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LONELINESS

An essential aspect of the wellbeing of older people

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“Men i ålderdomens ogenomträngliga ensamhet
besatt hon en sådan klarsyn i utforskandet av de
mest obetydliga händelser i familjen att hon för
första gången klart insåg sammanhang som
hennes tidigare mångsysslande hade hindrat
henne från att se.”

Ur ”*Hundra år av ensamhet*” av Gabriel García Márquez,
översättning: Karin Alin, Wahlström & Widstrand, 1982

Contents

Abstract

The overall aim of this thesis was to explore loneliness by identifying associated factors and predictors for loneliness among older people. This research was also undertaken to examine the association between loneliness and healthcare consumption. In addition, the reserach explored the experience of loneliness and evaluated the effects on loneliness, symptoms of depression and life satisfaction of a case management intervention for frail older people.

Study I was a quantitative study with a longitudinal design involving persons 78 yers or older and drawn from the Swedish National Study on Aging and Care. The sample comprised of 828 people at baseline (2001) who were followed-up after three years (*n*=511, 2004) and six years (*n*=317, 2007). The sample was divided into two groups, based on if the persons felt lonely or not. Factors such as personality traits, health complaints, self-reported health status and life satisfaction were included for identifying associated factors and predictors for loneliness. Studies II-IV were based on a main study with an experimental design, comprising 153 persons, 65+ years, living at home, with dependency in ADL and repeated contact with the healthcare services. Study II had a cross-sectional design drawn from the baseline assessment (*n*=153) of the main study. Self-reported data and register data was used to investigate the association between use of healthcare and loneliness, health status and health complaints. Study III had a qualitative design and explored the experience of loneliness by performing interviews with 12 persons (10 women), recruited from the main experimental study. The interviews were analysed by using qualitative content analysis. Study IV was a randomised controlled trial, including 153 persons randomised to an intervention (*n*=80) or control group (*n*=73) and evaluated the effect of a case management intervention after six and 12 months. Three outcomes were evaluated in regards to effectiveness; loneliness, symptoms of depression and life satisfaction.

The results in Study I showed that 52 per cent of the sample at baseline felt lonely sometimes or often (mean age 84 years). The strongest associated factor for loneliness was living alone (*OR*=6.1, 95%, CI=3.8-9.9) and the strongest predictors for loneliness at both follow-ups, at three and six years, was feeling lonely at baseline (*OR*=7.2, CI=3.9-13.4 and *OR*=5.4, CI=2.8-10.5). Those associated factors and predictors that were identified were mainly related to psychosocial outcomes. Study II showed that 60 per cent of the frail older participants (mean age 82 years) had

experienced loneliness occasionally or more often during the previous year. Those who felt lonely used significantly more outpatient services, including visits at the emergency department, compared to their peers who did not feel lonely (p=0.026). Only depressed mood was found to be independently associated with total use of outpatient services (B=7.4, p<0.001). In Study III, the experience of loneliness among frail older people was interpreted in the overall theme "*Being in a Bubble*" illustrating as being in an ongoing world but excluded because of the participants' social surroundings and the impossibility to regain losses. The theme "*Barriers*" illustrated how participants had to face barriers, physical, psychological and social barriers for overcoming loneliness. The theme "*Hopelessness*" revealed the experience when not succeeding in overcoming the barriers and was characterised by loss of spirit and seeing loneliness as an unchangeable state. The last theme "*Freedom*" illustrated a positive co-existing dimension of loneliness which offered independence and time for reflection and recharging. Study IV evaluated the effect of a case management intervention for frail older people living at home in regards to loneliness, symptoms of depression and life satisfaction. At baseline, there were no significant differences between the intervention and control groups in regards to the main outcomes or sociodemographic factors. According to intention-to-treat no significant differences were found for any of the outcomes, at any time point between the two groups. When accounting for complete cases, significant differences in favour of the intervention were found at six months for loneliness (RR=0.5, p=0.028) and life satisfaction (ES=0.4, p=0.028), as well as for depressive symptoms after 12 months (ES=0.5, p=0.035).

Loneliness is fairly common among older people and once the feeling is established, it is likely to stay. Factors related to psychological wellbeing appeared as the major reasons for loneliness. Frail older people tend not to differ in regards to prevalence, compared to older people in general. Frail older people who felt lonely used more outpatient services, including visits to the emergency department compared to their not lonely peers. However, it was not loneliness *per se* that was found to be associated with use of healthcare but rather depressed mood. The experience of loneliness among frail older people showed that it was a prevalent issue, regardless of intensity and was associated with physical and social losses. Case management for frail older people was not effective in regards to loneliness, symptoms of depression and life satisfaction. Nevertheless, there were indications that case management could be beneficial in terms of these outcomes. Loneliness is an important factor that could be associated with lower wellbeing and needs to be actively targeted. Because of the complexity, where single causes are difficult to isolate a comprehesive and individualised approach is recommended. Loneliness can be problematic regardless of intensity and is likely to be unresolved, if left unattended. This implies that appropriate assessments of loneliness and other aspects of psychological wellbeing should be undertaken.

Original papers

I Taube, E., Kristensson, J., Midlöv, P., Holst, G. and Jakobsson, U. (2013). Lonelinesss among older people: Results from the Swedish National Study on Aging and Care-Blekinge. *The Open Geriatric Medicine Journal*; *6*, 1-10.

II Taube, E., Kristensson, J., Sandberg, M., Midlöv, P. and Jakobsson, U. (2014). Loneliness and healthcare consumption among older people. *Scandinavian Journal of Caring Sciences*. (ahead of print: doi: 10.1111/scs.12147).

III Taube, E., Jakobsson, U., Midlöv, P. and Kristensson, J. Being in a bubble: The experience of loneliness among frail older people. (Submitted)

IV Taube, E., Kristensson, J., Midlöv, P. and Jakobsson, U. The use of case management for community dwelling frail older people: The effects on loneliness, symptoms of depression and life satisfaction in a randomised controlled trial. (Submitted)

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Abbreviations and definitions

Abbreviations

ADL	Activities of daily living
CBT	Cognitive Behavioural Therapy
CC	Complete cases
DSM-V	Diagnostic and Statistical Manual of Mental Disorders 5th edition
FFM	Five Factor Model
GDS-20	Geriatric Depression Scale-20
HRQoL	Health related quality of life
IADL	Instrumental activities of daily living
ITT	Intention-to-Treat
LOCF	Last observation carried forward
LSIZ	Life Satisfaction Index-Z
MD-HC	Minimum Data Set for Home Care
MMSE	Mini Mental State Exam
MRC	Medical Research Council
NEO-FFI	Neo Five Factor Inventory
PADL	Personal activities of daily living
QoL	Quality of life
RCT	Randomised controlled trial
SNAC	Swedish National Study on Aging and Care
WHO	World Health Organization

Definitions

Frail	In Studies II-IV, people with dependency in ADL and repeated contacts with the healthcare services.
Older person	A persons who is 65 years or older.

Introduction

Humans are social beings and can hardly survive alone (Rokach, 2011). Nearly 80 per cent of the waking hours are spent with others, where time shared with spouse, friends, relatives, children and co-workers is considered to be more rewarding than time spent on your own (Hawkley & Cacioppo, 2010). However, when perceived to be socially isolated, people feel lonely, and loneliness has serious consequences for cognition, emotion, behaviour, and health if left unattended (Hawkley & Cacioppo, 2010). Loneliness is a prevalent social phenomenon (Rokach, 2011), common among older people (≥ 65 years) (Luanaigh & Lawlor, 2008), and especially among people over 80 years of age, where around 40 to 50 per cent report being lonely 'often' (Dykstra, 2009). The influence of loneliness on morbidity and mortality in old age is well known (Luo, Hawkley, Waite, & Cacioppo, 2012; Valtorta & Hanratty, 2012), where the reciprocal association between loneliness and depression appears to be salient (Luanaigh & Lawlor, 2008). Moreover, loneliness predicts a decrease in wellbeing, as well as decreased wellbeing is a predictor of loneliness (VanderWeele, Hawkley, & Cacioppo, 2012).

With advancing age, wellbeing is fundamentally, relevant to both health and quality of life (Steptoe, Deaton, & Stone, 2014). Viewing wellbeing as a concept that encompasses life satisfaction, happiness, and purpose in life (Steptoe et al., 2014) has implications for successful ageing, which can be seen as a multidimensional concept encompassing these aspects (Bowling & Dieppe, 2005). Accordingly, loneliness can be seen as potentially counteracting a successful ageing. To be able to prevent or manage adverse outcomes associated with loneliness, as well as loneliness itself, causes and associated factors both need to be identified. Despite increasing research of predictors and associated factors, longitudinal research is still limited. Moreover, with advancing age the burden of disease increases (Ward, Parikh, & Workman, 2011), along with a decrease in overall health status (Chatterji, Byles, Cutler, Seeman, & Verdes, 2014). Therefore, focusing on older age groups would be of interest in relation to both predictors and unexplored associated factors.

Older people, who are frail, could be particularly vulnerable to experience loneliness, although the research in regards to loneliness among frail older people is sparse. Frailty is a vulnerable physiologic state leading to increased care needs, admission to hospital or long-term care (Clegg, Young, Iliffe, Rikkert, & Rockwood, 2013), as well as increased risk of death (Crome & Lally, 2011). There is also an association between frailty and low self-reported psychological wellbeing, which implies that frailty is not merely a physical matter (Andrew, Fisk, & Rockwood, 2012) but rather a dynamic, multidimensional, and holistic state (Gobbens, Luijkx, Wijnen-Sponselee, & Schols, 2010). When caring for frail older people the need for individualised preventive approaches has been stressed (Crome & Lally, 2011), as well as the importance for supporting and promoting positive psychological states (Steptoe et al., 2014), including loneliness (Boeckxstaens & De Graaf, 2011). However, it may be difficult to implement because of how current practice by default is organised around acute episodic models of care (Boeckxstaens & De Graaf, 2011). One suggested approach is case management, which has been practiced to meet the holistic needs of frail older peoples and promote cost-effectiveness (You, Dunt, Doyle, & Hsueh, 2012), by providing individualised, coordinated, and integrated care through one single entry point *i.e.* the case manager (Boeckxstaens & De Graaf, 2011). Case management, led by nurses, have shown to improve the wellbeing of frail older people (You et al., 2012), as well as being considered to be highly valued and psychosocially supporting by the receivers -the frail older persons themselves (Sheaff et al., 2009). It has been showed that loneliness, among older people in general, is an independent risk factor for visiting or consulting a physician, as well as being a predictor for emergency hospitalisation (Valtorta & Hanratty, 2012). Therefore, providing or guiding strategies for managing loneliness and thereby reduce use of care, especially at the emergency department, seem essential.

The complex situation of being frail, as well as the overall impact on health and wellbeing in regards to loneliness, stresses the need for addressing these issues and counteract the negative outcomes. As suggested by Valtorta and Hanratty (2012), the research agenda needs to focus upon the risk to public health by distinguishing cause and effect, as well as consider how intervention strategies can reach those who suffer from loneliness.

Background

Setting the current and future scene

Around the world populations are ageing rapidly, people are living longer (Chatterji et al., 2014) and this demographic shift challenges the health system (Beard & Bloom, 2014). There are indications that for people under the age of 85 postponing of limitations and disabilities will occur (Christensen, Doblhammer, Rau, & Vaupel, 2009). However, morbidity such as chronic diseases could be worsen and difficulties with instrumental activities in daily living (IADL) seem to be on the increase (Chatterji et al., 2014). Moreover, older people are likely to have multiple, co-existing and interacting problems resulting in loss of function and frailty (Beard & Bloom, 2014). Given the longer life expectancy, a key issue is whether years will be added to life or life will be added to years by ensuring maintained functioning and wellbeing (Chatterji et al., 2014). Accordingly, the health policy for ageing should focus on maximising functioning rather than disease, including promoting the ability to do the things that are of importance for the older person, regardless of functional capacity (Beard & Bloom, 2014).

Sweden is no exception from this demographic shift nor the challenges facing the health system (Lagergren, 2002; Rosen & Haglund, 2005). However, Sweden is considered to have a well-developed system for providing care and services for older people (Boeckxstaens & De Graaf, 2011; Lagergren, 2002). Briefly, the *Health and Medical Services Act* and the *Social Services Act* defines the responsibilities in regards to medical and health responsibilities as well as the right to social services and care for older people (Lagergren, 2002; National Board of Health and Welfare, 2006). Both acts emphasises respect for self-determination and integrity, along with a total view of a person's situation and needs for which demands planning, coordination and continuity (National Board of Health and Welfare, 2006). However, there are challenges to achieving continuity, due of insufficient resources, unclear responsibilities, as well as communication and information deficiencies between stakeholders (National Board of Health and Welfare, 2015). Regardless, municipalities are responsible for care according to the Social Services Act and share the responsibility with the county councils in regards to care according to the Medical Services Act (National Board of Health and Welfare, 2006). The older person can receive home help services (*e.g.* cleaning, shopping, meals-on-wheels, personal care), after a need assessment has been carried out by the municipality (Lagergren, 2002). If qualified and/or highly specialised medical care is needed, the older person can receive home nursing, or other assistance in the form of rehabilitation and auxiliary means (Lagergren, 2002). A main goal for the care of older people in Sweden is that they should be able to continue to live in their homes for as long as possible, despite extensive needs of care and social services, hence a great majority of older people live in their own homes (Lagergren, 2002; National Board of Health and Welfare, 2015). Previous research has indicated that the wellbeing among older women who are 'ageing in place' *i.e.* at home is good (Rioux, 2005). However, the increase in European single-person households, where in some countries over 50 per cent of women over the age of 65 live alone, could pose an increased risk of depression, isolation, and loneliness (Beard & Bloom, 2014). Accordingly, the potential risk for isolation, loneliness and depression among older people, currently and in the future, underscores the interest in addressing these aspects in regards to the health of older people.

Conceptualisation and prevalence of loneliness

Conceptualisation

First of all, loneliness is not merely an issue for older people, it arises in all ages (Dykstra, 2009) and people can be objectively socially isolated without feeling lonely, but on the other hand, people can have a rich social life and still feel lonely (Hawkley & Cacioppo, 2010). However, there is no straight answer to what loneliness is, or rather how it should be defined. Going back, there are three theoretical approaches that appear to have dominated over the decades; the *social needs* approach, the *behavioural/personality* approach, and the *cognitive process* approach (Marangoni & Ickes, 1989). The *social needs* approach focuses on unmet social needs that are considered to be the origin for experiencing loneliness (Marangoni & Ickes, 1989). The theory and definition formed by Weiss (1973) represents this approach by distinguishing *emotional loneliness* and *social isolation*. In the first case, loneliness is a result of the loss or the absence of someone close, usually a partner, relative or friend, and in the second case social isolation is a consequence of deficits in social network of involvement with other people or groups, for example co-workers, neighbours or friends (Weiss, 1973). The *behavioural/personality* approach involves behaviours, where a difference between lonely and individuals who are not lonely has been suggested, including social skills deficits and personality characteristic (Marangoni & Ickes, 1989). The *cognitive process* approach also suggests that loneliness is a consequence of a discrepancy between existing and desired relationships, as defined by Peplau, Perlman, Peplau, and Perlman (1982). More recently, a fourth approach, the *evolutionary*, has been suggested stating that loneliness is the social equivalent of physical pain, hunger and thirst (Cacioppo, Hawkley et al., 2006). The pain of social disconnectedness and the hunger and thirst for social connectedness motivates maintenance of existing social relations or creating new ones as a prerequisite for the survival of our genes (Cacioppo, Hawkley et al., 2006; Hawkley & Cacioppo, 2010). A merge of different theoretical approaches when investigating loneliness have been encouraged, whilst keeping core definitions (Marangoni & Ickes, 1989). However, critique towards defining loneliness (Nilsson, Lindström, & Nåden, 2006), as well as differentiating into several types such as existential, social, and emotional loneliness have been raised (Rokach, 2012). A definition would be too narrow to fully understand the complexity of the phenomenon (Nilsson et al., 2006), as well as when differentiate between types (Rokach, 2012). The many viewpoints and definitions make loneliness a problematic research area (Routasalo & Pitkälä, 2003). Despite these difficulties there are a few hallmarks that outline the conceptualization of loneliness in this thesis, that is; a) loneliness is a subjective and undesired experience involving a negative affect (Dykstra, 2009; Luanaigh & Lawlor, 2008), b) emotional loneliness and social isolation are relevant to distinguish because of death of ageing friends and relatives as well as the difficulty in having or finding a close attachment, such as a partner with advancing age, poses a possible risk of increased emotional loneliness (Luanaigh & Lawlor, 2008). It should also be noted that social isolation according to Weiss encompasses a subjective experience (Weiss, 1973) whereas social isolation in other cases is an objective condition of not having social connections (Dykstra, 2009).

Aloneness and solitude

An important distinction should be made between the unwanted loneliness and the more desirable *aloneness,* which implies a choice of being alone (Killeen, 1998; Luanaigh & Lawlor, 2008). The utter counterpart to loneliness is *solitude* and the difference can be expressed as the glory of being alone (solitude) versus the pain of feeling alone (loneliness) (Cacioppo, Hughes, Waite, Hawkley, & Thisted, 2006). Solitude is about being disengaged from immediate demands of other people, as well as a freedom to choose physical and mental activities (Long & Averill, 2003). Moreover, it provides opportunities for rest, creativity, imagination, reflection and personal control (Rokach, 2011). Therapeutic benefits of solitude have also been addressed where reading a good book, listening to music or experiencing the beauty of existence creates a tolerance towards oneself and others (Nilsson et al., 2006). However, the benefits of solitude depend on inner resources and the ability to find meaning in a situation in which external support is lacking, suggesting that it is not equally beneficial for all (Long & Averill, 2003). That is, people who are alone either distract themselves through activities or engage in productive activities (Long & Averill, 2003). Regardless, enhancing the benefits of solitude could be a useful approach for managing loneliness (Rokach, 2011). The concepts of aloneness and solitude are sometimes used interchangeably in literature. A continuum proposed by Killeen (1998), simplifies the relationship between the different concepts. This continuum ranges from *loneliness* to *solitude*, from a negative experience to a positive experience, in which *social isolation* is placed between loneliness and *aloneness*, where social isolation with a choice is aloneness and without a choice is loneliness.

Prevalence of loneliness in old age

In previous research, reported prevalence among older people varies depending on definition, assessment, and intensity. Albeit being essential for researchers to quantify and generalise the prevalence of loneliness, there is a challenge in doing so (Valtorta & Hanratty, 2012). However, in regards to previous studies the prevalence of feeling lonely sometimes or often/modest or severe seems to range between 20 to 50 per cent for people aged 65 years or older (Dykstra, 2009; Golden et al., 2009; Pinquart & Sörensen, 2001; Savikko, Routasalo, Tilvis, Strandberg, & Pitkälä, 2005). The prevalence of loneliness appears to increase with advanced age and among people over 80 years old a prevalence of 50 per cent of feeling lonely often has been reported (Dykstra, 2009; Pinquart & Sörensen, 2001). The reported prevalence's mainly accounts for the western world. However, differences may still occur, for instance, older Europeans in central and south of Europe are found to be lonelier that their peers in the north and west (Dykstra, 2009; Fokkema, De Jong Gierveld, & Dykstra, 2012). In regards to stability over time, loneliness has been found to remain stable for 60 per cent of people aged 65+ years in Great Britain, who were followed-up after eight years (*n*=287) (Victor & Bowling, 2012). In Sweden, a similar result has been reported where 80 per cent of people 70+ years reported an unchanged level of loneliness in a seven year follow-up (n=587) (Dahlberg, Andersson, McKee, & Lennartsson, 2014). However, despite an increase with age and stability over time there are older people who 'improve' their loneliness by reporting decreased levels of loneliness. Prevalence of such an improvement has been reported, ranging from ten per cent (Jylhä, 2004; Victor & Bowling, 2012) to almost 50 per cent (Dahlberg et al., 2014). Associations between other positive changes have been demonstrated, such as increased number of confidants, decrease in health deterioration and moving from living alone to live with others (Victor & Bowling, 2012). Nevertheless, it appears as though the proportion in loneliness increase is larger than the proportion of decrease over time (Dahlberg et al., 2014; Dykstra, Van Tilburg, & de Jong Gierveld, 2005; Jylhä, 2004; Victor & Bowling, 2012). Moreover, there is an apparent social stigma associated with loneliness and the view of lonely people is in general deemed to be socially unfavourable (Rokach, 2012). The reluctance or stigma in admitting loneliness indicates that older people may not report loneliness unless it is obvious or severe (Grenade & Boldy, 2008). Given the increased prevalence with age, the stability over time and the possible underreported prevalence among older people, underscores the importance of recognising loneliness as a prevalent and persistent problem in old age.

Successful ageing and loneliness

Successful ageing could be seen as the ideal state to be aimed for as a person gets older (Bowling & Dieppe, 2005). Pioneers within this field were Rowe and Kahn (1987) who made this into a concept central in ageing research by defining usual and successful ageing (Bülow & Söderqvist, 2014). In a further elaboration successful ageing was conceptualised as encompassing three main components; low probability of disease and disease related components, high cognitive and physical capacity, and active engagement with life (Rowe & Kahn, 1997). However, as pointed out by Bowling and Dieppe (2005) a disease-free older age is unrealistic for most people and alternative models encompassing aspects beyond disease, such as satisfaction with past and present life or psychological resources, have been proposed. One approach would be to consider successful ageing as a multidimensional concept encompassing physical and psychosocial aspects (Baltes & Baltes, 1993; Bowling & Dieppe, 2005) with no single trajectory of ageing being the 'gold standard' (Baltes & Baltes, 1993). Instead, it is the individual process of ageing, including values, attitudes, resources, and opportunities that form successful ageing (Baltes & Baltes, 1993; Bowling & Dieppe, 2005). Subjective definitions of the concept have shown to concern wellbeing and social connectedness, including adaptation to illness and symptoms, rather than absence of illness and symptoms being the norm (Jeste, Depp, & Vahia, 2010). Some general principles for successful ageing have been proposed which include engaging in a healthy lifestyle, encouraging individual and societal flexibility rather than simple solutions, and strengthen the person's own reserve capacities through *e.g.* health related activities, facilitation and nurturing of meaningful relationships (Baltes & Baltes, 1993). Rowe and Kahn (1997) suggest that active engagement through relations in the form of contact with others, exchange of information, emotional support, and assistance is crucial, where lack of social connections is underscored as a risk factor for health, hence, successful ageing. More specifically, it has been argued that loneliness itself counteracts successful ageing, along with depression among many other factors (Jeste et al., 2010). Conversely, optimism, coping, as well as high physical and mental quality of life (QoL) promote a positive outcome (Bowling & Iliffe, 2011; Jeste et al., 2010).

Successful ageing is influenced in a complex way and through multiple levels 'from genes to neighbourhood' (Jeste et al., 2010). Therefore, it is challenging to both grasp and assess the concept. However, aspects incorporated in successful ageing could be used as indicators, with emphasis on indication rather than a full-scale assessment of the concept. In regards to the underscored importance of psychological aspects of successful ageing (Bowling & Iliffe, 2011; Bülow & Söderqvist, 2014; Jeste et al., 2010) the concepts of life satisfaction, wellbeing, and QoL will therefore be presented, both in relation to each other and in relation to loneliness.

The concepts of life satisfaction, wellbeing and quality of life

Overall, there is a lack of consensus regarding definitions and conceptualisations of life satisfaction, wellbeing and QoL with the concepts sometimes used interchangeably (Haas, 1999). Nevertheless, in previous research, loneliness has been found to be related to all three concepts (Golden et al., 2009; Ní Mhaoláin et al., 2012; Routasalo & Pitkälä, 2003). Therefore, presenting and untangling these concepts seem useful for a further understanding of loneliness among older people.

Life satisfaction

Life satisfaction refers to an evaluation of peoples' lives in regards to thoughts about the quality or goodness of their life (Steptoe et al., 2014) and is sometimes considered to be a referral to happiness in life (Steptoe et al., 2014; Veenhoven, 1988). An operationalization of the definition of life satisfaction was developed by Neugarten, Havighurst, and Tobin (1961) comprising five components; *zest* (vs. apathy), *resolution and fortitude*, *congruence with desired and achieved goals*, *positive self-concept* and *mood tone*. If seeing life satisfaction as a continuum then being on the positive end of this range refers to enjoying activities that constitute everyday life, regarding life as meaningful and accepting how life has been, a sense of achievement in reaching major goals, holding a positive self-image and maintaining happy and optimistic attitudes and moods (Neugarten et al., 1961). Judgement of life satisfaction seem to be stable in shorter periods of time, such as one year, but as greater circumstances in life are likely to change over time, as does life satisfaction (Fujita & Diener, 2005). In addition, based on longitudinal data there are indications of a peak in life satisfaction around the age of 65 to 70 years, followed by a decline with advancing age (Mroczek & Spiro III, 2005).

Wellbeing

The concept of subjective or self-reported wellbeing, hereafter referred to as wellbeing, is an umbrella term for different valuations that people make regarding their lives, bodies and minds, events happening to them, and the circumstances in which they live (Camfield & Skevington, 2008; Diener, 2006). Moreover, according to Diener (2006) wellbeing includes life satisfaction, interests and engagement, emotional reactions to events in life *e.g.* joy and sadness. This is in line with a more recent description of wellbeing encompassing three different approaches; *life evaluation*, as in overall satisfaction with life, *hedonic wellbeing*, as in everyday feelings or mood, such as happiness, anger, or stress, and *eudemonic wellbeing*, as in meaning and purpose in life (Steptoe et al., 2014). Assessing satisfaction with life has been considered as a global/general indicator of wellbeing, albeit not being a specific indicator, this assessment is still informative and useful (Diener, 2006). There is a reciprocal relationship between wellbeing and physical health and wellbeing may be protective for maintaining health in old age (Steptoe et al., 2014). Moreover, promoting wellbeing is not just potentially beneficial for the person him/herself but also for society as whole (Diener, 2006), where addressing mental health needs, including loneliness, has been suggested as a key target for improving wellbeing (Ní Mhaoláin et al., 2012).

Quality of life

The concept of QoL has different meaning to people, as well a variation in meaning depending on the area of application (Fayers & Machin, 2007). QoL has also been used to refer to various concepts such as wellbeing, life satisfaction and happiness (Ferrans, Zerwic, Wilbur, & Larson, 2005). One common and widely used definition of QoL has been proposed by the WHO (Camfield & Skevington, 2008) where QoL is seen as a broad subjective and multi-dimensional concept influenced by a person's physical health, psychological state, level of independence, social relationships and their relationship to salient features of the environment (WHOQOL-group, 1995). In this context, the concept of health can be defined as "a state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity" (WHO, 1946) .

The relationship between the concepts

There appears to be consensus regarding life satisfaction being a salient concept to wellbeing and QoL, although being subordinate to the latter two concepts (Camfield & Skevington, 2008; Diener, 2006; Haas, 1999). The relationship between wellbeing and QoL is less clear, but it has been argued that wellbeing and life satisfaction relies on subjective assessments. Whereas QoL may have both subjective and objective assessments, *e.g.* living conditions (Diener, 2006; Haas, 1999). Therefore, wellbeing and life satisfaction are incorporated in QoL (Haas, 1999). However, on one hand it has been concluded that wellbeing and QoL, as defined by Diener (2006) and the WHOQOL-group (1995), are synonymous (Camfield & Skevington, 2008). On the other hand, QoL has also been considered as an outcome indicator of wellbeing (Bowling & Iliffe, 2011). Seemingly, the relationship of wellbeing and QoL is not fully clear and appears to depend on how the concepts are viewed and defined. Moreover, the inconsistencies make comparing findings across studies difficult, including conclusions and implications for clinical practice (Ferrans et al., 2005). This was one reason for making a refinement of the concept in terms of *Health Related Quality of Life* (HRQoL) (Ferrans et al., 2005), which provides an outcome of wellbeing (Sprangers et al., 2010).

Health related quality of life

HRQoL focuses on the effects of health, illness, and treatment on QoL (Bakas et al., 2012; Ferrans et al., 2005). There are several theoretical models and conceptual frameworks capturing HRQoL from various aspects of health and illness conditions (Bakas et al., 2012) but the definition is loose (Fayers & Machin, 2007). There are some shared theoretical underpinnings and it is generally agreed that HRQoL is dynamic, subjective, and multi-dimensional, including dimensions regarding physical, social, psychological, and spiritual factors (Bakas et al., 2012).

Research indicates that there are three commonly used models of HRQoL where the model by Wilson and Cleary being the most frequently used, and combines the biomedical and social science paradigms (Bakas et al., 2012). This includes pathological processes, biological, physical, and clinical outcomes as well as functioning and overall wellbeing (Wilson & Cleary, 1995). Sprangers et al. (2010) presents an extended model of Wilson and Cleary where a new approach is incorporated based on evidence that there is a genetic foundation of HRQoL. That is; genes have an impact on the experience of symptoms, perceptions of health, mood, and overall QoL (Sprangers et al., 2010). This notion was formed by an international, interdisciplinary consortium, GENEQOL, aimed to investigate biological pathways and genes involved in HRQoL (Ordoñana et al., 2013; Sprangers et al., 2010). It should be noted that the complexity in the interchangeable use of concepts such as wellbeing, QoL, and HRQoL partly remains, even after introducing a model. However, HRQoL, as presented in the model, refers to *patient-reported* QoL *i.e.* a more narrow concept applicable to patients (Sprangers et al., 2010), concerning aspects of QoL related to health (Ferrans et al., 2005). Therefore, HRQoL as a self-reported/patient-reported assessment of QoL will hereafter be referred to as *QoL*.

Using the model by Wilson and Cleary (1995) or the revised version by Ferrans et al. (2005) to start with and then build upon has been emphasised as favourable to achieve consistency and make cross-comparisons more accessible, as well as increasing the understanding of QoL in relation to health (Bakas et al., 2012). Therefore, the idea of placing loneliness in the context of a QoL model, originated in the Wilson and Cleary model and additionally inspired by Ferrans and colleagues, is intended to facilitate comprehensiveness in the complexity of loneliness and its influences in a larger sense. Moreover, regarding successful ageing as a preferable outcome seems to require multiple approaches and by placing loneliness in a context 'from genes to neighbourhood' is one attempt to assess the influence of loneliness on wellbeing and possibly successful ageing.

Loneliness in relation to quality of life and wellbeing

There are six levels in the model developed by Sprangers et al. (2010), arranged in a causal chain going from the biological levels on the left to psychological levels on the right. The more to the right, the larger influence on overall QoL. It should be noted that revisions of the model, in the form of amendments, are undertaken in this thesis for emphasising aspects of loneliness and associated factors. These amendments are represented by text in italics and by dotted arrows in bold (Figure 1).

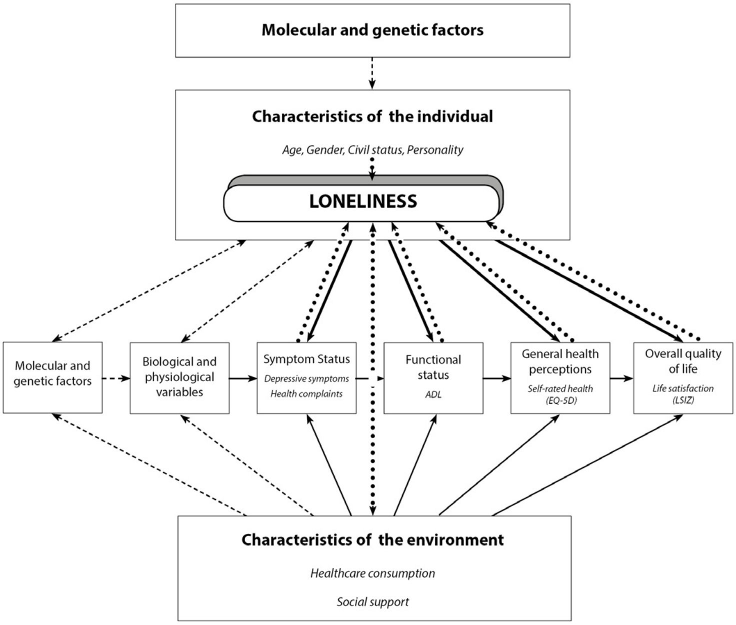

Figure 1. Overview of loneliness and associated factors placed in a model of QoL (Sprangers et al., 2010) originally developed by Wilson and Cleary (1995). The dashed arrows indicate the supplement made by Sprangers et al. (2010) from its original version and bold arrows highlight the acknowledged importance of the relationships they refer to.

Molecular and genetic factors influence *biological and physiological variables* such as the function of cells, organs and organ systems (*e.g.* creatinine level, pulmonary wheezes, diagnosis of cancer disease). The focus then shifts from cellular or organ level to the person as a whole, where perceptions of abnormal physical, emotional, and cognitive states are reflected in *symptom status* (*e.g.* pain in extremities, anxiety) influencing *functional status* as in physical, social, role and psychological behaviour related to the ability to perform certain tasks (*e.g.* ADL or coping with stress). These factors influence *general health perceptions* that refer to the subjective experience and evaluation of physical and mental health. Finally, the *overall QoL* is the subjective perception of how happy or satisfied the person is with his or her life in the light of a certain physiological state, symptom experience, functional status and subjective perception of physical and psychological wellbeing (Sprangers et al., 2010). Molecular and genetic factors affect the *characteristics of the individual*, which in turn influences all six levels. A relationship between mind and body are indicated through bidirectional arrows *e.g.* the expectation of a clinical benefit is seen as a major trigger for the placebo effect, involving several molecular mechanisms and triggers (Sprangers et al., 2010). *Characteristics of the environment* refers to culture, social support, family structure and neighbourhood (Ordoñana et al., 2013). Sprangers et al. (2010) presents an example where the environment can trigger depression through a distressing event that releases a specific protein related to the condition (*molecular and genetic factors*).

In a further elaboration, Ordoñana et al. (2013) reviewed the biological pathways and genetic mechanisms involved in social functioning, as well as addressing loneliness in relation to the model. Molecular and genetic factors may not influence social functioning directly. Instead, social functioning follows the causal chain where symptoms are its precursor (Ordoñana et al., 2013). In the next sections, variables of importance in this thesis will be presented in relation to the components in the model (Ordoñana et al., 2013; Sprangers et al., 2010) (Figure 1). However, the focus will be on what is considered to be most influential on QoL, namely; *individual characteristics*, *symptoms*, *function*, *health*, and *overall QoL* (Sprangers et al., 2010). An addition of *environmental characteristics* is made because of its relevance in relation to loneliness. Furthermore, a similar and well established (Bakas et al., 2012) model by Ferrans et al. (2005), based on the QoL model by Wilson and Cleary is used for additional support and clarification. Finally, it should be underscored that relationships between variables and levels other than those presented in the model may exist.

Characteristics of the Individual

Demographic factors such as age, gender, and marital status are considered to be a part of an individual's characteristics (Ferrans et al., 2005) and so is also personality, perception of illness, expectations, values, and coping strategies (Sprangers et al., 2010). Those characteristics that refer to the individual are considered to have a larger impact on self-reported outcomes (symptom status, functional status, general health perceptions, and overall QoL), compared to biological and physiological variables, such as an underlying disease (Sprangers et al., 2010). Factors such as age, gender, and marital status are well explored in loneliness research. Loneliness increases with age (Dykstra, 2009; Dykstra et al., 2005), although it may not be the age *per se* but rather increasing disability and decreasing social integration (Jylhä, 2004). It has been suggested that the increase in loneliness in the oldest age groups is due to the loss of close attachments (Luanaigh & Lawlor, 2008). In fact, those who lose their partner and become widowed/widowers have the greatest increase in loneliness (Dykstra et al., 2005). Women are more prone to reporting loneliness (Golden et al., 2009; Luanaigh & Lawlor, 2008), which could be a result of the fact that men appear to be less likely to admit feeling lonely or because of other confounding factors (Luanaigh & Lawlor, 2008).

In regards to personality, the major models in personality research include a personality trait related to a person's ability to engage and enjoy social relationships (Ordoñana et al., 2013). Personality, behaviour, interests as well as loneliness can be associated with frequency and intensity in social life (Ordoñana et al., 2013). A widely accepted classification of personality is the Five Factor Model (FMM) where *Openness*, *Conscientiousness*, *Extraversion*, *Agreeableness,* and *Neuroticism* are the five traits describing personality (McCrae & Costa, 2003). Among older people higher scores in neuroticism is a predictor of loneliness (Hensley et al., 2012; Margrett et al., 2011). This indicates that persons who tend to be more neurotic in their personality trait are more prone to be worrying *vs.* calm, temperamental *vs.* even-tempered, self-pitying *vs.* self-satisfied, self-conscious *vs.* comfortable, emotional *vs.* unemotional, and vulnerable *vs.* tough (McCrae & Costa, 2003). Neuroticism, in particular, has also been found to influence life satisfaction (Berg, Hassing, Thorvaldsson, & Johansson, 2011; Ní Mhaoláin et al., 2012) and lower self-reported health (Berg et al., 2011).

Characteristics of the environment

Even though individual factors are emphasised as most influential on QoL, environmental factors are of relevance in the context of loneliness. In fact, it has been argued that social and community participation is of fundamental importance for the wellbeing of older people (Allen, 2008). Cumulative empirical evidence from 148 studies indicated that peoples' experiences within social relationships is an independent predictor for mortality, even after controlling for age, gender, marital status, initial health status and cause of death (Holt-Lunstad, Smith, & Layton, 2010). Therefore, having adequate social relationships indicates a 50 per cent greater likelihood of survival, compared to having poor and insufficient relationships (Holt-Lunstad et al., 2010). Moreover, having supportive social relationships has a health promoting effect on disease outcomes (Tomaka, Thompson, & Palacios, 2006). Conversely, lack of connectedness to other individuals or social groups is associated with worse perceived (mental) health and social isolation is a mediating factor (Cornwell & Waite, 2009). Overall, negative impact on wellbeing is found to be related to feeling disregarded or undervalued by society, especially from a negative stereotypical point-of-view (Moyle et al., 2010). In addition, being confined, left alone (Kvaal, Halding, & Kvigne, 2014), having disrupted meaningful engagements with others (Smith, 2012), and being disconnected from society (Hauge & Kirkevold,

2010) are associated with the individual experience of loneliness. Furthermore, maintaining contact and belonging to society are considered to be important by the people themselves in relation to loneliness (Stanley et al., 2010).

According to Ordoñana et al. (2013) the relationship between genetic factors and social functioning can be mediated by environmental characteristics, that is; genetic factors lead to low levels of extroversion, *e.g.* being reserved, quiet, passive, loner, unplayful/sober (McCrae & Costa, 2003), which in turn might act in parallel with difficulties in having or extending a social network, resulting in a negative influence on social functioning (Ordoñana et al., 2013). Therefore, it is a complex web of interactions, although the influence of social interaction should be acknowledged, both in relation to loneliness as well as overall wellbeing.

One aspect of environmental characteristics is living arrangements and it has been suggested that wellbeing is closely related to the physical environment, as a mediator for ageing experiences and opportunities (Lui, Everingham, Warburton, Cuthill, & Bartlett, 2009). Living alone is an independent predictor for loneliness (Routasalo, Savikko, Tilvis, Strandberg, & Pitkälä, 2006), as well as associated with being dissatisfied with living circumstances (Routasalo & Pitkälä, 2003). Moreover, there is a tendency of an increase in single households in western countries and in regards to prevalence in loneliness, the majority of those feeling lonely live on their own (Allen, 2008). It should also be noted that moving to and living in residential care is associated with loneliness (Routasalo & Pitkälä, 2003; Tilvis, Laitala, Routasalo, & Pitkälä, 2011).

Ferrans et al. (2005) elaborates the components in environmental factors from the original model by adding institutional factors such as healthcare facilities. It is known that having a mix of health and social problems such as living alone, multi morbidity and severe ADL impairment are independent predictors for hospital admissions (Landi et al., 2004). Older people have also shown to have a higher level of acute and severe illness, including a five-fold higher acute admission rate, compared to younger age groups (Samaras, Chevalley, Samaras, & Gold, 2010). When using acute care, older people are likely to experience adverse health outcomes afterwards (Aminzadeh & Dalziel, 2002). Because of the lack of specific geriatric approaches they are also more likely to be misdiagnosed, as well as discharged with unidentified and untreated health issues (Samaras et al., 2010). Molloy, McGee, O'Neill, and Conroy (2010) showed that in a sample with community-dwelling older people (n=2, 033) greater loneliness independently increased the odds of emergency department attendance by 29 per cent. In fact, loneliness has been shown to predict visits at the emergency department, independently of chronic illness (Geller, Janson, McGovern, & Valdini, 1999). Planned care, however, has not shown to be associated with loneliness, suggesting similar planned healthcare needs among lonely and not lonely persons (Molloy et al., 2010). In primary care there is often a long-term commitment, which gives possibilities to identify issues related to the overall health situation, comprising issues related to frailty, dependency, multi-morbidity, social isolation, and loneliness (Boeckxstaens & De Graaf, 2011). However, in the U.S. the average general parctitioner visit lasts about 15 minutes, where the practitioner needs to assess physical and mental issues, provide care or refer to specialists as well as ensure confirmed decision making (Fiscella & Epstein, 2008). Mental ill-health among older Swedes is one of the country's largest public illnesses according to the National Board of Health and Welfare in Sweden. This poses current and future challenges for primary care services in terms of capacity, diagnosis, treatment, support and competence (National Board of Health and Welfare, 2013). There is also a challenge in identifying those who are in need of support since around 50 per cent of older people with probable mental diagnoses, such as depression, do not consult their healthcare providers (Préville et al., 2009; National Board of Health and Welfare, 2013). Accordingly the use, form and structure of current health services may affect overall QoL for older persons, which underscores the importance of acknowledging use of health services as an environmental characteristic that needs to be considered.

Symptom status

The experience and evaluation of symptoms is complexly influenced by individual factors, as well as environmental factors such as interaction with healthcare providers (Ferrans et al., 2005). In regards to the relationship between symptoms and loneliness, various associations and predictors have been identified. For instance, hopelessness has been found to be independently associated with loneliness (Golden et al., 2009) along with predictors such as uselessness, nervousness (Aartsen & Jylhä, 2011), poor vision, poor hearing and overall illness (Savikko et al., 2005). However, one salient symptom that appears to be of particular relevance in regards to loneliness is depression, which is considered to be an important public health problem among older people (Barg et al., 2006).

Overall, much depression is considered to be unrecorded and the prevalence varies (Allen, 2008; Djernes, 2006), although research shows that one in ten primary care patients has a major depression (Ell, 2006), and around 15 per cent of community-dwelling older people has clinically significant depressive symptoms (Djernes, 2006; Fiske, Wetherell, & Gatz, 2008). The onset and maintenance of depression in later life can be seen as an interaction between vulnerabilities such as genetic factors, age related neurobiological changes, and cognitive predisposition, together with stressful events that occur more frequently in old age compared to when you are young (Fiske et al., 2008). The Diagnostic and Statistical Manual of Mental Disorders 5th edition (DSM-5) (American Psychiatric Association, 2013) describes criteria for several depressive disorders, including major depressive disorder where at least five depressive symptoms must be prevalent and persistent over two weeks. Depressive symptoms encompasses *e.g.* depressed mood, significant change in weight or appetite, decreased energy, feelings of worthlessness and inability to enjoy pleasurable activities or events (Barg et al., 2006). Late life depression differs compared to earlier in the lifespan in regards to both obvious and subtle ways. For instance, fatigue, loss of interest in living and hopelessness about the future appear to be more common among older people whereas younger people may be more prone to display worthlessness, guilt, and dissatisfaction (Fiske et al., 2008).

Disability, losses in social network, low social support, and negative life events are risk factors for depression (Ell, 2006) and so are also personality traits, such as neuroticism (Ní Mhaoláin et al., 2012), anxiety as well as various physical illnesses (Fiske et al., 2008). There is a well-known reciprocal relationship between depression and loneliness (Cacioppo, Hughes, et al., 2006; Luanaigh & Lawlor, 2008). Loneliness has been found to increase depressive symptoms over time (Hawkley & Cacioppo, 2010), conversely, depressive symptoms have been found to predict loneliness (Aartsen & Jylhä, 2011; Dahlberg et al., 2014; Routasalo et al., 2006). Older people themselves, associate loneliness spontaneously to depression (Barg et al., 2006) and the experience of depression encompasses a sense of meaningless characterised by loneliness, isolation, and shielding (Holm, Lyberg, Lassenius, Severinsson, & Berggren, 2013). Given the close relationship between depressive symptoms and loneliness among older people, as well as the possible modifiable aspect, this suggests opportunities for intervening. However, the presumed prevalence of unrecorded diagnoses and the increased expectancy in prevalence of depression, due to the increasing older population (Allen, 2008), poses challenges in identifying, as well as intervening in regards to strategies, competence, and capacity.

Functional status

This level is about the capacity to perform tasks within several areas such as physical, psychological, and social (Ferrans et al., 2005; Sprangers et al., 2010). Impairment in social functioning can be seen as an effect of a disease or its treatment, as well as an effect of social support (Ferrans et al., 2005; Ordoñana et al., 2013). Having symptoms such as pain, fatigue, low mood and so on leads to impaired functional status of which can be manifested through *e.g.* restricted participation in social activities or withdrawal from social interaction (Ordoñana et al., 2013). Another aspect of functional status is the ability to perform ADL. If symptoms are severe enough they might intrude on the ability to ADL which in turn may lead to sedentary behaviour and an overall decline in functional status (Ferrans et al., 2005). The association between loneliness and physical function in regards to ADL has been previously investigated showing contradictory results. Drageset (2004) found that dependence in ADL reduced loneliness, although, this was among nursing home residents where the dependency may have facilitated social contacts and interaction. On the other hand, loneliness and dependency in ADL has shown to be associated (Cohen-Mansfield, Shmotkin, & Goldberg, 2009; Hacihasanoğlu, Yildirim, & Karakurt, 2012), as well as loneliness being a predictor for a decline in ADL (Perissinotto, Cenzer, & Covinsky, 2012). Conversely, having reduced mobility and difficulties in getting out of the house is a predictor of loneliness (Cohen-Mansfield & Parpura-Gill, 2007).

In regards to social functioning, there is a notion that lonely people tend to form more negative social impressions as means of self-preservation, which counteracts opportunities for connections with others (Cacioppo, Cacioppo, & Boomsma, 2014). Therefore, loneliness can be seen as a loop where lonely persons expect and remember more negative social interactions, negatively affecting the interaction with and response from others, which in turn confirms the lonely person's expectations, leading to social withdrawal (Hawkley & Cacioppo, 2010). The individual experience of loneliness is, for some, related to anger towards people whom they feel rejected by (Kvaal et al., 2014). In addition, self-blame and guilt for feeling self-centred and whining have also been expressed by older people who themselves are feeling lonely (Kvaal et al., 2014). Nevertheless, engaging in social activities is important when experiencing loneliness, where a reduction in the number of activities has been found to be a predictor of loneliness (Aartsen & Jylhä, 2011). Consequently, it is important to support older persons in regards to functional status as in social functioning as well as management in ADL, both for those who are lonely and for those who may be at risk of becoming lonely.

General health perceptions

The subjective experience of health merges all various aspects of health in an overall evaluation (Ferrans et al., 2005), be it physical and/or mental (Sprangers et al., 2010). There is evidence towards a relationship between loneliness and poor self-reported health, where loneliness is an associated factor (Jakobsson & Hallberg, 2005; Luo et al., 2012), predictor (Nummela, Seppänen, & Uutela, 2011) or the other way around (Savikko et al., 2005). When rating general health perceptions both single item questions and instruments are used. There are several instruments assessing subjective health and a commonly used assessment is the EQ-5D (Brooks, 1996; Fayers & Machin, 2007), where one item assesses the subjective rating of the persons' health. Moreover, EQ-5D measures five dimensions of health and the single items could cover aspects of *functional status* and *symptom status* in the applied model. However, the person describes his or hers own health status and a single index is generated for all the health states (Brooks, 1996). Depending on how QoL, or more specifically; HRQoL, is defined it can be congruent with definitions of health (O'Boyle & Waldron, 1997). Therefore, some studies assessing HRQoL can be considered to assess subjective health status. There appears to be a paucity of existing literature regarding self-reported health and loneliness among older people, especially through assessment of the EQ-5D. Hawton et al. (2011) investigated health status, assessed by EQ-5D, among socially isolated people and found that being isolated was independently associated with worse health, compared to those who were not.

Although social isolation is not equivalent to loneliness, especially not objective isolation, it indicates a possibility that this factor, to some extent, applies to those who are lonely as well.

Overall quality of life

This level refers to a self-reported state of physical and psychological wellbeing or how happy or satisfied a person is with his/her life (Sprangers et al., 2010). Therefore, life satisfaction can be used as an indicator of overall QoL. Loneliness predicts lower life satisfaction (Borg, Hallberg, & Blomqvist, 2006; Ní Mhaoláin et al., 2012) and there is also a reciprocal effect between these two variables, even after controlling for possible confounders such as depression, objective social support, and psychiatric conditions (VanderWeele et al., 2012). When comparing six European countries, life satisfaction, from the perspective of Neugarten et al. (1961) through assessment by the LSIZ (0-26 points), was shown to be lowest in Italy (*M*=12.2, *SD*=5.3) and highest in the Netherlands (*M*=16.3, *SD*=5.2), with Sweden placed in the middle (*M*=15.6, *SD*=5.6) (Borg et al., 2008). Moreover, there are other factors than loneliness that negatively influence life satisfaction among older people such as being depressed, feeling exhausted and neuroticism, whereas physical activity and being extroverted has been found to be positively influencing (Ní Mhaoláin et al., 2012). Regardless of the various influences affecting life satisfaction, enjoying living stimulates active involvement, encouraging social contacts (Veenhoven, 1988), is related to longer survival and may improve physical health (Steptoe et al., 2014). Therefore, there is both evidence and indications that loneliness is important for the experience of life satisfaction and overall wellbeing as in QoL.

Molecular and genetic factors, biological and physiological variables

These two levels of the model are beyond the scope of this thesis. However, since there is evidence towards a relationship with loneliness, hence, overall wellbeing, the impact will be mentioned briefly. Loneliness is seen as a characteristic of the individual influenced by molecular, genetic factors, and hereditability (Cacioppo et al., 2014; Harris, 2007). For instance, associations between increased cortisol levels have been demonstrated, affecting the inflammatory processes related to atherosclerosis, hypertension and coronary heart disease (Hawkley & Cacioppo, 2010). Moreover, loneliness predicts morbidity (Hawkley & Cacioppo, 2010; Verhagen, Ros, Steunenberg, & de Wit, 2014) and mortality among older people (Luo et al., 2012; Tilvis et al., 2011). One important negative consequence of feeling lonely or socially isolated is the decline in cognitive status and onset of dementia, where loneliness is seen as a predictor for dementia. In addition, dementia is seen as a barrier hampering social interaction resulting in loneliness (Hawkley & Cacioppo, 2010). According to Cacioppo et al. (2014) loneliness, from an evolutionary perspective is about promoting a person's genetic legacy which is dependent on caregiving, trust, cooperation and living in groups. Aspects of loneliness motivate the person to adapt to rapidly changing circumstances and thereby promote the genetic legacy. However, the prolonged survival rate of today, compared to our predecessors, does not match this mechanism. This may therefore have harmful consequences, although most individuals relieve their loneliness before harm occurs or even if not, new connections tend to be established over time (Cacioppo et al., 2014).

Frailty

For a person who is frail, it has been found to be vital to have and sustain social connections (Nicholson, Meyer, Flatley, & Holman, 2013). However, being frail is also associated with social isolation, feeling down, being anxious, physical limitations and not being able to do things one likes (Puts, Shekary, Widdershoven, Heldens, & Deeg, 2009). Among older people, across several nations, loneliness has been found to be associated with social isolation, physical and social losses, inactivity, and feelings of meaningless (Kirkevold, Moyle, Wilkinson, Meyer, & Hauge, 2013). Accordingly, older people who are frail could be particular vulnerable to experience loneliness. Despite the extensiveness in loneliness research among older people there is a paucity regarding frail older people, both in regards to loneliness and to associated factors concerning mental aspects of wellbeing.

The concept of frailty is generally accepted but the definition is not (Crome & Lally, 2011). Nevertheless, there is general agreement that frailty has a powerful negative impact on older people, their families and society at large (Karunananthan, Wolfson, Bergman, Béland, & Hogan, 2009). Two years ago, a consensus group formed a joint agreement defining physical frailty in the following statement:

> “a medical syndrome with multiple causes and contributors that is characterised by diminished strength, endurance, and reduced physiologic function that increases an individual’s vulnerability for developing increased dependency and/or death” (Morley et al., 2013, p.392)

Accordingly, being frail often means that a minor illness, such as a urinary tract infection, results in an dramatic and disproportional change in health status where the frail older person goes from independent to dependent, mobile to immobile, postural stable to prone to falling or going from being lucid to becoming delirious (Clegg et al., 2013) (Figure 2).

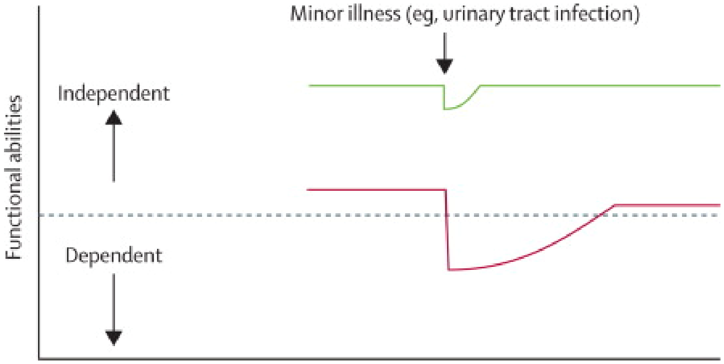

Figure 2. Vulnerability of frail older people resulting in disproportional change in health. The green line represent a fit older person undergoing a minor illness/stressor and then recovering. The red line represents a frail older person after a similar event, followed by a great deterioration. The dashed line indicate cut-off for independent to dependent (Clegg et al., 2013) © Lancet.

Physical frailty is a medical syndrome within a broader concept of frailty (Morley et al., 2013). Gobbens et al. (2010) conceptualises frailty in this broader sense by accounting for earlier formulated notions together with essential components of existing high impact definitions as follow:

> "Frailty is a dynamic state affecting an individual who experiences losses in one or more domains of human functioning (physical, psychological, social), which is caused by the influences of a range of variables and which increases the risk of adverse outcomes." (p. 342).

This emphasises frailty as being multidimensional, based on total functioning and a holistic view of the person (Gobbens et al., 2010). In western countries, frailty is found in approximately 20 to 30 per cent of the elderly population (75+ years) and has been shown to increase with age (Topinkova, 2008), where 25 to 50 per cent of older people over 85 years are estimated to be frail (Clegg et al., 2013). Frailty can be seen as a dynamic state on a continuum where accumulated deficits, such as multiple interacting illnesses, impairments, and disabilities increase the severity of the state (Clegg et al., 2013; Morley et al., 2013; Rockwood & Mitnitski, 2007). Being a dynamic state indicates a possibility of reversing or improving frailty, depending on the position in this continuum (Gobbens et al., 2010; Topinkova, 2008).

Commonly occurring physiological factors characterizing the phenotype of frailty are unintentional weight-loss, exhaustion, weakness, slowness and reduced physical activity (Clegg et al., 2013; Morley et al., 2013). However, numerous other variables have been found to be characteristic or predictive of frailty such as multi-morbidity, obesity, osteoporosis and difficulties with ADL (Lally & Crome, 2007). Among older people without cognitive impairment or psychiatric illness, primarily self-reported depression is associated with frailty, where increased severity in frailty increases the odds of psychiatric illness (Andrew & Rockwood, 2007). Frailty is also influenced by social factors such as frequency of contact with relatives and participation in community (Woo, Goggins, Sham, & Ho, 2004). There is an association with use of healthcare services and frailty (Crome & Lally, 2011), and when seeing frailty as a dynamic state, increased severity is followed by increased use of healthcare services (Rockwood, Song, & Mitnitski, 2011). Consequently, when identifying older people who are frail, dependency in ADL, and use of healthcare services can be used as general indicators, although they may not assess severity, the broadness of these two aspects can indicate reduced physiologic function and vulnerability.

The medical influence has dominated the conceptualisation and research agenda (Levers, Estabrooks, & Ross Kerr, 2006). However, social and psychological aspects of frailty are considered to be critically important, encouraging future research (Walston et al., 2006). To date, there is limited knowledge regarding loneliness among frail older people, regarding the individual experience, overall QoL and wellbeing, use of healthcare, and intervention strategies. Because of the complexity of frailty there is no generic treatment (Lally & Crome, 2007), and a holistic approach (Levers et al., 2006), with individually tailored interventions is emphasised (Crome & Lally, 2011). Therefore, by elaborating on aspects of loneliness, in the context of frail older people, further insights regarding overall wellbeing for this group of people may be gained, as well as implications for how interventions could be delivered.

Strategies to promote health and wellbeing: challenges and approaches

Due to the impact of wellbeing on older persons, the health system should provide supporting strategies to promote positive psychological states (Steptoe et al., 2014) and the importance of addressing loneliness and wellbeing in relation to potential health benefits has been stressed (VanderWeele et al., 2012). However, according to the National Board of Health and Welfare in Sweden there is no joint responsibility among the health services providers, *e.g.* geriatric care, psychiatric care, and primary care, when caring for older people with poor mental health. Consequently, older people are at risk of not receiving adequate care because of fragmentation and lack of sufficient knowledge among professionals regarding their complex physical and mental needs (National Board of Health and Welfare, 2013). It has been found that among older persons receiving home care in Finland (*n*=120, *M*=84 years), 28 per cent considered that those who cared for them (*i.e.* home service workers, nurses, physicians) were concerned about their feelings of loneliness whereas among the professionals, 55 per cent felt that they were concerned and regarded the care as good (*p*=<0.001) and similar results were found regarding feelings of depression (Eloranta et al., 2010). Accordingly, this indicates a discrepancy between receivers and providers in terms of satisfaction with care as well as psychological health needs not being recognized.

When caring for frail older people the approach taken should be subtle and personalised, where needs are assessed, preventive actions undertaken and the goals of the approach should matter for the person him/herself (Boeckxstaens & De Graaf, 2011). Given the notion of a possibility in decreasing the level of frailty (Fairhall et al., 2011; Morley et al., 2013; Rockwood & Mitnitski, 2007) identifying effective strategies, including assessing loneliness and related aspects seem essential. Various approaches to reduce prevalence or severity of frailty have been investigated in clinical trials (Clegg et al., 2013). Integrated and coordinated care, as in improving services in relation to access, quality, efficiency, and consumer satisfaction, as well as providing care that meets complex needs and is coherent across care settings and over time, has shown beneficial outcomes for frail older people (Eklund & Wilhelmson, 2009). However, as stated by Low, Yap, and Brodaty (2011) promoting physical and psychological health may be more important than improving satisfaction with services. Furthermore, according to Fairhall et al. (2011), there is a challenge in implementing evidence into clinical practice, and coordinating management of interventions addressing multiple issues. As a response to these challenges one approach to provide coordinated care by targeting multiple issues and promoting physical and mental health, including loneliness, could be through *case management.*

Case management

The origins of case management go as far back to the 1860s, although it was not until a century later, in the 1960s, that the term 'case management' was established (Kersbergen, 1996). Back then, case management was a response to a fragmented health system that lacked coordination (Kersbergen, 1996). Case management is considered to originate in social care to meet the needs of people with complex health and social problems (Hutt, Rosen, & McCauley, 2004). It can also be found in various settings, such as mental health, disability care, aged care as well as among health insurance companies (Kersbergen, 1996; You et al., 2012). The case managers providing case management are represented by multiple professions, such as nursing, social work, and rehabilitation, with some activities being profession specific and some sharing a commonality (Park et al., 2009). Nurses and social workers are traditionally the professions which dominate (Kersbergen, 1996). However, nurses play a key role when providing case management for frail older people, and are trained, preferably in gerontological practice, to undertake this role (Hallberg &

Kristensson, 2004). According to the Case Management Society of America, case management can be described as follows:

> “a collaborative process of assessment, planning, facilitation, care coordination, evaluation, and advocacy for options and services to meet an individual’s and family’s comprehensive health needs through communication and available resources to promote quality, cost-effective outcomes.” (CMSA, 2012).

Although, there is no single model or aim of case management, there are some unified core components, namely; case finding or screening *e.g.* of frail older persons, assessment, care planning, implementation, monitoring, and evaluation (Freund, Kayling, Miksch, Szecsenyi, & Wensing, 2010; Hutt et al., 2004). Patient advocacy case management models, also referred to as the socioeconomic model, focusing on patient centered and comprehensive coordination of services across the whole span of care, may be particular well suited for older people (Oeseburg, Wynia, Middel, & Reijneveld, 2009). Moreover, it is not mere medical needs that are assessed in this model, but also financial, psychological and social needs of the patient (Oeseburg et al., 2009). To achieve successful patient/client outcomes in case management, Ferry and Abramson (2006) highlights the importance of recognising, and addressing psychosocial problems as a prevalent issue, due to the strong negative influence on the older person. In addition, the relation between the user and the case manager, as well as the qualities of the case manager has also being emphasised for achieving a successful outcome (Ferry & Abramson, 2006).

In a systematic review by You et al. (2012) which evaluated the effects of case management for community-dwelling frail older people, 10 of the 15 studies were randomised controlled trials (RCT), and only one was rated as high quality. Accordingly, this indicates that there is a challenge in evaluating existing case management interventions and identifying successful approaches. Nevertheless, You et al. (2012) found indications that case management can improve frail older people’s subjective wellbeing, life satisfaction, and reduce depression. This finding is supported by previous research evaluating case management for frail older people, where reduction in depression and enhanced perceived social support has been reported (Markle-Reid et al., 2006).

Case management and loneliness

It appears as though no study has evaluated loneliness as a primary outcome in case management programmes for frail older people. However, qualitative research has demonstrated that case management, from the perspective of the receiver (>45-89 years), may have beneficial effects on their perceptions of psychosocial support, where participants experienced case management as reassuring, giving feelings of security, and social support, including fulfilling social needs (Williams, Smith, Chapman, & Oliver, 2011). This conclusion also applies to frail older people, in particular, where an increase in psychosocial support has been found (Sheaff et al., 2009) and has been regarded as equally important to clinical care among people with long-term conditions receiving case management (52-99 years, M=79 years) (Sargent, Pickard, Sheaff, & Boaden, 2007). Other, similar approaches to case management have been evaluated and the literature on interventions targeting loneliness is extensive, although the strategies and effectiveness varies. For instance, systematic reviews of interventions targeting social isolation and loneliness among older people (n=30 studies/n=32 studies), showed that those programmes involving the older person in planning, developing, and delivering activities were most likely to be effective (Cattan, White, Bond, & Learmouth, 2005; Dickens, Richards, Greaves, & Campbell, 2011). Other approaches for interventions have been suggested and in a recent systematic review (n=17 studies) it was found that those programmes involving new technologies such as internet video-based communication (e.g. Skype, FaceTime), a games console (Nintendo Wii) or a robotic dog, were shown to be most effective in reducing loneliness among older people (Hagan, Manktelow, Taylor, & Mallett, 2014). Furthermore, Masi, Chen, Hawkley, and Cacioppo (2011) underscores the importance of understanding the nature of loneliness, not being equivalent to social isolation, but a state where individuals who feel lonely act and think differently than when they are not lonely. Therefore, in their meta-analysis of interventions reducing loneliness (n=50 studies, all ages), it was concluded that the most successful interventions addressed 'maladaptive social cognition' through psychological reframing or cognitive behavioural therapy (CBT). The systematic reviews and meta-analysis of diverse strategies to reduce loneliness and social isolation (Cattan et al., 2005; Dickens et al., 2011; Hagan et al., 2014; Masi et al., 2011) elucidates the complexity and challenges in intervening against loneliness and it seems difficult to identify a ultimate strategy that works for all groups and settings. However, it does not make the importance of identifying effective strategies less important.

In regards to case management for frail older people, the lack of attention towards rigour, quantitative, evaluation of the effectiveness concerning loneliness, depressive symptoms and life satisfaction remains. Rockwood and Bergman (2012) concludes that the problem facing all health systems for ageing populations is that they are designed for treating one active illness at a time, although, it is not the burden of a single illness, but rather that these illnesses occur in people who have many other things wrong, which calls for person centred care and advocacy. Consequently, developing and evaluating strategies or programmes that are based on individual needs and preferences for promoting multiple aspects of wellbeing is warranted, not only from the perspective of the provider but also from the perspective of the receiver.

Aim

The overall aim of this thesis was to explore loneliness by identifying associated factors and predictors for loneliness among older people. This research was also undertaken to examine the association between loneliness and healthcare consumption. In addition, the reserach explored the experience of loneliness and evaluated the effects on loneliness, symptoms of depression and life satisfaction of a case management intervention for frail older people.

- To investigate prevalence, and predictors for loneliness over a six-year period among people aged 78 years or older. (Study I)
- To examine loneliness, health status and health complaints in relation to healthcare consumption of in- and outpatient care among older frail people living at home. (Study II)
- To explore the experience of loneliness among frail older people. (Study III)
- To investigate the effects of a case management intervention for frail older people living at home, focusing on loneliness, depressive symptoms and life satisfaction. (Study IV)

Methods

Design

The design of the thesis includes several methodological approaches for the purpose of exploring loneliness among older people and frail older people in particular.

Paper I has a longitudinal cohort design (Study I), Paper II has a cross-sectional design (Study II), Paper III has a qualitative design (Study III) and Paper IV has an experimental design (Study IV). An overview of Papers I-IV is presented in Table 1.

Table 1. Overview of Papers I-IV in the thesis

	Paper I	Paper II	Paper III	Paper IV
Design	Longitudinal cohort study	Cross-sectional	Qualitative	Experimental, RCT
Sample	*n*=828, age 78+ years, *M* 84 years	*n*=153, age 65+ years, *M* 82 years	*n*=12, age 73+ years, *M* 79 years	*n*=153, intervention group *n*=80, control group *n*=73, age 65+ years, *M* 82 years
Data Collection	Questionnaires, structured interviews, baseline, 3- and 6-years follow-up	Questionnaire, structured interviews, Registers	Individual, semi-structured interviews	Questionnaire, structured interviews, baseline, 6 and 12 month follow-up
Analysis	Student's *t*-test, Mann-Whitney *U* test, χ^2 test, Fischer's Exact test, Friedman test, Wilcoxon signed-rank test, Multiple logistic regression	Student's *t*-test, Mann-Whitney *U* test, χ^2 test, Multiple linear regression	Qualitative content analysis	Student's *t*-test, Mann-Whitney *U* test, χ^2 test, Fischer's Exact test, One-way-repeated-measures ANOVA, Cochran's Q test, Cohen's *d*, Relative Risk

A phenomena, such as loneliness is complex, and various methodological approaches can be used to generate information, including both breadth and depth regarding the phenomenon of interest (Polit & Beck, 2012; Teddlie & Yu, 2007). Therefore, both *quantitative* and *qualitative* approaches were applied in this thesis. In Papers I-II and IV various quantitative methods were used to assess cause and effect of loneliness through the answers of different questionnaires by the participants. In Paper III, a qualitative content analysis method was applied to illuminate meanings of loneliness as narrated by the participants, *i.e.* frail older people.

Complex interventions

The intervention evaluated in Paper IV was a complex intervention. Such an intervention can be described as containing several interacting components, with a difficulty in standardising the design and the delivery of the intervention (Craig et al., 2008a). As a reuslt of the complex nature of these interventions, there are difficulties in evaluating which suggests methodological as well as practical challenges (Craig et al., 2008b). The Case Management Study, which Paper IV aims to evaluate, was considered to be a complex intervention because of the many interacting components, the flexibility permitted within the intervention in regards to the individual tailoring as well as the number and variability of outcomes. Therefore, when designing the intervention study, the Medical Research Council's (MRC) framework for developing and evaluating complex interventions was adapted (Craig et al., 2008a). According to MRC there are four key elements when developing and evaluating a complex intervention: *Feasibility/piloting* (I) includes testing procedures, estimating recruitment and retention and determining sample size. *Development* (II) includes identifying the evidence base, identifying/developing a theory, modelling processes and outcomes. *Evaluation* (III) includes assessing effectiveness, understanding change process and assessing cost-effectiveness. *Implementation* (IV) includes dissemination, surveillance and monitoring and long term follow-up (Craig et al., 2008b). It should be noted that the key elements are not stepwise and interactions between the phases will occur as a part of the overall process (Craig et al., 2008a). A systematic review was undertaken to explore the evidence base of home care for frail older people (Hallberg & Kristensson, 2004), forming a rationale for the intervention. An intervention program was developed and pilot tested (Kristensson, Ekwall, Jakobsson, Midlöv, & Hallberg, 2010), including modelling of processes and outcomes, as well as assessing feasibility. The Case Management Study has been evaluated by assessing cost effectiveness and effect on healthcare consumption (Sandberg, Kristensson, Midlöv, & Jakobsson, 2015), as well as effect on falls (Möller, Kristensson, Midlöv, Ekdahl, & Jakobsson, 2014). In addition, there is one qualitative study aiming to explore the receivers and providers' experiences of a complex intervention (Sandberg, Jakobsson, Midlöv, & Kristensson, 2014). The key elements, mainly *Feasibility/Piloting* and *Development*, formed the base on which Paper IV stands on. However, the result in this thesis is mainly based on *Evaluation,* as in assessing effectiveness.

Sampling, procedure and settings

In Paper I the sample was comprised of 828 people aged 78 years or older and was drawn from the Swedish National Study on Aging and Care (SNAC). SNAC is a longitudinal, multicentre study involving four research centres in Sweden: Blekinge, Kungsholmen, Nordanstig and Skåne. The sample in Paper I was drawn from the center situated in the region of Blekinge (SNAC-B), in South-Eastern Sweden. SNAC-B covers one municipality with approximately 60, 600 inhabitants including rural and urban areas.

For the purpose of gaining comprehensive knowledge about the ageing process, the care and services for older people as well as the interplay between them, SNAC was designed to comprise of two parts: a population part and a care and services part (Lagergren et al., 2004). In Paper I data based on the population part was used. In the population part older people in ten different age cohorts were followed over time to describe and document different aspects of the ageing process such as health status, functional and cognitive ability, personality, social situation, life satisfaction and quality of life among others (Lagergren et al., 2004). The age cohorts began at 60 years and continued up to 96 years. Follow-ups were made with six year intervals for those cohorts aged 60 to 78 years (60, 66 ,72 , 77) and third year intervals for those cohorts aged 78 to 96 years (78, 81, 84, 87, 90, 93, 96). Among the cohorts 60-78 years, random sampling stratified for age was applied. However, among those cohorts starting at 81 years, all inhabitants in the region were selected (Halling & Berglund, 2006). An invitation to take part in the study and visit a research center was mailed out to potential participants on two occasions. For those who did not respond to the mailed invitation an additional invitation by telephone was made. At baseline in 2001-2003, the total sample in SNAC-B included 1, 402 participants. For Paper I the sample includes those age cohorts starting at 78 years and followed-up every third year, with *n*=828 at baseline in 2001 to 2003, *n*=511 in 2004-2006 and *n*=317 in 2007-2009. Among the 2, 312 potential participants who were invited to take part a total of 61 per cent agreed to do so. The reason was registered for those who declined to participate (Rennemark, Holst, Fagerstrom, & Halling, 2009). Reasons for not participating were: unwillingness (83%), being too ill (10%) and failure to reach potential participants (7 %). Gender distribution for non-participants was 39 per cent men and 61 per cent women (Rennemark, Lindwall, Halling, & Berglund, 2009). The response rate varied between 55 to 75 per cent and was highest for the younger cohorts and lowest for the oldest cohorts. An over-sampling in the oldest cohorts resulted in an age distribution where those participants aged 70 to 79 years represented 25 per cent, 80 to 89 years made up 38 per cent and 90 years or older comprised 9 per cent of the total sample (*n*=1402) (Fagerström, Persson, Holst, & Hallberg, 2008).

Papers II and IV are based on the Case Management Study, which is a study with a non-blinded, two-armed RCT design with repeated follow-ups, including a quasi-experimental cross-over design (Shadish, Cook, & Campbell, 2002). The setting was a Swedish municipality, with both rural and urban areas, in the County of Skåne with approximately 30, 000 inhabitants. In total, 153 participants were consecutively recruited between October 2006 and April 2010 from three primary healthcare centres in the municipality (*n*=117), by the participants contacting the research group themselves (*n*=3), at three clinics at the university hospital (*n*=20) or through the municipal home care (*n*=13). At the hospital nurses involved in the RCT screened for potential participants and gave information about the study. When consent was given the potential participant was contacted by a member of the research team for further information and assessment. In primary and municipal care staff identified possible participants whom were contacted by the research team for further information and eligibility assessment. Information leaflets were posted at various settings so that potential participants could contact the research team for information. In addition, a screening procedure was performed. All those aged 65+ years with four or more registered visits in primary care the previous year, were contacted by telephone or mail with information. Those contacted by mail also got a prepaid envelope and a reply form and were asked to send in consent that they allowed the research team to contact them to give additional information.

Inclusion criteria for the Case Management Study, hence, the samples in Papers II and IV, was that the participants should be living in an ordinary home in the municipality, be in need of assistance in two or more self-reported ADL, had been admitted to hospital on two or more occasions, or had been visiting primary/outpatient care at least four times during the last 12 months prior to being included. The participants were also required to communicate verbally and have no severe cognitive impairment. The Mini Mental State Exam (MMSE) (Folstein, Folstein, & McHugh, 1975), scoring from zero to 30 points, was used at baseline to measure cognitive status, where 30 points indicates no cognitive impairment. A cut-off value was used excluding all participants below 25 points. A total of 1, 079 potential participants were approached. Out of these, 926 were excluded: 231 did not meet the inclusion criteria, seven died before randomisation and 688 could not be randomised. The main reason for not being randomised was failure to respond to the letter in the primary care register recruitment procedure (*n*=571). Other reasons were inability to contact prospective participants (*n*=28), unwillingness to participate (*n*=71) or prospective participants feeling too tired or too ill (*n*=18) (Figure 3).

Members of the research team carried out the randomisation procedure using sealed envelopes containing a note informing the team member if the participant was allocated to the control or the intervention group. The possibility of being randomised to either group was equal and the procedure was undertaken after inclusion and prior to baseline. In Papers II and IV, 153 participants were included at baseline; 80 participants were randomised to an intervention group and 73 participants were randomised to a control group (Figure 3). For the cross-sectional design in Paper II the baseline assessment, including the intervention and the control group as a consolidated sample, was used along with healthcare consumption data. In the Case Management Study the participants were followed-up at three, six, nine, 12 and 24 months. In Paper IV the participants were followed-up at six and 12-months. Of the 153 participants randomised, 108 participants remained at the 12-month follow-up (*n*=12 died, *n*=33 dropped out), leaving 56 participants in the intervention group and 52 participants in the control group (Figure 3).

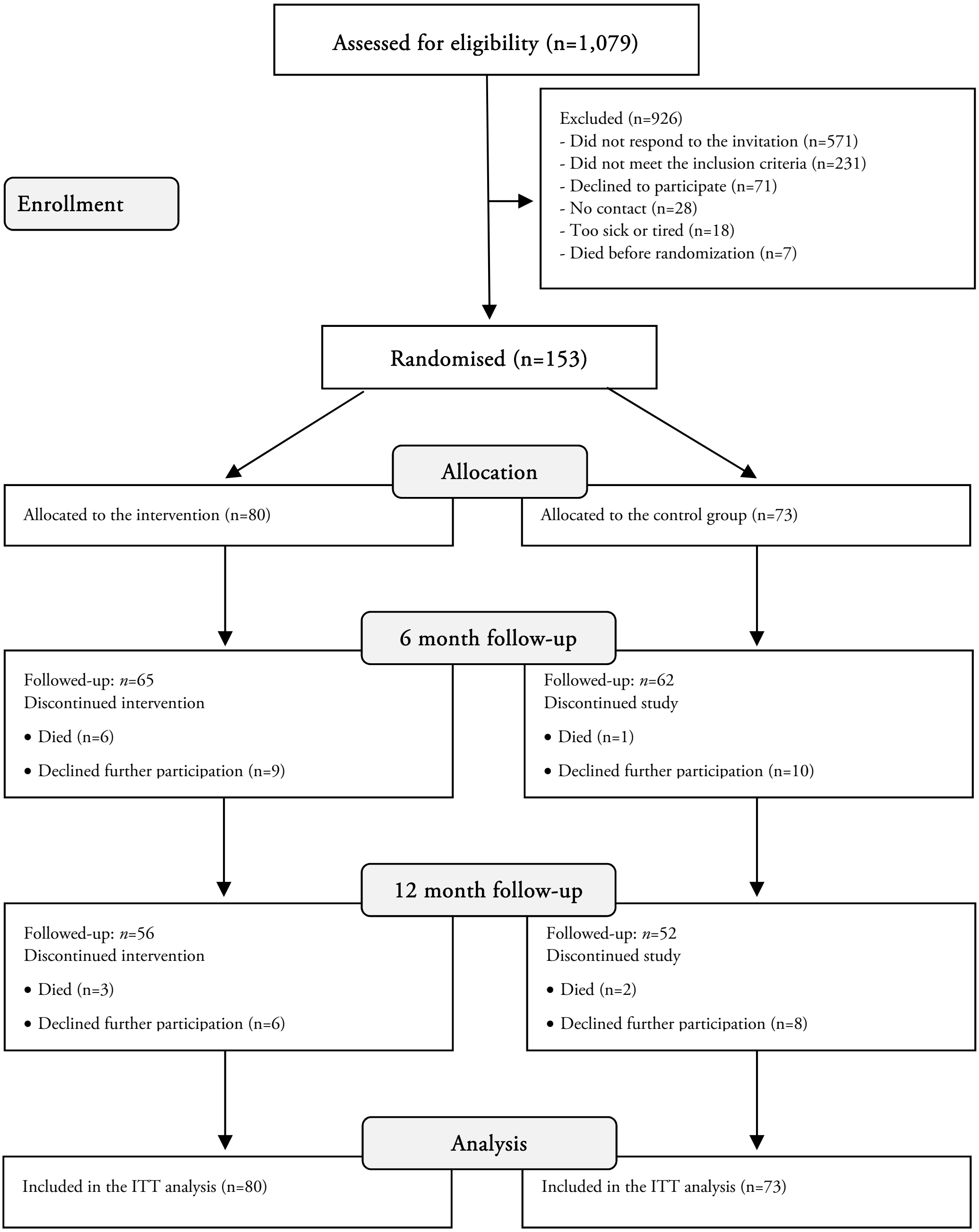

Figure 3. CONSORT flow diagram for the Case Management Study (Papers II and IV

For Paper III a purposive sample strategy was applied (Polit & Beck, 2012). The sample (*n*=12) was selected from the Case Management Study, hence the same inclusion criteria and setting. In addition, to be able to select those participants who had experience of the phenomenon one further inclusion criterion was made. The criterion was based on a single-item question in the questionnaire used in the Case Management Study, namely: *When you feel lonely, how strong is your feeling of loneliness?* a) Very strong b) Quite strong c) Neither strong nor weak d) Quite weak e) Very weak f) I don't feel lonely. The alternatives a-e served as inclusion criterion. When selecting participants, maximum variation sampling was sought, deliberatly selecting participants with different viewpoints and backgrounds to achieve richness in data (Polit & Beck, 2012). Primarily, this was done by including participants with diverse experiences in intensity but also in terms of gender and marital status. The first author (ET) identified potential participants when conducting structured interviews in the Case Management Study. The potential participant was verbally informed about the purpose, procedure and confidentiality of the study as well as the right to decline or withdraw at any time was given to the them. It was emphasised that the involvement in the intervention study was not affected by their answer. The first author made an appointment with the participant, face-to-face or by telephone if they expressed interest in participating. In total, 18 potential informants were consecutively approached. Reasons for not being interviewed were either declining participation or dropping out from the intervention study. For the included participants repeated verbal information and additional written information regarding the purpose of the study was given as well as the right to withdraw. The participants were also informed about the possibility to receive emotional support after the interview, if needed, through the nurse case managers, either by the case managers themselves or referring to other professional expertise. However, none of the participants used this option. Among those participants included, seven belonged to the intervention group and five to the control group. Participants randomised to the intervention group were interviewed either before the launch of the intervention but after baseline assessment or after the intervention was ended and follow-up assessment conducted. Note that one participant, randomised to the intervention group, was interviewed six months after launching the intervention.

The case management intervention

The intervention was given during a 12-month period and begun after the baseline assessment. In total, there were six case managers who delivered the intervention, four nurses and two physiotherapists. These case managers were employed on a part-time basis for between two and five years. During the study, two nurse case managers and two physiotherapists were employed at the same time. All case managers had experience of caring or rehabilitating older people from either geriatric wards at a hospital or in either municipal care or primary care centres. Participants in the intervention group were given a case manager from each profession. However, it should be noted that in the piloting phase of the intervention, there was only a nurse case manager (Kristensson, Ekwall, et al., 2010). The physiotherapist case manager was introduced after the piloting phase. Therefore, out of 80 participants in the intervention group 61 participants were given a case manager from both professions. After the piloting phase, two case managers (the nurse and physiotherapist) did either a visit together or separately. This occurred at least once a month for each case manager or more frequently if needed. Primarily, visits were made at the participants' homes. However, if the participant was hospitalised, the case managers could make visits at the hospital.

During the first visit the case managers made initial overall assessments. The nurse case manager used the Minimum Data Set for Home Care (MD-HC) (Landi et al., 2000), which is a comprehensive geriatric assessment tool covering demographic characteristics, functional and cognitive status and nursing needs. MD-HC was also used as a part of a regular assessment and follow-up during the intervention for the purpose of identifying problems and intervention needs. The physiotherapist case manager asked questions concerning physical abilities *e.g.* ADL, mobility aids and physical activities physiotherapist. As tools for initial and follow-up assessments the physiotherapist case manager used the General Motor Function Assessment Scale (Åberg, Lindmark, & Lithell, 2003), the Berg Balance Scale (Berg, Wood-Dauphineé, Williams, & Gayton, 1989), an ADL-staircase (Åsberg & Sonn, 1988) and a sensibility test (Kristinsdottir, Jarnlo, & Magnusson, 1997). Based on the assessments performed and together with dialogue with the participant, a care plan was developed, comprising of goals for the intervention. This care plan was monitored, evaluated and if needed, revised during the course of the intervention.

The intervention comprised of four main components: *general case management* (I), *general information* (II), *specific information* (III) and *continuity and safety* (IV) (Kristensson, Hallberg, & Ekwall, 2010; Sandberg, 2013). *General case management* (I) included assessment of lifestyle, functional and cognitive status and nursing needs of the individual. This component also included establishing a care plan, its monitoring and evaluation. Moreover, general case management comprises care coordination, navigation in the health system and advocating as well as encouraging social activities. This could mean guiding, assisting and supporting participants in their contact with different establishments in the health system. In addition, guiding towards an accurate level of care, accompanying the participant to outpatient visits as well as encouraging social activities, if needed, were included in this component. *General information* (II) was provided regarding the health system, as well as details concerning ageing and its consequences. This could mean informing about nutrition in old age or how the health system is organised. Information was also given regarding activities arranged by the municipality, such as social activities. *Specific information* (III) comprised of information focusing on the participants' specific health problems and needs, including the use of medication and exercise as well as psychosocial aspects. This could, for example, mean how and when to administer a certain medical product to achieve the optimal effect or give ideas and support for what to do if feeling lonely or isolated. *Continuity and Safety* (IV) included availability and reachability. This meant that the case managers were reachable by telephone to participants during office hours. They were there to answer questions, assist in solving problems as well as to provide assistance in crisis situations. The ambition was also to achieve continuity *i.e.* being assigned to the same case managers during the whole course of the intervention. The nurse and physiotherapist case managers intervened according to the four main components (I-IV), although focus differed depending on the professional expertise. The nurse case manager focused on nursing care, such as health and medications, as well as psychosocial aspects. The physiotherapist case manager focused on fall prevention and physical functioning. Moreover, the physiotherapist case manager could include a social activity as a part of an exercise session and the nurse case manager used a similar approach where a social activity could be combined with a practical errand, such as stopping for coffee on the way to the pharmacy. The case managers documented the given interventions to each of the participants and kept diaries with personal reflections (Kristensson, Ekwall, et al., 2010).

The case managers could contact a physician involved in the study if they needed to. This could for example be if a severe medical problem arose. It should be noted that if a member of the research team detected a severe problem among one of participants in the control group the same procedure could be applied. Moreover, the case managers also collaborated with the research group both by telephone and by attending steering group meetings. During the steering group meetings, the case managers presented specific participant cases that were brought up for discussion both from a problem solving aspect and/or success aspect. Finally, in both the intervention and control group, an evaluation of the participant's prescribed medications was made where a physician involved in the project reviewed the prescribed medications for inaccuracies.

Each nurse case manager made an average of 11 visits and two phone calls throughout the the course of the 12-month intervention period to those participants who completed the intervention. The physiotherapist case managers made each, on average, ten visits and one phone call. For participants who dropped out the mean duration of the intervention period was five months with four visits and one phone call on average from the nurse case managers and three visits and one phone call in average from the physiotherapist case manager (Sandberg, 2013). The participants in the Case Management Study, both intervention and control groups, were receiving standard care (see first section in Background) during the entire sudy including the intervention phase.

Data collection

In Paper I data was collected at a research centre by a trained research team, consisting of registered nurses and physicians. During the first visit at the research centre, medical examinations and structural interviews were conducted. The visit took approximately three hours and was divided in two sessions. In addition, a supplementary questionnaire was given to the participant to fill in between the two sessions. Those respondents who could not make it to the research centre were offered to be examined in their homes (Rennemark, Holst, et al., 2009). If needed, the respondents were also offered help to complete the questionnaire.

In Paper II data was collected by means of structural interviews in the participants' homes. A research team of trained research assistants and doctoral students collected the data. Healthcare consumption data was collected from two patient administrative registers in a time frame between 12 to zero months prior to collection of baseline data for the Case Management Study. These two registers were: Patient Administrative Support in Skåne (PASiS), which is a register for all publicly organised in- and outpatient healthcare in the county council in the region of Skåne, Sweden, and PrivaStat, which is the register for all privately organised outpatient care in the same region.

The data collection in Paper III consisted of face-to-face, semi-structural interviews performed by the first author (ET) in the respondents' homes. An interview guide was used covering different aspects of loneliness and in relation to everyday life. The purpose of the guide was to ensure that required information was obtained while at the same time allowing participants to speak freely and provide as many explanations as they wished (Polit & Beck, 2012). The interviewer started out with asking general questions such as: *"Can you please tell me what a regular day looks like for you?"* or *"What are your interests?"*. After the respondent was getting more comfortable in the situation the interviewer asked questions such as: *"Can you please describe an occasion when you felt lonely?"* or *"Is there anything that would make you feel less lonely?"* . Probing questions *e.g. "Can you tell me more about that please?", "How did it make you feel?", "Are there any other examples?"* were used to obtain more detailed information, enhance richness, and facilitate narration (Polit & Beck, 2012). The guide was developed by the first author by supervision from the last author (JK). Two pilot interviews were performed using the guide for the purpose of evaluating the questions and refining the data collection (Creswell, 2013). Since no major revisions were made of the guide the two pilot interviews were included in the study. The interviews were digitally recorded and transcribed verbatim by the first author. The interviews were conducted between December 2009 and August 2011 and lasted between 47 and 119 minutes. The sample size was determined using the principle of data saturation, meaning that interviews were performed until it was considered that no new information emerged (Polit & Beck, 2012). According to Morse (2000) reaching the point of saturation depends on several factors such as scope of the study, nature of the topic and useful information obtained from each participant *i.e.* data quality. It will take longer time to reach saturation when using a broad scope of the research question and the topic is difficult to grasp. However, fewer number of participants are needed when obtaining a great amount of useful data (Morse, 2000). The decision of reaching the point of saturation was taken in discussion with the last author. Each participant was assigned a code number, identical with their code number in the Case Management Study, which could only be accessed by members of the research team.

Measurements

Various instruments, scales and single-item questions were used in Papers I-II and IV. In Papers I, II and IV questions covering socio-demographic aspects were used with additional measurements as follows.

Single item questions

Loneliness was measured with four single-item questions with response alternatives. For Papers I-II and IV the single-item questions were similar but not identical. However, the questions covered if the respondent felt lonely at a) present as well as loneliness by the experienced b) frequency in the past five years (Paper I) or the past year (Paper II), c) intensity and d) comparability with others of the same age. The questions in Papers II and IV had previously been used (Ekwall, Sivberg, & Hallberg, 2005). Using self-reported single-item questions when assessing loneliness appears to be acceptable to participants in research studies (Luanaigh & Lawlor, 2008). The straightforward approach, such as asking about direct feelings of loneliness, and the feasibility are additional benefits when using this approach (Victor, Grenade, & Boldy, 2005). Other single-item questions were used, primarily in Paper I, to cover social contacts in the form of having a confidant, wanting more contact with friends, family and neighbours and contact with children of their own.

Instruments and scales

In Paper I, ADL was assessed by using the *ADL staircase,* based on a cummulative measure of functional performance in PADL and IADL (Åsberg & Sonn, 1988). The ADL staircase (Åsberg & Sonn, 1988) is an extended version of the Katz' ADL Index (Katz, Ford, Moskowitz, Jackson, & Jaffe, 1963) adding four IADL's. PADL's includes the activities: bathing, dressing, going to the toilet, transfer, continence and feeding. IADL's includes the activities: cleaning, shopping, transportation and cooking. The staircase assesses dependency (on another person) (1 point) or independency (0 points) in each of the activities, generating a score ranging from zero points as in independent in all ten activities to ten points as in dependent in all ten activites. The reliability and validity of the scale has been shown to be acceptable (Jakobsson, 2008; Åsberg & Sonn, 1988) with an internal validity (Cronbach's α) of 0.85 among people aged 75 to 89 years and of 0.85 among people 90 years or older (Jakobsson, 2008). The ADL staircase is appropriate for assessing the ability to perform ADL among individuals, groups and populations (Sonn, 1996) and appears to be more suitable for older people in particular (Jakobsson, 2008).

One item from the *Downton Fall Risk Index* (DFRI) (Downton, 1993) was used to assess whether prescribed anti-depressive medication was used among the participants in Paper IV.

The EuroQol instrument, *EQ-5D,* was used for assessing HRQoL/health status in Papers I and II. The EQ-5D covers five dimensions of self-reported health: mobility, self-care, usual activities, pain/discomfort and anxiety/depression (Brooks, 1996). There are three response levels to each of the five dimensions that can be used: no problems, some problems and severe problems. Together, the dimensions and response levels generate 243 (3^5) possible health states. By using a regression technique, based on health states in a representative sample of the population in the United Kingdom (UK) (*n*=2, 997), a tariff (the A1 York tariff) was created generating values ranging from -0.54 to 1.00 (Dolan, 1997; Dolan & Roberts, 2002). This tariff was used to obtain values for the data included in Papers I-II and IV. The highest score (1.00) indicates perfect health and the score of 0.00 indicates dead (Wolfs et al., 2007). However, scores can result in negative values meaning that there are health states worse than dead (Dolan, 1997). The EQ-5D instrument also contains a visual analogue scale (VAS), ranging from zero (worst imaginable health state) to 100 (best imaginable health state) on which the participant was asked to score his/hers current health status (Brooks, 1996). The instrument was simultaneously translated into Swedish and other languages by the EuroQol group during the development of the instrument (Rabin & Charro, 2001). Psychometric properties of the instrument, including the VAS, have been evaluated resulting in adequate performance in terms of convergent and construct validity among individuals ≥ 45 years in the UK (*n*=1, 737) (Barton et al., 2008).

When assessing the risk for depression in Papers II and IV the 20-item Geriatric Depression Scale, *GDS-20*, was used (Gottfries, Noltorp, & Noergaard, 1997). The GDS scale aims to measure symptoms of depression in older people and was developed by Yesavage et al. (1983). A further development of this 15-item GDS was made by Gottfries et al. (1997), with five extra items covering additional symptoms of importance in depressed older people. The GDS-20 comprises statements with self-reporting dichotomous response alternatives (yes/no). This generates a score between zero to 20 point on which a ≥ 6 points cut-off indicates that depression must be suspected (Gottfries et al., 1997).

Levels of life satisfaction was assessed with the Life Satisfaction Index-Z, *LSIZ* (Wood, Wylie, & Sheafor, 1969) which is a shorter version of the Life Satisfaction Index-A, LSIA (Neugarten et al., 1961). The scale consists of 13 items of both positive and negative statements about life in general, on a three-point Lickert scale (*agree; don't know; disagree*) (Wood et al., 1969). The score ranges from zero to 26 points, a higher score indicates greater life satisfaction (Fagerström et al., 2008). The LSIZ has been used previously on samples drawn from older populations (60+ years) and shown an internal consistency between 0.76 and 0.80 (Cronbach's α) (Borg et al., 2006; Fagerström et al., 2008). The LSIZ was used for the analyses in Papers I and IV.

For the assessment of cognitive impairment in Paper I the Mini Mental State Exam, *MMSE,* was used (Folstein et al., 1975). The instrument captures cognitive aspects of mental functions through eleven items comprising questions and tasks covering *e.g.* orientation, memory, attention, compliance to verbal commands, and copying a geometrical figure. Each item is given a score yielding a total score ranging from zero to 30 points, where 30 points indicates no cognitive impairment and lower scores indicates greater cognitive impairment (Folstein et al., 1975).

The Neo Five Factor Inventory, *NEO-FFI,* was used to clasify personality domains (Costa & McCrae, 1992) in Paper I. The 60 item NEO-FFI is a short form of the 240 item NEO-PI-R (Neo Personal Inventory Revised)(Costa & McCrae, 1992; McCrae & Costa, 2003). There are 60 items in the instrument that describe the five basic personal domains of personality: *Openness to Experience*, *Conscientiousness*, *Extraversion*, *Agreeableness*, and *Neuroticism*. The items are based on both positive and negative statements on a five-point Lickert scale (*strongly disagree; disagree; neutral; agree; strongly agree*). The self-reported response alternatives are summed up and generate five domain scores. Low and high scores from the domains are then used to characterise the participants according to the descriptions of the five personality factors. The 60-item version of the instrument gives an estimate of the five factors and is recommended mainly for exploratory research (McCrae & Costa, 2004). The instrument is widely used and has been shown to be valid and reliable in various contexts (McCrae & Costa, 2004). An internal consistency between 0.68 to 0.86 and a test-retest reliability ranging between 0.86-0.90 for the five domains has been reported (Robins, Fraley, Roberts, & Trzesniewski, 2001). In Paper III, a previously used Swedish version of the NEO-FFI was applied for the assessment (Rennemark & Berggren, 2006).

In total, 32 questions regarding common *health complaints* among older people were used in Papers I, II and IV. The questions included a revised version (Stenzelius, Westergren, Thorneman, & Hallberg, 2005) based on an original version developed by Tibblin, Bengtsson, Furunes, and Lapidus (1990). The questions cover 32 symptoms such as dizziness, difficulty walking, pain, among others assessed by their presence and severity during the past three months with four response alternatives ranging from *'no'* to *'very much'*. In Paper I, 11 of the health complaints were used, selected for their relevance in previous research. In Paper II all 32 complaints were used, including a total number of all reported complaints. Each health complaint was dichotomized where the *'no'*-alternative generated zero (0) and the other three alternatives generated one (1), summing up to a total number between zero to 32 complaints. In Paper IV, the item assessing depressed mood was used as a single item question.

Healthcare consumption

Beyond other applied measurements in Paper II, variables based on data regarding the use of in- and outpatient care were used. In regards to inpatient care, the number of visits and length of stay (LoS) for acute and planned care were included and for outpatient care as follows; the number of visits and contacts (face-to-face, telephone, other) with a physician and number of visits at the emergency department leading to admission to hospital or not. An acute admission could occur at any ward at the hospital and was registered as inpatient care. Visits at the emergency department were registered as outpatient care and could be categorized into visits leading to hospital admission or not.

Measured outcomes in relation to the quality of life model

The single item questions, the instruments, the scales as well as healthcare consumption can be applied to the extended QoL model (Ordoñana et al., 2013; Sprangers et al., 2010). Table 2 provides and overview of the assessments in relation to the levels and characteristics of the model. Because of the study design, Papers III and IV are not included.

Table 2. Assessments of indicators in Papers I-II, in relation to the QoL model.

Level/Characteristic	Assessment	Paper
Characteristics of the individual	Loneliness[a]	I, II
	NEO-FFI[b]	I
	Age, gender, marital status	I, II
Characteristics of the environment	Perceived social support	I, II
	Living arrangements	I, II
	Healthcare consumption	II
Symptom status	Health complaints including depressed mood[c]	I, II
	MMSE[d]	I
Functional status	ADL[e]	I
General health perceptions	EQ-5D[f]	I, II
	EQ-5D-VAS[f]	II
Overall QoL	LSIZ[g]	I, II

[a]Ekwall et al. (2005); [b] Costa & McCrae (1992); [c]Tibblin et al. (1990), Stenzelius et al. (2005); [d]Folstein et al. (1975); [e]Åsberg & Sonn (1998); [f]Brooks (1996); [g]Wood et al. (1969)

Analysis

Statistical analysis

In Papers I, II and IV descriptive and inferential statistics were used. For the inferential statistics hypothesis testing according to the null hypothesis was applied using an alpha level of 0.05 or less as statistically significant *i.e.* the null hypothesis could be rejected (Altman, 1991). It should be noted that for multiple comparisons, as in a post-hoc test, a reduced *p*-value according to the Bonferroni correction method was applied, controlling for Type I error *i.e.* making false positive conclusions (Altman, 1991). All statistical analyses were performed using PASW Statistics 18.0 or IBM SPSS Statistics 20.0-22.0.

In Paper I comparisons were made between two groups: those individuals who reported loneliness and those who did not. The single item-question *'Do you ever feel lonely?'* with four response alternatives was dichotomized as not lonely (0), including individuals who had answered *'never'* or *'seldom'* and, as lonely (1) if the individuals had answered *'sometimes'* or *'often'*. Loneliness was the dependent variable throughout the entire analysis. When describing the sample mean scores (*M*), standard deviations (*SD*), frequency and percentage was used. For statistics on nominal or ordinal data level, the Chi-square (χ^2) test or Fisher's Exact test was used. For normally distributed data (parametric) on interval or ratio data level, the Student's *t*-test was used and the

Mann-Whitney *U* test for data which was not normally distributed (non-parametric). The Friedman test was used for repeated measures and for post-hoc analysis the Wilcoxon Signed Rank test.

A multiple logistic regression analysis with a backward, manual approach, was performed for the purpose of identifying possible associated factors and predictors for loneliness. Three models were made, for each year respectively (2001, 2004, 2007). Following independent variables from baseline data (2001) was included in the models: gender (male=0/female=1), age, marital status (married=0/widower/ers=1), living alone (no=0/yes=1), ADL-score, health status (EQ-5D), life satisfaction (LSIZ), health complaints (depressed mood, fatigue, pain in extremities, difficulty hearing) (no=0/yes=1), personality traits (openness, conscientiousness, extroversion, agreeableness, neurotic) (NEO-FFI), cognitive impairment (MMSE) and lacking friends (no=0/yes=1). This set of variables were used for all the models with an addition of one variable; 'lonely at baseline' (no=0/yes=1), for the models identifying predictors in 2004 and 2007. The dependent variable was *'Do you ever feel lonely?'* (no=0/yes=1) for each measuring point and model respectively *i.e.* 2001, 2004, 2007. For the regression models' goodness-of-fit the Hosmer and Lemeshow goodness-of-fit-test, where a non-significant result indicates a good fit, and the Nagelkerke R^2 was used. Odds ratio (*OR*) and unadjusted *OR* was used to report the odds of the outcome in the lonely group compared to the odds of the outcome in the not lonely group. A 95 per cent confidence interval (CI) was adapted for the *OR*s. The model for the first measuring point in 2001 identified independent associated factors for loneliness and the models for the two follow-ups identified independent predictors for loneliness.

In Paper II loneliness was the dependent variable in most of the analyses and divided the sample into two groups based on the question; '*Looking back at the last year, which of the following alternatives corresponds with you?*' with four response alternatives. Those individuals who chose the response alternative '*I have not felt lonely at any occasion the last year*' were included in the 'not lonely' (0) group. Those individuals who chose the response alternatives '*I have experienced single occasions of loneliness*', '*I have experienced recurring periods of loneliness*' or '*More or less, I have experienced a constant feeling of loneliness*' were included in the 'lonely' group (1). Moreover, a dichotomization was made for each of the items covering health complaints, 0='no'-alternative and 1='yes'-alternatives. For comparisons between the two groups the following statistical tests were used: on nominal level the χ^2 test, for parametric data on interval/ratio level the Student's t-test and for non-parametric data on interval/ratio level the Mann-Whitney *U* test. All the analyses on healthcare consumption data was performed with the Student's *t*-test, supported by the central limit theorem *i.e.* means will approximate a normal distribution if the sample is large enough (>30) (Norman & Streiner, 2008). Median (*Mdn*), quartiles (*q*), *M*, *SD*, range and percentage were used for reporting the results.

A multiple linear regression analysis was performed with a backward, manual approach. The dependent variable was *'Total number of visits for outpatient care'* comprising the number of contacts with a physician including face-to-face visits, telephone contacts, and other contacts as well as the number of acute visits leading to hospital admission. The model, controlling for age, included the independent varibales "lonely" (no=0/yes=1) and health complaints who were significant in the bivariate analyses, namely: difficulties hearing, memory problems, dizziness, loss of appetite, nervousness and depression. The quality of the model was ascertained by the Hosmer and Lemeshow goodness-of-fit-test, the Nagelkerke R^2 and to rule out possible multicollinearity, estimated tolerance index and variance inflation index (VIF) which indicated no such risk *i.e.* tolerance <0.10 and VIF >10 (Norman & Streiner, 2008) In addition, to support the assumption of homoscedasticity, the residuals were visually examined through a probability plot with no apparent pattern (Norman & Streiner, 2008). When reporting the result of the regression model the unstandardised *B* was used.

The effect of the Case Management intervention was of interest in Paper IV. Three primary outcomes were chosen for this evaluation, namely; loneliness, depressive symptoms (GDS-20) and life satisfaction (LSIZ). Loneliness was assessed by the single item question *'Do you feel lonely nowadays?'* with three response alternatives (*'Yes, I feel very lonely', 'Yes, I feel rather lonely', 'No, I don't feel lonely'*). The response alternatives were dichotomized into not lonely ('no'-alternative=0) and lonely ('yes'-alternatives=1). In addition, for the purpose of describing background charactersistic single item questions covering socio-demographic aspects as well as use of municipal care were applied togheter with ADL-score, health status (EQ-5D), health complaints (no=0/yes=1), prescribed anti-depressive medication (no=0/ yes=1, DFRI) and having a confidant or not (yes=0/ no=1). For comparisons between the intervention (0) and the control group (1) the following tests were used; the χ^2 test or the Fischer's Exact test for nominal data, the Student's *t*-test for parametric data on interval/ratio level, the Mann-Whitney *U* test for non-parametric data on interval/ratio level. For comparisons over time One-Way-Repeated-Measures ANOVA and Cochran's Q test was used for interval and nominal data respectively. When significant values the effect size (ES) was determined by using Cohen's *d* for interval data, where 0.20 was considered to be a low effect, 0.50 a medium effect and 0.80 a large effect (Cohen, 1992). For nominal data, the relative risk (RR), presented in percentage, was used instead as an indicator of ES. In addition, differences (Δ) in the ES was calculated for the primary outcomes between the intervention and control groups for baseline and six months and baseline and 12 months, in accordance with the values suggested by Cohen (Cohen, 1992) or if RR in percentage.

Study IV, presented in Paper IV, was performed according to the *intention-to-treat principle* (ITT) (Polit & Gillespie, 2010). The three primary outcomes were included in the ITT-analysis whereas the other variables were considered as background variables, hence, not included in the ITT-analysis. In addition, for the primary outcomes a *complete case analysis* (CC) was performed. The purpose of an ITT-analysis is to keep all participants in the group that were initially assigned to or being accounted for in the final analysis of the treatment effects (Polit & Gillespie, 2010). Hence, it is regardless of whether the participants received the actual intervention or not (Shadish et al., 2002). To achieve this goal, an imputation method was chosen based on the missing outcome data pattern and considered plausible assumptions about the missing data (White, Horton, & Carpenter, 2011). The last observed value replaced the missing value, this according to the last-observation-carried-forward-method (LOCF) (Wood, White, & Thompson, 2004). In those cases where baseline data was missing for the outcome variable, the subsequent value replaced the missing value at baseline. If there was no value at any of the time points on item level *i.e.* baseline, six or 12 month follow-up, the value zero (0) as in 'not lonely' replaced the missing value. For the primary outcome 'loneliness' this occurred in two cases and for the primary outcome 'GDS-20', in seven cases. Supplementary analyses were performed for the three main outcomes to enhance the robustness of the ITT-analysis (White et al., 2011) *i.e.* a sensitivity analysis. For life satisfaction, LSIZ, and symptoms of depression, GDS-20, Expectation-Maximization (E-M) was used. E-M is a likelihood-based approach that estimates the missing values by a two-step procedure, which is iterated until the convergence between the iterations becomes negligible (Bennett, 2001). For the outcome 'loneliness' a best and worst case scenario was applied where all missing values for the item were given the value of zero (0) for a best case scenario and the value of one (1) for a worst case scenario.

Power analysis

To determine the sample size of Study IV, a power analysis was conducted *a priori* of the study. The intention is to reduce the risk of Type II errors (β) *i.e.* a false negative result (Polit & Beck, 2012; Shadish et al., 2002). Two of the primary outcomes were considered, depressive symptoms (GDS-20) and life satisfaction (LSIZ). A mean change of 1.5 points, *SD* 3.4 points was considered as relevant for the GDS-20 over 12 months. For the LSIZ, a mean change of 2.5 points and *SD* 4.8 points were considered as relevant for the same period of time. The α level was 0.05 and power (1-β) of 0.80, indicating a 20 per cent risk of Type II error (Polit & Beck, 2012). Accounting for these assumptions a sample between 59 (LSIZ) to 81 (GDS-20) participants was required in each group respectively.

Qualitative content analysis

Paper III was based on a qualitative methodology using content analysis. The method can be used in numerous ways with qualitative or quantitative data as well as with an inductive or deductive approach (Elo & Kyngäs, 2008). Qualitative content analysis can be described as a method to identify themes through a systematic process of coding data based on an interpretation of the content of a text (*i.e.* interview) (Hsieh & Shannon, 2005). Therefore, the analysis was inductive and was inspired by the methodological approach described by Graneheim and Lundman (2004). The analysis focused both on manifest content, the obvious, and the manifest content, the underlying meaning. Both levels comprised interpretation, albeit in different depth and level of abstraction (Graneheim & Lundman, 2004).

The process of analysis was performed in several steps. Initially, the transcribed interviews were read through several times by the first and the last author of Paper III. Notes of each interview were made along with a reflective summary of the overall impression from the interviews. The overall impression was discussed between the first and last author. Meaning units were identified and abstracted in to shorter units and coded by the first author. After coding two interviews, feedback was given to the first author by the last author. The process continued and the codes were sorted tentative sub themes and themes related to the aim. To this point, the first and the last author carried out the analysis in collaboration by discussing back and forth during the process. The second and third authors read the interviews and all the authors discussed the tentative sub themes and themes related to the aim. When consensus was met sub themes, themes and a final overall theme were established.

Ethical considerations

The studies were designed and conducted in accordance with the ethical principles developed by the World Medical Associations' Declaration of Helsinki (World Medical Association, 2013) with additional guidance from Beauchamp and Childress' (2001) four ethical principles; *respect for autonomy*, *non-maleficence*, *beneficence*, and *justice*. Approval by the Regional Ethics Committee at Lund University was obtained for Study I (LU 650/00, LU 744/00) and for Studies II-IV (LU 342/2006; 499/2008).

The principle respect for autonomy obligates the researcher to provide information, probe and ensure understanding and voluntariness as well as promote adequate decision making (Beauchamp & Childress, 2001). Written informed consent was obtained from all participants in the SNAC-B study (Study I) and the Case Management Study (Studies II-IV). This consent was based on information given regarding the purpose of the study, the possibility to decline or accept participation, the uncompromising right to withdraw at any time without explanation and confidentiality. In the SNAC-B study the informed consent was obtained at the first session at the research centre by the staff involved in the data collection. For the participant's in the Case Management Study information about the study, including voluntary participation, was given verbally when assessing for eligibility and was repeated again by the research staff during the first face-to-face appointment. At this point additional written information was given, including information regarding use of healthcare consumption data (PASiS, PrivaStat). The participant could ask questions before giving verbal and written informed consent and thereafter begin baseline assessment. For Study III, additional verbal and written information regarding the specific study aim was given to potential participants. The right to decline or withdraw from Study III, without this affecting their involvement in the main study was emphasised. Overall, the right to withdraw, as well as encouraging questions, was repeated several times throughout the study period for the participants involved in the Case Management Study.

The risk of harm or avoiding risk of harm *i.e. non-maleficence* was considered to be low for both the SNAC-B study and the Case Management Study. However, harm and discomfort can be emotional and psychological consequences are usually subtle (Polit & Beck, 2012). In all the studies, sensitive questions regarding personal views and issues were asked. This may be particular important when conducting qualitative research when probing sensitive personal issues that may expose previously repressed feelings or fears (Polit & Beck, 2012). When conducting the interviews, in particular for the qualitative study (Study III), the interviewer was attentive to signals or signs of emotional discomfort. All the participants were offered support from a case manager if needed, however, none of the participants used the service. It should also be underscored that the members from the research teams (SNAC-B and Case Management Study) were attentive to participants' reactions during the interviews and took measures, such as offering a break, if needed. Moreover, for the purpose of ensuring the participants' confidentiality in all studies (I-IV), a code number was assigned to each participant. In Studies II-IV, the code list, linking identity to codes, was electronically stored in an encrypted file, accessed by members of the research team. Additional material linking participants to codes was stored in locked cabinets. Studies I-II and IV, were presented at group level which ensured confidentiality.

The overall benefits (*beneficence*) of participation could be the gained knowledge of which could be useful in regards to improvements of care and wellbeing of older people. Benefits of a 'therapeutic-like' relation in qualitative studies, favouring the participant, has also been pointed out (Polit & Beck, 2012). For participants in the Case Management Study, being in the intervention group could provide benefits through the given intervention as well as the relation with the case manager. Moreover, if a member of the research team detected a problem, among participants in the intervention *and* control group, the case manager, physician, or the participant's next of kin was contacted and informed (after giving permission).

The principle of *justice* concerns fairness, including an equal chance of having the opportunity to access various resources (Beauchamp & Childress, 2001). In all studies, participants were selected based on study requirements, not vulnerability or being discriminated because of gender, beliefs, religion and so on. Those (potential) participants who declined or withdrew from the studies were treated in a non-prejudicial way (Polit & Beck, 2012). Moreover, the Case Management Study had also a cross-sectional design meaning that participants in the control group were offered the same intervention programme after completing the 12-month duration of the main study.

Results

The results based on Papers I-II are structured around the applied QoL model (Sprangers et al., 2010) and presented descriptively, as well as in comparison between ‘not lonely’ and ‘lonely’ individuals, along with identified associations and predictors of loneliness. Some additional analyses for comparisons between not lonely and lonely individuals in the SNAC-B sample and Case Management Study sample are made and referred to as ‘Framework’. Thereafter, the qualitative findings in Paper III are presented followed by the results from the RCT, *i.e.* the Case Management intervention (Paper IV). Finally, two case descriptions of the case management intervention are presented.

Characteristics of the individual

Age, gender, and marital status

The mean age of the individuals in Papers I and II at baseline was 83 years (66-99 years), a detailed description can be seen in Table 3. The majority in all samples were women and in regards to marital status, 53 per cent were widowed in Paper I (baseline), and corresponding prevalence was 49 per cent in Paper II (Table 3).

When comparing ‘not lonely’ and ‘lonely’ individuals in both samples, over 70 per cent of those who were lonely were women (Table 3). In regards to marital status significant differences (p=<0.001, Papers I-II) were found in both samples (Table 3). Among those who were widowed over 61 per cent (Paper II) to 67 per cent (Paper I) reported loneliness, compared to those who were married, where 16 per cent (Paper II) to 19 per cent (Paper I) reported feeling lonely. Note that the groups of lonely and not lonely individuals were based on different assessments of loneliness in the papers (Table 3).

Table 3. Demographic variables at baseline in Papers I and II, including a comparison between not lonely and lonely participants based on prevalence of loneliness.

	Paper I				Paper II			
	Total Sample *n*=828	Not Lonely§ *n*=347	Lonely *n*=371	*p*-value	Total sample *n*=153	Not Lonely§§ *n*=61	Lonely *n*=92	*p*-value
Age *M* (±*SD*)	84.2 (4.7)	83.0 (4.2)	84.6 (4.6)	**<0.001**^{a}	81.5 (6.4)	80.6 (6.5)	82.1 (6.2)	0.135^a
Gender, %				**<0.001**^{b}				0.134^b
Woman	59.4	48.1	71.2		66.7	60.7	70.7	
Civil status, %				**<0.001**^{b}				**<0.001**^{b}
Married*	34.9	53.5	19.2		34.0	60.7	16.3	
Widowed/-er	52.9	36.6	67.4		49.0	21.3	67.4	
Other**	12.2	9.9	13.4		17.0	18.0	16.3	
Children, %				0.240^b				0.439^b
Yes	98.6	99.3	97.7		88.2	86.9	89.0	

^{a} Student's *t*-test; ^{b} $\chi 2$ test

* Married/registered partner co-habitant (Paper II); ** Unmarried/divorced (Paper I), Live-apart/divorced/other (Paper II)

§ 'Do you ever feel lonely?' Not Lonely (0):'seldom' or 'never' Lonely (1): 'sometimes' or 'often'; §§ '*Looking back over the last year, which alternative corresponds best for you?*' (no=0/yes=1), capturing prevalence of loneliness during the last year.

Missing Paper I: 9-27%

In Paper I, a significant difference (p=<0.001) was found between 'not lonely' and 'lonely' individuals where those who were lonely were older (83 years *vs.* 85 years) (Table 3). Age was also found to be an independent predictor of loneliness at the six-year follow-up in Paper I (Table 4).

Table 4: Associated variables and predictors for loneliness at baseline and follow-ups (Paper I).

Final model	*OR* [a,b]	95% CI for *OR*	*p*-value
Baseline, 2001 (*n*=444)			
Living alone	6.09	3.75-9.88	**<0.001**
Lacking friends	4.26	1.83-9.93	**0.001**
Depressed mood (health complaint)	3.87	1.54-9.71	**0.004**
Neuroticism	1.09	1.04-1.14	**<0.001**
Conscientiousness	1.06	1.01-1.12	**0.014**
Life satisfaction (LSIZ)	0.92	0.87-0.98	**0.011**
Health status (EQ-5D)	0.14	0.03-0.63	**0.011**
Follow-up, 2004 (*n*=298)			
Lonely at baseline	7.21	3.88-13.41	**<0.001**
Leg pain (health complaint)	2.48	1.39-4.41	**0.002**
Living alone	2.19	1.21-3.95	**0.010**
Life satisfaction (LSIZ)	0.91	0.85-0.97	**0.006**
Follow-up, 2007 (*n*=191)			
Lonely at baseline	5.42	2.78-10.54	**<0.001**
Age	1.14	1.02-1.27	**0.021**
Openness	0.92	0.85-0.98	**0.015**

a: Nagelkerke R^2: 0.45 (2001), 0.43 (2004), 0.24 (2007); b: Hosmer and Lemeshow goodness-of-fit test: 0.919 (2001), 0.919 (2004), 0.284 (2007)

Missing values: 46.4% (2001), 41.7% (2004), 39,7% (2007)

Dependent variable dichotomized as: *'Do you ever feel lonely?'* Not Lonely (0): *'seldom'* or *'never'* Lonely (1): *'sometimes'* or *'often'*

Variables included in the model: gender, age, marital status, living alone, ADL-staircase sum, personality (neuroticism, extroversion, openness, agreeableness, conscientiousness), health status (EQ5D), life satisfaction (LSIZ), health complaints (depressed mood, fatigue, leg pain, hearing loss), cognitive capacity (MMSE), lacking friends. The variable 'lonely at baseline' was also included in the models for 2004 and 2007. Gender was dichotomised as male (0) female (1).

Loneliness

Over 50 per cent of the individuals in Paper I felt lonely sometimes or often, and this prevalence remained fairly stable over time, *i.e.* in the two follow-ups (Table 5). In the Case Management Study (Paper II) at baseline, 24 per cent felt rather or very lonely nowadays (*i.e.* at the time of data collection) (Table 5).

Looking back over the course of time, 60 per cent had felt lonely on single occasions or more often during the past year (Paper II), and when looking back over the last five years, 65 per cent had felt lonely occasionally or more often (Paper I) (Table 5). When rating the intensity in the feeling of loneliness 18 per cent (Paper II) to 22 per cent (Paper I) experienced it as 'rather' or 'very strong'. The most common prevalent intensity was 'neither strong nor weak' (49%, Paper I) and 'rather weak' (22%, Paper II) (Table 5). When identifying predictors for loneliness (Paper I), feeling lonely at baseline, independently predicted loneliness in the three-year follow-up as well as in the six-year follow-up (Table 4).

Table 5. Prevalence of loneliness in the total samples of Papers I and II, including a comparison between measuring points in Paper I

	Paper I					Paper II	
	Baseline n=828	3 year follow-up n=511	6 year follow-up n=317	p-value[a]	Post-hoc analysis[b]		Baseline n=153
Do you ever feel lonely? (%)				0.005	A, B, -	*Do you feel lonely nowadays?* (%)	
Often	8.8	7.5	8.8			Yes, I feel very lonely	7.4
Sometimes	42.9	43.5	40.6			Yes, I feel rather lonely	17.0
Seldom	29.0	32.3	31.8			No, I don't feel lonely	75.6
Never	19.4	16.7	18.8			-	
When you feel lonely, how strong is your feeling of loneliness?, (%				0.022 0.022	A, B, - A, B, -	*When you feel lonely, how strong is your feeling of loneliness?,* %	
Very strong	4.1	5.7	3.6			Very strong	6.7
Rather strong	18.3	23.6	17.1			Rather strong	11.4
Neither strong nor weak	49.1	54.2	60.7			Neither strong nor weak	14.8
Rather weak	17.8	12.7	15.7			Rather weak	21.5
Very weak	10.6	3.8	2.9			Very weak	5.4
-						Never lonely	40.3
Compared to others of your age, how lonely are you? (%)				0.299		*On the whole, do you believe that you are loneliner than other of your age?* (%)	
Much more lonely	2.7	2.4	3.4			Much more lonely	2.7
Slightly more lonely	8.0	7.0	8.5			Slightly more lonely	4.0
Just as lonely as others	34.3	33.1	31.6			Just as lonely as others	24.0
Sligthly less lonely	27.9	31.0	27.8			Slightly less lonely	17.3
Much less lonely	27.1	26.4	28.6			Much less lonely	14.0
-						Never lonely	38.0
Looking back over the last five years, which response alternative corresponds with you? (%)				0.120		*Looking back over the last year, which response alternative you?* (%)	
No occasions with feelings of loneliness	34.9	41.5	35.6			No occasions with feelings of loneliness	39,6
Single occasions	50.9	43.6	48.3			Single occasions	35.9
Recurring periods	11.1	11.6	12.7		-	Recurring periods	15.7
Constant feeling	3.0	3.3	3.4			Constant feeling	8.5

a: Friedman test; b: Wilcoxon Signed Rank test

Reduced p-value for post-hoc analyses (Bonferroni)= <0.0167

Significant differences between (A) baseline vs. 3-year follow-up, (B) baseline vs. 6-year follow-up, (C) 3-year follow-up vs. 6-year follow-up

Missing Paper I: 13-33% (baseline), 33-60% (3-year follow-up), 25-56% (six –year follow-up); Missing Paper II: 2-12%

Personality

In paper I, personality traits according to the FFM were investigated, four of five personality traits differed between 'not lonely' and 'lonely' individuals. When comparing the two groups those who were lonely scored significantly higher for the trait neuroticism (M=30.8, SD=6.7 *vs.* M=26.1, SD=6.4, p=<0.001) and significantly lower for the traits openness (M=34.4, SD=4.9 *vs.* M=35.4, SD=4.9, p=0.013), conscientiousness (M=43.7, SD=5.5 *vs.* M=45.0, SD=6.0 p=0.010) and extroversion

(*M*=36.8, *SD*=5.6 *vs.* *M*=38.8, *SD*=6.2,*p*=<0.001, Student's *t*-test). Moreover, the trait neuroticism showed to be independently associated with loneliness at baseline and openness was an independent predictor for loneliness at the follow-up in 2007 (Table 4).

Characteristics of the environment

Living arrangements

In Paper I, at baseline both residential care and ordinary housing was included in the sample, however, 90 per cent (*n*=665) of the total sample lived in ordinary housing whereas the remaining 10 per cent (*n*=74) lived in residential care. At baseline, the majority lived alone (62%) and of those living alone 80 per cent reported feeling lonely sometimes or often, compared to 40 per cent among those who were not lonely (*n*=718, *p*=<0.001, χ^2 test). Living alone was also found to be independently associated with loneliness as well as a being a predictor of loneliness at the three-year follow-up (Table 4).

Social support

Over 40 per cent of those who reported feeling lonely wanted more contact with relatives, friends and neighbours. This differed significantly between not lonely and lonely individuals (Paper I) (Table 6). Although significant differences were also found between these two groups in regards to having a sufficient number of friends, over 75 per cent of those who were lonely still considered having a sufficient number (Table 6). However, not having a sufficient number of friends (*i.e.* lacking friends) was found to be independently associated with loneliness at baseline (Paper I) (Table 4).

Healthcare consumption

In paper II, the use of healthcare is examined. No significant differences were found between those individuals who reported feeling lonely during the past year and those who did not, in regards to use of inpatient care (not in table). However, in regards to outpatient care those who reported loneliness had more contacts in total with a physician and more acute visits to the emergency department both leading to admission and not, as well as more total visits in outpatient care (Table 7).

When performing a multiple linear regression analysis the final regression model (n=153) identified one significant variable that was independently associated with total use of outpatient care - depressed mood (B, unstandardised 7.4, p=<0.001, Adjusted R^2 0.11).

Table 6: Aspects of social network and support including a comparison at baseline and follow-ups between participants reporting loneliness or not

	2001 (*n*=828)				**2004** (*n*=517)				**2007** (*n*=318)			
	Total sample	**Not lonely***	**Lonely***	***p*-value**[a]	**Total sample**	**Not lonely***	**Lonely***	***p*-value**[a]	**Total sample**	**Not lonely***	**lonely***	***p*-value**[a]
Children [1] (%)	86.4	92.5	80.9	**<0.001**	88.4	91.5	85.2	**0.096**	90.8	96.1	85.1	**0.008**
Friends [2] (%)	87.2	95.3	79.6	**<0.001**	84.5	93.4	76.0	**<0.001**	86.0	96.6	75.2	**<0.001**
Confidant [3] (%)	96.0	96.2	95.9	0.852	95.0	97.0	93.1	0.108	93.7	95.8	91.5	0.166
Wanting more contact [4] (%)	No values**				32.6	20.8	44.2	**<0.001**	32.6	22.0	43.5	**<0.001**

a: χ^2 test
1: "*Do you consider the contact with your children being sufficient?*" (yes)
2: "*Do you consider your number of friends being sufficient?*" (yes)
3: "*Do you have someone who you feel that you can be yourself in front of and who accepts you with all your advantages and shortcomings?*" (yes)
4: "*Would you like to have more contact with relatives, friends and neighbors?*" (yes)
* '*Do you ever feel lonely?*' Not lonely (0): '*seldom*' or '*never*' Lonely (1): '*sometimes*' or '*often*'
** The question was not included at baseline
Missing: 15%-29% (2001), 34%-46% (2004), 26%-39% (2007)

Table 7. Consumption for in- and outpatient care one year prior to gathering of baseline data including a comparison between participants reporting loneliness or not

	Total sample (*n*=153)			**Not lonely*** (*n*=61)			**Lonely*** (*n*=92)			
	mdn	***q*1-*q*3**	**range**	***mdn***	***q*1-*q*3**	**range**	***mdn***	***q*1-*q*3**	**range**	***p*-value[a]**
Outpatient Care										
Visits physician	10.0	7.0-13.5	1-41	11.0	7.0-14.0	2-23	10.0	7.0-13.8	1-41	0.508
Contacts in total[1]	19.0	14.0-27.0	5-66	17.0	13.0-24.5	5-51	20.0	14.0-30.0	5-66	**0.040**
Acute visits[2]	1.0	0.0-2.0	0-7	0.0	0.0-1.0	0-4	1.0	0.0-2.0	0-7	**0.009**
Acute visits leading to admission[2,3]	0.0	0.0-1.0	0-4	0.0	0.0-1.0	0-3	0.0	0.0-1.0	0-4	**0.029**
Acute visits not leading to admission[2,3]	0.0	0.0-1.0	0-4	0.0	0.0-0.0	0-2	0.0	0.0-1.0	0-4	0.069
Total visits[4]	20.0	14.0-29.5	5-69	18.0	13.0-25.5	5-52	21.0	14.25-30.0	5-69	**0.026**

*Not Lonely and Lonely is based on the question: '*Looking back over the last year, which response alternative corresponds best for you?'* (no=0/yes=1)

a: Student's *t*-test

1: Total number of visits, telephone contact and other contact with a physician

2: Acute outpatient visits at an emergency department

3: Admissions to hospital

4: Total number of visits for outpatient care regarding the total number of contacts in total with a physician[1] and acute visits at an emergency department leading to and not leading to an admission to hospital.

Symptom status

Health complaints

Various self-reported health complaints were assessed in Papers I and II (Tables 8-9). For Paper I the three most common complaints and prevalence of depressed mood in the total samples as well as in the two groups (not lonely/lonely) are presented in Table 8. A total number of health complaints based on 32 complaints assessed in Paper II is presented, followed by the three most common complaints, depressed mood, and those additional three complaints that differed significantly (Table 9), hence, included in the regression model for identifying predictors for healthcare consumption.

The three most common complaints in Paper I, for all measuring points, as well as in the two groups were fatigue, hearing loss, and leg pain (Table 8). When comparing the two groups the complaint fatigue differed significantly at baseline and the two follow-ups, where the 'lonely'-group had a higher prevalence with the greatest difference in prevalence at the three-year follow-up (71% *vs.* 52%, p=0.001) (Table 8). In Paper II, when comparing the total number of health complaints (32 items), those who were lonely had a significantly higher total compared to those who were not lonely (M=12.1 *vs.* 9.8, p=0.001) (Table 9) but no significant differences between the two groups were found for the three most common complaints (difficulties walking, pain in extremities, and unsteadiness) (Table 9). However, in regards to depressed mood, there was a significant difference between the two groups, where the 'lonely'-group has a higher prevalence (Table 9). In fact, the greatest difference in prevalence between the two groups for all 32 complaints was found for depressed mood (51% *vs.* 23%, p=0.001) (Table 9). In Paper I, 26 per cent in the 'lonely'-group reported depressed mood as a complaint in the six-year follow-up, compared to seven per cent in the 'not lonely'-group (p=<0.001) (Table 8).

In the regression analysis in Paper I depressed mood was also found to be independently associated with loneliness and having leg pain predicted loneliness at the three-year follow-up (Table 4).

The three most common complaints in Paper I, for all measuring points, as well as in the two groups were fatigue, hearing loss, and leg pain (Table 8). When comparing the two groups the complaint fatigue differed significantly at baseline and the two follow-ups, where the 'lonely'-group had a higher prevalence with the greatest difference in prevalence at the three-year follow-up (71% *vs.* 52%, p=0.001) (Table 8).

Table 8. Health complaints, health status (EQ-5D), and life satisfaction (LSIZ) at baseline and follow-ups including a comparison between participants reporting loneliness or not (Paper I)

	2001 (*n*=828)				**2004** (*n*=517)				**2007** (*n*=318)			
	Total Sample	Not Lonely*	Lonely*	*p*-value	Total Sample	Not Lonely*	Lonely*	*p*-value	Total Sample	Not Lonely*	Lonely*	*p*-value
Fatigue (%)	52.8	44.7	60.3	**<0.001**[a]	61.6	52.2	70.6	**0.001**[a]	58.0	51.2	65.0	**0.032**[a]
Hearing loss (%)	54.4	49.4	59.2	**0.010**[a]	58.5	57.6	59.4	0.743[a]	64.3	64.5	64.1	0.954[a]
Leg pain (%)	53.8	48.5	58.9	**0.006**[a]	50.6	43.0	57.9	**0.008**[a]	53.4	47.9	59.0	0.088[a]
Depressed mood (%)	15.2	7.7	22.4	**<0.001**[a]	16.8	12.8	20.6	0.062[a]	16.0	6.6	25.6	**<0.001**[a]
EQ-5D *M* (±*SD*)		0.78 (0.21)	0.64 (0.27)	**<0.001**[b]		0.78 (0.21)	0.65 (0.25)	**<0.001**[b]		0.75 (0.20)	0.66 (0.27)	**0.005**[b]
LSIZ *M* (±*SD*)		18.5 (4.0)	14.8 (4.7)	**<0.001**[c]		18.0 (4.4)	14.4 (5.0)	**<0.001**[c]		17.5 (4.4)	13.6 (4.9)	**<0.001**[c]

a: χ^2 test
b: Mann-Whitney *U* test
c: Student's *t*-test
Missing: 15%-29% (2001), 37%-56% (2004), 25% -29% (2007)
* *'Do you ever feel lonely?'* Not Lonely (0): *'seldom'* or *'never'* Lonely (1): *'sometimes'* or *'often'*

In Paper II, when comparing the total number of health complaints (32 items), those who were lonely had a significantly higher total compared to those who were not lonely (*M*=12.1 *vs.* 9.8, *p*=0.001) (Table 9) but no significant differences between the two groups were found for the three most common complaints (difficulties walking, pain in extremities, and unsteadiness) (Table 9). However, in regards to depressed mood, there was a significant difference between the two groups, where the 'lonely'-group has a higher prevalence (Table 9). In fact, the greatest difference in prevalence between the two groups for all 32 complaints was found for depressed mood (51% *vs.* 23%, *p*=0.001) (Table 9). In Paper I, 26 per cent in the 'lonely'-group reported depressed mood as a complaint in the six-year follow-up, compared to seven per cent in the 'not lonely'-group (*p*=<0.001) (Table 8).

In the regression analysis in Paper I depressed mood was also found to be independently associated with loneliness and having leg pain predicted loneliness at the three-year follow-up (Table 4).

Table 9. Health complaints and health status (EQ-5D) including a comparison between participants reporting loneliness or not (Paper II)

	Total Sample (*n*=153)	**Not Lonely*** (*n*=61)	**Lonely*** (*n*=92)	***p*-value**
Total number of health complaints *M* ± (*SD*)	11.2 (4.7)	9.8 (4.7)	12.1 (4.6)	**0.001**[a]
Health complaints (%)				
Difficulty hearing	49.7	37.7	57.6	**0.016**[a]
Memory problems	54.2	44.3	60.9	**0.043**[a]
Dizziness	51.6	41.0	58.7	**0.032**[a]
Unsteadiness	69.7	68.2	71.1	0.764[a]
Loss of appetite	19.0	4.9	28.3	**<0.001**[a]
Pain in extremities	69.9	63.9	73.9	0.188[a]
Difficulty walking	71.9	68.9	73.9	0.495[a]
Nervousness	43.1	27.9	53.3	**0.002**[a]
Depressed mood	39.9	23.0	51.1	**0.001**[a]
EQ-5D *M* ± (*SD*)[1]	0.59 (0.27)	0.63 (0.27)	0.56 (0.28)	**0.022**[b]
$\text{EQ-5D}_{\text{VAS}}$ *M* ± (*SD*)[2]	60.3 (17.5)	65.7 (14.2)	56.7 (18.7)	**0.001**[b]

a: $\chi 2$ test; b: Mann Whitney *U*-test

1: Missing n=1; 2: Missing n=3

*Not Lonely and Lonely is based on the question *"Looking back over the last year, which response alternative corresponds best for you?"* (no=0/yes=1), capturing the prevalence of loneliness during the last year

Functional status

Dependency in activities in daily living

Dependency in ADL was investigated in Paper I (Student's *t*-test), at baseline (*n*=706) those who were lonely had a higher mean average score of dependency compared to those who were not lonely (*M*=2.2, *SD*=2.6 *vs.* *M*=1.3, *SD*=2.1, *p*=<0.001). At the three-year follow-up corresponding prevalence was on average two activities for those who were lonely (*M*=1.8, *SD*=1.9) compared to one activity for those who were not (*M*=0.9, *SD*=1.4, *p*=<0.001) and at the six-year follow-up (*n*=238) a similar result was found (*M*=2.4, *SD*=2.4 *vs.* *M*=1.5, *SD*=1.8, *p*=0.001).

General health perceptions

The EQ-5D as an indication of health status

In Paper II, the total mean scores of the EQ-5D and VAS resulted in significant differences between those who were lonely and those who were not, where the former had a lower total score for both assessments (Table 9). In Paper I, significant differences were found at all time-points between the two groups, where the 'lonely'-group scored lower (Table 8). In addition, the EQ-5D total score was also found to be independently associated with loneliness (Table 4).

Overall quality of life

Life satisfaction

The LSIZ indicating level of life satisfaction was assessed in Paper I. Life satisfaction showed to be an associated factor for loneliness, as well as a predictor for loneliness in the three-year follow-up (Table 4). Moreover, at baseline and follow-ups there were differences between not lonely and lonely individuals, where the former scored significantly higher (Table 8). The highest level of life satisfaction among those who were lonely was found at baseline (*M*=14.8) and the lowest in the six-year follow-up (*M*=13.6), compared to not lonely individuals of whom corresponding levels were in mean average 19 and 18 points respectively (Table 8). An additional analysis was made in regards to life satisfaction between those who felt lonely and those who did not ("*Do you feel lonely nowadays*?" no (0)/yes (1)) in the Case Management study sample (*n*=135). This result showed that the mean average score in the 'lonely'-group was significantly lower (*M*=10.7, *SD*=4.5), compared to the 'not lonely'-group (*M*=16.0, *SD*=4.7,*p*=<0.001, Student's *t*-test) (Framework).

The experience of loneliness

Being in a bubble

In Paper III the experience of loneliness among frail older people was explored. The interpretation of the participant's narratives resulted in the overall theme '*Being in a Bubble*', and the underlying themes '*Barriers*', '*Hopelessness*', and '*Freedom*', together with sub-themes for each theme respectively (Table 10).

Table 10 Overall theme, themes and sub-themes identified in the analysis

Being in a Bubble		
Barriers	**Hopelessness**	**Freedom**
The aging body	A constant state	Having time to reflect and reload
Fear	Feeling sad, empty and anxious	Being free to make decisions
The influence of losses	Being invisible to others	Being able to create meaningfulness
No one to share daily chores with	Losing the spirit	Having a social belonging
		Being protected from disappointment

Being in a bubble illustrates how the participants were found to be in an ongoing world, but excluded because their social surroundings and the impossibility to regain what they no longer had in terms of own capacity and close attachments. The bubble was not optional, it was not possible to break and step out of the bubble. Therefore, the participants managed their lives within this bubble with elusive loneliness always present, but not always disturbing. Nonetheless, there was a wish to step out of the bubble resulting in efforts to overcome the physical, psychological or social barriers and be a part of the ongoing world. When not succeeding, the state of being in a bubble was coloured by hopelessness. The bubble was not merely a matter of barriers and hopelessness, it was also seen as a freedom where it was possible to make one's own decisions and thereby 'choosing' to in the bubble they could not escape from. The unwanted loneliness and the wanted 'aloneness' were two different experiences, although expressed interchangeably as loneliness.

Barriers

The barriers maintained loneliness and occurred on a daily basis. A persistent struggle was pursued in overcoming the barriers but because of the nature of them there were few possibilities to achieve this. The barriers were reflected in the sub themes '*The ageing body*', *'Fear'*, *'The influence of losses'* and *'No one to share daily chores with'*. The sub theme '*The ageing body'* revealed limitations in functional ability as well as experiencing health problems. A constant rethinking and readjusting to different situations was demanded because of the limitation. The ageing body sometimes created feelings of sadness and frustration but also feelings of loneliness because of the difficulties in being spontaneous and instead being dependent on other people's willingness or feasibility. The sub theme '*Fear*' could be about being afraid of falling or feeling insecure when going out, resulting in the participant deciding to stay at home. Fear as a barrier, and the resultant limitation was related to feelings of loneliness because it created a feeling of vulnerability. The sense of fear could also be on a more existential level, meaning that being old and frail also meant that things would not become better; the end of life was approaching, that there would be more sickness and more loneliness. The sub theme '*The influence of losses'* revealed that losing a partner appeared to be the most difficult loss and could be seen by some participants as the onset of the feelings of loneliness. Some participants also experienced a loss of having something meaningful to do in daily life, which was also associated with deficits in social networks. The experienced losses of close attachments in particular were expressed through feelings of grief, emptiness and a feeling of being the only one left. Loneliness was also associated with barriers grounded in the situation of practical issues in everyday life, interpreted in the sub theme '*No one to share daily chores with'*. For instance eating is a necessity but was not described as enjoyable when always eating by oneself. Instead, the activity of eating was a reminder of the absence or loss of it as a social situation, and was described as something that had to be done in as simple a way as possible.

Hopelessness

This theme was found to mean that loneliness was seen as a constant state, with no hope for cure, comprising of feelings of sadness, emptiness and anxiety. It was also feelings of being alienated as well as not having the energy to deal with barriers and loss of spirit. Depending on one's own resources and support from the surrounding social network the level of hopelessness experienced by an individual could be more or less persistent. The theme comprised of the sub themes; '*A constant state*', '*Feeling sad, empty and anxious*', '*Being invisible to others*', and '*Losing the spirit*'. The sub theme *Feeling sad, empty and anxious* highlighted a sense of elusiveness in the feeling of loneliness. It was found to be always there but not always disturbing. Loneliness was described as feelings of sadness, emptiness, anxiety and silence. The participants stated that they had strategies to avoid feeling lonely such as occupying themselves by stying busy. For exmple, trying to escape the feeling of loneliness by listening to the radio, reading a book or calling someone. However, it was not always possible to succeed in avoiding loneliness and sometimes they felt lonely, sad, empty and anxious.

Freedom

Loneliness could also be interpreted as a sense of freedom. The freedom was within the boundaries of being frail and co-existed with loneliness. It was seen as something positive, even though it did not change the negative experience of loneliness, per se. Having freedom was seen as being alone and was appreciated for its advantages. There was also a purpose and a goal with daily activities, as well as a protective social network. These were found to promote a sense of freedom and independency. This theme comprised the following sub-themes: '*Having time to reflect and reload*', '*Being free to make decisions*', '*Being able to create meaningfulness*', '*Having a social belonging*', and '*Being protected from disappointment*'. For instance, having satisfying relationships with friends and family was found to be important and protective against loneliness. These relationships could provide security, confirmation and guidance. This could be friends or family being around to help out or making phone calls showing that they cared for the participant, giving their opinion when making bigger decisions as well as inviting the participant to events. However, it was important that these relationships were maintained by own choice and on equal terms, with the importance of not being a burden clearly articulated.

The Case Management intervention

Baseline characteristics

When comparing the intervention and control group in Paper IV, no significant difference was found at baseline in regards to the variables describing the sample such as age, gender, civil status, health complaints, and health status (see Tables 3 and 9 for total sample characteristic).

No significant differences were found between the two groups at baseline, accounting for CC as well as ITT, for the three primary outcomes, loneliness, depressive symptoms (GDS-20), and life satisfaction (LSIZ) (Tables 11-12).

Table 11. Complete case analysis of primary outcome variables at baseline, six- and 12-month follow-ups, including a comparison between intervention and control group.

	Total Sample *n*=153	**Intervention** *n*=80	**Control** *n*=73	***p*-value**	**ES**	**Δ ES**
Loneliness, %						
Baseline	24.4^{1}	26.1	22.7	0.692^{a}		
6 months	23.3^{2}	15.9	31.6	**0.028**^{a}	0.49^{c}	0.03^{e}
12 months	28.8^{3}	27.3	30.6	0.829^{a}		0.22^{e}
GDS-20 *M* (±*SD*)						
Baseline	6.0^{4} (3.4)	6.0 (3.7)	5.9 (3.1)	0.802^{b}		
6 months	5.3^{5} (2.9)	5.0 (3.0)	5.7 (2.8)	0.208^{b}		0.23^{f}
12 months	5.8^{6} (3.7)	5.0 (3.5)	6.7 (3.7)	**0.035^{b}**	0.47^{d}	0.05^{f}
LSIZ *M* (±*SD*)						
Baseline	14.7 (5.1)	14.9 (5.1)	14.4 (5.2)	0.493^{b}		
6 months	15.3^{7} (5.0)	16.3 (4.7)	14.3 (5.1)	**0.028**^{b}	0.41^{d}	0.27^{f}
12 months	15.4^{8} (5.4)	15.8 (5.2)	15.0 (5.6)	0.447^{b}		0.06^{f}

a: χ^2-test ;b: Student's *t*-test; c: Relative Risk (RR); d: Cohen's *d;* e: Δ RR between intervention and control group at baseline and six months and baseline and 12 months; f: Δ Cohen´s *d* between intervention and control group at baseline and six months and baseline and 12 months respectively

Missing:1:18; 2:33; 3:49; 4:27; 5:48; 6:64; 7:37; 8:48

Table 12. ITT analysis (LOCF) of primary outcome variables at baseline, six and 12 month follow-ups, including a comparison between intervention and control groups

	Total Sample *n*=153	**Intervention** *n*=80	**Control** *n*=73	***p*-value**	**Δ ES**
Loneliness, %					
Baseline	26.1	26.3	26.0	0.975^{a}	
6 months	24.2	20.0	28.8	0.206^{a}	0.15^{c}
12 months	29.4	27.5	31.5	0.587^{a}	0.13^{c}
GDS-20 *M* (±*SD*)					
Baseline	6.2 (3.6)	6.3 (3.9)	6.2 (3.1)	0.862^{b}	
6 months	6.0 (3.5)	5.9 (3.7)	6.1 (3.2)	0.643^{b}	0.21^{d}
12 months	6.2 (3.8)	5.9 (3.9)	6.6 (3.8)	0.314^{b}	0.02^{d}
LSIZ *M* (±*SD*)					
Baseline	14.7 (5.1)*	14.9 (5.1)*	14.4 (5.2)*	0.493^{b}	
6 months	14.8 (5.1)	15.2 (5.0)	14.4 (5.2)	0.326^{b}	0.06^{d}
12 months	14.9 (54)	14.9 (5.3)	14.8 (5.6)	0.906^{b}	0.07^{d}

a: χ^2-test; b: Student´s *t*-test; c: Δ R.R. between intervention and control group at baseline and six months and baseline and 12 months; d: Δ Cohen´s *d* between intervention and control group at baseline and six months and baseline and 12 months respectively

*No missing values for LSIZ at baseline (CC-data)

Complete case analysis

In the six-month follow-up, the CC-analysis resulted in a significant difference, between the groups and in favour of the intervention, in regards to prevalence in loneliness (RR=0.49, *p*=0.028) and LSIZ (ES=0.41, *p*=0.028) (Table 11, Figures 4-5).

For the GDS-20, a medium sized effect was found in favour of the intervention at the twelve-month follow-up (ES=0.47, *p*=0.035) (Table 11, Figure 6). It should also be noted that the mean score of the intervention group was below cut-off for the GDS-20, compared to the control group where the mean score was above (Table 11).

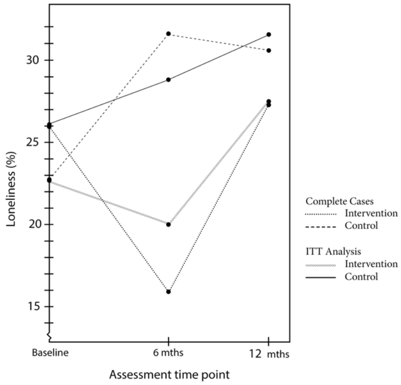

Figure 4. Prevalence of loneliness for the ITT and complete case analyses in the intervention and control group respectively.

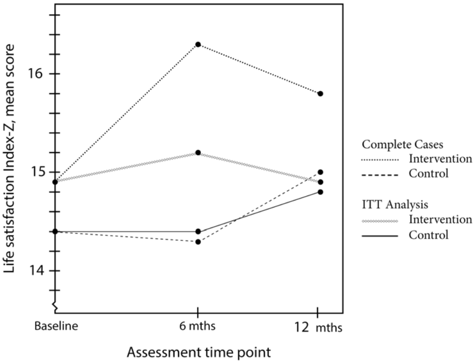

Figure 5. Mean score of the LSIZ for the ITT and complete case analyses in the intervention and control group respectively

Intention-to-treat analysis

After replacing missing data and performing the ITT-analysis no significant differences for the primary outcomes were found between the two groups neither at baseline nor at the follow-ups (Table 12, Figures 4-6). Additional repeated measures within the intervention and control group, respectively, resulted in no significant differences over time for loneliness (*p*=0.092 and *p*=0.532), depressive symptoms (*p*=0.398 and *p*=0.186), and life satisfaction (*p*=0.641 and *p*=0.421). The sensitivity analyses as in a worst- and best-case scenario for loneliness and the E-M approach for GDS-20 and LSIZ yielded no significant differences between the groups at any time point (Not in table) (Paper IV).

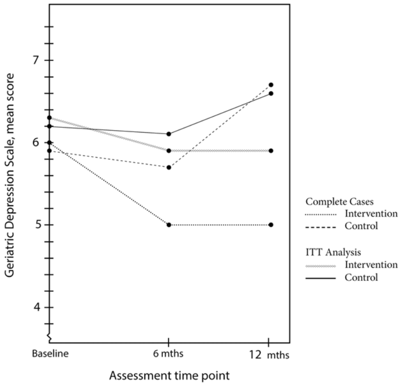

Figure 6. Mean score of the GDS-20 for the ITT and complete case analyses in the intervention and control group respectively

Case descriptions

The two case descriptions of Lotten and Vera (symbolical names) are based on audio recorded and transcribed interviews with the nurse case manager that was assigned to each case respectively.

"Lotten"

Lotten was an 84 year old lady who lived alone in an apartment. She had multiple health problems, such as pain in the extremities, poor vision and hearing, but was still very active and socially outgoing. As a result of the pain, Lotten stayed at home and had stopped participating in activities. It was also difficult to be in larger groups of people because of her difficulties hearing. Therefore, her option for activities was limited, and the only activity that was appropriate for Lotten was not offered as frequently as she wished. Lotten really wanted to have something to do, and the case manager could see that this had a negative impact on her. She also wanted the case manager to contact someone so it could be arranged for a smaller number of people to meet somewhere and have a cooking class. Lotten was eager to get started but because of the practical difficulties in finding a suitable place for the activity, she became frustrated and annoyed over the situation. She also felt disappointed over the health services not being available for her. The case managers role was, therefore, to talk with her and be reassuring. For the case manager, this intervention was about helping Lotten to accept the situation and make the most out of it, despite difficulties.

”Vera”

Vera was an 81 year old lady who had recently become a widow and now lived alone. She had experienced a previous loss of another close person and was very sad. Vera preferred staying at home. The case mangers (both nurse and physiotherapist) encouraged her to go out but she was unwilling. A great deal of the support given to Vera concerned social aspects, such as encouraging her to go out and take part in activities, although this was without success. Nevertheless, Vera needed to talk. The case manager suggested that someone from her church could be an option, but she did not want that, nor did she want any other organisations to come either. She did not have any medical needs. For the case manager it was therefore difficult to intervene. Although the intervention plan failed in regards to involving Vera more socially, the case manager was an appreciated social support. The relationship between the case manager and Vera had been good throughout the interaction, and the case manager also felt that she had done what she could to help Vera.

Discussion

Methodological discussion

To enhance rigour and support inferences drawn based on the findings, the quantitative methodological approaches as used in Papers I-II and IV will be discussed in terms of threats and strengths in regards to aspects concerning validity, reliability and generalisability (Polit & Beck, 2012). The qualitative study (Paper III) will be methodologically discussed from aspects concerning trustworthiness.

Validity

According to Shadish et al. (2002) validity is the 'approximate truth of an inference', indicating whether the inferences are being truthful or correct. This is a judgement, not an absolute truth and various degrees of validity can be stated (Shadish et al., 2002). Validity can be divided into *statistical conclusion*, *internal*, *construct* and *external validity* (Shadish et al., 2002).

Statistical conclusion validity

For establishing causality, a relationship between an independent and dependent variable needs to be demonstrated and various statistical methods can be used to support whether this relationship exists or not (Polit & Beck, 2012). Statistical conclusion validity concerns if there is a covariation between these two variables and if so, how strongly they covary (Shadish et al., 2002). There are several potential threats to this aspect of validity, such as low statistical power, fishing (*i.e.* repeated test for significant relationships) and unreliability of measures among others (Shadish et al., 2002). One important aspect is sufficient *statistical power*, of which demands sufficiently large samples to detect a true relationship among variables (Polit & Beck, 2012). In Paper I this was not an issue because of the large sample size and in Paper II the statistical power could be considered sufficient due to the fact that statistical significant differences were found between variables.

For Paper IV power is of interest because the intention was to establish whether a case management intervention was effective or not for three main outcomes. A power analysis was conducted *a priori* for the outcomes life satisfaction and depressive symptoms. In addition, an ITT-analysis was also conducted for missing data (see more detailed discussion under the section of '*Internal validity*'). However, all kinds of missing data lowers statistical power (Shadish et al., 2002) and it has also been argued that an ITT-analysis reduces the statistical power (Eysenbach, 2005). After replacing missing data no significant differences between the intervention and control group remained, compared to the complete case analysis where significant differences were found in favour of the intervention for all three primary outcomes. This could indicate lack of sufficient power to detect differences in the ITT-analysis. When imputing missing data the estimate of the treatment effect is often conservative (Gupta, 2011; Hollis & Campbell, 1999) or underestimated, because many participants did in fact not receive the intervention (Polit & Beck, 2012). Nevertheless, applying ITT when conducting a RCT is highly recommended and required according to the CONSORT statement (Moher et al., 2010). Therefore, using an ITT approach is default, although the potential threats for using this approach should be taken into consideration when interpreting the results.

Another threat to the statistical conclusion validity, in regards to *fishing,* was the multiple comparisons (Papers I and II) and repeated measures (Papers I and IV), of which could produce Type I error, *i.e.* detecting a false positive difference. For repeated measures, the Bonferroni correction method was applied to correct for this kind of error (Altman, 1991; Shadish et al., 2002). However, for multiple comparisons, such as when comparing various health complaints (independent variable) with not lonely and lonely individuals (dependent variable) (Paper II), there would likely be a false positive result in one of 20 comparisons (Altman, 1991). Accordingly, there is a risk that some demonstrated relationships might in fact not be true. However, in Papers I and II, findings from group comparisons were used in further analyses in the form of regression models. Therefore, it could be considered that group comparisons identified variables that were of interest for further analysis, hence, reducing the threat related to fishing.

Internal validity

This aspect of validity is about the independent variable causing the outcome, rather than something else causing the outcome (Polit & Beck, 2012). There are threats to the internal validity that need to be addressed. One threat, affecting Studies I and IV, was the *attrition*, of which involves loss of participants, as well as missing items due to failure of answering single questions or questionnaires (Shadish et al., 2002). The process of keeping participants in the study *i.e. retention*, is of particular importance in studies with longitudinal or experimental designs where participants need to be motivated for a longer period of time or committed to an intervention (Gul & Ali, 2010). The design in Paper I was longitudinal and between baseline and the last follow-up six years later, 63 per cent (*n*=511) of the participants dropped out. When conducting research with samples of older people it is inevitable that attrition occurs because of deterioration of the participants, resulting in illness or death. This could indicate that the remaining sample was healthier than the general population. However, efforts to compensate for or prevent attrition were made by an over sampling of the oldest age cohorts, along with creating a friendly climate and establishing media contacts that were positive.

The Case Management Study of which Paper IV is based on adopted various strategies to retain participants. Firstly, clinical trials addressing concerns of participants may result in better compliance and improved retention (Gul & Ali, 2010), which would apply to the Case Management Study programme. Secondly, the importance of establishing good relationships between the participants and the researchers has been underscored for retaining participants (Gul & Ali, 2010). In the study the researchers established contact with the participants by calling and making home visits. Usually it was the same researcher who contacted and visited the participant throughout the study period. The contact over telephone and in person is emphasised as a preferable strategy to retain reluctant participants (Polit & Gillespie, 2010). However, between baseline and the 12-month follow-up 29 per cent (*n*=45) of the participants dropped out, hence threatening the validity. Nevertheless, the random assignment of group allocation self-strengthened the internal validity by allowing other conditions, apart from the intervention, being experienced equally between the two groups, within limits of chance (Shadish et al., 2002). However, when a treatment-correlated attrition occurs the internal validity is negatively affected because the similarities between the intervention and control group may not sustain, hence, reducing the benefits of random assignment (Shadish et al., 2002). Therefore, an ITT analysis was undertaken in Paper IV, compensating for any kind of missing data in the three primary outcomes and preserving the benefits of random assignment. The dropouts and reasons for dropping out in Paper IV were fairly equally distributed between the intervention and control group, reducing the risk of attrition correlated with treatment. Ideally this would mean that the benefits of the random assignment remained. However, plausible assumptions of reasons for the attrition needs to be considered and can also be categorised (Polit & Gillespie, 2010). When examining the reasons for missing data, mainly through complete dropout, it could be assumed that data was missing at random (MAR). That is; a systematic difference could be found or predicted in the complete data set, but not directly due to the variables in which data were missing (Bennett, 2001; Polit & Gillespie, 2010). In regards to complete dropouts it could be assumed that the remaining sample was healthier than the average population. However, a dropout analysis of the Case Management Study sample has been published elsewhere, showing no significant difference between dropouts and remaining sample in regards to age, gender, financial status, health complaints, functional dependency or symptoms of depression (Sandberg et al., 2015).

When conducting the ITT analysis, appropriate strategies for replacing missing data, *i.e.* imputation, were chosen after careful consideration, resulting in the LOCF approach. Replacing a missing value with a previous value, *i.e.* single imputation, is often used but also criticised for generating a biased outcome (Kenward & Molenberghs, 2009; Polit & Gillespie, 2010; Sterne et al., 2009). Accordingly, it is possible that the replaced missing values in Paper IV could be biased. In contrast to the somewhat criticised single imputation methods, multiple imputation approaches have been pointed out as preferable (Bennett, 2001; Kenward & Molenberghs, 2009; Sterne et al., 2009). For the two primary outcomes, depressed symptoms and life satisfaction, a multiple imputation technique (E-M-approach) was adopted and served as a sensitivity analysis. However, the results from this approach were similar to the results from the LOCF in regards to these two outcomes, strengthening the validity of using LOCF. Moreover, the sensitivity analyses for a worst and best case scenario for missing values in relation to loneliness as an outcome did not result in any significant differences, suggesting that the inferences drawn from the ITT-analysis are valid. However, as previously discussed, attrition as well as ITT threatens both internal *and* statistical conclusion validity. Therefore, when interpreting the results of Study IV both ITT and CC should be taken into account.

Construct validity

Constructs, *i.e.* an abstraction or concept that is invented by a researcher for scientific purposes (Polit & Beck, 2012) and construct validity is about understanding these constructs and assessing them (Shadish et al., 2002). An important threat to validity concerns failure to explain a construct, potentially leading to incorrect inferences about the relationship between operation and construct (Shadish et al., 2002).

Loneliness as a construct poses challenges that could be related construct validity. In this thesis loneliness is conceptualised as a negative experience, which is a well-established viewpoint. However, for all studies (I-II and IV), when assessing loneliness in form of single item questions, no clear definition of loneliness was articulated. Therefore, it cannot be ruled out that participants may have interpreted the construct differently, hence, threatening construct validity. Since there were several items assessing various aspects of loneliness it would, however, be reasonable to assume that misinterpretation was not frequently occurring in any of the studies. Moreover, the stigma associated with loneliness as being a socially undesirable state (Rokach, 2012) may have resulted in an element of underreporting to a degree (Grenade & Boldy, 2008). It could be possible that this is a reflection of what can be called social desirability bias (Polit & Beck, 2012), which has implications for construct validity because the responses may reflect the participants' perception of being in a study situation (Shadish et al., 2002) rather than the 'true' reflection.

External validity

External validity is about the extent of which inferences drawn in a study holds over variations in people, settings and conditions as well as variation in treatment and outcomes. Simply speaking, it is about generalisation (Polit & Beck, 2012; Shadish et al., 2002). An important question is whether the samples in the studies (I-II, IV) were representative for its population. In regards to Paper I the design of including a large number of participants from a whole population strengthened the external validity. However, the oldest age groups in SNAC-B represented the highest rates of unwillingness to participate in the study, although an oversampling of the oldest age cohorts was made to compensate for unwillingness and dropouts. Nevertheless, it has been showed that the SNAC-B sample as a whole (60+ years) has a slightly better health and less functional disability, compared to the general Swedish population (Rennemark, Holst, et al., 2009), which should be kept in mind when interpreting the results.

Papers II and IV were based on the Case Management study and applied a different sampling strategy compared to Paper I. There was a defined inclusion criteria, and of those who were assessed for eligibility (*n*=1, 079) there were 231 persons who did not match the criteria. However, a large number of persons (*n*=571) did not respond to invitation and it is uncertain whether these persons would have matched the inclusion criteria and if so, would they have differed from the sample in the study. Two important questions would be if the study sample was representative for frail older people (Paper II and IV) and would a possible effect in this setting hold within another setting (Paper IV) (Shadish et al., 2002) One approach to reduce these issues is to describe the included sample and sampling procedures in as detailed a way as possible (Polit & Beck, 2012), and also use a framework such as the MRC framework and reporting guidelines such as CONSORT. Both the MRC framework and CONSORT would specifically apply to Paper IV. Regardless, both studies in Papers II and IV are context bound in such a way that there may be challenges to generalise the results to other countries because provision of health and social services may differ.

Trustworthiness

Trustworthiness in qualitative research is a parallel to validity in quantitative research (Polit & Beck, 2012). Paper III had a qualitative design and the quality of the study will be discussed in relation to aspects concerning trustworthiness as proposed by Lincoln and Guba (1985), namely; *credibility*, *dependability*, *confirmability*, and *transferability* with additional guidance from Graneheim and Lundman (2004).

One aspect of *credibility* of which could be seen as enhancing trustworthiness was to choose participants with different experiences of loneliness as well as choosing men and women. This could be considered to enrich the variation of the phenomena under study, *i.e.* loneliness, which is an important aspect to achieve credibility (Graneheim & Lundman, 2004). Another aspect concerns the treatment of data, such as selecting meaning units and how well sub-themes and themes cover the data (Graneheim & Lundman, 2004). Selection of meaning units was made in collaboration with the first and the last author, and the same strategy was applied when forming sub-themes and themes. Moreover, quotations of the data/text were presented in Paper III, along with a description of how data was coded in to meaning units, formed to sub-themes and themes. In regards to *dependability*, an interview guide was used reducing the risk of inconsistencies during data collection (Graneheim & Lundman, 2004). Although participants were able to speak freely about various topics the guide provided a tool for both the interviewer and the interviewees to keep on track covering topics that were of interest in relation to the aim. *Confirmability* deals with the researchers objectivity and that the findings were interpretations of the data and nothing else (Polit & Beck, 2012). For instance, maintaining objectivity when being in the most intensive phases of the analysing process may be challenging. However, all four authors read the text by themselves and then discussed the analysis and findings together using investigator triangulation as a means to enhance confirmability (Polit & Beck, 2012) and keep objectivity. In regards to *transferability* it should be kept in mind that the participants had some predefined characteristics, *i.e.* being dependent in ADL and frequent use of healthcare, due to their involvement in the Case Management Study. This may aggravate the possibilities to transfer the findings to other settings. However, to facilitate transferability a detailed description about participant characteristics and context was strived for along with description of data collection and process of analysis (Graneheim & Lundman, 2004). In addition, consolidated criteria for reporting qualitative research (COREQ) was used as a checklist to ensure that important aspects of the study were reported in the paper (Tong, Sainsbury, & Craig, 2007).

General discussion of the results

Prevalence of loneliness

In a population of people aged 78 years or older, over 50 per cent felt lonely sometimes or often at baseline (Paper I), whereas in a sample of frail older people 24 per cent felt rather or very lonely at the time when data was collected (Paper II). The two single item questions assessing loneliness were not identical, but could be considered to assess the same aspect, *i.e.* prevalence of loneliness in the present. When focusing on Sweden in particular, studies have shown a prevalence ranging from seven per cent (Dahlberg et al., 2014) to around 30 per cent (Holmén & Furukawa, 2002; Sundström, Fransson, Malmberg, & Davey, 2009). The fairly wide range could perhaps be explained by differences within the samples and contexts, assuming that older people as a group are heterogeneous and a wide range of factors may influence levels of loneliness.

When focusing on older people who are frail, as in Paper II, loneliness was less prevalent (24%), compared to the result in Paper I. Studies aiming to investigate loneliness among frail older people are still rare and due to the absence of consensus regarding the definition of frailty, identifying suitable studies with frail samples, is difficult. However, previous research targeting frail older people, as in being dependent in ADL, has reported a prevalence of around 28 per cent (lonely sometimes or more often) (Ollonqvist et al., 2008) to around 70 per cent of modest or severe loneliness (De Jong Gierveld Loneliness Scale) (Iecovich & Biderman, 2012). However, when accounting for the other single item questions assessing loneliness in Paper II, then only 40 per cent reported not feeling lonely. Accordingly, there is a discrepancy between feeling lonely in present and the other items assessing loneliness from other perspectives such as retrospectively and level of intensity. It could be that this is a reflection of the stigma associated with loneliness, implying a bias in the form of social desirability. The reluctance of admitting directly to being lonely, unless it is obvious or severe, has been pointed out as an issue (Grenade & Boldy, 2008). Consequently, since data was collected face-to-face it may be more difficult for the individual to admit to feeling lonely, compared to postal surveys, for instance. On the other hand, it could also be a reflection of the interview situation as a positive experience, resulting in the fact that the participant actually did not feel lonely at that particular point of time. Nevertheless, it appears as though loneliness among frail older people, as shown in Paper II, supports previous reported prevalences and indicates that frail older people do not differ from older people in general in this regard.

Moreover, the intensity of loneliness as being rather or very strong was less common, compared to having rather to very weak feelings or neither strong or weak feelings of loneliness (Paper I-II). This may indicate that loneliness is not that bothersome for older people in general (Paper I) nor frail older people in particular (Paper II). However, the qualitative findings in Paper III sheds light on this matter from another perspective by showing that loneliness is problematic regardless of its intensity. Previous qualitative research has indicated that loneliness is problematic when experiencing agonising loneliness (Hauge & Kirkevold, 2012). Seemingly, the findings in Paper III suggests that less severe forms of loneliness should also be taken into consideration and further probing should be considered.

Associated factors and predictors for loneliness

The strongest predictor for loneliness was feeling lonely at baseline. This implies that loneliness is a non-reversible state and that once the feeling is established it remains. This is in line with previous longitudinal research, showing that prevalence of loneliness remains fairly static over time (Victor & Bowling, 2012) or may increase (Heikkinen & Kauppinen, 2011). Conversely, previous research has also shown that older people may 'improve' or 'recover' from loneliness, although these number tend to be fairly small (Dahlberg et al., 2014; Victor & Bowling, 2012). Since the recovery from feelings of loneliness were beyond the scope of Paper I, it cannot be ruled out that some of the study participants recovered from their feelings of loneliness. However, the indication of loneliness as a non-reversible state is supported by the findings in Paper III. As described in the sub-theme '*A constant state*', loneliness was seen as something that was always present with no hope for a cure. This did not necessarily mean that the participants were constantly bothered by their loneliness, but it was there and had to be managed. In a study by Kirkevold et al. (2013), exploring loneliness among older persons (≥65 years) in Australia, Norway, and UK, it was found that those participants who described themselves as lonely were trapped in a life of loneliness and social isolation. Therefore, both qualitative and quantitative findings in the thesis, as well as in previous research, indicates that loneliness is not a self-resolving state, suggesting that an active approach is needed for achieving a change.

Loneliness was also found to be associated and predicted by various factors covering health, environment and personal factors. This highlights the diverseness among factors influencing loneliness. However, it should be emphasised that it is likely that the predictors are embedded in several other factors that were not identified in the study, but these identified predictors *increase* the probability that a person will experience loneliness (Shadish et al., 2002). For instance, having pain in the legs could be an indication of a physical deterioration in a larger sense. Research has shown that physical disabilities is a predictor of loneliness (Aartsen & Jylhä, 2011; Luo et al., 2012) and it would be reasonable to assume that this could imply difficulties such as leaving the home, resulting in isolation and loneliness. In Paper III the participants spoke about their feeling of loneliness as being associated with their functional limitations and health problems. This made it difficult to be spontaneous, which created a sense of dependency on other people's willingness or flexibility to assist. It is possible that a predictor such as having pain in the legs could be related to the findings in Paper III, in terms of an ageing body as a barrier creating loneliness. Regardless, both quantitative and qualitative findings illuminate the possible impact a physical condition or symptom may have on loneliness.

Health status and life satisfaction

Self-reported health status (EQ-5D), covering several dimensions of health (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) (Brooks, 1996) were assessed in both samples (Papers I–II). In both studies, those respondents who felt lonely, had a significantly lower total score, at all time points when data was collected, compared to those who did not feel lonely. When descriptively comparing the two samples, the results indicate a continuum where older people in general, who did not feel lonely, had the best health status and frail older people who felt lonely had the worst health status. For the results in Paper I, the mean score for the total sample is fairly similar to other older populations in Sweden where mean scores around 0.74 have been reported (Andersson, Marcusson, & Wressle, 2014; Burström, Johannesson, & Diderichsen, 2001). In regards to EQ-VAS, as applied in Paper II, Andersson et al. (2014) found that among people 85+ years (*n*=360) the mean score was around 68, similar to those who did not feel lonely in Paper II. Health status, assessed by EQ-5D, has been found to be negatively influenced by factors such as IADL, loneliness, and risk for depression (Andersson et al., 2014). This could both explain and support the finding of a lower reported health status among frail older people who reported loneliness, as in Paper II. In addition, the results in Paper I showed that health status (EQ-5D) was independently associated with loneliness. It is known that loneliness and a lower health status are related (Luo et al., 2012; Nummela et al., 2011; Savikko et al., 2005) and the EQ-5D is an indication of health status but it can also be considered an indication of QoL, by covering basic core aspects of QoL characteristics (Kind, Brooks, & Rabin, 2006). Moreover, self-reported health status origins from both body and mind and is associated with morbidity as well as mortality (Jylhä, 2009). This indicates that older people who experience loneliness, and in particular frail older people, are vulnerable and could be seen to be at risk for experiencing adverse health outcomes and a lower sense of wellbeing. This could also be reflected in the higher use of healthcare, which was found in Paper II, where those who felt loneliness used significantly more outpatient services, including visits at the emergency department, compared to their not lonely peers.

When assessing levels of life satisfaction in Paper I and in the framework the results in Paper I showed that those who felt lonely had significantly lower life satisfaction, at all time points when data was collected, compared to their not lonely peers. At the lowest, a mean average score around 14 of 26 could be seen, which could be compared with previous reported levels with mean averages of around 12 in Italy and 16 in Sweden (Borg et al., 2008). The additional analysis in the framework, of the sample in Paper II, showed an average level of 11, among those who felt lonely, compared to 16 among those who were not. Both poor self-rated health and loneliness has previously shown to correspond to similar levels of life satisfaction, as was found in the frail sample in Paper II (Borg et al., 2006). Since life satisfaction encompasses aspects such as happiness, zest for life, fortitude, mood and overall wellbeing (Bowling & Dieppe, 2005) the results could imply that opportunities for successful ageing are hampered for those who are frail and experience loneliness.

Furthermore, in Paper I it was also found that lower life satisfaction predicted loneliness but previous research has also found that loneliness predicts lower life satisfaction (Ní Mhaoláin et al., 2012). Accordingly, there is a reciprocal relationship and those who experience loneliness seem also to experience a lower life satisfaction and health status. It has been suggested that when entering the fourth age, around 80 to 85 years of age, sizeable losses of functioning may occur, especially in regards to aspects of emotions and wellbeing, such as loneliness, life satisfaction, and positive affect (Baltes & Smith, 2003). Fillit and Butler (2009) have proposed that a person who is frail needs to psychologically and emotionally adapt to the loss of physical independence and a poor resolution to this loss may lead to a 'frailty identity crisis', which could result in regret, sadness and depression. The notion of a challenging transition from independent to dependent has been further explored, showing a strong correlation between poor psychological wellbeing (Ryff psychological wellbeing index) and frailty (Andrew et al., 2012). This underscores the importance of recognising psychological wellbeing when caring for older people who are going through, or have gone through, transitions in physical and functional abilities (Andrew et al., 2012). For the sample in Paper II, 40 per cent of the total sample reported depressed mood as a health complaint and previous research on the same sample has shown that 52 per cent of the total sample were at risk for developing depression, according to the GDS-20 (Modig, Midlöv, & Kristensson, 2014). In addition, among those participants who reported loneliness, the prevalence of depressed mood was 51 per cent compared to 23 per cent among those who did not (Paper II). When investigating the association between loneliness, health complaints, health status, depressed mood and use of outpatient care, it was solely that of a depressed mood that was independently associated with the need for outpatient care. Despite that, experiencing a depressed mood only accounted for eleven per cent of the total use of outpatient care, but this still suggests that psychological wellbeing is an important factor for seeking healthcare.

The findings in Paper III provides further insights by illuminating that loneliness was associated with hopelessness, as in being invisible to others, feelings of losing the spirit, feeling sad, empty and anxious. The sense of hopelessness could be temporary but also a reflection of disappointment over their life situation with no future hope for improvement. It is possible that the experienced hopelessness was related to depression for some and depression has been described as experiencing feelings of meaninglessness, loneliness and isolation (Holm et al., 2013). The experience of loneliness itself has also been found to relate to a sense of lacking power and initiative, that makes everyday and social relationships difficult to maintain (Hauge &

Kirkevold, 2012). Accordingly, loneliness and depression are closely related and difficult to separate. Moreover, life satisfaction encompasses components such as taking pleasure from everyday activities, seeing life as meaningful and having an optimistic mood (Bowling, 2005; Neugarten et al., 1961). The qualitative findings supports the quantitative findings of lower life satisfaction being associated with loneliness, especially among frail older people. However, loneliness and life satisfaction are both complex phenomenas and it should be kept in mind that many other factors may influence the overall experience. Regardless, Ní Mhaoláin et al. (2012) has concluded that mental and emotional status in regards to life satisfaction are as important as physical functionality, as measures of wellbeing and successful ageing.

It would be reasonable to assume that for those who experience loneliness it is also likely that they experience depressive symptoms and this, together, is reflected in a lower life satisfaction as well as lower health status. It is known that older people who are lonely also often have depressive symptoms, but depressive symptoms is not always accompanied by loneliness (Luanaigh & Lawlor, 2008). Regardless, the findings sheds light on important aspects for the wellbeing of older people and could be a reflection of a possible frailty identity crisis. Therefore for those who are at risk, providing support to cope and adapt with losses, along with psychosocial aspects, including loneliness, seem important for achieving positive perceptions of health, as well as satisfaction with life.

The case management intervention

In Paper IV the effect of a case management intervention on loneliness, symptoms of depression and life satisfaction was evaluated. The intervention did not result in any significant effects on these outcomes, when applying ITT. However, when accounting for complete cases significant effects in favour of the intervention were found for all three main outcomes. Therefore, there are indications that case management may be beneficial in terms of these outcomes.

The MDS-HC (Landi et al., 2000) that was used by the case managers to assess, follow-up and evaluate care needs in the home, included items relating to depressive symptoms, as well as loneliness. However, items concerning loneliness were related to social function and environment, such as participation in activities and objective isolation. One dichotomous question assessed whether the participant felt lonely often (yes/no). Given the complexity in this phenomena, as well as the difficulty in assessing loneliness due to stigma and social desirability, the items used may be too narrow for assessing loneliness in such a way that would be required for achieving a successful interventional outcome. Nevertheless, according to the results from the complete cases and the trend for ITT in the intervention group, the intervention seemed successful in reducing loneliness in the first six months. This could indicate that feelings of loneliness that were related to social aspects were covered to some extent, for instance by going to social venues and participating in activities. Sandberg et al. (2014) found that the case managers in the study experienced their role as being a ‘coaching guard’ and solving problems related to loneliness by encouraging social venues or activities as well as providing social and emotional support by comforting and being someone to talk to. Moreover, the participants in the study experienced the case manager as an important source of social support and enjoyed having someone to talk to (Sandberg et al., 2014). However, in a RCT specifically targeting loneliness among frail older people, by using a network-based group rehabilitation programme (n=708), it was concluded that for a successful outcome in terms of reduced loneliness, it is not sufficient to increase the number of social contacts, rather, it is satisfaction and meaningfulness with social contacts that seem important (Ollonqvist et al., 2008). It has also been suggested that strategies such as increasing opportunities for social interactions and enhancement of social support addresses social isolation more than loneliness (Masi et al., 2011). Consequently, the emotional aspect of loneliness may be more difficult to cover, implying that the case management intervention covered social isolation, which also could explain the lack of effectiveness in the second half of the intervention period.

In Paper III the overall theme was ‘*Being in a bubble*’, illustrating loneliness as being in an ongoing world but excluded, because of the social surroundings and the impossibility to regain losses of own capacity and close attachments. This elucidates to some extent the complexity of loneliness and difficulty in intervening, simply because replacing the irreplaceable is impossible. Nevertheless, to retain QoL whilst being frail it is essential to sustain and facilitate new connections, adapt to changing circumstances and accumulated losses (Nicholson et al., 2013). However, among older people there is an association between loneliness and an inability to cope with losses (Kirkevold et al., 2013), as well as experiencing a state of passivity with difficulties in changing the situation on their own (Kvaal et al., 2014). Masi et al. (2011) found that the most promising strategy for reducing loneliness is through psychological reframing such as CBT, grounded in the fact that individuals who feel lonely act and think differently than when they do not feel lonely.

Furthermore, the lack of clear significant effects in favour of the case management intervention in terms of depressive symptoms and life satisfaction indicates than when assessing these aspects in the case management intervention the strategies appeared to be insufficient. Previous research has showed that because of the stigma, providing interventions targeting psychological wellbeing is difficult (Ell, 2006). Regardless, in line with suggested effective strategies to combat loneliness, CBT is considered to be effective in reducing depressive symptoms among older people (>60+ years), by changing thoughts, behaviour, skills and associated feelings (Pinquart, Duberstein, & Lyness, 2007). Although it may be challenging to achieve effective outcomes due to lack of openness for this kind of treatment, it is still emphasised as worth pursuing (Cacioppo, Grippo, London, Goossens, & Cacioppo, 2015). It should be underscored that further research is needed to establish whether this would be effective for frail older people or not, in particular in terms of loneliness and life satisfaction. Nevertheless, the idea of providing an intervention for frail older people comprising a strategy beyond social support seem intriguing.

The results in Paper IV still indicate that case management may be beneficial in regards to the three main outcomes. However, there is a need for further elaboration, which should include comprehensive assessments to appropriately assess loneliness, depressive symptoms and life satisfaction. The case manager has an important role in identifying those who are in need of support and guiding them towards accurate care as well as evaluating the outcome. It is possible that for some, encouragement and support in finding meaningful social activities and contacts is sufficient. Moreover, the findings of barriers related to loneliness in Paper III also indicates that loneliness is associated with situations in everyday life. One suggestion would be to identify and target barriers of importance for the individual. However, for others, additional support may be needed, such as referral to professional expertise providing therapies such as CBT. Regardless, as pointed out by Cacioppo et al. (2015) loneliness as a distress syndrome is receiving little attention in medical training and healthcare. Accordingly, this calls for increased awareness among future case managers and other healthcare providers of the nature, assessment and treatment of loneliness including related aspects. Given the impact loneliness, as well as related aspects, may have on overall wellbeing, recognition in clinical practice is of importance and identifying those persons who are negatively affected seems essential.

Loneliness in a larger sense

In the thesis, a model was applied to clarify relationships and mechanisms affecting loneliness and overall QoL. The model itself was not in focus of evaluation nor was QoL/wellbeing other than life satisfaction being an indicator of the former. However, according to Steptoe et al. (2014), improving the wellbeing of the population is a ‘key societal aspiration’ and it is known that high wellbeing can reduce physical health impairments. Consequently, increasing wellbeing among older people would be beneficial from both personal and societal perspectives. As suggested by Bakas et al. (2012) global models, such as the model used in this thesis, can be useful as templates and a starting-point. Although the model is not specific for loneliness building upon and further adapting the model to specific contexts has been emphasised for increasing consistency across studies, as well as increasing the understanding of QoL (Bakas et al., 2012). Since frailty, loneliness, depressive symptoms, as well as life satisfaction are complex in their nature, theoretical guidance was deemed to be beneficial. Therefore, when considering loneliness from ‘genes to neighbourhood’ the results and previous knowledge suggests that loneliness can be an essential aspect of the wellbeing of the older person. Accordingly, attention among healthcare providers and effective strategies to intervene is needed for promoting wellbeing and successful aging.

Conclusions and clinical implications

Loneliness is fairly common among older people and once the feeling is established it is likely to stay. Older people who felt lonely had a lower self-reported health status and lower levels of life satisfaction, compared to their peers who did not feel lonely. Loneliness was also found to be associated and predicted by factors that originated in the environment and by symptoms as well as health status and satisfaction with life. Factors related to psychological wellbeing seem to be the major reasons for loneliness.

Frail older people's health status as well as life satisfaction seem to be lower than older people in general. Depressed mood was also common among those who felt lonely. Those who felt lonely also used more outpatient services, including visits at the emergency department. However, it was not loneliness *per se* that was found to be associated with use of healthcare but rather depressed mood.

The experience of loneliness among frail older people showed that it was a prevalent issue, regardless of intensity, and was associated with physical and social losses. Loneliness was also seen as a constant state with no hope for cure but co-existed with a more positive dimension of loneliness, characterised by a sense of freedom.

Case management for frail older people was not effective in regards to loneliness, symptoms of depression, and life satisfaction, when applying intention-to-treat. However, when accounting for methodological considerations and complete cases, the results indicate that case management could be beneficial in terms of the three outcomes. The lack of a clear effect could be reflected in the complexity of the outcomes in focus, as well as lack of explicit and theoretically based strategies to intervene.

Loneliness is an important factor that could be associated with lower physical and psychological wellbeing and needs to be actively targeted upon in clinical practice. Appropriate assessment of loneliness and other aspects of psychological wellbeing are suggested for identifying people at risk. Single causes are difficult to isolate, suggesting that a comprehensive and individualised approach is needed as well as focusing on what those who experience loneliness actually require. One approach to intervene could be to both identify and target those barriers that can be related to loneliness and associated feelings. However, to achieve successful outcomes when intervening increased knowledge of-state-of-the-art effective treatments as well as the nature of the phenomena itself is needed among healthcare providers.

Further research

Research concerning loneliness is extensive and has gained increased attention in the recent years. However, older people are a heterogeneous group, and studies targeting specific groups would still be considered to be of interest. Frail older people is such a group where existing knowledge is limited. Moreover, qualitative studies, using alternative approaches to content analysis could add further insight of the experience of loneliness among frail older people, as well as the phenomena itself. Moreover, other aspects of psychological wellbeing among frail older people have also received limited attention in research and because of its potential impact, further research within this field would be useful.

Moreover, it would be useful to conduct studies addressing loneliness in gerontological nursing in terms of how professionals perceive loneliness and what they consider being important for the psychological wellbeing of older people. This would be of particular interest in a primary and municipal context, because this is where interventions preferably would be carried out. Studies with such focus could identify potential gaps in knowledge or yield valuable ideas. It could also increase the understanding of how loneliness and associated factors are perceived and handled by the providers.

Another important implication for future research is additional elaboration and evaluation of case management in regards to psychological wellbeing, which should include aspects such as loneliness, depressive symptoms and life satisfaction. A process evaluation of the Case Management Study would be useful to identify the barriers and facilitators of the intervention, as well as evaluating case management in other contexts. It would also be of further interest to evaluate interventions strategies of loneliness that is known to be effective in other populations and samples, but is yet to be tested upon frail older people.

Svensk sammanfattning

Merparten av vår vakna tid spenderas med andra och det anses vara mer givande att umgås med partnern, barnen, vännerna och kollegorna än att vara på egen hand. Att däremot uppleva sig som socialt isolerad resulterar i en känsla av ensamhet. En människa kan objektivt sett vara socialt isolerad utan att vara ensam men en människa kan också vara ensam trots ett rikt socialt liv. Klart är dock att ensamhet kan ha allvarliga konsekvenser för kognition, känslor, beteende och hälsa om inget görs. Ensamhet förekommer i alla åldrar men bland äldre (65+ år) är ensamhet vanligt. Tidigare forskning har visat att runt 40 procent känner sig ensamma och bland de allra äldsta åldersgrupperna (80+ år) upplever ungefär hälften sig som ofta ensamma.

Det finns ingen vedertagen definition av ensamhet eller vad ensamhet faktisk är. Däremot råder det enighet om att ensamhet är en subjektiv känsla som är oönskad. Detta till skillnad från att vara själv eller ”solitär”, som innebär att aktivt välja att vara på egen hand, vilket i sin tur kan vara positivt och välgörande. Tidigare forskning har visat att ett antal faktorer, både modifierbara och statiska, som kan sammankopplas eller förutspå, prediktera, ensamhet. I synnerhet är depression eller depressiva symptom en välkänd faktor, där ett samband av både orsak och verkan råder. Dock är det är det framförallt tvärsnittsstudier som ligger till grund för kunskapen kring äldre personer och ensamhet. På senare år har antalet longitudinella studier ökat, men äldre som grupp är heterogen och kunskapen kring de äldsta åldersgrupperna är fortfarande begränsad. Att identifiera prediktorer för ensamhet är värdefullt, inte minst ur ett förbyggande perspektiv och därför behövs mer kunskap kring detta.

Det “goda åldrandet” kan ses som ett mål att sträva mot, även om det nödvändigtvis inte behöver betyda frånvaro av sjukdom. Snarare handlar det om en känsla av att känna sig tillfredsställd med livet som är och har varit, där både fysiska och psykosociala aspekter formar utfallet. Således kan välbefinnande anses vara en viktig del av det goda åldrandet, eftersom både lycka samt tillfredställelse och mening med livet omfattas av detta koncept. Med stigande ålder är välbefinnande en viktig del av hälsan och ett gott åldrande. Det finns ett samband mellan ensamhet och sämre välbefinnande, inklusive livstillfredställelse och därför kan ensamhet ses motverka förutsättningar för ett gott åldrande.

En grupp som skulle kunna vara särskilt utsatta för att uppleva ensamhet är äldre personer som är sköra. Skörhet innebär ett utsatt fysiskt tillstånd där en mindre händelse såsom en lättare infektion kan leda till en kraftig försämring i hälsotillståndet liksom ökad vårdkonsumtion och behov av hjälp i det dagliga livet. Det är också känt att det finns ett samband mellan psykologiska aspekter av välbefinnande och skörhet, vilket antyder att skörhet inte enbart är beroende av fysiska faktorer. Kunskapen kring ensamhet bland sköra äldre är begränsad och det finns ett behov av att utöka denna kunskap, till exempel utifrån den individuella upplevelsen liksom utifrån fysisk och psykisk hälsa samt utnyttjandet av vård. Detta skulle kunna bidra till utökad kunskap kring ensamhet som fenomen, identifiera faktorer som kan sammankopplas med ensamhet liksom vilken typ av vård denna grupp kan tänkas utnyttja.

I Sverige och resten av Europa råder ”kvarboendeprincipen”, där allt fler äldre bor kvar hemma, vilket kan resultera i isolering och ökad risk för ensamhet. Därför behövs insatser i hemmet som motverkar ensamhet och främjar välbefinnande. En sådan insats skulle kunna vara enligt ”case management”-modellen. En ”case manager”, exempelvis en sjuksköterska, gör då hembesök och arbetar utifrån att planera, koordinera, övervaka och utvärdera den äldre personens vård och omsorg. Case management-modellen bygger på flexibilitet och individuell anpassning, där den äldre personens specifika behov står i centrum. Trots att modellen utvärderats i tidigare studier och det finns kvalitativa fynd som indikerar att case management kan minska känslan av ensamhet, finns ingen utvärdering av effekten på ensamhet. Likaså saknas det utvärdering av case management för sköra äldre personer som bor hemma med avseende på depressiva symptom och livstillfredställelse.

Denna avhandling utgörs av fyra delstudier som övergripande syftar till att utforska ensamhet genom att identifiera associerade faktorer och prediktorer för ensamhet i en population av äldre personer (78+ år) liksom undersöka ensamhet i relation till vårdkonsumtion bland sköra äldre personer (65+ år) som bor hemma samt dessa personers upplevelse av ensamhet. Avhandlingen syftar också till att utvärdera effekten av en case management-intervention till sköra äldre personer som bor hemma med avseende på ensamhet, depressiva symptom och livstillfredställelse.

Den första delstudien omfattade ett urval av 828 personer som var 78 år eller äldre som var inkluderade i det longitudinella forskningsprojektet Swedish Study on Aging and Care (SNAC). Projektet omfattar fyra studieområden i Sverige (Blekinge, Kungsholmen, Nordanstig, Skåne), där det aktuella urvalet var inhämtat från Blekinge. Studiens startade 2001 och personerna i denna delstudie följdes upp två gånger med tre års mellanrum, 2004 respektive 2007. Vid den första mätningen var det 828 deltagare, 511 personer deltog vid uppföljningen efter tre år och 317 personer deltog i uppföljningen efter sex år. Data samlades in genom strukturerade intervjuer och genom enkäter som deltagarna själva fick fylla i. En uppdelning av deltagarna gjordes baserat på om de kände sig ensamma eller inte. Resultatet visade att över 50 procent av deltagarna vid första mätningen var ensamma och den starkaste faktorn som kunde kopplas till ensamhet var ensamboende följt av brist på vänner och nedstämdhet. Vidare var den främsta prediktorn för ensamhet, vid båda uppföljningarna, att känna sig ensam vid den första mätningen. Andra prediktorer var till exempel smärta i benen, livstillfredställelse och ålder. Dessutom visade resultatet att de som kände sig ensamma hade betydligt lägre livstillfredställelse och självrapporterad hälsostatus, jämfört med de som inte kände sig ensamma. Således visar resultatet från denna studie att ensamhet är vanligt förekommande bland äldre och verkar bestå över tid. Det som kan sammankopplas och förutspå ensamhet är till synes främst sprungna ur psykosociala faktorer. Resultaten indikerar att det krävs en aktiv insats för att mildra ensamheten där faktorer såsom ensamboende, ålder, nedstämdhet och livstillfredställse kan ses som riskfaktorer för ensamhet som kan behöva vidare uppföljning.

Den andra delstudien omfattade ett urval om 153 sköra äldre personer som bodde i eget boende och syftade till att undersöka ensamhet, hälsostatus och hälsobesvär i relation till vårdkonsumtion. Urvalet baserades på "Projekt Närsjuksköterska" som är en randomiserad kontrollerad studie som syftar till att utvärdera effekterna av case management till sköra, hemmaboende äldre personer. Projektet startade 2006 och genomfördes i en mellanstor kommun i södra Sverige. För att bli inkluderad krävdes att personen skulle vara 65 år eller äldre, vistats på sjukhus minst två gånger eller varit på läkarbesök minst fyra gånger under det gångna året, behöva hjälp med minst två aktiviteter i dagligt liv (exempelvis städning, matinköp, dusch/bad) samt bo i ordinärt boende. Totalt inkluderades 153 personer och i denna delstudie användes data från den första mätningen. Utöver detta användes också vårdkonsumtionsdata av öppen och slutenvård, som inhämtades från två olika patientregister upp till ett år före den första mätningen. Resultatet visade att de som kände sig ensamma hade betydligt fler hälsobesvär och sämre hälsostatus, jämfört med dem som inte kände ensamma. Det visade sig också att de som kände sig ensamma utnyttjade betydligt mer öppenvård i form av läkarbesök och läkarkontakter, inklusive besök på akutmottagning, jämfört med dem som inte kände sig ensamma. Ingen skillnad kunde påvisas mellan de två grupperna beträffande slutenvård. Resultatet visade också att det inte är ensamhet i sig som kan sammankopplas med utnyttjande av öppenvård, utan snarare nedstämdhet. Det ska dock påpekas att det är svårt att avgöra orsaker till utnyttjande av vård, på grund av den komplexa situation som råder för den sköra äldre personen. Resultatet skulle kunna indikera att de som känner sig ensamma kan sakna någon nära som kan hjälpa och stötta dem, vilket kanske gör primärvården till den enda möjliga kontakten som kan erbjuda stöd. När primärvården inte är tillgänglig blir akutmottagningen och eventuell inläggning alternativet. Som en strategi för att förebygga besök på akutmottagningen skulle till exempel primärvården kunna erbjuda individuellt utformat stöd utifrån för den sköra äldre personens specifika problem och behov, inklusive psykosociala aspekter.

Den tredje delstudien var en intervjustudie som syftade till att utforska upplevelsen av ensamhet bland sköra äldre personer som bor hemma. De tolv deltagarna till studien rekryterades från “Projekt Närsjuksköterska”. Utöver de kriterier som ställts inom ramen för detta projekt valdes deltagarna i den här delstudien ut baserat på olika nivåer av intensitet i känslan av ensamhet. Såldes innebar detta att alla deltagarna kände sig ensamma men styrkan varierade från mycket svag till mycket stark. Individuella intervjuer genomfördes med hjälp av en intervjuguide, spelades in på band och transkriberades sedan ordagrant. Intervjuerna analyserades med hjälp av kvalitativ innehållsanalys. Analysen resulterade i det tolkande övergripande temat ”*Att vara i en bubbla*” som illustrerade en tillvaro av att vara inkluderad i omvärlden men samtidigt exkluderad på grund av deltagarnas sociala omgivning och omöjligheten i att ersätta förluster. Temat ”*Barriärer*” belyste hur deltagarna möttes av olika fysiska, psykologiska och sociala barriärer eller hinder som de var tvungna att övervinna för att inte känna sig ensamma. Temat ”*Hopplöshet*” belyste upplevelsen av när det inte var möjligt att övervinna hindren, vilket resulterade i en känsla av att tappa orken liksom att uppleva ensamheten som något bestående. Det visade sig också att det fanns en mer positiv dimension av ensamhet som samexisterade med ensamhetens baksidor. Detta återspeglas i temat ”*Frihet*” där ensamheten kan erbjuda oberoende liksom tid för att reflektera och samla kraft. Således visade denna delstudie att ensamhet kan vara ett problem, oavsett om en stark eller svag känsla av ensamhet anges. Likaså är resultatet från den här delstudien i linje med tidigare forskning och stärker indikationen att ensamhet är bestående. Detta kan innebära att det är svårt att bryta ensamheten på egen hand, både för att det inte finns några förväntningar om att ensamheten ska försvinna men också för att barriärerna är för svåra att komma över. Det ska också understrykas att fast ensamheten upplevdes som konstant är det inte alltid besvärande. Eftersom både ensamhet i sig, liksom att vara skör, är mångfacetterat behövs individuellt anpassade insatser som baseras både på vetenskap och klinisk erfarenhet. Vidare skulle de hinder som återspeglas i temat *“Barriärer”* kunna ge vägledning vid utformandet av insatser för att motverka ensamhetens baksidor.

Den fjärde och sista delstudien i avhandlingen syftade till att utvärdera effekten av en case management-intervention till sköra äldre personer som bor hemma med avseende på ensamhet, depressiva symptom och livstillfredställelse. Denna studie baseras på “Projekt Närsjuksköterska” som tidigare beskrivits under delstudie två. I samband med den första mätningen lottades 153 deltagare till en interventionsgrupp (*n*=80) som fick en intervention eller en kontrollgrupp (*n*=73) som inte fick någon intervention. Båda grupperna fick dock under studieperioden sedvanlig vård som erbjuds av kommun och landsting. Två case managers, en sjuksköterska och en sjukgymnast gjorde minst ett hembesök var per månad under tolv månaders tid. Interventionen innehöll fyra delar: 1) traditionell case management som till exempel inkluderade utvärdering, planering, monitorering och koordinering. 2) allmän information såsom aktiviteter som erbjuds i kommunen, säkerhet i hemmet och fysisk aktivitet. 3) specifik information anpassat till deltagarens individuella behov såsom information om specifika sjukdomar eller möjliga aktiviteter att delta i om deltagaren kände sig ensam. 4) Tillgänglighet och säkerhet såsom i att vara anträffbar per telefon under kontorstid. I analysen utvärderades effekten vid sex och tolv månader. Vid den första mätningen var det ingen skillnad mellan grupperna med avseende på de tre utfallsmåtten (ensamhet, depressiva symptom och livstillfredsställelse). Det bortfall av deltagare och enskilda mätningar som skedde under interventionens gång ersattes av ett uppskattat värde för att undvika missledande effekter. Resultatet visade då inte på några effekter för något av utfallsmåtten vid någon av mätpunkterna. Däremot visade de kompletta fallen, dvs. utifrån befintlig data, att interventionen hade en effekt till interventionens fördel utifrån samtliga utfallsmått. Detta skulle kunna innebära att även om case management inte visade på tydliga effekter, så finns det ändå ett visst stöd för att detta skulle kunna vara fördelaktigt för sköra äldre personer med avseende på de tre utfallsmåtten. Däremot behöver interventionen vidareutvecklas till att innefatta strukturerade angreppsätt för aspekter relaterat till psykosocialt välbefinnande, inklusive ensamhet, där tidigare visade effektiva interventioner, även riktade till andra målgrupper, beaktas.

Sammanfattningsvis visade resultaten av de fyra delstudierna att ensamhet är tämligen vanligt förekommande bland äldre personer. Ensamhet kan sammankopplas och förutspås av både fysiska och psykiska faktorer. Dock är det framförallt faktorer relaterat till psykiskt välbefinnande som verkar ha störst inverkan på ensamhet. Sköra äldre personer, som känner sig ensamma, utnyttjar mer öppenvård, inklusive besök på akuten. Dock är det är inte ensamhet i sig som är orsaken till vårdkonsumtion, utan nedstämdhet. Vidare tenderar ensamhet att bestå över tid, både utifrån mätbara data liksom sköra äldre personers egna upplevelser. Även om ensamhet inte alltid upplevs som besvärlig är det tydligt att de som känner sig ensamma har både sämre självrapporterad hälsa och lägre livstillfredställelse, jämfört med de som inte känner sig ensamma. Det kan konstateras att ensamhet verkar vara en viktig del för välbefinnandet och behöver således uppmärksammas. Avslutningsvis visade resultaten att en intervention med case management till sköra äldre som bor hemma inte har någon effekt på ensamhet, depressiva symptom och livstillfredställelse. Däremot finns indikationer på att det kan vara fördelaktig med case management med avseende på dessa tre utfallsmått, även om en vidareutveckling av innehållet i interventionen är rekommenderat.

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