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Assessment of Support Interventions in Dementia

Methodological and Empirical Studies

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To my Family

Everything is simpler than you think and at the same time more complex than you imagine

Johann Wolfgang von Goethe

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ABSTRACT

Dementia means a continuous deterioration of abilities and has a large impact on the persons affected as well as on family members and others close to the persons with dementia. Interventions aimed at this population in order to support and alleviate the often straining situation may be of great importance. There is a need to increase the knowledge and understanding of the impact and consequences of these interventions, both at an individual level and at a societal level. The demand for information concerning, e.g., economic and medical impact of technologies and interventions within health care is increasing. Assessment of technologies and interventions in dementia is related to certain methodological issues. The overall aim of this thesis is to contribute to the development of methodological knowledge concerning assessment studies and understanding of support interventions in dementia.

This thesis work includes four studies that examine methodological aspects of assessment of support interventions in dementia and also report empirical research on the perception of support interventions from the perspectives of family caregivers of persons with dementia. In study I, an assessment model for assistive technology (AT) interventions in dementia was developed. In study II, part of the assessment model is applied, and a process evaluation of the AT intervention is presented. Study III examines family caregivers' perception of the importance of different types of support and services. In the final study, study IV, a well-acknowledged methodological challenge within the field of assessment in dementia is addressed: measuring health-related quality of life (HRQoL). The studies are based on different data materials.

An assessment model of AT interventions was developed that includes health economic evaluation from a societal perspective as well as evaluation of the intervention process. The perspectives of both persons with dementia and their relatives were incorporated in the model. The process evaluation was applied in study II in order to study the relatives' perception of an AT intervention process. Assistive technology interventions in dementia may be of great significance for the relatives. By performing the process evaluation, several important aspects that need to be acknowledged in AT intervention processes in dementia were identified.

Family caregivers of persons with dementia perceived different types of support/services within the comprehensive areas of counselling, relief and information as very important. Knowledge of the caregivers' preferences is significant so that more directed support interventions may be provided.

One specific methodological issue was addressed in study IV. The results of study IV showed that there were large differences in the results of cost-effectiveness analyses depending on whether patient self-ratings or proxy ratings (ratings of persons close to the patient) of patient HRQoL were used for the same analysis. These differences in the results could ultimately have an important impact on decision making and resource allocation.

Support interventions aimed at persons with dementia and their relatives may be of great value. Conducting assessment studies of technologies and interventions within health care is important in order to increase the knowledge concerning, e.g., economic and medical impact. Assessment studies of support interventions dementia entails methodological issues that need to be addressed. There is a need for increased knowledge within this field and suggestions on methodology are made.

SAMMANFATTNING

Demens innebär kognitiv funktionsnedsättning som medför stora konsekvenser både för den drabbade personen liksom för närstående. Stödinterventioner riktade mot denna population för att avhjälpa och stötta den ofta tunga situationen kan vara av stor betydelse. Det finns ett behov av ökad kunskap angående konsekvenserna av stödinterventioner till denna grupp. Detta gäller både på individ- och på samhällsnivå. Efterfrågan på information vad gäller exempelvis ekonomisk betydelse samt klinisk effekt av interventioner inom hälso- sjukvården ökar. Utvärdering av interventioner vid demenssjukdom är relaterat till ett antal metodologiska frågor. Det övergripande syftet med denna avhandling är att bidra till utvecklingen av metodkunskap på utvärderingsområdet samt till förståelsen av stödinterventioner vid demenssjukdom.

Avhandlingen inkluderar fyra olika delstudier som syftar till att undersöka metodologiska aspekter av utvärdering av stödinterventioner vid demenssjukdom. Syftet är även att genomföra empiriska studier av närståendes perspektiv på stödinterventioner. En utvärderingsmodell för hjälpmedelsinterventioner vid demenssjukdom utvecklades i delstudie I. I delstudie II appliceras en specifik del av utvärderingsmodellen: processutvärdering av en hjälpmedelsintervention. I delstudie III undersöks vad närstående anser är betydelsefulla typer av support och service. I den sista delstudien, studie IV, belyses ett metodologiskt frågeställning vid demenssjukdom, nämligen att mäta hälsorelaterad livskvalitet. De fyra delstudierna är baserade på olika material.

En utvärderingsmodell av hjälpmedelsinterventioner vid demenssjukdom utvecklades i delstudie I, som inkluderar hälsoekonomisk utvärdering från ett samhällsligt perspektiv samt utvärdering av interventionsprocessen (processutvärdering). Både perspektiven från personerna med demenssjukdom samt deras närstående inorporerades i modellen. Processutvärderingen applicerades i delstudie II för att studera närståendes uppfattning av en hjälpmedelsintervention. Hjälpmedelsinterventioner för personer med demens och deras närstående kan vara av stor betydelse för närstående. Vid processutvärderingen identifierades flertalet aspekter av vikt vid hjälpmedelsinterventioner vid demenssjukdom.

Närstående till personer med demenssjukdom uppfattade olika typer av support och service inom områdena information, avlastning och rådgivning som mycket viktiga. Kunskap angående närståendes uppfattning om support och service är av betydelse för att på ett bra sätt kunna rikta stödinsatser till dem.

I delstudie IV belystes en specifik metodfråga angående mätning av hälsorelaterad livskvalitet hos personen med demens. Resultaten visade att det har stor betydelse vem som skattar patientens livskvalitet, patienten själv eller en närstående, så kallad proxyskattning. Analysen visade på stora skillnader i resultatet av den hälsoekonomiska analysen beroende på vem som skattade patientens livskvalitet. Detta kan i sin tur medföra konsekvenser för beslutsfattande och resursfördelning.

Stödinterventioner riktade till personer med demens och deras närstående kan vara av stor betydelse. Att genomföra utvärderingsstudier av teknologier och interventioner inom hälso- sjukvården är av stor vikt för att öka kunskapen angående exempelvis ekonomisk påverkan samt medicinsk effekt. Att genomföra utvärderingsstudier av stödinterventioner vid demenssjukdom innebär metodologiska frågor som måste belysas. Det finns ett behov av ökad kunskap inom området och rekommendationer angående metodik för sådana studier ges.

LIST OF PAPERS

This thesis includes four original papers. The papers have been reprinted with the permission of the journals.

- I. Alwin J., Krevers B., Johansson U., Josephsson S., Haraldson U., Boström C., Rosshagen A., & Persson J. Health Economic and Process Evaluation of AT Interventions for Persons with Dementia and their Relatives – a Suggested Assessment Model. *Technology and Disability*. 2007; 19(2,3): 61–71¹
- II. Alwin J., Persson J., & Krevers B. Perception and Significance of an Assistive Technology Intervention – the Perspectives of Relatives of Persons with Dementia. *Submitted to Disability and Rehabilitation*. 15 December 2009²
- III. Alwin J., Öberg B., & Krevers B. Support/Services among Family Caregivers of Persons with Dementia – Perceived Importance and Services Received. *International Journal of Geriatric Psychiatry*. 2010; 25(3): 240–248³
- IV. Alwin J., & Brodtkorb T-H. Could the Choice of Patient versus Proxy Ratings for Assessing Quality of Life in Dementia Affect Resource Allocation in Health Care? *Manuscript*

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ABBREVIATIONS

| | |
|-----------|--------------------------------------------------------|
| AD | Alzheimer’s disease |
| ADL | activity of daily living |
| AT | assistive technology |
| CAT | common assessment tool |
| CEA | cost-effectiveness analysis |
| CMT | Center for Medical Technology Assessment |
| COPE | Carers of Older People in Europe |
| COPM | Canadian Occupational Performance Measure |
| CUA | cost-utility analysis |
| DQoL | dementia quality of life |
| EQ-5D | EuroQol, five dimensions |
| GS group | Great Significance of intervention group |
| HRQoL | health-related quality of life |
| HTA | health technology assessment |
| HUI | Health Utility Index |
| IADL | instrumental activity of daily living |
| ICER | incremental cost-effectiveness ratio |
| MCI | mild cognitive impairment |
| MMSE | Mini-Mental State Examination |
| NI | negative impact |
| NICE | National Institute for Health and Clinical Excellence |
| OT | occupational therapist |
| PADL | personal activity of daily living |
| POCR | Patient perspective On Care and Rehabilitation process |
| QALY | quality-adjusted life year |
| QoL | quality of life |
| QoL-AD | quality of life – Alzheimer’s disease |
| SEK | Swedish kronor |
| SD | standard deviation |
| SF-6D | short form, six dimensions |
| SG | standard gamble |
| SNS group | Some/No Significance of intervention group |
| TTO | time trade-off |
| VaD | vascular dementia |

INTRODUCTION

Dementia has a very large impact both on the lives of the affected persons and on others close to the persons with dementia. The situation is often straining due to the cognitive, emotional and physical impairment brought on by the dementia illness. Supporting interventions aimed at persons with dementia and their relatives may be of importance in alleviating the situation and helping to manage the emerging everyday difficulties. Knowledge concerning the impact and understanding of interventions in dementia, both at an individual level and at a societal level, needs to be improved. Reaching this knowledge is accomplished through assessment studies. Health technology assessment (HTA) means comprehensive assessment processes of technologies⁴ within health care. Health technology assessment includes aspects such as economic impact and clinical effectiveness, and other consequences of technologies and interventions. Performing assessment studies within the field of dementia entails specific methodological issues that need to be addressed.

This thesis work, *Assessment of support interventions in dementia – methodological and empirical studies*, sets out to explore both methodological issues concerning assessment of support interventions in dementia, and empirical issues, such as perceptions of certain support interventions.

Outline

Four studies are included in this thesis work. The topics included are family caregiver support/service preferences and the family caregiver's situation in dementia, assessment studies of certain support interventions and also, methodological assessment issues and challenges within this field.

The outline of this thesis is as follows: first, a brief background is given to the reference population – persons with dementia and their relatives. Next, the family caregiver's situation in dementia and support measures is described.

⁴The term *technology*, as used in this thesis, includes not only medical technical products, but also procedures within health care (e.g. surgical), and pharmaceutical and other treatments.

Ethical aspects concerning research including persons with reduced autonomy are presented next.

Thereafter, the concept of HTA, including health economic evaluation studies and process evaluation of interventions, is introduced and methodological issues and challenges within the field of dementia are presented.

The Methods and Materials section and the Results section are divided study-wise in the thesis. In the final part of the thesis, a general discussion is presented. The thesis ends with a presentation of the overall conclusion of the studies.

Comments on Terminology

The four studies included in this thesis were performed within different projects and fields. This has had implications for the use of terminology, as different terms have sometimes been used for the same, or closely related, concepts.

The persons with dementia are also referred to as *the patients*.

In studies I and II, the term *relatives* of persons with dementia is used (the relatives in study I and II were never asked whether they saw themselves as caregivers). By contrast, in study III, the term used is *family caregivers*, or simply *caregivers* (not *relatives*), of persons with dementia (the family caregivers in study III perceived themselves as caring for someone). Within health economics, family caregivers are often referred to as *informal caregivers* when they do not receive payment for their caring efforts.

The terms *caregiver burden*, *caregiver strain* and *negative impact (NI)* due to caregiving are used synonymously.

A distinction has been made between the terms *support* and *services*. *Support* refers to informal measures not organized by the community or institutions (such as support given by friends or neighbours), while *services* refers to more organized measures.

The use of a specific term within this thesis is connected to a certain study. The use of different terms has been deliberate and intends to preserve the slight differences in meaning.

BACKGROUND

Dementia

Dementia is a syndrome that includes different diagnoses. The most common diagnosis is Alzheimer's disease (AD) and the next most common is vascular dementia (VaD) [1]. AD constitutes approximately 60–70% of all dementia diagnoses in Europe, Africa and North America and VaD constitutes about 10–20% [2]. Alzheimer's disease is a progressing disease that brings about a slow deterioration of brain functioning. The progression of AD can be divided into different stages following a certain course of deterioration [3]. Vascular dementia is caused by changes in the blood vessels and blood flow in the brain, due to e.g. arteriosclerosis, and has a more irregular course of deterioration [3]. Dementia leads to cognitive impairment and may also include psychological problems such as depression and hallucinations and behavioural changes [4]. Depending on stage, persons with dementia may need assistance performing all activities of daily living (ADLs).

Dementia is strongly related to age. At the ages of 60–64, the prevalence of dementia is about 1%, while dementia is present in a little less than half (45%) of the population at 95 years of age and older [2]. The total prevalence of dementia in Sweden, with a total population of approximately 9.3 million inhabitants [5], is estimated to be approximately 140,000 persons; this number is calculated to increase in relation to the rising life expectancy of the population [2].

The societal costs for care of persons with dementia in Sweden are large. Calculations from the Swedish Board of Health and Welfare showed that the societal costs for care of persons with dementia for 2005 amounted to approximately 50.1 billion SEK (4.4 billion Euro) [6]. This included costs for formal care, pharmaceuticals, societal services (e.g. dementia day care, special housing, etc.), loss of production, and informal care. The largest cost in the calculations was special housing, which constituted 67% of the total costs [6]. Informal care (care performed by unpaid persons such as a relative)

constituted approximately 9% of the total costs [6]. The authors of the report summarize ([6] p. 7, own translation):

... The care efforts by relatives also represent a great societal value in both human and economic terms. Improved support for the dementia ill and their caregivers is therefore one of the foundations of good dementia care ... [6]

Family Caregiver Situation

There is a great amount of research and literature concerning the situation for family caregivers of persons with dementia. Dementia is also known as the “relatives’ disease” due to the impact it has on persons close.

Much of the literature has focused on negative aspects of giving care in dementia [7, 8] and several factors have been identified to have a negative effect on caregivers. Donaldson *et al.* (1998) [9] found certain, other than cognitive, factors to have this negative effect, such as depression, behavioural changes and sleep disturbances of the persons with dementia. These findings are in concordance with previous research. Several factors related to the person with dementia have been identified to explain caregiver depression or burden, such as behavioural problems [10-12] and problems in performance of ADLs [10]. Factors identified as related to the caregiver, explaining caregiver depression or burden, are, e.g., hours of informal caregiving [10] and level of social support [11, 12]. Gender issues have also been shown to influence the situation as female caregivers of persons with dementia seem more likely to report being burned out [13]. Female caregivers have also been shown to experience lower levels of health-related quality of life (HRQoL) as compared with peers in the general population [14].

It has been acknowledged that caregiving also has positive elements. Nolan *et al.* (1996, p. 82) [15], however, call satisfaction of giving care “the neglected dimension”. It has been pointed out that caregivers may experience both negative aspects, such as burden, and positive aspects, such as satisfaction from caregiving [15, 16].

Support for Persons with Dementia and their Relatives

There are different types of services or support interventions developed specifically for persons with dementia and their relatives. These include services such as respite care, e.g. day care for the persons with dementia, and support groups for caregivers. Eters *et al.* (2008) [7] conclude in a review study that interventions including several elements ("multicomponent interventions") may be effective in alleviating family caregiver strain in dementia.

According to international research in developed countries, the use of support and services among caregivers of persons with dementia is low. There are several reasons for not using services, such as caregivers perceiving that they do not need the service [17, 18], or not having knowledge of what is available [17-19], as well as stigmas [19], inconveniences in accessing services [20], relationship with the persons with dementia [21, 22], and unwillingness on the part of the caregiver and/or the persons with dementia [20]. Zhu *et al.* (2009) [23] report that approximately 4/5 of the persons with dementia in their study received informal care, while only 1/5 received home help services. The use of formal services among persons with dementia was associated with, e.g., level of function and depressive symptoms [23].

Over the past years, attention has been directed towards assistive technology (AT) as a way to support persons with dementia and their relatives. Persons with dementia may have several difficulties in interacting with familiar technologies in their homes [24]. Assistive technology aimed at this population includes specifically developed devices, such as electronic calendars or easy-to-use telephones as well as more security-oriented AT such as stove guards and door alarms. Factors such as motivation [25, 26] and insight [26] of the persons with dementia may be important for successful use of AT. Further issues of, e.g., timing of implementation of the AT have been pointed out as important [25]. Several European projects concerning ATs in dementia have been accomplished [27, 28]. A review study from 2009 includes 46 articles concerning AT use in dementia [29]. The author of the review [29] concludes that the research concerning AT for persons with dementia is in its early years and that development of methodology is needed.

Raivo *et al.* (2007) [30] have shown that support and services provided by the community often do not match the needs of the caregivers. To be able to direct

support interventions for persons with dementia and their relatives, it is of importance to have knowledge and an understanding of their preferences when it comes to support and services.

Ethical Aspects

Within medical research, ethical aspects are of uttermost importance. Three important comprehensive principles are [31]:

- Autonomy
- Beneficence – non-maleficence
- Justice

The issues of informed and voluntary consent to participate in research (part of the principle of autonomy) need extra and careful consideration before conducting research within the field of dementia. Dementia is a syndrome that means a loss of autonomy due to cognitive impairment.

The World Medical Association has developed ethical principles concerning research that includes human subjects, known as the *Declaration of Helsinki* [32]. The Declaration of Helsinki contains certain principles dealing with the subject of research including persons with reduced autonomy [32]. Importantly, concerning all medical research, it states that the health, life, dignity, integrity, etc. of the participants should be protected (principle No. 11) and that the potential burdens and risks of conducting research need to be carefully assessed in relation to potential benefits of the research (principle No. 18).

With regard to conducting research with persons with reduced autonomy (*vulnerable populations*), it is stated in the Declaration of Helsinki [32] that the research is justified only if the population or community is likely to benefit from the research and if the research is sensitive to the specific needs of the population (principle No. 17).

Three principles of the Declaration of Helsinki are explicitly directed towards including persons with reduced autonomy (*persons deemed incompetent*) in research, principles No. 27–29. These principles state, in short, that if a person cannot give consent, a legal representative can give their consent on behalf of

that person. Being included in research should then mean benefits for the participants. Exceptions can, however, be made if, e.g., the research involves minimal risks or burden for the participants.

Health Technology Assessment

Health technology assessment is the name for comprehensive assessment processes of technologies within health care aimed at providing decision makers with information regarding, e.g., clinical effectiveness, economic impact as well as ethical and organizational consequences of technologies. One definition by the European Network for Health Technology Assessment of HTA is [33]:

Health technology assessment (HTA) is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective health policies that are patient focused and seek to achieve best value. [33]

As shown in the definition, HTA is comprehensive and includes diverse issues. When only one part of an HTA is made, such as an economic evaluation, this is known as a *partial assessment*.

The use of HTA has undergone development over the years. This is true for many Western countries, including Sweden to a high degree [34]. According to Stevens *et al.* (2003) [35], there are three main motives for development of HTA: 1) concerns regarding adoption of new and/or not previously assessed technologies, 2) high expectations of the consumers of health care, and 3) the important issue of the increasing health care costs. Evaluations aimed specifically at examining costs and effects of technologies in health care will be presented in the next section.

Health Economic Evaluations

One important part of HTA is economic evaluations. Resources in health care are limited, and costs are increasing. The increase in costs is due to factors such as ageing populations and the development of new, often costly,

technologies making it possible to treat more diseases [35]. This leaves decision makers in health care with the difficult task of allocating available resources. Health economic evaluations aim to provide decision makers with information regarding costs and effects of technologies in health care in order for them to make informed decisions regarding resource allocation and priority setting.

There are different types of health economic analyses. One common analysis is the cost-effectiveness analysis (CEA). The CEA is often advocated for use in decision-making contexts [36, 37]. The CEA aims to study effects of technologies in relation to their costs and always includes a comparison between two or more treatments. The result of a CEA is expressed as a ratio, the incremental cost-effectiveness ratio (ICER). Figure 1 illustrates how the ICER is calculated, comparing two treatments (A and B):

$$ICER = \frac{(CostsA - CostsB)}{(EffectsA - EffectsB)} = \frac{\Delta C}{\Delta E}$$

Figure 1. Calculation of the incremental cost-effectiveness ratio (ICER).

Which costs (and effects) to include in the analysis depends on the chosen perspective of the analysis. One often advocated perspective is the so-called *societal perspective* [37-39]. According to the societal perspective, all costs affected by the technology under investigation should be included in the analysis, regardless of where the costs occur [38].

In dementia, large caring efforts are made by family caregivers [6, 23]. Informal care has been shown to amount to up to 8.5 times the formal care in terms of hours per month [40]. Including cost of informal care in the economic analyses is therefore of great importance [39, 41]. In the year 2000, informal care was largely left out of health economic analyses [42]. According to Koopmanschap *et al.* (2008) [41], the attention towards informal care has increased but not to a satisfactory extent. The authors [41] suggest that this may be due to reasons such as lack of standardized methods, since measuring informal care is a methodological challenge. The difficulties are associated with both how to measure the amount of informal care (e.g. in hours per week) and how to value the care in monetary terms. Studies have yielded

different results when it comes to hours per week and the cost of informal care [43]. There are methods for attaining this information [41, 43-45]. Informal care can, e.g., be measured by asking caregivers to keep a diary for a specified time in order to monitor the time spent caregiving. Another option is to ask the caregivers to recall the amount of time spent on caregiving activities during a certain period of time, e.g. the last week/month [46]. One challenge with measuring informal care is, however, how to discriminate between caregiving activities and other activities [43]. When it comes to valuing informal care in monetary terms, a range of different methods are available (see, e.g., [41, 47, 48] for comprehensive descriptions).

Effect measures for assessment of health care interventions can be expressed in, e.g., life years, quality of life (QoL), level of functioning, or other, more disease-specific measures. In dementia, frequently used disease-specific outcomes are disease stage [49] and cognitive ability [39]. Since health economic studies aim to aid decision makers on issues regarding resource allocation and priority setting, it is central that different studies and interventions be compared. To be able to do this, it is of importance that an effect measure that allows for comparisons is used [50]. The general effect measure for use in health economic studies is the quality-adjusted life year (QALY). The QALY is non-disease-specific (i.e. it is generic) and applicable to various patient groups. When QALY is used as effect measure, the analysis is more specifically called *cost-utility analysis (CUA)*. In this thesis, however, no distinct difference has been made in the use of the terms *CEA* and *CUA*.

Quality-adjusted life years are calculated by multiplying a QALY weight with life years. The QALY weight is expressed as a number between 1 and 0, where 1 represents full health and 0 represents death. Figure 2 illustrates a simple example of how to calculate QALYs for two alternative treatments, A and B:

Treatment A: $(0.7 * 3.5) + (0.6 * 1.5) = 3.35$ QALYs

Treatment B: $(0.7 * 2) + (0.6 * 1) + (0.5 * 1) + (0.4 * 0.5) = 2.7$ QALYs

The QALYs gained, derived when comparing treatment A with treatment B, are illustrated by the area between the two curves. In the present example, shown in Figure 2, the QALYs gained are: $3.35 - 2.7 = 0.65$ QALYs.

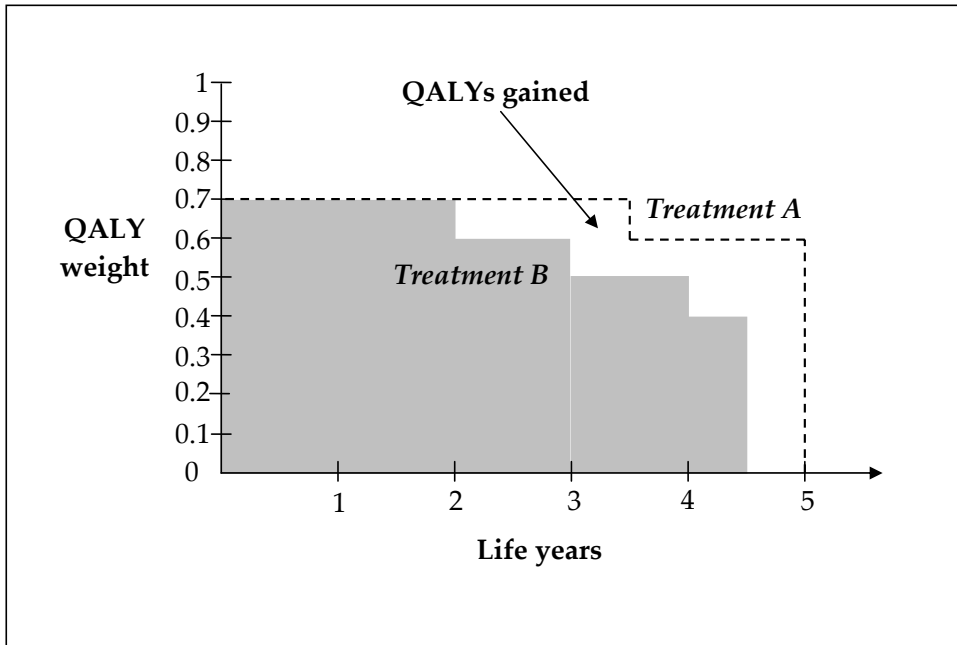


Figure 2. Illustration of calculation of quality-adjusted life years (QALYs).

Valuation of quality of life and quality-adjusted life years

Valuation of QoL is central in health economics and can be accomplished by using different methods. When the goal is to obtain QALY weights for QALY calculations, so-called “direct methods” are available, e.g. time trade-off (TTO) and standard gamble (SG) (see, e.g., Drummond *et al.* (2005) [51] for a comprehensive description). Furthermore, QALY weights can be obtained by using a group of instruments called *preference-based instruments*. These instruments yield QALY weights previously estimated through direct methods. Examples of such instruments are the EQ-5D [52, 53], Health Utility Index (HUI) [54] and short form, six dimensions (SF-6D) [55]. When instruments are used to obtain the QALY weight, this is referred to as use of indirect methods.

One commonly used preference-based health-related QoL (HRQoL) instrument, the EQ-5D [52, 53], comprises five dimensions: Mobility, Self-care, Usual activities, Pain/Discomfort, and Anxiety/Depression. There are three response alternatives to each dimension that correspond to “No problems”, “Some problems” and “Severe problems”. The EQ-5D renders a health state that can be transformed into a QALY weight by using an algorithm [56]. The

QALY weights are based on TTO ratings from the general population, and modelled for each of the EQ-5D health states [57]. The EQ-5D, based on scores from the UK general population, renders a score of between -0.594 and 1 (1 representing full health) [56].

When using the EQ-5D (as well as other preference-based HRQoL instruments), the patient is asked to self-report his or her own HRQoL in the five dimensions. In dementia, however, this is not without challenge on account of cognitive limitations of the patients. In such cases, the use of a *proxy* is an option. This will be further explained in the next section.

Measuring quality of life in dementia

Measuring QoL in dementia is a recognized methodological challenge [50, 58]. This is due to the nature of the disease. Dementia means cognitive impairment, making self-ratings of QoL difficult. *Proxy raters* may be used instead when a patient cannot make his/her own ratings. The proxy is often a family caregiver or health care personnel. The use of proxies as a representative for a person unable to make self-ratings has been recommended by, e.g., the National Institute for Health and Clinical Excellence (NICE) in England and Wales [36].

However, there are certain issues related to patient-proxy ratings of QoL in dementia that complicate the matter. There are differences between patient self-ratings and proxy ratings of patients' QoL [59-63]. The patients rate their QoL higher compared with the proxies. These differences may be explained by factors such as caregiver burden [61] or patient characteristics [64]. The way in which the proxy is asked to rate the QoL of the patient may also yield differences. A proxy may be asked to rate how they judge the patient's QoL, termed the *proxy-proxy perspective* by Pickard & Knight (2005) [65]. An alternative way is to ask the proxy to rate the patient's QoL according to how they think the patient would rate his/her QoL; this has been called the *proxy-patient perspective* [65]. The difference between these two proxy perspectives has been named the *intra-proxy gap* [65].

Different recommendations on how to measure QoL in dementia have been made. This includes collecting data from both patient and proxies [62], or letting persons with mild/moderate dementia rate their own QoL owing to bias issues of the proxy ratings [61]. The choice of proxy, such as a family

member versus a health care proxy, has also shown to be of importance as different proxies provide different results [60].

Disease-specific QoL instruments have been developed specifically for dementia. Examples of such instruments are the Dementia Quality of Life (DQoL) [66] and the Quality of Life–Alzheimer’s Disease (QoL-AD) instruments [67]. Both of these instruments have been developed to include direct assessment of QoL by the patients themselves through interviews [66, 67]. Disease-specific instruments may be more sensitive to changes and better able to capture differences regarding the specific disease, compared with generic instruments. They do, however, not allow for comparison between different groups.

When it comes to measuring HRQoL in dementia for use in health economic evaluations, the choice between the different raters of patient HRQoL will likely have an impact on the results of a CEA due to the established differences in ratings [59, 60]. It is important to know to which extent this choice may influence the results as it may affect decisions on resource allocation.

Health economic decision modelling

Health economic evaluations can be conducted in relation to clinical trials with limited time frames and data sources. The possibility to learn about the cost-effectiveness of a technology from studies using short time horizons has, however, been questioned [49]. To understand the impact of a technology over a longer period of time, we can use health economic decision modelling. According to Briggs *et al.* (2006) [68], the appropriate time frame for health economic analyses for decision making is as long as there are differences between the treatment alternatives with regard to costs and effects. The authors [68] point out that this may mean a life-time perspective. In a health economic decision model, data on costs and effects from various sources, such as randomized controlled trials as well as other studies, can be used as input, and extrapolated into longer time spans. Health economic decision models always include a certain degree of assumptions and simplifications of reality. It is, as Wimo (2007, p. 503) [49] puts it, important to acknowledge that –

... a model does not claim to predict the future. A model presents estimates of potential cost-effectiveness under various assumptions when empirical data are not available or impossible/difficult to obtain. [49]

Within the field of dementia, health economic decision modelling has frequently been used to study the costs and effects of pharmaceutical treatments [49]. Types of health economic decision models are decision trees and Markov models [69]. The Markov model is suitable for modelling progressing diseases, such as dementia, over time and is constructed of “nodes” representing different health or disease states (called *Markov states*) [70]. Patients move in the model, from one state to another, determined by certain transition probabilities [69]. Costs and effects can be assigned to each state in the model, and accumulated as a patient cohort moves in the model. In the final part of the analysis, the costs and effects are summarized.

Process Evaluation

Economic evaluations focus mainly on outcomes of interventions within health care. There are also aspects of HTA that concerns other dimensions of technologies and interventions, such as the process. The process evaluation, as the term is used here, focuses on understanding the process of health care interventions rather than on the outcome of interventions only.

Donabedian (1988, p. 1745) [71] describes the term “process” in the following way:

...Process denotes what is actually done in giving and receiving care. It includes the patient’s activities in seeking care and carrying it out as well as the practitioner’s activities in making a diagnosis and recommending or implementing treatment.

Donabedian (1988) [71] suggests that there is a link between three categories vital to the assessment of quality of care: 1) structure, 2) process, and 3) outcome. These categories are related so that a good quality of, e.g., the process positively affects the possibility that the outcome will be good. An understanding, through direct assessment, of the process is therefore important in explaining the outcome [71].

Evaluations of processes are complex. During the care process, a patient has different needs [72]. The perception of these needs and also the perception of the care process is influenced by factors such as past experience, expectations, and health outcomes [73]. It has been pointed out that in order to adapt care to the individual patient, the needs and perspectives of the patient have to be understood [73].

AIMS OF THE THESIS

Overall Aim

The overall aim of this thesis is to contribute to the development of methodological knowledge of assessment studies and understanding of support interventions in dementia. This comprises 1) examining methodological issues concerning assessment of support interventions in dementia from both a family caregiver and a patient perspective, and 2) empirically investigating caregivers' perceptions of certain support interventions in dementia.

Specific Aims of Studies I–IV

- Study I To outline an assessment model for health economic and process evaluations of AT interventions for persons with dementia and their relatives.
- Study II To examine the relatives' perception of an AT intervention in dementia. The aim was also to examine whether the intervention process was perceived differently between two groups of relatives valuing the intervention as being of high and low significance, respectively.
- Study III To examine what is perceived as important types of support and services among family caregivers of persons with dementia experiencing higher and lower negative impact (NI) due to the caregiving situation. The aim was further to study whether family caregivers received the support and services perceived as important.

Study IV To demonstrate how the choice of rater (patient or caregiver proxy) of patients' HRQoL in AD, for use in CEAs, could potentially have an effect on resource allocation in health care.

METHODS AND MATERIALS

Table 1 illustrates the characteristics of the four studies in this thesis work.

Table 1. Background description of the four studies included in the thesis.

| | Study I | Study II | Study III | Study IV |
|-------------------------------------|-----------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| Overall study description | To outline an assessment model for AT interventions in dementia | To study relatives' perception of an AT intervention <i>Application of one part of the assessment model – the process evaluation</i> | To study caregivers' perceptions of important types of support/services, and whether the caregivers receive the support/services | To address one important methodological challenge in assessment studies in dementia |
| Methodological | √ | | | √ |
| Empirical | | √ | √ | |
| Study based on | Literature | Telephone interviews | EUROFAMCARE project database | Literature |
| Ethical approval | NA | √ | √ | NA |
| Population (N) | NA | n=47 | n=110 | NA |
| Study population perspective | Relatives and Persons with dementia | Relatives | Family caregivers | Family caregivers and Persons with dementia |

AT = assistive technology.

NA = not applicable.

Studies I and II

Studies I and II were both conducted within the framework of a project called “Technology and Dementia”. Firstly in this section, the Technology and Dementia project is described along with the AT intervention developed within this project. Thereafter, studies I and II are presented separately.

Framework

The Technology and Dementia project was initiated by the Swedish Institute of Assistive Technology (in Swedish: *Hjälpmedelsinstitutet*) and run by the Swedish Institute of Assistive Technology in collaboration with the Alzheimer Society in Sweden and the Dementia Association. Funded by the Swedish Inheritance Fund, the project was started in 2004 and ended in 2008.

The overall objective of the Technology and Dementia project was to increase the use of AT among persons with dementia [74]. The work included creation of two national resource centres with specialized competence of AT in dementia. The national resource centres were contracted to develop methods of working with AT in the dementia field, such as assessment of needs, training, and evaluation, and also to disseminate the knowledge to persons with dementia, relatives and health care personnel. Further, the project was involved with adjusting and developing products and environments to support persons with dementia, clarifying rules and practice, and attempting to decrease differences in AT provision within the country. The final aim of the project was to carry through CEAs of AT use within the field of dementia (see the report [74] or project homepage [75]).

Two national resource centres were appointed within the Technology and Dementia project. The resource centres were clinical units with close links to research departments. Specialized occupational therapists (OTs) at the resource centres, in collaboration with the research departments, developed an AT intervention with methods for assessment of needs. This included use of the COPM instrument [76]. A questionnaire for assessment of needs was also developed [74].

During the intervention, several house visits were made by the OTs as well as telephone contacts with the participants. The intervention included provision of AT both to the persons with dementia and to their relatives where relevant, and it also included teaching of support strategies to enable the participants to manage difficulties that can occur in everyday life. The intervention was based on assessments of the individual participant's needs; hence the intervention was different (e.g. including type and amount of AT and strategies) for each participant in the project depending on their specific situation and needs.

Aim of Study I

To outline an assessment model for health economic and process evaluations of AT interventions for persons with dementia and their relatives.

In study I, an assessment model for health economic and process evaluation of AT interventions in dementia was developed, using the Technology and Dementia project as example.

Procedure

The assessment model in study I was developed by reviewing relevant literature in the field. This included literature both on methodology in theory and on feasibility aspects for carrying out assessment studies. Literature searches were made in order to identify relevant costs and outcomes for AT interventions in dementia. Methods were chosen based on theory and the choice of specific instruments was based on theory, experience and feasibility. The development process of the study design included obtaining expert opinions and discussions with clinicians within the project.

The suggested assessment model was presented both as a general model and a study-specific operationalized model to be used in the Technology and Dementia project.

Aim of Study II

To examine the relatives' perception of an AT intervention in dementia. The aim was also to examine whether the intervention process was perceived differently between two groups of relatives valuing the intervention as being of high and low significance, respectively.

In study II, a process evaluation was made of the AT intervention developed within the Technology and Dementia project (see previous description). The procedure for study II was based on the assessment model developed in study I (see pages 39-40).

Participants

Inclusion criteria for study II (same criteria as for the Technology and Dementia project) were having dementia or a similar condition (e.g. mild cognitive impairment, MCI, with increasing difficulties), having ADL problems, and speaking Swedish. Also, there were two desired criteria, living at home and having a relative who performs informal care.

The participants were recruited through consecutive recruitment. Consent to participation was sought from both the relative and, as far as possible, the persons with dementia. The final population in the Technology and Dementia project was 47 relatives and 48 persons with dementia. Study II is based on the relatives in the project, i.e. 47 persons. One of the persons included in the group of relatives was a formal caregiver of the home-help services.

Procedure

Data for study II concerning the relatives' perception of the AT intervention process were collected through telephone interviews on three different occasions of measurement: baseline (before the intervention), first follow-up (4 weeks after start of the intervention) and second follow-up (12 weeks after start of the intervention) (Figure 3). The intervention was an iterative process conducted not only between baseline and the first follow-up, since it could be changed or adjusted during the study period. Assistive technologies could also be withdrawn during the study period.

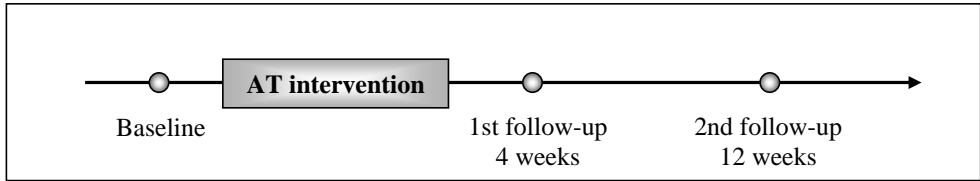


Figure 3. Before/after study design with three occasions of measurement.

Data were collected using a modified version of the Patient perspective On Care and Rehabilitation process (POCR) instrument [77]. The POCR consists of two scales, one measuring the importance of a certain aspect of a process (importance scale) and on the other measuring the fulfilment of this aspect (fulfilment scale). A high fulfilment of important needs means good quality of the process. Table 2 illustrates the construction of the POCR instrument.

Table 2. Construction of the Patient perspective On Care and Rehabilitation process (POCR) instrument. The table gives an example of one POCR question (modified for use in study II).

| Fulfilment scale | Importance scale |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>1. Did you learn enough about the intervention from the OT?</p> <p>Response alternatives: 4: <i>Yes, definitely</i> 3: <i>Yes, for the most part</i> 2: <i>Yes, to some extent</i> 1: <i>No, not at all</i></p> | <p>2. How important was it to you that the OT gave information concerning the intervention?</p> <p>Response alternatives: 4: <i>Of greatest possible importance</i> 3: <i>Of great importance</i> 2: <i>Of some importance</i> 1: <i>Of no importance</i></p> |

OT = occupational therapist.

Three extra response alternatives were also used: ‘Not applicable’, ‘Do not remember’ and ‘Do not know’. Modifications were made to the POCR instrument to adapt it to the AT intervention that was being examined.

Background questions and demographic data on both the relatives and the persons with dementia were also included in the analysis.

The relatives and persons with dementia were divided into two groups depending on how the significance of the intervention was valued by the relatives. The significance of the whole intervention was rated at the second follow-up by means of one summary question: *How do you value the significance of the intervention?*

The two groups were relatives perceiving the intervention to be of ‘great significance’ or of ‘greatest possible significance’ (the “Great Significance of intervention (GS)” group, n=33), and relatives perceiving the intervention to be of some or no significance (the “Some or No Significance of intervention (SNS)” group, n=13). One relative did not answer the summary question. The population of the analyses that includes the GS and SNS group is therefore 46 relatives.

The AT received by the relatives and persons with dementia in the project was categorized into four broad groups (see below). The AT included low-tech items, such as colourful tape for marking of handles, etc. in the home and Post-its as memory aids, as well as high-tech devices such as hand computers, emergency transmitters, and telephones.

- Time orientation, day planning and memory
 - e.g. electronic calendars, reminders, memory aids (electronic or low-tech), whiteboards and automatic pill dispensers
- Alarms/security
 - e.g. door alarms, bed alarms, emergency transmitters, timers and stove guards
- Communication – telephony and other AT
 - e.g. easy-to-use telephones, picture telephones and easy-to-use remote controls
- Spatial orientation/management and ADL personal care
 - e.g. night lights, light sensors, toilet seats, shower stools, support rails, colourful tape, etc.

Statistical Analysis

In study II, the responses to the POCHR questions were dichotomized into high and low fulfilment (response alternatives 3–4, and 1–2, respectively, of the fulfilment scale; see Table 2) and high and low importance (response alternatives 3–4 and 1–2, respectively, of the importance scale; see Table 2). Statistical analyses were performed using Fisher’s exact test to calculate differences between dichotomized variables. Differences between the fulfilment and importance scale were tested using Wilcoxon’s signed rank test. Differences between mean values were tested using independent *t*-tests. A significance level of $p \leq 0.05$ was assumed.

Study III

Framework

Study III is based on previously collected data from the EUROFAMCARE project database. The aim of the EUROFAMCARE project can briefly be described as studying the situation, needs, and use of support and services among caregivers in Europe [78]. The EUROFAMCARE project was conducted in six different European countries: Germany, Greece, Italy, Poland, Sweden and the UK. The inclusion criteria were: being over the age of 18, perceiving yourself as a carer for a person >65 years old, and giving support or care for >4 hours per week. The participants were recruited either randomly to the project or through other recruitment methods based on accessibility. The majority of the data were collected through telephone interviews with the caregivers. A comprehensive questionnaire, the “Common Assessment Tool (CAT)” [79], was developed and used within the EUROFAMCARE project, including existing instruments and also questions developed by the research team. The CAT comprised questions concerning the caregiver as well as questions concerning the older person who was being cared for.

Study III is based on the Swedish part of the EUROFAMCARE project database. In Sweden, a total of 921 participants were included in the EUROFAMCARE project.

Aim of Study III

To examine what is perceived as important types of support and services among family caregivers of persons with dementia experiencing higher and lower negative impact (NI) due to the caregiving situation. The aim was further to study whether family caregivers received the support and services perceived as important.

Population

Based on the Swedish caregivers in the EUROFAMCARE project database (n=921 persons), selection criteria for study III were being a caregiver to a

person with dementia in domestic living situations. A total of 113 persons met the selection criteria. The population of 113 caregivers was divided into two groups. One group consisted of caregivers experiencing higher levels of NI due to the caregiving situation (higher NI group), and the other group were caregivers experiencing lower levels of NI (lower NI group). Level of NI was based on how the caregivers reported their situation on the NI scale in an instrument called the *Carers of Older People in Europe (COPE) index* [80], using the validated scale solution from 2008 [81]. The COPE index includes 3 separate scales (Table 3).

The NI scale of the COPE index comprises seven questions and the score ranges from 7 to 28 (see Table 3), where a high score represents high NI (lower NI group, range 7–11, and higher NI group, range 12–28). Three persons did not complete the COPE index NI scale; consequently, the final population in study III was 110 persons. The lower NI group included 39 caregivers while the higher NI group included 71 caregivers.

Table 3. The 3 scales of the COPE index, Balducci *et al.* (2008) [81].

| COPE index, positive values (range 4–16) <i>High score = high positive value</i> | Response alternatives |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|
| 1 Finding caregiving worthwhile? 2 Good relationship with the person cared for? 3 Feeling appreciated as a caregiver? 4 Coping as a caregiver? | 1 = Never 2 = Sometimes 3 = Often 4 = Always |
| COPE index, NI scale (range 7–28) <i>High score = high NI</i> | |
| 1 Caregiving having a negative effect on emotional wellbeing? 2 Finding caregiving too demanding? 3 Caregiving having a negative effect on physical health? 4 Caregiving causing difficulties in relationship with family? 5 Feeling trapped in role as caregiver? 6 Caregiving causing difficulties in relationship with friends? 7 Caregiving causing financial difficulties? | 1 = Never 2 = Sometimes 3 = Often 4 = Always |
| COPE index, quality of support (range 4–16) <i>High score = high quality of support</i> | |
| 1 Feeling supported by friends or neighbours? 2 Feeling supported by family? 3 Feeling supported by health and social services? 4 Overall, feeling supported in role of caregiver? | 1 = Never 2 = Sometimes 3 = Often 4 = Always |

COPE = Carers of Older People in Europe.

NI = negative impact.

Procedure

Two outcome questions from the CAT, measuring the caregivers' perception of the importance of 14 different support/services (see below) and whether these types of support/services were being received, were used as dependent variables in study III (Table 4):

Table 4. Two outcome questions used in study III.

| 1) Importance of different types of support/services | 2) Support/services received |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Perception of importance of 14 different types of support/services Response alternatives: <ul style="list-style-type: none"> ○ “Very important” ○ “Quite important” ○ “Not important” | Were caregivers receiving the support/services perceived as very important? Response alternatives: <ul style="list-style-type: none"> ○ “Mostly yes” ○ “Mostly no” |
| The results of study III are based on caregivers reporting a support/service as “Very important” | The results concerning support/services being received are based only on those caregivers who perceived a support/service as “Very important” |

The 14 different types of support/services from the CAT were categorized into four groups:

Information

1. Information and advice about the type of help and support that is available and how to access it
2. Information about the disease that ELDER⁵ has

Counselling

3. The opportunity to talk over my problems as a carer
4. Opportunities to attend a carer support group
5. Help with planning for the future care
6. Training to help me develop the skills I need to care
7. Help to deal with family disagreements

⁵ELDER in this study refers to the person with dementia. The term is taken from the EUROFAMCARE Common Assessment Tool (CAT).

Relief

8. Opportunities to enjoy activities outside of caring
9. Opportunities to have a holiday or take a break from caring
10. Help to make ELDER's environment more suitable for caring
11. Opportunities for ELDER to undertake activities they enjoy
12. Opportunities to spend more time with my family
13. The possibility to combine caregiving with paid employment

Financial support

14. More money to help provide things I need to give good care

Several background questions as well as demographic data on the caregivers and the person with dementia were obtained from the CAT.

Statistical Analysis

The data for study III were analysed using chi square when testing variables that were dichotomized. When the cell count in cross-tabulations was less than five (making chi square inappropriate), Fisher's exact test was used. Background data based on mean values were tested using independent *t*-tests. A p-value of ≤ 0.05 was considered significant.

Study IV

Aim of Study IV

To demonstrate how the choice of rater (patient or caregiver proxy) of patients' HRQoL in AD, for use in CEAs, could potentially have an effect on resource allocation in health care.

Procedure – Health Economic Decision Model

A Markov model (see page 23 for description) was constructed that included four stages of AD (stage 1 representing onset of cognitive impairment; stage 4 representing severe AD) (Figure 4). The stages, defined by Jönsson, Andreasen *et al.* (2006) [59], were based on scores from the Mini-Mental State Examination (MMSE) instrument [82], ranging from 30 (representing no cognitive impairment) to 0. The MMSE is a common instrument used in dementia for measuring cognitive ability [39]. A MMSE score of ≤ 24 represents the onset of cognitive impairment in the model [83]. The persons with AD moved in the Markov model from onset of cognitive impairment to more severe stages of AD (see arrows, Figure 4). The progression of AD, expressed as MMSE scores, was retrieved from a study by Mendiondo *et al.* (2000) [84]. A monthly cycle length was used in the model, and the risk of death was based on all cause mortality [85].

Costs for each of the four AD stages in the model were obtained from a study by Jönsson, Eriksdotter Jönhagen *et al.* (2006) [86], in which the mean annual costs per patient for the MMSE stages were calculated (see boxes, Figure 4). Costs for medical, community, informal, and in- and outpatient care were included [86]. The QALY weights based on ratings from both the person with dementia and their family caregiver were retrieved from a study by the same group, Jönsson, Andreasen *et al.* (2006) [59] (see boxes, Figure 4). The QALY weights in Jönsson, Andreasen *et al.* (2006) [59] were obtained using the EQ-5D

instrument [52] (see chapter “Valuation of quality of life and quality-adjusted life years”). Both costs and HRQoL weights were discounted using a 3% rate.

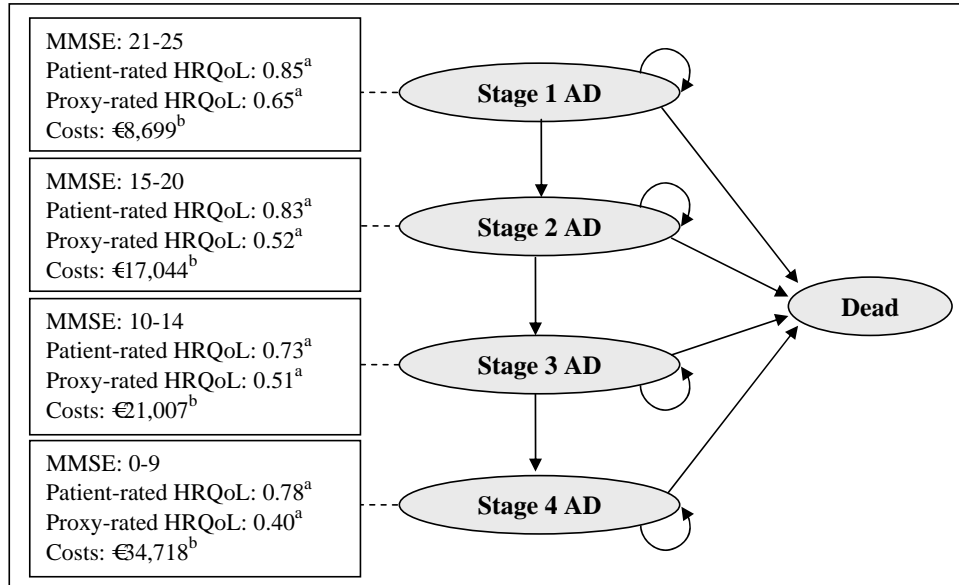


Figure 4. Markov model illustrating the four stages of dementia. The boxes show the input data for the model.

^a = HRQoL data retrieved from Jönsson, Andreasen *et al.* (2006) [59].

^b = cost data retrieved from Jönsson, Eriksdotter Jönhagen *et al.* (2006) [86], 2003 values.

AD = Alzheimer’s disease.

HRQoL = health-related quality of life.

MMSE = Mini-Mental State Examination.

The model illustrates the natural progression of AD. As comparison alternative, a hypothetical treatment strategy was introduced, which meant a decrease in the monthly deterioration of cognitive ability, as measured by the MMSE, by 10%, with an additional monthly cost of €100. Also, results of using different treatment effects (5–10%), in relation to the use of both patient and proxy ratings, were examined in the model.

RESULTS

Study I

An assessment model was constructed including both health economic and process evaluation aspects, as well as the perspectives of both the persons with dementia and their family caregivers. Two versions of the assessment model were presented, a general model and an operationalized model including specific instruments for use in AT assessment studies in dementia.

The general assessment model holds a societal perspective, meaning that all relevant costs and effects should be included in the assessments. The general model includes process evaluation as well as evaluation of costs and outcomes as vital parts of AT assessment studies in dementia. Measuring outcomes and costs in dementia involves certain methodological issues and challenges. It was suggested to include process evaluation in order to study the quality of the intervention process and also, to increase the understanding of the intervention process and outcome.

In the operationalized model, specific outcomes were suggested along with instruments and methods for measuring outcome. Also, an instrument for process evaluation was recommended. A feasible study design was suggested (Figure 3, p. 31), a before/after design with a short follow-up of 3 months due to the deterioration associated with the disease. Further, suggestions on identified costs to include in health economic analyses of AT interventions in dementia and also on how to measure the costs are presented in study I.

In Table 5, factors identified as important for assessment of AT interventions in dementia are presented.

Table 5. Factors identified as important in assessment studies of assistive technology (AT) interventions in dementia.

| Relatives | Persons with dementia |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> + Outcomes - Quality of life (QoL) - Caregiving situation + Expectations & Process + Costs - Formal care - Pharmaceuticals - Informal care | <ul style="list-style-type: none"> + Outcomes - Quality of life (QoL) - Instrumental activities of daily living (IADL) + Expectations & Process + Costs - Living costs - Formal care - Pharmaceuticals - Search costs - Production loss |
| <p>+ Costs of the intervention (Concerns both relatives and persons with dementia)</p> | |

Study II

The aim of study II was to study the relatives' perception of the AT intervention process developed within the Technology and Dementia project (application of one part of the assessment model from study I). The aim was further to study whether the intervention process was perceived differently between two groups of relatives valuing the intervention to be of high or low significance. The delivery of AT to the two groups was likewise examined.

Results concerning the perception of the AT intervention for the whole group (all 47 relatives) showed that aspects such as OTs taking time to listen and showing consideration and respect were highly fulfilled. There were certain differences, indicated as significant, in the perception of the intervention process, where the level of fulfilment was lower than the level of importance (see Table 6).

Table 6. Aspects of the intervention where the level of fulfilment was lower than the level of importance.

| POCR item | Fulfilment scale | | Importance scale | | p-value |
|---------------------------------------------------------------------------------------------------------------------|------------------|--------|------------------|--------|---------|
| | Mean [SD] | Median | Mean [SD] | Median | |
| At the beginning when the intervention was planned, did you know to which extent NN would get support? | 2.20 [1.09] | 2 | 2.78 [0.76] | 3 | 0.001* |
| Did you, in the planning stages, know to which extent you would get support? | 2.09 [0.88] | 2 | 2.84 [0.63] | 3 | 0.000* |
| Did the OT ask you in the planning stages what you thought would be important for you to get help and support with? | 2.51 [1.15] | 3 | 3.26 [0.71] | 3 | 0.002* |
| Do you think the OT understood what was most important for you to get support and help with? | 3.23 [0.72] | 3 | 3.41 [0.62] | 3 | 0.025* |
| Has the situation improved for NN since the intervention? <i>First follow-up</i> | 2.43 [0.96] | 2 | 3.53 [0.63] | 4 | 0.000* |
| Has the situation improved for NN since the intervention? <i>Second follow-up</i> | 2.36 [0.97] | 2 | 3.25 [0.69] | 3 | 0.000* |

POCR = Patient perspective On Care and Rehabilitation process instrument (modified version).

* Significant difference at the 0.05 significance level.

NN = the person with dementia.

OT = occupational therapist.

SD = standard deviation.

Two groups were formed among the relatives in the Technology and Dementia project, the SNS (n=13) and the GS group (n=33) depending on how they valued the significance of the intervention (see procedure, study II).

The analysis indicated that there was one significant difference between the SNS and GS groups concerning background data. A larger proportion of persons with dementia in the GS group had high personal activity of daily living (PADL)/IADL abilities, as measured by one background question (p=0.019). There was furthermore an indication that the relatives in the SNS group, compared with the GS group, experienced a higher NI, as measured using COPE index NI scale (p=0.053).

The analysis indicated that the intervention process was perceived differently between the GS and the SNS groups for two items on the importance scale and five items on the fulfilment scale (see Table 7).

Table 7. Items of the modified Patient perspective On Care and Rehabilitation process (POCR) instrument where the perception of fulfilment or importance differed between the Some/No Significance (SNS) and the Great Significance (GS) group.

| POCR items | Highly fulfilled/ highly important | | p-value |
|-----------------------------------------------------------------------------------------------------------------|---------------------------------------|---------------------------|---------|
| | SNS group (n=13) (%) | GS group (n=33) (%) | |
| <i>Fulfilment scale</i> | | | |
| OT asking in the planning stages what would be important for the person with dementia to get help/support with? | 58.3 | 90.6 | 0.025* |
| <i>Fulfilment scale</i> | | | |
| Learning enough about the intervention from the OT? | 53.8 | 90.3 | 0.012* |
| <i>Importance scale</i> | | | |
| Importance of OT giving information concerning the intervention? | 61.5 | 90.6 | 0.034* |
| <i>Fulfilment scale</i> | | | |
| OT understanding what was most important for the person with dementia to get support/help with? | 69.2 | 100.0 | 0.005* |
| <i>Importance scale</i> | | | |
| Importance to person with dementia that the OTs understood what was most important to get support/ help with? | 40.0 | 86.7 | 0.007* |
| <i>Fulfilment scale</i> | | | |
| The person with dementia getting the help/support he/she needs? | 46.2 | 87.1 | 0.008* |
| <i>Fulfilment scale</i> | | | |
| Situation improving for the person with dementia since the intervention? | 7.7 | 51.5 | 0.007* |

All answers above are according to the relative of the person with dementia.

* Significant difference at the 0.05 significance level.

OT = occupational therapist.

All items in Table 7 were perceived as highly fulfilled or highly important by a larger proportion of relatives in the GS group, compared with relatives in the SNS group.

Assistive technologies from the category *Time orientation, day planning and memory* were the most common for participants in both groups, received by 67% in the GS and 92% in the SNS group (the categories of ATs are outlined on page 32). The analysis indicated that there was a significant difference in receiving *Alarm/Security* ATs, a higher proportion of participants in the GS group having received such ATs (55% in the GS group, as compared with 15% in the SNS group).

Study III

The aim of study III was to examine what was perceived as important types of support/services among family caregivers of persons with dementia experiencing different levels of NI due to the caregiving situation. The caregivers were divided into a “lower NI group”, caregivers experiencing lower levels of NI due to the caregiving situation, and a “higher NI group”, caregivers who experienced higher levels of NI.

The results indicated that overall there were almost no differences regarding what caregivers of persons with dementia experiencing different levels of NI perceive as important types of support/services (Table 8). Two differences were indicated in the analysis.

The support/service *Opportunities to enjoy activities outside of caring* was perceived as very important by a larger proportion of caregivers in the higher NI group than in the lower NI group ($p=0.014$) (Table 8).

The analysis further indicated that a larger proportion of caregivers in the lower NI group perceived the support/service *Information about the disease that ELDER has* as very important ($p=0.051$).

Many types of support/services within the categories *information, relief and counselling* were perceived as very important by >40% of the caregivers in both groups. Certain types of support/services, e.g. *Help to deal with family disagreements* and *More money to help provide things I need to give good care*, were perceived as very important by a smaller proportion of the caregivers (table 8).

Table 8. Percentage of caregivers who perceived the support/services as “very important” and percentage of caregivers receiving the support/services they rated as “very important”

| Groups | Types of support/services | Caregivers who perceived support/service as very important | | Caregivers who received the support/service they rated as very important | |
|--------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------|---------------------|--------------------------------------------------------------------------|---------------------|
| | | Lower NI group (%) | Higher NI group (%) | Lower NI group (%) | Higher NI group (%) |
| <i>Information</i> | <ul style="list-style-type: none"> ▪ Information about the disease that ELDER has | 95 | 81 | 84 | 71 |
| | <ul style="list-style-type: none"> ▪ Information and advice about the type of help and support that is available and how to access it | 87 | 82 | 64 | 59 |
| <i>Counselling</i> | <ul style="list-style-type: none"> ▪ The opportunity to talk over my problems as a carer | 74 | 80 | 72 | 83 |
| | <ul style="list-style-type: none"> ▪ Opportunities to attend a carer support group | 54 | 56 | 43 | 56 |
| | <ul style="list-style-type: none"> ▪ Help with planning for the future care | 49 | 51 | 53 | 46 |
| | <ul style="list-style-type: none"> ▪ Training to help me develop the skills I need to care | 41 | 38 | 31 | 39 |
| | <ul style="list-style-type: none"> ▪ Help to deal with family disagreements | 3 | 7 | 0 | 60 |
| <i>Relief</i> | <ul style="list-style-type: none"> ▪ Opportunities to enjoy activities outside of caring | 49 | * 73 | 68 | 47 |
| | <ul style="list-style-type: none"> ▪ Opportunities to have a holiday or take a break from caring | 49 | 64 | 58 | 57 |
| | <ul style="list-style-type: none"> ▪ Help to make ELDER’s environment more suitable for caring | 42 | 52 | 50 | 58 |
| | <ul style="list-style-type: none"> ▪ Opportunities for ELDER to undertake activities they enjoy | 46 | 49 | 47 | 71 |
| | <ul style="list-style-type: none"> ▪ Opportunities to spend more time with my family | 32 | 41 | 92 | * 33 |
| | <ul style="list-style-type: none"> ▪ The possibility to combine caregiving with paid employment | 28 | 26 | 60 | 67 |
| <i>Financial support</i> | <ul style="list-style-type: none"> ▪ More money to help provide things I need to give good care | 13 | 26 | 0 | 19 |

Lower NI group = caregivers experiencing lower negative impact (n=39). Higher NI group = caregivers experiencing higher negative impact (n=79). * Significant difference between higher and lower NI group at the 0.05 significance level. ELDER = person with dementia.

The support/services were received to varying degrees. Most types of support/services, 9 out of 14, were being received by 50% of the caregivers or more in both groups (Table 8). The data on support/services received are based only on those caregivers who perceived a support/service as very important. The analysis indicated that there was one significant difference with regard to support/services received between the two groups. A higher proportion of caregivers in the lower NI group, compared with the higher NI group, had received support/services giving them *Opportunities to spend more time with my family* (Table 8).

Two types of support/services had not been received by any of the caregivers in the lower NI group; they were *Help to deal with family disagreements* and *More money to help provide things I need to give good care* (Table 8).

Study IV

A health economic decision model was constructed to demonstrate the potential effects on resource allocation when using patient self-ratings compared with proxy ratings of patients' HRQoL for the same analysis. The study showed that there may be large differences in CEA results depending on choice of rater. When patient self-rated HRQoL was used for the analysis, using a 10% treatment effect, the cost per QALY gained was much higher (approximately €54,500) than when proxy ratings were used for the same analysis (cost/QALY gained = approximately €11,100) (see Table 9).

Following the value range concerning what is considered effective resource use, set by the National Institute for Health and Clinical Excellence NICE [36], the treatment would most likely not be considered cost-effective in an analysis based on ratings made by the patient (see Table 9). However, if ratings made by the proxies were used for the same analysis, the treatment would very likely be considered cost-effective. The value range set by the NICE should not be considered to be absolute threshold values for whether or not a technology will be accepted; other factors may also play an important role in the decision-making process [36].

Table 9. Results of study IV in relation to the value range concerning cost/quality-adjusted life year (QALY) gained, as specified by the National Institute for Health and Clinical Excellence (NICE) [36].

| | Cost/QALY gained ICER |
|----------------------------------------------------------------------------------------|----------------------------------|
| Result of study IV | |
| ICER patient ratings | €4,497 |
| ICER proxy ratings | €1,110 |
| NICE value range [36] | |
| <i>NB. Departures from the range values can be made depending on different factors</i> | |
| Technology most likely to be accepted | <€2,100 |
| Technology likely to be accepted following certain criteria | €2,100–€3,200 |
| Strong arguments needed for the technology to be accepted | >€3,200 |

ICER = incremental cost-effectiveness ratio.

Analyses were also performed using different treatment effects (5–10%) in the model. The results showed that at the lower treatment effects, of 5–7%, the ICERs from both patient self-ratings and proxy ratings were high (>€50,000). When higher treatment effects were used in the model, the ICER of the analysis based on proxy ratings at a 9% treatment effect was <€30,000, while at 10% it was <€20,000. Analyses based on patient self-ratings were never <€30,000 at any treatment effect used in model. Incremental cost-effectiveness ratios based on both patient and proxy ratings, however, decreased in relation to the increase in treatment effect.

GENERAL DISCUSSION

Dementia means dramatic changes for the person diagnosed as well as for their relatives. Family caregivers of persons with dementia may experience low HRQoL [14] and high levels of caregiver burden [87] and burnout [13]. The support and care given by relatives of persons with dementia, known as “informal care”, has a large societal value [6]. In efforts to alleviate the situation, supporting interventions aimed at persons with dementia and their relatives may be of great importance. More knowledge and understanding of the impact and consequences of these interventions in dementia is needed. Performing assessment studies of support interventions within the field of dementia is associated with certain methodological issues related to the nature of the disease. In this thesis, the overall aim is to contribute to the development of methodological knowledge concerning assessment studies and to increase the understanding of support interventions in dementia. This has been divided into two sub-aims, viz. to examine methodological issues concerning assessment of support interventions in dementia from a family caregiver and a patient perspective, and to empirically investigate caregivers’ perceptions of certain support interventions.

Assessment studies of interventions within health care have become increasingly important [35]. Health technology assessment consists of comprehensive assessment processes within health care [33]. Within the field of dementia, there are certain methodological issues that need to be addressed when making assessment studies. In this thesis, an assessment model was developed for one type of intervention (AT interventions) for persons with dementia and their relatives. The assessment model deals with methodological assessment issues and challenges within this field and includes recommendations on methodology. The inclusion of health economic evaluation in the model is suggested as there is a demand for information on costs and effects of technologies and interventions within decision-making contexts [36, 37]. Further, due to the large impact dementia has on the lives of the persons affected, as well as to the high societal costs associated with dementia [6], information on costs and effects of interventions is of great importance. The inclusion of process evaluations is suggested in the assessment model as a complement to the outcome evaluation in order to examine the quality, and increase the understanding, of the intervention

process. An understanding of the process has also been emphasized as important in gaining an understanding of the outcome [71]. The importance of making process-oriented AT assessments in dementia has been acknowledged by Nygård (2009) [25]. Health economic evaluations have mainly focused on outcomes of interventions. The importance of the process in relation to health economic evaluations has also been acknowledged by Olsen (2009, p.7) [88]:

The economic evaluation of health care interventions has traditionally focused on the measurement of health outcomes and has largely ignored the less tangible, and consequently harder to measure, processes of care. Nonetheless, it is important to try to measure the “goodness” from the various types of care since it is futile to take the view that all types of care are equally good. [88]

One key, and well-acknowledged, methodological challenge in the field of dementia is measuring HRQoL [50, 58]. Emphasis was therefore put on this particular outcome measure in this thesis (study IV). As shown in study IV, the choice of rater (using a caregiver proxy rating or patient self-rating of patient HRQoL) has a large effect on the results of a CEA. These differences in the results may have an important impact on decision making and on resource allocation. A fictitious treatment example was used in study IV to demonstrate this methodological issue. The results of the CEA were never below the levels of what is considered cost-effective [36] when patient self-ratings of HRQoL were used in the analysis. When using proxy ratings for the CEA for higher treatment effects, the ICER was within or below the NICE value range. However, when smaller treatment effects were used in the model, the ICERs based on both patient and proxy ratings were high and would not be viewed as effective resource use.

In study IV we do not aim to determine the most appropriate rater of patient HRQoL in dementia. The issue of whose ratings to use has important ethical implications. For instance, would it be ethically just to use ratings for health economic analyses of persons with cognitive impairment when it may have consequences for resource allocation? Ethical aspects are key issues to consider when deciding between patient and proxy ratings for use in health economic analyses. In the assessment model developed in study I, the use of both patient and proxy ratings is suggested, and this has also been previously recommended by others [62]. The use of both patient and proxy ratings is also suggested in study IV because of the large differences in the ICERs. Also, since

the choice of rater does not always affect how the results are interpreted, e.g., at smaller treatment effects, this should be displayed. Presenting results of a CEA, using both patient self-ratings and proxy ratings, allows for open and critical appraisals of the results. More research is needed to determine the best way to measure HRQoL of persons with dementia.

As previously described, inclusion of process evaluation is suggested in the assessment model in study I. An application of the process evaluation from the suggested assessment model in study I was made in study II of this thesis work. The aim of study II was to study the relatives' perception of the AT intervention developed within the Technology and Dementia project. The aim was also to study whether the experiences of the intervention were different for two groups of relatives valuing the intervention to be of great or of some/no significance (the GS and SNS group). Overall, the results indicated that a larger proportion of relatives who valued the AT intervention to be of great significance perceived the intervention process to be highly fulfilled as compared with the relatives valuing the intervention to be of some/no importance. This supports the theories of Donabedian (1988) [71] concerning the link between process and outcome. It further shows the importance of measuring both aspects, process and outcome, as previously suggested by Donabedian (1988) [71] and Krevers *et al.* (2002) [73].

There were aspects of the intervention, identified in study II, perceived to be of importance that were not fulfilled, i.e. aspects of the intervention process where improvements could be made. These concerned, e.g., issues such as involving the relatives themselves to a greater extent in the intervention process. By performing the process evaluation, several aspects that need to be acknowledged in AT intervention processes in dementia were identified. This knowledge is of importance for development of future AT interventions in dementia. Study II, which was performed at a group level, showed that the ranked significance of the AT intervention ranged from not being significant at all to being of greatest possible significance. The individual use of AT in dementia needs to be further examined in future studies.

In study II, the provision of different types of AT was also examined. The ATs that were most frequently provided to the participants were ATs for supporting time orientation, day planning and memory, provided to participants in both the GS and the SNS group. The analysis indicated that a larger proportion of participants in the GS group, compared with the SNS

group, received alarms and security devices. These latter types of ATs may bring a positive sense of security for relatives of persons with dementia. There was one difference between the persons with dementia in the GS and SNS groups in terms of PADL/IADL ability, as measured by one background question. The PADL/IADL ability may have an effect on AT use. Aspects such as insight, motivation and timing seem to be important when it comes to successful AT use by persons with dementia [25, 26].

In study II, the perception of the relatives was examined. However, the views and perceptions of persons with dementia in research should not be overlooked. There are ways to obtain their views and experiences [89-91]. These include, e.g., telephone interviews using carefully planned implementation strategies [90], and qualitative observations and interviews with adapted questions [89]. In the assessment model (study I), both the perspectives of the relatives and those of the persons with dementia are included; this is also suggested for measuring HRQoL in dementia (study IV). Further investigations of the perceptions of persons with dementia have, however, not been the focus of this thesis.

As previously mentioned, dementia means a dramatic change of way of life; and many times this also includes the people close to the persons with dementia. Supporting interventions for this population may be of uttermost importance. To successfully provide interventions to family caregivers of persons with dementia, it is vital to know what is perceived by them as important types of support. As shown in study III, different types of support/services were perceived as very important to caregivers experiencing different levels of NI due to the caregiving situation. These support types/services were received to varying degrees by the caregivers. Support/services perceived as very important by a larger proportion of caregivers were found within the areas of counselling, relief and information. Since not having knowledge is one known obstacle to support/service use in dementia [18], giving information should become one explicit support/service delivered to caregivers. In a review study, Eters *et al.* (2008) [7] conclude that interventions including several components (called “multicomponent interventions”) seem to be effective in alleviating caregiver burden. With regard to this, effective help could include a combination of the different types of support/services within the categories information, counselling and relief, perceived as very important. The impact and understanding of these types of interventions need to be investigated in future assessment studies.

Ethical Aspects

Conducting research including persons with reduced autonomy requires careful consideration. The process evaluation study based on the Technology and Dementia project was approved by the Regional Ethical Vetting Board at Linköping University, Sweden. The EUROFAMCARE project was approved by ethics committees in each of the six European countries in the project.

The Technology and Dementia project included both persons with dementia and their relatives. The potential risks and burdens of the intervention, as well as the possible violation of integrity, were carefully considered in relation to the possible benefits of project participation, according to the Declaration of Helsinki concerning medical research involving humans [32]. We considered the benefits of project participation to outweigh the drawbacks. The persons with dementia were informed about the project and asked for consent to participate as far as possible. The relatives of the persons with dementia included in the project were asked to consent to participation for both themselves and the persons with dementia before being included in the project.

The participants were informed, both in writing and orally, of the aim of the project and the right to withdraw at any time. Information concerning the right to withdraw at any time was repeated at each telephone interview during the data collection period of the Technology and Dementia project.

A previous European project called “Technology, Ethics and Dementia” dealt with issues surrounding ethics of the provision and implementation of AT for persons with dementia. Within this project, Bjørneby *et al.* (1999) [27] included ethical aspects as one important part of the decision-making process of AT provision for persons with dementia. Issues raised were ethical dilemmas such as how to consider, e.g., the wish of a relative or a formal caregiver if that wish meant risking to inflict on the integrity of a persons with dementia [27]. The authors refer to the three principles of beneficence, autonomy and justice to guide the care of persons with dementia, and conclude that the ethical issues need to be discussed based on these principles [27]. These three principles also formed the basis of comprehensive ethical considerations of AT implementation in dementia in a subsequent European project, ENABLE [92]. Others have raised issues concerning the ethics of specific ATs, such as use of tracking devices in dementia care [93].

Limitations and Suggested Revisions

In study I, an assessment model for AT interventions in dementia was developed within the Technology and Dementia project, which included a suggestion for study design. A before/after design was suggested (see Figure 3), which would include three occasions for data collection. In this design, the persons act as their own controls and follow-up data are compared with baseline data in order to study the effect of the intervention. The time for the last follow-up was set to 3 months after the intervention. Dementia is a progressing disease and the follow-up time was therefore set to be short so that the persons would not significantly deteriorate during the study period. The study design, however, needs to be revised when it comes to performing outcome studies of AT in dementia. At an individual level, a person with dementia may deteriorate during less than 3 months. Since it is difficult to achieve sufficiently large populations in AT assessment studies, individual deviations may have an important impact on the results. If a person deteriorates in his/her disease, then remaining at the same level as before the deterioration when using AT would mean a positive result. This cannot be captured without the use of a control group. Use of control groups for outcome studies of AT interventions in dementia is therefore important.

However, the inclusion of a control group is not without challenges. If two groups are to be compared, the groups need to be regarded as initially equal. Since dementia is a deteriorating disease with individual variations, either the individuals in the groups need to be matched on a number of characteristics (e.g. age, gender, dementia type, progression rate, caregiver situation, etc.) or the groups need to be large to have sufficient power in, e.g., a randomized controlled trial, both of which is difficult to achieve within the field of AT outcome assessment in dementia. Other study types may be considered. These, however, have limitations when it comes to generalizability; also, they move us away from outcome studies at a group level. Case studies can be used to study outcomes of individual cases. Furthermore, qualitative studies may be used for generating hypotheses and for increasing the understanding of AT use in dementia. However, assessing the impact of interventions, such as costs and effects, is of increasing importance. The above discussed challenges therefore need to be further addressed. The use of quasi-experimental designs needs to be explored, and health economic decision modelling may enable the assessments of cost-effectiveness of AT interventions in dementia.

The Markov model used in study IV included several assumptions. Importantly, the model uses cognitive ability, as measured by the MMSE, to define the dementia stages. This is a simplification of the dementia illness which means a limitation of the model [94]. Dementia stage is determined by several factors, and to model dementia solely on cognitive ability has been criticized [95]. Also, a hypothetical treatment was used in the model. It is important to acknowledge that the model used in study IV does not claim to reflect the medical actuality. The assumptions of the model were made in order to illustrate the methodological issue concerning patient versus proxy ratings of patient HRQoL.

In studies II and III, chi square or Fisher's exact test was performed in order to study differences between the lower and the higher NI group (study III) and between the SNS and GS group (study II). The p-values in these analyses were not adjusted for multiple testing as the domains/items under investigation were considered to be of different characteristics. This may be viewed as a limitation and for this reason, the results need to be interpreted with caution.

Concluding Words

Support interventions aimed at persons with dementia and their relatives may be of great individual as well as societal value. Conducting assessment studies of interventions within health care is necessary as information on the impact and other consequences of technologies and interventions is of increasing importance. Assessment studies of support interventions in dementia raise methodological issues and hold challenges that need to be addressed. Hopefully, these challenges will not discourage from making assessment studies within this field.

On those terms, and before concluding this thesis with the words of Albert Einstein, it needs to be remembered that taking two steps forward, plus the step back that is an inevitable part of research, will still get us forward.

"In the middle of every difficulty lies opportunity"

Albert Einstein

CONCLUSIONS

- Assessments of AT interventions in dementia should include health economic and process evaluations as well as the perspectives of both persons with dementia and their relatives.
- Assistive technology interventions aimed at persons with dementia and their relatives may be of great significance for the relatives. Process evaluations of AT interventions are effective in increasing the understanding of the intervention process, and in identifying important aspects and aspects for improvement.
- The choice of patient self-ratings or proxy ratings of patient HRQoL for use in CEAs is of great importance as it has large effects on the results of the analysis. This could ultimately have an impact on decision making and resource allocation.
- Cost-effectiveness analyses in dementia should include HRQoL ratings of both the patients and the proxies to allow for comparisons and critical appraisals of the results. Further research is needed to determine the most valid way to measure HRQoL of persons with dementia for use in health economic analyses.
- Different types of support/services within the comprehensive areas of counselling, relief and information are perceived as very important by family caregivers of persons with dementia experiencing higher and lower levels of NI.

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