completed a self-administered questionnaire at two specific points in time: 1) when placed on the waiting list (baseline), and 2) at hospital admission. The questionnaires were distributed to patients at hospital. Return of the questionnaires was via postal means. Common guidelines for administering the questionnaires were provided at each hospital.

For each patient, two population controls matched by age, gender, housing (living alone vs. living with someone)

Table 1: Characteristics of patients and population controls

Characteristic	Patients n = 133	Population controls n = 129–133[b]	Patients excluded n = 61–64[b]	P value[c]	P value[d]
Age, years (mean ± SD)	67.6 (8.8)	67.6 (8.8)	66.0 (13.2)	1.000	0.375
Females [n, (%)]	83 (62.4)	81 (60.9)	43 (67.2)	0.801	0.513
Home municipality [n, (%)]				0.900	0.534
Capital area	72 (54.1)	71 (53.4)	38 (59.4)		
Other urban area	36 (27.1)	39 (29.3)	18 (28.1)		
Rural area	25 (18.8)	23 (17.3)	8 (12.5)		
Housing, living alone [n, (%)]	39 (29.3)	40 (30.3)	29 (47.5)	0.862	0.014
Professional examination, yes [n, (%)]	45 (33.8)	61 (47.3)	23 (37.7)	0.027	0.600
Employment status [n, (%)]				0.229	0.066
Employed	17 (12.8)	27 (20.3)	16 (26.2)		
Retired	112 (84.2)	101 (75.9)	43 (70.5)		
Other	4 (3.0)	5 (3.8)	2 (3.3)		
Comorbidity, yes [n, (%)]	89 (66.9)	98 (73.7)	48 (78.7)	0.227	0.095
BMI[a] (mean ± SD)	29.0 (4.4)	26.8 (4.4)	28.3 (4.7)	<0.001	0.280
Waiting time, days [Md, range]	71 (8–600)				
Months waiting for surgery [n, (%)]					
0–3 months	94 (70.7)				
> 3–6 months	20 (15.0)				
> 6 months	19 (14.3)				

[a] BMI, body mass index (wt/ht^2)
[b] Number of observations varies due to missing values.
[c] Between patients and population controls
[d] Between the patients who completed the questionnaires (baseline and admission, n = 133) and those excluded (n = 64)

and home municipality were obtained from the National Population Register of Finland. To minimise the loss of participants, two controls per patient were selected. Thus control subject who did not return the questionnaire was replaced with the other control of the same patient. In the autumn of 2003, controls were mailed a self-administered questionnaire similar to the patients' questionnaire.

HRQoL instrument

We assessed HRQoL using 15D. The 15D is a generic and standardised HRQoL instrument consisting of 15 dimensions: moving, seeing, hearing, breathing, sleeping, eating, speech, elimination, usual activities, mental function, discomfort and symptoms, depression, distress, vitality and sexual activity. For each dimension, the respondent must choose one of the five levels that best describes his/her state of health at the moment (best level = 1; worst level = 5) [19,20]. The single index (15D score) on a 0–1 scale, representing the overall HRQoL, is calculated from the health state descriptive system by using a set of population-based preference or utility weights. Such a weight for each level of each dimension is obtained by multiplying the level value by the importance weight of the dimension at that level [21]. The level values on a 0–1 scale, reflecting the goodness of the levels relative to no problems on the dimension (= 1) and to being dead (= 0), and the importance weights summing up to unity, have been elicited from representative population samples. The 15D has been/is being utilised among different patient groups (e.g. patients undergoing hip or knee arthroplasty) to assess outcomes from health care interventions [13,20,22]. In most of the important properties (eg. responsiveness, sensitivity, reliability and validity), the 15D compares favourably with other instruments of the same kind, such as EQ-5D, HUI3, SF-6D and AQoL [20,21,23-25].

The interpretation on the minimum clinically important difference in the 15D score is a difference ± 0.03 or more (on a scale 0–1) in the sense that people can feel the difference in health status [26].

Statistical analysis

Data were analysed using SPSS for Windows, version 12.0.1. Descriptive statistics were used to describe demographic characteristics. Comparative analyses of demographic characteristics between patients and population controls were computed using either the independent samples t-test or the Chi-squared test depending on the levels of measurement.

Univariate analyses were conducted to determine a) the differences in the 15D score and dimensions between patients and population controls, and b) the differences between the baseline and admission measurements within the patient group. Mean group scores were compared using the paired samples t-test test within the patient group, and independent samples t-test between

Table 2: The average 15D scores and dimension level values between patients and population controls

Health outcome	Patients	Population controls	Mean difference[b] (95% CI)
15D dimension[a]			
Moving	0.565 (0.127)	0.883 (0.172)	0.317*** (0.281, 0.354)
Seeing	0.909 (0.176)	0.943 (0.140)	0.034ns (-0.004, 0.073)
Hearing	0.914 (0.142)	0.941 (0.143)	0.027ns (-0.007, 0.062)
Breathing	0.866 (0.204)	0.867 (0.219)	0.001ns (-0.050, 0.052)
Sleeping	0.685 (0.224)	0.803 (0.186)	0.117*** (0.068, 0.167)
Eating	0.992 (0.053)	0.992 (0.053)	0.000ns (-0.013, 0.013)
Speech	0.989 (0.057)	0.978 (0.079)	-0.011ns (-0.028, 0.005)
Elimination	0.848 (0.202)	0.876 (0.193)	0.028ns (-0.020, 0.076)
Usual activities	0.655 (0.217)	0.870 (0.199)	0.214*** (0.164, 0.264)
Mental function	0.864 (0.178)	0.897 (0.170)	0.033ns (-0.009, 0.075)
Discomfort and symptoms	0.473 (0.236)	0.784 (0.204)	0.311*** (0.258, 0.364)
Depression	0.829 (0.177)	0.902 (0.138)	0.074*** (0.035, 0.112)
Distress	0.831 (0.188)	0.892 (0.155)	0.061** (0.019, 0.102)
Vitality	0.748 (0.172)	0.852 (0.152)	0.104*** (0.065, 0.143)
Sexual activity	0.731 (0.273)	0.869 (0.239)	0.138*** (0.076, 0.200)
15D score	0.778 (0.091)	0.883 (0.103)	0.105*** (0.082, 0.129)

n = 133

[a] Data are mean (SD) scores. The scale is 0–1, worst to best.

[b] Baseline scores between patients and population controls. Positive difference indicates better score and negative difference indicates worse score for population controls than for patients. ns, non-significance

* P < 0.05, ** P < 0.01, *** P < 0.001

patients and population controls. Two-sided P-values were calculated in all tests. A P-value < 0.05 was considered statistically significant.

A multiple linear regression (MLR) model on the patient data was constructed to determine the relationships between the independent variables (waiting time, BMI, affected joint, 15D score at baseline, gender, age, education, housing) and 15D score at admission. Waiting time was skewed and thus included in the model as a categorical variable (over 3–6 months, over 6 months and 0–3 months as a reference level). All available independent variables were included in the model. The results are presented in the form of unstandardised β-coefficients.

Missing values for the 15D dimensions were predicted with the responses on the other dimensions, age and gender as explanatory variables [19]. The missing value was substituted if a minimum 80% of dimensions were present.

Results

Patient and population controls characteristics

Of the 197 eligible patients recruited into the study, 30 were excluded because their controls declined to participate. In addition, 6 patients did not complete the baseline and 28 did not complete the admission questionnaire and were excluded. The analysis presented here focuses on 133 pairs with completed questionnaires.

The average age of the study population including patients and age matched population controls was 67.6 years (range, 36–86 years) (Table 1). Of patients, 73 (55%) were waiting for primary THR and 60 (45%) were waiting for primary TKR. The majority (54%, n = 143) of the participants (including patients and population controls) were from capital area. A total of 75 (28%) participants were from other urban area and 48 (18%) from rural area.

A comparison between patients and population controls showed that controls had more often professional education than patients and patients were heavier than controls. Of patients, 21 (16%) had a normal BMI (<25) and 112 (84%) were overweight or obese (BMI ≥ 25). Of population controls, 45 (34%) had a normal BMI, and 86 (66%) were overweight or obese.

For the patients, the waiting time from the surgeon appointment to the surgery was skewed such that a total of 94 (71%) patients waited for surgery 0–3 months, 20 (15%) waited > 3–6 months and 19 (14%) waited over 6 months. Two patients waited over one year.

A comparison between patients who completed the questionnaires (baseline and admission) and those who were excluded showed that those who were excluded were more often living alone than the completers ($X^2 = 6.1$, P = 0.014). There was, however, no statistically significant or clinically important difference in the baseline 15D score

Table 3: Multiple linear regression coefficient estimates for the patients' 15D score at admission

Explanatory variables	β[a]	95% CI for β	P value
Waiting time			
0–3 months	Reference		
> 3–6 months	0.013	-0.016, 0.043	0.381
> 6 months	0.017	-0.014, 0.047	0.286
BMI	-0.003	-0.005, -0.0004	0.020
Affected joint (0 = hip, 1 = knee)	0.013	-0.009, 0.035	0.232
15D score at baseline	0.752	0.637, 0.867	<0.001
Gender (0 = female, 1 = male)	-0.008	-0.032, 0.015	0.479
Age	-0.0004	-0.002, 0.001	0.539
Professional education (0 = no, 1 = yes)	-0.0003	-0.023, 0.022	0.976
Housing (0 = living alone, 1 = living with someone)	0.009	-0.016, 0.034	0.469
Constant	0.301		
R square	0.613		
F	21.430***		
n	133		

A positive value indicates improvement in the 15D score, and a negative value indicates worsening.

[a] multivariate unstandardised linear regression coefficient

*** $P < 0.001$

between the completers and those excluded (0.778 and 0.777, respectively; Δ0.001, t = 0.03, P = 0.980).

HRQoL among patients and population controls

At the time the patients were placed on the waiting list, the average (SD) 15D score was 0.778 (0.091) (Table 2). Among the population controls, the mean (SD) 15D score was 0.883 (0.103). The difference was statistically significant and clinically important. The difference between the groups remained statistically significant and clinically important when patients' HRQoL at admission was compared with the HRQoL among the population controls. At baseline, patients had statistically significantly lower scores on the dimensions of moving, sleeping, usual activities, discomfort and symptoms, depression, distress, vitality and sexual activity compared to population controls.

Change in patients' HRQoL while waiting

In patients, the 15D score improved while waiting, but the change was not statistically significant or clinically important (Δ0.008, t = 1.6, P = 0.123, 95% confidence interval, CI: 0.002–0.019). The patients showed, however, statistically significantly improved average scores at admission for moving (Δ0.032, t = 2.2, P = 0.026, 95% CI: 0.004–0.060), sleeping (Δ0.042, t = 3.0, P = 0.004, 95% CI: 0.014–0.071) and discomfort and symptoms (Δ0.038, t = 2.1, P = 0.041, 95% CI: 0.002–0.075) compared with the baseline measurement (not shown).

Patients' HRQoL at admission

The results of the MLR analysis indicated that BMI (β = -0.003, P = 0.020) and the 15D score at baseline (β = 0.752, P < 0.001) were significantly associated with the 15D at admission (Table 3). A higher BMI when placed on the waiting list was associated with the worse 15D score at admission and the higher 15D score at baseline was associated with higher HRQoL at admission. The length of waiting was unrelated to the 15D score at admission.

Discussion

The aim of this multi-centre study was to assess HRQoL in patients awaiting major joint replacement and to compare the HRQoL of patients with that of population controls. Patients were recruited into the study in three large Finnish hospitals across two hospital districts and were prospectively followed from the time the patient was placed on the waiting list to the time of admission, with waiting times calculated exactly. HRQoL was measured by the 15D, which is a generic, standardised, self-administered measure and has been utilised in clinical economic evaluations and population studies [20].

Some previous studies have reported that those awaiting hip or knee replacement have a significantly poorer quality of life – especially in physical and social life – than a general population [5,27]. The results of this study are in line with those studies. Our first main finding was that at both measurement points, patients awaiting major joint replacement suffered from a significantly poorer HRQoL – especially in moving, sleeping, usual activities, discomfort and symptoms, depression, distress, vitality and sexual activity – compared to the population controls. However, mental function seemed unaffected by the disease. This finding seems to be in line with an English case-control study of patients awaiting hip replacement for osteoarthritis [5], but in contrast to a recent Australian study by Ackerman et al. [28] who found that patients waiting for joint replacement suffered significantly higher psychological distress compared with the general population.

Our second main finding was that patients' overall HRQoL improved while waiting although the improvement was not statistically significant or clinically important. The patients showed, however, statistically significantly improved average scores at admission for moving, sleeping and discomfort and symptoms compared with the time when placed on the waiting list. This is somewhat paradoxical and may reflect patients' expectations on the coming surgical intervention that is supposed to relief the disabling symptoms and to improve function.

Multivariate analysis found that baseline HRQoL and BMI were associated with HRQoL at admission. An increased BMI was associated with a poorer HRQoL and better HRQoL at the time of listing for surgery predicted a better HRQoL at admission. We found, however, no association between the length of waiting time and HRQoL at admission. This result is partially in line with the studies [14-17,27] that have found no significant differences in HRQoL between patients with short waits and those with longer waits. The explanations are various and should be analysed in more detail. For example, it might be possible that after making a decision to operate, the certainty of treatment has a positive impact on health status. Nilsdotter et al. [15] have talked about "regression to the mean", in that with the decision, the health status may even improve. In addition, Achat et al. [29] have found that optimism in older patients is associated with better general health perception. Although patients' HRQoL did not seem to decrease while waiting and no association between waiting time and poorer HRQoL at admission was found, this does not, however, affect our general conclusion that patients awaiting major joint replacement due to OA suffer from discomfort and symptoms, and have a clear reduction in moving, usual activities, sleeping, energy, sexual life and some mental aspects (distress, depression). Although further deterioration in HRQoL may be limited after placement on the waiting list, delayed access to surgery impose the burden of disease.

There were some limitations in our study. First, most patients were residing in the urban area, which may limit our study's generalizability to rural populations. A previous study has shown that urban THR patients may differ from rural patients with respect to pain threshold and perceptions on function [30]. Second, the median length of waiting time among patients was rather short (72 days) and thus the sample may have under-represented those having to wait longer and resulted in an underestimation of the waiting time effect on HRQoL. As the median waiting times in Finland are longer, the study's finding should not necessarily be generalised to all patients awaiting THR or TKR. Further, we measured the time between placement on the waiting list and hospital admission instead of following patients from general practitioner's consultation to treatment. Ideally, the whole waiting time from initial referral to the specialist should be monitored [31]. In prospective studies, it is, however, difficult to collect waiting time data through the care process from primary care consultation to treatment. Third, the population controls had more often a professional education compared to the patients, which may have impacted on the findings as socioeconomic status (SES) has been shown to be associated with health status [30,32].

Conclusion

In these analyses, we found that the length of waiting was unrelated to the poorer HRQoL at admission. Further, moving, sleeping and discomfort and symptoms improved while waiting for surgery. An interesting view concerning these dimensions is that we do not know the association of disease specific medication with HRQoL and reduction in pain during the waiting time. Although patients' HRQoL measured by the generic 15D instrument improved minimally while waiting, a consistently worse HRQoL was observed in patients waiting for major joint replacement compared with population controls. Thus, it is essential to identify on the waiting list those in the poorest health.

Competing interests

The author(s) declare that they have no competing interests.

Authors' contributions

JH was the correspondence author of the manuscript and responsible for the integrity of the work as a whole. She contributed as a principal researcher and writer including drafting the article and the analysis and interpretation of data. MB was the leader of the research project. She made contributions to conception and design, acquisition and interpretation of data and participated in the writing process by commenting the manuscript. UT made contributions to design, acquisition, and interpretation of data. HS and PR contributed as specialists in the field, were involved in the design of the study and hypothesis formation and revised the manuscript. SS, ML, PP, KH contributed as specialists in the field of orthopaedic surgery. They made contributions to design and acquisition of data and revised the manuscript. All authors read and approved the final manuscript.

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Evaluating waiting time effect on health outcomes at admission: a prospective randomized study on patients with osteoarthritis of the knee joint

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quality of life, randomized controlled trial, total knee replacement, waiting time

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Abstract

Aims To evaluate the effect of waiting on health-related quality of life (HRQoL), pain and physical function in patients awaiting primary total knee replacement (TKR) due to osteoarthritis.

Methods Some 438 patients awaiting TKR were randomized to a short waiting time (WT) group (≤3 months) or a non-fixed WT group. In the final assessment, 310 patients (213 women) with a mean age of 68 years were included. HRQoL was measured on being placed on the waiting list and again at hospital admission using the generic 15D. Patients' self-report pain and physical function were evaluated using a scale modified from the Knee Society Clinical Rating System.

Results The median WTs for patients with short and non-fixed WT were 73 days (range 8–600 days) and 266 days (range 28–818 days), respectively. At admission, as assessed by the intention-to-treat analysis, there were no statistically significant differences between the groups in the 15D total score and disease-specific pain and function.

Conclusions Our study showed that longer WT did not result in worse pre-operative HRQoL.

Introduction

Joint replacement has proven to be cost-effective [1,2], with a high volume of demand but relatively long periods of time spent on the waiting list for patients. The Organization for Economic Cooperation and Development (OECD) Waiting Times project on waiting time (WT) variations for elective surgery across OECD countries showed WTs to be 'a significant health policy concern' in almost half of all OECD countries [3]. It was found that in 2000, the median WT of patients admitted to an inpatient or day-case surgical unit for knee replacement was 120 days in Australia, 136 days in Canada (British Columbia), 261 days in the United Kingdom and 202 days in Finland [3]. Explanations for delayed access have varied from demand factors [4] and insufficient surgical capacity [5], to the impact of social factors (e.g. gender, ethnicity) on WT [6,7]. Nevertheless, evidence on the effects of WT on health status is incomplete.

Although there are a number of quality of life assessments measuring the success of treatment among patients who have undergone total knee replacement (TKR) [8–10], few of these assessments have examined the change in health-related quality of life (HRQoL) that occurs while waiting for surgery. A few studies examining WT effects on health status in orthopaedic patients have not been able to show that patients having to wait longer would suffer from more severe pain, functional difficulties or poorer HRQoL than those with shorter waiting [11–13]. However, as the studies have not been based on a random allocation of patients, estimates on the effects of waiting on health outcomes may have been biased.

Due to this inconsistency in results, more studies on the effects of increased lengths of wait are needed. We therefore wished to examine the effect of WT on HRQoL, pain and physical function among patients awaiting primary TKR due to osteoarthritis of the knee joint.

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Methods and materials

Patients and data acquisition

After being informed of the study, consecutive patients attending pre-operative assessment by the orthopaedic surgeon were recruited into the study from three Finnish hospitals (HUCH Surgical Hospital, Helsinki; HUCH Jorvi Hospital, Espoo; and Coxa Hospital for Joint Replacement, Tampere) from August 2002 to November 2003. The last patient was admitted to hospital in May 2005. Eligibility criteria for the study were a need for a primary TKR as evaluated by the surgeon (excluding rheumatoid arthritis, fractures, haemophilia and deformity); aged 16 years or above; and that the patient who was placed on the hospital waiting list was willing and mentally able to participate in the study. All patients provided informed consent, and ethics approval for the study was obtained from the Helsinki University Central Hospital Surgery Ethics Committee.

After being placed on the hospital waiting list, patients were randomly assigned into two groups: (i) short WT (maximum 3 months) or (ii) non-fixed WT (surgery was performed according to the hospital's routine procedure during the period from the date the patient was added to the waiting list to the date of surgery). The number of patients placed on the waiting list varied from one month to another, being specific to each hospital. Therefore no advance estimate could be made of the number of patients to be placed on the list. The patients randomized into the short WT group could only be operated on every fourth month, and only half of the hospital's 1-month surgical capacity could be allocated as short WTs, so the number of short WTs was restricted and determined specifically for each hospital.

Patients were recruited into the study in three (one hospital) or four (two hospitals) recruitment periods. Recruitments were made in periods of 3 months in order to avoid the WT for the short WT group exceeding 3 months, and patients in the short WT group were operated within 2 weeks after the recruitment period. It was ensured that all eligible patients placed on the waiting list had a chance of getting recruited into the study (including the possibility of short WT) by not restricting the size of the non-fixed WT. Therefore, the groups were different in size.

Computer-generated randomization sequences were accomplished in the National Research and Development Centre for Welfare and Health, and were supplied to hospitals using consecutively numbered and sealed opaque envelopes. The patient's named nurse assigned participants to their groups after the decision on surgery had been made. The randomization envelope contained information on whether the patient belonged to the short WT or non-fixed WT group.

Surgeons were blinded with regards to patient allocation into the short or non-fixed waiting.

Measurement instruments

The primary endpoint with respect to WT effect was HRQoL measured by the 15D. The 15D is a generic, self-administered and standardized multi-attribute utility scale (MAUS) measure consisting of 15 dimensions: moving, seeing, hearing, breathing, sleeping, eating, speech, elimination, usual activities, mental function, discomfort and symptoms, depression, distress, vitality and sexual activity. For each dimension, the respondent must choose one of the five levels that best describes his/her state of health at the moment (best level = 1, worst level = 5) [14,15].

The single index (15D score) yielding values between 0 (being dead) and 1 (no problems on any dimension) is calculated from the health state descriptive system by using a set of population-based preference or utility weights [14,15]. Such a weight for each level of each dimension is obtained by multiplying the level value by the importance weight of the dimension at that level [16]. The level values on a 0–1 scale, reflecting the goodness of the levels relative to no problems on the dimension (=1) and to being dead (=0), and the importance weights summing up to unity, have been elicited from representative population samples. In most of the important properties, the 15D compares favourably with other instruments of the same kind, such as EuroQol (EQ-5D), Health Utilities Index (HUI3), Short Form (SF-6D) and Assessment of Quality of Life (AQoL) [14,17,18].

Condition-specific pain and physical function were evaluated using patients' self-report scales modified from the Knee Society Clinical Rating System [19]. Functional performances were assessed using walking distance and stair climbing. By the Knee Society rating system, stair climbing is considered normal if the patient can ascend and descend stairs without holding a railing. Walking distance was expressed in metres and recorded in the categories of unable, housebound, 100–500 m, 1–1.5 km and unlimited.

Data were collected using a self-administered questionnaire at baseline when patients are placed on the waiting list and at hospital admission. The questionnaires were distributed to patients at hospitals. Return of the questionnaires was via postal means. Common guidelines for administering the questionnaires were provided in each hospital.

Statistical analysis

Determining the sample size was based on the primary outcome variable (15D). Subgroups of 177 patients would give a power of 80%, assuming a type I error α of 0.05 to detect whether changes in the 15D score are of clinical significance between the randomized groups. A difference of $\Delta 0.03$ in the 15D score is clinically important in the sense that people can on average feel the difference [20].

Data analysis was carried out using SPSS for Windows, version 12.0.2 (SPSS Inc., Chicago, IL, USA). The baseline sociodemographic and clinical characteristics between patients who completed the questionnaires and those lost to follow-up were carried out using either the independent samples *t*-test or the chi-squared test depending on the levels of measurement.

Intention-to-treat (ITT) analysis was conducted to determine the differences in the 15D score and dimensions between randomized groups. Mean group scores were compared using the independent samples *t*-test. Per-protocol analysis, where short WT patients who were admitted beyond short WT (WT > 3 months) were excluded, was used as a supplementary analysis. In addition, linear regression analysis was used to determine the relationship between WT (months) and HRQoL at admission, with WT as an independent variable.

95% confidence intervals (CI) were presented for the estimated effect. Chi-squared tests were used to test differences in pre-

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operative pain and function between patients with short and non-fixed WT. Two-sided *P*-values were calculated in all tests. A *P*-value < 0.05 was considered to be statistically significant.

Missing values for the 15D dimensions were predicted by regression models, with the responses on the other dimensions, age and gender, as explanatory variables [15]. A missing value was substituted if a minimum 80% of responses on the dimensions were present.

Results

Of the 555 eligible patients, 117 patients (90 women) with a mean age of 71 (SD = 10.1) years were excluded after being informed on the study. Thus, 438 patients after providing a signed informed consent were randomly allocated into short WT ($n = 172$) or non-fixed WT ($n = 266$) (Fig. 1). Some 98 patients were lost to follow-up between the baseline and admission and were not included in the final analyses; three patients died while waiting, 75 did not return the questionnaire at admission (reason unknown), one declined to continue filling in questionnaires, surgery was cancelled for 16 patients, and three patients were operated on elsewhere. The questionnaires (baseline and admission) were filled in by a total of 310 patients (213 women), with a mean age of 68 (SD = 9.1) years, of whom 127 were in the short and 183 in the non-fixed WT group. Of the short WT patients, 43 were not operated on within 3 months and in fact waited longer (median 191 days).

The baseline characteristics of the randomized groups were similar (Table 1). The mean baseline 15D scores for patients with short and non-fixed WT were 0.778 (SD = 0.104) and 0.796 (SD = 0.088), respectively; the difference was not statistically significant or clinically important (Δ0.018, $t = 1.7$, $P = 0.099$, 95% CI: −0.004 to 0.041, not shown). At baseline, the majority of the patients ($n = 200$, 65.4%) experienced moderate (either occasional or continual) pain, and 39 (12.7%) patients experienced severe pain. A total of 282 (92.2%) patients had restrictions in climbing stairs, and 18 (5.9%) patients were totally unable to climb stairs.

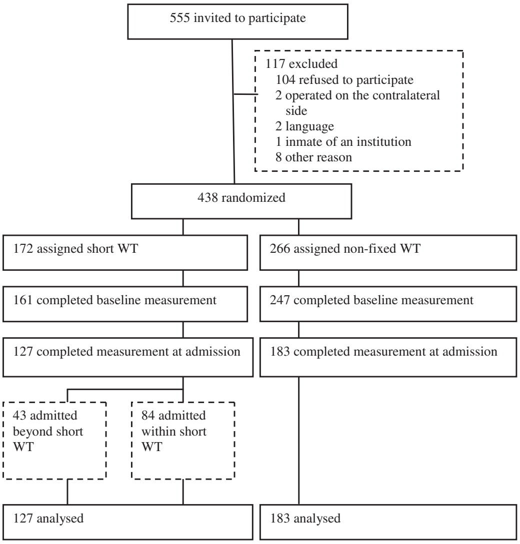

Figure 1 Trial profile. WT, waiting time.

A comparison between patients who completed the questionnaires (baseline and admission) and those who were lost to follow-up between measurement points showed that those who were lost to follow-up were more often living in the capital area ($\chi^2 = 13.8$, $P < 0.001$) than the completers. However, baseline HRQoL did not differ statistically significantly (Δ0.001, $t = 0.1$, $P = 0.898$, 95% CI: −0.020 to 0.023) between patients who completed the questionnaires and those who were lost to follow-up.

In the ITT analysis, a comparison between the randomized groups at admission found that there was no statistically significant or clinically important difference in the 15D total score at admission (Δ0.015, $t = 1.4$, $P = 0.170$; Table 2). The per-protocol analysis showed that at admission, patients with short WT had significantly lower 15D score than those with non-fixed WT ($P = 0.038$).

By a linear regression analysis, WT did not show a significant effect on the 15D score at admission ($\beta = 0.001$, $P = 0.294$, 95% CI: −0.001 to 0.003, data not shown).

The majority of the patients experienced moderate to severe pain (73.8% in patients with short, and 70.3% in patients with non-fixed WT; Table 3) at admission. Only four patients (1.3%) reported no pain. There was no statistically significant difference in the degree of pain between the groups ($\chi^2 = 3.0$, $P = 0.889$).

At admission, 274 (90.7%) patients reported that their ability to walk was limited, and the majority of the patients ($n = 241$, 79.3%) were able to ascend and descend stairs only with rail. A total of 22 (7.2%) patients were totally unable to climb stairs at admission. The group comparison showed that there were no statistically significant differences in stair climbing ($\chi^2 = 2.7$, $P = 0.745$) and walking distance ($\chi^2 = 2.9$, $P = 0.715$) between the groups at admission.

Discussion

Despite the growth in surgical facilities in many Western countries, the demand for joint replacement has increased faster than the surgical capacity, arousing problems in the availability of services and extending the utilization of conservative management (e.g. physiotherapy and medication). Still, scientific evidence on the relationship between WT and health status is inconsistent, and the absence of randomized trials has prevented an accurate assessment of whether longer waiting is related to poorer pre- and post-operative health status in patients awaiting TKR.

Several studies [11–13,21] have found no significant differences in HRQoL between patients with short waits and those with longer waits. The results of this study were partially in line with these studies. Within the range of WTs examined, longer waiting did not result in poorer health status at admission. Both the generic 15D instrument and the disease-specific pain and function measures supported the main finding. The results may reflect patients' expectations on the coming surgical intervention that is supposed to relief the disabling symptoms and to improve function, and thus individuals' ability to tolerate delayed access may increase while waiting. Most patients may be placed on the waiting list when symptoms are severe and after making a decision to operate, the

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Table 1 Details of the patients (intention-to-treat) and those lost to follow-up

Characteristics at baseline	Short WT (*n* = 127)	Non-fixed WT (*n* = 183)	Lost to follow-up (*n* = 98)	*P*-value*
Age, years (mean ± SD)	66 ± 9.3	69 ± 9.0	69 ± 9.6	0.453
Women [*n* (%)]	89 (70.1)	124 (67.8)	63 (64.3)	0.414
Living alone [*n* (%)]	45 (35.4)	56 (30.8)	38 (38.8)	0.268
Home municipality [*n* (%)]				0.001
Rural area	26 (20.5)	45 (24.7)	10 (10.2)	
Capital area	62 (48.8)	65 (35.7)	60 (61.2)	
Other urban area	39 (30.7)	72 (39.6)	28 (28.6)	
Professional examination, yes [*n* (%)]	47 (37.0)	67 (36.8)	29 (29.6)	0.187
Employment status [*n* (%)]				0.581
Employed	25 (19.7)	27 (14.8)	16 (16.3)	
Retired	99 (78.0)	150 (82.0)	77 (78.6)	
Other	3 (2.4)	6 (3.3)	5 (5.1)	
Co-morbidity, yes [*n* (%)]	98 (77.2)	144 (78.7)	80 (81.6)	0.450
Body mass index, kg m^{-2} (mean ± SD)	30.4 ± 4.9	29.4 ± 4.4	29.7 ± 4.7	0.898
Waiting time, days [mean (range)]	73 (8-600)	266 (28-818)		
Months waiting for surgery [*n* (%)]				
0–3	84 (66.1)	16 (8.8)		
>3–6	21 (16.5)	42 (23.2)		
>6	22 (17.3)	123 (68.0)		
15D score[†] [mean (SD)]	0.778 (0.104)	0.796 (0.088)	0.790 (0.091)	0.898

*Difference between those who completed the questionnaires at baseline and at admission and those lost to follow-up between measurements.

[†]The scale is 0–1, worst to best.

WT, waiting time.

Table 2 The average 15D scores at admission between the randomized groups

Mean (SD) 15D score*	Short WT (*n* = 127) Admitted within 3 months *n* = 84 (66.1%)	Non-fixed WT (*n* = 183) Admitted after 3 months *n* = 43 (33.9%)	Mean difference[†] (95% CI)	*P*-value
Intention-to-treat analysis	0.787 (0.100)	0.802 (0.094)	0.015 (–0.007, 0.037)	0.170
Per-protocol analysis	0.775 (0.102)[‡]	0.802 (0.094)	0.027 (0.001, 0.052)	0.038

*The scale is 0–1, worst to best.

[†]Positive difference indicates better score for non-fixed WT patients than for short WT patients.

[‡]Short WT patients admitted after 3 months (*n* = 43) were excluded from the per-protocol analysis

WT, waiting time.

certainty of treatment may have a positive impact on health perceptions. Nilsdotter & Lohmander [22] have talked about 'regression to mean', in that with the decision, the health status may improve.

Some previous studies [12,13] have reported that patients awaiting major joint replacement have a significantly poorer HRQoL than a general population. In this study, patients scored their general baseline HRQoL on average at 0.789 – a level that is substantially below the 15D scores for the age-matched general Finnish population [23]. Furthermore, the majority of the patients experienced moderate to severe pain and limitations in function when they were placed on the waiting list.

The strengths of this study were: (i) patients awaiting primary TKR were prospectively followed from the time the patient was placed on the waiting list to the time of admission, with WTs calculated exactly; (ii) walking and stair climbing have been identified as critical functional activities of subjects with knee or hip arthroplasty, and several studies have emphasized the importance of considering pain and symptoms in addition to measures of functional performance when evaluating the outcome of knee replacement [10,24]. In this study, both generic and disease-specific instruments were utilized, allowing a more global assessment of health status than if the measures were utilized separately [25]; self-report questionnaires provided the advantage of obtaining data by mail without recalling patients for formal evaluation [26]; (iii) with respect to age and gender, our study population was representative of the wider Finnish population of patients awaiting primary TKR [27]; and (iv) the median waiting for the patients with non-fixed WT (266 days) was comparable with the median WT for primary prosthetic replacement of knee joint in Finland. In 2002, the median WT varied across the 20 Finnish hospital districts from 129 to 574 days [28].

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Table 3 Patients' self-reported pain and function at admission (intention-to-treatment)

Outcome measure	Short WT (%)	Non-fixed WT (%)	*P*-value
Degree of pain			0.889
None	0.8	1.7	
Mild or occasional	7.1	11.2	
Mild, stairs only	0.8	0.6	
Mild, walking and stairs	17.5	16.2	
Moderate, occasional	40.5	39.1	
Moderate, continual	23.0	22.3	
Severe	10.3	8.9	
Stairs			0.745
Normal up and down	0.8	1.1	
Normal up, down with rail	9.5	8.4	
Up and down with rail	78.6	79.8	
Up with rail, unable down	4.8	2.8	
Unable	6.3	7.9	
Walking distance			0.715
Unlimited	8.0	10.2	
1–1.5 km	25.6	26.6	
100–500 m	51.2	47.5	
Housebound	15.2	14.7	
Unable	0	1.1	
N*	125–126	177–179	

*Number of observations varies due to missing values.
WT, waiting time.

There were limitations to our study, too. A total of 117 subjects were excluded from the trial. That patients excluded (mean age 71 years) were older than those who were randomized (mean age 68 years) may have resulted in more positive outcomes if the elderly had had worse outcomes. There is evidence from elsewhere that the outcome of knee replacement is worse for older patients than for younger patients [29], whereas a cross-sectional, community-based survey of knee replacement patients found that age does not seem to have a negative impact on patient-relevant health outcomes [10]. However, patients who were randomized suffered from poor HRQoL, pain and functional difficulties at the time they were placed on the waiting list. Patients were randomized irrespective of their disability and baseline characteristics, and the difference in age between participants and those who were excluded did not affect our general conclusion.

Some 98 patients were lost to follow-up between the measurement points. A comparison between the patients who did not return the questionnaire at admission and those who did showed some differences. Those who were lost to follow-up lived more often in the capital area than those who completed the questionnaires. There was, however, not a statistically significant or clinically important difference in the baseline HRQoL between those who completed the questionnaires and those lost to follow-up.

Of the short WT patients, 43 were not operated on within 3 months and in fact waited longer. The study protocol reveals some explanations for this: patients wanted to postpone surgery that inconveniently arrived too soon, they were not clinically ready for surgery, or there was no surgical capacity within 3 months. For the study setting, the primary analysis was based on the ITT principle and results reported by the randomized group regardless of the deviation from the WT. In addition, a regression model with WT as an independent variable did not show a significant effect of WT on HRQoL at admission. However, a per-protocol analysis, where those short WT patients who were admitted beyond short WT were excluded from the analysis, showed that patients waiting longer had better HRQoL at admission than among those with shorter WT. The per-protocol analysis may, however, introduce bias related to excluding patients from analysis. Therefore, the results of the ITT analysis were considered as primary, but the results of the per-protocol analysis and regression analysis supported the finding that longer WT did not result in worse pre-operative HRQoL.

Our study showed that longer WT did not result in poorer pre-operative HRQoL. Only patients with osteoarthritis of the knee joint were followed in this study, which may limit our study's generalizability to other patients awaiting elective treatment. Osteoarthritis is, however, one of the most prevalent chronic diseases in adults. As the population ages, it is likely that the demand for TKR will increase – a justified reason for paying attention to the burden of waiting for major joint replacement. To our knowledge, none of the previous studies have been based on the random allocation of patients to specific WT. The results of the study are of clinical relevance when developing effectiveness evaluation in specialized medical care. An interesting, but less discussed, view is that we do not know the association of medication, supporting services (e.g. physiotherapy, transport services), social support and personal pain management strategies with health and reduction in pain during the WT. This could provide broader information on the burden of waiting for health care resources.

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III

Is longer waiting time associated with health and social services utilization before treatment? A randomized study

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Objective: **To determine whether longer waiting time for major joint replacement is associated with health and social services utilization before treatment.**

Methods: **When placed on the waiting list, patients were randomized to short ($\leqslant$3 months) or a non-fixed waiting time. Utilization measures were the use of home health care, rehabilitation and social services before treatment.**

Results: **A total of 833 patients with osteoarthritis of the hip or knee joint were recruited into the study. Six hundred and twenty-two patients were included in the analysis. The majority of patients were not using any services before hospital admission for joint replacement surgery. The most commonly used service was unpaid home help provided by relatives, neighbours, friends and volunteers (informal care). In both groups, private support services were utilized more often than public ones. Patients with a short waiting time were more likely than those with a non-fixed waiting time to use rehabilitation (13.5% versus 8.2%, $P = 0.032$) and visiting care services (7.5% versus 3.9%, $P = 0.054$).**

Conclusions: **Only a few patients used professional care. They were more likely to require informal care during the waiting time. A longer waiting time did not result in a higher utilization rate before admission for treatment.**

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Introduction

In publicly-funded systems, waiting time (WT) to treatment is a basic rationing device. A commonly held view is that delayed access to care indicates problems in the performance of the system which, in turn, has driven policy-makers to allocate additional resources to shorten waiting times.[1] The rationale for the policies seems to be similar in systems with long waiting times: long WT may threaten equal access to treatment and impose costs such as welfare losses, more severe treatment due to delayed waiting, longer absence from work, income losses, and increased medication and service utilization.[2,3]

Patients awaiting total hip or knee replacement suffer from a chronic, slowly progressive disorder.[4] Although osteoarthritis (OA) is one of the most common chronic diseases in elderly people, little is known about the extent to which patients utilize services while waiting. Instead, most research in the field focuses on health status, pre-operative pain and disability, surgical outcomes and prognostic indicators of treatment benefit (e.g. age, gender, education, body mass index, co-morbidity).[5] For example, several studies have shown that patients awaiting total hip replacement (THR) or total knee replacement (TKR) suffer from severe pain, limitations in physical function and losses in health-related quality of life (HRQoL).[6–9]

An Australian study investigated health service utilization following THR.[10] According to the study, postoperative utilization was low. Although the results

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indicated adequate discharge planning and successful recovery, pre-operative utilization was not taken into account.

The purpose of this multicentre randomized controlled trial was to analyse the use of health and social services in patients awaiting major joint replacement, and to examine whether waiting time is associated with service utilization at admission.

Methods

Design and data collection

Patients were enrolled into this study in three Finnish hospitals (Helsinki University Central Hospital, HUCH; HUCH Jorvi Hospital, Espoo; and Coxa Hospital for Joint Replacement, Tampere) between August 2002 and November 2003.

Inclusion criteria for the study were: a need for a primary major joint replacement; the patient aged 16 years or older; the patient was placed on the waiting list at a research hospital; and the patient was willing and mentally able to participate in the study. In order to recruit a patient group likely to experience similar surgical techniques, patients with rheumatoid arthritis, fractures, haemophilia and deformity were excluded. The study had ethical approval from the HUCH Surgery Ethics Committee.

After giving informed consent, those willing to participate were randomly assigned to either a short WT ($\leqslant 3$ months) or a non-fixed WT (the patient waited the usual time for the particular hospital).

The number of patients placed on the waiting list varied from one month to another, being specific to each hospital. Therefore, no advance estimate could be made of the number of patients to be placed on the list. The patients randomized into the short WT group could only be operated on every fourth month, and only half of the hospital's one-month surgical capacity could be allocated for short WTs, so the number of short WTs was restricted and determined specifically for each hospital.

Patients were recruited into the study in three (one hospital) or four (two hospitals) recruitment periods. Recruitment was in periods of three months in order to avoid the waiting time for the short WT group exceeding three months and patients in the short WT group were operated within two weeks of each recruitment period. All eligible patients placed on the waiting list had some chance of being recruited into the study since the size of the non-fixed WT was not restricted. Therefore, the groups were different in size.

The random allocation sequence was drawn up in the research institute using a computer-generated randomization list. In each hospital, after a patient was placed on the waiting list and had provided signed informed consent, the patient's named nurse assigned participants to one of the two groups using consecutively numbered, sealed, opaque envelopes. For ethical reasons, double-blinding was not possible.

Data were collected prospectively by means of a self-administered questionnaire at baseline when a patient was placed on the waiting list and at hospital admission for joint replacement. The questionnaires were distributed to patients in hospital and returned by mail. Common guidelines for administering the questionnaires were provided in each hospital. Before data collection, six people (one aged under 70 years and five aged over 70 years) tested the questionnaire.

Service utilization variables

Data on service utilization were expressed as the percentage of patients with at least one visit. Participants were asked at baseline and at admission for treatment whether they had had visits at home from a nurse, chiropodist or physician (public or private) and if they had used rehabilitation services (public or private) within the last three months due to hip or knee disease. Further, patients were asked whether they had used any support services (public or private) including regular or temporary meals-on-wheels, housework services, laundry services, bathing services and transportation. Concerning informal care, patients reported the use of unpaid care provided by relatives, neighbours, friends and volunteers.

Statistical analysis

All analyses were conducted using SPSS for Windows, version 12.0.1. Descriptive analyses (χ^2 and t-tests) were used to compare the baseline characteristics of patients who completed the questionnaires and those who were lost to follow-up.

Each of the utilization variables was compared between short and non-fixed WT patients. Primary analyses were performed on an intention-to-treat principle, so that patients were analysed in the groups to which they were randomly allocated, regardless of their actual WT. The significance of the effect of waiting time on service utilization was assessed using the χ^2 test. Confidence intervals (CIs) of 95% were calculated for differences in proportions.

A secondary per protocol analysis was carried out, where patients who were admitted beyond a short WT were excluded. In addition, service utilization at admission for treatment was analysed by means of logistic regression (using the enter method). Each regression model included the following variables: baseline utilization, WT (days), randomized group, gender, home municipality, education and HRQoL measured by the 15D. The 15D is a generic and standardized HRQoL instrument consisting of 15 dimensions: moving, seeing, hearing, breathing, sleeping, eating, speech, elimination, usual activities, mental function, discomfort and symptoms, depression, distress, vitality and sexual activity. The single index (15D score) on a 0–1 scale, representing overall HRQoL, is calculated from the health state descriptive system by using a set of population-based preference or utility weights.[11]

Results

Patient characteristics

Of the 1058 eligible patients, 225 patients (160 women) with a mean age of 70 years were excluded (Figure 1). A total of 833 patients gave informed consent and were randomized into the short or non-fixed WT. A total of 622 returned the questionnaires and were included in the final analysis.

The mean age of the patients was 66 years ranging from 34 to 89 years (Table 1). Of the patients who completed the questionnaires, 213 (34%) waited 0–3 months and 138 (22%) waited over three months but less than six months. A total of 269 (43%) patients waited six months or over, of which 90 patients waited a year or more.

Service utilization before admission for joint replacement

In the three months before admission, the number of visits to home from a nurse, chiropodist or physician ranged from 1 to 20 among short WT patients and from 1 to 8 among those with non-fixed WT. Furthermore, 36 (13.5%) short WT and 29 (8.2%) non-fixed WT patients had used rehabilitation services in the three months before admission. Only seven (3%) patients in the short WT group and two (1%) patients in the non-fixed WT group had used rehabilitation services over 10 times in the three months before admission.

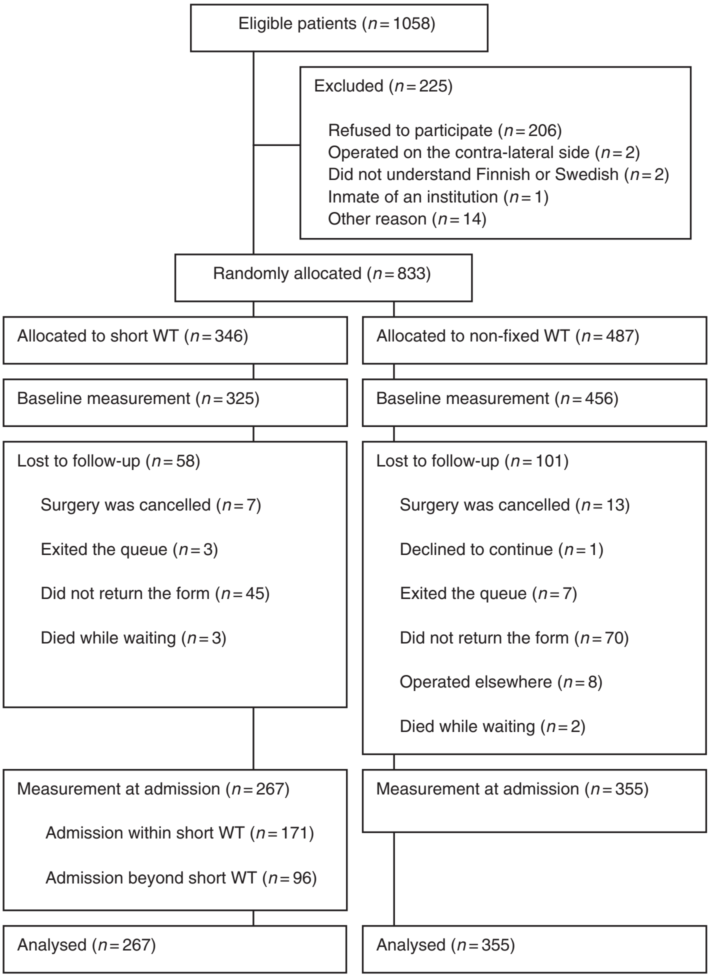

Figure 1 Recruitment of participants to trial

The most commonly used service among the patients was informal care (Table 2). Approximately 27% ($n=73$) of those with short WT used informal care in the three months before admission compared with 30% ($n=107$) of those with non-fixed WT. The most common provider of informal care was a relative. Only two patients received support from a neighbour, four from a friend and one used home help services provided by an association. The majority of patients in both randomized groups did not use any visiting care, rehabilitation or support services.

Patients with short WT used rehabilitation services ($P=0.032$) and visiting care services (visits to home from nurse, chiropodist or physician) significantly more often ($P=0.054$) than those with non-fixed WT. In the per protocol analysis, the difference in the utilization of rehabilitation services between the randomized groups remained statistically significant (Table 3).

After adjusting for baseline utilization, WT, gender, home municipality, education and HRQoL, patients with short WT were more likely to use visiting care and rehabilitation services relative to those in the non-fixed WT group (Table 4). Baseline utilization predicted utilization at admission.

Discussion

To our knowledge there have been no previous studies that have randomly allocated patients to a specific WT to assess the effect of waiting on service utilization. In this multicentre randomized trial we found that health and social services use was low in both WT groups and only a minority of patients received visits to their home from nurse, chiropodist or physician (public or private); the most common services used while waiting were rehabilitation services and informal care including unpaid care provided by relatives, neighbours and volunteers. Patients with shorter WT were more likely to use rehabilitation and visiting care (visits to home

Table 1 Baseline characteristics of the respondents and those lost to follow-up

Characteristic	**Short WT ($n=267$)**	**Non-fixed WT ($n=353$–355)**[*]	**Lost to follow-up ($n=153$–159)**[*]	***P* value**[†]
Age, years (mean [SD])	66.0 (9.5)	66.7 (9.6)	68.4 (9.9)	0.023
Women (*n* [%])	171 (64.0)	210 (59.2)	101 (63.5)	0.600
Living alone (*n*, [%])	88 (33.0)	95 (26.8)	67 (42.1)	0.002
Professional examination, yes (*n* [%])	99 (37.1)	134 (37.9)	51 (32.1)	0.203
Place of residence (n [%])				0.002
Capital	138 (51.7)	151 (42.8)	98 (61.6)	
Other urban area	80 (30.0)	121 (34.3)	41 (25.8)	
Rural area	49 (18.4)	81 (22.9)	20 (12.6)	
Joint (n [%])				0.008
Hip	140 (52.4)	172 (48.5)	61 (38.4)	
Knee	127 (47.6)	183 (51.5)	98 (61.6)	
BMI[‡] (mean [SD])	29.3 (4.5)	28.9 (4.5)	28.8 (5.0)	0.568
Co-morbidity, yes (*n* [%])	194 (72.7)	258 (72.7)	124 (78.0)	0.174
Waiting time, days (median [range])	75 (8–600)	222 (7–818)		
Visiting care services[§], yes (*n* [%])	6 (2.2)	10 (2.8)	5 (3.1)	0.416
Rehabilitation[**], yes (*n* [%])	39 (14.6)	47 (13.2)	17 (10.7)	0.693
Public support services[††], yes (*n* [%])	12 (4.5)	16 (4.5)	9 (5.7)	0.297
Private support services[††], yes (*n* [%])	18 (6.7)	22 (6.2)	6 (3.8)	0.204
Informal care[‡‡], yes (*n* [%])	66 (24.7)	86 (24.2)	44 (27.7)	0.401

WT, waiting time

[*] Number of observations varies due to missing values

[†] Between patients who completed the questionnaires and those lost to follow-up

[‡] Body mass index (kg/m^2)

[§] Visits to home from nurse, chiropodist or physician (public or private)

[**] Public and private rehabilitation services including physiotherapy and occupational therapy

[††] Regular or temporary meals-on-wheels, housework services, laundry services, bathing services and transportation

[‡‡] Unpaid care provided by relatives, neighbours and volunteers

Table 2 Health and support services utilization at admission (intention-to-treat analysis)

	Short WT ($n=267$)		**Non-fixed WT ($n=355$)**			
Service	**User (%)**	**Non-user (%)**	**User (%)**	**Non-user (%)**	**Difference (95% CI)**	***P* value**
Visiting care services[*]	7.5	92.5	3.9	96.1	3.6 (−0.1, 7.3)	0.054
Rehabilitation[†]	13.5	86.5	8.2	91.8	5.3 (0.3, 10.3)	0.032
Public support services[‡]	2.6	97.4	5.1	94.9	−2.5 (−5.2, 0.2)	0.124
Private support services[‡]	6.4	93.6	6.8	93.2	−0.4 (−4.1, 3.3)	0.845
Informal care[§]	27.3	72.7	30.1	69.9	−2.8 (−10.0, 4.4)	0.446

WT, waiting time

[*] Visits to home from nurse, chiropodist or physician (public or private)

[†] Public and private rehabilitation services including physiotherapy and occupational therapy

[‡] Regular or temporary meals-on-wheels, housework services, laundry services, bathing services and transportation

[§] Unpaid care provided by relatives, neighbours and volunteers

Table 3 Health and support services utilization at admission (per protocol analysis)

	Short WT ($n=171$*)		**Non-fixed WT ($n=355$)**			
Service	**User (%)**	**Non-user (%)**	**User (%)**	**Non-user (%)**	**Difference (95% CI)**	***P* value**
Visiting care services[†]	4.1	95.9	3.9	96.1	0.2 (−2.9, 3.3)	0.934
Rehabilitation[‡]	13.5	86.5	8.2	91.8	5.3 (0.3, 10.3)	0.057
Public support services[§]	3.5	96.5	5.1	94.9	−1.6 (−4.9, 1.7)	0.421
Private support services[§]	5.8	94.2	6.8	93.2	−1.0 (−5.1, 3.1)	0.690
Informal care**	30.4	69.6	30.1	69.9	0.3 (−7.0, 7.6)	0.950

WT, waiting time
*Ninety-six short WT patients admitted beyond short WT were excluded
[†] Visits to home from nurse, chiropodist or physician (public or private)
[‡] Public and private rehabilitation services including physiotherapy and occupational therapy
[§] Regular or temporary meals-on-wheels, housework services, laundry services, bathing services and transportation
**Unpaid care provided by relatives, neighbours and volunteers

Table 4 Logistic regression models predicting five types of service utilization

	Visiting care services[a]	**Rehabilitation[b]**	**Public support services[c]**	**Private support services[c]**	**Informal care[d]**
Baseline utilization	1.88** [6.54]	2.15*** [8.55]	3.62*** [37.39]	3.92*** [50.49]	2.40*** [11.05]
Waiting time	−0.002 [1.00]	−0.001 [1.00]	0.001 [1.00]	−0.003* [1.00]	−0.001 [1.00]
Randomized group	−1.07* [0.34]	−0.67* [0.51]	1.19** [3.28]	−0.42 [0.66]	0.13 [1.14]
Gender	0.51 [1.66]	0.61 [1.83]	0.70 [2.01]	0.99** [2.66]	0.87* [2.39]
Home municipality					
Rural area	Reference	Reference	Reference	Reference	Reference
Capital area	−0.88 [0.41]	0.49 [1.64]	−0.83 [0.44]	−0.31 [0.74]	0.41 [1.51]
Other urban area	−0.19 [0.83]	0.59 [1.81]	−0.82 [0.44]	−0.78 [0.46]	0.19 [1.20]
Professional education	0.34 [1.41]	−0.52 [0.60]	−0.27 [0.76]	−0.41 [0.66]	0.46 [1.58]
15D score[e]	0.72 [2.06]	2.15 [8.60]	3.94 [51.32]	−2.92 [0.05]	4.58*** [97.47]

Log odds coefficients with odds ratio in brackets. Utilization at admission is outcome variable coded 0 = user, 1 = non-user. Randomized group coded 0 = non-fixed waiting time, 1 = short waiting time. Gender coded 0 = woman, 1 = man. Professional education coded 0 = no, 1 = yes
[a] Visits to home from nurse, chiropodist or physician (public or private)
[b] Public and private rehabilitation services including physiotherapy and occupational therapy
[c] Regular or temporary meals-on-wheels, housework services, laundry services, bathing services and transportation
[d] Unpaid care provided by relatives, neighbours and volunteers
[e] On a scale 0–1, worst to best
*Significant at $P<0.05$
**Significant at $P<0.01$
***Significant at $P<0.001$

from nurse, chiropodist or physician) services before admission than those with non-fixed WT.

There are various explanations possible for this. One explanation for the generally low levels of utilization might be that after a decision to treat, a patient may 'hang on' until the surgery using informal care and personal networks instead of professional care. Secondly, use of services may be low universally in patients awaiting joint replacement. It is also possible that Finnish thresholds for joint replacement are low compared with other countries. This argument is, however, not consistent with studies[12,13] that have reported severe pain, limitations of physical function and losses of HRQoL in patients awaiting joint replacement. Alternatively, national eligibility criteria for using supportive health and social care while waiting might be set high. There is some evidence for this. The availability of home help services has declined by almost a half since 1990[14] as local authorities have implemented strict budget constraints. Further, some studies have identified unmet need for social and health services among Finnish elderly people.[15–17] It is also possible that elderly people are poorly informed about services.[18] A final explanation might be that the measures of use were flawed. All of the data were self-reported. Reijneveld[19] has suggested that self-reports of health care utilization are accurate, whereas Nelson *et al.*[20] found that 5% of subjects over-reported and 25% under-reported outpatient consultation rates.

This study had limitations. Only one aspect of waiting was assessed – service use – and none of the other effects such as health status, pain or disability. Because patients reported the utilization in the three months before admission, it was not possible to assess whether service utilization changed between primary care and specialist consultation, and between placement on the waiting list and surgery. In addition, patients who were excluded from the study (21%) were older than participants (mean age of 66 years versus 70 years), which could have restricted the generalizability of the results to younger patients.

For ethical reasons and in order to avoid selection bias among the patients, the randomized groups were different in size. A degree of inequality would have resulted if some patients had been made to wait for access to treatment longer than normal or if short waiting times had accounted for more than half of the hospital's surgical capacity, for instance. Patients would not have had any chance of being assigned to the short WT group if all short WTs had already been allocated during the first month of each three-month recruitment period.

A total of 96 patients in the short WT group waited over three months. The reasons were hospitals' limited capacity to carry out surgery within the three-month waiting period and patients' unwillingness to have surgery within three months. Due to this, the differences between the randomized groups may have been underestimated. To compensate for the deviation from protocol, we compared the groups in a per protocol analysis by excluding in the short WT group those who had waited over three months. The results of the additional analysis supported the original analysis.

This study focused on Finnish THR and TKR patients and so utilization patterns may be different in other health care systems and other patient groups. OA is, however, one of the most prevalent chronic diseases in adults and as the population ages, it is likely that the demand for major joint replacement will increase. Although several studies[4,21,22] have shown that pain and functional limitations appear to restrict the daily activities of patients with OA of the knee or hip joint, relatively few of the patients in this study used professional care to support activities of daily living, but instead received informal care.

Apart from rehabilitation, use of services was similar during WT as it had been at baseline. Nonetheless, there is likely to be higher total use of services over time by people who wait longer, simply because they are using services for a longer period. In economic terms this might still represent a negative impact of waiting. Thus, continued investigation of the pre- and post-operative effects of waiting time is increasingly necessary.

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IV

The effect of waiting time on health-related quality of life, pain and physical function in patients awaiting primary total hip replacement: A randomized controlled trial

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Submitted

Background: The purpose of this prospective randomized study was to assess the effect of waiting time on health outcomes in Finnish patients admitted to hospital for primary total hip replacement.

Methods: A total of 395 consecutive patients with a need for a primary total hip replacement due to osteoarthritis were placed on the waiting list between August 2002 and November 2003. After placement on the waiting list, patients were randomly assigned to a short waiting time (≤3 months) group (n = 174) or a nonfixed waiting time group (n = 221). Health-related quality of life was measured by the generic 15D instrument. Hip pain and function were measured by the patient self-report Harris Hip Score. Patients completed self-administered questionnaires at the time of placing on the waiting list and at hospital admission.

Results: Of the 395 patients, 312 (79%) completed the follow-up (140 patients with short waiting time and 172 with nonfixed waiting time). At admission, the mean 15D scores for patients with short and nonfixed waiting time were 0.784 and 0.783 respectively. In the intention-to-treatment analysis the difference between the groups (Δ 0.001, 95% CI: -0.019 to 0.021) was not statistically significant or clinically important. The mean self-report Harris Hip Score in patients with short waiting time was 43.5 and among those with nonfixed waiting time 41.9. The difference (Δ 1.6, 95% CI: -1.77 to 4.87) was not statistically significant.

Conclusions: Both generic and disease-specific measures revealed that longer waiting times did not result in poorer health status at admission.

Keywords: Waiting time, total hip replacement, HRQoL, randomized controlled trial

Introduction

Major joint replacement is an example of surgery with a high volume of demand and relatively long waiting periods for patients. Interest in examining the relationship between health status and time spent waiting for surgery has increased since the beginning of 2000. The majority of studies have found no relationship between health-related quality of life (HRQoL) and time spent on the elective waiting list.[1-3] However, some disease-specific instruments have indicated significant deterioration in physical function and increase in pain while waiting.[4-5] A prospective Canadian study concluded that clinically important losses in HRQoL and mobility occur in total hip arthroplasty (THA) patients waiting more than six months.[6] Further, some studies[7-8] have shown that patients in a later phase of disease do not achieve the same level of outcome as those with better preoperative function, a justified reason for paying attention to the changes in health status while waiting.

Inconsistency in empirical results is partly explicable due to differences in study settings, measures (disease-specific or generic), sample size and follow-up period. The absence of controlled trials that randomly assign patients to specific waiting time (WT) prevents the establishing of a relationship between the length of wait and the health outcome.[6]

The aim of this prospective, multi-centre randomized controlled trial (RCT) was to assess the relationship between HRQoL, pain, physical function and WT in total hip replacement (THR) patients with short WT and those where the WT was not fixed in advance, but the patient was following the hospitals' routine practice.

Methods

Study population

Patients were enrolled into this study in three Finnish hospitals (HUCH Surgical Hospital, Helsinki; HUCH Jorvi Hospital, Espoo and Coxa Hospital for Joint Replacement, Tampere). Two hospitals were university hospitals providing services for municipalities in the capital area. The third hospital is specialised in endoprosthetic surgery and provides services for municipalities, local and central hospitals, as well as for patients paying the costs themselves.

The inclusion criteria were: a need for a primary unilateral or bilateral THR due to osteoarthritis (OA) as evaluated by the orthopaedic surgeon; aged 16 years or older; patient was placed on the waiting list in a research hospital; and the patient was willing and mentally able to participate in the study. Patients with rheumatoid arthritis (RA), fractures, haemophilia and deformity were excluded. The study had ethical approval from the Helsinki University Central Hospital Surgery Ethics Committee.

Randomization

Consecutive patients were recruited into the study through regular contact with the orthopaedic surgeons and nursing staff between August 2002 and November 2003. The last patient was admitted to hospital in May 2005. Patients came for an outpatient orthopaedic surgeon assessment with a referral from a health centre, local hospital or a private physician.

After being placed on the waiting list according to clinical criteria, those meeting the inclusion criteria were asked to take part in the study. Those willing to participate were randomly assigned to either short (maximum three months) or non-fixed WT (patient received surgery according to the hospitals' routine procedure from the date he or she was added to the waiting list to the date of surgery).

The number of patients placed on the waiting list varied from one month to another, being specific to each hospital. Therefore no advance estimate could be made of the number of patients to be placed on the list. Consequently, the following arrangements were made: 1) the patients randomized into the short WT group could only be operated on every fourth month, and only half of the hospital's one-month surgical capacity could be allocated as short waiting times, so the number of short waiting times was restricted and determined specifically for each hospital and patients were recruited into the study in three (one hospital) or four (two hospitals) recruitment periods of three months (Table 1); 2) recruitments were made in periods of three months in order to avoid the waiting time for the short WT group exceeding three months; 3) patients in the short WT group were operated within two weeks after each recruitment period; 4) it was ensured that all eligible patients placed on the waiting list had a chance of getting recruited into the study (including the possibility of short WT) by not restricting the size of the non-fixed WT. Thus, the groups were different in size.

The tasks of generating the random sequence and implementing the assignment were separated between researchers and clinical staff. The random allocation sequence was drawn up using a computer generated randomization list. In each hospital, after a patient was placed on the waiting list, was informed of the study and had provided a signed consent, the patient's named nurse assigned participants to their groups using consecutively numbered, sealed, opaque envelopes. A separate randomization procedure was performed within each hospital.

Surgeons were unaware of the assigned intervention. For ethical reasons, double-blinding was not possible.

Measures

The primary outcome measure was patient's HRQoL measured by the 15D. The 15D is a generic and standardised HRQoL instrument consisting of 15 dimensions: moving, seeing, hearing, breathing, sleeping, eating, speech, elimination, usual activities, mental function, discomfort and symptoms, depression, distress, vitality and sexual activity. For each dimension, the respondent must choose one of the five levels that best describes his/her state of health at the moment (best level=1; worst level=5).[9-10] The single index (15D score) on a 0–1 scale, representing the overall HRQoL, is calculated from the health state descriptive system by using a set of population-based preference or utility weights. Such a weight for each level of each dimension is obtained by multiplying the level value by the importance weight of the dimension at that level. The level values on a 0–1 scale, reflecting the goodness of the levels relative to no problems on the dimension (=1) and to being dead (=0), and the importance weights summing up to unity, have been elicited from representative population samples. The 15D has been/is being utilised among different patient groups (e.g. patients undergoing hip or knee arthroplasty) to assess outcomes from health care interventions.[11] In most of the important properties (eg. responsiveness, sensitivity, reliability, validity), the 15D compares favourably with other instruments of the same kind, such as EQ-5D, HUI3, SF-6D and AQoL.[10,12-14]

The patient self-report Harris Hip Score (HHS) disease-specific test was used as a secondary outcome measure to measure hip pain and function.[15] The self-report HHS consists of pain (0–44 points) and function (0–46 points) subdivided into activities of daily living (ADL, 0–13 points) and gait (0–33 points). The total score ranges from 0 to 90 points, with a high score representing the best health state. Deformity and motion were excluded because the items could not be measured in a patient self-administered questionnaire. The performance of a self-reported HHS is comparable to that of a surgeon-assessed HHS and has shown to be less burdensome to patients than physician-administered HHS.[15]

Patients completed a self-administered questionnaire at two points in time: 1) when placed on the waiting list (baseline); and 2) at hospital admission. The questionnaires were distributed to patients at hospital and returned by mail to the research institute. Common guidelines for administering the questionnaires were provided in each hospital and the protocol specified that a named nurse distributed the questionnaire to the patient.

Statistics

The sample size estimate was based on the primary outcome variable (15D). A subgroup of 177 patients would provide the 80% power (two-tailed α error 5%) to detect clinically important differences (Δ0.03) in the 15D score between the groups.[16]

Primary analyses were based on the intention-to-treat (ITT) principle and comparisons were between the randomized groups. Comparative analyses of baseline socio-demographic and clinical characteristics between patients who completed the questionnaires (baseline and admission) and those lost to follow-up were carried out using either the independent samples t-test or the Chi squared test depending on the level of measurement. In a further per-protocol analysis, we excluded those short WT patients who were admitted beyond short WT (waiting time > three months). In addition, linear regression analysis was used as a supplementary analysis to determine the relationship between WT and HRQoL at admission with WT as an independent variable.

The group differences in the 15D score, pain, ADL and gait were tested by the independent samples t-test. Confidence intervals (CI) of 95% were calculated for mean differences in the outcomes at admission. All differences are presented as short WT minus non-fixed WT. Two-sided P-values were calculated in all analyses with the minimum significant level set at 5%. Data analyses were performed using SPSS for Windows, version 12.0.1 (SPSS Inc., Chicago, IL).

Missing values for the 15D dimensions were predicted by regression models with the responses on the other dimensions, age and gender as explanatory variables.[9] A missing value was substituted if a minimum 80% of responses on the dimensions were present.

Results

Participants

Of the 503 eligible patients, 108 (21.5%) patients (70 females) with a mean age of 70 (SD 10.4) years were excluded after being informed on the study (Figure 1). Thus, 395 patients were randomly allocated into short WT (n = 174) or non-fixed WT (n = 221). A total of 373 patients completed the baseline questionnaire. Some 61 patients were lost to follow-up between the baseline and admission measurements and were not included in the final analyses. Both the baseline and admission questionnaires were filled in by 312 patients, of which 140 were in the short WT and 172 in the non-fixed WT group.

Baseline characteristics

Baseline characteristics of the patients are presented in Table 2. Both randomized groups were comparable in baseline demographic and clinical characteristics. The mean (standard deviation, SD) baseline 15D score of the 312 patients was 0.783 (0.087). The majority of the patients (n = 271, 88.6%) experienced moderate to severe pain and six (2.0%) patients were totally disabled. A total of 158 (51.3 %) patients used walking support and 294 (95.5%) patients had difficulties with climbing stairs.

Of the patients who completed the questionnaires, 113 (36%) waited 0–3 months and 78 (25%) waited over three months but less than six months. A total of 121 (39%) patients waited over six months, of which 26 patients waited a year or more.

A comparison between patients who completed the questionnaires (baseline and admission) and those who were lost to follow-up showed that those who were lost to follow-up were older than patients who completed the questionnaires ($t = 2.1$, $P = 0.034$), were more often living alone ($X^2 = 11.0$, $P = 0.001$) and scored lower for gait ($t = 2.5$, $P = 0.014$).

Outcomes

In patients with short WT, the mean (SD) 15D score at admission was 0.784 (0.089) and in non-fixed WT patients 0.783 (0.090) (Table 3). The mean difference (Δ0.001) between the groups was not statistically significant or clinically important.

A per-protocol analysis was performed as a supplementary analysis. In the short WT group, those compliant with allocated waiting time (n = 87) and all patients in the non-fixed WT group (n = 172) were included in the analysis. Similar results were obtained in a per-protocol analysis and WT did not show a significant effect on the 15D score at admission (Δ-0.003).

A linear regression analysis was performed to estimate the relationship between waiting time and 15D score at admission. WT did not show a significant effect on the 15D score at admission ($\beta = -0.0002$, $P = 0.867$, 95% CI: -0.002 to 0.002, data not shown).

The patient self-report HHS, pain, ADL and gait were used as secondary outcome measures. At admission, the mean HHS scores in the short and nonfixed WT groups were 43.5 (SD 15.1; range 6 to 90) and 41.9 (SD 14.5; range 2 to 80) respectively. In patients with short WT, the mean (SD) pain score was 17.8 (8.0) and in patients with nonfixed WT, 17.1 (8.6). The pain score of HHS at admission ranged from 0 (totally disabled, pain at rest, n = 13, 4.3%) to 44 (no pain, n = 5, 1.6%). A total of 22 patients (7.2%) reported mild pain after unusual activity, 157 (51.5%) reported moderate pain and 101 (33.1%) reported marked or severe pain.

With regard to function, the great majority of patients reported limitations in ADL and gait. At admission, 128 patients (41.7%) did not need any support and the rest 178 (58.3%) patients used cane, crutch, walker or were totally unable to walk.

The results of the ITT analysis showed that there were no statistically significant differences in the self-report HHS total score and the levels of pain, ADL and gait between the groups at admission (Table 3). In the per-protocol analysis, no statistical differences between the groups were found (Table 4).

Discussion

The main findings of our study are: (i) at admission there were no statistically significant and clinically important differences in HRQoL, pain and function between the groups with different average waiting time; (ii) both disease-specific and generic measures supported the conclusion that waiting times were unrelated to the health status at admission.

Our findings corroborate previous studies that have found no significant difference in HRQoL between patients with short and longer waits.[2-3] Those studies were, however, not based on a randomized design and thus in those studies, patients with more severe symptoms may have had surgery more quickly than those with less severe symptoms and longer WT.

One of the strengths of this multi-centre study was that patients awaiting primary THR were prospectively followed from the time the patient was placed on the waiting list to the time of admission, with waiting times calculated exactly. Further, patients were randomly assigned to either short or nonfixed WT, providing evidence of the effect of WT on pre-operative health status. The findings were also based on the simultaneous use of both a generic and disease specific instrument as outcome measures, allowing a more global assessment of THR than if the measures were utilised separately.[17]

The sample was drawn from three large hospitals across two hospital districts and the sex and age structure of the patients in this study was similar to that of Finnish THR patients.[18] Further, the median WT for the patients with nonfixed WT (194 days) was longer than was the median WT for Finnish patients awaiting primary prosthetic replacement of hip joint in 2003 (155 days), although the WT in this study was comparable to national waiting times when taking into account the significant regional differences.[18] For example, in 2002, the shortest median WT for the primary hip replacement was 84 days and the longest 327 days when comparing the 20 hospital districts.[19] In relation to some countries, the median WT in patients with nonfixed WT was long. For example, in Australia, the median inpatient waiting time of the THR patient admitted in 2000 was 98 days, in Canada (British Columbia) 112 days and in Norway 99 days.[20]

Most patients (81%) were residing in the urban area, which may limit our study's generalizability to rural populations. A previous study has shown that urban THR patients may differ from rural patients with respect to pain threshold and perceptions on function.[21]

For the ethical reasons, that is, in order to avoid selection bias among the patients, the randomized groups were different in size. Such inequality would have resulted if some patients had been made to wait for access to treatment longer than normally or if short waiting times had accounted for more than half of the hospital's surgical capacity, for instance. Furthermore, the patient would not have had any chance of getting assigned to the short WT group if all short WTs had already been allocated during the first month of the recruitment period of three months. However, randomization resulted in good comparability in the baseline characteristics between the two groups.

A limitation of the study was that 53 patients in the short WT group waited longer than three months before being operated on. This may have resulted in an underestimation of the WT effect. The primary analysis was, however, based on the ITT principle to address the question of clinical effectiveness and treatment policy and to avoid the bias associated with a non-random loss of participants. The additional analyses – a per-protocol analysis where the short WT patients who were admitted beyond short WT were excluded from the analysis and a regression model with WT as an independent variable – supported the main finding and did not show a statistically significant or clinically important difference in HRQoL between the randomized groups. Nurse's feedback on the study protocol revealed explanations of why 53 patients in the short WT group did not receive the allocated intervention in time. Some patients wanted to postpone surgery that inconveniently arrived too soon, some were not clinically ready for surgery, randomization had not been clearly noticed in the hospital or there was no capacity to carry out surgery within three months. These explanations relate to current clinical practice in Finnish health care. The nationwide principles of access to health care within a reasonable period came into force in March 2005. Although "maximum waiting time guarantee" has improved access to treatment, some areas have reported problems in access to care due to the hospitals' limited surgical capacity or patients' unwillingness to care within the time specified.[22]

A total of 108 eligible subjects were excluded from the trial. That those excluded (mean age of 70 years) were older than completing participants (mean age of 65 years) may have resulted in more positive outcomes if only those with relatively mild disease at the time of listing for surgery were randomized. Completing participants experienced, however, substantially poorer HRQoL compared to that of an age matched general Finnish population sample[23] and the majority of patients experienced moderate to severe pain and limitations in function while waiting.

For ethical reasons, double-blinding was not possible and the patients were aware of the length of wait. Thus, the knowledge that they were accessing treatment within three months may have influenced the patients' self-evaluation of their HRQoL. For example, Achat et al.[24] have found that optimism in older patients is associated with higher scores in health status.

Patients' subjective perceptions as measured by validated and standardised generic health measurement instruments are of clinical relevance when planning and developing recommendations for priority setting in clinical decision-making. In this study, longer WT did not result in poorer HRQoL at admission, but patients seemed to be tolerate of moderate waiting. We even found that some patients wanted to postpone surgery. However, OA is slowly progressive disorder, and thus it is essential to identify the patients in the poorest health. The findings of this study have health political relevance when searching for more sustainable ways of allocating waiting times and developing recommendations and criteria for assessing health care needs for elective treatment. Continued investigation of the long-term effects and the stability of the effects of waiting time, as well as the effects of waiting on the demand for social and health services and medication are becoming increasingly necessary and important.

Acknowledgements

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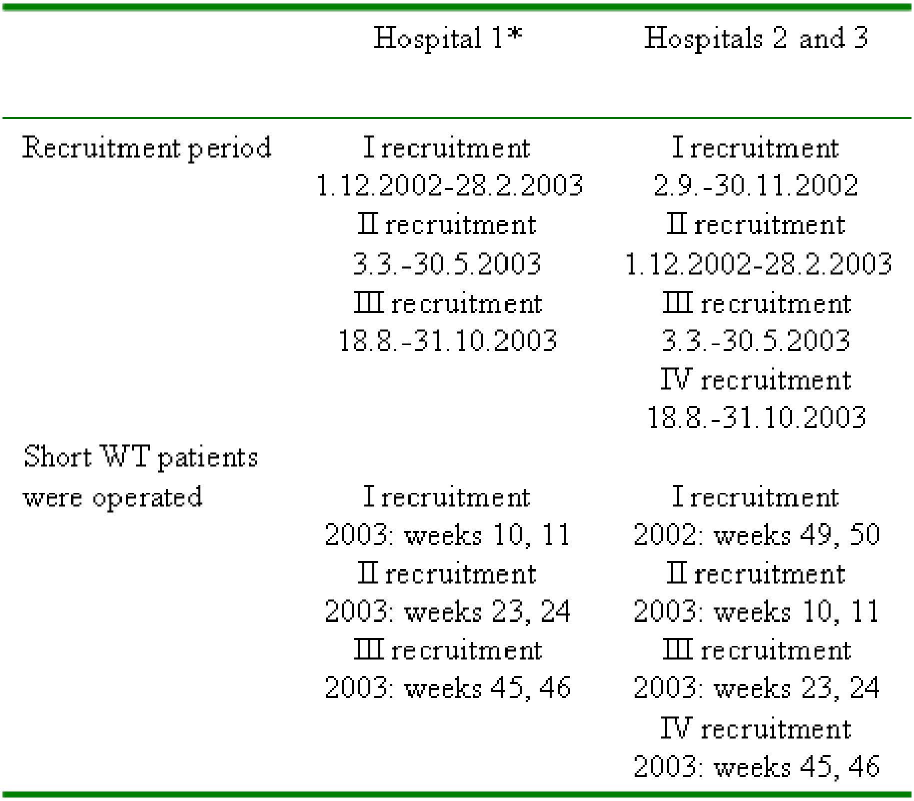
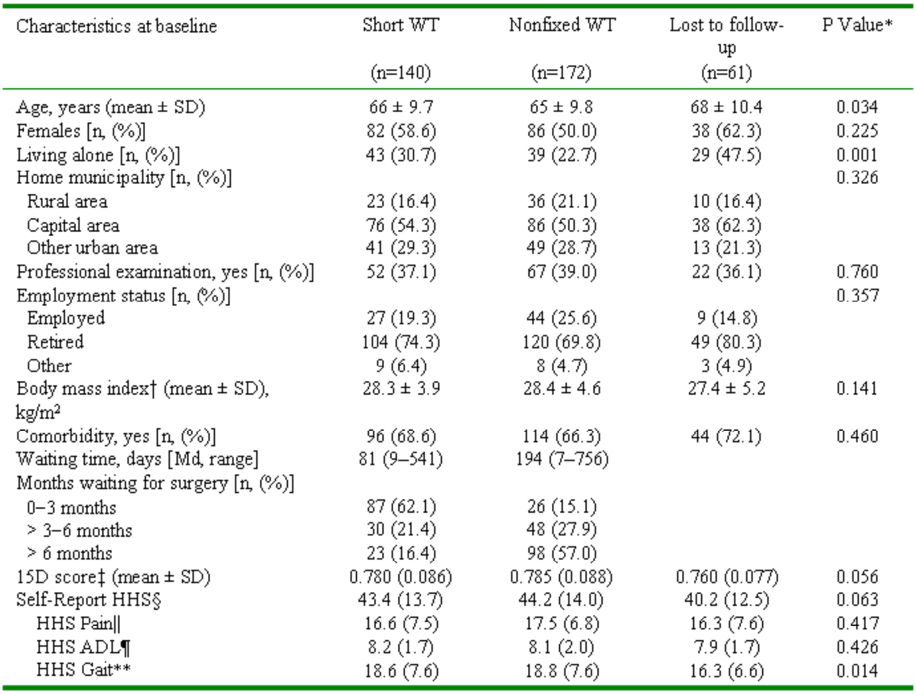
TABLE 1. Recruitment periods



	Hospital 1*	Hospitals 2 and 3
Recruitment period	I recruitment 1.12.2002-28.2.2003 II recruitment 3.3.-30.5.2003 III recruitment 18.8.-31.10.2003	I recruitment 2.9.-30.11.2002 II recruitment 1.12.2002-28.2.2003 III recruitment 3.3.-30.5.2003 IV recruitment 18.8.-31.10.2003
Short WT patients were operated	I recruitment 2003: weeks 10, 11 II recruitment 2003: weeks 23, 24 III recruitment 2003: weeks 45, 46	I recruitment 2002: weeks 49, 50 II recruitment 2003: weeks 10, 11 III recruitment 2003: weeks 23, 24 IV recruitment 2003: weeks 45, 46

* Due to hospital's capacity, only three recruitment periods were needed.

TABLE 2. Demographic and clinical characteristics of patients (ITT analysis)



Characteristics at baseline	Short WT (n=140)	Nonfixed WT (n=172)	Lost to follow-up (n=61)	P Value*
Age, years (mean ± SD)	66 ± 9.7	65 ± 9.8	68 ± 10.4	0.034
Females [n, (%)]	82 (58.6)	86 (50.0)	38 (62.3)	0.225
Living alone [n, (%)]	43 (30.7)	39 (22.7)	29 (47.5)	0.001
Home municipality [n, (%)]				0.326
Rural area	23 (16.4)	36 (21.1)	10 (16.4)	
Capital area	76 (54.3)	86 (50.3)	38 (62.3)	
Other urban area	41 (29.3)	49 (28.7)	13 (21.3)	
Professional examination, yes [n, (%)]	52 (37.1)	67 (39.0)	22 (36.1)	0.760
Employment status [n, (%)]				0.357
Employed	27 (19.3)	44 (25.6)	9 (14.8)	
Retired	104 (74.3)	120 (69.8)	49 (80.3)	
Other	9 (6.4)	8 (4.7)	3 (4.9)	
Body mass index† (mean ± SD), kg/m²	28.3 ± 3.9	28.4 ± 4.6	27.4 ± 5.2	0.141
Comorbidity, yes [n, (%)]	96 (68.6)	114 (66.3)	44 (72.1)	0.460
Waiting time, days [Md, range]	81 (9–541)	194 (7–756)		
Months waiting for surgery [n, (%)]				
0–3 months	87 (62.1)	26 (15.1)		
> 3–6 months	30 (21.4)	48 (27.9)		
> 6 months	23 (16.4)	98 (57.0)		
15D score‡ (mean ± SD)	0.780 (0.086)	0.785 (0.088)	0.760 (0.077)	0.056
Self-Report HHS§	43.4 (13.7)	44.2 (14.0)	40.2 (12.5)	0.063
HHS Pain‖	16.6 (7.5)	17.5 (6.8)	16.3 (7.6)	0.417
HHS ADL¶	8.2 (1.7)	8.1 (2.0)	7.9 (1.7)	0.426
HHS Gait**	18.6 (7.6)	18.8 (7.6)	16.3 (6.6)	0.014

* Difference between those who completed the questionnaires (baseline and admission) and those lost to follow-up

† n=171 in the group of nonfixed WT; n=59 among those lost to follow-up due to missing values

‡ The scale is 0–1, worst to best.

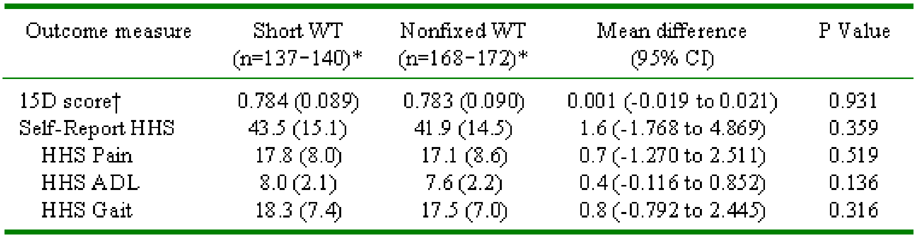
§ Total score. Data are mean (SD) scores on the scale 0–90, worst to best

|| Data are mean (SD) scores on the scale 0–44 (0=disabled, 10=marked pain, 20=moderate, 30=mild, 40=slight, 44=no pain)

¶ Activities of daily living. Data are mean (SD) scores on the scale 0–13, worst to best (stairs 0–4, shoes and socks 0–4, sitting 0–5)

** Data are mean (SD) scores on the scale 0–33 worst to best (limp 0–11, the support required 0–11, distance walked 0–11)

TABLE 3. Outcome measures at admission (ITT analysis)

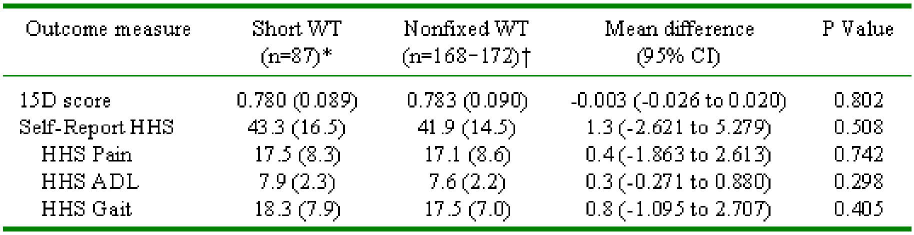


Outcome measure	Short WT (n=137-140)*	Nonfixed WT (n=168-172)*	Mean difference (95% CI)	P Value
15D score†	0.784 (0.089)	0.783 (0.090)	0.001 (-0.019 to 0.021)	0.931
Self-Report HHS	43.5 (15.1)	41.9 (14.5)	1.6 (-1.768 to 4.869)	0.359
HHS Pain	17.8 (8.0)	17.1 (8.6)	0.7 (-1.270 to 2.511)	0.519
HHS ADL	8.0 (2.1)	7.6 (2.2)	0.4 (-0.116 to 0.852)	0.136
HHS Gait	18.3 (7.4)	17.5 (7.0)	0.8 (-0.792 to 2.445)	0.316

*Number of observations varies due to missing values

† Mean (SD) 15D score. The scale is 0–1, worst to best.

TABLE 4. Outcome measures at admission (Per-protocol analysis)



Outcome measure	Short WT (n=87)*	Nonfixed WT (n=168-172)†	Mean difference (95% CI)	P Value
15D score	0.780 (0.089)	0.783 (0.090)	-0.003 (-0.026 to 0.020)	0.802
Self-Report HHS	43.3 (16.5)	41.9 (14.5)	1.3 (-2.621 to 5.279)	0.508
HHS Pain	17.5 (8.3)	17.1 (8.6)	0.4 (-1.863 to 2.613)	0.742
HHS ADL	7.9 (2.3)	7.6 (2.2)	0.3 (-0.271 to 0.880)	0.298
HHS Gait	18.3 (7.9)	17.5 (7.0)	0.8 (-1.095 to 2.707)	0.405

* 53 short WT patients admitted beyond short WT were excluded

† Number of observations varies due to missing values