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Frailty in Acutely Admitted Older Medical Patients

Identification, Meaning and Consequences of Frailty at Hospital Discharge

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FRAILITY IN ACUTELY ADMITTED OLDER MEDICAL PATIENTS

– IDENTIFICATION, MEANING AND CONSEQUENCES
OF FRAILITY AT HOSPITAL DISCHARGE

**BY
JANE ANDREASEN**

DISSERTATION SUBMITTED 2016



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ENGLISH SUMMARY

Background: An increasing number of older people are acutely admitted to the medical wards in Denmark and a substantial proportion of them are frail. Frailty is a condition that may have far-reaching consequences. It is therefore important to investigate how to validly and feasibly identify frail patients and explore the impact of frailty in relation to older medical patients who have been acutely admitted to hospital.

Aim: The overall aim of this PhD project was to validly identify, explore meaning and assess consequences of frailty at hospital discharge in acutely admitted older medical patients by i) a translation and cross-cultural adaption of the Tilburg Frailty Indicator (TFI) to a Danish context, ii) a content validation of the TFI, iii) exploring how frail older medical patients experience daily life one week after discharge from an acute admission to the hospital, and iv) assessing whether frailty measured by TFI in acutely admitted older medical patients was associated with unplanned readmission or death within six months after discharge, and assessing whether the basic functional mobility measured by Timed-Up-and-Go (TUG) and grip strength (GS) was associated with unplanned readmission or death within six months.

Methods: In Study I, the TFI was translated, cross-culturally adapted and face-validated into a Danish version using an internationally recommended procedure. In Study II, a content validation of the TFI by the target population was performed with the use of qualitative individual semi-structured interviews and a deductive content analysis. In Study III, the experiences of daily life of acutely admitted frail older medical patients one week after discharge were explored by individual interviews and by using Interpretive Description as methodology. Study IV, an observational cohort study including register-based follow-up, assessed whether self-reported frailty and functional status at discharge were associated with unplanned readmission and mortality six months after discharge in acutely admitted older medical patients.

Results: In Study I a rigorous procedure including cognitive interviewing (N=34) ensured that the Danish version of the Tilburg Frailty Indicator was valid, so that the instrument could be used and tested in clinical practice. Study II (N=14) showed that the majority of important items related to frailty seemed to be covered in the Tilburg Frailty Indicator from a target population perspective. The importance of pain, sleep quality, spirituality and meaningful activities in relation to the screening of frailty should be further investigated. Study III described four categories - “The system”, “Keeping a social life”, “Being in everyday life” and “Handling everyday life” - that

greatly affected how everyday life was experienced and showed that several elements and stressors affected the wellbeing of the participants in daily life one week after discharge. In particular, contact with the health-care system created frustrations and worries, but also physical disability, loneliness, and inactivity were issues of concern. Study IV (N=1328) showed a consistent association between self-reported frailty measured by the TFI and readmission or death within six months in the crude, the gender and age, and the gender, age and co-morbidity adjusted models. Likewise, consistent associations were seen between the performance-based measures of functional status, TUG and GS, and readmission or death within six months in the crude and adjusted models. When adjusted for gender and age an 88% higher risk of readmission or death was present if TFI scores were 8–13 points than if they were 0–1 points for the total sample (HR 1.88, CI 1.38;2.58). If the TUG score was between 12.0 and 23.9 seconds compared to 4.0 to 7.9 seconds there was a 98% higher risk of readmission or death (HR 1.98, CI 1.46;2.68) when adjusted for gender and age. Finally GS was also associated with readmission or death.

Conclusion: TFI is a self-reporting comprehensive assessment tool reflecting the multidimensionality of frailty. Study I provided a valid Danish version of the TFI and the instrument was considered ready to be implemented and further tested in clinical practice in a Danish context. The findings of Study II added to the scientific body of evidence in relation to the robustness and validity of the TFI from a target population perspective. Study III provided in-depth knowledge about how acutely admitted frail older medical patients experienced daily life one week after discharge. Contact with the health-care system, social relations, loneliness, and constraints in handling daily life influenced overall wellbeing. Future interventions should incorporate a multidimensional perspective when acutely admitted frail older medical patients are discharged from the hospital. Stakeholders should evaluate present practice to ensure a high quality of integrated care across the primary and secondary sector. The findings of Study IV showed that self-reported and performance based frailty measures with high clinical applicability were associated with readmission or death. These results are a promising first step towards identifying high-risk patients who need comprehensive discharge planning and action with the aim of preventing readmissions.

The findings in this PhD project have contributed to new insights and reflections in relation to a valid and simple way of identifying frailty. The project has further documented an association between self-reported frailty and lower functional status and risk of readmission or death, and has finally contributed to an understanding of the meaning and serious consequences of frailty in acutely admitted older medical patients in relation to discharge.

DANSK RESUME

Baggrund: Stadigt flere ældre bliver akut indlagt på medicinske afsnit i Danmark og en stor andel af disse patienter er skrøbelige. Skrøbelighed er en tilstand, som kan have vidtrækkende negative konsekvenser. Det synes derfor vigtigt at undersøge hvorledes man validt og enkelt kan identificere skrøbelige patienter og ligeledes undersøge betydning og konsekvenser af skrøbelighed hos akut indlagte ældre medicinske patienter.

Formål: Ph.d projektets formål var at identificere, undersøge betydning og konsekvenser af skrøbelighed ved ; i) at oversætte screeningsredskabet The Tilburg Frailty Indicator (TFI) og adaptere dette til danske forhold; ii) at indholdsvalidere TFI; iii) at undersøges hvorledes akut indlagte skrøbelige ældre patienter oplever deres hverdag en uge efter udskrivelse og; iv) at undersøge hvorvidt skrøbelighed, målt ved TFI, ved gangtesten Timed-Up-and-Go (TUG) og gribestyrke (GS) ved udskrivelsen var associeret med genindlæggelse eller død hos den akut indlagte skrøbelige ældre patient seks måneder efter udskrivelse.

Metode: I studie I blev TFI oversat, tværkulturelt adapteret og face-valideret til en dansk version ud fra en internationalt anbefalet metode. I studie II anvendtes kvalitative individuelle semi-strukturerede interviews og deduktiv indholdsanalyse til at indholdsvalidere TFI ud fra et patient perspektiv. I studie III undersøgte hvorledes akut indlagte skrøbelige ældre patienter oplevede deres hverdag en uge efter udskrivelse ved hjælp af individuelle semi-strukturerede interviews og metodologien Interpretive Description. I studie IV gennemførtes et prospektivt kohorte studie med register follow-up for at undersøge hvorvidt skrøbelighed og funktionsevne var associeret til genindlæggelse eller død seks måneder efter udskrivelse.

Resultater: Studie I: En anbefalet procedure, hvor kognitive interviews indgik (N=34), resulterede i en valid dansk version af TFI, som kan anvendes og testes yderligere i klinisk praksis. Studie II: Størstedelen af vigtige elementer fra et patientperspektiv (N=14) syntes dækket i TFI. Vigtigheden af elementerne smerte, søvn kvalitet, spiritualitet og meningsfulde aktiviteter i forhold til screening af skrøbelighed bør undersøges yderligere, da disse ikke er inkluderet i TFI. Studie III: Fire kategorier blev analyseret frem; ”Systemet”, ”At beholde et socialt liv”, ”At være i hverdagen” og ”At håndtere hverdagen” og disse kategorier påvirkede i høj grad, hvorledes hverdagen blev oplevet en uge efter udskrivelsen hos akut indlagte skrøbelige ældre medicinske patienter (N=14). Adskillige elementer og stressorer påvirkede i høj grad velbefindende i dagligdagen, særligt kontakten med

sundhedssektorerne skabte bekymringer, men også nedsat funktionsevne, ensomhed og inaktivitet influerede på velbefindende i dagligdagen. I studie IV (N=1328) påvistes en konsistent association mellem selv-rapporteret skrøbelighed, målt ved TFI, og genindlæggelse eller død inden for seks måneder i såvel den rå, i den køns- og alder justerede og i den køns-, alder, og komorbiditetsjusterede model. Ligeledes sås konsistente associationer mellem funktionsevne, målt ved gangtest og gribestyrke og genindlæggelse eller død inden for seks måneder i såvel den rå, i den køns- og alder justerede og i den køns-, alder, og komorbiditetsjusterede model. Risikoen for genindlæggelse eller død efter seks måneder var 88% højere hvis TFI scoren var mellem 8 - 13 point sammenlignet med en score mellem 0 - 1 point for den samlede gruppe (HR 1.88, CI 1.38;2.58). En TUG score mellem 12 - 23,9 sekunder sammenlignet med en score mellem 4 - 7.9 sekunder viste en øget risiko på 98% for genindlæggelse eller død indenfor seks måneder (HR 1.98, CI 1.46;2.68). Gribestyrke var ligeledes associeret med genindlæggelse og død.

Konklusion: TFI er et fyldestgørende selv-rapporteret screeningsredskab som afspejler en multidimensionel forståelse af skrøbelighed. Studie I resulterede i en valid dansk version af TFI, som ansås klar til at blive implementeret og yderligere testet i en dansk kontekst. Resultaterne fra studie II bidrog til viden om robusthed og validitet af TFI ud fra en population af skrøbelige ældre medicinske patienter. Studie III bidrog med dybdegående viden og forståelse om hvorledes skrøbelige ældre patienter oplevede hverdagen en uge efter en akut indlæggelse. Kontaktet med sundhedssystemet, sociale relationer, ensomhed og udfordringer ved at håndtere dagligdagen påvirkede deres velbefindende. Fremtidige indsatser inden for dette område skal implementere et multidimensionelt perspektiv, når akut indlagte skrøbelige ældre bliver udskrevet fra hospital. Interessenter bør evaluere nuværende praksis for at sikre en høj kvalitet og en integreret indsats på tværs af primær og sekundær sektor. Studie IV påviste at selvrapporteret skrøbelighed og basis funktionsevne målt ved gangtest og gribestyrke var associeret med genindlæggelse eller død. Disse resultater er et første lovende skridt mod at identificere højrisiko patienter som behøver en fyldestgørende udskrivelsesplan og tilknyttede handlinger som kan medvirke til forebygge genindlæggelser.

Resultaterne fra dette Ph.d projekt har bidraget til nye indsigter og ny viden i forhold til at identificere skrøbelighed på en valid og enkel måde. Projektet har dokumenteret en association mellem selvrapporteret skrøbelighed(TFI) og nedsat funktionsevne (TUG og GS) og genindlæggelse og død inden for seks måneder og har endeligt bidraget til en forståelse af betydningen og alvorlige konsekvenser af skrøbelighed ved udskrivelsen hos akut indlagte skrøbelige ældre medicinske patienter.

PAPERS

The scientific work presented in this PhD thesis was performed at the Department of Physiotherapy and Occupational Therapy at Aalborg University Hospital and the Department of Clinical Medicine at Aalborg University, Denmark.

The PhD project and thesis are based on four papers:

I: Andreasen J, Sørensen EE, Gobbens RJJ, Lund H, Aadahl M. Danish version of the Tilburg Frailty Indicator – Translation, cross-cultural adaptation and validity pretest by cognitive interviewing.

Published in: Archives of Gerontology and Geriatrics. 2014. Vol. 59, Nr. 1, s. 32-8 (1).

II: Andreasen J, Lund H, Aadahl M, Gobbens RJJ, Sorensen EE. Content validation of the Tilburg Frailty Indicator from the perspective of frail elderly. A qualitative explorative study.

Published In: Archives of Gerontology and Geriatrics. 2015. Vol. 61, Nr. 3, s. 392-99 (2).

III: Andreasen J, Lund H, Aadahl M, Sørensen EE. The experience of daily life of acutely admitted frail elderly one week after discharge from the hospital.

Published in: International Journal of Qualitative Studies on Health and Well-being. 2015. Vol. 10, 27370 (3).

IV: Andreasen J, Aadahl M, Sorensen EE, Eriksen HH, Lund H, Overvad K. Self-reported frailty at hospital discharge is associated with short-term readmission and mortality in acutely admitted older patients. A Danish cohort study.

Submitted October 2016 (in review) (4).

THESIS AT A GLANCE

The overall aim of this PhD project was to validly identify frailty, to explore how frail older acutely admitted medical patients experienced daily life shortly after discharge, and to assess whether frailty measured at discharge was associated with readmission and mortality within six months in acutely admitted older medical patients.

Figure 1 shows the conducted studies as a timeline. Table 1 shows an overview of the included studies.

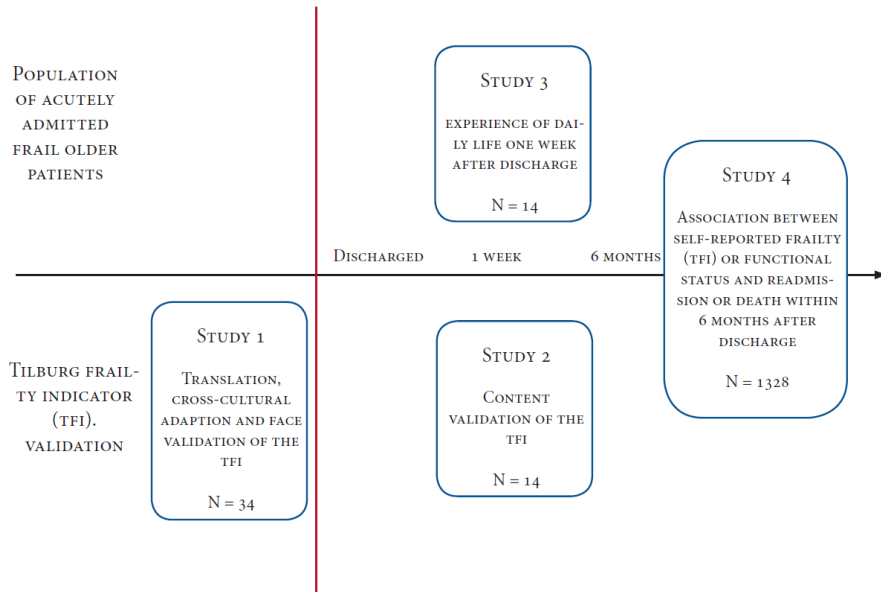


Figure 1. A visual glance of the included studies. The red vertical line represents the time point of discharge. The black line represents the timeline.

Table 1. An overview of the four included studies

Study	Aim	Study design	Participants	Results and conclusion
1	To translate and undertake a cross-cultural adaption of the TFI to a Danish context including a face validation of the TFI by using cognitive interviewing in both home-dwelling and hospitalized older patients.	Translation, cross-cultural adaption and face validation study.	Eight members in harmonization group and 34 for cognitive interviewing (21 acutely admitted 65+ medical patients and 13 home-dwelling 65+ patients).	TFI is a short field-friendly tool with an integral approach, it is not time-consuming, the instruction is simple and the score is easily calculated. In this study internationally recognized procedures were applied. In conclusion, we consider the TFI to be translated and adapted in such a manner that the instrument can be implemented and be further tested in clinical practice, the objective being to improve the identification and interventions towards frail older persons in Denmark.
2	To validate the Tilburg Frailty Indicator on content by exploring the experience of daily life of community dwelling frail older people shortly after discharge from an acute admission, in relation to the physical, psychological and social domain of the TFI.	Qualitative content validation study.	14 acutely admitted frail older medical patients one week after discharge.	All 15 questions in the TFI, Part B, were confirmed from a target population perspective and it seems likely that the majority of important items related to frailty are covered in the TFI. The four issues of pain, sleep quality, spirituality and meaningful activities that seem to be important elements in daily life for a frail population of participants are not directly covered by the TFI.
3	To explore how frail older patients experience daily life one week after discharge from an acute admission to the hospital.	Explorative qualitative study		The patients' experiences of daily life one week after discharge from the hospital were affected by different factors. Contact with the health-care system, social relations, mood, and constraints in handling daily life significantly influenced overall wellbeing or non-wellbeing and some of the elderly expressed great concern and worry in relation to their daily life. Future interventions should incorporate a multidimensional perspective when acutely admitted frail elderly are discharged from the hospital.
4	To assess whether frailty in acutely	Observational	1328 acutely admitted frail	Acutely admitted older medical patients' frailty assessed using a

	<p>admitted older medical patients, assessed by a self-report multidimensional questionnaire at discharge, was associated with unplanned readmission or death within six months after discharge. Secondly, to assess whether the basic functional mobility and grip strength were also associated with unplanned readmission or death within six months.</p>	<p>cohort study.</p>	<p>older patients at discharge were included.</p>	<p>self-reported multicomponent frailty questionnaire, the Tilburg Frailty Indicator (TFI), at hospital discharge showed a higher risk of readmission or death at higher frailty scores within six months. Timed-Up-and-Go and grip strength measuring functional status were also associated with readmission or death. These findings are a first step towards identifying high-risk patients who need comprehensive discharge planning and action with the aim of preventing readmissions.</p>
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ABBREVIATIONS

TFI – Tilburg Frailty Indicator

TUG – Timed-Up-and-Go test

GS – Grip strength

ID – Interpretive description

95% CI – 95% confidence interval

IQR – Inter quartile range

N – Number

CHAPTER 1. INTRODUCTION

1.1. SETTING THE SCENE: POPULATION AGING AND FRAILITY

Population aging worldwide has major consequences and implications for societies as well as for individuals. The global share of people aged 60 years or more was approximately 12 % in 2013 and the share will increase to 21 % in 2050 (5). In Europe alone it is estimated that almost 35 % of the population is expected to be over 60 years in 2050, up from 22 % in 2009, and the older population is in itself aging (6). In 2009, the share of older adults aged 65 or more in Denmark was 16% and this number was estimated to rise to 25% in 2035 (7). The older Danish population is getting older as well and the number of people over the age of 80 has increased by 71% from 1980 until today (8).

Internationally and in Denmark as well, the increasing share of older people will put pressure on various support systems for older persons (5,7). One of the explicit consequences of these demographic changes is that the prevalence of frailty in the older population will increase considerably (9). One important challenge is the necessity of finding ways to meet the needs of a growing older population including more frail older people, in a well-coordinated, safe and effective way in and between the primary and secondary health-care sectors (9). It seems important to investigate how frailty has an impact especially in relation to older medical patients who have been acutely admitted as frailty is a condition that has far-reaching consequences for this population.

This PhD project therefore addressed a way to validly and feasibly identify frailty at discharge from hospital in these patients, their experience of daily life shortly after discharge and the serious consequences frailty may have in terms of readmission or death within six months after discharge.

In this thesis, the term “older” instead of “elderly” will be used in relation to older adults, persons and patients as “elderly” may be considered inappropriate and the term “older” or “senior”, according to Avers and colleagues, was preferred by older adults themselves (10). This is, however, not consistent across the four included papers.

1.2. ACUTELY ADMITTED FRAIL OLDER MEDICAL PATIENTS

In and between the primary and secondary health-care sectors an increasing number of frail older medical patients having been hospitalized are present. Half of the patients admitted to the medical wards at hospitals in Denmark are aged 65 years or more and 80% of these are acutely admitted. Approximately 20% of all admitted medical patients aged 65 or more are readmitted within 30 days in Denmark and internationally as well (11-14). Readmissions and mortality have large personal consequences for the patients and relatives, as well as economic consequences for society (15,16). Readmissions are an economic marker for expensive care and may also be a marker of the quality of care during and after an acute hospitalization (15,17). To accommodate this challenge in Denmark, the National Danish Health Board and other stakeholders have published several reports that focus on the effort towards health and quality of life in a growing older population including more frail people, to provide knowledge that can support both sectors when prioritizing initiatives and interventions. Knowledge sharing within sectors, systematical quality improvements by using available data and a higher degree of patient involvement in the team are all elements that have been called for (15,18-20).

In general, the older medical patient population is characterized by the following conditions; high age, severe illness, comorbidity, decreased functional status, polypharmacy and the need for personal assistance (19). The prevalence of frailty ranges depending on the measurement tool applied, the population and the setting. Sternberg et al. (2011) reported a range between 5 and 58% across 22 studies (21). In acute settings the prevalence has been reported as high as 70% (22). Acutely admitted older medical patients are characterized by high age, serious illness, co-morbidity, low functional status, poor nutritional status and low quality of life (23-26). When hospitalized, frail older patients are furthermore at higher risk than non-frail patients of developing a hospitalization- associated disability between the onset of the illness and discharge from the hospital (27). Evidence shows that frail older people are at higher risk than the non-frail of negative outcomes such as disability, dependency, low quality of life, hospital admissions and readmissions, a need for long-term care and death (28-32). Furthermore, the prevalence of frailty is higher among older people with lower educational levels and lower socio-economic status (33-35). A review by García-Pérez et al. (2011) concluded that morbidity and functional disability were the most common risk factors for hospital readmission in the elderly, whereas age and gender were not associated with readmission (36). However, the methodological quality of the included studies was problematic and several of the studies only measured readmissions to the same hospital, not to other hospitals (36). A review by Kasangara et al. (2011) found that the majority of readmission prediction models performed poorly and recommended that future studies should include psychosocial factors and functional tests and called for real-time studies to provide data to act on prior to discharge (37).

A systematic literature search on associations between frailty in admitted older medical patients and readmissions and death, showed that positive associations were seen in studies investigating readmissions (13,38-42) and studies investigating mortality (43-46). Different methods for measuring frailty, test times, periods and populations were presented in the studies, however none of the studies used a feasible multidimensional approach in real -time to define the degree of frailty in this population. A generic and feasible screening tool with high clinical applicability that identifies frailty and indicates adverse outcomes of frailty would provide an alternative to specialized or time-consuming procedures. The aim being to improve individualized care and interventions to prevent or minimize consequences such as readmission or death and to be able to act at a point in time where it still seems beneficial to intervene in order to prevent further decline.

If a screening for frailty in acutely admitted older medical patients were implemented in clinical practice a test time at discharge would seem suitable as the hospitalization itself can influence frailty either positively or negatively (27,47-49). Furthermore it seems that a 30-day readmission period as used in many countries may be too short as frailty may not be a condition that is easily treated and improved (50,51). A follow-up time of six months may therefore be considered an appropriate shorter-term outcome period that would make the findings highly relevant for both the primary and secondary health-care sectors.

1.3. DEFINING FRAILITY

The term “frailty” was introduced in the 1970s. There is today still no consensus on a theoretical or operational definition of frailty (21,52). However, there seems to be a general understanding, regardless of the specific definition, that frailty is a valid construct that can be seen as a state of increased vulnerability to adverse outcomes such as disability, hospitalization, long-term care and mortality (28,53-55). As a consequence of this understanding, frail older people can experience adverse outcomes due to even minor events or stressors (53). A biomechanical and physical definition of frailty as a syndrome dominated at first (28,56,57). Recently a broader definition with a multidimensional integral perspective of frailty has been introduced, a definition underlining that it is not only the physical perspective that is considered important in the life of elderly frail people (35,50,52,58-60). The integral way of conceptualizing frailty include the physical, the psychological and the social aspects of frailty. In an integral perspective, the three aspects are seen to interact positively or negatively in the development of frailty and all aspects are seen as important aspects of being human (61). Furthermore, this perspective can support a multidisciplinary and patient involving approach. Both perspectives of frailty, the medical syndrome approach (50) and the integral approach (62,63) agree that frailty is a threatening

condition for older persons and should be identified by using validated screening tools. Regardless the approach, it is also agreed that the physical domain is very important and that sarcopenia may play an important role in relation to frailty in the physical domain (64,65). Finally, it is generally also agreed that frailty can be distinguished from co-morbidity and disability, although there is substantial overlap between the three concepts. Disability may exacerbate the frailty of an older person whereas comorbidity may contribute to the development and degree of frailty, and both co-morbidity and frailty predict disability (34,56,66,67). Essentially, frailty is considered a manageable condition, if identified, and it seems possible to prevent or delay adverse consequences (50,61,68). Because frail older patients are very sensitive to treatment complications, immobility and malnutrition frailty should be recognized by all specialities and health professionals (69). Importantly, frailty is considered to be a clinically useful concept by health professionals (70).

1.3.1. MEASURING FRAILITY IN ACUTELY ADMITTED OLDER PATIENTS

Several different definitions of frailty exist as do multiple ways of measuring and identifying frailty. As frailty is an unobservable complex construct to measure and there is currently no gold standard for the construct, indirect measurement with multi-item instruments is recommended (71).

When frailty is defined as a physical syndrome only, a rule-based approach where certain physical symptoms/items are present or absent is used, especially Fried's phenotype of frailty has been widely applied (28). The rule-based approach has been criticized for being too narrow as a definition (57,72). When frailty is seen as an integral multidimensional condition, the cumulative deficit approach is frequently used. This approach adds together the number of impairments/items to define the degree of frailty, and the more deficits there are, the frailer the person. Comprehensive Geriatric Assessment (up to 50 items) and the CSHA Clinical Frailty Scale (up to 70 items) are both examples of this approach (62,73). The critique stated is that these approaches are complex, time-consuming and impractical for bedside screening because they require multidimensional data, data management and special training before use. A pragmatic but still multidimensional approach aimed at identifying patients at risk of serious adverse events such as readmission and death is warranted for use in a broad and not only geriatric context (74).

A self-report multidimensional assessment tool may therefore provide a feasible alternative to an entirely physical approach and to a complex time-consuming

approach in a hospital setting. The self-report approach has proven useful multiple times in relation to frailty and the association with adverse events in community-dwelling older people (75,76). There seems to be no literature on self-reported assessment tools in relation to frailty and risk of readmission or death in hospitalized older patients, although this approach would be feasible and usable across health professions and patients as well. One valid and reliable screening questionnaire that shows better psychometric properties than other multidimensional self-reporting frailty questionnaires is the Tilburg Frailty Indicator (TFI) (56,63,72,76,77). A recent systematic review assessing psychometric properties in multicomponent frailty instruments using the COSMIN checklist, concluded that the TFI had the most robust evidence on reliability and validity and had been the most extensively examined. However, the TFI still needs further evaluation in some areas (78).

1.3.2. THE TILBURG FRAILTY INDICATOR

In 2010, Gobbens et al. defined frailty as a dynamic state affecting an individual who experiences losses in one or more domains of human functioning (physical, psychological, social) that are caused by the influence of a range of variables and which increases the risk of adverse outcomes (56). On the basis of this understanding of frailty, the multi-dimensional and self-reporting questionnaire the “Tilburg Frailty Indicator” (TFI) was constructed (63,72). An illustration of this conceptual understanding of frailty can be seen in Figure 2. The model shows that life course determinants affect the occurrence of diseases and the effect of life course determinants on frailty may be mediated by diseases. Frailty can occur in all three domains - the physical, the psychological and the social - and increases the risk of adverse outcomes (72). The comprehensive approach to frailty is in alignment with the integral model as the TFI is considered very important for avoiding fragmented care for frail older persons (61).

An integral conceptual model of frailty

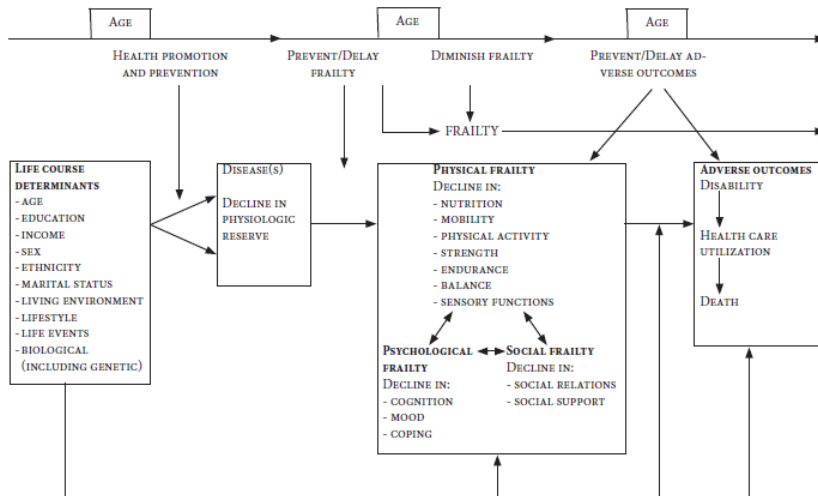


Figure 2. An integral conceptual model of frailty by Gobbens et al. (2010). (with kind permission from Dr. Robbert Gobbens).

The TFI consists of a part A that registers life course determinants of frailty containing sociodemographic factors (the box to the left in Figure 2) and a part B screening for components of frailty in the physical, psychological and social domains (the large third box in Figure 2) (72). The TFI takes a maximum of 15 minutes to complete and health professionals can quickly calculate the degree of frailty. The Dutch cutoff threshold for frailty is defined as five on a scale from zero to 15 (63,72,79). TFI was developed and validated for community-dwelling older people, but it has been suggested by the developers that it has potential applications in hospital or primary care settings as well (63). No studies have yet been identified that test the TFI in any of these settings. A robust, feasible, multidimensional and self-reporting screening tool has seemingly not previously been tested when studying the association between frailty at discharge and readmission or death in a population of acutely admitted older medical patients within six or more months after discharge.

However, no Danish version of the TFI exists and therefore there is a need to translate, cross-culturally adapt and validate the TFI to a Danish context. Furthermore, the TFI has not yet been thoroughly content-validated. A questionnaire about frailty with a bio-psycho-social approach should ideally be in alignment with what frail elderly

themselves experience as troublesome and problematic in daily life. A target population is therefore an important source of knowledge for testing the content of a questionnaire in relation to subjective elements in life and for patient-reported outcomes particular representatives of the target population are considered the experts (71,80). Qualitative in-depth interviews are defined as a source of information that can explore whether a construct gives meaningful answers from a target population perspective (80). Exploring a subjective perspective would establish evidence if it is likely that all relevant components are included and the TFI is comprehensive (80,81).

It has been and still is questioned whether self-reporting questionnaires such as the TFI, as opposed to objective measurements, provide valid answers in relation to frailty (74,82,83). A recent review suggested the use of both subjective and objective measures as a combination in relation to identifying frailty as a combination showed the strongest prediction of risk of adverse outcomes (84). A feasible approach to objective measures in relation to frailty may be to use simple and generic performance-based tests when testing an acutely hospitalized older medical population of patients. Obviously this approach primarily assesses the physical component of frailty.

1.3.3. FUNCTIONAL STATUS AS A PERFORMANCE-BASED MARKER OF FRAILITY

Sarcopenia is recognized as a key feature of the physical domain of frailty and one consensus definition is that sarcopenia is a syndrome characterized by progressive and generalized loss of skeletal muscle mass and strengths with a risk of adverse outcomes (85). It is emphasized that sarcopenia should not only be defined solely on the basis of muscle mass but also on aspects of functional capacity and it is recommended that sarcopenia is measured by grip strength(GS) and gait speed or Timed-Up-and-Go test (TUG) (85). Physical frailty, however, is not identical to sarcopenia (64). Functional status in general is a known well-established risk factor for various adverse outcomes such as falls, disability, length of stay at hospital, readmission and mortality (86,87). Assessment of functional status may potentially support an association between frailty and unplanned readmission or death in acutely admitted older medical patients. Basic functional mobility performance measured by TUG or usual gait speed and GS measured by hand grip dynamometry have been identified as strong risk factors for readmission and death (86,88,89). Previous research has shown that TUG and average gait speed performed equally in regard to predictive ability in relation to disability and function (90,91). A study by Greene et al. (2014) concluded that maximum GS and TUG were strong independent predictors of frailty, which is in alignment with other studies as well (92-94). Importantly, both GS and TUG are feasible and easy to apply

across settings and specific skills are not required of health professionals, although training is necessary to minimize tester variation. Both tests are easy to understand the meaning of and to perform from the perspective of the acutely admitted older medical patient.

1.4. THE EXPERIENCE OF DAILY LIFE AS FRAIL OLDER PATIENTS AFTER DISCHARGE FROM AN ACUTE ADMISSION

As mentioned previously knowledge sharing and a higher degree of patient involvement are seen as essential elements in relation to the older population (15,18-20). Therefore knowledge and insight about how acutely admitted frail older patients experience and live their daily lives shortly after discharge was important. A real-world view can provide an insight into what frail older patients themselves see as challenges in daily life and this is essential and called for if a patient-involving approach is the aim (18,20).

To seek this knowledge a systematic literature search was performed and a total of two studies were identified, that described the daily life experiences of frail older people in relation to hospital admission and discharge (95,96). Activity, independence and adaptation were important elements of life satisfaction for frail older people after being hospitalized. Adaptation was a way to cope with negative consequences caused by activity limitations and decreasing independence (95). Frail older people experienced a feeling of having power or being powerless in encounters with staff, and their satisfaction with the care and services provided differed (96).

A systematic search targeting studies describing experiences of daily living of community-dwelling frail older people, who had not been hospitalized and discharged described a lower quality of life than for the non-frail and it seemed that quality of life decreased as frailty increased (97). Across the identified studies a variety of experiences related to being frail and old were seen and many frail older people experienced challenges and defeats that were beyond their control (98-101). No studies were identified, that focused on the first few days after discharge of frail older medical patients even though this is considered a high-risk period with a peak in readmissions (15,27). Furthermore, knowledge about the experience of daily living of frail older patients shortly after discharge seems crucial for a future strategy of a patient-involving approach where health professionals and patients together identify and address issues related to future interventions, care and treatment.

1.5. IN SUMMARY

In summary, frailty is a serious condition for the older population, especially acutely admitted older medical patients and it is considered essential to look into frailty in acutely admitted older medical patients from both a subjective and objective perspective as both approaches can provide insight and knowledge for future strategies.

There is a need for a feasible self-reporting multidimensional questionnaire such as the TFI, which can validly identify frailty in a Danish setting, in both the primary and secondary sector. A translated Danish version should be adapted to a Danish context and ideally be in alignment with frail older patients' experiences of what is important in daily life as well. A thorough content validation of the TFI is therefore appropriate. Frailty at discharge from an acute medical admission may be detected by this self-reporting approach and functional status may be an additional, but important and feasible marker of physical frailty in particular in acutely admitted older patients. One of the most serious and dangerous adverse events after hospitalization is readmission or death and it is therefore important to assess the association with frailty as this may provide a tool for identifying those at highest risk. And using the presented generic and feasible measures may be an alternative to disease-specific and time-consuming approaches. In future strategies frail older patients and their relatives are to be much more involved in the treatment processes and it is therefore also important to know and seek to understand how frail older medical patients experience their daily lives shortly after discharge from an acute admission.

CHAPTER 2. THE GENERAL AND SPECIFIC AIMS OF THE PROJECT

2.1. THE OVERALL AIM

The overall aim of this PhD project was to validly identify frailty, to explore how frail older acutely admitted medical patients experienced daily life shortly after discharge, and to assess whether frailty measured at discharge was associated with readmission and mortality within six months in acutely admitted older medical patients. The PhD project and this thesis are based on four studies.

2.2. STUDY-SPECIFIC AIMS

Study I: To translate and undertake a cross-cultural adaption of the TFI to a Danish context including a face validation of the TFI by using cognitive interviewing in both home-dwelling and acutely hospitalized older medical patients (1).

Study II: To validate the Tilburg Frailty Indicator on content by exploring the experience of daily life of community-dwelling frail older medical patients shortly after discharge from an acute admission, in relation to the physical, psychological and social domains of the TFI (2).

Study III: To explore how frail older medical patients experience daily life 1 week after discharge from an acute admission to the hospital (3).

Study IV: To assess whether frailty in acutely admitted older medical patients, assessed by a self-report multidimensional questionnaire at discharge, was associated with unplanned readmission or death within six months after discharge. Secondly, to assess whether the basic functional mobility and grip strength were also associated with unplanned readmission or death within six months (4).

2.3. HYPOTHESES AND RESEARCH QUESTIONS

In Studies I and II no specific hypotheses were defined a priori. However, it was assumed that the content of the TFI (Study II) would cover most relevant items that frail older people themselves found important and therefore be comprehensive.

In Study III, which was an explorative qualitative study, the research question was: “How do frail elderly patients experience daily life one week after discharge from an acute admission to hospital?” The assumption in advance was that challenges and stressors would affect the patients’ experiences of their daily lives a lot and primarily negatively.

In Study IV it was hypothesized that a positive association between frailty measured by the TFI, by TUG and by GS and readmission or death was present within six months. Secondly it was hypothesized that a dose-response relationship would exist so that the frailer the patient was, the higher the risk of readmission or death within six months.

CHAPTER 3. METHODS AND MATERIALS

3.1. DESIGN

The overall research design of this PhD project was a multi-method design including four studies (102). The four specific aims of the studies defined the design, methodology and methods used to answer the research questions or hypotheses related to each of the studies. Both quantitative and qualitative methodologies and subsequently sources of data were used as neither alone could sufficiently provide the answers for the specific aims. For an overview of the studies see Figure 1 and Table 1.

Study I was a translation, cross- cultural adaption and face validation study (1). **Study II** was a qualitative content validation study (2) and **Study III** was a qualitative exploratory study (3). The same dataset was used for Studies II and III. **Study IV** was an observational cohort study (4).

3.2. SETTINGS

The data collection for **Study I** was conducted at the acute medical units, AMA 1 and 2, at Aalborg University Hospital and at Fyensgade Centret, a community activity centre primarily for older citizens situated in Aalborg City (1). The data collection for **Studies II and III** was conducted in the home of the participants, after they were recruited shortly before discharge from Aalborg University Hospital (2,3). The data collection for **Study IV** was conducted in seven medical wards, including the geriatric ward and the acute medical units AMA 1 and 2 at Aalborg University Hospital (4).

3.3. STUDY PARTICIPANTS

Study I (1): Patients aged 65 or more in the two settings were eligible for cognitive interviewing about the preliminary version of the translated TFI. Participants were excluded if they were severely cognitively impaired or very ill. The sample size was approximated to 30 - 40 respondents depending on the ongoing coding and analysis as recommended by Beaton et al. (103,104) .

Studies II and III (2,3): The study participants were acutely admitted frail older medical patients discharged to their own home from one of the seven medical wards at Aalborg University Hospital, aged 65 years or more, with the ability to participate in an interview. The exclusion criteria were severe dementia and terminal illness.

Study IV (4): The patients eligible for inclusion were aged 65 years and older, acutely admitted to and scheduled for discharge from one of the seven medical wards or the two acute medical units, and able to provide informed consent. The exclusion criteria were terminal illness, inability to cooperate due to serious conditions and severe cognitive impairment assessed by the Short Portable Mental Status Questionnaire (105). Patients that were not discharged more than two days after inclusion and testing were subsequently excluded.

In all the studies the participants had to be able to speak and understand Danish.

3.4. PROCEDURES

Study I (1): An internationally recognized and recommended procedure was applied as a basis for a formalized translation process (103,106). The primary tasks in the ten-step procedure are shown in Table 2.

Table 2. The ten steps of the translation, adaption and validation procedure of the Tilburg Frailty Indicator (1).

Steps	Procedure
Step1 Permission	Written permission from the Dutch developers to translate the TFI was obtained.
Step 2 Forward translation	Three bilingual persons living in Denmark with mother tongue Danish independently translated the TFI into the target language. T1 and T2 (Danish/Dutch) translated the original Dutch version into Danish and T3 translated the English version into Danish (Danish/English).
Step3 Reconciliation	A consensus meeting addressing any discrepancies in the translations resulted in a synthesized version, T123, of the TFI.
Steps 4-5	Version T123 was translated back to Dutch by two bilingual translators with mother tongue Dutch (Dutch/Danish). The two versions were compared to the original Dutch version of the questionnaire as a validity check of both semantic and conceptual equivalence.

Back translation and review	
Step 6 Harmonization	The pre-final version was developed during e-mail correspondence and discrepancies were resolved by consensus. All reports and drafts of the TFI were sent to all members of the harmonization committee to ensure transparency. The original developers were contacted in order to clarify any possible misunderstandings.
Steps 7-8 Cognitive interviewing and review	A test and review of the preliminary version by cognitive interviewing were performed. The interviews and the coding of the cognitive interviews were performed by two experienced interviewers, one of whom was the project manager.
Step 9-10 Final version	The finalized translation was proofread and checked for spelling and grammar issues. The layout was hereafter finalized.

Data collection and analysis in relation to Steps 1-6 was performed by the project leader and the task-specific members of the harmonization group in the different phases. In Steps 7 and 8 cognitive interviewing was performed as a validity check to investigate whether respondents understood and responded to the translated items in accordance with the intention of the TFI. This is important for the future use of the instrument, as the aim of cognitive interviewing is to reduce incomplete data and non-response (107). Purposive sampling was used for recruiting participants from the acute medical units and the community centre. A wide range of diagnoses and degrees of frailty, various backgrounds and demographic characteristics representing diversity were looked for. Due to the potentially frail population especially in the acute setting, concurrent verbal probing was used as the primary technique by the two interviewers and concurrent thinking aloud as a supplement as this technique is more demanding (108). Two health professionals performed the interviews, one being the author of this thesis, using a standardized procedure. The interviews were audio-recorded (108).

Studies II and III (2,3): Purposive sampling was used to recruit participants from seven medical wards. A wide range of diagnoses and degrees of frailty and demographic characteristics were secured to catch nuances and to facilitate maximum information and sufficient data richness (109). The required sample was expected to be 10-15 participants to cover all or most possible perspectives (110).

In total 22 patients were informed about the study and 20 gave their consent. For various reasons (death, illness, delayed discharge, withdrawal of consent), 14 participants were interviewed. Once they had been included the study participants

filled in the Danish version of the TFI (1). Participant characteristics are presented in Table 3. The mean age of the 14 included participants was 80.6 years (range 69–93 years) and all reported having co-morbidity. Three of the participants wanted their partner to be present during the interview. The partners contributed during parts of the interview. The interviews were conducted from November 2013 to September 2014.

Table 3. Characteristics of the study participants in Studies II and III.

Participant pseudonym	Age/sex ♀	Living situation	Educational level	Primary diagnosis	Length of stay/ days	TFI* total score	TFI physical score	TFI psychological score	TFI social score
1/Anders	79/M	Spouse	Elementary	Pneumonia	12	12	8	3	1
2/Maria	78/F	Spouse	Elementary	Embolism	12	5	4	1	0
3/Peter	71/M	Alone	University/college	Bilat. amputee	24	7	5	1	1
4/Leonora	93/F	Alone	Elementary	Fall	5	7	5	1	1
5/Allan	87/M	Spouse	Elementary	Pneumonia	6	7	6	0	1
6/Richard	82/M	Alone	Elementary	Brain abscess	73	10	5	3	2
7/Anna	72/F	Alone	Elementary	Weight loss	13	9	7	1	1
8/Anne	87/F	Alone	University/college	Hypoglycaemia	9	11	7	2	2
9/Elisabeth	81/F	Alone	Elementary	Renal failure	28	7	2	3	2
10/Simon	69/M	Spouse	Elementary	Bilat. pneumonia	4	7	4	2	1
11/Johanes	83/M	Spouse	Elementary	Pancreatitis	16	6	6	0	0
12/Edith	83/F	Alone	University/college	Type 2 diabetes	7	9	5	2	2

13/Mick	89/M	Alone	Elementary	Pneumonia	9	9	6	1	2
14/Betty	75/F	Alone	Elementary	Dizziness	15	8	4	2	2

♠M=male, F=female. *A total cut-off score of five on the Tilburg Frailty Indicator is defined as frail, with a possible maximum score of 15 and a minimum score of 0.

The first author of Papers II and III performed all the interviews. The role of the interviewer was to be a neutral facilitator, so that the study participants could explain themselves as fully as possible (109,110). The semi-structured interview guide consisted of questions concerning daily life:

- i) How do you feel at the moment?
- ii) Can you describe a typical day and tell me what you experience throughout a typical day?
- iii) What is a good daily life to you in a broad sense, and how do you experience your daily life at the moment?
- iv) What is important to you in relation to daily life?
- v) The way things are in your life right now, how do you experience and how do you manage the circumstances?
- vi) Are there any elements or issues in relation to the transition from hospital to home you want to tell me about?
- vii) Is there anything else you want to tell me, something you find important?

The interviews lasted for up to 80 minutes and were audio taped and transcribed verbatim by the first author. The transcribed material contained 185 pages in Calibri font size 11 (110).

Study IV (4): This prospective cohort study consecutively included acutely admitted older medical patients at discharge from Aalborg University Hospital with follow-up in central registers for six months.

The one year of recruitment took place at seven medical wards and two acute receiving medical units from May 2014 to May 2015. The medical subspecialties were: endocrinology, gastroenterology, haematology, infectious disease, nephrology, pulmonology and geriatrics. Due to there being only two testers and different bed capacities in the seven wards, a random testing sequence was prepared based on the number of discharges in the previous year, meaning that wards with higher discharge rates were approached more frequently. The two testers included and tested eligible patients from Monday to Friday using the prepared random testing sequence to approach the wards. For a two-month period it was checked that patients discharged during the early or late hours of the day and at weekends did not differ from the

included patients regarding age and gender. To accommodate inter-tester variation during data collection the two testers switched departments after six months of the one-year enrolment period. All the included patients were assessed in one session. The first author of the paper tested if one of the two testers were absent due to holidays or sick leave.

The primary exposure variable in this cohort study was the TFI as a measure of self-reported frailty. The Danish version of the TFI, which had been face- and content-validated in an acute medical setting in Studies I and II, was used (1,2).

Patients also performed two tests as a measure of functional status; TUG (time measured in seconds), where the best outcome out of three tests was used for data analysis (111,112), and hand grip strength dynamometry (GS) using a SAEHAN DHD-1 Digital Hand Dynamometer, measured in kilograms (87,113,114). The patients repeated the GS test three times with each hand, and the best result out of the six tries was used for data analysis.

Various covariates such as gender, age, place of discharge and educational level were registered at baseline. Data regarding diagnoses from admissions in the previous five years were obtained from the patient administrative system to assess a Charlson Comorbidity Index score (115).

The primary outcome of Study IV was the first unplanned readmission to any Danish hospital or death from all causes within six months after discharge. The outcome variables were extracted from central registers using the patients' unique 10-digit identification numbers that are assigned to all citizens in Denmark.

The obtained data were entered twice in Epidata (<http://www.epidata.dk/>) by two independent persons and validated. All data files were provided with an identification number, which was used when data were analysed.

3.5. DATA ANALYSIS AND STATISTICS

Study I (1): The cognitive interviews performed in relation to the preliminary version of the TFI were analysed using a matrix constructed in advance. The response errors were categorized, coded and defined using a predefined matrix (108,116). Eight of the interviews were coded independently by the two interviewers to ensure agreement and objectivity in the coding process and the coding showed perfect agreement between the two coders regarding error identification. A few errors were however categorized

differently in the matrix by the two coders. The prevalence and severity of the identified problems in the matrix would determine whether the items were revised.

Statistics: The descriptive analyses were performed using SPSS version 20.0 (SPSS, IBM Corp., Somers, NY, United States of America). Continuous variables were expressed as mean (SD) or as median (25 and 75% inter quartile range).Categorical variables were expressed in absolute numbers and frequencies.

Study II (2): This study was a secondary analysis of primary interview data (Study III) as commonly used in relation to content analysis (117). A deductive content analysis with categories structured in advance, was used. This method is considered a content-sensitive method that can be used to test previous knowledge or models (117-119). The transcripts of the interviews were read to enable familiarity with the data set and the deductive content analysis was applied to extract meaning units from the transcribed text (118). The meaning units containing perspectives in relation to the three domains and the questions related to the domains of the TFI were identified and linked. The identified meaning units in the three domains that were not covered in the 15 questions of the TFI were also identified (117,118). The coding constructed an overview of the specific frequencies of the predetermined categories and units, and in addition, units uncovered by the TFI and the data analysis grounded the data to the context of the frail elderly (119). The analytic process was primarily carried out by the first author supported by the last author, and the linking procedure and the interpretation of the meaning units were discussed throughout the analysis. The other co-authors systematically followed the process, questioning and discussing the approach and findings.

The analysis of the transcribed data was performed by using NVivo, version 10 (<http://www.qsrinternational.com/nvivo-product>).

Study III (3): The methodological approach in this study was interpretive description (ID) as described by Thorne and colleagues (109,120,121). The foundation of ID is smaller-scale qualitative investigations where the point of seeking knowledge is to use it to improve quality of life for human beings caught in complex and difficult human health problems. The purpose of investigations of a clinical phenomenon is to capture themes and patterns within subjective perceptions, thereby generating an interpretive description capable of informing clinical practice around complex clinical questions. ID does not have the purpose of theorizing and Thorne states that the approach of ID is most comfortable within a somewhat atheoretical context (109,121).

The authors used a step- by- step approach to go back and forth in the analytic process to continuously question, define, decide and conclude (109). Readings of the

interview data were carried out to get a sense of the material as a whole. The analysis was initiated as soon as the first interviews were transcribed and the analytic interpretation was open to prevent any “early disclosures” of the emerging categories in the data (109). The preliminary categories were extracted from the data material by using a comparative approach from parts to the whole and vice versa. An iterative approach was used to qualify and clarify those preliminary categories and this process finally resulted in four categories (109,121). The first author of Paper III primarily conducted the analysis supported by the last author, who also read and coded five interviews independently to ensure agreement of the analytical process. The other authors closely followed the process.

The reporting of the study was in accordance with the Consolidated Criteria for Reporting Qualitative Research (COREQ) (122).

Study IV (4): Statistical analysis: Descriptive statistics were used for baseline characteristics for the total sample, and for gender- and age-stratified analyses. Cox regression was applied to calculate hazard ratios (HRs) and 95% confidence intervals (CIs) for the association between frailty, and readmission or death. Frailty was modelled as continuous spline variables using the following knots: TFI score (knots at 2, 5 and 8 points), TUG (knots at 8, 12 and 24 seconds) and GS (knots at 14, 22 and 35 kilograms). The data within 5% and 95% of the range and the model default settings were used to define the knots. Three Cox regression models were constructed: a crude model, a gender- and age-adjusted model, and a gender-, age- and comorbidity-adjusted model as these covariates were considered to be the main potential confounders. The analyses were performed for the total sample and stratified according to gender and age +/- 75 years. Sensitivity analyses using quartiles were performed for the three exposure variables. Subgroup analyses were performed for the seven medical wards (data not shown). Due to there being very few missing data, except for the physical performance tests, especially TUG, a complete case data analysis approach was used. Statistical analyses were performed using Stata version 13 (StataCorp, 2013, Stata Statistical software: Release 13. College Station, TX: StataCorp LP). The significance level was defined as 0.05.

The reporting of the study was presented in accordance with the STROBE guidelines (123,124).

3.6. ETHICS

Study I (1): All participants received oral and written information before an informed written consent was obtained. The Danish Data Protection Agency (number 2008-58-0028) approved the study. The Ethics Committee in the Region of North Jutland, Denmark, stated that no approval was necessary since no interventions were part of the study.

Studies II and III (2,3): The Ethics Committee in the Region of North Jutland responded that no approval was necessary according to Danish Law (<http://www.cvk.sum.dk>). All participants gave informed written consent prior to participation after both oral and written information were provided. The participants were assured of confidentiality and anonymity and it was emphasized that withdrawal of consent was possible at any time and without consequences. The participants were frail and newly discharged from hospital and the interviewer was therefore conscious of the integrity of the participants during the interviews. The study was approved by the Danish Data Protection Agency (2008-58-0028).

Study IV (4): The Ethics Committee in the Region of North Jutland responded that no approval was required as the project was classified as a quality assurance project (ID-number N-20140016). Informed oral consent was obtained from all participants prior to inclusion. The study was approved by the Danish Data Protection Agency (2008-58-0028).

All four studies were conducted in compliance with the Declaration of Helsinki (125).

CHAPTER 4. RESULTS

The results are presented in relation to each study. For readability the aim of each study is presented in relation to the specific study. Please consult Papers I-IV (1-4) for further elaboration.

4.1. STUDY I

Aim: To translate and undertake a cross-cultural adaption of the TFI to a Danish context including a face validation of the TFI by using cognitive interviewing in both home-dwelling and acutely hospitalized older medical patients.

Results (1): No major problems were observed in the forward translation of the TFI as a large agreement and only minor discrepancies between the translators were seen and these were unproblematic and mostly due to synonyms. The project manager contacted the original developer to be sure of the original meaning of the wording in item 9 and 10 and the response guided the final decisions. The reconciled version and additional report were agreed upon by all three translators. The back translation of the reconciled version was used as a quality control and the two back translations were identical in the majority of the items. However, the validity check revealed unclear wording and thereby introduced a high risk of response error relating to item numbers 13-18 about physical conditions and the wording in these items was therefore revised.

Afterwards the harmonization committee discussed the items 7,9,10 and 13-18 of the TFI and a change to a synonym was made in item 7, with the rest of the items remaining unchanged. Thereafter the committee approved the translated version of the TFI.

Table 4. Participant characteristics Study I (1)

Characteristics	Participants in total N=34	Acutely admitted to hospital N=21	Home dwelling N=13
Age, mean (SD)	78.8 (6.9)	80.6 (6.5)	75.9 (6.9)
Gender female, N (%)	21 (62)	11 (52)	10 (77)
Comorbidity, N (%)	13 (38)	9 (43)	4 (31)
Married/living together	13 (38)	9 (43)	4 (31)
Healthy lifestyle, N (%)	27 (79)	18 (86)	9 (69)
Satisfied with home living environment N (%)	33 (97)	20 (95)	13 (100)

TFI total, Median (IQR)	4.0 (2; 7)	6.0 (3.5; 8.5)	2.0 (1; 4)
TFI physical, Median (IQR)	2.0 (0; 4)	3.0 (1.5; 5)	1.0 (0; 1.5)
TFI psychological, Median (IQR)	1.0 (0; 2)	2.0 (0.5; 2.0)	1.0 (0; 1.0)
TFI social, Median (IQR)	1.0 (0.75; 2)	1.0 (0.5; 2)	1.0 (0.5; 2)

N= number. SD= standard deviation. IQR= inter quartile range

After the approval of the TFI by the harmonization committee 34 native Danish participants were cognitively interviewed about the TFI (see Table 4 for patient characteristics). After having carried out and coded 10 of the interviews performed in the acute medical ward, items 9 and 13-18 of the questionnaire were revised. Item 9 was revised due to both response errors and non-responses. Items 13 to 18 were also revised, due to response errors. After this revision, 13 participants were interviewed at a local community centre. These interviews resulted in a minor revision of item 9. Finally, 11 participants in the acute medical ward were interviewed, and after the third round of interviewing and coding no revisions were made. Table 5 shows the changes made during the cognitive interview process in relation to items 13-18.

Table 5. Changes made to items 13 – 18 after the cognitive interviews (1)

Preliminary TFI	English version	Final TFI	Remarks
Har du problemer i dagligdagen på grund af 13. du er dårligt gående? 14. dårlig balance? 15. dårlig hørelse? 16. nedsat syn? 17. nedsat kraft i hænderne? 18. fysisk træthed?	Do you experience problems in your daily life due to: 13...difficulty in walking? 14...difficulty maintaining your balance? 15...poor hearing? 16...poor vision? 17...lack of strength in your hands? 18...physical tiredness?	13. Har du problemer i dagligdagen på grund af, ar du er dårligt gående? 14. Har du problemer i dagligdagen på grund af dårlig balance? 15. Har du problemer i dagligdagen på grund af dårlig hørelse? 16. Har du problemer i dagligdagen på grund af nedsat syn? 17. Har du problemer i dagligdagen på grund af nedsat kraft i hænderne? 18. Har du problemer i dagligdagen på grund af fysisk træthed?	Five out of 11 respondents did not relate the physical condition to problems in daily life, but only answered whether the physical condition was present or not. Due to a potential response error that might raise the degree of frailty we chose to construct six independent questions.

The finalized version was proofread, and the layout was revised. Adjustments were made to text type size, specific font and lining to improve the readability compared to the Dutch and English versions. An introduction was added at the beginning of the final version. A final quality control was performed by a senior researcher experienced

in translation and cross-cultural adaption. See Appendix A for the Danish and an English version of the TFI.

4.2. STUDY II

Aim: To validate the Tilburg Frailty Indicator on content by exploring the experience of daily life of community-dwelling frail older patients shortly after discharge from an acute admission, in relation to the physical, psychological and social domains of the TFI.

Results (2): The questionnaire, which contain the three domains and the 15 frailty components of the TFI, were empirically confirmed by the interview content from the participants. However, some identified meaning units could not be linked to the TFI. In total, 422 meaning units were extracted from the transcriptions, of these were 131 units related to the physical domain, 106 units to the psychological domain and 185 units to the social domain. Fifty-six units were not linked into the existing structure of the TFI. In what follows, the overall content of the three domains and related questions will be described and the units not linked into the existing structure in the respective domains will be presented together with an empirical confirmation. The empirical confirmation of the 15 questions in the TFI is not presented here (please see Paper II).

All participants experienced challenges related to the physical domain due to a decrease in their functional levels caused by illness or physical disability. The frail older people were concerned about health and loss of health and this was seen as important, as the issue was frequently mentioned. Physical constraints were a major issue in daily life with the frailest older people experiencing the most physical challenges. Some of the participants were accepting of their condition but others were very much hoping to regain their feeling of strength. Tiredness was a daily challenge for all the participants regardless of their state of frailty.

The eight questions in the physical domain of the TFI were mainly confirmed by the interview content. Question one concerned feeling physically healthy in general, and this was an issue of concern. Question two about unintended weight loss, was not a frequently presented issue and participants in general did not explore this subject. A few participants talked about food and appetite, however only two mentioned issues regarding weight loss or weight gain, and none directly addressed unintended weight loss, and the question was therefore not clearly confirmed. Questions three to eight all related to difficulties in walking, maintaining balance, poor hearing, poor vision, poor

strength in hands, or due to physical tiredness. The issues of walking and physical tiredness were mentioned more frequently than the remaining issues. Walking was an issue of concern for the frail elderly and was considered a very important function in daily life. Physical tiredness was frequently mentioned, with the consequences of tiredness being inactivity, lethargy and a lack of energy. The interviews also identified two topics not covered by the TFI; pain and sleep disturbances. Pain significantly affected daily life and well-being negatively for a number of participants. Compromised sleep quality and disturbed sleep was also a topic of concern (see Table 6 for empirical confirmation).

The psychological domain had the fewest linked meaning units. Memory was rarely mentioned in the interviews. Daily life was influenced by feelings related to nervousness, anxiety and “feeling down” or depression, which clearly negatively affected the frail older people in daily life. The frail older people described different methods of coping with problems in everyday life; some found alternative ways of managing daily life, while others were disillusioned and tired and did not feel that they had the strength to cope with their problems. Problems were related to either health-care services, family or to challenges in everyday life. Religious and spiritual issues were expressed by a few of the participants, and this element is not covered in the TFI (see Table 6 for empirical confirmation).

The majority of the identified meaning units in the data material were related to the social domain, especially the issue of receiving sufficient support. Family and friends were emphasized as being very important elements in everyday life that were very supportive in most cases. Another element related to the issue of receiving enough support was the support received from the formal health-care system. Positive as well as negative and frustrating experiences were related. An often-experienced event was the loss of a spouse, a family member, or friends. A number of the participants expressed loneliness and grief, and some expressed a wish to die. Spending time participating in meaningful activities or having the possibility of taking up a meaningful hobby or activity was an issue that participants valued and they were frustrated when this could not be a part of their everyday life. The issue of meaningful activity is not covered in the TFI (see Table 6 for empirical confirmation).

Table 6. Empirical validation of uncovered topics related to the three domains in the Tilburg Frailty Indicator (2)

Uncovered in the Tilburg Frailty Indicator - physical dimension	Empirical confirmation
Pain	Yes well I have had the nurse this morning and she again spoke to the doctor about

	whether I could get some stronger [medication]. I got some strong pills and the doctor did say that he himself should take care that the pain disappeared, but it would take a long time. So well.(4)
Sleep disturbances	But well I do not sleep at night, I sit up at night, well I do not have a good rhythm, I can as well admit that now, I do not have that.(12)
Uncovered in the Tilburg Frailty Indicator - psychological dimension	Empirical confirmation
Religion/spirituality	Well I am raised in a Christian home, didn't care as long as I was young. But it is definitely something I think more about now, that it is.(10)
Uncovered in the Tilburg Frailty Indicator - social dimension	Empirical confirmation
Meaningful activities	I am unsatisfied because I do not have anything to do. I cannot figure out what it should be that I should be activated with. Before I was active in unions and things like that. (5)

4.3. STUDY III

Aim: To explore how frail older patients experience daily life one week after discharge from an acute admission to the hospital.

Results (3): The analysis resulted in four categories; -“The system”, “Keeping a social life”, “Being in everyday life” and “Handling everyday life” - and these are described in the following section (3). All names used are pseudonyms.

The system

“The system”, meaning the health-care sector in a broad sense greatly influenced the frail participants' experience of daily life in relation to health-care service, transition, and medicine.

The provision of health-care and/or social services (cleaning) was a matter of concern and frustration, or it was satisfactory and uncomplicated. The latter was especially the

case if the same health-care worker provided service and saw the client as a human being and fulfilled her/his needs. Leonora appreciated a close relationship with her care worker in this way: *I have had the same girl [care worker] for many years and she knows when my bedding needs to be changed and all things like that, and she is very very sweet and I am happy about that.* Richard, who had been in the hospital for a long period, could not work out why all the different people visited him and felt it was needless and disturbing his effort to get back to his daily routines, indicating that the system over-supplied. As he said: *Somebody is coming all the time to help with this or that. Actually I asked for help in the mornings and evenings myself, but it is actually needless. I am already up and washed and all before they come.* In other situations the system either under-supplied or supplied, however not in relation to expressed needs. In situations where needs were not met after discharge the patients felt treated like objects and as insistent and tiresome cases and the feeling of being objectivized had negative consequences. Anders and his wife were offended by the small amount of help they received although their situation was complex and demanding. They felt it was a battle and felt violated. Anders was still weak after discharge and his ambulation skills were greatly affected. He got up at seven o'clock to have coffee and breakfast with the help of his wife. Afterwards he was assisted back to bed again and waited for home care. Anders and his wife felt left alone and let down by the system. The disillusioned and tired wife expressed her feelings: *I am just so disappointed with the municipality; there is actually no help from them, it is rotten, it is all calculations about money. There are no humans in it at all. It sounded uhh so fine, but coming here telling us that they have fourteen minutes, that is what they are saying when they arrive. I find it too bad. The time varies between nine and twenty to eleven and we do not know when they arrive.*

Participants experienced a transition to home that felt insecure and in some instances unsafe and even dangerous. The experience, for some, was that you cannot trust the system as information from the hospital to the municipality gets lost in the transition. This led to a feeling of a system that really did not take proper and professional care of you as an ill human being in need. Peter, who had had both legs amputated, came home in the late afternoon in a wheelchair. He was asked about the transition: *Ohh will you stop it! I came home to a house, where nothing was taken care of. Nothing! There was a "bedpan chair" with no bedpan beneath, so I could just shit on the floor. That was it! So everybody [staff at hospital] says, we are ready now, transportation is ordered and so forth and then you return to a house where you find a toilet chair, where there is nothing to pick up in. Thank God I had a bricklayer bucket in the utility room, otherwise only the floor would have been left. Something like that is not professional. I came home Thursday and then Annette [the home carer] came Friday starting to phone God and everybody, and she just got this message everywhere: "But*

this is Friday, so it can't be until next week. The feeling of being let down by the system and dependent upon help and care from neighbours after discharge and the feeling of being discharged without a diagnosis or explanation gave anxiety and uncertainty. As Betty said: *But you know, I live alone right. And what if it [the illness] came back? Now when they haven't figured something out. I was afraid of that. And I found it awful that is for sure. And did I not have such good neighbours; I would never have succeeded, never.* An experience of a well-prepared and timely discharge, on the other hand, resulted in a harmonic feeling and readiness for coming back to daily life at home.

Medicine was a challenge for many and ten different types of medicine was not unusual. The lack of coordination of medicine between the physician in private practice and the public urban hospital caused frustrations. The participants had a hard time getting an overview of their medicine, as the name of the preparations changed all the time and also the types of medicine changed. Different approaches to the prescribed medicine were used as new medicine could be met with full control or alternatively with confidence in the health professionals, meaning that the patients did not get involved themselves. Finally, some did not feel at all safe and secure in handling the medicine but were confused and expressed a high level of anxiety, like Elisabeth: *These pills, I think a lot about them because I am not at all used to them. And I am always scared that a mistake should happen. What if I get something I cannot tolerate, that is what I am scared of the most.*

Keeping a social life

“Keeping a social life” described the participants’ experiences of relationships and loss and their efforts to maintain social relations despite physical or psychological challenges in daily life. Positive and strong relations with a spouse, family (especially children), friends and/or neighbours were emphasized as maybe the most important in daily life. The social dimension as being characterized by a feeling of closeness and understanding was emphasized. Becoming ill and dependent on one’s spouse, children or neighbours could, on the other hand, be stressful, and the feeling of being a burden in relation to the closest relatives caused anxiety and guilt. A loss in social life in which somebody close had died was frequently described and this created consequences such as loneliness and no one to exist for, and this seriously negatively affected the returning to home. As Edith stated: *Yes, contact with my children is important for me. I don't think anything else means that much anymore. I am very much a family person. It means the world to me.* Although very important, it was also an element that was troublesome because relationships had changed due to illness and therefore the relationship with the spouse and children changed. Anders was asked what was really important in daily life and he said: *What is really important for me is,*

in fact, that our marriage is functioning and I think it still does, but I have, in fact, been nervous that it maybe would break down, because this has been too big a strain. Another type of loss was loss of contact with children or friends due to illness, abuse or problematic relationships. Problematic relationships with children or friends show how conflicts caused stressful thoughts and resulted in a distressed social life that was compromised and reduced.

Being in everyday life

“Being in everyday life” described the influence of mood and mind-set on daily life. Some participants experienced daily life as a struggle while others experienced it as more peaceful and satisfying. Psychological as well as social and physical resources influenced the way the patients acted and coped after discharge: the greater the resources, the more there seemed to be a tendency to keep up spirit and initiative. However, it also seemed that the more challenges they experienced the more difficult it was to maintain a positive mood. Leonora had been living alone in her apartment for three decades. In the late afternoon she was sitting quietly in the dark. She suffered from severe back pain, had no appetite and felt weak. She was asked what she valued the most in her life: *Nothing is important anymore. No, there is no meaning to anything. Sometimes I want to die, because there is no meaning to anything. The kids have grown old and the great grandchildren and all that, so I have experienced that.* Mick, whose wife had passed away recently, could not do what he used to and he felt odd and down: *I cannot tell you how it is; it is strange; it is kind of tingling all over. It is like I am lacking a little pep. I do get “the happy pill”, but maybe I need double of it, I don’t know. It is a bit difficult to say. One is sent home from the hospital to an empty apartment, and one of the kids is always here then, but they leave too you know. Do you know what I think? I have always been happy in life and always been involved and then suddenly you can’t anymore, but I am still happy in life, love to live. But today I feel like I say; I wish I could close my eyes; that is the way I feel today.* It seems that being inactive, not participating in meaningful activities and/or feeling alone shortly after discharge caused distress and a wish to die seemed to emerge. Their mind-set revealed the different ways in which participants dealt with their situations. Leonora had become kind of resigned to the situation: *I am as handicapped as one can be, but it is of no use just to sit down and say: ‘What am I going to do?’ I just have to take the day as it comes, right?* Maria was convinced that your own attitude was important: *Don’t you think that it depends on how you yourself are minded. You know if you give up on it all and think never mind. I think you need to have an attitude saying “Now I am heading forward and I myself have to take care.*

Handling everyday life.

“Handling everyday life” was influenced by physical constraints and symptoms and was closely related to participants’ present illness or to a general decrease in physical functioning. The focus on health and health-related symptoms was stressful for the older people and for some it clearly created restlessness and worries about getting more ill. Spending time participating in activities was important but not all were capable of this. Being tired was a very common condition after discharge and resulted in inactivity. The feeling of being inactive in daily life, for instance due to tiredness or incapability, was unsatisfactory. Peter was concerned about his future mobility in this way: *So I am anxious about whether I will be locked up in this house or I may happily be able to use prostheses, and for God’s sake please do not lock me up in here, but give me a handicap vehicle, so that I can get around.* Participants emphasized the possibility of exercising as important. Allan was waiting for the municipality to offer exercise, but he did not agree with the way the offer was handled. The offer was short term and therefore any regaining of mobility and strength would diminish shortly after: *I only have one goal and that is to get going again, to get a possibility for rehabilitation and self-training afterwards. You get ten sessions of training, and when the ten sessions are over it is good-bye. They could as well have spared the offer, because you will have the same result afterwards.* However, overall, participants did not explore knowledge or awareness of their conditions and illnesses and how they could improve their physical condition. One commonly experienced physical condition was tiredness. Anders was talking about the day and said: *But it is actually spent mostly in bed; I am extremely tired all the time. Although I don’t do anything, I am very tired.* Participants emphasized the ability to manage daily activities such as cooking, reading or knitting, although some participants did not have the ability anymore. Without exception, television was an important and time-consuming activity in daily life, some were selective about programmes, others were not picky and watched television for many hours as this made the time go by. Leonora was asked what time she went to bed: *Oh it is sometimes at five o’clock or 6 pm; it depends on how I feel. But I have a television by the bed, so I can watch that. Then the time goes alright there.*

4.4. STUDY IV

Aim: To assess whether frailty in acutely admitted older medical patients, assessed by a self-report multidimensional questionnaire at discharge, was associated with unplanned readmission or death within six months after discharge. Secondly, to assess whether the basic functional mobility and grip strength were also associated with unplanned readmission or death within six months.

Results (4): Approximately 9,000 patients aged 65 or more were acutely admitted during the 12-month period. Of these, 2,793 were consecutively screened for eligibility, of whom 1,328 were included in the study during the one-year study enrolment period (Figure 3).

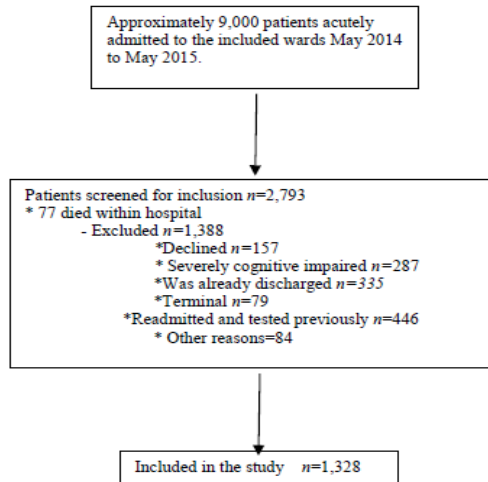


Figure 3. Flow chart Study IV (4)

Baseline data for the total sample and stratified by gender and age are presented in Table 7.

Table 7. Study IV. Baseline data for the acutely admitted older medical patients at discharge in total, gender and age stratified (4)

Median (10/90) or % (n)	Total	Women			Men		
	n=1,328	n=669	Age 65-74 n=261	Age 75- n=408	n=659	Age 65-74 n=283	Age 75- n=376
Age, Median (10/90)	77.1 (67.5;87.7)	77.4 (67.6;88.7)	70.2 (66.4;74.1)	81.9 (76.3;91.1)	76.9 (67.3;86.7)	69.5 (66.0;74.3)	81.2 (76.6;88.7)
Tilburg Frailty Indicator, total score. Median (10/90) n=1,267	5 (1;9)	5 (2;10)	5 (2;10)	5 (2;10)	4 (1;8)	4 (1;8)	5 (1;8)
Timed-Up-and-Go#, Median (10/90) n=994	12.1 (7.2;27.1)	13.1 (7.5;28.4)	10.5 (6.6;21.7)	15.6 (8.9;31.1)	11.3 (6.9;25)	9.6 (6.5;19.9)	13.1 (7.8;29.0)
Grip Strength*, Median (10/90) n=1,241	22.2 (12.5;38.1)	17.9 (10.1;24.9)	20.3 (11.6;26.6)	16.9 (9.7;23.3)	29.2 (18.2;42.9)	34.9 (22.2;47)	26.4 (17.2;36.2)
SPMSQ [‡] , Median (10/90)	9 (6;10)	9 (6;10)	9 (7;10)	8 (6;10)	9 (6;10)	9 (7;10)	8 (6;10)
No. of comorbidities, Median (10/90)	1 (0;3)	1 (0;3)	1 (0;3)	1 (0;3)	1 (0;3)	1 (0;3)	1 (0;3)
Charlson Comorbidity Index Score, Median (10/90)	1 (0;4)	1 (0;4)	1 (0;4)	1 (0;4)	2 (0;5)	2 (0;5)	2 (0;5)
BMI [§] , Median (10/90)	25.0 (19.2;33.1)	24.4 (18.4;33.6)	24.8 (18.3;35.5)	24.1 (18.6;32.5)	25.6 (20.4;33.0)	26.8 (21.0;34.4)	25.0 (20.1;31.3)
Length of stay in days, Median (10/90)	5 (1;15)	5 (1;17)	5 (1;15)	5 (1;17)	5 (1;15)	5 (1;15)	6 (1;15)
Discharged to own home, % (n)	89.9 (1,194)	88.2 (590)	93.9 (245)	84.6 (345)	91.7 (604)	94.7 (268)	89.4 (336)
Living alone, % (n)	50.5 (671)	63.1 (422)	46.4 (121)	73.8 (301)	37.8 (249)	32.9 (93)	41.5 (156)
Level of education [¶] , % (n)							
- Public school/short education	83.6 (1,110)	85.7 (573)	80.5 (210)	89.0 (363)	81.5 (537)	80.2 (227)	82.5 (310)
- Medium edu.	10.8 (144)	11.7 (78)	17.2 (45)	8.1 (33)	10 (66)	12.7 (36)	8 (30)
- Long edu.	4.7 (63)	1.8 (12)	2.3 (6)	1.5 (6)	7.7 (51)	6.7 (19)	8.5 (32)
Satisfied with neighborhood, % (n)	94.7 (1,257)	94.0 (629)	94.6 (247)	93.6 (382)	95.3 (628)	95.1 (269)	95.5 (359)

#The best outcome from three tests. *The best test result of six, three repeated tests with each hand. [‡]Short Portable Mental Status Questionnaire.

[§]Body Mass Index. [¶]Public school/short education = up to ten years, Medium education = up to 13 years, Long education = more than 13 years.

The overall median (10/90 percentiles) TFI score was 5 (1;9) and it was for women 5 (2;10) and 4 (1;8) for men. Median (10/90 percentiles) TUG score was 12.1 (7.2;27.1) seconds and GS score for the strongest hand was 22.2 (12.5;38.1) kilograms for the total sample (Table 7).

Complete follow-up on outcomes was achieved for all patients. In total, 21.9% (n=291) of the patients were readmitted or dead within 30 days and 50% (n=664) within six months. Twenty-nine patients died without having been readmitted within six months and 635 patients were readmitted. Of these 635 patients, 347 patients were readmitted once, 147 were readmitted twice, and the remaining 141 patients were readmitted between three and 13 times within six months. Among men, readmission or death was slightly more frequent than among women, 52.8% versus 47.2% (difference 5.6 %, CI 0.2;10.9) and among patients aged 75 or more readmission or death was slightly more frequent than among those below 75 years of age, 51.4% versus 48.0% (difference 3.4 %, CI -2.0;8.9).

The crude association between frailty measured by the TFI and the risk of readmission or death was positive, although levelling out with TFI scores beyond seven points. When the TFI was categorized with zero to one point as the reference value, higher frailty score categories were associated with a higher HR of readmission or death. When data were adjusted for gender and age the associations became slightly stronger in all three categories: HR 1.2 (CI 0.89;1.62), 1.61 (CI 1.19;2.17) and 1.88 (CI 1.38;2.58). Adjusted for gender, age and co-morbidity, the association attenuated slightly to HR 1.14 (CI 0.84;1.53), 1.47 (CI 1.09;1.99) and 1.72 (1.25;2.35). In gender- and age-stratified analyses the associations persisted in all subgroups indicating minor effect measure modification (Table 8).

The crude analyses of the TUG also showed a positive association between test score and readmission or death. Gender- and age-adjusted associations were slightly stronger, whereas gender-, age- and co-morbidity-adjusted values were essentially unchanged. When stratifying, the associations were present in all gender and age subgroups (Table 8). The GS score was inversely associated with risk of readmission or death. Adjustment for gender and age attenuated the associations and so did adjustment for co-morbidity in two of the categories. The stratified analyses again indicated consistent associations (Table 8). Subgroup analyses for the seven different medical wards were performed (data not shown). Associations between the frailty indicator and the results of functional tests were consistently present although uncertain, due to the low number of patients in the individual wards.

Table 8. Hazard ratios and 95% confidence intervals for readmissions and death using Cox regression with cubic splines. Full data set. N=1328. 664 readmitted/dead in 182 days (4)

	TFI total 0-1 pts. Reference	TFI total 2-4pts. HR, (CI)	TFI total 5-7pts. HR, (CI)	TFI total 8-13pts. HR, (CI)	TUGmin 4-7.9 sec Reference	TUGmin 8-11.9 sec. HR, (CI)	TUGmin 12-23.9 sec. HR, (CI)	TUGmin 24-sec HR, (CI)	GSmx 2.2-13.9 kg Reference	GSmx 14-21.9 kg HR, (CI)	GSmx 22-34.9 kg HR, (CI)	GSmx 35-kg. HR, (CI)
Crude	1.0	1.16 (0.86;1.56)	1.57 (1.17;2.11)	1.77 (1.3;2.4)	1.0	1.26 (0.92;1.71)	1.86 (1.39;2.49)	1.75 (1.24;2.47)	1.0	0.62 (0.5;0.79)	0.67 (0.53;0.84)	0.57 (0.43;0.76)
Adjusted Sex, age	1.0	1.2 (0.89;1.62)	1.6 (1.19;2.17)	1.88 (1.38;2.58)	1.0	1.29 (0.95;1.77)	1.98 (1.46;2.68)	1.9 (1.32;2.72)	1.0	0.58 (0.46;0.74)	0.49 (0.37;0.64)	0.35 (0.25;0.51)
Male Adjusted for age	1.0	1.03 (0.72;1.46)	1.46 (1.03;2.08)	1.63 (1.1;2.42)	1.0	1.21 (0.82;1.78)	1.93 (1.32;2.82)	1.75 (1.09;2.8)	1.0	0.68 (0.4;1.16)	0.60 (0.37;0.99)	0.43 (0.25;0.75)
Female Adjusted for age	1.0	1.76 (0.94;3.28)	2.19 (1.17;4.0)	2.69 (1.44;5.03)	1.0	1.45 (0.85;2.46)	2.09 (1.25;3.47)	2.14 (1.2;3.82)	1.0	0.56 (0.43;0.73)	0.42 (0.29;0.6)	No events
Age 65-74 Adjusted for sex	1.0	1.24 (0.81;1.89)	1.88 (1.21;2.9)	2.39 (1.53;3.73)	1.0	1.48 (1.01;2.18)	1.96 (1.33;2.89)	1.92 (1.11;3.31)	1.0	0.47 (0.31;0.70)	0.29 (0.19;0.45)	0.19 (0.12;0.31)
Age >75 Adjusted for sex	1.0	1.11 (0.72;1.7)	1.37 (0.9;2.08)	1.51 (0.97;2.34)	1.0	1.07 (0.62;1.83)	1.87 (1.12;3.1)	1.76 (1.02;3.03)	1.0	0.66 (0.5;0.88)	0.66 (0.47;0.91)	0.65 (0.39;1.07)
Adjusted Sex, age, comorbidity	1.0	1.14 (0.84;1.53)	1.47 (1.09;1.99)	1.72 (1.25;2.35)	1.0	1.23 (0.9;1.69)	1.83 (1.35;2.49)	1.77 (1.23;2.55)	1.0	0.61 (0.49;0.78)	0.54 (0.41;0.7)	0.42 (0.29;0.6)
Male Adjusted for age, comorbidity	1.0	0.97 (0.68;1.38)	1.31 (0.92;1.87)	1.42 (0.95;2.11)	1.0	1.14 (0.77;1.68)	1.73 (1.18;2.53)	1.64 (1.02;2.63)	1.0	0.79 (0.46;1.36)	0.72 (0.44;1.2)	0.57 (0.33;0.99)
Female Adjusted for age, comorbidity	1.0	1.71 (0.92;3.19)	2.09 (1.12;3.92)	2.59 (1.38;4.84)	1.0	1.42 (0.84;2.42)	2.03 (1.22;3.39)	2.02 (1.13;3.61)	1.0	0.57 (0.44;0.75)	0.44 (0.3;0.64)	No events
Age 65-74 Adjusted for sex, comorbidity	1.0	1.13 (0.74;1.73)	1.7 (1.1;2.63)	2.05 (1.31;3.21)	1.0	1.43 (0.97;2.09)	1.83 (1.24;2.7)	1.76 (1.02;3.04)	1.0	0.5 (0.33;0.75)	0.33 (0.21;0.5)	0.24 (0.14;0.4)
Age >75 Adjusted for sex, comorbidity	1.0	1.09 (0.71;1.67)	1.3 (0.86;1.97)	1.45 (0.94;2.25)	1.0	1.02 (0.6;1.75)	1.74 (1.05;2.9)	1.67 (0.98;2.89)	1.0	0.68 (0.51;0.91)	0.71 (0.51;0.98)	0.69 (0.42;1.15)

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CHAPTER 5. DISCUSSION

This thesis is based on four studies performed in relation to a population of acutely admitted older medical patients (1-4). The aim of this project was to validly identify and explore the meaning and consequences of frailty in terms of readmissions or death in acutely admitted frail older medical patients. The four studies provided important contributions and knowledge in relation to frailty and acutely admitted frail older medical patients.

5.1. KEY FINDINGS

Firstly, a Danish version of a multi-component and feasible screening instrument for frailty, the Tilburg Frailty Indicator was provided after a rigorous ten-step procedure including translations, cross-cultural adaption and face validation by cognitive interviewing. The forward and back translation of the original version of the TFI was unproblematic except for items 13-18 where an important revision was carried out. The cognitive interviews were used to face-validate the TFI and make a quality check in relation to response errors and non-responses and this procedure resulted in changes to both content and layout. Thereafter the TFI was approved and considered ready for further testing and implementation in a Danish context (1).

The TFI was further thoroughly validated by using individual semi-structured interviews as secondary data in relation to content from the perspective of the target population of acutely admitted frail older medical patients. All components except unintended weight loss were confirmed from a target population perspective and the majority of elements expressed in the interviews were covered by the TFI. However other elements experienced as having an influence on daily life one week after discharge were not covered by the TFI. These were pain and sleep quality in the physical domain, spirituality in the psychological domain and meaningful activities in the social domain (2).

Individual semi-structured in-depth interviews explored the experiences of daily lives of acutely admitted frail older patients one week after they were discharged from hospital to their homes. The four categories “The system”, “Keeping a social life”, “Being in everyday life” and “Handling everyday life” greatly affected how everyday life was experienced. Whether the study participants experienced well-being by feeling calm and in control or the opposite by feeling restless and without control depended on how their needs were met and how they experienced their lives and challenges. The frailer the participants were the more they tended to experience stressors and struggles in everyday life. Their contact with the health-care system, social relations, mood and constraints in handling life significantly influenced overall

well-being or non-well-being. Some of the participants expressed great concern and worry in relation to their daily life and their quality of life was clearly affected (3).

Finally, an observational cohort study showed a consistent association between self-reported frailty measured by the TFI and readmission or death within six months in the crude, the gender and age, and the gender, age and co-morbidity adjusted models. Likewise, consistent associations were seen between the performance-based measures of functional status, TUG and GS and readmission or death within six months in the crude and adjusted models. When adjusted for gender and age an 88% higher risk of readmission or death was present if TFI scores were 8–13 points than if they were 0–1 points for the total sample (HR 1.88, CI 1.38;2.58). If the TUG score was between 12.0 and 23.9 seconds compared to 4.0 to 7.9 seconds there was a 98% higher risk of readmission or death (HR 1.98, CI 1.46;2.68) when adjusted for gender and age. Finally, GS was inversely associated with readmission or death. Analyses stratified according to gender and age also indicated that the associations were consistently present in all subgroups. Generally, in all three measures, TFI, TUG and GS, a dose-response association was seen so that the higher the frailty score or the lower the functional status the higher the risk of readmission or death within six months after discharge (4).

5.2. THE TILBURG FRAILTY INDICATOR

There is consensus that researchers should avoid creating a new questionnaire if a psychometrically sound questionnaire measuring the construct of interest already exists in another language (71,80,126). Previous research suggested this with the TFI, and in particular the recent review by Sutton et al. supported this point of view (76-78). Instead a translation and cross-cultural adaption of an existing questionnaire or instrument should be considered. The purpose of the cross-cultural adaption is equivalency of content and if the process is of high quality other psychometric properties might be retained (103). A recent review concluded that no superior method of translation and cross-cultural adaption of self-reporting questionnaires existed, however it was recommended that a systematized methodological approach that accommodated all important phases in the procedure should be used (126). We used the approach recommended by Beaton et al. and Wild et al. and included all the steps proposed (103,106). Another recent review concluded that, in particular, the use of an expert committee was important for the quality of the translation whereas the back translation step did not seem to add anything important (127). The back translation of the TFI did result in an important revision, and therefore in this case a back translation did add an important contribution. We did establish an expert committee (the harmonization group), but the committee did not meet face to face due to time and geographical issues. They did, however, see the different versions of the translations and responded to these, but nevertheless this may have affected the final result.

It is important that a transparent and available version of translated instruments is published as this prevents the existence of multiple versions. Furthermore it is important to verify that the version is of high quality, and finally it is important to have frailty measures that can be used across nationalities. In this case, many countries in for instance Europe and North America have similar challenges and tendencies in relation to frailty meaning that knowledge can be shared (50,51,53,128).

The TFI is a formative model with latent unobservable variables where the items form or cause the construct under study (71). In a formative model, each item should contribute to a part of the construct but the items do not necessarily correlate with each other and are therefore not interchangeable. Therefore missing an important item inevitably means that the construct is not measured comprehensively. Comprehensibility is of major importance in self-reporting instruments like the TFI and this implies, that all items that cause considerable frailty should be included (71,80,129). Content validity refers to whether the content of an instrument is an adequate reflection of the construct to be measured in terms of the relevance and comprehensiveness of the included items (71,80,81,130). Gobbens and colleagues did to some extent content validate the TFI, but not thoroughly in relation to the target population of frail older persons (63). Furthermore, it is recommended that when a self-reporting instrument is considered applied in a new target population the content validity should be tested in that population as well (81). The data used for content validation in Study II were obtained in the new target population of acutely admitted frail older medical patients shortly after discharge. Data were secondary as they were obtained with the aim of Study III and no leading questions were given in relation to the TFI and the content of the TFI, which is considered a strength (80). Even though four issues were described that were not included in the TFI it does not necessarily mean that changes are requested, and further research should investigate this. The data in study II was based on 14 participants and more solid knowledge may be needed before any conclusions can be drawn. However, previous research do support the findings in Study II as it confirms that these four issues seem important from an integral health perspective (131-138). Despite the support of the findings it should still be considered as the challenge is to keep the instrument simple and user-friendly and exhaustive at the same time and in relation to a vulnerable target population practicality is an important criterion (56). This is very much the case with the target population of this PhD project.

The findings of Studies I, II and IV, along with the body of scientific knowledge around the TFI, enable us to state that we may have provided a valid way of identifying frailty in acutely admitted frail older patients in a Danish context by self-report (63,76-78). However, as the review from Sutton et al. (2016) states, there is still a need for more research before the TFI can be regarded as the gold standard for multicomponent screening instruments (78). Although the findings in study IV show a robust association between frailty as measured by the TFI and readmission or death, there is a need for more evidence regarding the properties of the TFI in primary care

and hospital settings. The research findings in these settings are still very scarce as Study IV is the first study to use the TFI in an acute hospital setting.

5.3. SELF-REPORTING VERSUS PERFORMANCE-BASED FRAILTY APPROACH

Self-reporting is a feasible, user-friendly and non-costly way of obtaining data about frailty directly from older persons themselves. Furthermore, according to Fayers and Machin (2007), observers are poor judges of patients' opinions no matter if the observer is a relative or a health professional as both underestimation and overestimation occurred in different settings (129). We did not use proxy respondents in our study as the self-reporting approach would thereby get somewhat compromised. On the other hand, it has also been problematized that self-reported frailty measures are at risk of being flawed by social desirability bias, recall bias and personal factors (74,84,139). Differences between gender have been shown; the paradox being described is that women as a population reported higher frailty but had fewer serious adverse events than men who reported lower frailty but had more events (84). Only a very few missing answers were seen in relation to the 15 components about frailty in the TFI in study IV, with the item missing most being "Are you able to cope with problems well?"

We did not analyse which of the three domains of the TFI were the most associated with the adverse events of readmission or death. Literature has shown that the physical domain of the TFI seems to be a stronger predictor of adverse events in community-dwelling older people than the psychological and social domains. The present findings of associations between the performance-based markers of frailty and readmission or death seem to support these previous findings of the physical component of frailty as being the most important in relation to the prediction of adverse events (65,79). However, even though frailty and sarcopenia are linked, they are distinct correlates of aging. Poor functional capacity in a frailty perspective results from a large number of causes, not all linked to skeletal muscle amount or function (64).

Physical performance measures also have advantages and disadvantages. One advantage is that a test that measures a specific performance has a clear face validity for the task that it assesses (83). Furthermore, a physical test can be reproduced more easily and it is less influenced by personal factors and cognitive function. The disadvantages include the fact that they might be time consuming, they require training of examiners and potentially injuries may occur (83). Not all the included patients wanted or were able to perform the two functional tests, but importantly no injuries were recorded, which may be due to the experienced and trained testers. By using both TUG and GS the possibility that the patients could perform at least one of the tests was high as the two assessment tools covered two different body areas.

Additionally, GS is not as demanding a task as TUG. It could, however, be questioned as to whether the scores were influenced by the medical illness or the time point in the day when they were tested. A recent Danish study showed that average gait speed and GS were feasible in acutely admitted older medical patients and a high inter-rater reliability was seen for the two tests and both tests had an acceptable standard error measurement (140).

Different assessment tools have been shown to identify different aspects of frailty and different risk profiles of which none has been assessed as comprehensive in itself (51,84,141,142). A combination of the two approaches (self-reporting and objective measures) using feasible methods was recently recommended as a reasonable future strategy (84). The approach in this thesis of not making it an “either or” but instead including self-reporting and simple performance-based assessment tools with high clinical applicability may in particular be a usable approach in acute hospital settings as associations between frailty and readmission or death were present using either of the three assessment tools for frailty.

5.4. ASSOCIATION BETWEEN FRAILITY AND READMISSION OR DEATH

Even though the literature generally describes a readmission proportion of approximately 20% after 30 days it was a surprisingly high number when data from the Danish register showed that 50% of all the patients enrolled in Study IV were readmitted or dead six months after discharge, regardless of their state of frailty. Furthermore, the most frail and ill patients were probably excluded beforehand, due to the exclusion criteria. Another Danish study with a similar population reported close to a similar readmission proportion after six months (143). Conrad et al. (2013) reported a readmission proportion of 33% after 90 days in a Canadian population of older medical patients admitted to an acute medical ward, indicating that these high proportions may not be unusual (40). However, 50% after six months seems very high and this finding in itself should give rise to considerations.

The crude analysis in Study IV showed an association between frailty and readmission in all three measures. To accommodate any potential confounding by gender and age in Study IV the cohort was adjusted for these variables in multivariate analyses and both were also stratified to assess consistency across the strata of gender and age. The HRs were only slightly affected, indicating that sex and age only had a minor influence, as also shown in previous studies (11,40). The TFI does not include comorbidity as a frailty component however this is debatable, especially due to its close relationship with frailty (17,41,42). The TFI as well as other instruments see comorbidity as a separate concept (28,61,66). Therefore a possible effect of morbidity was investigated by adjusting for Charlson Comorbidity Index Score in Cox

regression analyses. Generally the HR decreased slightly, indicating that co-morbidity was a confounding variable explaining a minor part of the association. The interpretation was, however, not clear when morbidity was included in the analyses as the variation in frailty measures was no longer due to morbidity and certain co-morbidities may still be closely related to parts of the multi components in the TFI. It was chosen not to adjust further for confounders as these may also be closely related to the multicomponent frailty indicator.

The findings of Study IV were supported by, and consistent with, a number of recently published studies investigating readmissions or death combined, despite using different frailty instruments (11,13,17,38-42,142,144,145). Even though there were differences in populations, wards included, frailty models and frailty prevalence and in the frequency of events and follow-up time, it can be concluded that a self-reported approach to frailty showed similar positive trends between frailty in older medical and geriatric patients and the risk of being readmitted or dying. It has been stated that self-rated measures of health alone have no place in frailty assessment in clinical settings (82,144,146). The findings of this study do not support this point of view.

The two functional measures used in this study have previously been associated with mortality and readmissions, even though readmissions seem to have been investigated less (38,87,88,147). These findings were supported by the present study showing that the two functional measures were associated with readmission or death. However, the two tests are still not seen as sufficient measures in clinical practice, as frailty in a bio-psycho-social understanding consists of several elements that should be taken into consideration (59,61,78). But the findings indicate that the physical domain is a key component of multidimensional frailty.

Screening of frailty performed in relation to discharge seemed timely and reasonable as the hospital admission, treatment and clinical stabilization or the potential subsequent functional deterioration may influence the condition of the patient (27,148). In a complex setting of medical wards it is important to have a feasible instrument that can identify older patients at risk regardless of specific symptoms and diagnoses (41,146). Study IV is the first study to use the TFI for screening for frailty in an acute setting to analyse the association with serious adverse events such as readmission or death within a short term of six months. This is an important first step in introducing feasible self-reported frailty screening in acute and medical wards in hospitals. Previous research in these settings has primarily used more time-consuming and specialized approaches when establishing the association between multi-component frailty and readmission or death.

The findings from Study IV make it highly relevant to look at the qualitative findings of Study III with the intention of providing a nuanced picture about important issues from the perspective of frail older medical patients.

5.5. THE EXPERIENCE OF DAILY LIFE AS FRAIL

Study III provided findings that could be of importance in relation to discharge, transition and readmission as the 14 participants expressed their experiences, needs and concerns one week after discharge from an acute admission. The findings may contribute to a deeper understanding thereby also indicating solutions for future initiatives to be investigated.

The 14 interviews revealed positive elements but also plenty of potential stressors and unmet needs, which were all elements that greatly affected the experience of daily life. In particular, the experiences in relation to the transition to home were of importance for the participants, for instance the character and amount of help, medication worries, communications gaps, and being alone and ill. Our study supports earlier research showing unsafe transitions in relation to elderly patients' discharge from hospital (149,150). The quality of the discharge for elderly patients aged over 75 with multifaceted care needs, amongst other things, was impaired by lack of systematic information exchange between health care professionals and next of kin (150,151). Furthermore, short time in hospital, limited involvement and preparation for patients' transition and the lack of a professional system and role competence of health-care professionals were described. A focus on the identification of these problems seems to be an important step in the process of improving transition, to secure wellbeing, and avoid serious adverse events. The large number of readmitted or dead patients within six months after discharge as the findings in Study IV showed, clearly indicates that some procedures must be reflected upon and improved.

The interviews showed that some elements and stressors not only affected the physiological system, but also the psychological and social systems. In particular, the contact and communication with the health-care system created frustrations and worries, but also physical disability, loneliness, and inactivity were issues of concern. Frail older people have previously been described as complex physiological systems, where stressors disturb the homeostasis of the system, thereby increasing the risk of adverse consequences (53,66,152). As a consequence of the presented findings in Studies II and III, health professionals should include psychological and social elements as well, as this approach may contribute to better identification of stressors and therefore a better understanding of the needs of the older patients. A recent qualitative study describing the experiences of older high-risk patients in transition

from hospital to their own home supports these findings and points out that it is not only medical needs that need attention but also social needs (153). A recent study explored the experiences of loneliness in frail older people and confirmed that loneliness was affecting their daily life and the participants wanted to overcome the physical, psychological and social barriers that made them feeling lonely (154). Finally, these findings are supported by a recent study that confirmed the negative impact of frailty on social functioning and loneliness (155).

In Study III it seemed that system failure was related to physical, psychological or social challenges such as disability, loneliness and loss or lack of support. A system failure cannot be easily restored and to do so is a complex and expensive task (156,157). It is therefore important to focus on homeostasis and an in-depth understanding of the system complexity in frail older medical patients to avoid failure and ensure wellbeing. The complex system of the frail older individual is part of another complex system: the health-care system consisting of a community sector and a hospital sector. Several stressors were identified shortly after discharge, such as the amount and type of help, help devices and medication, all factors that can lead to system failure and to unnecessary suffering for older patients (143,158). Previous research supports the belief that the two health-care sectors are having difficulties coordinating, communicating, and coping with these issues. Importantly, these system failures can lead to adverse events such as early readmissions, drug events and falls (15,143,159). A review by Laugaland et al. (2012) strongly indicated that targeted interventions were needed to improve transitions across health-care settings (159). The health-care system seems to need a defined explicit strategy that captures the nature of complex systems so it becomes capable of identifying, adapting to and acting against stressors and potential failure in and between both sectors (160,161). A bio-psycho-social approach would have the profound consequence that the perspectives of frail older medical patients should be heard in decision-making related to transition and discharge, which still seems not to be the case for a large number of older hospitalized patients (162). The organizational structure of the health-care system may need to be redefined and reorganized to be capable of dealing with the complexity. The findings of Study III, which show a large diversity in experiences and challenges, indicate that an individualized and holistic approach may be one element that should be strengthened. Another indication seems to be that the patient and family should have the opportunity, be invited and maybe even recommended to become more active partners as patients have different needs and expectations as well as diverging conditions and capabilities.

The majority of the participants did not mention the character of their illness and condition and it seemed as if they were unaware of, or did not pay much attention to, the consequences of physical inactivity and other lifestyle patterns in relation to daily

life. Frailty can be reversed as well as it can deteriorate and, in particular, exercising, nutritional support, and reduction of polypharmacy are evidence-based interventions (50). The TFI may be the tool that could mediate individualized patient-involving dialogues about illness and prognoses, so that patients become aware of their own role and capability in relation to their situation. From an individual patient perspective and a health economic perspective, physical training and dietary advice should also be provided immediately after discharge and perhaps even on a long-term basis as these two aspects are very important elements. This is supported by the findings in a recent update from an ongoing longitudinal Dutch cohort (128). Managing all the medications was another challenge for the patients and therefore initiatives addressing this issue should also be strengthened (50).

5.6. IDENTIFICATION, MEANING AND CONSEQUENCES OF FRAILITY

The TFI is an internationally acknowledged simple screening indicator for identifying multidimensional frailty and the translation into a Danish version made it usable in a Danish acute hospital setting. The content validation showed that the content was in alignment with frail older medical patients' daily life experiences, which is reassuring when the intention is an integral and patient-involving approach in the management of frail older medical patients. Generic functional measures are known to identify older medical patients at risk and a combination of self-reporting and performance-based assessment tools may be mutually complementary and lead to a comprehensive assessment of frailty. The association between frailty status and unplanned readmission or all cause death became quite clear in a population of 1,328 patients and present in all three measures at discharge from hospital. Additionally it was seen that the frailer the individual and the lower functional status the higher the risk, and this was also consistent in all three measures. When interviewing the 14 patients about their daily life, a heterogeneous group with challenges in all aspects of life was seen and it seemed that the frailer the patients, the harder the struggles they experienced. Some coped well and some were very disturbed. It seems that an individualized integral approach may be needed *after* the frail patients in risk are identified by the TFI, TUG and GS. Some elements from the interviews call for an individualized approach to patients but also a focus on the health-care system level should perhaps be addressed. The elements included: i) individualized information and dialogue for the patient and family to create awareness about illness and lifestyle; ii) knowledge about the evidence on how to prevent or decrease frailty and empower patients to change unhealthy behavior in daily life; iii) careful consideration of whether the frail patients and the system are truly ready for discharge; iv) education of all bed-side and home care health professionals about frailty and frailty-decreasing interventions; v) evaluation of whether the right interventions and initiatives are offered and whether

the quality, intension and/or duration of the offered interventions are sufficient, and finally; vi) how to minimize disruptions of information, care and treatment in and between sectors.

To improve the identification and well-being of patients and decrease the readmission rates, changes are seemingly needed on both a personal micro level for both patients and health professionals, and also on a larger structural level in relation to transmission processes and health-care services. Finally evaluation is needed on a political level to reflect upon and improve the health-care system for this vulnerable population. A recent statement about involving and partnering with patients and families also underlined that these three levels should be prioritized in future approaches (163). A recent consensus statement focusing on frailty as an emerging public health priority underlined similar (and more) challenges and issues as the ones that evolved on the basis of this PhD project (51).

5.7. METHODOLOGICAL CONSIDERATIONS

The rigorous approach of the translation, cross-cultural adaption and face validation is considered a strength in Study I.

According to the COSMIN checklist, the sample size for cognitive interviewing in relation to cross-cultural adaption should be the number of items multiplied by 5 which indicates that a total number of 75 participants from the target population should have been cognitively interviewed in Study I. Due to the fact that we interviewed 34 participants and not 75 as recommended in the COSMIN checklist Sutton et al. (2016) scored the quality of Study I as poor in their recent review. However, there is no consensus on this topic generally in the recommendations from experts within the cognitive interviewing area. Furthermore, it does not seem to be important how the cross-cultural adaption using cognitive interviewing is performed. The element that seemed to have an impact was that the cross-cultural adaption was performed in a systematic way, according to a recent review (126). The conclusions in two recent reviews addressing cross-cultural adaption may indicate that a revision of these issues is needed in relation to the COSMIN statement as the checklist and the Delphi method could be supplied by evidence using the findings from the two reviews on cross-cultural adaption (126,127).

A reliable test is one that measures a construct in a consistent, repeatable and reproducible manner and it should obtain the same measurement in the absence of real change. It is recommended that test-retest studies are undertaken whenever a new target population is under study in self-reporting as well as other assessments (71,81). No test-retest of the TFI has been performed in relation to the population of acutely admitted older medical patients. A test-retest study could have contributed to more

robust psychometric properties of the TFI. However previous research has shown quite high reliability in community-dwelling frail elderly people (78). But it would have strengthened the findings further in this PhD project. Likewise we did not establish test-retest or inter-rater reliability ourselves in relation to TUG and GS either.

The participants included in studies II and III met the predefined criteria of diversity in diagnosis, age, sex and degree of frailty as intended. Due to the sample size the findings may be considered as unique with no scientific value. However, there are aspects of the universal in the unique cases (110) and the study did provide rich and varied data to a degree that ensured a qualified and credible response to the aims of both Studies II and III. One methodological consideration has been whether a week after discharge was too short a time span for the frail elderly to settle into the home environment, but adverse events more often occur shortly after discharge and in phases of transition (15,149). Thorne emphasizes that only research questions producing timely and relevant knowledge should be chosen. With the ID approach in Study III the intention was to provide knowledge relevant for clinical practice, especially with the aim of improving the quality of life for human beings caught in complex and difficult health problems (109). To ensure rigor in study III we strived to ensure that each step of the study matched the research objective and methodology. The findings and description of the complex health issues in everyday life should be used in other studies or projects or to inform clinical practice if the aim of improving practice is to be reached. However, one limitation may be that the population diversity may not be fully reflected within a study of this nature with a sample size of 14, thereby indicating that the research findings in Study III may not be entirely valid (109).

Assessment of the validity of the findings in Study IV is important to determine whether the observed associations are seemingly truly causal or the results of bias, random variation or confounding (164). In relation to Study IV, the Danish Civil Registration System contains a unique personal identifier for all Danish citizens and the Danish National Registry of Patients, which covers all inpatient non-psychiatric hospital treatment in Denmark since 1977 make the reliability of the data in the cohort study very high (165,166). Therefore the primary strengths of Study IV include the large study sample and complete follow-up on outcomes for all patients. Due to limited examiner resources we could not include all eligible patients. The included patients were assessed as being representative of the population admitted to the hospital as they did not differ in age and gender from patients discharged at other time points and a random testing sequence was used when approaching the wards and patients. Furthermore only few patients refused to participate. Only little selection bias may be present in Study IV as no missing data on outcome was seen. This is

considered a strength as selection biases are distortions that come from procedures used to select subjects and factors that influence study participation (164). Furthermore, information regarding the outcomes was obtained from registries and independently from the exposure information. Information bias resulting from inaccuracies in the measurement or incorrect classification therefore seems unlikely (164).

Confounding should always be considered present in epidemiological cohort studies as it is an extraneous risk factor. A confounder is associated with the exposure variable as well as the outcome measured and can therefore confound the association (164). To accommodate potential confounding by gender and age in Study IV we adjusted for both in multivariate analyses and stratified analyses to assess consistency across the strata of gender and age. Furthermore, a model adjusting for gender, age and comorbidity was constructed. This approach was chosen as these covariates were considered the main potential confounders. Unaccounted confounding by other factors cannot be ruled out, however it was decided not to adjust for more potential confounders as these may also be closely related to the multicomponent frailty indicator.

One limitation of Study IV was that the study undertaken at one geriatric, six medical and two acute wards at a single university hospital in Denmark and findings should therefore be generalized to other populations or settings with caution. Study IV is seemingly the first to use the self-reporting TFI, and the generic measurements GS and TUG, to describe the association with readmission or death within six months of discharge in a sample of acutely admitted older medical patients at discharge. Therefore the study should be replicated in other samples in other settings to validate the findings.

A multi-method design including both quantitative and qualitative methodologies may be seen as a limitation as the different approaches hinder depth in relation to one methodology and related knowledge. However, in this PhD project it is considered a strength as the different methodologies and therefore findings complement each other. Studies I, II and IV together contribute to the robustness of the TFI in a Danish and international context, while study III provides an in-depth understanding in relation to acutely admitted frail older medical patients. Finally it was documented in Study IV that self-reported frailty and physical lower function in a frail population in acutely admitted older medical patients at discharge were associated with a higher risk of readmission or death within six months.

CHAPTER 6. CONCLUSION

The overall aim of this PhD project was to validly identify frailty, to explore how frail older acutely admitted medical patients experienced daily life shortly after discharge, and to assess whether frailty measured at discharge was associated with readmission and mortality within six months in acutely admitted older medical patients.

The TFI is a self-reporting comprehensive assessment tool reflecting the multidimensionality of frailty. At the same time it is short and practical enough for use in both clinic-based and research-based settings. In Study I (1) internationally recognized procedures were applied and the TFI was translated, cross-cultural adapted and face validated in a rigorous manner so that the instrument was considered ready to be implemented and further tested in clinical practice in a Danish context.

The findings of Study II (2) added to the scientific body of knowledge and evidence in relation to the robustness and validity of the TFI. All questions in the TFI were confirmed from the perspective of a target population of acutely admitted frail older medical patients and it seemed likely that the majority of important items related to frailty were covered in the TFI. The four issues of pain, sleep quality, spirituality and meaningful activities, which seemed to be important elements in daily life for a frail population, were not directly covered by the TFI.

Study III (3) provided in-depth knowledge about how acutely admitted frail older medical patients experienced daily life one week after discharge. Contact with the health-care system, social relations, mood, loneliness, and constraints in handling daily life influenced overall well-being or non-well-being and some of the frail older patients expressed great concern and worry in relation to their daily life. Therefore future interventions should incorporate a multidimensional perspective when acutely admitted frail older medical patients are discharged from the hospital. Stakeholders should evaluate present practice and consider a redefinition and reorganization of the health-care system to ensure high quality of integrated care across the primary and secondary sectors.

Study IV (4) showed that acutely admitted older medical patients' frailty assessed using a self-reported multicomponent frailty questionnaire, the Tilburg Frailty Indicator (TFI), at hospital discharge showed a higher risk of readmission or death at higher frailty scores within six months in both the crude and adjusted models. Likewise TUG and GS measuring functional status were associated with readmission or death. Generally, the frailer or the lower functional status of the patients, the higher

the risk of readmission and death within six months. The findings showing that using frailty measures with high clinical applicability was associated with readmission or death are considered a promising first step towards identifying high-risk patients who need comprehensive discharge planning and action with the aim of preventing readmissions.

Overall, across the included studies, the findings in this project contributed to new insights and reflections in relation to a valid and simple way of identifying frailty. The project documented an association between frailty and lower functional status and risk of readmission or death, and finally contributed to an understanding of the meaning and serious consequences of frailty in acutely admitted older medical patients in relation to discharge.

CHAPTER 7. CLINICAL AND RESEARCH IMPLICATIONS

7.1. CLINICAL IMPLICATIONS

Discharge of acutely admitted frail elderly patients should be based on mutual understanding of frailty as a complex bio-psycho-social system. A valid and simple screening tool with a multidimensional approach may, together with generic functional tests, provide the possibility of a shared language about frail older medical patients and their lives and risk of serious adverse events. By having a shared language it may make it easier to define a shared goal and share the responsibility for all involved partners and these may be important elements in systemizing the health-care process within and between the health-care sectors in the future. Identification of frail older medical patients at risk while hospitalized could make it possible to initiate an early targeted intervention to avoid adverse events. More research is needed to address these specific challenges.

Health-care professionals should inform frail older medical patients in transition more thoroughly about their situation and about the consequences of their condition. Actively trying to empower patients to decrease the level of frailty and knowing the consequences of not acting should be a necessity in relation to discharge. Consequently, acutely admitted frail older medical patients and relatives should be more involved in decision-making and goal-setting in relation to discharge. The health care system seemed to be better geared to taking care of issues related to physical conditions in relation to home care, but the psychological and social issues reflected as restlessness, loneliness or disillusion were also stressors that need to be addressed.

7.2. RESEARCH IMPLICATIONS

Reliability and validity, especially the predictive validity of the TFI needs to be established in relation to acute settings such as hospitals as this is an essential element in relation to assessment and screening for frailty when no gold standard exists (71,81). Sutton et al. also request further research in relation to the TFI, as even though it was assessed as the most robust multicomponent frailty assessment tool it is still not comprehensively validated (78).

The four issues of pain, sleep quality, spirituality and meaningful activities, which seemed to be important elements in daily life for a frail population of participants were not directly covered by the TFI. Future research should investigate further into these issues to explore whether these elements are explainable factors when trying to identify adverse events in relation to frailty.

Literature shows that the physical components of frailty have greater importance for the prediction of adverse outcomes than do the psychological and social domains in the TFI. Further TFI subdomain analyses of the presented findings in this PhD project may contribute to the evidence regarding the importance of the physical frailty domain.

A continuous score of multicomponent frailty provides access to the nuances of a relationship between frailty and serious adverse events, thereby indicating that the degree of frailty seems important. This has also been discussed recently in relation to frailty and risk prediction (144,167). A future approach for developing an algorithm combining the three different outcome measures related to frailty may be even more beneficial in predicting readmission and death. This would create a platform for a differentiated approach to frailty and could provide guidance for clinical practice decisions on when to act upon the different levels of frailty. A recent Danish study documented that polypharmacy, defined as five or more medications daily, together with frailty seemed to increase the risk of readmission substantially and this variable may be a further element to include in an algorithm as this information is easily identified in the electronic medical journals (145).

Important knowledge about the experiences right after discharge has been described in this project and these experiences should be taken into consideration when frail older medical patients are discharged after an acute admission. Further research is needed to investigate how the discharge phase can be improved, and especially to investigate the impact on the well-being of the elderly. After having identified frailty using simple assessment tools, individualized goals and interventions towards decreasing the frailty should ideally be initiated. In this area there are several publications in relation to the different specific interventions. As this is a multifaceted and highly complex area, this is an easier and more manageable research strategy. However, there is a need for comprehensive research taking a holistic approach in attempting to establish evidence for several coordinated interventions (51,168).

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APPENDICES

Appendix A. The Danish and English version of the Tilburg Frailty Indicator.....91

Appendix A. The Danish and English version of the Tilburg Frailty Indicator

The Tilburg Frailty Indicator (TFI-DK)

Læs hvert enkelt spørgsmål grundigt og kryds derefter det svar af, som du synes passer bedst.

DEL A

1. Hvad er dit køn?	<input type="radio"/> Mand <input type="radio"/> Kvinde
2. Hvor gammel er du?	_____ år
3. Hvad er din civilstand?	<input type="radio"/> Gift/samboende med partner <input type="radio"/> Ugift <input type="radio"/> Separeret/skilt <input type="radio"/> Enkeltmand
4. Hvor er du født?	<input type="radio"/> Danmark <input type="radio"/> Andet land: _____
5. Hvad er dit højeste uddannelsesniveau? (sæt kun ét kryds)	<input type="radio"/> Folkeskolen <input type="radio"/> Gymnasium, HF, HH <input type="radio"/> Faglært inden for håndværk, handel, kontor eller lignende <input type="radio"/> Kort videregående uddannelse (f.eks. tandplejer, lægesekretær) <input type="radio"/> Mellemlang videregående uddannelse (f.eks. sygeplejerske, folkeskolelærer) <input type="radio"/> Lang videregående uddannelse (f.eks. læge, advokat, ingeniør)
6. Hvor høj er den samlede månedlige indkomst i husstanden efter skat?	<input type="radio"/> 5.000,- eller mindre <input type="radio"/> 5.001,- til og med 8.000,- <input type="radio"/> 8.001,- til og med 11.000,- <input type="radio"/> 11.001,- til og med 14.000,- <input type="radio"/> 14.001,- til og med 17.000,- <input type="radio"/> 17.001,- til og med 20.000,- <input type="radio"/> 20.001,- til og med 23.000,- <input type="radio"/> 23.001,- til og med 26.000,- <input type="radio"/> 26.001,- eller mere
7. Hvordan vil du beskrive din levevis generelt?	<input type="radio"/> Sund <input type="radio"/> Ikke sund, ikke usund <input type="radio"/> Usund
8. Har du to eller flere sygdomme og/eller kroniske lidelser?	<input type="radio"/> Ja <input type="radio"/> Nej
9. Har du oplevet en af følgende hændelser inden for de seneste 12 måneder?	
• Alvorlig sygdom	<input type="radio"/> Ja <input type="radio"/> Nej
• Skillemisse eller afslutning af et længerevarende forhold	<input type="radio"/> Ja <input type="radio"/> Nej
• Et trafikuheld	<input type="radio"/> Ja <input type="radio"/> Nej
• En forbrydelse	<input type="radio"/> Ja <input type="radio"/> Nej
• En nærtstående død	<input type="radio"/> Ja <input type="radio"/> Nej
• Alvorlig sygdom hos en nærtstående	<input type="radio"/> Ja <input type="radio"/> Nej

10. Er du tilfreds med dit nabolag?	<input type="radio"/> Ja <input type="radio"/> Nej
-------------------------------------	---

DEL B

11. Føler du dig fysisk rask?	<input type="radio"/> Ja <input type="radio"/> Nej
12. Har du tabt dig meget for nyligt uden at ville det? (meget = 3 kilo den seneste måned eller 6 kilo eller mere i de seneste seks måneder)	<input type="radio"/> Ja <input type="radio"/> Nej
13. Har du problemer i dagligdagen på grund af, at du er dårligt gående?	<input type="radio"/> Ja <input type="radio"/> Nej
14. Har du problemer i dagligdagen på grund af dårlig balance?	<input type="radio"/> Ja <input type="radio"/> Nej
15. Har du problemer i dagligdagen på grund af dårlig hørelse?	<input type="radio"/> Ja <input type="radio"/> Nej
16. Har du problemer i dagligdagen på grund af nedsat syn?	<input type="radio"/> Ja <input type="radio"/> Nej
17. Har du problemer i dagligdagen på grund af nedsat kraft i hænderne?	<input type="radio"/> Ja <input type="radio"/> Nej
18. Har du problemer i dagligdagen på grund af fysisk træthed?	<input type="radio"/> Ja <input type="radio"/> Nej
19. Har du problemer med at huske?	<input type="radio"/> Ja <input type="radio"/> Nogle gange <input type="radio"/> Nej
20. Har du følt dig nedtrykt i den seneste måned?	<input type="radio"/> Ja <input type="radio"/> Nogle gange <input type="radio"/> Nej
21. Har du følt dig nervøs eller ængstelig i den seneste måned?	<input type="radio"/> Ja <input type="radio"/> Nogle gange <input type="radio"/> Nej
22. Er du god til at håndtere problemer?	<input type="radio"/> Ja <input type="radio"/> Nej
23. Bor du alene?	<input type="radio"/> Ja <input type="radio"/> Nej
24. Savner du sommetider at have mennesker omkring dig?	<input type="radio"/> Ja <input type="radio"/> Nogle gange <input type="radio"/> Nej
25. Får du tiltrækkelig med støtte fra andre mennesker?	<input type="radio"/> Ja <input type="radio"/> Nej

Score del B: komponenter af skræbelighed

Grænse: 5 (-eller = med 5 betegnes som skræbelig i Holland)

Spørgsmål nummer:	Scoring:
Spørgsmål 11	Ja= 0 Nej=1
Spørgsmål 12	Ja=1 Nej=0
Spørgsmål 13-18	Ja=1 Nej=0
Spørgsmål 19	Ja=1 Nej/Nogle gange=0
Spørgsmål 20-21	Ja/Nogle gange=1

Figure 2. The English version and the final Danish version of The Tilburg Frailty Indicator

Appendix 1. The Tilburg Frailty Indicator (TFI)¹

Part A: Determinants of frailty

1. Which sex are you?	0 male	1 female
2. What is your age?	0 65-74 years	1 75-84 years
3. What is your marital status?	0 never/never with partner	1 partner
	0 unmarried	
	0 separated/divorced	
	0 widowed/widower	
4. In which country were you born?	0 The Netherlands	1 Other
	0 Former Dutch East Indies	
	0 Suriname	
	0 Netherlands Antilles	
	0 Turkey	
	0 Other	
5. What is the highest level of education you have completed?	0 none or primary education	1 secondary education
	0 higher professional or university education	
6. Which category indicates your net monthly household income?	0 0-1000 €	1 1000-1500 €
	2 1500-2000 €	3 2000-2500 €
	4 2500-3000 €	5 3000-3500 €
	6 3500-4000 €	7 4000-4500 €
	8 4500-5000 €	9 5000-5500 €
	10 5500-6000 €	11 6000-6500 €
	12 6500-7000 €	13 7000-7500 €
	14 7500-8000 €	15 8000-8500 €
	16 8500-9000 €	17 9000-9500 €
	18 9500-10000 €	19 10000 € or more
7. Overall, how healthy would you say your lifestyle is?	0 healthy	1 not healthy, not unhealthy
8. Do you have two or more diseases under chronic treatment?	0 none	1 one or more
9. Have you ever had one or more of the following events during the past year?	0 no	1 yes
- the death of a loved one	0 no	1 yes
- a serious illness yourself	0 no	1 yes
- a serious illness in a loved one	0 no	1 yes
- admission or ending of an important intimate relationship	0 no	1 yes
- a traffic accident	0 no	1 yes
- a fall	0 no	1 yes
10. Are you satisfied with your home living arrangement?	0 yes	1 no

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Appendix 1. (Continued)

Part B: Components of frailty

B1 Physical components

11. Do you feel physically healthy?	0 yes	1 no
12. When you feel a bit of energy, usually without wanting to do so? Do you do it a lot or more during the last month, or 2 or 3 or more during the last month?	0 yes	1 no
13. Do you experience problems in your daily life due to:		
- difficulty in walking?	0 yes	1 no
- difficulty maintaining your balance?	0 yes	1 no
14. Do you have problems with your hearing?	0 yes	1 no
15. Do you have problems with your vision?	0 yes	1 no
16. Do you have problems with your back?	0 yes	1 no
17. Do you have problems with your weight?	0 yes	1 no
18. Do you have problems with your energy?	0 yes	1 no
19. Do you feel often during the last month?	0 yes	1 no
20. Do you feel nervous or anxious during the last month?	0 yes	1 no
21. Are you able to sleep well sometimes?	0 yes	1 no
22. Are you able to sleep well sometimes?	0 yes	1 no

B2 Social components

23. Do you live alone?	0 yes	1 no
24. Do you sometimes miss having somebody around you?	0 yes	1 no
25. Do you receive enough support from other people?	0 yes	1 no

The TFI was translated into English using the method of back-translation.

Scoring Part B: Components of frailty (range 0-15)

Question 11: yes = 0, no = 1

Question 12: no = 0, yes = 1

Question 13: no = 0, yes = 1

Question 14: no = 0, yes = 1

Question 15: no = 0, yes = 1

Question 16: no = 0, yes = 1

Question 17: no = 0, yes = 1

Question 18: no = 0, yes = 1

Question 19: no = 0, yes = 1

Question 20: no = 0, yes = 1

Question 21: no = 0, yes = 1

Question 22: no = 0, yes = 1

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Læs først enkelt spørgsmål grundigt og kryds derefter det svar af, som du synes passer bedst.

DEL A

1. Hvad er din køn?	0 Mand 1 Kvinde
2. Hvor gammel er du?	0 65-74 år 1 75-84 år
3. Hvad er din civilstand?	0 Gift/ambosende med partner 1 Ugift 2 Separeret/divorceret 3 Enkeltborgermand
4. Hvor er du født?	0 Danmark 1 Andet land:
	2 Folketalen 3 Gymskolen, HF, HH 4 Fagbært skole for håndværk, håndlæge, kontor eller lignende
5. Hvad er dit højeste uddannelsesniveau? (Sæt kun ét kryds)	0 Kort videregående uddannelse (1-6 kl., sprog, lægekandidat) 1 Videregående uddannelse (1-6 kl., sprog, lægekandidat) 2 Lang videregående uddannelse (1-6 kl., sprog, advokat, ingeniør)

6. Hvor høj er den samlede månedlige indkomst i husstanden efter skat?	0 0.000,- eller mindre 1 0.001,- til og med 2.000,- 2 2.001,- til og med 3.000,- 3 3.001,- til og med 4.000,- 4 4.001,- til og med 5.000,- 5 5.001,- til og med 6.000,- 6 6.001,- til og med 7.000,- 7 7.001,- til og med 8.000,- 8 8.001,- til og med 9.000,- 9 9.001,- til og med 10.000,- 10 10.001,- til og med 11.000,- 11 11.001,- til og med 12.000,- 12 12.001,- til og med 13.000,- 13 13.001,- til og med 14.000,- 14 14.001,- til og med 15.000,- 15 15.001,- til og med 16.000,- 16 16.001,- til og med 17.000,- 17 17.001,- til og med 18.000,- 18 18.001,- til og med 19.000,- 19 19.001,- til og med 20.000,- 20 20.001,- til og med 21.000,- 21 21.001,- til og med 22.000,- 22 22.001,- til og med 23.000,- 23 23.001,- til og med 24.000,- 24 24.001,- til og med 25.000,- 25 25.001,- eller mere
7. Hvordan vil du beskrive din leveris generelt?	0 Sund 1 Både sundt, både usund 2 Usund
8. Har du to eller flere sygdomme og/eller kroniske tilstande?	0 Ja 1 Nej
9. Har du oplevet en af følgende hændelser inden for de seneste 12 måneder?	0 Ja 1 Nej
- Et alvorligt sygdomsforløb	0 Ja 1 Nej
- Et dødsfald eller afslutning af et længerevarende forhold	0 Ja 1 Nej
- Et trafikulykke	0 Ja 1 Nej
- En forulykke	0 Ja 1 Nej
- Et nærbesødes død	0 Ja 1 Nej
- Et alvorligt sygdomsforløb hos en nærstående	0 Ja 1 Nej
10. Er du tilfreds med dit boligforhold?	0 Ja 1 Nej

DEL B

11. Føler du dig fysisk stærk?	0 Ja 1 Nej
12. Har du følt dig meget for udfordret, letet af eller dårligt i løbet af de seneste 12 måneder?	0 Ja 1 Nej

13. Har du problemer i dagligdagen på grund af at du er dårligt tilpasset?	0 Ja 1 Nej
14. Har du problemer i dagligdagen på grund af dårligt balance?	0 Ja 1 Nej
15. Har du problemer i dagligdagen på grund af dårligt hørelse?	0 Ja 1 Nej
16. Har du problemer i dagligdagen på grund af dårligt syn?	0 Ja 1 Nej
17. Har du problemer i dagligdagen på grund af dårligt ryg?	0 Ja 1 Nej
18. Har du problemer i dagligdagen på grund af dårligt energi?	0 Ja 1 Nej
19. Har du problemer i dagligdagen på grund af dårligt søvn?	0 Ja 1 Nej
20. Har du problemer i dagligdagen på grund af dårligt nerves?	0 Ja 1 Nej
21. Har du problemer i dagligdagen på grund af dårligt støtte?	0 Ja 1 Nej
22. Har du problemer i dagligdagen på grund af dårligt støtte?	0 Ja 1 Nej
23. Har du problemer i dagligdagen på grund af dårligt støtte?	0 Ja 1 Nej
24. Har du problemer i dagligdagen på grund af dårligt støtte?	0 Ja 1 Nej
25. Har du problemer i dagligdagen på grund af dårligt støtte?	0 Ja 1 Nej
26. Har du problemer i dagligdagen på grund af dårligt støtte?	0 Ja 1 Nej
27. Har du problemer i dagligdagen på grund af dårligt støtte?	0 Ja 1 Nej
28. Har du problemer i dagligdagen på grund af dårligt støtte?	0 Ja 1 Nej
29. Har du problemer i dagligdagen på grund af dårligt støtte?	0 Ja 1 Nej
30. Har du problemer i dagligdagen på grund af dårligt støtte?	0 Ja 1 Nej
31. Har du problemer i dagligdagen på grund af dårligt støtte?	0 Ja 1 Nej
32. Har du problemer i dagligdagen på grund af dårligt støtte?	0 Ja 1 Nej
33. Har du problemer i dagligdagen på grund af dårligt støtte?	0 Ja 1 Nej
34. Har du problemer i dagligdagen på grund af dårligt støtte?	0 Ja 1 Nej
35. Har du problemer i dagligdagen på grund af dårligt støtte?	0 Ja 1 Nej

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