Advance Care Planning and the staff perspective: The development, implementation, and investigation of a complex intervention in the nursing home

Irene Aasmul

Thesis for the degree of Philosophiae Doctor (PhD)
University of Bergen, Norway
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“You matter because you are you,
and you matter to the end of your life.
We will do all we can, not only to
help you die peacefully,
but also to live until you die.”

Dame Cicely Saunders (1918-2005)

Scientific environment

My doctoral work was completed in a professional and interdisciplinary milieu at the Centre for Elderly and Nursing Home Medicine (SEFAS), University of Bergen, Faculty of Medicine, Department of Global Public Health and Primary Care. I have participated in the Research Groups for General Practice and the Centre for Elderly and Nursing Home Medicine. I was enrolled in the National Research School in General Practice (NAFALM). My PhD scholarship was financed by the Research Council of Norway (Sponsor's Protocol Code 222113/H10 "the COSMOS trial"). In addition to the Research Council of Norway, the COSMOS trial was funded by the Rebekka Ege Hegermann Endowment and the University of Bergen.

Main supervisor

Associate Professor Elisabeth Flo, Department of Clinical Psychology, University of Bergen.

Co supervisor

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Courses and presentations

I have participated in relevant academic courses at the University of Bergen and the University of Oslo, many of them arranged by the National Research School in General Practice. I gave oral presentations of my PhD work at the 31st International Conference of Alzheimer's Disease in Budapest (2016) and at the 6th International Conference on Advance Care Planning & End of Life in Banff, Canada (2017). Additionally, I have given several poster presentations at conferences both nationally and internationally.

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9.2 PAPERS 1 – 3

List of publications

Aasmul I, Husebo BS, Flo E. Staff Distress Improves by Treating Pain in Nursing Home Patients with Dementia: Results from a Cluster-Randomized Controlled Trial. *Journal of Pain and Symptom Management*. 2016;52(6):795-805.

Aasmul I, Husebo BS, Flo E. Description of an Advance Care Planning Intervention in Nursing Homes: Outcomes of the Process Evaluation. *BMC Geriatrics*. 2018;(1):26.

Aasmul I, Husebo BS, Sampson EL, Flo E. Advance Care Planning in Nursing Homes – Improving the Communication Among Patient, Family, and Staff: Results from a Cluster-Randomized Controlled Trial (COSMOS). *Frontiers in Psychology*. 2018; 9:2284

The respective publishers for each paper have given permission for reprints in this thesis.

Other scientific publications not included in this thesis

Husebo BS, Flo E, Aarsland D, Selbaek G, Testad I, Gulla C, Aasmul I, Ballard C. COSMOS – Improving the Quality of Life in Nursing Home Patients: Protocol for an Effectiveness-Implementation Cluster-Randomized Clinical Hybrid Trial. *Implementation Science*. 2015;10(1):131.

Husebo BS, Ballard C, Aarsland D, Selbaek G, Slettebo DD, Gulla C, Aasmul I, Habiger T, Elvegaard T, Testad I, Flo E. The Effect of a Multicomponent Intervention on Quality of Life in Residents of Nursing Homes: A Randomized Controlled Trial (COSMOS). *Journal of the American Medical Directors Association*. 2019;20(3):330-339.

List of Abbreviations

ACP	Advance Care Planning
CATS	Cognitive Activation Theory of Stress
CGIC	Clinical Global Impression of Change
CI	Confidence Interval
CMAI	Cohen-Mansfield Agitation Inventory
COSMOS	Acronym for the trial used in Paper 2 and 3: COmmunication, Systematic pain assessment and management, Medication review, Organisation of activities, and Safety
cRCT	Cluster Randomized Controlled Trial
FAST	Functional Assessment Staging Tool
MeSH	Medical Subject Headings
MMSE	Mini Mental State Examination
MOBID-2	Mobilisation-Observation-Behaviour-Intensity Dementia-2 Pain Scale
NPI-NH	Neuropsychiatric Inventory – Nursing Home Version
PAIN-BPSD	Short title for the study used in Paper 1: The Impact of Pain on Behavioural Disturbances in Patients with Moderate and Severe Dementia
PPI	Patient and Public Involvement
RCT	Randomized Controlled Trial
SEFAS	Centre for Elderly and Nursing Home Medicine

Abstract

Background

Nursing home patients represent a heterogeneous, complex, and clinically challenging population. A crucial concern is that most of the patients lack the capacity to provide informed consent, as approximately 80% have dementia along with multimorbidity and polypharmacy. Once admitted, most patients die in the nursing home, which puts significant demands on the staff to provide adequate end-of-life care. Ideally, the end-of-life process in the nursing home, be it acute or chronic, should be characterised by trust and understanding shared by the patient, family, and staff and by high awareness of the patient's values and wishes.

However, for many patients and family members difficult question arise. We know that it is essential to involve patients in medical decision-making, but this is increasingly difficult when the patient does not understand the situation or is not able to form an opinion and communicate it. In these instances, family members are often asked to become guardians. Making decisions on a person's behalf is demanding, and the family might not know what their loved ones would have thought about treatment and end-of-life care. The staff might also experience this uncertainty as distressing because they do not know what the patient and family need. This uncertainty increases the risk of unwanted treatments and disagreements within the family and between family and staff. This necessitates a systematic approach that is developed, implemented, and tested in the nursing home setting.

Advance Care Planning (ACP) aims to address the patients' preferences, values, and potential concerns about treatment and care. Providing ACP represents an important tool that can help the patient, family, and staff to achieve a common understanding of "what matters" and to be better prepared for the end-of-life process and medical emergencies by creating a common understanding and trust. ACP can help the staff understand the patients' values, wishes, and needs and make them more confident in their patient care. In turn, this might also affect the staff in terms of reduced distress.

The complexity of the situation becomes even more evident by the fact that most nursing home patients with dementia have neuropsychiatric symptoms such as

agitation and depression, which are distressing for both the patients and the staff. The lack of competence and knowledge to deal with difficult symptoms can also be distressing for the staff, leading to increased risk of burnout, sick leave, and turnover. Increasing the staff's knowledge and competence along with providing effective interventions that improve challenging symptoms are central for the patients' wellbeing and might also reduce staff distress.

Aims

The overarching aim of this thesis was twofold. First it sought to develop, implement, and test the effects of ACP, and second it sought to address the staff perspective in the nursing home setting. Specifically, it was a key to explore how staff received the ACP intervention and implementation and if staff distress was affected by improved patient treatment and routines in the nursing home.

Methods

Two studies provided the data for this thesis. In paper 1, we used data from a cluster randomised controlled trial (cRCT) called "The Impact of Pain on Behavioural Disturbances in Patients with Moderate and Severe Dementia" (PAIN-BPSD). Papers 2 and 3 used data from the cRCT called the COSMOS trial (**CO**mmunication in the form of ACP, **S**ystematic pain assessment and management, **M**edication review, **O**rganisation of activities, and **S**afety). All of the included patients were 65 years or older and received long-term care in Norway.

Paper 1: Staff distress was investigated by secondary analyses from the PAIN-BPSD study, which was originally designed to test the effects of pain treatment on neuropsychiatric symptoms in nursing home patients with dementia. Nursing home units were allocated to the intervention group (33 units; n = 175) or control group (27 units; n = 177). Patients in the intervention group received a stepwise protocol for treating pain for eight weeks, followed by a four-week washout period. The control group received care as usual. Staff informants (n = 138) reported neuropsychiatric symptoms in patients and their own distress in relation to these using the Neuropsychiatric Inventory–Nursing Home version (NPI-NH). Additional outcomes were pain as measured by the Mobilisation-Observation-Behaviour-Intensity-

Dementia-2 Pain Scale (MOBID-2) and cognitive functioning as measured by the Mini Mental Status Examination (MMSE).

Paper 2: The development and implementation of the ACP component in the COSMOS trial was investigated, and facilitators and barriers were identified. The COSMOS trial lasted for four months with a nine-month follow-up. Paper 2 used data from the intervention group (297 patients from 36 nursing home units) focusing on the four-month intervention period. The participating staff (COSMOS ambassadors) received a standardised education programme on ACP. The implementation was ensured using a train-the-trainer approach involving the whole nursing home unit. The implementation process was assessed using individual patient logs and structured staff feedback. Facilitators and barriers were identified by qualitative analysis of the feedback from the patient logs and from a midway evaluation seminar.

Paper 3: A cRCT using secondary analyses from the COSMOS trial was performed to investigate the effects of ACP on frequency of communication and satisfaction with communication as perceived by nursing home staff and families. Data included 36 intervention clusters (n = 297) and 31 control clusters (n = 248) using data from baseline, month four, and month nine. Communication was evaluated using a data collection form and questionnaires answered by the patients' family and by the staff.

Results

Paper 1: We found that agitation had the largest contribution ($\beta = 0.24$) to staff distress at baseline, and we found significantly lower total staff distress in the pain treatment group compared to the control group at the eight-week assessment ($B = -3.53$, 95% CI $= -5.47$ to -1.58). Still, staff distress was also significantly reduced in the control group ($B = -2.98$, 95% CI $= -4.38$ to -1.59). The effect remained significant within both the intervention group ($B = -6.24$, 95% CI $= -8.01$ to -4.48) and the control group ($B = -2.53$, 95% CI $= -4.34$ to -0.71) throughout the four-week washout period.

Paper 2: The ACP component was well received, and 105 healthcare providers participated at the education seminar. The staff reported that the educational material was relevant for their efforts to implement ACP. According to the patient logs, ACP was successfully implemented in 62% (n = 183) of the patients. Important facilitators included a clear communication to nursing home managers and staff that ACP was an essential part of adequate care and having clearly defined routines, roles, and responsibilities when implementing ACP. Lack of competence and time and conflicting cultures and staff opinions were identified as barriers.

Paper 3: ACP had a positive effect on communication; meetings between the families, patients, and nurses were organised more frequently in the intervention group compared to the control group at month four (OR = 3.9, 95% CI = 1.6 to 9.4, $p = 0.002$). There were also more monthly contacts between families and nurses in the intervention group compared to the control group (OR = 6.5, 95% CI = 1.6 to 3.5, $p = 0.010$). Nursing home staff ($B = 1.9$, 95% CI = 0.80 to 2.91, $p = 0.001$) and the patients' families ($B = 0.4$, 95% CI = 0.02 to 0.85, $p = 0.040$) were more satisfied with the communication in the intervention group compared to the control group. We also detected reduced staff distress in the intervention group compared to the control group ($B = -1.8$, 95% CI = −3.1 to −0.4, $p = 0.012$). These effects did not remain significant at the nine-month follow-up, suggesting that a closer follow-up is needed to ensure sustainability of the communication process.

Conclusion

This thesis describes the development, implementation, and testing of ACP in the nursing home, involving the staff perspective as a prerequisite for optimal communication between patients, families, and staff. ACP was successfully implemented leading to improved frequency of and satisfaction with the communication between the staff and family. We also found reduced staff distress, both in the PAIN-BPSD study and in the COSMOS trial. The need to involve the nursing home management and to clearly define roles and responsibilities is important so that ACP is prioritised and adopted in the nursing home setting. The focus on education and staff competence is suggested as crucial for a sustainable ACP intervention that lasts beyond the active implementation phase of a research project.

Sammendrag på norsk

Bakgrunn

Sykehjemspasienter representerer en heterogen og kompleks gruppe med store klinisk utfordringer. De fleste av pasientene mangler evne til å gi informert samtykke, cirka 80% har demens, i tillegg er multimorbiditet og polyfarmasi vanlig. Majoriteten av dem som får sykehjemsplass dør på sykehjemmet. Dette stiller betydelige krav til personalet ved omsorg i livets slutt. Ideelt sett skal prosessen rundt omsorg i livets slutt være preget av tillit og forståelse mellom pasienten, familien og personalet, samt bevissthet om pasientens verdier og ønsker.

Beslutninger knyttet til behandling og omsorg i livets slutt kan være krevende for mange pasienter og familiemedlemmer. Det er viktig å involvere pasienter i medisinske beslutninger. Imidlertid blir dette stadig vanskeligere når pasienten ikke forstår situasjonen, ikke er i stand til å gjøre seg opp en mening eller mangler evne til å formidle sine tanker og beslutninger. I disse tilfellene blir familiemedlemmer ofte bedt om å være med i beslutninger. Å ta avgjørelser på vegne av en person er utfordrende; familien vet kanskje ikke hva deres kjære ville ønsket av behandling og tiltak. Personalet kan også oppleve denne usikkerheten som belastende, siden de ikke vet hva pasienten og familien trenger. Denne usikkerheten øker risikoen for uønsket behandling, samt konflikt innad i familien og mellom familien og de ansatte. Disse utfordringene bør møtes med en systematisk tilnærming som er utviklet, implementert og testet i sykehjem.

Forhåndssamtaler, Advance Care Planning (ACP) tar sikte på å adressere pasientenes preferanser, verdier og potensielle bekymringer rundt behandling og omsorg. Å tilby ACP kan hjelpe ansatte, pasienter og familie til å oppnå en felles forståelse av "hva som er viktig". Videre kan ACP bidra til at en er bedre forberedt på livets slutt og potensielle medisinske beslutninger i akutte situasjoner ved å skape en felles forståelse og tillit. ACP kan hjelpe personalet til å forstå pasientenes verdier, ønsker og behov, og trygge dem i utøvelsen av pleie og omsorgen til pasienten. Dette kan igjen føre til reduksjon av opplevd belastning hos pleiepersonalet.

De fleste personer med demens opplever nevropsykiatriske symptomer som agitasjon og depresjon. Slike symptomer er belastende både for sykehjemspasientene som rammes og for personalet. Mangel på kompetanse og kunnskap om håndtering av vanskelige symptomer kan også være belastende for de ansatte, noe som igjen kan føre til økt risiko for utbrenthet, sykefravær og hyppig utskifting av personalet. Det å øke de ansattes kunnskap og kompetanse, samt å initiere tiltak som reduserer nevropsykiatriske symptomer, er viktig for pasientenes velvære, og kan også redusere belastning hos pleiepersonalet.

Mål

Det overordnede målet med denne avhandlingen har vært todelt; å utvikle, implementere og teste effekten av ACP, samt å vektlegge pleiepersonalets perspektiver. Det var viktig å utforske hvordan ACP intervensjonen ble mottatt og om forbedret pasientbehandling og rutiner i sykehjemmet påvirket personalets belastning.

Metoder

Denne avhandlingen er basert på data fra to studier. I artikkel 1 brukte vi data fra en klynge-randomisert, kontrollert studie (cRCT) kalt "The Impact of Pain on Behavioural Disturbances in Patients with Moderate and Severe Dementia" (PAIN-BPSD). I artikkel 2 og 3 ble det benyttet data fra en cRCT kalt KOSMOS-studien (KOmmunikasjon i form av ACP, Systematisk Smertevurdering og behandling, Medikamentgjennomgang, Organisering av aktiviteter og Sikkerhet). Alle de inkluderte pasientene var 65 år eller eldre og hadde langtidsplass på sykehjem i Norge.

Artikkel 1: Det ble gjennomført sekundære analyser av data fra PAIN-BPSD studien for å undersøke belastning hos pleiepersonalet. Studien var opprinnelig designet for å teste effekten av smertebehandling på nevropsykiatriske symptomer hos sykehjemspasienter med demens. Sykehjemsavdelinger ble allokert til intervensjonsgruppen (33 avdelinger; n = 175) eller kontrollgruppen (27 avdelinger; n = 177). Pasienter i intervensjonsgruppen mottok smertebehandling etter en trinnvis protokoll. Behandlingen varte i åtte uker, etterfulgt av en fire ukers utvaskingsperiode. Kontrollgruppen fikk behandling, pleie og omsorg som vanlig. Pleiepersonalet (n =

138) var informanter og rapporterte om nevropsykiatriske symptomer hos pasienter og egen belastning knyttet til disse ved å bruke verktøyet Neuropsychiatric Inventory - Nursing Home Version (NPI-NH). Ytterligere utfallsmål var smerter målt med Mobilisation-Observation-Behaviour-Intensity-Dementia-2 Pain Scale (MOBID-2) og kognitiv funksjon ved bruk av Mini Mental Status Examination (MMSE).

Artikkel 2: Utviklingen og implementeringen av ACP-komponenten i KOSMOS-studien ble undersøkt og fremmere og hemmere ble identifisert. KOSMOS-studien varte i fire måneder etterfulgt av oppfølgingmålinger ved måned ni. Artikkel 2 brukte data fra intervensjonsgruppen (297 pasienter fra 36 sykehjemsavdelinger) med fokus på intervensjonsperioden som varte i fire måneder. De ansatte som deltok på kurs (KOSMOS-ambassadører) fikk et standardisert utdanningsprogram om ACP. Implementeringen ble sikret ved bruk av en *train-the-trainer* tilnærming, som involverte hele sykehjemsavdelingen. Implementeringsprosessen ble vurdert ved bruk av individuelle pasientlogger og strukturerte tilbakemeldinger fra pleiepersonalet. Fremmere og hemmere ble identifisert ved kvalitativ analyse av tilbakemeldinger fra pasientloggene og et midtveisevalueringsseminar.

Artikkel 3: Sekundære analyser med KOSMOS-data ble benyttet for å undersøke effekten av ACP knyttet til frekvensen av kommunikasjon, samt tilfredshet med kommunikasjonen blant de ansatte på sykehjemmet og pasientens familie. Dataene inkluderte 36 intervensjonsklynger (n = 297) og 31 kontrollklynger (n = 248), med datainnsamling ved baseline, måned fire og måned ni. Kommunikasjon ble evaluert ved bruk av et datainnsamlingsskjema og spørreskjemaer gitt til pasientenes familie og til personalet.

Resultater

Artikkel 1: Vi fant at agitasjon bidro i størst grad ($\beta = 0{,}24$) til personalets belastning ved baseline. Det ble funnet signifikant lavere total belastning hos de ansatte i gruppen med pasienter som fikk smertebehandling sammenlignet med kontrollgruppen ved åtte ukers vurdering (B = -3,53, 95% KI = -5,47 til -1,58). Samtidig var det også signifikant redusert belastning hos kontrollgruppen (B = -2,98, 95% KI -4,38 til -1,59).

Effekten på belastning forble signifikant i både intervensjonsgruppen (B = -6,24, 95% KI= -8,01 til -4,48) og kontrollgruppen (B = -2,53, 95% KI = -4,34 til -0,71) i løpet av en fire ukers utvaskingsperiode.

Artikkel 2: ACP-komponenten ble godt mottatt, da det var 105 helsepersonell som deltok på KOSMOS-utdanningsseminaret. De ansatte rapporterte at læringsmateriellet var relevant for deres innsats ved implementering av ACP på avdelingene. Pasientloggene viste at ACP ble vellykket implementert hos 62% (n = 183) av pasientene. Tydelig kommunikasjon til sykehjemsledere og ansatte om at ACP var en viktig del av forventet omsorg, sammen med klart definerte rutiner, roller og ansvar var fremmere for implementeringen av ACP. Mangel på kompetanse og tid, samt en kultur preget av forutinntatthet ble identifisert som barrierer.

Artikkel 3: Vi fant at ACP hadde en positiv effekt på kommunikasjonen, ettersom møter mellom familie, pasient og sykepleiere ble organisert oftere i intervensjonsgruppen sammenlignet med kontrollgruppen ved måned fire (OR = 3.9, 95% CI = 1.6 to 9.4, p = 0.002). Det ble også rapportert hyppigere månedlig kontakt mellom familie og pleiere i intervensjonen sammenlignet med kontrollgruppen (OR = 6.5, 95% CI = 1.6 to 3.5, p = 0.010). I intervensjonsgruppen var både de ansatte (B = 1.9, 95% CI = 0.80 to 2.91, p = 0.001) i sykehjemmet og pasientenes familier (B = 0.4, 95% CI=0.02 to 0.85 p = 0.040) mer fornøyd med kommunikasjonen, sammenlignet med kontrollgruppen. Vi identifiserte redusert belastning hos pleiepersonalet i intervensjonsgruppen sammenlignet med kontrollgruppen (B = -1,8, 95% CI = -3,1 til -0,4, p = 0,012). Disse effektene var ikke lenger signifikante ved måned ni, noe som tyder på at det er nødvendig med en tettere oppfølging for å sikre at kommunikasjonsprosessen vedvarer.

Konklusjon

Denne avhandlingen beskriver utvikling, implementering, og testing av ACP på sykehjem, og involverer personalets perspektiv som en forutsetning for optimal kommunikasjon mellom pasienter, familier og personalet. Vår ACP-intervensjon ble i stor grad implementert, noe som førte til forbedret hyppighet og tilfredshet med kommunikasjonen mellom personalet og familien. Vi fant også redusert belastning hos de ansatte både i BPSD- og KOSMOS-studien. Behovet for å involvere sykehjemsledelsen sammen med tydelig definerte roller og ansvar er viktig for at ACP skal bli prioritert og anerkjent i sykehjemmet. Fokuset på utdanning og personalets kompetanse foreslås som avgjørende for en bærekraftig ACP-intervensjon som varer utover den aktive implementeringsfasen av et forskningsprosjekt.

1. Introduction

The topic covered in this thesis has been a professional concern in my clinical practice for many years. I worked as a registered nurse at Haukeland University Hospital from 1999 to 2011, and during this time I became interested in the experiences that nurses (including myself), patients, and families had in situations where frail, elderly people were admitted to the hospital. The nurses were often “on the front line” when acute situations occurred in the hospital. We rarely knew these patients, who often had limited cognitive and communicative abilities. Furthermore, the patients and their families had rarely been introduced to relevant medical issues or been involved in communication processes and decision-making before hospitalisation. This often led to a challenging situation for the patients and families, and it was also distressing for the staff.

In my master’s thesis from 2009, I interviewed hospital nurses on their experiences and opinions of the pre-assessment of do not resuscitate orders and investigated hospital routines from the staff´s perspective. Interestingly, the hospital nurses believed that nursing home routines for discussing and documenting medical and ethical decisions in advance could help prevent both unnecessary treatments and hospitalisations. Hospital admission is recognised as a "demand" for full treatment if nothing else is specified by the patient, family, or nursing home referral. The nurses that I interviewed reported that this often led to unnecessary and painful procedures, and possibly a lonely and undignified death. This was described as difficult for the nurses, who often had to perform lifesaving procedures that perhaps should have been avoided (1).

While my master’s thesis solely focused on the hospital perspective, I was able to further pursue the topic of communication with nursing home patients and staff as part of my PhD thesis. In 2014, I started my PhD scholarship related to the COSMOS trial, which is a multi-component intervention study consisting of **CO**mmunication in the form of Advance Care Planning, **S**ystematic pain assessment and management, **M**edication review, **O**rganisation of activities, and **S**afety. When developing, implementing, and investigating the effects of the COSMOS trial, my main focus was the Advance Care Planning (ACP) component. Although the rationale for the ACP component in the COSMOS trial was established based on existing literature from 2014 and earlier (2), the papers that are included in this thesis were also influenced by more recent publications. The latest literature search for this thesis was conducted in July 2019.

The COSMOS trial was a comprehensive study with a four-month intervention and nine-month follow-up period. Before we had completed the COSMOS data collection, I also had the opportunity to use data from a previous nursing home study conducted in Bergen. The PAIN-BPSD study was a multicentre, cluster-randomised controlled trial (cRCT) investigating the efficacy of treating pain on behavioural disturbances in nursing home patients with dementia. We used these data to explore how the intervention affected staff distress related to the behavioural disturbances in patients with dementia.

The focus of this thesis was twofold; a) investigating ACP in nursing homes and b) investigating the staff perspective related to interventions in nursing homes. These two parts are closely linked. It is important to recognise the staff perspective along with the patient perspective when conducting intervention studies in nursing homes. The staff perspective is a natural part in understanding the implementation of ACP in this setting. ACP represents an important tool that can improve the relationship between the patient, family, and staff, and ACP is often implemented through staff education and skills training. Thus, ACP might improve the work life for the staff and potentially affect staff distress. Figure 1 illustrates the complex contextual space and components involved in the development, implementation, and investigation of ACP, including the staff perspective in a patient-centred system. Thus, the goal of this thesis was to describe the development, implementation, and testing of the ACP intervention.

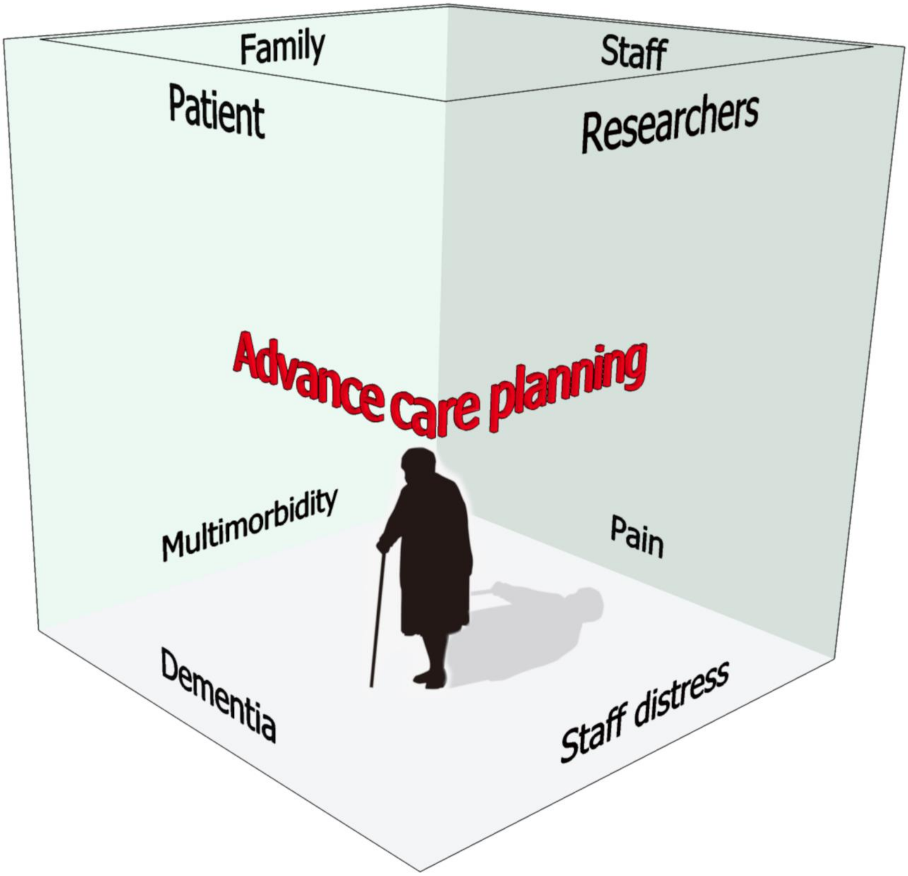


Figure 1: Illustration of the complex contextual space and components involved in the development, implementation, and investigation of ACP.

2. Background

The purpose of this thesis is to describe the development and implementation of ACP in nursing homes and to test the effects of this intervention. A key scope of the thesis was to focus on the staff's perspective and to consider how the nursing home staff experienced the implementation of ACP and whether improved patient treatment and routines affected staff distress.

2.1 Advance Care Planning

2.1.1 The historical development of Advance Care Planning

ACP is defined as a repeated communication process between a patient, their family, and a healthcare professional aiming to ascertain individual preferences, values, goals, and potential concerns about treatment, care, and end-of-life care (2-4). The aim is to ensure the patient's right to make informed decisions (5, 6).

The precursor of today's ACP concept was the introduction of a legal form called a living will in the US in the 1960s, emphasising the principle of the patient's autonomy (7). The intention of the living will was to give people an opportunity to choose their preferred treatment in case of illness and in particular in end-of-life care. A living will becomes effective when a person is terminally ill and is unable to express their wishes regarding health care or is permanently unconscious. The legal status of "power of attorney" by which a person is authorised to speak or act on another person's behalf was subsequently introduced. Still, there was no systematic effort to help people make a living will document, and they were often not completed in clinical practise. The format of a living will varies within the US, and many people need a lawyer and/or a health professional to help make a statement. Typically, a living will states wishes related to abstaining from invasive treatment such as feeding tubes or resuscitation efforts. If there is no such document, the healthcare personnel must do what they can to keep the patient alive. In the 1990s, healthcare providers were required by law to give patients information about their rights to make a living will, now referred to as an advance directive. Different programmes were subsequently designed to promote and support the completion of such directives. Parallel developments related to legal and clinical advances have taken place in other countries such as the UK, Canada, and Australia (4).

The history described above is dominated by legislation that was devised to avoid unnecessary and invasive medical treatment (7). However, the advance directive approach has been strongly criticised for simplifying a complex matter and also for lacking any impact in end-of-life decision-making (8). A chart-based "tick off" system cannot convey a patient's underlying wishes and values. Moreover, it might impede reflective discussions (2). Research suggests that patients and their families need guidance from healthcare professionals on issues concerning treatment, prognosis, and end-of-life care in order to make informed decisions (9). This distinguishes ACP from advance directives, where clarifying treatment options in a chart or a legal form is the main focus.

Notably, the legal development of advance directives and the progress of ACP was *not designed for nursing home patients or people with dementia*. However, this is where the need for ACP becomes prominent. Close to half of the Norwegian population die in nursing homes (10). This is higher than in many comparable countries, where the majority of deaths occur in hospitals (11, 12). Nursing home patients represent a complex and vulnerable patient group in terms of end-of-life care, and few are cognitively intact (13), and many die unexpectedly (14). It is particularly difficult to identify imminent death in nursing home patients because most show prolonged deterioration over time and signs and symptoms for such prognostication have not yet been established (14-17). This leaves the nursing home staff with a challenging responsibility – they must communicate with patients and families in advance in order to establish preferences for care, make prognostications, provide end-of-life care, and provide pain and symptom management (14). Indeed, many nursing home patients with advanced dementia are hospitalised multiple times during their last 90 days of life (18), although numbers vary greatly between countries (19).

2.1.2 **Advance Care Planning programmes**

Over the last two decades, researchers and clinicians have acknowledged the need for a flexible and repeated communication process that allows patients and families to discuss issues related to wishes for treatment, care, and end-of-life care and to reflect together with healthcare professionals. Several countries have now adapted ACP programmes to their cultural and legal realities (20). As such, completion of advance directives remains an important part in some ACP interventions, while other legal situations do not necessitate such legal documents.

In recent years, numerous standardised ACP programmes and interventions have been developed, many of which have been designed for the nursing home setting, and some of them have also included people without the capacity to give informed consent. A review by Flo et al. (2016) reported that most of the published research on ACP in nursing homes used unique ACP programmes (2). This finding was repeated in a recent review by Dixon and colleagues who reviewed a large set of ACP interventions with different communication strategies and staff training interventions (21). To provide an overview of the ACP programmes that have been developed for nursing home patients and/or people with dementia, Table 1 summarises the authors, year, and nationality of the ACP programmes identified in the review by Flo et al. (2) from 2016 supplemented by an updated literature search from 2019. The different legal prerequisites in different countries appear to be mirrored in the content and focus of the ACP programmes. For example, in the "Let Me talk" programme from Hong Kong, there was less focus on the legal documentation, and more focus on the sensitive initiation and continuation of communication on values and wishes for end-of-life care. Meanwhile, in the Physician Orders for Life Sustaining Treatment (POLST) from the US there was a clear focus on completing a legal document. Table 1 indicates whether a programme focused on the ACP communication process or had an advance directives focus with dedicated medical choices (resuscitation, intravenous fluids, or hospitalisation). In some of these publications, the legal status of the document is unclear. Despite there being so many different interventions, common denominators are discernible. An ACP intervention often includes *repeated* *communication* organised by the nursing home staff or physician, and decisions made in such conversations are *documented*. It is also common that ACP interventions focus on the appropriate *timing for initiation* and that ACP that includes *people with dementia* also involves the *family* or other legal guardians (2, 21). In the following paragraphs, a short description of key components of ACP delivered in the nursing home setting is provided.

Table 1: ACP programmes adapted to the nursing home setting, presented in the review by Flo et al. (2) and supplemented with an updated literature search from July 2019.

ACP programme, author (year), (ref), country (state)	**Main focus: Process or chart based (AD)**
Sævareid et al. (2019), (22), Norway	Process: repeated communication focuses on the future in terms of worries, hopes, and preferences.
Aasmul et al. (2018), (23), Norway	Process: repeated conversations and monthly contact with the family. Introducing 7 relevant questions/topics.
EVINCE, Mitchell et al. (2018), (24), US (Boston)	AD: documenting decisions regarding DNH, tube-feeding, intravenous hydration, and documented goals of care discussions. Preferred level of care comfort vs. basic or intensive care stated by proxies.
Brazil et al. (2018), (25), Northern Ireland	Process: communication focus on guiding families who are uncertain in decision-making about the care for the patient, aiming to achieve satisfaction among families.
GOC, Hanson et al. (2016), (26), US (North Carolina)	Process and AD: communication focus on satisfaction and completion of a directive form (POLST), e.g. CPR, antibiotics, and tube feeding.
weDecide, Ampe et al. (2015), (27), and Ampe et al. (2017), (28), Belgium	Process: communication focusing on the presence of choice; “choice talk”. Helping families and patients to understand their choices, identifying their preferences, and reaching decisions in case of a crisis.
Beizeiten begleiten, In der Schmitten et al. (2014), (29), Germany	AD: flyers, posters, and personal contact with the patient and the family. Aiming to document and sign an AD.
Making Health Choices, Silvester et al. (2013), (30), Australia (Victoria)	Process and AD: repeating communication leading to decisions (directives) regarding end-of-life care documented in a standardised form.
POLST, Hickman et al. (2011), (31), US (Oregon, Wisconsin and West Virginia)	AD: documenting decisions regarding CPR, medical intervention, antibiotics, and nutrition (feeding tube) in case of changes in a patient’s condition.
GSFCH, Hockley et al. (2010), (32), Scotland and Livingston et al. (2013), (33), UK (England)	Process: communicating using a form including open-ended questions about preferences for care. Using a form to document the wishes for potential emergency situations.
Let me Talk, Chan & Pang (2010), (34), Kina (Hong Kong)	Process: repeating communication regarding the individual’s life stories, concerns, preferences for life-sustaining treatment, and appointment of a decision-maker.
Let Me Decide, Caplan et al. (2006), (35), UK (England), Molloy et al. (2000), (36), Canada (Ontario) and McGlade et al. (2017), (37), Ireland	Process and AD: repeating communication with an aim to complete a legally binding document (CPR, tube feeding, care level).
Markson et al. (1994), (38), US	AD: documenting decisions regarding life-sustaining treatment and declining long-term mechanical ventilation, artificial nutrition, and CPR.

ACP: Advance Care Planning, AD: Advance Directive, CPR: Cardiopulmonary Resuscitation, DNH: Do Not Hospitalise, EVINCE: The Educational Video to Improve Nursing home Care in End-stage dementia, GOC: Goals Of Care, GSFCH: Gold Standards Framework for Care Homes, POLST: Physician Orders for Life Sustaining Treatment.

Communication

There is a general consensus in ACP research that the communication should be a repeated transaction, allowing the necessary time to establish a relationship of trust between the nursing home staff, the patient, and their family (2, 21, 39). However, "good communication" is operationalised differently in many of the ACP interventions. Open-ended questions to facilitate discussions are often highlighted as important, as is evident in the "Gold Standards Framework for Care Homes" (32, 33). Other ACP approaches such as "Let Me Talk" (34) and "Making Health Choices" (30) have specific themes that should be covered in the ACP conversations. For example, the "Let Me Talk" intervention gradually introduces questions about end-of-life care by covering themes such as life stories, illness narratives, and life views before asking about end-of-life care preferences. "Making Health Choices" recommends that ACP communication should include discussions on current health status, goals, values, beliefs, and future preferences. In their ACP intervention, Kiely et al. specified that a physician should communicate with nursing home patients and their families in order to inform them about health problems that the patient might experience later in their nursing home stay and about life expectancy (40). The themes that are discussed might in part determine whether nurses, physicians, or other relevant professionals need to be involved in the conversations. This leads to another important question: Who should participate in the ACP discussions and meetings?

Key people involved in Advance Care Planning

Research suggests that patients and their families expect guidance from health professionals on issues concerning the nursing home stay, prognosis, and end-of-life care and that they need help to make informed decisions (9). The nursing home physician is important, especially when the patient and family need information and help to understand medical conditions and prognoses (9, 40). In a review investigating how physicians can provide better end-of-life care in nursing homes, Fosse et al. found that nursing home physicians were expected to follow preferences for care and at the same time provide guidance and advice (9). In a New Zealand study, Sankaran et al. found that the patient and family thought that it was difficult to make decisions without a physician present to explain potential medical issues and options (41). Meanwhile, several studies note that it is difficult to involve the physician in ACP interventions (2, 9). This is often due to lack of time. Indeed, a majority of ACP interventions in nursing homes involve the nurses who receive the ACP education and are responsible for implementing the intervention (2, 21).

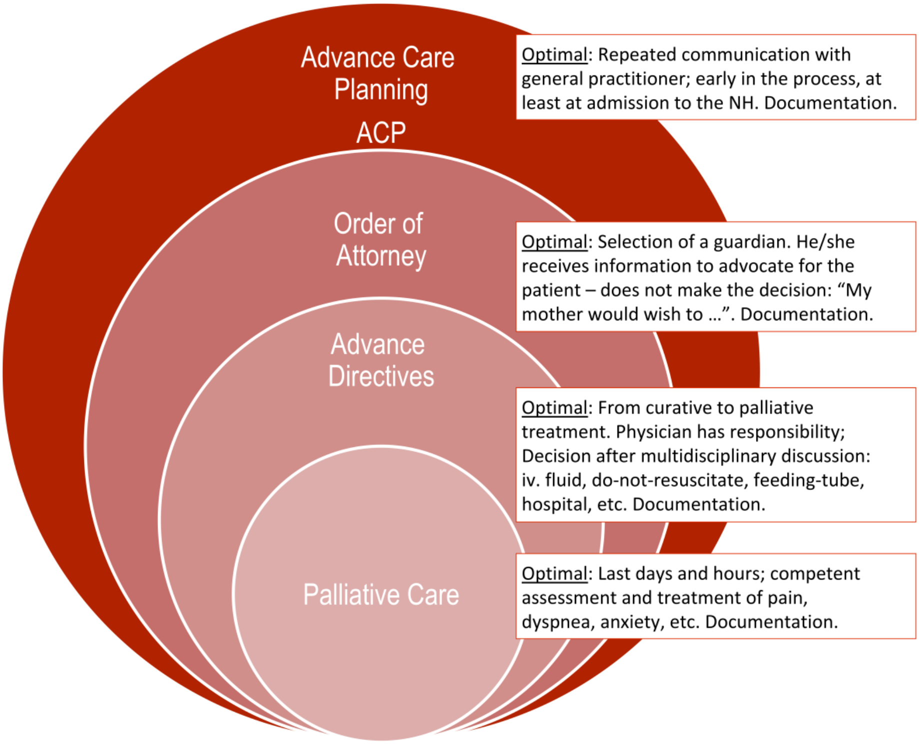
Depending on the type and advanced state of dementia, people with dementia might have the capacity to provide informed consent on some issues. People with dementia can be capable of understanding and reaching a decision on certain questions, while not comprehending other dilemmas. As such, it is important to try to involve a person with dementia in decision-making as much as possible (42, 43). Unfortunately, cognitive decline is often seen as a barrier for initiating ACP, and people with dementia are often excluded from such conversations (44). In the reviews by Flo et al. and Denning et al., a considerable part of the research on ACP in nursing homes was found to exclude patients with dementia (2, 43). This is regrettable because research suggests that ACP can be beneficial for people with dementia and their families if adequately adapted to this group (45). Wickson-Griffiths and colleagues conducted a review published in 2014, investigating whether existing ACP programmes for nursing homes are adapted to people with dementia (42). They included six publications in their review, five of which were considered dementia friendly (36, 46-49). This entailed that the interventions were *person-centred* and showed a respect for the person with dementia and their needs, values, and choices. None of the included studies were conducted in Europe, four of them were from the US (46-49), one was from Canada (36), and one was from Hong Kong (34). Wickson-Griffiths et al. highlight that ACP programmes in nursing homes need to be accessible for people with dementia and their families in order to be relevant in this setting. If conducted correctly, ACP represents an opportunity to provide person-centred care by recognising the individual's preferences for care and treatment (50).

Most ACP interventions in nursing homes including people with dementia endeavour to involve the family in the ACP process as early as possible. Some studies have also included the family in the intervention (2); for example, Caplan et al. provided information and education to the family concerning the terminal nature of dementia and the ACP content and goals (35). Early ACP discussions that include family members can help them to confront their understanding of medical issues and end-of-life care prior to critical deterioration of the patient's condition (51). Timing is thus another important aspect of ACP.

Timing

Questions regarding care and treatment often arise when a person's health is failing, due to either dementia or other terminal diseases. It is desirable that healthcare professionals start to discuss relevant questions in order to discern values and preferences before nursing home admission, when the person still have the cognitive resources to make decisions for themselves (52, 53). This is illustrated in Figure 2, which shows the stages involved in ACP and end-of-life care and the necessary measures that should be taken (54). However, optimal timing is elusive – a person might experience cognitive and functional decline for several years before they receive a diagnosis, and discussing end-of-life care when a person has just been diagnosed with dementia might be too early, while it is too late when the person is critically ill (2). When a person is admitted to a nursing home, he or she is fragile and has on average two years of life left (55), and it is essential to involve the family before a medical emergency arises (56, 57). The difficult timing of conversations regarding end-of-life care has long been recognised. A study conducted in Denmark in 1997 interviewed nursing home patients with capacity to provide informed consent (n = 101) and patients without this capacity (n = 106), their families (n = 142), and the nursing home staff (n = 207) about this topic. They concluded that treatment preferences should be discussed prior to an acute situation. This was especially important in patients who lacked the capacity to provide informed consent because there were more often disagreements concerning treatment between the staff and the patient's family in such situations (58).

When an ACP conversation has been initiated, it is also important to consider how such communication should be maintained. An ethnographic study by Saini and colleagues points out that conversations regarding end-of-life issues and treatment decisions should not be rushed and that time to process and reflect is necessary (59). In other words, although it is possible to rush through a checklist of questions in one session, it is unlikely that the patient or family will fully understand the medical issues they were asked to decide on. The number of meetings between family, patients, and staff – and the topics discussed in these meetings – can thus represent important ACP outcomes.



Optimal: Repeated communication with general practitioner; early in the process, at least at admission to the NH. Documentation.

Optimal: Selection of a guardian. He/she receives information to advocate for the patient – does not make the decision: "My mother would wish to …". Documentation.

Optimal: From curative to palliative treatment. Physician has responsibility; Decision after multidisciplinary discussion: iv. fluid, do-not-resuscitate, feeding-tube, hospital, etc. Documentation.

Optimal: Last days and hours; competent assessment and treatment of pain, dyspnea, anxiety, etc. Documentation.

Figure 2: Key aspects related to the ACP process in the nursing home (NH); from early conversations to end-of-life care. Importantly, the need to documenting the content and decisions is highlighted at all stages in the figure. From Husebo et al., 2017 (54), with permission from *BMC Medical Ethics* and *Springer Nature*.

Documentation

Although the "good conversation" is a crucial part of ACP, it is not possible to disregard the fact that proper documentation is essential (30, 33, 48). While the process of ACP is on-going, any specific statements that the patient or family make regarding treatment or care should be documented and readily available. This way, when a crisis occurs, the staff on duty are able to easily find the patient's specified preferences for care and treatment.

With a clear need for documentation, it is relevant to ask what is more important – to complete an advance directive or to achieve a proper ACP process? advance directives and ACP can be used together or separately. In international ACP research, the written documents that clarify patient's care and treatment preferences are often advance directives or similar legal documents (60). Concordance between documented decisions and actual provided care and satisfaction with the communication are important measures of how successful the ACP intervention has been (2, 21).

2.1.3 **Legal and cultural issues**

ACP is being promoted internationally as important both for nursing home patients in general and for people with dementia in particular (2, 21, 43). However, the cultural, legal, and ethical premises for ACP vary regionally and between countries (2, 4, 61). Consequently, the ACP process and content vary between nursing homes and countries worldwide (2, 62). For example, the importance of completing a legal document as part of an ACP intervention varies according to the legal status of such documents. In England, documents of general preferences and decisions to refuse medical interventions in certain circumstances are usually legally binding (21). Similar conditions are found in the US, Canada, Australia, and many European countries (2). For example, according to the Patient Self-Determination Act (1990) of the US, Medicare or Medicaid facilities must provide information to patients about advance directives and enter existing directives into patients' medical records. By comparison, according to The Norwegian Health Personnel Act the patient's physician ultimately makes the medical decisions (63, 64). According to the Norwegian Patients' and Users' Rights Act, the patient has the right to make their own decisions when possible (65). The patient's family has the right to be involved in decision-making when the patient lacks the capability to consent, but they are obliged to act according to the patient's presumed wishes, not according to their own preferences or needs. The physician is obliged to listen to the patient's and family's wishes, and thus documentation of preferences is a guideline, not a legally binding document (2). There is no official standard for ACP in Norwegian nursing homes, although the government recognises the need for involving patients and families when considering the nursing home stay and end-of-life care (66). Recently, the Norwegian government has launched national recommendations for dementia care and treatment, and these include recommendations for end-of-life conversations (67). In some countries, the completion of a legal document represents an important end goal, while in other countries the development of trust and agreement between patients' families and health professionals is more relevant (2).

Topics typically covered in ACP conversations may still be considered as unthinkable to bring to the table for some cultures and older generations. The cultural diversity may affect both the care environment in the nursing home and whether the patient and the family are included in discussions regarding treatment and care (68). The variation of culture and healthcare systems in different countries may in part explain the large number of different ACP interventions and programmes. For example, the lack of legal status related to documented medical decisions in Norway necessitates a different ACP focus and implementation strategy than in countries where living wills and similar documents are supported by legislation. Hence, it might not be possible to simply adopt programmes from other nations. The adoptability of an ACP intervention between cultural settings depends on a flexible implementation strategy, allowing the complex intervention to be receptive to the local institutional and individual context. Although it is natural to expect that an ACP intervention should use standardised communication routines, it is necessary to reflect upon when to be flexible and when to aim for consistency.

Standardisation does not mean that all the components of an intervention are the same in different settings (69). Indeed, Hawe and colleagues point out the importance of standardising the functions and the process of the interventions, but not standardising the components themselves. Consequently, it should be possible to adapt the intervention to local conditions between cultures and thus improve its effectiveness (69).

2.1.4 The nursing home

The definition of what a nursing home is, and the level of care provided in such institutions, varies between countries, and this has led to the imprecise use of the term in the international scientific literature. Despite national variations, some common themes can be identified (70). In general, nursing homes provide around the clock care, managing acute and chronic medical conditions and palliative or end-of-life care (55, 70, 71). A distinction is generally made between short-term care units that often rehabilitate patients and long-term care units that aim to provide a supportive and safe *home* for the patients. In Norway, the majority of patients who are admitted to long-term care units live there for the rest of their lives (72). In this thesis, the term "nursing home" is used to denote long-term care. There are different types of long-term care units, such as specialised dementia care or palliative care units (usually for older cancer patients) (73). Notably, the majority of patients in non-specialised units also have dementia (13).

Nursing homes represent the largest institution in Norway, with more than 41 000 registered nursing home beds and 32 234 people registered with long-term placement (74). In Norway, most nursing homes are run by the municipalities, and a person is offered nursing home placement based on individual needs as evaluated by the municipal health authorities. Consequently, in Norway and comparable countries such as the UK, Sweden, and the Netherlands, patients admitted to nursing homes are in high need of care (75), and require high medical competence in specialised facilities. The need for specialised care is even more pronounced when considering that today almost 50% of the Norwegian population die in the nursing home (76). In order to provide adequate palliative care and to avoid unnecessary hospitalisations and treatments, the nursing home staff must be skilled in handling end-of-life care. ACP is arguably a key factor in adequate end-of-life care.

2.1.5 **The nursing home patient**

Dementia

Approximately 80% of Norwegian nursing home patients have dementia (77). The term “dementia” is a syndrome that denotes several conditions where the decline in brain function is due to physical changes in the brain (78). In the Diagnostic and Statistical Manual of Mental Disorders (DSM-5), dementia is classified as a “Neurocognitive Disorder” (79). This diagnostic category includes disorders with a primary cognitive deficit that is acquired, not developmental, and that is distinct from mental illness. Dementia may negatively impact i) Executive abilities (e.g., planning, decision-making, working memory), ii) Learning and memory, iii) Language (e.g., naming, fluency, grammar, and syntax), iv) Perception (including motor-visual perception), and v) Social cognition (e.g., emotional and behavioural regulation and social appropriateness) (79, 80). The diagnostic criteria are similar, though not identical, in the International Classification of Diseases, 10th revision (ICD-10) (80).

Dementia affects nearly 10% of persons aged 65 and older (56). In Alzheimer´s disease, 95% are diagnosed after the age of 65 (late onset), and the incidence doubles every five years after the age of 60 (81). Alzheimer’s disease and vascular dementia are considered to be the two most common causes of dementia worldwide (82), with a relative frequency of approximately 50–75% and 20–30%, respectively (83, 84). However, the prevalence varies across countries and ethnicity, and mixed pathologies are more frequent than “pure” diagnoses (85). In a recent Norwegian cohort study including 696 nursing home patients, Roen et al. found that 83,8% had dementia; 71% had Alzheimer’s disease, 7.9% had vascular dementia, 1.9% had mixed Alzheimer’s and vascular dementia, 8.1% had frontotemporal dementia, 3.7% had Lewy body dementia, and 7.4% had other types of dementia (13). Importantly, the study by Roen et al. was largely based on anamnestic interviews, while research suggests that mixed pathologies are more common and are often detected when investigating the affected brain post-mortem (56, 85). Indeed, it is challenging to diagnose dementia, and although Roen and colleagues reported that 83.8% of the nursing home patients had dementia, only 55.9% of them had a dementia diagnosis documented in their medical records (77). This is in line with previous studies (86, 87).

The trajectory of dementia can be described in stages (88). In the early stage of dementia, forgetfulness and/or slight changes in mood, behaviour, and motivation might be overlooked and attributed to “old age”. In the middle stage of dementia, the deterioration is more prominent in the form of reduced functional status and problematic behaviour. In late-stage dementia, the individual is completely dependent on others (89, 90). Dementia is terminal and curtails the lifespan. A person with dementia in high-income countries dies on average about 4–7 years after onset/diagnosis, depending on the type of dementia (89, 90). Notably, dementia affects each individual differently depending on their predisposition, personality, lifestyle, social resources, and health (91, 92). A cure for dementia does not yet exist.

Behavioural and psychological symptoms due to dementia, often referred to as neuropsychiatric symptoms, include agitation, aggression, disinhibition, irritability, aberrant motor behaviour, hallucinations, delusions, depression, anxiety, euphoria, apathy, and changes in sleep and appetite (93, 94). Over the course of their disease, up to 90% of individuals with dementia will develop neuropsychiatric symptoms (95, 96), and studies have shown that most neuropsychiatric symptoms become more prevalent as the dementia progresses (97). Selbaek and colleagues identified a differential prevalence of distinct symptoms at different stages of dementia, and the presence of depression and anxiety decreased, while agitation/aggression, disinhibition, irritability, and apathy increased in severity as the dementia progressed (96). Neuropsychiatric symptoms are known to be distressing both for the person with dementia and for their carers, and the burden of neuropsychiatric symptoms increases the risk of sick days, burnout, and turnover in the nursing home staff (98-101). Neuropsychiatric symptoms not only reflect neurological changes, and they may also be triggered or exacerbated by other circumstances such as medications or pain (102). Neuropsychiatric symptoms should be closely evaluated in order to clarify whether symptoms are a sign of neurodegeneration or of unmet needs, pain, or discomfort (103, 104).

Multimorbidity and polypharmacy

The Norwegian nursing home patient is fragile, multimorbid, and dies on average 2.1 years after admission (55). Multimorbidity is defined as the presence of two or more chronic medical conditions (105), and common diagnoses in nursing home patients include dementia, ischemic heart disease, stroke, fractures, diabetes, Parkinson's disease, and cancer (106). These diagnoses can be difficult to handle separately, and the added challenges of multimorbidity generate a considerable symptom burden for the patient (107). Because most patients have several diagnoses and conditions, polypharmacy is also common in the nursing home setting. Polypharmacy is usually defined as taking five or more medications daily (108), and studies have found that Norwegian nursing home patients on average receive up to nine drugs on a regular basis (109, 110). Polypharmacy is associated with increased risk for inappropriate drug use, side effects, and even hospitalisation (111), but drug prescription is still increasing (112). It is thus important to inform the nursing home patient and family about medications and the advantages and disadvantages involved.

Pain

Research suggests that between 40% and 60% of nursing home patients suffer from pain (113, 114). Pain may be defined as "*an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage* " (115). Pain is a complex and multidimensional experience for the afflicted person (116), and because pain is subjective self-reporting is commonly seen as the gold standard for pain assessment both clinically and in research (117). Cognitive decline impairs the ability to evaluate and report pain reliably. Because of this, observational pain assessment scales, usually rated by health professionals, are necessary for appropriate pain assessment in people with dementia (118). Due to insufficient self-reporting and the complex nature of observational pain assessment, there is an increased risk that pain remains undetected and untreated in people with dementia (119, 120).

When the ability to verbalise pain and discomfort is lost, behaviour remains a means of communication. In people with dementia, research suggests an association between pain or discomfort and the presence of behavioural and psychological symptoms similar to neuropsychiatric symptoms (121-124). Untreated pain may trigger or exacerbate such symptoms (120), and previous studies have suggested that systematic pain treatment can reduce behavioural and psychological symptoms such as depression in people with dementia (120, 125). However, not all patients seem to benefit in this regard, and a recent trial found that pain treatment might not be effective in treating depression in people with dementia (126). Research has suggested that untreated pain can also be distressing for the staff, especially when expressed as neuropsychiatric symptoms (98, 127, 128).

Capacity to provide informed consent and the need to involve the family

Another important aspect in being a nursing home patient is that the comprehensive symptom burden necessitates medical decision-making. Studies have reported that 44–69% of nursing home patients have impaired decision-making abilities, which is a prerequisite for giving informed consent to medical treatment (129). Determining the capacity to give informed consent is necessary to be able to balance between respecting a patients' autonomy and protecting those with cognitive impairment. Capacity is evaluated based on the perceived ability to comprehend information, to understand the situation and consequences, to reason, and to make decisions based on available information and to communicate these decisions to others (130). Capacity depends on the complexity of the information, and it varies over time (131). Although there is a correlation between cognitive tests and capacity, each medical decision may have different levels of complexity, thus necessitating a new evaluation. Therefore, assuming that all people diagnosed with dementia are unable to provide informed consent might deny them the opportunity to make an informed decision (132).

When a patient cannot provide informed consent, a family member or another appropriate person must be identified as a legal guardian. When this person makes informed presumed decisions, he/she should consider the question, "What would 'my loved one' have wished in this situation?" (54).

2.1.6 The effect of Advance Care Planning

ACP is an important tool to support the patient's right to be informed about their disease and treatment options and subsequently to make informed decisions (5, 6). Over the last decades, more research has investigated the effect of ACP in nursing homes and in people with dementia. The latest follow-up literature search to the review by Flo et al. (2) was performed by the author of this thesis in collaboration with the University of Bergen Library in July 2019. From 2012 to 2019, 24 579 publications related to the MeSH term 'Advance Care Planning' were published in the PubMed (MEDLINE) database alone. A search limited by date (from 2012) in the PubMed (MEDLINE), EMBASE, and Cochrane Library databases for the combination 'nursing home' and 'Advance Care Planning' resulted in 1293 publications, while 'dementia', 'Advance Care Planning', and 'nursing home' resulted in 94 publications. Table 2 shows the relevant newly published papers with a main focus on the effect of ACP in nursing homes. Additionally, seven relevant reviews focusing on ACP in the nursing home setting were published between 2012 and 2019 (Table 3). Also, two recent reviews include studies in nursing homes and in people with dementia alongside other populations and settings (21, 133). Most of these reviews comment on the diversity in this line of research, both in terms of interventions and outcome variables, and some main effects have been summarised (2, 52, 134-136). The review by Flo and colleagues reported that ACP in nursing homes has been found to improve palliative care procedures, to lower costs, and to reduce hospital admissions and deaths (2). In a recent review published in 2018 by Dixon et al., 16 out of 18 studies found a positive association between ACP and end-of-life outcomes (21). For example, a study published in 2016 by Garden and colleagues including 283 nursing home patients with dementia found that hospital admissions were decreased by 55% after implementing ACP (137). The authors also found that 67 of the 68 patients who died during the study were in their preferred place of death. Additionally, ACP has been found to reduce uncertainty among families that are requested to make decisions on behalf of their loved ones (25). Family members have also been found to experience a greater concordance between stated preferences and provided care (26).

A central part of ACP is to establish opportunities for good communication between patients, families, and staff. Good communication improves more than just outcomes related to end-of-life care and hospitalisation rates. For example, Sprangers and colleagues found that improving nursing home staff's communication skills was related to a higher quality of life and a decrease in verbal and physical aggression and depression in 26 nursing home patients with dementia (138).

The positive outcomes of ACP have led to an increasing interest in establishing ACP as a routine part of nursing home care (21). As described above, in Norway, the government recommends the involvement of nursing home patients and their families in planning for care and treatment (66, 67). Importantly, A new Delphi report underlines the need for a common definition of ACP (61), thus this will improve knowledge transfer.

Table 2: Quantitative or mixed methods studies focusing on the *effect of ACP in NHs* identified in literature search (2016–2019).

Author (year) country, state	**Number of participants**	**Design**	**Aim**	**Intervention**	**Conclusion**
Sævareid et al. (2019), Norway (22)	8 NH units, 154 patients	Paired-matched cRCT	To improve ACP participation in NH patients	A project team in each unit was offered a 2-day training. Guidelines on ACP, Pocket card (a short version of ACP). Train-the-trainer approach.	Increased patient participation in end-of-life treatment conversations. Improved concordance between treatment and patient preferences, as well as increased family participation in ACP together with the patient.
Aasmul et al. (2018), Norway (23)	67 NH units, 545 patients	cRCT	Effects of ACP on communication, satisfaction among staff, patients, and families, and staff distress	ACP lectures as a part of a two-day education of NH staff. Educational material brought back to the units. A train-the-trainer strategy for implementation. 4-month intervention and follow-up at month 9.	Increased number of shared conversations between family, patient, and the primary nurse and monthly contacts with the families. Reduced nursing staff distress. Lack of effect at month 9, indicating a need for staff support. Improved satisfaction with the communication among nurses and families.
Mitchell et al. (2018), US, Boston (24)	64 NHs, 402 residents	cRCT	Effects on ADs, care preferences, and treatment discussions	A 12-minute ACP video for the patients' proxies with written communication of their preferred level of care.	No effects on "do not hospitalise" status or burdensome treatments among residents with dementia. Increased directives to withhold tube-feeding.
Brazil et al. (2018), UK, Ireland (25)	24 NHs	Paired cRCT	Effectiveness of ACP with family carers in dementia	Trained facilitator, family education, meetings, documentation of decisions. Including GPs and staff.	Reduced uncertainty among family carers in decision-making concerning the care of their family members.
Ampe et al. (2017), Belgium (28)	18 NH units	Quasi-experimental pretest-posttest	Effects of the 'we DECide' programme on the policy and practice of ACP	Education programme for NH staff and management. Three modules: two 4-hour workshops and a homework assignment.	ACP policy was more compliant with best practice. No increase in ACP discussion or involvement of patients and families. Barriers: staff's limited responsibilities. Facilitators: support by management staff and involvement of the whole organisation.

Table 2 continued.

Author (year), country	**Number of participants**	**Design**	**Aim**	**Intervention**	**Conclusion**
McGlade et al. (2017), UK, Ireland (37)	2 NHs 1 community hospital (290 beds)	Feasibility study	Identifying challenges in implementing the “Let me decide” ACP program	Staff education on ACP.	Over 50% of all residents had completed some form of end-of-life care plan. Of 70 residents who died during post-implementation, 14% had no care plan, 10% (with capacity to consent) completed ADs, and 76% (lacking such capacity) had special end-of-life care plans completed for them by the health care team. Logistical challenges in training staff triggered the development of an e-learning programme to facilitate training.
Hanson et al. (2016), US, North Carolina (26)	22 NHs 302 patients and their families	A single-blind cRCT	To test a Goals of care (GOC) decision aid intervention to improve the quality of communication and palliative care.	A GOC video decision aid plus a structured discussion with NH healthcare providers compared to controls with an informational video and usual care planning.	Family decision-makers reported better quality of communication and end-of-life communication. Goal concordance did not differ at 3 months, but family decision-makers with the intervention reported greater concordance by 9 months or death. Family ratings of treatment consistent with preferences, symptom management, and quality of care did not differ.
Ouslander et al. (2016), US (139)	64 NHs	Retrospective RCA	To identify lessons learned, reducing transfers to hospital from NHs	Quality improvement programme (INTERACT).	Staff identified 1044 (23%) of the transfers as potentially preventable with earlier ACP. Condition could have been detected earlier and/or could have been managed safely in the NH.

ACP: Advance Care Planning, ADs: advance directives, GP: general practitioner, SDM: Shared Decision-Making, DNH: do not hospitalize, GOC: Goals of care, RCA: root cause analysis, INTERACKT: Interventions to Reduce Care Transfers, ED: emergency department, cRCT: cluster-randomised controlled trials.

Table 3: Overview of reviews on Advance Care Planning related to nursing home patients.

Author (year), included studies	**Focus**	**Inclusion and exclusion**	**Conclusion**
Beck et al. (2017) N=14 (135)	To synthesise the evidence on HCPs' perspectives on ACP for people with dementia in LTC settings	Inclusion: I) English language. II) Published in international peer-reviewed journals. III) Qualitative, quantitative, and mixed methodologies studies. IV) Systematic literature reviews. Focus on the perspective of HCPs in relation to ACP for people with dementia. Conducted in long-term care. Exclusion: I) Studies only focusing on people with dementia/and or their families. II) Discussion and editorial papers.	Identification of four themes regarding discussion of HCPs' perspectives on ACP for people with dementia in LTC. I) Early integration and planning for palliative care in dementia. II) HCPs' ethical and moral concerns regarding ACP. III) Communication challenges when interacting with the person with dementia and their families. IV) HCPs' need for education and training.
Gilissen et al. (2017) N=38 (136)	Preconditions for successful ACP in NHs	Inclusion*:* I) Qualitative, quantitative reviews and systematic reviews. II) English language. III) In NHs. Exclusion*:* I) Focus on specific condition or specific medical treatment (except dementia and/or Alzheimer's disease). II) Main focus on end-of-life decisions (e.g. euthanasia, DNR-orders). III) If ACP is an outcome of another intervention rather than the intervention itself. IV) Article concerning general care planning.	Seventeen preconditions at five different levels were identified: I) Resident. II) Family. III) Healthcare professional. IV) Facility. IV) Community. Preconditions were summarised in five domains: I) Sufficient knowledge and skills. II) Willing and able to participate in ACP. III) Good relationships. IV) Administrative system in place. V) Contextual factors supporting ACP within the NH.

Table 3 continued.

Author (year), included studies	**Focus**	**Inclusion and exclusion**	**Conclusion**
Flo et al. (2016) N=16 (2)	To review research that focus on the implementation of ACP interventions in NHs	Inclusion: I) NH patients, relatives, and/or NH personnel. II) ACP defined as a conversation between patients and/or families and health personnel concerning thoughts, expectations, and preferences for end-of-life-care. Qualitative and quantitative study designs. Exclusion: I) Focus on specific diagnoses. II) Only using chart-based interventions (e.g. AD without conversations). III) Only treatment limits (e.g., DNR, DNH).	Studies on ACP in NHs found improved palliative care procedures, lower costs, and reductions in hospital deaths and admissions. Variation in ACP definitions together with limited information about procedures made it hard to compare research results.
Martin et al. (2016) N=13 (52)	The effect of ACP in NH patients	Inclusion: I) RCT or CT. II) NH residents. III) Intervention using medication reviews with outcomes of hospitalisation or mortality. IV) English, Swedish, Norwegian, or Danish Exclusion: I) Medication review only on specific drug classes or conditions.	ACP decreased hospitalisation rates by 9% to 26%. In the two studies that included mortality, the decrease in hospitalisation was not associated with increased mortality. ACP increased the number of residents dying in their NH by 29% to 40%. Medical treatments being consistent with ones' wishes were increased with ACP, although not to 100% compliance. Two studies showed a decrease in overall health costs. One study found an increase in community palliative care use but not in-patient hospice referrals. The types of ACP interventions vary, and it is difficult to identify superiority in effectiveness of one intervention over another.

Table 3 continued.

Author (year), included studies	**Focus**	**Inclusion and exclusion**	**Conclusion**
Sechaud et al. (2014) N=23 (60)	To identify the best care strategies, particularly for institutionalised older people.	Inclusion: I) “Advance care planning” in title and/or abstract, II) Publication date (1999–2012). III) Language English or French. IV) Age ≥65 years. Exclusion: I) Historical approaches. II) Specific diseases (e.g., kidney, dementia and cancer). III) Contexts other than NHs.	ACP requires a paradigm shift in caregivers’ attitudes to focus on personal values. Some studies report that ADs are relatively inefficient due to challenges in completing them, their lack of stability over time, the lack of availability when needed, and non-compliance by professionals. Advocating approaches of ACP, rather than AD.
Wickson-Griffiths et al. (2014) N=6 (42)	Explore the impact of ACP programmes in LTCHs in order to select a programme that best suits residents’ needs.	Inclusion: I) Programme focused on ACP and/or ADs or sharing goals of care. II) LTCH setting. III) Available description of the ACP programme. IV) Quantitative design; comparison or control group. Exclusion: Studies that used an uncontrolled, before-after design.	Five of the six included ACP programmes were considered to be more “dementia friendly”. The programmes indicated a variety of positive impacts in the planning and provision of end-of-life care for residents and their family members, most notably increased ACP discussion and documentation.
Robinson et al. (2012) N=4 (134)	To determine the effectiveness of ACP interventions in NHs for people with cognitive deficits and to identify factors influencing implementation.	Inclusion: I) People with acquired cognitive impairment of any age including people with dementia. II) People who were chronically cognitively impaired but did not fulfil the accepted criteria for the classification of dementia, for example, those living in nursing and residential care where research has confirmed a high level of undiagnosed dementia. III) English.	Three studies reported formal processes of capacity assessment, and only up to 36% of participants had capacity. Three studies reported positive findings in documentation of patient preferences. Two studies reported significant reductions in hospitalisation, and a third found increased use of hospice services in the intervention group. Evidence is limited for the effectiveness of ACP in people with cognitive impairment/dementia in terms of ACP documentation and healthcare use.

Studies included in these reviews explored ACP in the nursing home setting

ACP: Advance care planning, ADs: Advance directives, DNH: Do not hospitalize, DNR: Do not resuscitate, HCP: Healthcare provider, LTCH: Long-term care home, NH: nursing home, RCT: Randomized controlled trails, CT: Controlled trials

2.1.7 Implementation of Advance Care Planning

When implementing ACP in nursing homes, individual, social, and organisational mechanisms must be considered. Research suggests that few nursing home patients partake actively in ACP, which might indicate that the implementation of ACP is not optimal (136). ACP may be defined as a complex intervention, because it usually includes multiple interacting components, because difficult actions are required by multiple actors from different organisational levels, and because it has multiple outcome measures (69, 140). It also requires that the nursing home staff be proficient in communication skills, end-of-life care issues and decisions, and the documentation of preferences. Thus, an important prerequisite for ACP implementation is having an appropriately skilled person among the nursing home staff (136). According to the literature, this can be a physician, a nurse, or both. In their review, Flo et al. identified several promoters and barriers for successful implementation of ACP in nursing homes. Interestingly, many barriers were related to organisational issues such as lack of competence and experience, unclear legal implications of the documented preferences, resource problems (such as staff shortage or lack of time), poor occupational culture, and lack of administrative support. Mirroring this, their review also identified several promoters for ACP implementation, of which education about providing information about ACP was most frequently listed as an important facilitator (2). In their recent review, Gilissen and colleagues identified 17 preconditions for successful implementation of ACP interventions in nursing homes, of which sufficient knowledge and skills were emphasised domains (136). Likewise, in a recent narrative review on ACP for people with dementia in nursing homes, Beck and colleagues emphasised the need for staff education and training (135). Most intervention studies have used an educational approach to implementing ACP in nursing homes, although the education varies in terms of how extensive the courses are and the participants that are involved (2, 21). Multicomponent educational programmes that involved numerous sessions, and several recipients (nurses, physicians, and families) were used in many studies for example by Sankaran et al., Morrison et al., Hockley et al., and Livingston et al. (32, 33, 41, 48). Others have used an external consultant or facilitator who coaches the nursing home staff (21, 35). More recently, Garden and colleagues included two specially trained registered general nurses and a consultant psychiatrist as facilitators, while also completing a group-training programme in management of end-stage dementia for nursing home staff (137). Sprangers and colleagues concluded that ACP education for physicians and nursing staff is important in order to provide care in accordance with the patient's individual needs and wishes (138). Apart from communication skills, research suggests that training should include documentation procedures and the legal status of such documents (43, 141).

Perceived lack of skills among staff has often been identified as a barrier for adequate ACP implementation (38, 141, 142). This might lead to lack of staff confidence and to staff feeling uncomfortable with initiating ACP conversations (44). Poppe and colleagues highlighted that staff training and supervision is necessary in order to increase the staff confidence in organising ACP meetings (143).

2.2 Staff perspective

The nursing home is a challenging working place. It is a *residence*, and the staff are deeply involved in their patients' personal lives. At the same time, the patients' reduced capacity to give informed consent, as well as their fragility and multimorbidity, represent a complex medical challenge. The available medical competence varies in Norwegian nursing homes, but on average they have one registered nurse per 10 patients, one licensed practical nurse per seven patients, and one unskilled nurse per 16 patients on a normal day shift (144). Physicians in Norwegian nursing homes use on average half an hour weekly per patient (145). A new report from 2019, assessing the provision of medical professionals in the nursing homes, points out variations between municipalities. However, they found that in 2017 it was common that the nursing home physician was engaged by the municipality and typically in a 49% position in the nursing home. Only 24% of the physicians had full time positions, but the proportion is increasing (146). Statistics show that there has been an increase in full-time equivalence (FTE) registered nurses in institutions in the municipalities, which increased by 17% from 2010 to 2016. For the physicians, the increase was 31% in the same period (146).

The nursing staff have a key position in establishing routines and quality of care. It is therefore essential to consider the nursing staff perspective when conducting research in the nursing home setting. The term “staff perspective” is broad and may encompass a wide array of themes. In this thesis, the staff perspective has involved two enquiries – how the staff cope with work-related stressors (staff distress) and how staff are involved in and experience the implementation of a complex intervention (i.e. ACP). In this thesis, the term “staff” refers to the nursing staff working close to the patient, mostly registered nurses and licensed practical nurses. When discussing other nursing home personnel, i.e., physicians, the profession is mentioned specifically. This section will first describe staff distress, and this will be followed by an overview of the effect of staff competence and of providing education.

2.2.1 **Staff distress**

Nursing home staff often report job stress, which is caused by various factors, including psychosocial factors and patient-related factors such as dementia and agitation (147). Research on nursing home working conditions often refer to “staff distress” or “staff burden”, but these terms lack a scientific consensus in terms of definition and operationalisation. It is natural to understand staff distress and burden in relation to the more established stress theories. Stress theories, such as the well-known stress model “the cognitive activation theory of stress”, (CATS) seek to explain when and how stress is problematic both in humans and in animals. A person’s resources, with particular emphasis on learning and coping (cognitive processes), are in focus. The cognitive processing of a stimulus (stressor) is central for triggering a stress response. CATS defines four aspects of stress – the psychological and physiological stress (stressor) that we are exposed to, the cognitive processing (filtering of stimuli), the stress response (activation), and the physiological reactions that occur in the body (the subjective experiences of both the stressor and the stress response). The cognitive activation theory of stress shows how our expectations of specific situations and our coping thereof determines the level of stress we experience. Stress is triggered when there is a discrepancy between what should *be* (e.g., expectations) and what actually *is* (e.g., our resources or abilities) (148). In the nursing home setting, this can be related to challenges in the treatment and care and how the staff evaluate their resources and ability to cope with work demands. The societal impact of staff distress is significant, with increased risk of burnout, sick leave, and turnover and increased economic costs (94, 101, 127, 149).

A search related to the MeSH terms ‘staff distress’ or ‘staff burden’ performed in July, 2019, yielded 5602 publications in the PubMed (MEDLINE) database, while the combination ‘staff distress’ or ‘staff burden’ and ‘nursing home’ and ‘dementia’ resulted in 112 publications.

Neuropsychiatric symptoms and staff distress

A prevalent reason for admission to long-term care is family caregiver distress related to neuropsychiatric symptoms (150, 151). These symptoms are also difficult to handle for the staff and tending to patients who display neuropsychiatric symptoms is associated with increased risk of depression, anxiety, and sleep problems among carers (152).

Not all neuropsychiatric symptoms have an equally distressing effect. A Japanese study by Miyamoto et al., including 445 nursing home staff, found that disruptive behaviours such as aggression and screaming were the most burdensome (149). Likewise, a US study by Wood et al. that interviewed 24 nurses found that aggression and agitation were more distressing than other nonaggressive neuropsychiatric symptoms (94). In a Dutch study, Zwijsen and colleagues investigated staff distress in 17 nursing homes using the neuropsychiatric inventory (153), for assessing both patient symptoms and staff distress (98). Agitation/aggression had the highest mean distress score, followed by disinhibition and irritability/lability. Euphoria, hallucinations, and apathy had the lowest mean distress scores. Zwijsen et al. also found that the severity of a symptom had more impact on the distress score than the symptom’s frequency (98). A recent study by van Duinen-van den Ijssel and colleagues also found that agitation/aggression was highly distressing along with night-time behaviour and delusions, while euphoria and apathy were the least distressing (101). Successful treatment of neuropsychiatric symptoms has also been shown to reduce staff distress (154). In an open-label pilot study on 31 long-term care patients, Herrmann and colleagues found that memantine reduced agitation and at the same time reduced staff distress. A better system for treating and handling neuropsychiatric symptoms might therefore help reduce the risk of staff distress.

Competence and moral distress

Staff distress has been associated with lack of competence. For example, if a patient is vocal and screams, this may evoke emotional reactions in the staff. They wish to comfort, understand, and help the patient but lack the ability to do so (155, 156). Research suggests that disruptive neuropsychiatric symptoms may interfere with and create insecurity in the nursing home setting, especially if the staff have not received training in managing such symptoms (127). This is in line with stress theories, showing that a discrepancy between demands and abilities is a fundamental stressor (148, 157).

Nursing home staff constantly meet ethical dilemmas and difficult questions relating to the care of their patients. Moral distress may be triggered when the staff believe they know the right thing to do but feel unable to pursue that course of action due to organisational issues or other constraints (e.g., lack of skills or competence) (158). In a recent review on moral distress in nursing homes, one of the important causes of distress was poor communication (159). A study by Whitehead et al., including different health professionals, found that poor communication was among the top three causes of distress for all health professionals (158). It follows that alleviating these issues may reduce the risk of staff distress. Interestingly, Edvardsson et al. found that providing staff education regarding guidelines for person-centred care for people with dementia reduced staff's stress of conscience (160). Stress of conscience is similar to the moral distress concept, and these findings suggests that the staff were relieved when they perceived themselves as able to provide the care they thought was needed. ACP represents a systematising of knowledge and institutional practice that may help staff improve their competence and communication with patients and families.

2.2.2 **Competence and education**

The involvement of nursing staff in research and in the implementation of new practice often depends on their knowledge and attitude. Implementation strategies are often based on the provision of education and training to the staff (161), and the need for education of nursing home staff has been recognised as an important challenge (162). There has been an increase in complex patient needs, while educational opportunities in the nursing home setting have not been improved accordingly (163). Most of the staff, including registered nurses, have not had the opportunity to develop their skills in accordance with increasing job demands (164). A recent study that explored staff competence in Norwegian nursing homes and home care services detected a lack of relevant competence, especially regarding palliative care, observation, advanced nursing, and documentation (163). This discrepancy between skills and demands can potentially lead to poor patient care and staff distress, while education and training may reverse such effects. For example, perceived competence in dementia care among staff has been linked to both dementia-sensitive attitudes and improved job satisfaction (165, 166).

Education and staff distress

Opportunities for competence development at work have been associated with work satisfaction among nursing home staff (167). Indeed, Edvardsson and colleagues found that a significantly higher proportion of staff who experienced job strain were less educated compared to those who reported lower strain (168). Moreover, studies that explored the effect of interventions on the nursing home staff found that education may have a positive effect on their emotional distress (169, 170). Jeon and colleagues found in their cRCT that implementing person-centred approaches of care reduced burnout and psychological distress in staff (169).

Pharmacological treatment of neuropsychiatric symptoms can also reduce staff distress (154), although to fully address the complexity of neuropsychiatric symptoms in dementia, nursing home staff need to be educated in the clinical assessment and management of neuropsychiatric symptoms and of other conditions that may trigger neuropsychiatric symptoms (e.g., pain). The importance of staff understanding and their appraisal of neuropsychiatric symptoms was highlighted in a study by Rodney et al., where aggressiveness perceived to be threatening was significantly related to staff distress (128). Staff knowledge of neuropsychiatric symptoms, for example, that pain may cause the patient`s aggressive behaviour, may lead to decreased experience of threat and also to reduced distress. Such education may also empower the staff by providing a clinical tool to assess symptoms and handle them adequately. Spector and colleagues performed a systematic review to explore the impact of staff training in dementia care and found that it could help staff to manage challenging behaviour (161). Studies also indicate that increased competence and knowledge may empower staff to cope with difficult symptoms (127, 171). Staff distress in nursing homes is also found to correlate with the psychosocial work climate and the possibility to provide person-centred care (172).

Education in complex interventions

In recent years there has been an increased focus on the nursing staff and their competence and the impact it has on the quality of care (173-175). The heterogeneity and complex conditions observed in nursing home patients means that universal solutions are neither a realistic nor advisable goal. A feasible scientific solution may thus be to design a set of clinical approaches that can be adapted to different patients and settings. This is a central aspect of a complex intervention. Here, the word "complex" refers to interventions with interacting components that require behaviours or actions by individuals receiving or delivering the intervention, and with variable outcomes in different contexts (69, 176, 177). Typically, complex interventions entail educational and behavioural interventions targeting processes of care. Instead of defining the integrity of the intervention as "*having the dose delivered at an optimal level and in the same way in each site*", complex interventions standardise the process and function (69).

ACP can be regarded and designed as a complex intervention. In most ACP programmes, training and education of staff is a key intervention component, and thus a better understanding of dementia and the concept of ACP is required in order to improve communication practice in nursing homes. Educational interventions to improve staff communication skills have also been shown to affect staff satisfaction (137). Thus, as a recurring principle in taking the staff perspective, education may improve both clinical practice and reduce staff distress.

2.3 Rationale for this thesis

There is a high symptom burden in nursing home patients and people with dementia, which also entails a challenging and potentially distressing work situation for the staff. ACP represents an important intervention that can help nursing home patients, people with dementia, their family, and staff to reach a common understanding of the wishes, needs, and values that are important in treatment, care, and end-of-life-care. This was the basis for the following rationales for this thesis:

- A lack of routines, knowledge, and skills can lead to inadequate care conditions for the patient, and may be distressing for the staff, both in terms of demanding symptoms and in terms of feelings of inadequacy.
- Complex interventions that seek to improve quality of care and treatment, for example, ACP, require educating and training staff in order to achieve successful implementation.
- There is a need to develop an ACP programme that is adapted to the Norwegian nursing home setting.
- It is necessary to document and investigate the implementation process of the complex ACP intervention.
- Both the intervention outcomes and the implementation process need to be documented and systematically evaluated to ensure an evidence-based approach.
- Hence, when implementing complex interventions like ACP, the staff perspective, including potential distress, must be explored alongside the patient perspective.

3. Aims of the thesis

The main aim of this thesis was twofold. First to describe the development and implementation of ACP in the nursing home and to test its effects, and second to consider the staff perspective both in terms of staff distress and the staff's experiences of the implementation of ACP.

The thesis includes three papers that had the following aims:

In paper 1, we aimed to investigate:

- the cross-sectional association between patient's neuropsychiatric symptoms and staff distress
- if systematic pain treatment had a between-group effect on staff distress, in particular, i) if the distress was reduced in the intervention as compared to the control group after eight weeks of treatment and ii) if staff distress increased after the washout period in the intervention group vs. the control group
- potential within-group effects on staff distress within both the intervention and control groups

In paper 2, we aimed to describe the development and implementation of ACP in the nursing home setting. We aimed to evaluate and investigate:

- how the nursing home staff received the ACP and the implementation strategy
- to what degree ACP was implemented successfully
- the facilitators and barriers for implementing ACP in the nursing home

In paper 3, we aimed to investigate whether ACP potentially:

- improved the communication among patients, their families, and staff
- increased the satisfaction with communication between the family and staff
- reduced staff distress in the intervention group as compared to the control group

4. Methods

4.1 Outline of data sources

This PhD thesis is based on secondary analyses from two studies, both conducted in long-term care units in Norwegian nursing homes. Paper 1 used data from the PAIN-BPSD (The Impact of Pain on Behavioural Disturbances in Patients with Moderate and Severe Dementia) study, which was completed before I started my PhD period (120). Papers 2 and 3 used data from the COSMOS trial (178), in which I had an active role in the planning, organisation, data collection, and analysis. An overview of the design, study aims, and study participants is given in Table 4.

In what follows, the outcome measures and assessment instruments used in papers 1, 2, and 3 will be described. Subsequently, the PAIN-BPSD study will be presented along with the specific methods, setting, and participants in paper 1. The COSMOS trial will then be presented, followed by the specific methods and analyses for paper 2 and paper 3. Finally, the ethical considerations for all papers will be outlined.

Table 4: Overview of the studies that have provided data for the three papers in the thesis.

Paper	Data source & design	Main focus	Study population
1	- PAIN-BPSD study - cRCT	Staff distress in relation to pain treatment and changes in neuropsychiatric symptoms.	352 NH patients, and 138 nursing staff as proxy raters
2	- COSMOS trial - Descriptive, qualitative study and process evaluation	The development and implementation of ACP, identifying facilitators and barriers	Only participants from the COSMOS intervention group: 297 NH patients 105 healthcare professionals attending the 2-day education seminar and 126 NH staff attending the midway seminar
3	- COSMOS trial - cRCT	Evaluating the effect of ACP in NHs	545 NH patients and their next of kin and 117 nursing staff as proxy raters

ACP: Advance Care Planning, COSMOS: Communication in form of advance care planning, Systematic pain assessment and treatment, Medication Review, Organisation of activities, Safety, cRCT: cluster randomized controlled trial, PAIN-BPSD: The Impact of Pain on Behavioural Disturbances in Patients with Moderate and Severe Dementia, NH: nursing home

4.2 Assessment

The two studies included in this thesis used similar methods and instruments for the data collection. Both in the PAIN-BPSD study and the COSMOS trial, nurses in daily contact with the patients were asked to be proxy raters and to report symptoms using instruments and assessment tools. These proxy raters were closely followed up by researchers who were present in the nursing homes during data collection. The full list of instruments from the PAIN-BPSD study and the COSMOS trial that were used in papers 1–3 is presented in Table 5a. In addition, a patient log was developed for the COSMOS trial in order to document and support the ACP implementation process in the intervention group. The individual logs were used to report every fourth week which key ACP components (deliverables) had been completed for each patient (Table 5b). To compare the intervention and control group in terms of communication activities (i.e. deliverables), key ACP components were assessed during data collection at months four and nine (Table 5b). A Clinical Global Impression of Change (CGIC) questionnaire was used at month four to compare the intervention and control group in terms of satisfaction with communication (Table 5b).

Table 5a: Clinical assessment tools used in all study participants in the PAIN-BPSD study and the COSMOS study and their use in papers 1-3.

Clinical tool [reference]	What the tool measures	Characteristics & psychometric properties of the tools	How the instrument was used in this thesis
CMAI*† (173)	Agitation and behavioural disturbances.	29 items where behaviours are scored on frequency (never to multiple times an hour; 1-7). Good reliability and validity.	Used as an inclusion criterion (score $\geq$ 39) in paper 1 (PAIN-BPSD).
FAST*† (179, 180)	Severity of dementia.	Seven stages of dementia where patients receiving a score of 1-2 are considered to have normal cognition, 3 indicates mild dementia, 4-5 moderate dementia, and 6-7 severe dementia. Good validity and reliability.	Used to assess level of dementia as a part of the inclusion criteria in paper1 (PAIN-BPSD).
MMSE*† (181-183)	Degree of cognitive impairment.	30-point scale where 26 to 30 = normal cognition, 21 to 25 = mild impairment, 11 to 20 = moderate impairment and 0 to 10 = severe impairment. Good validity and reliability.	Baseline score used as a predictor in paper 1 and as descriptive data in papers 2 and 3 (PAIN-BPSD and COSMOS).
MOBID-2*† (184)	Pain location and intensity in people with dementia.	Measures pain intensity in five standardised, guided movements and five domains related to internal organs, head, and skin in the last week. Good reliability, validity, and responsiveness.	Baseline score was used as a predictor in paper 1 (PAIN-BPSD).
NPI-NH*† (153, 185)	Neuropsychiatric symptoms in dementia.	12 items (delusions, hallucinations, agitation, depression, anxiety, euphoria, apathy, disinhibition, irritability, aberrant motor behaviour, night-time behaviour, and eating disturbances) are scored according to frequency (0–4) and severity (1–3). All items are summed to a total score (range 0–144). Good validity and reliability.	Baseline score was used as a predictor in paper 1 and as descriptive data in paper 3 (PAIN-BPSD and COSMOS).
NPI-NH-distress scale (94, 186)	Staff distress in relation to neuropsychiatric symptoms.	NPI-NH distress scale where staff assess their experienced distress in relation to each NPI-NH item. The scale ranges from 0 (not at all distressing), to 5 (extremely distressing). All items may be summed to a total score (range 0–60)	Week 8 and 12 data were used as outcome measures in paper 1 (PAIN-BPSD). Month 4 and 9 data were used as outcome measure in paper 3 (COSMOS).

*Proxy-rated instrument, † Validated for use in people with dementia. CMAI: Cohen-Mansfield Agitation Inventory; FAST: Functional Assessment Staging; MMSE: Mini Mental Status Examination; MOBID-2: Mobilisation-Observation-Behaviour-Intensity-Dementia-2 Pain Scale; NPI-NH: Neuropsychiatric Inventory-Nursing Home version

Table 5b: Additional measures for evaluating the implementation of ACP.

Additional measures	What the tool measures	Characteristics and psychometric properties of the tools	How the instrument was used in this thesis
CGIC communication (incl. nurses and families; month 4)	Changes in communication	Changes in communication were recorded on a Likert scale adapted from the CGIC with scores ranging from −5 (*much worse communication*) to +5 (*much better communication*) (187, 188).	Used at month 4 in both the intervention and control groups. Administered to nurses and to the patients' families. Assessed any perceived change in communication between the family, nurses, and nursing home physicians. This scale was used in paper 3.
Key ACP components (incl. nurses rating for the entire unit; month 4 and 9)	Frequency of 5 key ACP components.	Addresses five key actions (yes, no, not applicable, and don't know): (1) Have the patient and family been invited to a conversation with the physician? (2) Have the patient and family had a shared conversation with the primary nurse? (3) Have there been monthly phone calls to the family? (4) Have you had contact with the family in the last month? (5) Is the communication documented?	Used at month 4 and 9 in both the intervention and control group. The proxy raters (nurses) answered these questions along with the clinical assessment tools in the data collection form. The data were used in paper 3.
Patient logs (incl. primary nurses rating for their patient; every month)	Frequency of 5 key ACP components.	Addresses five key actions for each individual patient (yes, no, not applicable, and don't know): (1) Have the patient and family been invited to a conversation with the physician? (2) Have the patient and family had a shared conversation with the primary nurse? (3) Have there been monthly phone calls to the family? (4) Have you had contact with the family in the last month? (5) Is the communication documented? There was also room for free-text comments.	Used monthly in the intervention group only. Primary nurses (i.e. responsible nurse for the patient) filled in the logs for their patients. The log had a second function as it was designed to facilitate implementation by guiding and reminding nursing home staff of the COSMOS intervention (see also page 65-67 *Implementation strategy*). The patient logs were used in paper 2.

ACP = Advance Care Planning, CGIC = Clinical Global Impression of Change

4.3 The Pain-BPSD study

4.3.1 **Paper 1**

Design

Paper 1 investigated the association between neuropsychiatric symptoms and nursing home staff distress and the effect of the pain treatment on staff distress (189). This paper was based on secondary analyses using data from the PAIN-BPSD study. The PAIN-BPSD study was a cRCT aiming to test the effect of a stepwise protocol for treating pain to reduce behavioural disturbances in nursing home patients with dementia and agitation. The intervention period lasted for eight weeks, followed by a four-week washout period (120).

Setting and Participants

The PAIN-BPSD study was conducted in Western Norway from October 2009 to June 2010 (120). The study included 352 patients from 60 units in 18 nursing homes with moderate to severe dementia and clinically significant behavioural disturbances. To avoid contamination from the intervention to the control conditions, each unit was defined as one cluster. The nursing home units were randomised to a stepwise protocol for treating pain for eight weeks with additional follow-up four weeks after the end of treatment (33 clusters, n = 175) or to the control condition of care as usual (27 clusters; n = 177). Staff (n =138, 93% registered nurses and assistant nurses) who knew the patient and had direct patient contact for at least four weeks participated as proxy raters (informants). The proxy rater nurses reported their experienced distress when scoring the NPI-NH. Eligible patients had to be ≥65 years, show severe agitation (CMAI ≥ 39), and have moderate or severe dementia according to the Diagnostic and Statistical Manual of Mental Disorders (fourth edition) and a FAST score ≥ 4. Patients were excluded if they had a shorter stay than four weeks, a severe mental health disorder, estimated survival less than six months, or had an identified allergy to the study medicine.

Intervention

Patients in the intervention group received pain treatment according to a systematic pain treatment protocol adhering to the American Geriatric Society's recommendations for pharmacological pain management (190). The first step started with paracetamol 3 g/day. If this pain treatment was already provided at baseline, patients were allocated to step 2 (oral morphine, maximum 20 mg/day). If swallowing problems were present, patients were assigned to step 3 (buprenorphine transdermal patch, 5–10 µg/h). If the patient had neuropathic pain, they were allocated to step 4 (Pregabalin 25mg - 300 mg/d) (120).

Assessments and data

In the PAIN-BPSD study, data collection was conducted at baseline, week two, week four, week eight, and week twelve. All staff assessing the patients both in the intervention and control group received a half-day training in the use of the assessment instruments and how to assess relevant symptoms in the patients. Paper 1 used data on cognition (MMSE), pain (MOBID-2), and neuropsychiatric symptoms and staff distress (NPI-NH) from baseline, week eight, and week twelve (see Table 5a).

Outcomes and analyses

In paper 1, the primary outcome was staff distress, as assessed by the NPI-NH. The associations between each neuropsychiatric symptom measured by the NPI-NH and total staff distress at baseline were analysed using a hierarchical linear regression analysis. We used the robust estimator of variance allowing for intragroup correlation, and total staff distress was entered as the dependent variable. The patients' age, gender, pain (MOBID-2 total score), cognitive functioning (MMSE), and all 12 NPI-NH item scores were entered as predictors. In this analysis, age, gender, and MMSE were entered in the first step, pain was entered in the second step, and all NPI-NH items were entered in the third and final step.

We examined whether the level of staff distress was reduced after implementing individual pain treatment and whether staff distress increased after the analgesic washout period in the control versus intervention group. The intervention effect was estimated by linear mixed effect models using maximum likelihood estimation. The analyses were conducted separately for each of the following outcome variables: total staff distress, the 12 distinct NPI-NH staff distress items, and the three symptom clusters of mood, agitation, and psychosis for a total of 16 analyses. Time was set as a categorical variable and the models included fixed effects for time, intervention, and their interaction. The significance level was set to 0.05.

Randomisation and blinding

Each nursing home unit was defined as a cluster and randomised to the intervention or control group. There was no crossover of staff between units. Eligible patients within the intervention clusters received a stepwise protocol for treating pain, and patients in the control group continued with care as usual. The nursing home staff and research assistants were blinded to allocation to the intervention or control group during the clinical assessments. Staff who were responsible for delivering the intervention, including the medication, did not participate in the data collection. In addition, the staff were encouraged not to talk about management procedures during the study period. The trial did not use a placebo condition.

Contributions

Access to the data was granted by Professor Bettina Husebo, Centre for Elderly and Nursing Home Medicine, Department of Global Health and Primary Care, University of Bergen. I did not contribute to the data collection.

4.4 The COSMOS trial

Papers 2 and 3 present results from the COSMOS trial. In the following, the study design, intervention, and implementation strategies are described.

Design

The COSMOS trial was a four-month cRCT (2013–2016), with follow-up assessment at month nine. The multicomponent intervention consisted of five different components – Communication in the form of ACP, Systematic pain assessment and management, Medication review, Organisation of activities, and Safety (Figure 3) (178). The main aim of this multicomponent intervention was to increase quality of life in nursing home patients.

Figure 3: The COSMOS logo with the main components represented with a specific colour code and with safety centred between the COSMOS components.

Setting and participants

The COSMOS trial was completed in eight municipalities (Askøy, Bergen, Bærum, Fjell, Kvam, Sarpsborg, Sund, and Øygarden) from three counties (Hordaland, Østfold, and Akershus). Data collection was completed by Christine Gulla and myself together with medical students Torstein Habiger and Tony Elvegaard.

We invited 37 nursing homes, in total 72 units and 765 patients, to participate. To achieve a representative sample, both small and large and rich and poor municipalities were invited. Inclusion of nursing homes and data collection was performed from May 2014 to December 2015. Nursing home patients both with and without dementia were eligible to participate if they were ≥65 years and had a minimum nursing home stay of two weeks before the assessment. Exclusion criteria were life expectancy less than six months or active schizophrenia. The intervention lasted four months with assessments and data collection performed at baseline, at month four, and at follow-up after nine months. The COSMOS trial has so far generated 10 publications (23, 109, 142, 178, 191-196).

Intervention

The development of the COSMOS components was based on literature reviews, and as such the components were considered to include evidence-based treatment and care (178). The COSMOS intervention was piloted in four municipalities and subsequently optimised. To ensure implementation in all intervention units, a comprehensive education programme covering all COSMOS components was developed (see *Implementation strategy* page 65-67 for more details). Because this thesis focuses on communication in the form of ACP, the description of this component will be more comprehensive.

Communication in the form of Advance Care Planning

As defined in the background section, ACP is "*a repeated conversation between patients, and/or relatives and healthcare professionals concerning thoughts, expectations and preferences for care, treatment and end-of-life-care*" (2, 3). The COSMOS ACP component was based on a literature review, clinical experience, and national and international collaboration (2, 43, 66). The theoretical background for ACP has also been described in the Background section of this thesis. The staff were educated in the theoretical background and practical use of ACP communication. The educational material included a list of questions, and these were also available as flash cards (please see appendix 9.1.1). A detailed description of key ACP components covered in the COSMOS trial is presented in Table 6.

Table 6: ACP components included in the COSMOS trial*.

Content	ACP was designed so that it also can benefit nursing home patients with dementia. ACP entailed an open and clear communication regarding the patient's medical conditions, values, goals, ideas, and expectations. Seven essential ACP questions/topics were provided to facilitate initiation and to ensure that the staff also asked the "difficult questions". Timing and sensitivity to the patient's and family's present situation and understanding of the patient's health status were addressed in the education seminar. The ACP education stressed that it was beneficial to initiate communication as early as possible. However, it was not advised that decisions should be finalised at an early stage when they still seem alien to the patient or family.
Frequency	The expected frequency of meetings and communications was clearly defined in the ACP component. Because most patients could potentially experience a rapid deterioration in health and cognitive functioning, it was considered urgent to initiate ACP communication. The ACP frequency standard was: (I) a meeting with the physician and/or primary nurse (i.e. responsible nurse for the patient and contact person for the family) offered within 2–3 weeks after admission and subsequently quarterly, and (II) monthly telephone contact with the family (which could be replaced by talks at the unit).
Responsibilities	The responsibility for organising meetings, maintaining the continuity of contact, and involving the physician when necessary was given to the primary nurses.
Documentation	It was highlighted that the patient's preferences or thoughts on medical decisions should be documented and easily accessible to the staff on duty.

*Adapted from paper 2.

Systematic pain assessment and treatment

The nursing home staff were trained in the use of MOBID-2 to detect and monitor pain (197). The staff were encouraged to use MOBID-2 as part of their routines if the patient's behaviour changed, before the initiation of pain treatment, 2–4 days after pain treatment had been initiated, and after 8–12 weeks of treatment. Also, the COSMOS intervention urged the staff to perform a re-assessment if the patient changed the prescribed pain medication.

Medication review

In this COSMOS component, the aim was to have a medication review for each patient once during the intervention period. The medication review was initiated in meetings between two physicians from the COSMOS team (Bettina S. Husebø and Christine Gulla), one nursing home nurse, and the nursing home physician. The units were encouraged to establish a routine for medication review twice a year. The education focused on effects and side effects of drugs and how to assess effectiveness. Clinical assessments of patients, medical records, and lab tests were used in the review. To support decisions, the START/STOPP 2 screening tool (198) and the Norwegian Medicines Agency's check-list for medication reviews were used (199).

Organisation of activities

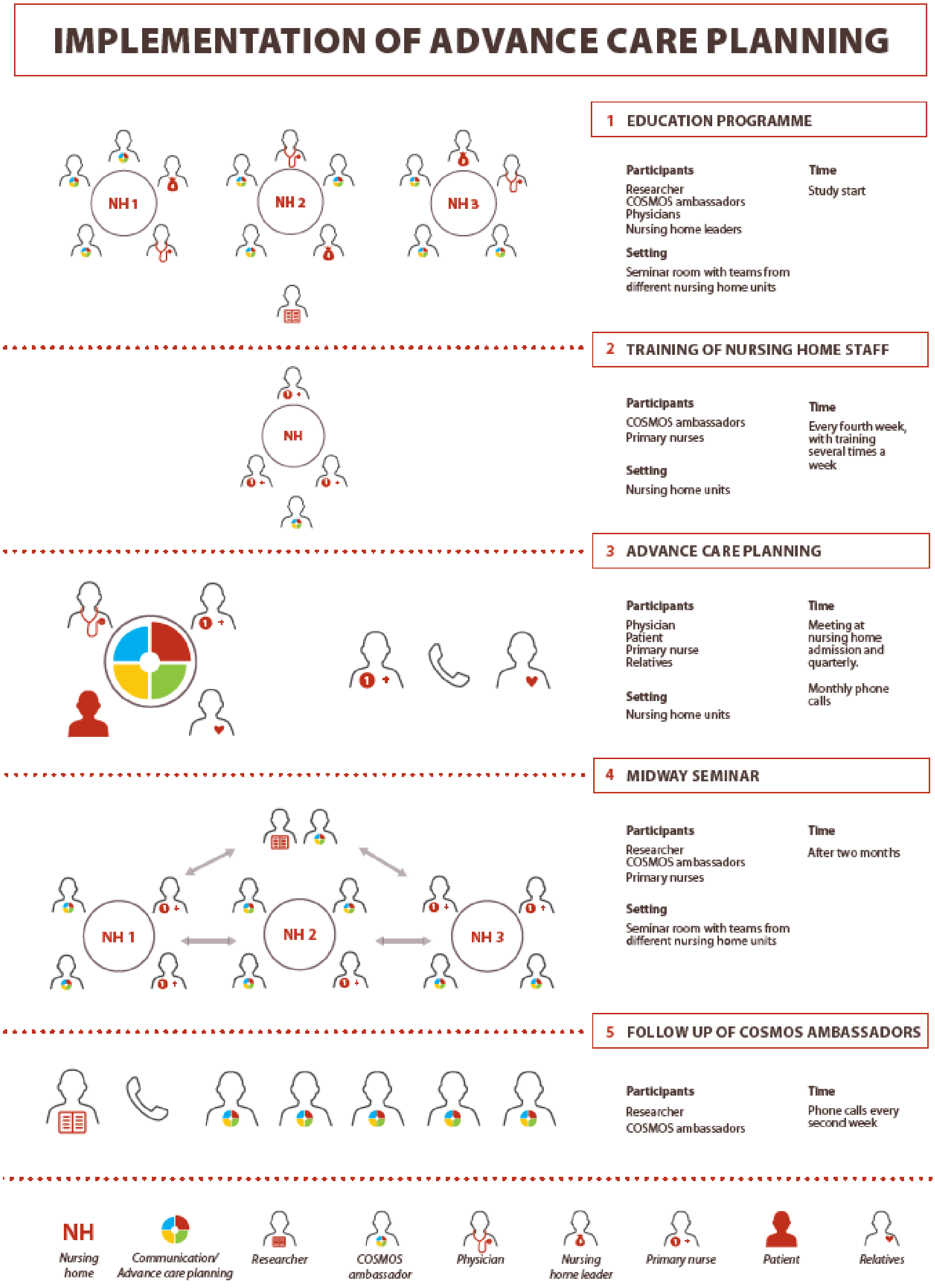
This COSMOS component highlighted the importance of providing individually tailored activities catering to the patient's capabilities and interests (200). The nursing home staff were provided with tools for mapping and organising individual activities based on the patients' interests, as well as their physical and cognitive capabilities. The nursing home staff were urged to organise weekly individual activity plans, and the patient's primary nurse was responsible for organising an individual activity plan encompassing at least 90 minutes of engagement per week. If the patients already had such an activity schedule, an increase in activities by 25% was called for.

Safety

By covering all the aforementioned components in the COSMOS trial, the intention was to increase the quality of care and patient safety through changes in routines and nursing home culture.

Implementation strategy

Education programme. We invited all nursing home managers, registered and licensed practical nurses, and physicians to participate in a two-day education seminar prior to the baseline data collection. At least two nurses from each nursing home unit with hands-on experience with nursing home patients had to attend the education. These participants were titled COSMOS ambassadors and were given the responsibility of bringing the COSMOS intervention to the units. The two-day education seminar consisted of lectures, role-play, and prepared the ambassadors in the use of the educational materials. Figure 4 illustrates the implementation of ACP in the COSMOS trial.



IMPLEMENTATION OF ADVANCE CARE PLANNING

1 EDUCATION PROGRAMME

Participants
Researcher
COSMOS ambassadors
Physicians
Nursing home leaders

Setting
Seminar room with teams from different nursing home units

Time
Study start

2 TRAINING OF NURSING HOME STAFF

Participants
COSMOS ambassadors
Primary nurses

Setting
Nursing home units

Time
Every fourth week, with training several times a week

3 ADVANCE CARE PLANNING

Participants
Physician
Patient
Primary nurse
Relatives

Setting
Nursing home units

Time
Meeting at nursing home admission and quarterly.

Monthly phone calls

4 MIDWAY SEMINAR

Participants
Researcher
COSMOS ambassadors
Primary nurses

Setting
Seminar room with teams from different nursing home units

Time
After two months

5 FOLLOW UP OF COSMOS AMBASSADORS

Participants
Researcher
COSMOS ambassadors

Time
Phone calls every second week

Figure. 4: The five-step COSMOS ACP implementation process: 1) Education seminar, 2) COSMOS ambassadors training the staff in the units, 3) ACP communication involving patients, families, nurses, and physicians, 4) Mid-way seminar with COSMOS ambassadors and primary nurses, and 5) follow-up of COSMOS ambassadors every 14 days. The figure is retrieved from paper 2, with permission from *BMC Geriatrics*.

Training of the nursing home staff. A train-the-trainer focus (201) involving the whole nursing home unit was employed to ensure that the implementation was sustainable (202). After the two-day seminar, the COSMOS ambassadors were responsible for teaching their colleagues in the unit (Figure 4). The implementation was depending on several contributors; the ambassadors, the primary nurses (responsible nurse and contact person for the family) and nursing home managers. Although time-consuming, staff training is essential to facilitate change and development (203). The ambassadors were encouraged to find an optimal setting, according to their local routine, to train their colleagues. The researchers recommended the ambassadors to give talks during lunch and/or reports (10–20 min), several times per week to reach the best coverage (204). The ambassadors were advised to keep a focus on ACP every fourth week as the ACP was one of the four COSMOS components.

Training material. At the education seminar, the ambassadors were provided with educational material, including guidelines, educational binders, and flash cards. The training material was written with the intention to appeal to all personnel responsible for the patient, regardless of their education and experience. All of the patients had their own patient log that was administrated by their primary nurse. The logs contained information about the intervention and listed the key deliverables (i.e. five questions regarding the provided communication) for the COSMOS components to be filled in every fourth week. These logs were also used to evaluate the implementation (see also 4.2 Assessment and Table 5b). The ACP component and the COSMOS intervention as a whole were complex. To ensure implementation in the various units, several procedures were standardised. At the same time, the intervention allowed the units and staff to be flexible in the way they adopted the protocol. In this sense, even though the essence of the COSMOS intervention and the ACP component were targeting the Norwegian nursing home setting, it aimed to be adaptable to different cultural contexts.

Randomisation and blinding

When nursing home managers had agreed to participate in the trial, the units were randomised to COSMOS (the intervention group) or care as usual (the control group) per included municipality. Randomisation was performed as a constrained complete list randomisation and stratified to approximate an equal matched distribution to geographic location and economic status. Patients and relatives were then contacted in order to obtain informed or presumed consent. Because of the use of active and overt interventions such as staff education, the researchers could not be fully blinded regarding group allocation (140). Meanwhile, the COSMOS trial endeavoured to conceal group allocation for the included nursing home units. As such, a single-blinded design is described as the most suitable for implementation research (140).

Contributions

The trial was administered by the Centre for Elderly and Nursing Home Medicine, University of Bergen, and was funded by the Research Council of Norway (222113/H10). The research team consisted of project manager Bettina S. Husebø, post-doctoral fellow Elisabeth Flo, and the two PhD candidates Christine Gulla and Irene Aasmul. Additionally, two medical students – Torstein Habiger and Tony Elvegaard – participated on the team as part of a Medical Student Research Programme at the University of Bergen. All team members contributed in the development of the education and implementation material. Bettina S. Husebø and Elisabeth Flo were responsible for the content of the education programme and provided the lectures at the two-day seminars and the midway seminars. I made a major contribution in terms of planning and coordinating the trial, organising seminars, collecting data, keeping contact with and supervising COSMOS ambassadors, and providing information to the nursing home management, staff, patients, and their families in collaboration with fellow PhD candidate Christine Gulla.

4.4.1 **Paper 2**

Design

Paper 2 was a research methods paper that described the development and evaluated the implementation of the ACP component. This paper introduced the conceptual framework for the ACP component and employed a mixed-methods approach in the evaluation of the ACP implementation and the identification of facilitators and barriers.

Participants

Paper 2 included 36 nursing home units with 297 patients allocated to the COSMOS intervention. The COSMOS ambassadors, primary nurses (i.e. the nurse responsible for the patient and contact person for the family), and the nurses involved in the data collection were the informants.

Outcomes and analyses

Staff characteristics for those involved in the data collection included gender, nationality, age, years as a healthcare professional, and years worked in the current nursing home. Participants at the education and mid-way seminars were also registered in terms of profession. We did not collect information on all primary nurses. We also registered whether the units had previously been involved in research or quality improvement projects.

With regards to the ACP implementation, there are several implementation outcomes (202). Acceptability and adoption were assessed by investigating whether the staff attended the education seminar and the midway seminar and to what degree they used the individual patient logs. The patient logs were also used to evaluate fidelity, i.e., to what degree the ACP component was implemented as intended. The ACP component was defined as successfully implemented with reasonable fidelity if the tasks (i.e., deliverables) documented in the patient logs corresponding to questions 1 or 2 *and* 3 or 4 were completed during the four-month trial period:

1) Have the patient and family been invited to a conversation with the physician?
2) Have the patient and family had a shared conversation with the primary nurse?
3) Have there been monthly phone calls to the family?
4) Have you had contact with the family in the last month?
5) Is the communication documented?

The demographic variables for the nursing home staff and patients, as well as the clinical characteristics, were summarised using frequencies and percentages or means and standard deviation. The implementation outcomes, including patient log entries and seminar participation, were summarised as frequencies and percentages.

To explore the implementation process in closer detail, free text areas in the patient logs and feedback at the midway seminars were analysed to identify facilitators and barriers. The free text feedback from the logs and discussions in the midway seminar were transcribed, and categories and subcategories were identified based on qualitative content analysis in accordance with the research aim of identifying facilitators and barriers (205). Three researchers (Irene Aasmul, Elisabeth Flo, and Bettina S. Husebø) read and analysed the text individually, and identified potential main topics (206). Prominent and recurring themes were noted. Emerging categories and subcategories of facilitators and barriers were then cross-compared and discussed until consensus was reached (206). This process, ending with an agreement between the researchers, was completed to achieve trustworthiness of the final topics (207). Meaningful quotes were obtained from dialogues with the nurses during the midway seminar.

4.4.2 **Paper 3**

Design

Paper 3 included secondary analyses from the COSMOS trial, investigating the effect of the intervention on communication among nursing home staff, patients, and families. In addition, paper 3 investigated whether the nursing staff was affected during the intervention in terms of staff distress.

Participants

All eligible patients for the COSMOS trial (n = 545) were included in this paper, with data from baseline, month four, and month nine. Nursing home units (n = 67) were randomised to the intervention group (n = 36) or to the control group (n = 31) receiving care as usual. Staff (n = 117, 79% registered nurses) acted as proxy raters (i.e., informants) also reported the staff distress.

Outcomes and analyses

The COSMOS data collection used a data collection form including all instruments, along with information that was to be extracted from the patient journal. The COSMOS team assisted the nursing staff in both the intervention group and the control group to use the form and to document the communication activities for each patient.

The communication activities questionnaire listed five key ACP components (deliverables) as described in the assessment section. The response alternatives were "yes", "no", "not applicable", and "don't know". In the statistical analyses, the "not applicable" option was combined with the "no" category and the "don't know" option was set to missing. To investigate the effect of ACP, we conducted separate analyses with each of the key components (deliverables) as an outcome variable. Mixed effect logistic regression models were used to estimate the changes in the outcome measures from baseline to month four and month nine. Time were treated as a categorical variable and the models included fixed effects for time, intervention, and their interaction. To account for clustering, the models were fitted with patient-specific random intercepts and nursing home unit-specific random intercepts if this improved the fit. Model selections were based on likelihood ratio tests.

In addition, the CGIC was adapted to measure the nurses' perceived change in communication with the family and the physician (see 4.2 Assessment) (187, 188). This Likert scale was used at month four to assess change in communication at the unit as whole, thus one assessment per unit. This was the only assessment performed on the unit level instead of in connection to each patient. A similar survey was mailed to each of the patients' families and/or legal guardians at month four.

Separate linear regressions with the robust estimation of standard error were performed to investigate nurses' and families' experiences of change in communication. The perceived changes related to communication with the physician, nurse or family were set as the outcome variables and the dichotomous variable intervention group or control group were set as the predictor variable.

The NPI-NH distress scale was used to investigated staff distress (153, 186). Linear mixed effect models with restricted maximum likelihood estimation were used to analyse the effect of the intervention on staff distress. The total NPI-NH staff distress score was the outcome measure, and the dichotomous variable of intervention group or control group was set as the predictor variable. To account for clustering, we included random intercepts for both nursing home unit effects and patient-level effects and a nursing home unit-specific random slope for time. The significance level was set to 0.05.

4.5 Ethics and approvals

This thesis was based on two cRCTs that included a vulnerable group, namely nursing home patients with dementia and/or other severely debilitating conditions. Both the PAIN-BPSD study and the COSMOS trial were approved by the Regional Committee for Medical Ethics and Health Research Ethics, West Norway (respectively; REK-Vest 248.08 and REK-Vest 2013/1765). The PAIN-BPSD study is registered in ClincalTrials.gov (NCT01021696) and in the Norwegian Medicines Agency (EudraCTnr. 2008-007490-20). The COSMOS trial is registered in clinicaltrial.gov (NCT02238652).

It is a prerequisite to obtain written informed consent in research involving humans. (208). In both studies, written information was available in three different versions – information to the participant, information to the nursing home staff and management, and information to the family or legal guardian. The information included the aim, interventions, funding, institutional affiliations of the researchers, potential benefits, and potential risks and discomforts of the study. All were informed that participation in the study was voluntary and that they could withdraw participation at any time without giving any reason. Additionally, all were informed that the patient could withdraw from the study without this having any consequences for their future care and treatment (208).

According to the Helsinki Declaration, research should also focus on groups that are underrepresented (208). Including people with dementia in clinically relevant research is important, though it necessitates a high level of quality control and awareness of the ethical implications. To ensure complete transparency, all the patients' families were contacted by mail and telephone regardless of the patient's cognitive status.

Written informed consent was obtained from all patients having sufficient capacity to provide it. We suggested that those with MMSE ≥16 were capable to give informed consent (209), but we also involved the relatives. Additionally, we made a face-to-face assessment of the participant's capacity to consent together with the nursing home staff and/or physician (209, 210). If the patient did not have the ability to consent, written presumed consent was provided by the family or the legal guardian.

All five COSMOS components were considered evidence-based and had already been tested individually (178). Hence, the study was considered to represent minimal risk for the patients. All the nursing homes were provided with information about the study for the patient, family, and staff. In the PAIN-BPSD intervention which involved providing medication, it was important that no on-going treatment was terminated in either the control or intervention groups. Strict procedures ensured that medication was discontinued when harmful side-effects were suspected. Nursing home physicians could prescribe any medication they believed necessary during the trial period. All adverse events, changes in medication and vital signs were documented. As recommended by the Helsinki Declaration when doing medical research, both study had a plan for recruitment, distribution, and hypotheses as well as ethical approvals and registrations in online databases (208).

5. Main results

Paper 1

Aasmul I, Husebo BS, Flo E. Staff Distress Improves by Treating Pain in Nursing Home Patients With Dementia: Results from a Cluster-Randomized Controlled Trial. *Journal of Pain and Symptom Management*. 2016;52(6):795-805.

- All NPI-NH items, except for euphoria, were significantly related to a higher risk of total staff distress at baseline. The individual effect of NPI-NH items on staff distress varied, and agitation (β = 0.235), disinhibition (β = 0.201), and delusions (β = 0.202) were the only items showing coefficients over 0.20.
- Pain treatment of nursing home patients with dementia and agitation reduced total staff distress significantly at week 8 in the intervention group compared to the control group (B = −3.53, 95% CI −5.47 to −1.58).
- Between-group comparisons at week 12 showed significantly less total distress in the intervention group compared to the control group in relation to total staff distress (B = −3.72, 95% CI −6.24 to −1.20) and in relation to the mood and agitation symptom cluster and to the following single items: agitation, depression, anxiety, apathy, irritability, and appetite/eating disorder.
- Within-group comparisons showed a significant decrease in total staff distress from baseline to week 8 in both the intervention group (B = −6.51, 95% CI −7.88 to −5.14) and control group (B = − 2.98, 95% CI −4.38 to −1.59), but with larger effects in the intervention group.

Paper 2

Aasmul I, Husebo BS, Flo E. Description of an Advance Care Planning Intervention in Nursing Homes: Outcomes of the Process Evaluation. *BMC Geriatrics*. 2018;(1):26.

- The ACP component was well received both in terms of participation at the COSMOS education seminars and at the midway seminars. The participants reported that the seminars were helpful and that the ACP material was useful.
- The COSMOS ACP component was frequently implemented. All units used the patient logs, and 81% of the patients had log entries over the four months.
- ACP was implemented in 183 (62%) patients by month four.

- We identified two main categories of facilitators: i) the focus on institutional organisation and routines, with clearly defined roles and responsibility, and ii) the education seminar and material were often experienced as accurate for practical use and highlighted the relevance of the ACP education. This helped the ambassadors to convey "the message" convincingly.
- Three main categories of barriers emerged in our analyses, namely lack of time, conflicting opinions and culture, and lack of staff competence.

Paper 3

Aasmul I, Husebo BS, Sampson EL, Flo E. Advance Care Planning in Nursing Homes – Improving the Communication Among Patient, Family, and Staff: Results from a Cluster-Randomized Controlled Trial (COSMOS). *Frontiers in Psychology*. 2018;9:2284.

- The COSMOS ACP component improved the communication among patients, their families, and nursing home staff.
- There was an increase in shared conversations between the family, patient, and primary nurse (OR = 3.9, 95% CI = 1.6 to 9.4, p = 0.002) and an increase in contact with the families during the last month (OR = 6.5, 95% CI = 1.6 to 3.5, p = 0.010) in the intervention group compared to the control group.
- There was no significant increase in invitations to a meeting with the physician, calls to the family, or improved documentation of the communication.
- None of the improvements in communication had a long-term effect as assessed at the nine-month follow-up.
- Both the nurses (B = 1.9, 95% CI = 0.80 to 2.91, p = 0.001) and the families (B = 0.4, 95% CI = 0.02 to 0.85, p = 0.040) were more satisfied with the communication with each other in the intervention group compared to the control group.
- Neither the families nor nurses reported improved satisfaction concerning the communication with the nursing home physician.
- We found a significant reduction in staff distress in the intervention compared to the control group at month four (B = −1.8, 95% CI = −3.1 to −0.4, p = 0.012).

6. Discussion

6.1 General considerations

The overarching aim of this thesis was to describe the development and implementation of ACP in nursing homes and to test its effects. The staff perspective was in focus in terms of investigating staff distress and the staff experiences related to the implementation of ACP in nursing home units.

The focus on the staff perspective in this thesis was not at the expense of the patient perspective. Instead, the staff perspective may in part be viewed as an expansion of the user involvement in the COSMOS trial. The focus on how the staff experienced the implementation and their involvement in the implementation process is comparable to the objectives of patient and public involvement (PPI). User involvement in health care may include being involved in decision-making about one's own situation or participating in health services research, health policy development, or organisational reforms. During the work with this thesis, we have strived to be in contact with nursing home staff and management in order to adapt the implementation strategies to meet their reality and needs, aiming to increase the focus on patient-centred care and patient security.

ACP is central for each patient's satisfaction, and at the same time ACP impacts both the local organisation and larger societal institutions. The societal impact of ACP and staff distress is unfortunately beyond the scope of this thesis, but should be considered in the light of the results presented in papers 1, 2, and 3. Better understanding and attention toward staff distress and a focus on improvement of the communication in form of ACP will likely benefit healthcare professionals and nursing home patients and their families.

6.2 Discussion of study methods

The three papers included in this thesis had different study designs that are described in detail in the method section of each paper and in the method section of this thesis (collated in Table 4). The papers also share key methodological features – all three studies were conducted in the nursing home setting, and the PAIN-BPSD and COSMOS trials were both cRCTs.

In general, it can be problematic to generalise findings from nursing homes due to considerable heterogeneity in practise, e.g. culture of care (211). This is an important consideration, both in terms of how the study results should be interpreted and in terms of what recommendations we can make based on the results. Also, an inherent challenge when conducting research involving people with dementia is the lack of ability to report symptoms and to provide informed consent. We are reliant on proxy rating. All the proxy rater tools employed in this thesis were validated for proxy rating (please see Table 5a) and are used both in research and in clinical practise, which makes it possible to compare findings with other studies. Meanwhile, it should always be taken into consideration that the symptoms reported are not evaluated objectively or by self-report.

This section will initially discuss methodological issues unique to paper 1 and to papers 2 and 3, including study design and internal and external validity. To assess the relevance of the method, the internal validity has to be clarified. This includes an evaluation of how robust the research method is. Clarifying the external validity is important in considering to what extent the research results are possible to transfer to other settings (212).

6.2.1 **Paper 1**

Study design

Paper 1 used secondary outcomes from the PAIN-BPSD study. This cRCT was originally designed to investigate the effect of pain treatment on neuropsychiatric symptoms in dementia. The stepwise protocol for treating pain was based on the American Geriatric Society clinical guidelines for adults. Although these guidelines do not specifically cater to people with dementia, the careful stepwise increase is highlighted as a careful way of treating pain with less side effects (190).

The study was not designed to investigate work-related stress or staff distress, and changes to the design might have allowed for a more suitable study of staff distress in the nursing home setting. Stress and distress are subjective concepts, and semi-structured interviews with a qualitative approach might have given valuable perspectives on staff distress in the nursing home. In terms of quantitative methods, established and validated questionnaires covering work-related stressors (see for example Testad 2010) might have given a more in depth understanding of the relationship between pain treatment, behavioural and psychological symptoms of dementia, and staff distress (147).

Due to the nature of the PAIN-BPSD study, staff distress was only assessed in the nurses who were rating the nursing home patients. Ideally, all nurses working in the unit should have been invited to report staff distress. Meanwhile, the large number of patients and clusters made the randomisation robust. There was no overlapping of staff between the intervention and control group. The research assistants and the staff who collected the data were blinded to group allocation and type of intervention during the intervention period, further strengthening the results.

Internal validity

A key question to reflect on in research is whether the chosen study method was suitable to answer the research question. Internal validity pertains to how confident we can be with the associations we have found and is based on the degree to which the study method deals with potential alternative explanations for its findings (such as sources of systematic error or bias) (213). The internal validity of paper 1 is strengthened by the fact that the study had a cRCT design, which is often seen as the gold standard when exploring the effect of an intervention (214). Meanwhile, because paper 1 used data from a study that was originally designed to answer a different scientific inquiry, internal validity is not automatically ensured through the rigorous design. The objective of randomisation is to distribute as evenly as possible all of the unknown variables that might affect the outcome of a clinical trial. Because the secondary outcomes investigated in paper 1 derived from the same randomised population that the primary outcomes were based on, many biases should be controlled for in the secondary analyses.

The inclusion criteria in a study are designed to limit variables that might confound the results, and they define the population for which the outcomes will be valid. It is possible that the inclusion/exclusion criteria fit the primary outcome but not the secondary outcome. Here, paper 1 is in a unique situation because the staff were not selected for trial participation. As such, they represent a convenience sample. Indeed, there may be some biases related to the characteristics of the included staff. The staff were in part selected because of their motivation for partaking in the data collection, and in part based on their competence and knowledge of the nursing home patients. As such, the staff included in the analyses might be more educated, interested, and involved in the care of the nursing home patients than the staff in general. This could influence staff distress in both directions. Knowledge can help staff cope better with difficult symptoms (127, 166), but at the same time being close to the patients and knowing them well might have sensitised them to the symptoms that the patients experienced and/or their lack of means to alleviate these symptoms (moral distress) (158). Moreover, because staff in both the intervention and control units received education in questionnaires and clinical evaluation, which could have influenced the distress outcome, it is not possible to divide the staff categorically into an intervention or control group. On the other hand, the fact that staff from both the control and intervention group received training strengthens the hypothesis that the pain treatment and alleviation of distressing symptoms did have an impact on the reduction of staff distress.

Because paper 1 investigated staff distress in relation to each NPI-NH item along with the total score and symptom clusters, multiple analyses with significance testing were performed. A correction for this, such as the Bonferroni correction, which intends to reduce the possibility of false-positive results, was not used in our study. Even though such a correction is suggested to be conservative and potentially increase the risk of type II errors (215), the lack of correction for multiple comparisons should be taken into consideration when interpreting the results.

The PAIN-BPSD study confirmed its primary hypothesis and outcome that pain treatment reduces agitation in nursing home patients with dementia well before I started drafting paper 1 of this thesis (120, 125, 216). This strengthens the further investigation of secondary outcomes. Also, the use of a validated tool such as the NPI-NH with all the patients in the units provided several valid data points and depicted the nurses' responses to most patients, not just one case. Although the inclusion criteria were not specifically related to distress, the selected patient group had a high prevalence of agitation, which is known to be highly associated with staff distress (98).

Because the NPI-NH version explores both neuropsychiatric symptoms in patients and the staff distress associated with each symptom, it provided a unique opportunity to take a deeper look at this relation. The internal validity is suggested to be appropriate in this study because the NPI-NH is a reliable and validated instrument (185). There are several tools to assess staff distress in healthcare. However, when specifically looking into staff distress in relation to neuropsychiatric symptoms in people with dementia, the NPI-NH assessment scale is very specific as an outcome measure. Meanwhile this specificity is also an impediment because it does not provide insight into other aspects that might be related to staff distress. The fact that both symptoms and distress are measured with the same instrument might increase the risk of common method bias where the variance is attributable to the measurement method rather than to the actual symptoms or other constructs that the measures attempt to identify (217).

External validity

The fact that this study did not include all the nursing home patients in each unit, but a selected group with a specific attribution, can also be used as an argument against the external validity because the knowledge might not suit all nursing home patients or units. The same can be argued in terms of the selection of the staff that reported the distress scores. Meanwhile, we know that the majority of nursing home patients have dementia, and neuropsychiatric symptoms are highly prevalent. In addition, the included staff were typically nurses working "on the floor" with the patients, and not unit leaders or nursing home managers, making them more representative of the general nursing home staff. Moreover, the staff in the study cared for all the patients in the unit and not only patients with dementia and agitation problems. This knowledge might arguably be represented in the data. The knowledge of staff distress that is highlighted in this paper might be relevant for nursing homes elsewhere, and especially in those that have patients with dementia and neuropsychiatric symptoms. It is also possible to replicate this method because it has a clear-cut and strict design.

6.2.2 **Papers 2 and 3**

Study design

As highlighted in previous sections, the ACP intervention in this thesis was one of the COSMOS trial components. The rationale for combining the components (Communication in the form of ACP, Systematic pain assessment and management, Medication review, Organisation of activities, and Safety) into one intervention was based on experiences from previous research in nursing homes (120, 125, 216, 218, 219). The health personnel involved in research projects often reported that there was rarely one single problem, be it be it pain, communication, or polypharmacy. The multicomponent approach made it more difficult to ascertain whether it was the ACP component that yielded the effects we found, or one of the other components, or indeed, the total sum of the combined components. However, the study design arguably addresses the real-world challenges of multimorbid frail patients with dementia in a complex nursing home setting.

The COSMOS trial was a multi-component intervention focusing on implementation. At the same time, it met the strict criteria of an RCT. Some might argue that complex interventions necessitate different designs than RCTs, often with the idea that RCTs are too strict in terms of inclusion criteria, study setting, and standardisation to allow for necessary adaptation and flexibility in the real-world setting. At the same time, many researchers argue that RCTs could and should be conducted in naturalistic and realistic clinical settings and, importantly, include the patients that are going to receive the intervention if it is deemed effective (69). To ensure implementation, the COSMOS trial was designed to allow for adaptation of certain aspects of the intervention to fit the different nursing home units. Meanwhile, the essential components of the intervention remained standardised (220). The dual focus both on the effect of the intervention and on the implementation has also been labelled a hybrid trial (221). In the end, the goal of the COSMOS study was to achieve real world relevance while at the same time adhering to the stringent scientific design of an RCT.

ACP may be viewed as a complex intervention in itself, with several involved actors, goals, and outcomes (69, 140). It is also closely intertwined with the other COSMOS components. Good communication and ACP in the nursing home naturally involves discussions on treatment options and medications. Furthermore, it is difficult to talk about values and wishes for the future if the patient is in pain, not adequately medicated, or not able to engage in activities. To be able to provide individualised activities and to set the right treatment level, it is vital to interact with the patient and their family to meet their individual needs and to create trust. When implementing a complex intervention, it is crucial that the study design, method, implementation strategies, and the level of implementation are assessed and reported. Indeed, the documentation and reporting of methods development and implementation have been a central part of this thesis.

Internal validity of paper 2 and 3

The objectives of paper 2 were to describe the content of the COSMOS ACP component and to investigate the reception of the ACP component and the implementation strategy, the level of implementation, and the facilitators and barriers to implementing ACP in the nursing homes. These objectives did not necessitate an RCT design, and other methods are more sensible. Because paper 2 focused on the method and the ACP implementation process, and only included the intervention units, the RCT design was not considered relevant.

Paper 2 provides a detailed description of different steps involved in the implementation of ACP (illustrated in Figure 4 in the methods section). There were several implementation strategies and outcome measures in the COSMOS trial and in the ACP component. Thus, it would have been misrepresentative if the implementation assessment were based on a single outcome, for example, the numbers of hospitalisations, without also reporting on the process. In line with recommendations for implementation studies, to increase the internal validity, we had multiple data points with quality control at every phase of the research project rather than only investigating effects at the end of the trial (204, 222).

The implementation assessment was adapted from the model proposed by Proctor and colleagues, focusing on central aspects such as acceptability and adoption of the study, as well as fidelity (202). These aspects can serve as indicators of the success of the implementation (204). Other important implementation measures, such as feasibility, were evaluated in the pilot study (178). Implementation measures such as penetration and sustainability are considered to be relevant during the mid- to late stage of a research project, but these were not reported in paper 2 because the paper focused on the early and on-going process and the immediate implementation outcomes of the COSMOS ACP component. It might have been constructive to use a specific theory or framework to assess the implementation process. Meanwhile, the adaptations we made to the theoretical framework were to allow for a process evaluation that fit the needs of the project and considered both theory and practice (223). The aim of our adaptation of Proctor's theoretical framework was to arrive at a method that helped our knowledge production in our context. Proctor and colleagues also include adaptations, and they refer to different established theoretical frameworks in their "taxonomy of implementation outcomes" (202).

The written material in the individual patient logs and the feedback given by the staff at the midway seminar represented important information on the implementation process. The individual patient logs had two purposes – they were an implementation tool helping the staff to keep track of what to do, while at the same time the logs documented what had been done during the trial, which was important data for assessing the implementation process. More specifically, paper 2 used the logs to ascertain acceptability and adoption (the overall use of the logs) as well as fidelity (to what degree the ACP deliverable was completed). In paper 2, the logs were supplemented with data on participation in the COSMOS education seminar and the transcribed feedback received at the midway evaluation. Paper 2 included both quantitative and qualitative methods to evaluate the implementation. Proctor and colleagues recommend suitable methods to assess implementation at different phases of the project, and in order to ascertain early uptake and implementation, surveys, administrative data, data on refusals to participate, and semi-structured interviews are recommended (202). Arguably, the logs and midway seminars largely met these methodological recommendations, thus increased the internal validity.

It could have been of interest to validate the logs used in the COSMOS trial. However, the logs were only intended to count the number of performed actions, not to record latent constructs like behaviours and attitudes that we cannot assess directly. Nevertheless, it remains uncertain whether these data points were optimal to assess implementation. It is also worth considering whether the cut-off criteria used to identify "successful implementation" holds merit. It is possible that these criteria were too strict and that successful adoption of ACP had taken place even though the criteria were not fully met. However, the cut-off criteria rest on the project group's theoretic and evidence-based deductions of the prerequisites for an adequate ACP process (2). In addition to the methods reported in paper 2, in-depth, semi-structured qualitative interviews with nurses from the intervention group were conducted. These qualitative data are comprehensive, and the analyses and reporting of such data constitute at least one more publication. Thus, a description of the use of such data was beyond the scope of this thesis. Nevertheless, an important next step in understanding the implementation of the COSMOS intervention and ACP component will be to analyse the interviews.

In paper 2 the qualitative data collected in the midway seminars and free text feedback from the logs were analysed based on the qualitative content analysis method. The analyses were in accordance with the research aim of identifying facilitators and barriers (205) and could thus arguably fall within the category of directed content analysis (albeit mildly directed) (224). While conventional content analysis is often used to describe or explore a concept or phenomenon, directed content analysis is used when research on the phenomenon already exists. The goal is to extend a conceptual framework or hypotheses (224), and the existing research is used to guide the discussions and analysis. The strength of this approach is the pragmatic investigation on a subject matter that might be important for the researchers. In our situation, this was the concern about facilitators and barriers for the implementation of the ACP component. However, this approach might lead to evidence-based and informed preconceptions, which ultimately are biases. Asking the participants at the midway seminars specifically what they experienced had helped them, and what they experienced as difficult in implementing ACP, might have given them cues to answer in a certain way. Meanwhile, it might be argued that the questioning and analysis were only “mildly directed” because the questions gave room for a wide range of thoughts and experiences, as did the broad concepts of “facilitators” and “barriers” in the analysis process.

The combination of both qualitative and quantitative methods of data collection and analysis allows for multiple perspectives, different types of causal pathways, and multiple types of outcomes, all of which are common features of implementation research (204). The design in the current study is further strengthened by the close follow-up by researchers. The fact that each patient in the intervention group had their own patient log that the primary nurse was responsible for filling out increased the chance for all patients to be included.

Paper 3 aimed to determine whether the COSMOS ACP component improved the communication and satisfaction with the communication in patients, their families, and staff and reduced nursing staff distress. The COSMOS trial confirmed in part its primary hypotheses and outcomes related to quality of life and neuropsychiatric symptoms. This supports the further investigation of secondary outcomes. Meanwhile, because the ACP component was part of the COSMOS trial, the other components might potentially affect the outcomes presented in paper 3. The improved communication between patients, families, and staff could be caused by an increased general awareness of quality of care among staff, or even the families’ experience that something new was “finally” happening in the nursing home. On the other hand, the multicomponent intervention can be seen as a strength for both the internal, external, and ecological validity (i.e. the link between phenomena in the real-world and their appearance in the trial settings), by representing the context and the reality in the nursing home setting. As mentioned previously, the background for this study was based on experience with previous trials and feedback from clinicians, indicating that it was ineffective to only focus on one problem area in a complex nursing home setting having several interconnected factors.

With regards to data collection, we did not record any of the ACP conversations between patients, families, and staff. Thus, there is limited information about the content of these conversations. We listed seven relevant questions or topics recommended as guidance for the ACP conversations (please see appendix 9.2, also listed in paper 2). In retrospect, the study could have been strengthened if a researcher had participated as an observer in a selected number of ACP meetings. On the other hand, this might have made the situation appear less naturalistic and more distant from the daily practice in the nursing home, thus negatively affecting the external validity of the study. Instead, we based our inquiry on the patient logs and the data collection. The data collection form consisted of five questions regarding the provided communication (deliverables) filled out by staff at month four and month nine. As with the patient logs used in paper 2, these questions were not validated, but the questions were only intended to document the number of completed deliverables (i.e. provided communication activities), not to identify latent constructs. The issues related to assessing staff distress using the NPI-NH are discussed in the paper 1 internal validity section.

An important advantage in a cRCT is the reduced risk of contamination bias compared to individual randomised trials. None of the nurses in the intervention units worked in any of the control units, and this increased both the internal and external validity (225). An important aspect in RCTs in general is the level of blinding, and blinding can be challenging when interventions involve training and education of staff (225). In our study, the cluster-randomisation was performed using methods to avoid bias and to facilitate a representative sample. However, as mentioned, blinding was difficult in this study due to the practical intervention by offering education seminars. Even if double blinding indicates a strong design, it is not the primary indicator of general trial quality (226). It was simply not possible to completely blind participants in this study because the staff could potentially recognise if they were a part of the intervention group or not.

External validity of papers 2 and 3

It can be argued that the external validity of papers 2 and 3 is limited due to different definitions and understandings of ACP in different countries. However, because the intervention was designed with a focus on ecological validity, implementation, and flexibility, I argue that it is possible to adapt and implement the COSMOS ACP component in other institutions, cultures, and countries.

An effort to establish methodological congruence has already been conducted in the description of the COSMOS study's methodological framework and methods. It can be argued that it is hard to follow this process because the intervention needs to be very flexible concerning the individual patient's needs. However, it is an important principle that implementation research strives to recognise and to work with in real world environments, i.e. ecological validity, rather than trying to control for these conditions or to eliminate their influence as causal effects (204, 227). As such, the main focus on completing communication deliverables, with flexibility for how each unit achieves this, makes the COSMOS ACP component and the methods and results of paper 2 feasible to generalise to an international context. Meanwhile, our lack of focus on legal documentation would make the ACP procedure insubstantial in countries where this documentation is necessary.

6.3 Discussion of the main results

In this section, I will first discuss and compare the results of paper 1, 2 and 3 in relation to existing research.

As highlighted in paper 1, the concept of staff distress in nursing homes is multifaceted and affected by several factors. In paper 1, only people with dementia and agitation were included. This makes staff distress relevant because it is known that dementia and behavioural disturbances are experienced as distressing for the staff. As shown in this paper, there was an intervention effect regarding decreased staff distress, even though we also found a decrease in the level of staff distress within the control group. Figure 5 illustrates different factors that might have affected staff distress, several of which are relevant for the reduction of staff distress seen in both the intervention and control group. Even though the main intervention in the BPSD study was pain medication, the intervention also included attention toward the staff with lessons on assessments of neuropsychiatric symptoms and pain, as well as assessing staff distress.

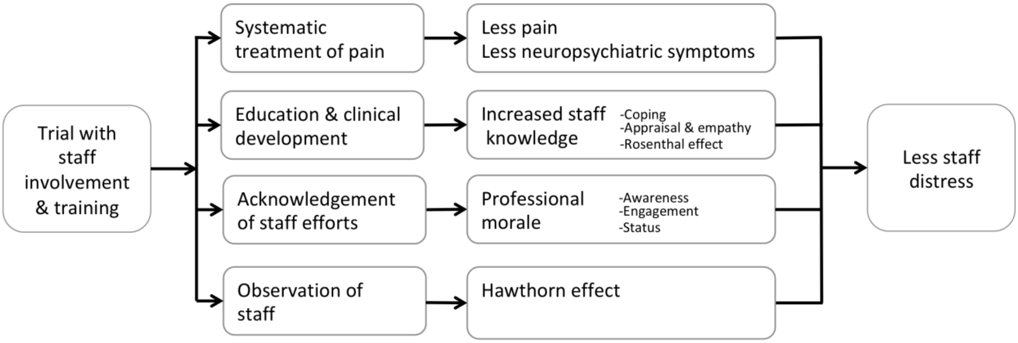


Figure 5: Potential factors affecting staff distress in the nursing home setting.

The full hierarchical linear regression model included the neuropsychiatric symptoms (NPI-NH scores) and explained 81% of the total staff distress variance. The effects of pain and reduced cognitive functioning were precluded when controlling for neuropsychiatric symptoms. This knowledge is of clinical relevance because it suggests that ultimately the presence of distressing symptoms was the main issue related to staff distress in our study. The findings also correspond with research showing that a common reason for nursing home admission is the distress experienced by the next of kin regarding the patients' neuropsychiatric symptoms (150, 151). Understanding and competence among staff to systemically assess and address these symptoms are of importance both for the patient and for decreasing staff distress. However, as Figure 5 illustrates, there are multiple factors that in the end affect staff distress. The components in Figure 5 deal directly with the research setting of paper 1. Meanwhile our results and hypotheses regarding sources of distress might be related to general models of stress and work stress (148, 228). As mentioned, stress might in a simple form be related to a mismatch between the individual and their resources and the demands from the environment. From a more nuanced perspective, the experience of there being a mismatch depends on an individual's appraisal of their own resources and of the situation at hand (148). In the setting of paper 1, the education of staff may have changed the staff's appraisal of their own resources, i.e., competence, and the presence of researchers may have affected how they perceived their role and their environment. Ultimately, the pain treatment may have been experienced as a resource ("I have the means to help my patients"), and it may have reduced the stressors in the environment by reducing neuropsychiatric symptoms.

Meanwhile, staff distress may also be related to other factors that were not assessed in the PAIN-BPSD study. In a paper by Testad and colleagues, occupational stress was not related to agitation, but rather to other work-related factors such as organisational and psychosocial factors (147). The lack of association between agitation and stress in the study by Testad and colleagues may be due to the type of measurements used in their survey, as compared to the use of the staff distress scale used in the PAIN-BPSD study of paper 1. Conversely, other studies have focused on how staff education may increase job satisfaction. In a study published in 2016 by Rokstad and colleagues, an education programme related to dementia care and person-centred practise increased staff job satisfaction (166). These findings, alongside the results in paper 1, suggest that increased focus on staff competence may be beneficial for staff, and potentially reduce staff distress.

Our analyses also showed to what degree the different neuropsychiatric symptoms were associated with staff distress. The findings were in line with the research by Zwijsen and colleagues who also found agitation and disinhibition to provide the highest distress score (98).

Paper 2 describes the ACP component, implementation strategies, and evaluation of the implementation process, and this focus is in line with another newly published ACP study conducted in Norway (229). Paper 2 also identified important facilitators and barriers to the ACP implementation. The involvement of nursing home leaders was emphasised as an important facilitator because this created a common awareness and recognition of the process. Previous studies have also identified the involvement of nursing home management as important for successful implementation (33). The COSMOS trial also emphasised the need for engaging and empowering the primary nurse to initiate the ACP process. Stressing the need for primary nurses to take responsibility was considered vital because they often know the patient the best, which is particularly important when the majority of patients have dementia or reduced cognitive capacity. This was also based on previous studies that experienced difficulties in involving the physician (2, 9). Indeed, in paper 2 we also found that lack of time, especially among the physicians, represented an important barrier. In their publication from 2017, Ampe and colleagues underlined the need for establishing team meetings in the nursing homes in order to make everyone on the team responsible for these discussions and to increase the awareness of shared responsibilities (28). This is the same argumentation for the train-the-trainer approach in the COSMOS ACP implementation and for the clearly defined roles of COSMOS ambassadors and primary nurses.

Previous studies suggest that difficulties in adopting the ACP component are associated with variations in culture for ACP (2, 33, 34). A type of "conspiracy of silence" toward difficult conversations has been suggested to be a barrier in some cultures, and both family and healthcare professionals often want to protect the patients from sensitive issues, although silence is rarely comforting (34). As the world has become more multi-cultural, so have the nursing homes. Our finding that cultural issues could represent a barrier is important, both when considering the local work culture among staff and when considering cultural differences between staff, family, and patients. ACP deals with difficult and sensitive issues that may still be considered taboo in different cultures and in older generations, and this may lead to inequality in terms of care services. Studies in the US have shown that immigrants to a lesser extent have end-of-life care plans, and consequently experience more unwanted treatments during the last days of their lives as compared to white Americans (68). Due consideration of cultural diversity may represent an important foundation for a caring nursing home environment that strives to meet the patients' needs (68).

In paper 3, an intervention effect was detected in terms of more conversations between the family, patient, and primary nurse when comparing the intervention and control groups during the intervention period. However, this effect did not remain significant at the 9-month follow-up. Sustainability is a challenge for health care intervention studies because many implementation studies typically focus on initial uptake at one time point (204, 230). The ACP components of the COSMOS study did not focus on the traditional outcomes when introducing ACP (e.g., number of "do not resuscitate" or "do not hospitalise" orders or use of a feeding tube). Thus, it is challenging to compare the results of paper 3 with previous ACP research in nursing homes. Meanwhile, the outcomes are in line with another recent Norwegian study that found increased family participation in ACP conversations together with the patient (22). This was a mixed method study that was conducted simultaneously with the COSMOS trial (22, 231). This study included observations of the ACP conversations and interviews with the participants afterwards. All of the involved families gave positive feedback regarding the ACP conversations (232). However, one should bear in mind that not all patients and families wish or are able to participate in such meetings.

We encouraged the nursing home staff to include the patients with dementia when possible. However, because not all patients are able to participate, we did not press the issue blindly. We discussed cases where patients should be "spared from" such meetings (e.g. severely anxious or aggressive patients). To avoid pressing the issue, we did not define the inclusion of patients as an implementation outcome in the patient logs. Thus, the number of patients with dementia that were actually included in the ACP conversations remains uncertain.

Paper 3 showed that the patient's family and the nurses experienced increased satisfaction with the communication with each other at the end of the intervention period. However, neither families nor staff reported any improvement in the communication with the physician. This may be caused by the lack of requirement for the physicians to participate at the education seminar prior to the implementation. Previous studies have also reported on lack of time as a barrier for physicians in the nursing home setting (2, 233). It is problematic that the physicians do not have the time to partake in these conversations because they have the medical responsibility for the patient. Our main focus was targeted towards the nurses because they are the ones communicating with the patient on a daily basis and are most often in contact with the patient's family. Nevertheless, the physician should ideally be more involved in such meetings.

The increased satisfaction among both staff and family corresponds with the reduced staff distress during the intervention period. This is interesting and of clinical relevance. Our findings suggest that the COSMOS intervention changed nursing home routines (e.g. increased the number of meetings and conversations) and enhanced staff competence, which is also proposed to affect the reduction of staff distress in paper 1. Even though staff distress was reduced in the COSMOS trial, we cannot verify a causality between reduction in staff distress and ACP. Because ACP was part of a larger multicomponent study, the reduction we found could also be linked to other components of the COSMOS intervention or to the combination of components. Interestingly, Detering and colleagues included stress as one of their outcome measures in their ACP study with an RCT design and found reduced stress among the relatives in the intervention group compared to controls (3). There was lack of a significant effect on staff distress at the nine-month follow-up. It is possible that a longer period of support from the researchers or other implementation strategies could have made the effects on staff distress more sustainable.

6.4 Ethical considerations

The studies that this thesis is based on were all approved by The Regional Committee for Medical and Health Research Ethics, West Norway. Additionally, the research was performed in line with the Norwegian law on research (234) and the Norwegian law on ethics and integrity in research (235). These laws incorporate the Declaration of Helsinki (208). However, research in nursing homes including people who are old, fragile, and often lacking capacity to provide informed consent, calls for a heightened sensitivity towards ethical dilemmas and issues.

ACP has the potential to address ethical issues that often arise in medical practice. At the same time, implementing ACP also elicits ethical concerns. One framework for understanding such issues is the four principles of medical ethics postulated by Beauchamp and Childress: respect for autonomy, beneficence (doing what is good), nonmaleficence (doing no harm), and justice (236). In healthcare, *autonomy* refers to the patients' right to decide for themselves. Beauchamp and Childress acknowledge that not all patients are fit to make autonomous choices (e.g., lack of competence), but early ACP can to some degree help maintain a patient's autonomy, even when capacity to provide informed consent is reduced or lost. The principle of beneficence emphasises the importance of taking action in order to benefit an individual, as compared to the principle of nonmaleficence, which is passive and requires the avoidance of actions that cause harm (236). There are often grey areas concerning beneficence. For example, a terminal patient may wish to end lifesaving but burdensome treatment regimes. This will lead to a shortened lifespan, but perhaps greater quality of life. The dilemma of deciding what is beneficial to an individual can be exceedingly difficult, but a thoughtful and on-going dialogue between the patient, family, and health professionals may be advantageous. Likewise, aiming at "doing no harm" can include abstaining from performing invasive lifesaving treatment. This is particularly pertinent if ACP discussions have documented that a patient wishes to be spared from certain medical procedures.

However, depending on a person's abilities, health literacy, and culture the prospect of abstaining from treatment "down the road" may be misconstrued. ACP procedures that focus on avoiding hospitalisations and elaborate treatments have been accused of doing the health care system an economic favour. Reduced treatment might be money saved. It is therefore crucial to be cautious when discussing outcomes such as reduced hospital admissions as an exclusively positive outcome. In some instances, sending a nursing home patient to the hospital may be the correct medical decision.

The duty to treat similar cases equally is the core in the principle of justice (236). Related to nursing home patients, the practise concerning ACP differs in many countries, including Norway. Thus, official standards for the provision of ACP in nursing homes are needed.

People with dementia often have difficulties understanding the concept of the research and the consequences of their choices (131). Thus, people with dementia are often excluded from research (237). The intention of doing no harm and of protecting persons with reduced capacity might therefore lead to lack of research among groups who need such evidence-based treatment the most (237, 238). Nursing home patients and people with dementia represent a particularly vulnerable group, and this is acknowledged by most studies on ACP in nursing homes and in people with dementia. There are challenges that may have ethical implications, and even when ACP is implemented and conducted appropriately there are certain risks and apprehensions. When implementing ACP, it is important that the nursing home staff are properly educated in terms of communication and situational awareness and sensitivity. No single patient or family dynamic is the same as others, and being aware of this complexity also underlines why nursing home staff cannot perform ACP conversations in the same way with all patients.

Particular care must be taken when involving people with reduced cognitive capacity in ACP conversations, and it has been discussed in several studies whether it is beneficial for people with dementia to be included in ACP at all. One systematic review highlighted the importance of initiating ACP early using a strategy that takes into account timing and family and patient receptiveness or reluctance (53). The need to be aware of timing and the need to initiate the process is of relevance, and Ampe et al. point out that a typical characteristic of dementia is that although the disease implies a degeneration of cognitive functions, there are moments when a person with dementia functions well and can indicate their preferences for care (28). Research suggests that people with dementia may benefit from being involved in ACP conversations together with their families if the conversation is adequately adapted (45). Interestingly, Gjerberg et al. conducted a survey in Norwegian nursing homes published in 2017, where 57% gave their response on routines regarding ACP. Two thirds stated that they had some form of ACP, but the conversations mainly took place only when the patient entered the last phase of life, and the topics were mostly connected to hospitalisation, resuscitation, and pain relief. The patient was rarely participating in these discussions (239).

Despite the fact that there are numerous ethical challenges when performing research in the nursing home setting, it is important to initiate projects that are of high clinical relevance and that potentially could increase the quality of care. The World Health Organization also points out the need for ACP in the nursing home setting (240).

The PAIN-BPSD intervention involved medication, which raises unique ethical concerns. As previously described, no on-going treatment was terminated in either the control or intervention groups. However, in an ethical perspective it is necessary to reflect on beneficence versus maleficence when providing analgesic treatment to frail elderly adults. Medications can have harmful side effects, on the other hand it can also be argued that keeping patients from possible beneficial treatment is both harmful and unjust. Certainly, potential harm should be minimal and be justified by the potential therapeutic value to the patient participating in the study. Importantly, if people with dementia are not included in medical studies, it might also exclude them from receiving the best treatment. This view is stated in the Helsinki declaration, emphasising that medical research within a vulnerable group is acceptable when the research is helpful to the health needs or priorities of this group.

Neither the PAIN-BPSD nor the COSMOS trial collected written consent from the involved staff who were proxy raters. However, they were informed about the study and that it was voluntary to participate as informants. This was also the case for staff who evaluated their distress toward patients with neuropsychiatric symptoms. Importantly, the use of the NPH-NH, including the distress scale was approved by

REK. The staff was kept completely anonymous and no health information about staff were registered.

7. Conclusion

The overarching aim of this thesis was to describe the development, implementation and effects of ACP in nursing homes. Additionally, this thesis focused on the staff perspective both in terms of how staff received the ACP intervention and implementation, and how aspects related to improved patient treatment and routines affected staff distress.

We found the ACP component in the COSMOS trial to be well received among the nursing home staff. The intervention was largely implemented, and the majority (81%) of the patients had log entries during the intervention period. The ACP implementation was performed successfully in 62% of the patients based on the predefined criteria. The thesis also identified important facilitators, including: i) the focus on the nursing homes' organisation and routines with clearly defined roles and responsibilities and ii) the education seminar and material that highlighted the relevance and need for ACP in nursing homes. Common barriers for implementing ACP were as also identified: i) lack of time, ii) conflicting opinions and culture, and iii) lack of staff competence.

The COSMOS ACP improved the communication among patients, their families, and nursing home staff. Lack of a lasting effect at the 9-month follow-up indicates the necessity for on-going staff support regarding ACP.

Staff distress was reduced in both the COSMOS trial (paper 3) and the PAIN-BPSD - study (paper 1). The intervention in the PAIN-BPSD study was pain medication, which indicated a multifactorial model of staff distress in which enhanced knowledge and understanding of neuropsychiatric symptoms and pain in people with advance dementia may play an important role. Knowledge and understanding may have played a key role in the reduced staff distress that was observed in the COSMOS trial, although more research is needed to fully understand the associations between interventions in the nursing home and staff distress.

The staff played an essential role in both the PAIN-BPSD and COSMOS trials. This thesis illustrates the necessity of involving the staff both in the implementation and in the evaluation process when conducting complex clinical trials in the nursing home.

8. Implications and perspectives for the future

This thesis provides some knowledge regarding the development, implementation, and potential outcomes of ACP in nursing homes, while also considering the staff perspective. This thesis found successful ACP implementation in a majority of patients in the implementation group. The results of this thesis suggest that the implementation strategy should focus on educating the nursing home staff to improve communication between the patients, their families, and staff rather than emphasising documentation alone. Moreover, a train-the-trainer strategy should be a part of the nursing home culture, aiming to spread competence and making all staff aware of their responsibility for care and treatment. Even if ACP has been successfully implemented, it is not necessarily sustainable. In order to ensure that ACP becomes a part of routine care, institutional systems must be in place to ensure that ACP is delivered to patients and families. This typically requires an institutional and cultural change, which takes time and effort, and nurses, physicians, and nursing home management should all be committed to delivering ACP. The results of this thesis suggest that four months may not be enough to achieve this, which is important to communicate to national and regional administrations and health care providers that aim to implement ACP.

ACP was successfully implemented in terms of increased meetings and monthly contact, and the intervention group showed improved communication between nursing home staff and families. These results represent an argument for standardising and implementing ACP in Norwegian nursing homes and should be communicated to decision-makers.

Hopefully, this thesis also generates new hypotheses, and more research is needed to optimise the ACP procedure and ensure full implementation. For example, documentation of ACP conversations and contact with the physician was not significantly improved in the intervention group in this thesis. The results of this thesis show that increased efforts are needed to uncover how physicians can be involved. In terms of documentation, it would be of interest to investigate whether targeted journal systems could facilitate both documentation of and access to decisions made by the patient and family.

In addition, there is still a need to investigate optimal procedures for involving people with dementia. Although the ACP component used in this thesis encouraged the inclusion of people with dementia, it remains uncertain how to best enable nurses to competently guide family and patients with dementia in an ACP conversation that is meaningful and inclusive.

Ideally, ACP should be initiated before a person has lost their capacity to provide informed consent. This means that increased effort should be made to implement ACP among general practitioners and home care service. Thus, future research should not only focus on nursing homes, but also should investigate how ACP can be implemented as a part of home care services and among general practitioners.

Aspects of ACP that are perceived and disseminated as beneficial to one group of patients may not be helpful for others with a different cultural frame of reference. In an increasingly multi-cultural society, it is necessary to investigate how ACP is received in a wide range of minority groups. Ideally, cultural awareness and flexible use of ACP should make it beneficial to a broad societal spectrum.

Although the research of this thesis suggests that interventions in the nursing home can positively impact staff distress, future research should further explore if and how ACP interventions may affect staff distress and, conversely, staff satisfaction. Reduced staff distress and increased competence and satisfaction are important to achieving sustainable implementation of ACP. It is also a valuable goal in itself because nursing home staff represent a large group of people who are often personally involved in the welfare of the senior citizens in our society. Increasing job satisfaction and status for this group of people will ultimately benefit society as a whole.

An important goal with this thesis was to generate ideas for further efforts of researchers and clinicians. This is a prerequisite for improving the care for nursing home patients and people with dementia. There is great potential for achieving a general implementation of ACP in Norwegian nursing homes. This thesis represents one piece of a bigger puzzle, and researchers in Norway, Scandinavia, and worldwide are developing promising tools and implementation strategies that will benefit nursing home patients and people with dementia. This provides hope for the future because the complexity of ACP demands a systematic scientific and clinical effort. George Bernard Shaw (1856–1950) once said that "*the single biggest problem in communication is the illusion that it has taken place". With comprehensive and systematic development, implementation, and testing of ACP, the illusion may perhaps become a reality.

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9. Appendices

9.1 Tools providing and assessing implementation of ACP

9.1.1 Appendix: Flash card

9.1.2 Appendix: Patient logs / 5 key ACP components

9.1.3 Appendix: Likert scale (Global Impression of Change)

9.2 Papers 1 – 3

9.1.1 Flash card

ADVANCE CARE PLANNING

This is a repeating process where the patient together with relatives gets the opportunity to:

- Understand the disease and potential treatment alternatives
- Talk about his/her values, beliefs and earlier choices
- Identify his/her needs and goals for the stay
- Nominate a representative (surrogate) when the patient is no longer able to make decisions

WHEN AND HOW OFTEN?

- Patient, relatives, physician and care staff should have a conversation 2-3 weeks after the admission
- Have phone contact with relatives 1 time per month
- Regular follow up meetings every 3rd month
- Take active contact if changes in the disease, medical and treatment related questions and with hospital admission
- Be available when expressed needs for conversations from family and/or patient

WHO SHOULD PATICIPATE?

Patient, relatives, physician and caregivers should be included in advance care planning. Patient who explicitly do not want to take part, unconscious and persons with seriously behavioral disturbances should not participate.

HOW? 7 good questions for conversations

1. How involved have you been in the patients’ treatment, care and decision making as family, and how much would you like to be included?
2. What have both of you (patient and family) understood about the situation and the disease?
3. What kind of additional information do both of you (patient and family) need to better understand the situation?
4. What should we know about the patient’s life and values to ensure the best care? What matters and what makes life in general meaningful?
5. What goals, ideas and expectations do you both (patient and family) have for the nursing home stay?
6. Does the patient struggle with unfinished business?
7. Have both of you (patient and family) previously discussed end-of- life treatment e.g. hospitalization in case of acute illness?

TIPS FOR THE CONVERSATION

- Ask open ended questions and supplementary questions to understand the message:
  "What do you think about what we've talked about today?"
- When the patient cannot give informed consent, relatives should contribute to presumed consent, *"What would he/she have wanted in such a situation?"*
- Document the content of the conversation
- Carry out the measures that you agreed on

The main goal is to build trust, confidence and contribute to predictability for all involved!

Read more in the guidelines!

9.1.2 Patient logs / 5 key ACP components. Excerpts from the patient logs showing 5 key ACP components assessed every fourth week for the patients in the intervention group. Similar assessment of the 5 ACP components in both the intervention and control group was a part of the data collection.

KOMMUNIKASJON og forberedende samtaler er en gjentagende prosess mellom pasient, pårørende og personale for å øke trygghet og tillit gjennom kjennskap til hverandre. Målet er å identifisere pasientens verdier og ønsker for oppholdet på sykehjemmet og å gi grundig og fortløpende informasjon om pasientens helsetilstand og individuelle behandling. KOSMOS prosjektet øker fokuset på etiske spørsmål og gjør helsepersonell i stand til å identifisere pasientens verdier og spørsmål som er avgjørende for hennes/hans hverdag, behandlingstiltak og individuelle beslutningsprosesser i livets slutt.

UKE 4

Kommunikasjon		**Ja**	**Nei**	**Ikke aktuelt**
1	Har pasient og pårørende blitt invitert til en felles samtale med lege?	☐	☐	☐
2	Har pasient og pårørende hatt felles samtale med primærkontakt?	☐	☐	☐
3	Har dere hatt månedlig telefonkontakt med familien?	☐	☐	☐
4	Har dere hatt kontakt med pårørende den siste måneden? Utdyp i kommentarfeltet	☐	☐	☐
5	Er kommunikasjonen dokumentert?	☐	☐	☐

Kommentarer og problemer ved gjennomføring:

9.1.3 Likert scale (Global Impression of Change). Excerpts from the CGIC questionnaire – assessing perceived change in communication by families and nurses

a) Change in communication answered by the patients family at month 4:

Opplever du at det har blitt endring på følgende områder de siste måneder?

Kommunikasjon med legen:

Mye dårligere Ingen endring Mye bedre

-5 -4 -3 -2 -1 0 1 2 3 4 5

Kommunikasjon med ansvarlig sykepleier:

Mye dårligere Ingen endring Mye bedre

-5 -4 -3 -2 -1 0 1 2 3 4 5

b) Change in communication answered by a nurse in each nursing home unit at month 4:

Opplever du at det har blitt endring på følgende områder de siste måneder?

Kommunikasjon med legen:

Mye dårligere Ingen endring Mye bedre

-5 -4 -3 -2 -1 0 1 2 3 4 5

Kommunikasjon med pårørende:

Mye dårligere Ingen endring Mye bedre

-5 -4 -3 -2 -1 0 1 2 3 4 5

9.2 Papers 1-3

Paper 1

Original Article

Staff Distress Improves by Treating Pain in Nursing Home Patients With Dementia: Results From a Cluster-Randomized Controlled Trial

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Abstract

Context. Most people with dementia develop neuropsychiatric symptoms (NPSs), which are distressing for their carers. Untreated pain may increase the prevalence and severity of NPSs and thereby staff burden.

Objectives. We investigated the association between NPSs and the impact of individual pain treatment on distress in nursing home staff.

Methods. Nursing home (NH) units were cluster-randomized to an intervention group (33 NH units; $n = 175$) or control group (27 NH units; $n = 177$). Patients in the intervention group received individual pain treatment for eight weeks, followed by a four-week washout period; control groups received care as usual. Staff informants ($n = 138$) used the Neuropsychiatric Inventory–NH version (including caregiver distress) as primary outcome to assess their own distress. Other outcomes were pain (Mobilization-Observation-Behavior-Intensity-Dementia-2 Pain Scale) and cognitive functioning (Mini–Mental State Examination).

Results. Using hierarchical regression analysis, all NPS items at baseline were associated with staff distress ($P < 0.01$) apart from euphoria; agitation had the largest contribution ($\beta = 0.24$). Using mixed models, we found significantly lower staff distress in the intervention group compared to the control group. Moreover, we also found significantly reduced distress in the control group, and there were still effects in both groups throughout the washout period.

Conclusion. Individual pain treatment reduced staff distress in the intervention group compared to control group especially in regard to agitation-related symptoms and apathy. Furthermore, our results indicated a multifactorial model of staff distress, in which enhanced knowledge and understanding of NPSs and pain in people with advanced dementia may play an important role. J Pain Symptom Manage 2016;52:795–805. *© 2016 The Authors. Published by Elsevier Inc. on behalf of American Academy of Hospice and Palliative Medicine. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).*

Key Words
Staff distress, staff education, nursing home, dementia, neuropsychiatric symptoms, pain

Introduction

Approximately 35 million people worldwide and 10 million people in Europe suffer from dementia, a progressive and terminal condition.[1] During the first years of the disease, the majority of patients live at home with their family; consequently, a vast number of people with informal caregiving responsibilities are indirectly affected by the condition.[2] As the dementia progresses, people lose their independence and 90%

Trial registration: ClinicalTrials.gov, number NCT01021696 and at the Norwegian Medicines Agency (EudraCT no: 2008-007490-20).

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develop neuropsychiatric symptoms (NPSs) such as agitation, psychosis, and sleep disturbances.[2,3] These symptoms are distressing, not only for the patients but also for the carers, and lead to institutionalization as reflected in the nursing home (NH) population, 80% of whom have dementia.[4]

Distressing symptoms do not recede with NH admission, and the care for these patients is found to affect formal carers, both emotionally and physically, leading to depression, anxiety, and sleep problems.[5] The societal consequences are significant: burnout, sick leave, turnover, and increased economic costs.[2,6,7] Interestingly, only a few and mostly cross-sectional studies specifically investigate the differential effect of discrete NPSs on distress in NH staff.[2,6,8,9] Interviews with licensed nurses and certified nursing aides ($n = 24$) demonstrated that aggression and agitation were more distressing than other NPSs such as euphoria and nonaggressive behaviors.[2] Results are supported by 445 formal caregivers in Japan who experienced the presence of disruptive behaviors such as aggression and screaming as most burdensome.[6] To handle NPSs, psychotropic drugs are often used as a first-line therapy and are prescribed to approximately 75% of people with dementia in NHs.[4] A placebo-controlled trial with risperidone in older people with dementia ($N = 279$) demonstrated a significant reduction in NH staff distress.[10] Another intervention study using the cognitive enhancer memantine in people with dementia and behavioral disturbances also found supplementary amelioration of staff distress.[11]

Although the etiology of NPSs is largely unknown, undiagnosed, and untreated, pain may be an important trigger for the increased prevalence of NPSs[12–14] and is thereby, indirectly, an important concern for staff distress. Recently, our research group completed a cluster-randomized controlled trial (RCT) that included people with advanced dementia and agitation who received either individual pain treatment (intervention) or care as usual (control). Beneficial effects were found in relation to several NPSs.[15–17] Study results also suggested that a Hawthorne effect can be of matter because NPSs improved in both intervention and control groups, possibly related to training and staff support. Increased knowledge may empower staff to cope with difficult symptoms in contrast to being helpless witnesses of the suffering with untreated pain in patients.[7,18] These complex issues have not yet been addressed.

In the present study, the objectives may be divided into three stages: 1) a prestage investigating the nature of staff distress and patient symptoms, 2) the main objectives as a second stage, 3) and a third stage investigating secondary effects of the study protocol.

1) We aimed to investigate the association between different NPSs and level of staff distress at baseline as we hypothesized that different NPSs would not all be equally distressing to staff.

2) We have already shown that pain treatment reduces NPSs in NH patients and that this effect was reverted during washout.[15,17] Thus, the main aim of this study was to investigate if the introduction of a systematic pain treatment also had an effect on staff distress. In particular, we wished to investigate 1) whether the level of distress was reduced in the intervention as compared to control group after eight weeks of systematic pain treatment and 2) whether staff distress increased after the analgesic washout period in intervention group vs. control group. We hypothesized that introducing individual pain treatment would reduce staff distress but did not have any scientific grounds to suggest if the effect was large enough to detect change after washout.

3) Because both the intervention and control groups received education regarding pain, neuropsychiatric symptoms, and received training in several assessment tools, we also aimed to investigate the effect of the study intervention within both the intervention and control groups. We hypothesized that the mere participation in a study would entail positive effects also for the control group.

Methods

This study is based on secondary data analyses from a cluster-RCT including 352 long-term care patients from 18 NHs in Western Norway. The study was conducted between October 2009 and June 2010. Participants were included from 60 NH units (1 NH unit = 1 cluster), randomized to control (27 NH units; $n = 177$) or intervention (33 NH units; $n = 175$). Inclusion criteria were as follows: age 65 years or more, expected survival of more than six months, advanced dementia (Mini–Mental State Examination [MMSE], score <20), and high levels of agitation (Cohen-Mansfield Agitation Inventory score ≥ 39).

NH Staff Participation

Primary caregivers ($n = 138$) who knew the patient and had direct patient contact for at least four weeks participated as proxy raters (informants). The informants in both the intervention and control groups received a half-day specific training in clinical assessment of pain, cognition, NPSs, activities of daily living, and functional assessment staging. They were later interviewed by research assistants in connection with data collection. Research assistants and caregivers were blinded to allocation of treatment and control groups during the clinical assessments. Those who were responsible for delivering the intervention, including the medication, did not participate in the data collection. To further ensure blinding, the staff was encouraged not to talk about management procedures during the study period.

Study Intervention

Patients in the intervention group received pain treatment according to a Systematic Pain Treatment Protocol (SPTP) adhering to the American Geriatric Society's recommendations for pharmacological pain management.[19] Patients receiving treatment were individually assessed by the responsible team including the NH physician, primary patient caregiver, and a pain therapist (B. S. H.). The team discussed and agreed on the appropriate pain medication and dosage according to the standardized SPTP.[20] The intervention lasted eight weeks, followed by a four-week washout period. The control group received care as usual. The inclusion, design, and study intervention (SPTP) have been described in detail in previous publications.[15–17,20]

Outcome Measures

The main outcome measure in this study was staff distress, as measured by the Neuropsychiatric Inventory–NH (NPI-NH) version. The inventory is a 12-item proxy-rated instrument addressing different NPSs in the patient, and self-reported distress of these symptoms for the staff.[21] Both the international[21–23] and Norwegian[24] versions of the inventory have shown satisfactory validity and reliability. Each symptom is rated both according to its severity/intensity (0–3) and frequency (0–4) often expressed as a product (frequency score × severity score, F × S) ranging from 0 to 12. The staff distress scale, also known as occupational disruptiveness scale for the NPI-NH, consists of six levels: "not at all distressing" (0), "minimally distressing" (1), "mildly distressing" (2), "moderately distressing" (3), "severely distressing" (4), and "extremely distressing" (5). This means that NH staff assesses how emotional distressing the patient's behavior is for them and if it entails more occupational burden. In previous studies, the NPSs in patients have been collated into symptom clusters: mood (depression, apathy, anxiety, night-time behaviors, and appetite/eating disorders), agitation (agitation/aggression, disinhibition, irritability, and aberrant motor behavior), and psychosis (delusions and hallucinations) with euphoria as a single item.[25]

Pain was assessed using the Mobilization-Observation-Behavior-Intensity-Dementia-2 (MOBID-2) Pain Scale, developed and validated for use in NH patients with advanced dementia.[26] MOBID-2 is an instrument in which pain behavior, such as vocalization, facial expression, and defensive body movements are observed to ascertain pain presence and intensity using a 10-point numerical rating scale (range 0–10). MOBID-2 has demonstrated good reliability and validity[27] as well as responsiveness.[28]

We used the MMSE to ascertain the patients' cognitive functioning. It produces a sum score ranging from 0 to 30 that can be used to follow the course of patients or for case detection using cutoff scores. It has been used extensively in clinical and research settings and has high test-retest reliability, internal consistency, and interrater reliability.[29,30]

Statistical Analyses

All analyses were performed using IBM SPSS statistics version 23 and Stata/IC version 14 (StataCorp LP, College Station, TX, USA). Descriptive data including demographic data of the NH staff were calculated showing means and percentages.

According to the main Objective 1, the differential associations between each NPS and total staff distress were analyzed at baseline using a hierarchical linear regression analysis, and we used the robust estimator of variance, allowing for intragroup correlation. Total staff distress was entered as the dependent variable. The patients' age, gender, pain (MOBID-2 total score), cognitive functioning (MMSE), and all 12 NPI-NH item scores were entered as predictors. In this analysis, age, gender, and MMSE were entered in the first step, pain was entered in the second step, and all NPI items were entered in the third and final step. Before performing regression analysis, the data were checked for multicollinearity, normality, linearity, homoscedasticity, independence of residuals, and outliers.

The second objective for the study was to examine whether the level of staff distress was reduced after implementing individual pain treatment and whether staff distress increased after the analgesic washout period in control group versus intervention group. Although the third aim was to investigate the effect of the study intervention within both the intervention and control groups, the change of NPI-NH staff distress scores from baseline to eight and 12 weeks were estimated by linear mixed-effect models, using maximum likelihood estimation. The analyses were conducted separately for each of the following outcome variables: total staff distress; the 12 distinct NPI-NH staff distress items; and the three combined items mood, agitation, and psychosis, in total 16 analyses. We treated time as a categorical variable and included fixed effects for time, intervention, and their interaction in the models. To account for clustering, patients were nested within NH-units and NPI-NH scores within patients, and the models were fitted with random intercepts and slopes for both NH-units effects and for patient-level effects. The covariance structures were specified using an unstructured model within individuals and identity model within NH units. The model selections were based on best fit according to likelihood ratio tests, AIC, and BIC.

The regression coefficients for time indicates the within-group change of the NPI-NH score from baseline to Week 8 and Week 12 in the intervention and the control groups, and the corresponding CIs indicate the within-group change statistical significance. The regression coefficient for the interaction term shows the difference in within-group change at eight weeks and 12 weeks between the intervention group and the control group and is thus interpreted as the effect of the intervention. The corresponding CIs were used as a measure of statistical significance. The significance levels were set to 0.05. *P* for interaction was obtained by likelihood ratio tests comparing the models with interaction to the models without interaction. Significant *P*-values indicate an overall difference in within-group change over time between the intervention group and the control group. The intracluster correlation (ICC) coefficients were reported at the NH unit level and at the patient level. The ICC at NH-unit level is the correlation between the responses in the same NH-unit but for different patients, whereas the ICC at the patient level is the correlation between responses for the same patient at different time points.

Ethics

The NH staff gave informed consent to participate as informants. Informed consent was also obtained from all patients who had sufficient capacity. If patients did not have the capability, written consent was provided by the next of kin or the authorized legal representative. The study was approved by the Regional Committee for Medical Ethics, Western Norway (REK-Vest 248.08).

Results

Baseline Characteristics of NH Patients and Staff Informants

At baseline, the included NH patients ($n = 341$) had a mean age of 86 years, and mean MMSE of 8. Patients' demographics and symptoms are presented in Table 1. The attrition rate of 17.6% did not cause significant differences between the intervention and control groups.[15]

Table 1

Patient Characteristics and Neuropsychiatric Symptoms and NH Staff Distress at Baseline

	NH Patient Characteristics		Staff Distress	
Characteristics and Symptoms	Intervention Text	Control	Intervention	Control
Age (SD)	84.9 (7.0)	86.5 (6.8)		
Women%	74.9	74		
Cognitive function/MMSE (SD)	7.51 (6.5)	8.40 (6.7)		
Pain/MOBID-2 (SD)	3.70 (2.7)	3.67 (2.5)		
NPI-NH	NH Patient Neuropsychiatric Symptoms		NPI-NH Distress Score	
Total NPI-NH score (SD)	35.42 (21.7)	31.35 (20.8)	15.06 (9.6)	13.10 (9.2)
Symptom clusters				
Mood (SD)	6.0 (4.4)	5.1 (4.4)	5.98 (4.4)	5.08 (4.4)
Agitation (SD)	6.5 (4.7)	5.9 (4.7)	6.53 (4.7)	5.88 (4.7)
Psychosis (SD)	2.3 (2.6)	1.9 (2.4)	2.28 (2.6)	1.89 (2.4)
Single items				
Delusions (SD)	3.52 (4.3)	2.60 (3.8)	1.50 (1.7)	1.21 (1.6)
Hallucinations (SD)	1.67 (3.1)	1.48 (2.9)	0.78 (1.4)	0.68 (1.3)
Agitation (SD)	4.19 (4.2)	3.66 (4.0)	2.09 (1.9)	1.81 (1.7)
Depression (SD)	2.80 (3.5)	2.86 (3.7)	1.42 (1.5)	1.31 (1.5)
Anxiety (SD)	3.58 (4.3)	3.09 (4.0)	1.55 (1.7)	1.31 (1.6)
Euphoria (SD)	0.57 (1.9)	0.71 (2.1)	0.26 (0.9)	0.24 (0.8)
Apathy (SD)	3.80 (4.3)	2.56 (3.7)	1.19 (1.4)	0.68 (1.1)
Disinhibition (SD)	2.92 (3.9)	2.98 (4.0)	1.33 (1.6)	1.33 (1.6)
Irritability (SD)	4.35 (4.1)	3.72 (3.7)	1.96 (1.7)	1.71 (1.6)
Aberrant motor behavior (SD)	3.44 (4.6)	3.04 (4.5)	1.18 (1.6)	1.02 (1.5)
Sleep disturbance (SD)	2.02 (3.4)	2.17 (3.2)	0.92 (1.5)	1.02 (1.5)
Appetite/eating disorder (SD)	2.61 (4.2)	2.48 (4.1)	0.90 (1.5)	0.76 (1.4)

NH = nursing home; MMSE = Mini–Mental State Examination; MOBID-2 = Mobilization-Observation-Behavior-Intensity-Dementia-2; NPI-NH = Neuropsychiatric Inventory–Nursing Home; n = number of patients.

Intervention group = NH units: 33, $n = 177$; control group = NH units: 27, $n = 175$. Numbers represent mean (SD). Numbers of women are expressed in percentage.

The primary caregivers ($n = 138$) had a mean age of 43 years; 136 were women. Their average professional experience was 17 years, with nine years of work experience in their current institution. Most of the included informants were of Norwegian national origin (93.3%) and educated health workers, of which 44% were registered nurses and 49% assistant nurses, whereas the remaining 7% were unskilled workers. Staff distress was assessed in relation to 341 patients at baseline.

The Relationship Between Different Neuropsychiatric Symptoms and Staff Distress

As summarized in Table 2, the full hierarchical linear regression model including the NPI-NH scores entered at Step 3 explained 81% of the total staff distress variance. At Step 1, higher cognitive functioning assessed by MMSE was related to lower total staff distress. This association persisted when pain was entered at Step 2. At Step 2, pain was also significantly related to staff distress. In essence, staff experienced less distress related to patients with higher cognitive functioning and less pain compared to patients with lower cognitive functioning and more reported pain. When NPI items were entered at Step 3, cognitive functioning and pain were no longer related to total staff distress. Thus, the effects of pain and reduced cognitive functioning were precluded when controlling for NPSs.

All NPI-NH items, except for euphoria, were significantly related to a higher risk of total staff distress at baseline. The individual effect of NPI-NH items on staff distress varied, with standardized coefficients ranging from 0.048 (small effect) to 0.235 (moderate effect). Agitation ($\beta = 0.235$), disinhibition ($\beta = 0.201$), and delusions ($\beta = 0.202$) were the only items showing coefficients over 0.20, closely followed by sleep ($\beta = 0.185$).

Effect on Staff Distress During the Treatment Period

Within-group comparisons (Table 3) showed a significant decrease in total staff distress from baseline to Week 8, in both the intervention group (B −6.51, 95% CI −7.88 to −5.14) and control group (B −2.98, 95% CI −4.38 to −1.59). As seen in Table 3, the majority of the staff distress items, including NPI-NH symptom clusters, showed a significant decrease in both the intervention and control groups, but with larger effect in the intervention group (Table 3).

In terms of between-group comparisons at Week 8, there were significantly lower staff distress in the intervention group compared to control group in relation to single items such as agitation, anxiety, apathy, aberrant motor behavior, and appetite/eating disorder (Fig. 1). There was also less staff distress in the intervention group compared to control group in relation to total distress (B −3.53, 95% CI −5.47 to −1.58) and symptom cluster: mood (B −1.74, 95% CI −2.66 to −0.83) and agitation (B −1.62, 95% CI −2.60 to −0.65) (Fig. 2).

Table 2

Multiple Hierarchical Linear Regression Analysis ($n = 341$) for the Baseline Associations Between Patient Characteristics and Neuropsychiatric Symptoms and the Dependent Variable Total Staff Distress as Measured by the Neuropsychiatric Inventory—Nursing Home Version

Distress Associated to	R^2	Δr^2	B	SE	β
Step 1	0.017	0.008			
Age			0.019	0.082	0.014
Female			1.051	1.176	0.049
MMSE			−0.176	0.080	−0.123[a]
Step 2	0.04	0.025[a]			
Age			0.050	0.086	0.037
Female			0.969	1.220	0.045
MMSE			−0.180	0.082	−0.125[a]
MOBID-2 total score			0.491	0.194	0.134[a]
Step 3	0.810	0.800[b]			
Age			0.047	0.042	0.034
Female			−0.278	0.515	−0.013
MMSE			0.002	0.041	0.002
MOBID-2 total score			0.078	0.080	0.021
Neuropsychiatric symptoms					
Delusions			0.467	0.069	0.202[b]
Hallucinations			0.507	0.099	0.164[b]
Agitation			0.542	0.064	0.235[b]
Depression			0.356	0.073	0.136[b]
Anxiety			0.401	0.061	0.178[b]
Euphoria			0.230	0.218	0.048
Apathy			0.283	0.085	0.120[b]
Disinhibitions			0.480	0.065	0.201[b]
Irritability			0.266	0.072	0.109[b]
Aberrant motor behavior			0.271	0.056	0.128[b]
Sleep			0.535	0.096	0.185[b]
Appetite/eating disorder			0.278	0.083	0.122[b]

n = number of patients; B = coefficient; β = standardized coefficient; SE = standard error; MMSE = Mini—Mental State Examination; MOBID-2 = Mobilization-Observation-Behavior-Intensity-Dementia-2.

[a] $P < 0.05$.

[b] $P < 0.001$.

Effect on Staff Distress After the Washout Period

Neither the intervention group nor the control group showed significant within-group changes in total staff distress during the washout period, from Week 8 to Week 12. However, the intervention group demonstrated a significant increase in distress scores for aberrant motor behavior ($P < 0.05$), whereas staff in the control group felt more stressed by patients' irritability ($P < 0.05$).

Between-group comparisons at Week 12 showed significantly less total distress in the intervention group in relation to total staff distress, to the mood (B −2.13, 95% CI −3.28 to −0.98) and agitation (B −1.69, 95% CI −2.93 to −0.45) symptom cluster, and to the following single items: agitation, depression, anxiety, apathy, irritability, and appetite/eating disorder (Table 3).

Table 3

Changes in Staff Distress[a] Within Groups From Baseline to Week 8 and From Baseline to 12 Weeks, and Estimated Intervention Effects Between Groups at Week 8 and Week 12[b]

	Change From Baseline to Eight Weeks			Change From Baseline to 12 Weeks					
	Intervention Group	Control Group		Intervention Group	Control Group				
Symptoms	B (95% CI)	B (95% CI)	B-Interaction (95% CI)	B (95% CI)	B (95% CI)	B-Interaction (95% CI)	P-Int.	ICC NH-Units	ICC Pat.
Total staff distress	−6.51 (−7.88, −5.14)	−2.98 (−4.38, −1.59)	−3.53 (−5.47, −1.58)	−6.24 (−8.01, −4.48)	−2.53 (−4.34, −0.71)	−3.72 (−6.24, −1.20)	0.003	0.15	0.78
Symptom cluster									
Mood	−2.57 (−3.21, −1.94)	−0.84 (−1.47, −0.20)	−1.74 (−2.66, −0.83)	−2.80 (−3.59, −2.00)	−0.68 (−1.48, 0.12)	−2.13 (−3.28, −0.98)	<0.001	0.16	0.75
Agitation	−2.96 (−3.64, −2.29)	−1.34 (−2.02, −0.66)	−1.62 (−2.60, −0.65)	−2.54 (−3.39, −1.70)	−0.86 (−1.71, −0.003)	−1.69 (−2.93, −0.45)	0.005	0.10	0.75
Psychosis	−0.87 (−1.25, −0.49)	−0.71 (−1.07, −0.35)	−0.15 (−0.70, 0.39)	−0.86 (−1.34, −0.37)	−0.80 (−1.25, −0.35)	−0.05 (−0.74, 0.65)	0.758	0.01	0.75
Single items									
Delusions	−0.61 (−0.86, −0.36)	−0.46 (−0.71, −0.20)	−0.15 (−0.54, 0.23)	−0.59 (−0.90, −0.29)	−0.54 (−0.85, −0.22)	−0.05 (−0.55, 0.44)	0.597	0.03	0.70
Hallucinations	−0.25 (−0.43, −0.08)	−0.24 (−0.41, −0.07)	−0.01 (−0.26, 0.23)	−0.26 (−0.46, −0.05	−0.24 (−0.44, −0.04)	−0.01 (−0.30, 0.28)	0.995	0.03	0.73
Agitation	−1.01 (−1.28, −0.74)	−0.39 (−0.65, 0.13)	−0.62 (−0.99, −0.25)	−0.87 (−1.19, −0.56)	−0.29 (−0.61, 0.02)	−0.58 (−0.03, −0.14)	0.006	0.04	0.69
Depression	−0.60 (−0.84, −0.36)	−0.31 (−0.55, −0.07)	−0.29 (−0.63, 0.05)	−0.66 (−0.96, −0.36)	−0.22 (−0.52, 0.08)	−0.45 (−0.87, −0.02)	0.128	0.04	0.71
Anxiety	−0.79 (−1.00, −0.57)	−0.32 (−0.53, −0.11)	−0.47 (−0.77, −0.17)	−0.85 (−1.10, −0.59)	−0.36 (−0.61, −0.11)	−0.49 (−0.85, −0.13)	0.008	0.04	0.76
Euphoria	−0.11 (−0.24, 0.03)	−0.03 (−0.17, 0.10)	−0.07 (−0.26, 0.11)	−0.04 (−0.21, 0.12)	−0.08 (−0.24, 0.09)	0.03 (−0.18, 0.26)	0.373	0.04	0.64
Apathy	−0.67 (−0.86, −0.49)	0.13 (−0.06, 0.31)	−0.80 (−1.06, −0.54)	−0.63 (−0.85, −0.42)	0.07 (−0.14, 0.28)	−0.70 (−1.00, −0.40)	<0.001	0.14	0.65
Disinhibitions	−0.61 (−0.85, −0.37)	−0.33 (−0.57, −0.10)	−0.28 (−0.61, 0.06)	−0.51 (−0.78, −0.23)	−0.23 (−0.50, 0.04)	−0.27 (−0.66, 0.11)	0.249	0.07	0.65
Irritability	−0.74 (−1.00, −0.47)	−0.40 (−0.66, −0.14)	−0.34 (−0.71, 0.03)	−0.78 (−1.09, −0.46)	−0.15 (−0.47, 0.17)	−0.63 (−1.08, −1.17)	0.029	0.03	0.65
Aberrant motor behavior	−0.65 (−0.89, −0.41)	−0.20 (−0.43, 0.04)	−0.45 (−0.79, −0.12)	−0.43 (−0.72, −0.13)	−0.15 (−0.45, 0.15)	−0.28 (−0.69, 0.14)	0.017	0.08	0.73
Sleep disturbance	−0.20 (−0.40, −0.004)	−0.31 (−0.50, −0.12)	0.11 (−0.17, 0.38)	−0.28 (−0.52, −0.04)	−0.16 (−0.39, 0.08)	−0.12 (−0.56, 0.22)	0.146	0.08	0.77
Appetite disorder	−0.31 (−0.54, −0.08)	0.04 (−0.19, 0.27)	−0.35 (−0.67, −0.03)	−0.37 (−0.65, −0.10)	0.07 (−0.20, 0.35)	−0.45 (−0.83, −0.06)	0.069	0.07	0.66

P-Int = interaction was obtained by likelihood ratio test; ICC NH-units = intracluster correlation on NH-units level meaning correlation between the responses in the same NH-unit but for different patients; ICC Pat. = intracluster correlation on patient level meaning the correlation between responses for the same patient at different time points.

[a] Measured by Neuropsychiatric Inventory—Nursing Home version.

[b] Mixed-model analyses.

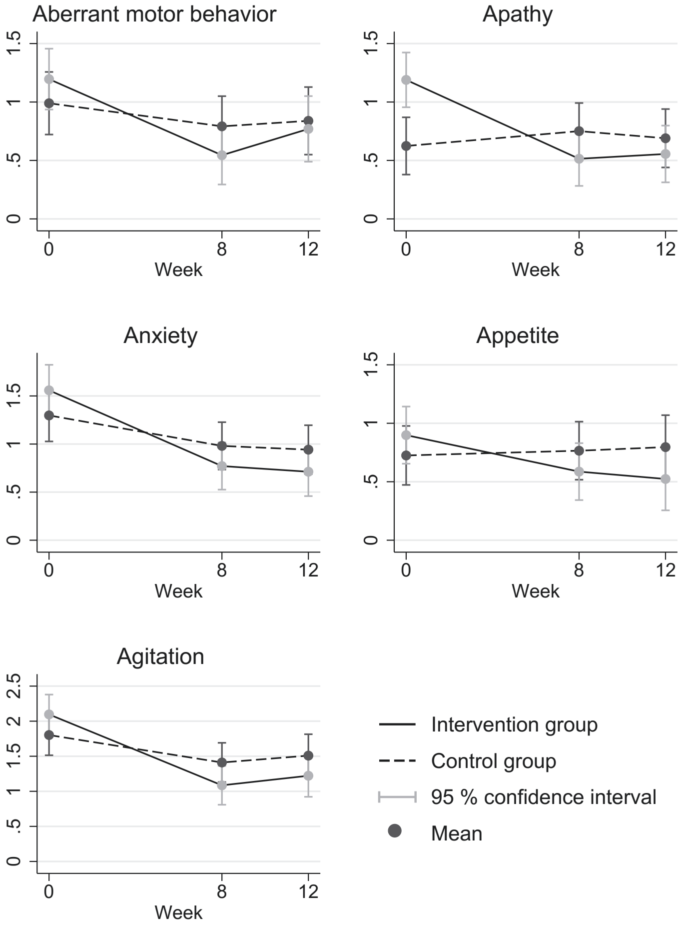

Fig. 1. Staff distress in relation to single items (agitation, anxiety, apathy, aberrant motor behavior, and appetite) in the Neuropsychiatric Inventory—Nursing Home version at baseline, Week 8, and Week 12.

Discussion

This present study suggests that individual pain treatment in people with advanced dementia and NPSs may improve staff distress as a secondary effect of the treatment. Staff distress was especially provoked by agitation and disinhibition, whereas euphoria was least distressing for the carers. These findings confirm our hypotheses and highlight that pain treatment, and thereby ameliorated NPSs, may additionally improve staff distress as a valuable secondary effect. Our results also highlighted the potential value of education and enhanced knowledge of NH staff because the changes in total staff distress from baseline to Week 8 persisted throughout the washout period. In addition, we also saw beneficial effects of the trial in the control groups.

The Relationship Between Different Neuropsychiatric Symptoms and Staff Distress

The higher risk of staff distress related to agitation, disinhibition, delusions, and disturbed sleep may be explained by the disruptive nature of these symptoms, both for other patients in the NH unit and the staff. This may have some unfortunate clinical results, as Zwijsen et al.[8] points out, if for example apathy causes little disruption, staff may not feel the same urgency to address this symptom. Indeed, the finding is in line with previous studies where the highest caregiver distress scores were related to externalized and disruptive behavior such as agitation, aggression, and disinhibition.[2,6,8] In addition, although disturbed sleep has not been previously highlighted in studies on staff

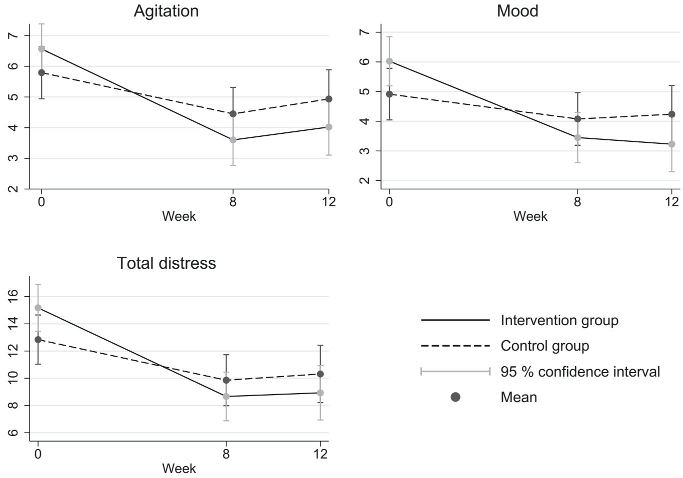

Fig. 2. Total staff distress and symptom clusters of mood (depression, anxiety, apathy, sleep disturbance, and appetite) and agitation (agitation, disinhibitions, irritability, aberrant motor behavior) in the intervention group compared to the control group at baseline, Week 8, and Week 12.

distress, it has been identified as one of the most frequent symptoms to negatively impact in-formal caregivers and thus increase the risk of institutionalization.[31]

Furthermore, none of the other variables (age, gender, cognitive functioning, and pain) included in the full hierarchical regression model were related to staff distress. Meanwhile, we did find effect of both cognition and pain before the model accounted for NPSs. The association we found between severe dementia and staff distress before the NPSs were entered may be an effect of low MMSE representing an added burden when a patient additionally had demanding NPSs. Likewise, the fact that the total pain intensity score was only associated with staff distress at Step 2 may imply that a patients' pain is distressing for caregivers largely due to the behavior triggered by the pain.[7] Indeed, studies that previously have investigated pain as distressing for carers have focused on the agitated pain behavior.[7,13,32] This supports results from previous studies suggesting untreated pain is difficult to identify and is primarily distressing for the staff when expressed as NPSs.[7,8,33]

Effect on Staff Distress During the Treatment Period

Several of the distress scores were significantly reduced in the intervention group at Week 8 confirming our second hypothesis that pain treatment would reduce staff distress. Although staff distress was reduced in the control group as well, the effect was substantially higher in the intervention group. Importantly, comparison of groups showed significantly less total staff distress in the intervention group as well as single NPI-NH items. It is a peculiar contradiction that staff in our study did not experience significant distress related to pain, yet individual pain treatment ameliorated staff distress. Because typical pain behavior may be similar to behavioral disturbances related to dementia, we suggest that symptoms related to pain and discomfort are incorrectly labeled as behavioral problems related to dementia.[13]

This reduction in staff distress after eight weeks' systematic pain treatment is in line with our previous studies where individual pain treatment significantly reduced several NPSs.[15–17] Taken together, the better effect in the intervention group and our previous findings are suggestive of an indirect link between pain treatment and reduced staff distress via reductions in behavioral problems. This is also in line with the study by Norton et al.[7] relating pain to staff distress associated with behavioral problems. However, the results are not unequivocally indicative of this reasoning. Although the effects of pain treatment on NPSs in people with dementia receded during the washout period described in previous publications,[15,16,20] most staff distress differences between the intervention and control groups persisted throughout the washout period.

Impact of Clinical Studies

The subjective experience of distress is affected by phenomena such as coping and appraisal.[34] Agitation and NPSs may, in general, interfere and create insecurity in the NH setting, especially if the staff have not received training in dealing, that is coping, with such symptoms.[7] The importance of staff understanding and appraisal of symptoms were highlighted in a study by Rodney[33] where the appraisal of aggressiveness as threatening was significantly related to staff stress.[33] Participation in research projects may lead to higher staff competence, consequently expanding their understanding of symptoms.[34] The use of systematic assessment of NPSs and pain by NPI and MOBID-2, respectively, directs the NH staff to see symptoms as a part of the patients' clinical condition rather than a maleficent threat. In addition, training in symptoms assessment allows the staff to describe the patient's condition more competently with evidence-based knowledge. This training is needed; previous studies have highlighted a lack of knowledge around persons with dementia- and cancer-related pain in NH.[35] Meanwhile, our findings do not imply a model where pain management and staff training are the sole factors necessary to reduce staff distress. As illustrated by Testad et al.,[36] psychosocial factors such as feelings of proficiency and control at work as well as leadership and organizational culture also affect staff stress.

Although this study was double-blinded, the staff knew that they were part of a study. In previous publications, from this RCT, we have observed effects in the intervention and control groups which may indicate a Hawthorn effect.[37] The finding may be of particular interest for the clinician and can be connected to the Rosenthal's Pygmalion effect,[38] the phenomenon where high expectations improve performance due to more attention and positive reinforcement. Such improvements in trial control conditions are common in studies investigating treatments of NPSs and are consistent with potential benefits of participating in a trial such as social interaction.[39,40] The presence of researchers provided recognition of the staff's daily work in the NH, which may additionally have had a positive effect for the staff.

Strengths and Limitations

This is the first well-powered RCT that investigates the link between different NPSs and staff distress in NH patients with severe dementia. This represents a strength due to the interrelated and often cooccurring nature of NPSs.[41] Thus, controlling for other NPSs, age, gender, cognitive functioning, and pain allows us to rule out distress related to a total symptom burden. Although some of the informants were without formal competence, they were selected because of their skills and knowledge of the clinical condition to the participating NH patients. In addition, a research assistant was present and provided guidance throughout the whole assessment procedure. As such, this represents a strength and ensures high data quality.

Unfortunately, our data do not fully link proxy rater or workplace characteristics to the staff distress scores because we lack elements such as sick leave, staff attitude, or details about organizational issues that might impact staff distress. We did not assess the effect of staff education in either the control or the intervention group. Organizational and psychosocial aspects (personality) to identify risk factors for staff distress should be addressed in future studies. To focus on education of staff and implementation is a prerequisite to better understand these effects and should be taken into consideration in complex intervention studies.

Although it is common to collate NPSs in NPI-NH version into symptom clusters,[25] symptom clustering of the NPI-NH distress scale has not been validated. In practice, it can be difficult to distinguish the NPSs, which also often cooccur.[41] It is thus reasonable to collate staff distress in the same symptom clusters used to describe NPSs.

We reported staff distress and NPSs as measured with the NPI-NH scale. Hence, the informants who reported the patients' NPSs also reported the staff distress in relation to these symptoms. This represents a potential source of common method bias. Partly addressing this issue, statistical analyses excluded concerns of multicollinearity. Although precautions were taken to blind research assistants and NH staff to group allocation, the efforts to fully blind staff will always be difficult in these studies due to the requirements in an NH setting. In addition, this study only included patients with severe dementia and clinically significant agitation. When including a patient group with high symptoms burden (i.e., agitation), there is always a possibility that some of the improvement may be attributed to a mere regression toward the mean. We cannot exclude this effect in our study. Although our patient sample is not representative for the general NH population, this sample was relevant for our study focus.

Conclusions

This study shows that individual pain treatment in people with advanced dementia indirectly reduced staff distress by improved NPSs. The lasting positive effect on staff distress after the washout period may suggest that introducing clinical tools and training is of key importance not only for the well-being of patients but also for the NH staff participating in a relevant research project for the NH setting. Participation in research projects may lead to higher staff competence, consequently expanding their understanding of symptoms. This effect signalizes the manifold importance of enabling proper medical patient follow-up in NHs.

Disclosures and Acknowledgments

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Paper 2

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RESEARCH ARTICLE Open Access

Description of an advance care planning intervention in nursing homes: outcomes of the process evaluation

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Abstract

Background: Advance Care Planning (ACP) is the repeated communication and decision-making process between the patient, family, and healthcare professionals. This study describes an ACP intervention in nursing homes and evaluates the outcomes of the implementation process.

Methods: The ACP intervention was part of a 4-month complex, cluster randomized controlled trial (COSMOS). 37 Norwegian nursing homes with 72 units (1 cluster = 1 unit) and 765 patients were invited to participate and eligible units were randomised to the intervention group or control. Nursing home staff in the intervention group was offered a standardized education programme to learn early and repeated communication with patients and families and to implement ACP in their units. We used a train-the-trainer approach to educate staff in the units, supported by regular telephone calls and a midway seminar after two months. Individual patient logs consisting of different communication deliverables were used to evaluate the implementation process. Supported by Qualitative Content Analyses, we identified facilitators and barriers of the ACP implementation based on feedback during midway seminars and individual patient logs.

Results: The ACP intervention was conducted in 36 NH units ($n = 297$); 105 healthcare providers participated at the education seminar prior to the study, and 3–4 employees from each unit participated in the midway seminar. NH staff reported the educational material relevant for the implementation strategy. The patient logs showed that ACP was successfully implemented in 62% ($n = 183$) of the patients using our predefined implementation criteria. The staff emphasized the clear communication of the relevance of ACP addressed to leaders and staff as important facilitators, along with the clearly defined routines, roles and responsibilities. Identified barriers included lack of competence, perceived lack of time, and conflicting culture and staff opinions.

Conclusion: Monthly communication with the family was the most frequently conducted communication, and the predefined criteria of successfully implemented ACP were largely achieved. Nursing home routines and engagement of leaders and staff were crucial facilitators, whereas lack of time and competence reduced the implementation success.

Trial registration: The COSMOS-trial was registered in the ClinicalTrials.gov (NCT02238652) July 7th, 2014

Keywords: Advance care planning, Education, Implementation, Nursing home, Staff training, Train-the-trainer

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Background

Death is inevitable. However, medical progress has postponed and institutionalized the last period of life. With considerable variations between different countries, figures demonstrate that most deaths in Europe occur in nursing homes (NH) or hospitals [1–3]. In general, NH patients are characterized by multimorbidity and polypharmacy; most of them have dementia [4–7]. When dying is imminent, these individuals are no longer able to participate actively in medical and ethical decision-making. Consequently, nursing home patients with and without dementia depend on others to make qualified choices at the end-of-life [6].

Advance Care Planning (ACP) is a repeated communication process between the patient, family, and healthcare professionals to evaluate the individual preferences, values and goals, and potential concerns about treatment and care of the patient [8–10]. This procedure is approached by shared decision-making, including NH patients with dementia and their family to take part in in this process [11, 12]. The ACP concept is based on the patient's basic human right to be informed about her disease and treatment options, in order to make informed decisions [13, 14]. In people with dementia, the conversation should preferably start while the patient is still capable of active participation. If a patient has no ability to provide informed consent, it is a key premise that the family are empowered to make informed presumed decisions following the question "What would my loved one have wished in this situation?" [15].

Early communication increases the opportunity to respect the patient's and family's needs and preferences in the light of their spiritual and cultural background [16]. The number of studies investigating the implementation and efficacy of ACP is limited [17]. This may in part be due to its complex nature, along with variations in terms of study design, setting, and outcome measures. The goals of ACP may also vary between different countries and depend on spiritual and cultural implications, and values and legal systems [9]. Meanwhile, only a few countries have developed and implemented an official standard for the ACP process [18], leading to a more coincidental communication between staff and family [9, 15].

In a recent systematic review, we identified 16 ACP studies conducted in NHs [9]. A Hong Kong-based study using the "Let me Talk" programme found that patients in the intervention group ($n = 59$) communicated their treatment preferences more frequently compared to controls [17]. However, involving the participants' family in the ACP conferences was challenging because the patients suggested that family members were too busy to spare the necessary time to attend [17]. Another study by Cornally et al. (2015) utilised the "Let Me Decide" programme in three NHs in Ireland, leading to enhanced communication and prevented last-minute decisions. The study however, reported barriers associated with lack of physician involvement and difficulties using the required screening instrument to assess the patients' capacity to consent [19]. Our review also highlighted the lack of staff competence as a key challenge, rendering education a prerequisite for proper ACP implementation [9].

In a complex intervention like the ACP, it is highly necessary to describe and assess the evidence-based implementation strategy [20, 21]. The strategy of ACP is just as important to describe as its content, yet few studies have investigated the strategy and definition of implementation [9, 22]. The aim of this study was to describe the content of ACP in the COSMOS study, as well as the evaluation of the implementation process of the intervention in Norwegian NHs, using the following research questions:

1. How did the NH staff accept the ACP intervention and implementation strategy?
2. To what degree was the ACP intervention implemented successfully?
3. What were the barriers to and facilitators of implementing ACP in the NH?

Method

The ACP intervention described in this study was a part of the COSMOS trial, a 4-month complex randomised controlled trial executed from August 2014 to December 2015. The COSMOS acronym refers to the trial components: *CO*mmunication (in the form of Advance Care Planning), *S*ystematic assessment and treatment of pain, *M*edication review, *O*rganization of activities, and *S*afety [23]. We invited eight Norwegian municipalities from three counties, including 37 NH with 72 NH units (1 unit = 1 cluster) and 765 NH patients to participate. Eligible NH units were randomised to the intervention or control group. In the current study, we focus on the intervention group, by describing the content, implementation strategies of the ACP intervention, and the outcomes of the evaluation process. To achieve a representative sample, both somatic and specialized dementia long-term units from rural, urban, rich and poor municipalities were invited. Patients who were 65 years or older and had a minimum stay of two weeks before assessment were eligible participants. Patients with life expectancy ≤ 6 months or with schizophrenia were excluded. For detailed information on study design and sample size analyses, please see the published COSMOS protocol [17]. NH managers, registered and licensed practical nurses, and physicians related to the intervention group were invited to participate in a two-day education seminar, which offered a standardized education programme about ACP with patients and families. Nurses attending the education seminar were named COSMOS ambassadors.

Content of the advance care planning intervention

The content of the ACP intervention was based on literature reviews, clinical experience, and national and international collaboration [9, 22, 24]. The content was guided by the aim of achieving rapport and trust between NH staff, patient and families, to allow a necessary clarification of the patient's values and needs, and to achieve quality of life and quality of dying. We designed the ACP intervention so that most patients, including those with dementia, would benefit from being included in ACP discussions [25]. The ACP content included an open and clear communication about the patient's medical conditions, treatment choices, possible disease trajectories, and potential future medical decisions (Table 1). To facilitate initiation and ensure that the staff also asked the "difficult questions", we provided seven questions to cover important themes to be introduced in the conversation (Table 2). Due to the high prevalence of patients with advanced dementia in Norwegian NHs [6], these questions were created with family members in mind. It focused on the importance of achieving knowledge and to bring out the patient and the families' preferences not only for specific types of treatment but also for a focus on life values [12]. Timing and sensitivity to the patient and family's current situation and understanding of the patient's health status was therefore emphasized [26]. The intervention stressed that it was beneficial to create space for patients and families to discuss these issues as early as possible, instead of postponing them until a crisis required decisions to be made. Importantly, we did not recommend that decisions should be finalized at an early stage, when they do not yet appear relevant to the patient or family (e.g., use of antibiotics, or use of morphine at the end-of-life).

Frequency of ACP communication was clearly defined in the COSMOS ACP intervention (Fig. 1, step 3): (i) a meeting with the physician and primary nurse was offered within 2–3 weeks after admission and subsequently repeated quarterly, (ii) telephone contact was maintained with the family on a monthly basis (could be replaced by talks at the unit). Meetings and calls should be conducted when the patient had good periods, and if the patient could only participate in parts of the meetings, the conversation should be held with the family [27, 28]. The frequency of contact was operationalized based on the frailty of the population, with a potentially rapid deterioration in health and cognitive functioning.

Table 1 The main themes of the education programme

- Understanding the definition and perspectives of Advance Care Planning, and potential consequences of not providing Advance Care Planning
- Topics that the Advance Care Planning should cover and how to identify the patients' needs
- Potential challenges related to nursing home patients and their family (e.g. dementia, loss of capacity to consent)
- How to involve families, and initiate the communication process
- Basic considerations to ensure good communication (e.g. open-ended questions versus closed-ended, attentive listening, providing both written and verbal information)
- The necessity of organizing formal meetings and not only informal (coincidental) communication
- Practical considerations (e.g. the use of a meeting room to ensure suitable facilities and good atmosphere)
- Documentation of communication to ensure adherence in practice

Table 2 Seven key questions and themes in Advance Care Planning[a]

1. How involved have you been in the patient's treatment, care and decision-making as family, and how much would you like to be included?
2. What have both of you (patient and family) understood about the situation and the disease?
3. What kind of additional information do both of you (patient and family) need so as to better understand the situation?
4. What should we know about the patient's life and values to ensure the best care? What matters and what makes life in general meaningful?
5. What goals, ideas and expectations do you both (patient and family) have for the nursing home stay?
6. Does the patient struggle with unfinished business?
7. Have both of you (patient and family) previously discussed end-of-life treatment e.g. hospitalization in case of acute illness?

[a] The questions were listed in the ACP flash card, available as an online Additional file 2

Roles and responsibilities were clearly defined. The primary nurses were responsible for organizing meetings and maintaining the frequency of contact, which is considered a realistic task, provided proper training (Fig. 1, step 3) [22]. We emphasized that it was optimal to provide verbal and written information in the form of a meeting agenda when organizing the meetings. Based on previous research, we emphasized the value of having the physician, preferably with an established patient relationship, attend the quarterly meetings [29–31].

Documentation of the ACP communication was a vital element of the intervention. It was stressed that information regarding the patient's and family's preferences or thoughts on medical decisions should be documented and readily available for the staff on duty. Since different NHs used different record systems and routines, it was stressed that the COSMOS ambassadors should discuss with their colleagues and manager, how their documentation could be improved so that vital information was available in case of an emergency.

Implementation of advance care planning

Education programme

The content of the two-day education seminar was based on previous studies, systematic reviews, and

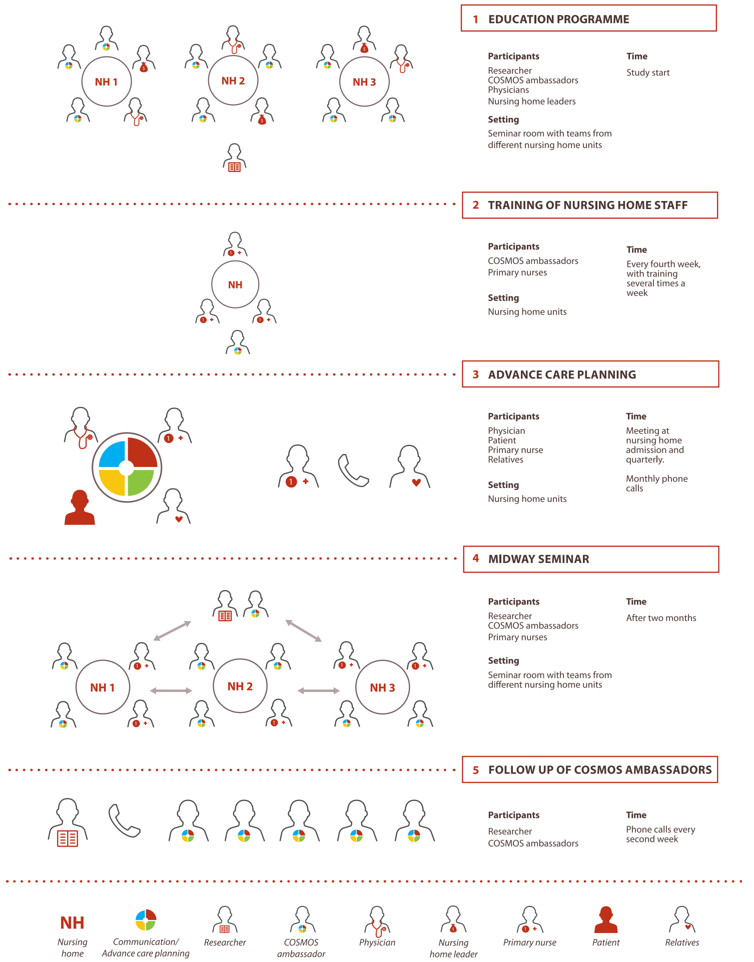

Fig. 1 Implementation of Advance Care Planning. Legend: Overview of the COSMOS ACP implementation process in the different steps. Step 1: Gathering the intervention group to the education seminar. Step 2: COSMOS ambassadors training the staff back in the NH unit. Step 3: ACP, involving patient, family, nurses and physicians by meetings, and regular phone calls. Step 4: Gathering COSMOS ambassadors and primary nurses to a midway seminar. Step 5: Researchers' follow-up of COSMOS ambassadors every second week

clinical experience [9, 22, 24]. At least two nurses from each NH unit, with hands-on experience with NH patients were required to attend the education. These participants were titled COSMOS-ambassadors (Fig. 1, step 1). The seminar was led by two of the researchers (BSH and EF). It included lectures, skills training, role-play, and rehearsed use of the implementation material (see step 1 in Fig. 1) [23]. The role-play aimed to create realistic situations and experiences on the use of open-ended questions to clarify the individuals' understanding and needs. The programme stressed that details in the formulated questions must be adapted to the patient's cognitive function [13, 14]. It was also stressed as essential that questioners must be attentive to the patient's responses, e.g. non-verbal reactions, frustration and uncertainty as a response to the use of open-ended questions especially if discussing different choices [15–17]. An important principle provided in the education was to include both patient and family in the shared conversations with the healthcare providers, even if the patient had cognitive impairment. Challenges and advantages of this principle were discussed [26]. However, an important part of the ACP education explained the need for flexibility and adaption in the communication process to ensure that both family and patient had the opportunity to partake in the decision making.

Training of NH staff

A train-the-trainer focus [32] involving the whole nursing staff in the unit was employed to ensure that the ACP implementation was sustainable [33]. After the two-day seminar, the COSMOS ambassadors were responsible for teaching their colleagues in the unit about the ACP process (Fig. 1, step 2). Based on barriers identified in our review [9], the implementation strategy did not depend on one single person, i.e., the ambassador, but also on the primary nurses and NH managers. Although time-consuming, it is crucial to educate staff in order to facilitate change and development in large organizations [34]. The ambassadors were encouraged to find an optimal setting, according to their local routine, in which to train colleagues (see Fig. 1 step 2). The researchers advised the ambassadors to talk during lunch and/or report (10–20 min.), several times per week to enable optimal coverage [35]. Since ACP was one of four COSMOS components, the ambassadors were advised to keep a focus on ACP every fourth week. However, staff were encouraged to organize an ACP meeting regardless of the week (Fig. 1, step 3).

Training material

During the two-day education seminars, the ambassadors received training material, including guidelines, educational binders, and flash cards (see Table 3). The wording in all of the training material was adapted to both registered and licensed practical nurses, aiming to appeal to all caregivers responsible for the patient.

Midway seminar

All intervention units were invited to a midway seminar after 2 months (Fig. 1, step 4), led by the research team. A brief lecture to review the ACP intervention was provided. Further, the COSMOS ambassadors presented their successes and challenges in a plenary session so that experiences, support and ideas were discussed and shared between the participating units. We used the metaphor of a traffic light to identify and organize areas of success and challenges; each NH-unit noted three successes in the implementation process “green light”, two challenging elements “yellow light”, and one element not completed at all “red light” (See traffic light illustration as online Additional file 1).

Table 3 Advance Care Planning material used to train the NH staff in the unit

What	Content
Guidelines	A booklet (two per unit) was provided to describe the content of ACP, with evidence-based facts and referenced literature.
Educational Binder	Abridged power point slides from the two-day education seminar, collected in an educational binder, used for teaching colleagues.
Flash cards	Cards which fitted in the staffs’ pocket, reminding staff of the main focus of ACP; what it is, who should participate and how often communication should be initiated. Cards also included examples of suitable questions and themes (Table 2) to be discussed in meetings.

Follow-up of COSMOS ambassadors

Researchers were in contact with the NH units during the intervention period by means of regular telephone contact every second week to support the implementation (Fig. 1, step 5). In addition, there was a telephone/email hotline (Monday to Friday 08:00–16:00).

Assessments and implementation outcomes

The NH managers filled in a questionnaire on the NH’s prior participation in research projects or quality improvement initiatives. Staff demographics and characteristics were collected for all staff involved in data collection at the NH units. Patient demographics and characteristics were recorded from the patient records. Data were collected at baseline, and at month 4.

The patients’ cognitive status was assessed by researchers using the Mini Mental State Examination (MMSE). This test provides a sum score ranging from 0 to 30 and can be used for case detection using cut-off scores, i.e. 26–30 normal cognition, 21–25 for mild dementia, 11–20 for moderate, and 0–10 for severe dementia [36, 37]. MMSE has high test-retest reliability, internal consistency and inter-rater reliability [36–39].

The acceptance of the ACP intervention was assessed by investigating whether participants attended the education programme, midway seminar and how they used the individual patient log. Further information was collected during the regular telephone call every second week. The primary nurses were responsible for documenting the implementation by filling in an individual log for each patient every fourth week. Questions in the logs are listed in Table 5. These logs were used to evaluate the outcome of the implementation process. The ACP intervention was defined as successfully implemented if the tasks in the log corresponding to questions 1 or 2 *and* 3 or 4 were completed during the 4-month trial period. The logs assessed the key ACP intervention deliverables with the following questions (Yes – No – Not applicable):

(1) Have the patient and family been invited to a conversation with the physician?

(2) Have the patient and family had a shared conversation with the primary nurse?
(3) Have there been monthly phone calls to the family?
(4) Have you had contact with the family the last month?
(5) Is the communication documented?

Additionally, there was a free text area in the logs to write comments. Together with the assessment of facilitators and barriers from the logs and the midway seminar, this provided insight about how this study contributed to implement the ACP intervention [35].

Analyses

Statistical analyses were performed using IBM SPSS Version 23. The demographics for NH staff, patients, and clinical characteristics were summarized using means and standard deviation (SD) or frequencies and percentages.

The implementation outcomes, including entries to each intervention deliverable in the log were summarized as frequencies and percentages for the whole 4-month period and for each time point (months 1, 2, 3 and 4).

The free text feedback from the logs and discussions in the midway seminar were transcribed. Categories and sub categories were identified, based on Qualitative Content Analysis in accordance to the research question: identifying facilitators and barriers [40]. Three researchers (IA, EF, and BH) read and analysed the data individually and registered the main topics that emerged [41]. Topics were identified by attending to prominent and recurring themes. Identified categories and sub categories of facilitators and barriers were then cross-compared and discussed until consensus was achieved between the researchers [41], this process was intended to achieve trustworthiness with agreement between the researchers [42]. Meaningful quotations were extracted from conversations with the nurses during the midway seminar.

Results

One municipality with four NHs declined to participate. In addition, one unit withdrew from the study, leaving 67 units from 33 NHs with 723 patients to be randomized. We subsequently excluded 178 patients due to: lack of consent (151), age < 65 years (15), moved before study start (6), terminal condition at study start (2), death before study start (1), schizophrenia (1), withdrawal of consent (1), and unknown reason (1). Accordingly, 545 patients from 67 units were included in the main study. In this paper, we investigated those receiving the intervention and implementation strategy, i.e., the intervention group, including 36 NH units, with 297 patients. All results reported below, relate to the intervention group.

Nursing home units and staff characteristics

One unit had previously participated in a research project on communication and end-of-life care, while three units had carried out local initiatives. The staff coverage was 3.2 patients each at daytime (range 1.6 to 4.0), 4.7 (2.3–6.0) in the evening, and 13.0 (4.0–30.3) at nighttime. The staff (*n* = 67) had worked an average of 18 years (SD = 10.8) in the healthcare sector, and 9 years (SD = 7.3) in the current NH unit. Close to 80% (*n* = 52) were registered nurses of whom 22% (*n* = 15) had additional education. More than 20% (*n* = 14) did not have Norwegian as their first language, originating from Europe (*n* = 8, 12%) and Southeast Asia (*n* = 6, 9%).

Patients' characteristics

The included patients (*n* = 297) had a mean age of 86.5 (SD = 7.7) years, 73% (*n* = 216) were females. As shown in Table 4 the mean MMSE score was 10.4 (SD = 7.6) and 141 (47%) patients had severe dementia [37]. During the 4-month intervention period, 33 (11%) patients died in the intervention group, 14 (5%) moved, and 13 (4%) patients were hospitalized.

The acceptance of the advance care planning intervention

Due to different starting points of the study for the nursing homes, four 2-day education seminars were completed with 105 persons attending, of which 74 were staff with daily patient contact. All participating units sent the required two nurses to the education seminar (44 registered and 9 licensed practical nurses); 7 of the 21 invited physicians attended, 24 NH managers participated, while 21 participants had other or unknown occupations. Most COSMOS ambassadors expressed that the ACP flash card was very useful. The feedback on the binders was mixed; some expressed that they were too comprehensive, while others enjoyed the opportunity to learn more about ACP. At the midway seminar, all 36 units participated with 3–4 NH employees from each

Table 4 Patients characteristics

	Patients (*n* = 297)
Age, mean (SD)	86.5 (7.7)
Females, N (%)	216 (73)
Cognition, N (%)	
MMSE	
Normal	9 (3)
Mild dementia	21 (7)
Moderate dementia	107 (36)
Severe dementia	141 (47)

MMSE: Mini Mental Status Examination
The sums of percentages of the MMSE score are not 100, due to missing values

unit (both COSMOS ambassadors and primary nurses, but no physicians). Participants reported these seminars to be helpful.

Results of the implementation of advance care planning

All units used the patient logs. 19% ($n = 56$) of the patients had no log entry over four months because most of them (77%) had moved or died during this period. As the total number of patients remaining in the study declined, the total number of patients changed throughout the intervention period. For the first four weeks, the log was filled in for 73% (215 of 294) of the patients, at week 8: 72% (206 of 288), at week 12: 50% (137 of 276) used it, and at week 16: 73% (198 of 271). Successful implementation was achieved in 183 (62%) of the patients by month 4, which means that they had fulfilled the following criteria: patient and family were invited to a meeting with the physician or the primary nurse, and family was contacted monthly by phone or in the unit. Monthly communication with family ($n = 165$, 76%) and documentation of the communication ($n = 217$, 73%) were the two most frequently conducted items (Table 5).

Facilitators for the advance care planning implementation

Based on patient logs and feedback at the midway seminars, we identified two main categories of facilitators: the clearly defined impact on routines, roles and responsibility, as well as the clear communication of the relevance of ACP (Table 6). The staff reported that the intervention's focus on institutional organization and routines, with clearly defined roles and responsibility, was helpful. For example, the primary nurses were defined as responsible for establishing communication and organizing ACP meetings for "their" patients. This left no room for arguing about "who should have done what" to achieve such meetings. The staff also reported that the specified routines for communication suggested in the ACP education (e.g. asking open-ended questions, attentive listening and using the seven key questions and themes) helped guide them to initiate and maintain contact.

> *The questions from the flash cards have helped a lot, to use as introductory questions. (They) made it much easier to address individual wishes concerning end-of-life and preferences for the individual in their daily life.*

The new routines for monthly contact helped the staff to keep families systematically updated, which substantially improved the contact with family members, including those living far away. The relevance and need for education regarding ACP was highlighted in the education seminar and material. The content of ACP was considered relevant for the daily work in the unit, and the education seminars and material were often experienced as spot-on for practical use. This helped the ambassadors to convey "the message" convincingly.

> *Talking through these questions provides a high level of assurance and the families thought it was very good to use time to talk about these subjects. It leaves few things unsaid.*

Barriers to the advance care planning implementation

Lack of time emerged as a prominent barrier, particularly time to train and involve colleagues. Furthermore, because few physicians found the time to take part in the two-day seminar, it was difficult to motivate them to participate in the intervention. Other barriers were: existing culture and staff opinions, that conflicted with the ACP intervention. For example, a common opinion was that patients with dementia should not participate in ACP conversations, while this was promoted in the ACP intervention. Lack of competence among staff also emerged as an important barrier. For example, the ambassadors experienced that untrained staff did not understand the significance of the ACP intervention, and were thus not motivated to read the guidelines and engage in the training. In addition, some staff had poor Norwegian language competence, which affected both their ability to understand the ACP content and to have

Table 5 Response in the patient logs during the intervention period of 4 months; $n = 297^{b}$

	Yes		No		Not applicable/ Don't know	
	N	%	N	%	N	%
Implemented Advance Care Planning[a]	183	62%	58	20%	0	
1. Have the patient and family been invited to a conversation with the physician?	98	33%	135	45%	7	2%
2. Have the patient and family had a shared conversation with the primary nurse?	166	56%	72	24%	2	1%
3. Have there been monthly phone calls to the family?	165	56%	62	21%	12	4%
4. Have you had contact with the family the last month?	226	76%	12	4%	2	1%
5. Has the communication been documented?	217	73%	19	6%	2	1%

[a] ACP was defined as implemented if units had completed questions 1 or 2 and 3 or 4, during the 4-month trial

[b] Due to missing data the number of participants does not add up to 297 per item

Table 6 Facilitators of and barriers to implementing ACP in the nursing home unit

Facilitators:

- Clear impact on the organization, routines and responsibilities:
  - Systematic involvement of nursing home managers
  - Systematic training of all staff in the unit to clarify new routines
  - Assigning responsibility to all primary nurses
  - Routines for dialogue between the physician and nurses (clarifying responsibilities)
  - Enabling agreement on documentation
  - Clear schedules for internal training
  - Clear schedules for conversation with patient and family
  - Clarified routines for including the patient in relevant discussions
  - Routines for communications: e.g., telephone and email
  - List of questions to clarify the needs for the patient and family, including the family's preferences for involvement
  - A specified routine for contacting the family without a specific reason
  - Defined space in staff schedule to discuss ACP as an important topic
- Clear communication of the relevance and need for education regarding ACP:
  - The education conveyed ACP as important and inspiring
  - Education showed in what way there was potential for improvement
  - The training material was understandable and improved the competence on ACP
  - Flash cards were interesting and easy to use, even when time was limited

Barriers:

- Lack of time:
  - to teach colleagues in the unit
  - for the physician to participate at the two-day education seminar, and meetings
- Conflicting opinions and culture:
  - The patient considered not capable to participate at a shared conversation
  - Perception of already sufficient contact with family
- Lack of staff competence:
  - Challenging to engage staff with lower education and understanding of ACP
  - Difficult to get everyone to read the documentation in the journal
  - Lack of documentation skills
  - Lack of Norwegian language skills
  - Too large quantity of training material for part-time or uneducated staff
  - High level of sick leave among staff leading to unskilled replacements

sensitive conversations. The cultural aspect of not being accustomed to discussing delicate matters like end-of-life care was also prominent.

Discussion

This study describes the content and implementation strategy of an ACP intervention in Norwegian NHs including patients with and without dementia. Based on the patient logs, 62% of patients and their families fulfilled the predefined criteria of having received ACP. The intervention was well received among the staff and they gave positive feedback on the close follow-up with support from the researchers every second week. The gathering of different NH units at the midway seminar motivated them to keep up the implementation of ACP. We identified facilitators, including the convincing communication of the relevance of ACP to leaders and staff, and the clearly defined routines, roles and responsibility. We also identified relevant barriers that may hinder a proper implementation process, such as lack of time, lack of competence, and conflicting culture and staff opinions. Furthermore, we discovered challenges in engaging NH physicians, as they had less time or interest to participate in the education programme and the conversation with patients and families. These results are of key importance, as they provide information on the implementation process, useful for the practical field.

This process evaluation study achieved a somewhat high implementation rate of 62%, although the result was difficult to compare with other studies due to the different operationalization of ACP. Previous studies have defined ACP as fully implemented if a legally binding document for future medical decisions (e.g., advance directive) has been completed [43, 44]. For example, in the study by McGlade et al. (2017), approximately half the participants ($n = 290$ patients) were reported to have received ACP, when implementation was defined as a completed end-of-life-form [44]. A legal document/directive is more relevant in countries with legislative and cultural pressures [9]. In Europe, several countries (e.g., Norway, Ireland, Italy, Poland and Sweden) have not yet ratified laws for advance directives, whereas 15 countries have instated specific legislation. Regardless of legislation, the numbers of completed directives do not provide insights to the process of systematically improving communication skills and providing repeated ACP discussions. The implementation strategy, implementation outcomes and the definition of successful implementation are rarely described systematically in ACP studies [9, 43, 45].

Facilitators and barriers

An important facilitator in the current study pertained to the communication and education about ACP as a crucial element of best clinical practice in NHs, which facilitated implementation and reduced the workload for the ambassadors. This is in line with facilitators identified by Livingston et al., who highlighted education and motivation as key facilitators [46]. Another crucial facilitator was the clear standards for the institutional structure, routines and staff responsibilities advocated in the COSMOS ACP intervention. This ensured that implementation was not dependent on one individual, but was anchored at the organizational level. This facilitator included several interesting subthemes, amongst which involvement of NH managers and unit leaders was crucial. We recruited NHs by motivating the top managers, who allocated resources to conduct the implementation adequately. Unlike the study by Sankaran et al. (2010), who reported that staff had difficulties attending the education [29], the managers were motivated to send their employees to the COSMOS education programme. This facilitator is also in agreement with Livingston et al., who highlighted the importance of motivated managers [46]. This strategy also answered previous findings suggesting that unclear responsibility might be a barrier for providing ACP [45].

Lack of time was identified as a main barrier in our study and has also been underlined as a major barrier in several studies on ACP in NHs [29, 45–47]. Although this is a common barrier, there is no clear answer as to how this challenge should be resolved. Alternative approaches such as focus on multidisciplinary staff competence, better organization of the NH services, and attractive working conditions for health-care students may be important contributions [48, 49]. Conflicting culture and opinions also represented an important barrier. Not all staff members were initially convinced that it was a good idea to include people with dementia in ACP discussion. The patients in our study had a low MMSE score, which complicates the implementation of ACP due to patients' inability to communicate sufficiently and provide consent. At the same time, this is the reality in the today's NH population, where most are multimorbid and have dementia, resulting in a high need for education in delivering ACP to people with reduced capacity [8, 22, 44, 48, 50, 51]. Importantly, the COSMOS education programme met this need, which subsequently influenced the feasibility, fidelity, and sustainability of the implementation [52, 53]. Some previous ACP intervention studies have included people with dementia [46, 54], others have not clearly specified cognitive status [47, 55], or only recruited cognitively intact residents [17, 43]. Dening et al. (2011) points out that ACP has benefits for people with dementia, a point which was clearly communicated in the COSMOS ACP education [22]. Another barrier pertained to lack of competence, of which lack of language comprehension was a challenge. Staff members of different nationalities demonstrated disparities in Norwegian language skills, which reduced the staff's capability to understand and formulate sensitive questions. In general, unskilled staff showed lower motivation to engage in the implementation of ACP. Previous studies suggest that reluctant personnel represent a major barrier for implementing ACP [56, 57].

We argue that implementation of ACP is a necessity in today's NH population. However, this study also has some limitations. The ACP intervention was multifold and time-consuming, which could preclude feasibility. Importantly, however, the required NH home staff attending the 2-day education seminar was achieved. The train-the-trainer approach did not have a multidisciplinary approach, as it was implemented as a part of the nurse's daily routines. In addition, the inclusion rate of physicians was rather low for the 2-day education seminar. We do not know how many training sessions each unit managed to implement; however, as the researchers kept phone contact with the COSMOS ambassadors every second week, they were able to motivate the ambassadors when needed.

The implementation rate after only 4 months suggests that a sustained focus on ACP over time may ensure its implementation. The physicians' involvement should ideally have been higher in our study, as they are responsible for the medical decision-making. ACP in the frail NH patients is complex, thus the communication need to be customized with respect for each individual [26]. This demands training of nurses and physicians to make the interdisciplinary team conscious of the complexity of ACP. Future studies may benefit from making a more top-down strategy for involving the NH physicians. Due to shift schedules and limited time, we could not assess all staff in each unit. Instead, we assessed the staff who participated in the data collection. This may have biased the data towards describing a more educated staff than generally present in the units.

This study has a comprehensive size and a variety of units, which promote generalizability. In addition, the present study provides detailed descriptions of the implementation process, the definition of successful implementation and information on the involvement of staff, which facilitates replicability and meaningful comparisons with future studies as well as the adaptability of the knowledge to the clinical field [9, 58].

Conclusion

The content of ACP was considered relevant for the daily work in the unit, and the education seminars and material were often experienced as spot-on for practical use. Monthly communication with the family was the most frequently conducted communication from the patient log, and the predefined criteria for successfully implemented ACP were largely achieved. Nursing home routines and engagement of leaders and staff were crucial facilitators, whereas lack of time and competence limited the success of implementation.

Additional files

Additional file 1: Traffic light used at the midway seminar. (PDF 49 kb)

Additional file 2: Advance Care Planning flash card front and back page. (PDF 327 kb)

Abbreviations

ACP: Advance Care Planning; COSMOS: COmmunication, Systematic assessment and treatment of pain, Medication review, Organization of activities and Safety; MMSE: Mini-Mental Status Examination; NH: Nursing home; SD: standard deviation

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Availability of data and materials
Data can be made available by reasonable request to the corresponding author.

Authors' contributions
All authors meet the ICMJE criteria for co-authorship, providing substantial intellectual contributions to the published study. BSH developed the study idea and applied for funding. BSH and EF designed the study protocol, while IA had a main role in the data collection together with CG, TH and TE. IA drafted the first version of the manuscript with supervision from BSH and EF. All authors participated in interpreting the study result, and have given final approval of the manuscript and have agreed to be accountable for all aspects of the work by ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Ethics approval and consent to participate
The Regional Ethical Committee for Medicine and Health Research Ethics, West Norway approved the study prior to initiation (2013/1765). The study is registered in clinicaltrial.gov (NCT02238652). Patients and their next of kin received both written and verbal information about the study. Written informed consent was obtained from all patients with mental capability to understand the implications of the study. The assessment of capability was done by trained researchers and the patients' health care providers. In patients lacking the ability to consent, written presumed consent was obtained from his or her legal guardian.

Consent for publication
Not applicable

Competing interests
The authors declare that they have no competing interests.

Publisher's Note

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Paper 3

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Advance Care Planning in Nursing Homes – Improving the Communication Among Patient, Family, and Staff: Results From a Cluster Randomized Controlled Trial (COSMOS)

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Introduction: The majority of nursing home (NH) patients suffer from complex diseases, including dementia. This makes advance care planning (ACP) particularly important.

Objectives: The aim was to investigate the effect of an ACP intervention on communication among NH staff, patient, and family. We further investigated whether the intervention affected nursing staff distress.

Methods: The ACP intervention was a part of the 4-month cluster randomized controlled COSMOS trial with a 9-month follow-up. Norwegian NH units (n = 72), with 765 patients were invited, and eligible units were cluster randomized to usual care or the intervention group. The ACP intervention consisted of an education program targeting all NH staff (nurses and physicians) and managers. Implementation was supported by a train-the-trainer approach, with regular phone calls from the researchers. The effect of the intervention was assessed by a data collection form and questionnaires. Nursing staff distress was assessed by the Neuropsychiatric Inventory -Nursing Home version.

Results: Five hundred and forty five patients from 67 NH units were included and randomized to the intervention (N = 297; 36 units) and control group (N = 248; 31 units). Organized meetings between the family, patient, and nurses were conducted more frequently in the intervention compared to the control group at month 4 (OR = 3.9, 95% CI = 1.6 to 9.4, p = 0.002). Monthly contact between family and nurses was also more frequent in the intervention group (OR = 6.5, 95% CI = 1.6 to 3.5, p = 0.010). Nurses and families were more satisfied with their communication in the intervention compared to the control group. Staff distress was reduced in the intervention group at month 4 (B = −1.8, 95% CI = −3.1 to −0.4, p = 0.012). The intervention effect at month 4 did not persist during follow-up at month 9.

Conclusion: Compared to control, the ACP intervention improved the communication, and family and staff satisfaction as well as reduced staff distress. However, during the follow-up period these positive effects were not persistent. Indicating the necessity for ongoing staff support regarding ACP.

Trial Registration: www.ClinicalTrials.gov (NCT02238652).

Keywords: advance care planning, dementia, nursing home, train-the-trainer, staff distress, COSMOS

INTRODUCTION

The world's population is aging rapidly (World Health Organization, 2018), and an increasing number of individuals are placed and ultimately die in nursing homes (NHs) (Hall et al., 2011). The majority of NH patients have dementia and multimorbidity is common (Gordon et al., 2014; Helvik et al., 2015). This leads to challenges in treatment and care, as the patients often have difficulties in expressing their individual needs (Selbaek et al., 2007).

Advance care planning (ACP) is an ongoing process of communication between healthcare providers, the patient and the family to clarify their understanding, wishes, values, and potential concerns about treatment and care at the end of life (Detering et al., 2010; Flo et al., 2016; Rietjens et al., 2017). Because cognitive decline and physical deterioration are difficult to predict, it is advisable that healthcare providers start the communication process even before NH admission when the person may still have capacity to make decisions for themselves (van der Steen et al., 2014; Martin et al., 2016).

The ACP process varies between NHs and countries worldwide. Local, cultural, and legal premises are essential because they determine the form and content of the ACP process (Sharp et al., 2013; Flo et al., 2016; Gjerberg et al., 2017). In a recent publication, we describe a novel ACP intervention in NHs as part of the COSMOS trial. We found that our clearly defined roles and responsibilities among the staff facilitated implementation of ACP, as well as targeting engagement of the NH managers (Aasmul et al., 2017). In a current Irish feasibility study including 290 long-term care and community hospital patients, McGlade et al. (2017) reported that more than 50% completed an end-of-life care plan, despite the reluctance of some nurses to participate in the ACP process because they thought of it as the responsibility of the NH managers (McGlade et al., 2017). In another study, Brazil et al. (2018) showed that uncertainty in decision-making related to patient care was reduced among the families who met with an ACP facilitator and received information about end-of-life care by mail (Brazil et al., 2018). Though family involvement is essential, previous studies have shown that patients and relatives rely on health personnel to initiate this type of communication (Fosse et al., 2014).

It is essential to educate the staff and create awareness of the need for ACP, and how the process should be conducted (Lacey, 2005). Today, the level of nursing staff competence varies, and training opportunities are scarce (Bing-Jonsson et al., 2016). Increasing complexity of patients' conditions along with tougher job demands may lead to a lack of competence, and subsequent feelings of hopelessness and distress (Gautun and Syse, 2013). Consequently, education may reduce the gap between the nursing staffs' competence and job demands and potentially also reduce staff distress (Sprangers et al., 2015).

Even though there has been an increased number of studies focusing on ACP, there is a need for well-powered RCTs that explore the communication in NHs, while also exploring the association with staff distress. Thus, the main objective in this paper was to investigate the effect of ACP on the communication among the NH staff, patient and family and whether the ACP intervention ameliorates staff distress. In particular, we hypothesized that the ACP intervention would:

- Improve the communication among staff, patients, and families;
- Increase the satisfaction with communication between the family and staff;
- Decrease nursing staff distress in the intervention compared to the control group.

METHODS

Study Design

The ACP intervention was a part of the multicomponent, cluster randomized controlled COSMOS trial. The COSMOS acronym refers to each of the intervention components: ***Co***mmunication (in the form of ACP), ***S***ystematic pain assessment and treatment, ***M***edication review, ***O***rganization of activities and ***S***afety. Detailed information on the design, procedure, randomization and sample size analysis is described in the published protocol (Husebo et al., 2015). In brief, the calculation of sample size was based on change in the total score of the Neuropsychiatric Inventory -Nursing Home (NPI-NH) version. It was estimated that 520 patients from 64 NH units (clusters), would yield an 80% power to detect a 25% decrease in the NPI-NH total score in the intervention group compared to the control group, with a significance level of 5%. Eligible NH units were randomized to the intervention groups or care as usual (control groups) in each of the included municipalities. The randomization procedure was constrained to ensure that the intervention or control distribution was approximately equal matched to urban and rural, and prosperous and less well-to-do status.

Participants and Settings

We invited eight municipalities from three counties in Southern Norway to participate. These included 37 NHs with 72 units and 765 patients. To achieve a representative sample, rural and urban, rich and poor municipalities were invited. The study was performed from August 2014 to December 2015.

Patients both with and without dementia were eligible to participate if they were $\geq$65 years, and had a minimum stay of 2 weeks in the NH before assessment. Exclusion criteria were: life expectancy < 6 months and schizophrenia. The intervention lasted 4 months, with assessments and data collection performed at baseline and month 4, additional follow-up assessments at month 9 were conducted to evaluate long-term effects of the intervention.

Study Intervention

In a recent publication, we provide a detailed description of the content of the ACP intervention and evaluation of the implementation process in connection with the COSMOS trial (Aasmul et al., 2017). All registered and licensed practical nurses, physicians, and NH managers were invited to a 2-day education seminar. At least two nurses from each intervention unit were obliged to participate and were appointed COSMOS ambassadors. The nurses were given responsibilities in implementing the intervention in the units and in reporting progress to the researchers. The seminar included lectures, training, and role-play. The ACP education program was founded on evidence-based knowledge about ACP (Dening et al., 2011; Norwegian Directorate of Health, 2013; Flo et al., 2016). Amongst others, the ambassadors were introduced to the definition and perspectives of ACP. They were trained in how to involve family and initiate the communication process while remaining aware of question formulation: open-ended versus closed-ended questions and attentive listening. In relation to this, essential themes formulated as seven key questions were disseminated as flashcards the staff could carry in their uniform pockets, described and illustrated in our previous publication (Aasmul et al., 2017). The ambassadors were given a thorough presentation of the implementation material to be used back in the units, as the implementation relied on a train-the-trainer strategy (Orfaly et al., 2005). The COSMOS intervention included clearly defined tasks that should be performed by either staff or physician (COSMOS deliverables): providing an invitation to the patient and family to have a conversation with the physician and/or the primary nurse. Communication between the patient's primary nurse and the family should be maintained monthly, and the family was also offered to be contacted by phone regularly by the primary nurse (phone calls could be replaced by occasional talks at the NH unit). Formal meetings including patient, family, primary nurse, and preferably the physician should be organized quarterly. Any stated preferences should be documented. To support implementation, the researchers followed up the ambassadors with phone calls every other week, and with discussions during a 1-day midway seminar comprising repetition and troubleshooting sessions.

Assessments and Outcome Measures

Patient demographics including age and gender were extracted from the medical records. Cognitive function was assessed using the Mini Mental Status Examination (MMSE). It produces a sum score ranging from 0 to 30 used to follow the course of patients or to indicate the presence of cognitive impairment using cutoff scores, i.e., points $\geq$ 26 = no/questionable impairment, 21–25 = mild impairment, 11–20 = moderate, and 0 –10 = severe impairment (Folstein et al., 1975; Perneczky et al., 2006). The MMSE has been used extensively in clinical and research settings and has high test–retest reliability, internal consistency, and inter-rater reliability (Folstein et al., 1975; Velayudhan et al., 2014).

The NH managers documented whether the unit had participated in organized efforts to improve communication procedures during the past 3 years. Demographic data on the nursing staff were collected using short paper forms, during data collection at each unit.

The nursing staff used a data collection form in both the intervention and the control group to document the communication activities for each patient. As shown in **Table 1**, this form listed five different topics of communication deliverables: (a) Conversation with the NH physician, (b) Conversation with the patient's primary nurse, (c) Monthly phone calls to the family, (d) Contact with the family the last month, and (e) Documented communication activities. The response options were yes, no, not applicable, and don't know. In the statistical analyses, the "not applicable" option was combined with the "no" category and the "don't know" option were set to missing.

To avoid situations where difficult subjects were forced on patients or family members, we encourage staff to organize a communication process with repeated meetings quarterly and to have contact with the family on a monthly basis (telephone and/or talks in the unit) (Aasmul et al., 2017). The different communication types provided during the study period were compared by the intervention and control group.

Each unit, represented by one nurse was asked to fill in a survey to document their perceived changes in communication both with the family and the physician on a Likert scale adapted from "Clinical global impression of change" (CGIC) with scores from minus 5 (*much worse communication*) to plus 5 (*much better communication*) (Olin et al., 1996; Schneider et al., 1997). A similar survey was mailed to the patients' family and legal guardians at month 4, investigating whether the family had perceived changes regarding the

TABLE 1 | Concrete communication deliverables with patient and/or family*.

Questions regarding types of communication deliverables the last month?
Have the patient and families been provided with an invitation to have a conversation with the physician?
Have the patient and families had a shared conversation with the primary nurse?
Have there been monthly phone calls to the family?
Have you had contact with the family during the past month?
Has the communication been documented?

**An overview of the registration of communication types at baseline, month 4 and month 9.*

communication with the patient's primary nurse and the NH physician. Answers were given on an identical Likert scale from minus 5 (*much worse communication*) to plus 5 (*much better communication*).

Nursing staff distress was investigated by the use of the distress scale in the NPI-NH version, also known as occupational disruptiveness scale for the NPI-NH (Cummings et al., 1994; Kaufer et al., 1998). The inventory is a 12-item *proxy-rated* instrument, addressing different neuropsychiatric symptoms in the patient, and *self-reported* distress of these symptoms for the staff (Cummings et al., 1994). The staff distress scale consists of six levels: 'not at all distressing' (0), 'minimally distressing' (1), 'mildly distressing' (2), 'moderately distressing' (3), 'severely distressing' (4), and 'extremely distressing' (5). This means that the NH staff assesses how emotionally distressing the patient's behavior is for the staff and if it entails more occupational burden (Ballard et al., 1996; Kaufer et al., 1998; Wood et al., 1999). It produces a sum score ranging from 0 to 60.

Statistical Analyses

Statistical analyses were performed using Stata version 14 and IBM SPSS version 23. Descriptive data including demographic data of the NH staff and different communication types were calculated showing means, percentages and response rates. Differences in groups at baseline were examined by independent samples t-tests for normally distributed continuous variables, Mann–Whitney U-test for non-normal distributed continuous and Pearson X^2 tests for categorical variables.

To investigate the effect of ACP on the communication between the NH staff, patient, and family, we conducted separate mixed effect logistic analyses with each of the

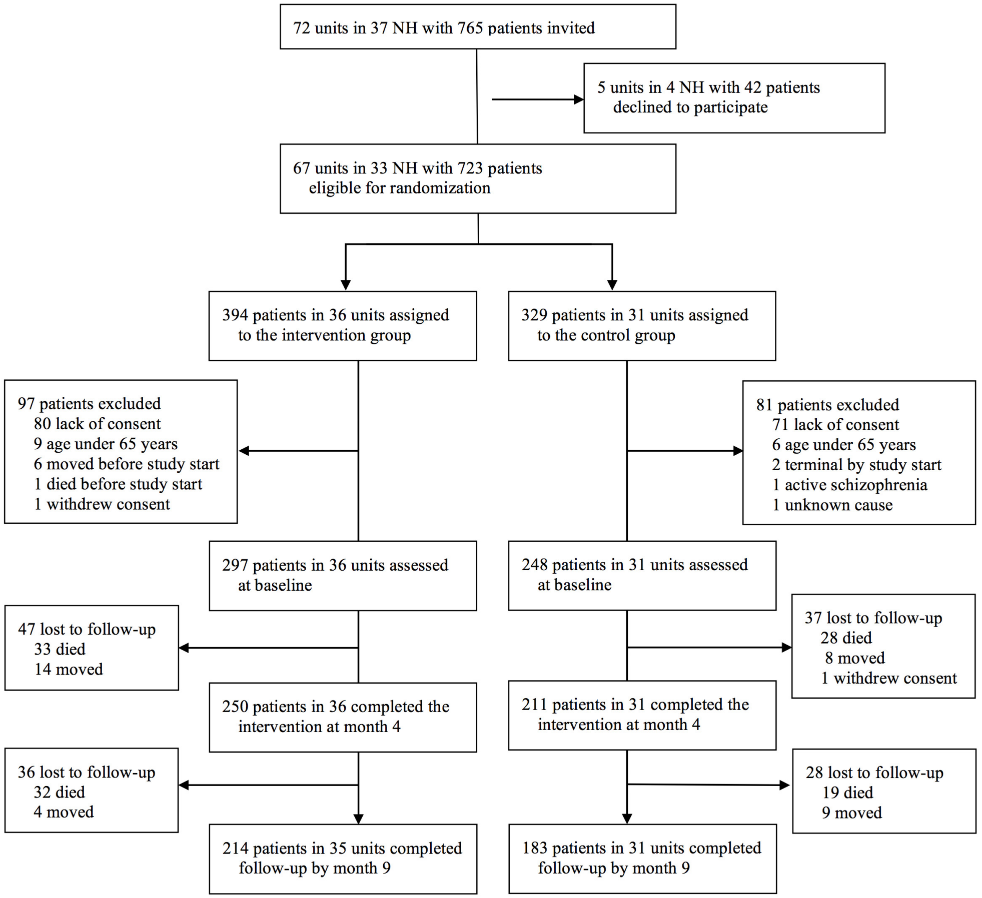

FIGURE 1 | Flow-chart showing recruitment.

following communication topics (**Table 1**) as outcome variables: (a) Conversation with the NH physician, (b) Conversation with the patient's primary nurse, (c) Monthly phone calls to the family, (d) Contact with the family the last month, and (e) Documented communication activities. Changes in the outcome measures from baseline to 4 and 9 months were estimated by mixed effect logistic regression models. We treated time as a categorical variable, and included fixed effects for time, intervention, and their interaction in the models. To account for clustering, the models were fitted with patient specific random intercepts and NH-unit specific random intercept if it improved fit. Model selections were based on likelihood ratio tests.

To investigate nurses' and families' experiences of change in communication, separate linear regressions with robust estimation of standard error were performed with perceived change related to communication with the physician and nurse as outcome variables, and the dichotomous variable intervention group or control group as predictor variable.

To analyze the effect of the intervention on staff distress, we used linear mixed effect models with restricted maximum likelihood estimation (REML). The outcome measure was the NPI-NH staff distress score. We treated time as a categorical variable, and included fixed effects for time, intervention, and their interaction in the models. To account for clustering we included random intercepts for both NH-unit effects and patient-level effects, and a NH-unit specific random slope for time. The significance level was set to 0.05.

Ethics Statement

The Regional Committee for Medical and Health Research Ethics, West Norway, approved the study (2013/1765). Written and verbal information about the study was provided to the patient and their family. The assessment of capability was done by trained researchers and the patient's health care providers. In patients lacking the ability to consent, presumed written consent was obtained from his or her legal guardian, usually a family member.

RESULTS

There were 5 units in 4 NHs with 42 patients that declined to participate, leaving 723 patients in 67 units from 33 NHs eligible for randomization. 36 units (394 patients) were randomized to the intervention group and 31 units (329 patients) to the control group (**Figure 1**). As explained in **Figure 1**, we excluded 97 patients from the intervention group and 81 from the control group, yielding 297 patients in the intervention (36 NH-units) and 248 patients in the control group (31 NH-units).

The included patients (n = 545) had a mean age of 87 years and 74% were women (**Table 2**). The mean MMSE score was 10.4 (SD = 7.6) in the intervention and 11.4 (SD = 7.9) in the control group. Of the total number of patients, 43% (n = 237) had severe cognitive impairment, and 3% (n = 18) of the patients had no or questionable cognitive impairment in accordance to the MMSE. At baseline, there were no significant differences between key patient characteristics (**Table 2**) or any of the other outcomes apart from more invitations to conversations with the NH physician reported in the intervention group (n = 28, 19%) compared to the control group (n = 15, 11%), p = 0.05 (**Table 3**). Between baseline and month 4, 13 patients were hospitalized in the intervention and 18 in the control group; this difference between groups was not significant.

As shown in **Table 4** the nurses had an average of 17.5 years of working experience from the health sector, with 9 years from the current institution. None of the units had previously provided systematic education in ACP.

As shown in **Table 5**, the registration showed an increased number of the listed communication deliverables; "shared conversations between family, patient and the primary nurse" (OR = 3.9, 95% CI = 1.6 to 9.4, p = 0.002) and "contact with the families during the last month" (OR = 6.5, 95% CI = 1.6 to 3.5, p = 0.010) in the intervention group as compared to controls. There were no significant effects on the following communication deliverables; "Conversation with the physician," "Monthly phone calls to the family," or "Documentation of the communication." Interestingly, none of the listed communication deliverables (**Table 1**) had a long-term effect at month 9.

The nurses in the intervention group reported an improved communication with the patients' families at month 4 compared to the controls (total response rate 55% n = 37/67, B = 1.9, 95% CI = 0.8 to 2.9, p = 0.001). Similarly, the families in the intervention group reported an improved satisfaction regarding the communication with the primary nurses (total response rate 67% n = 308/461, B = 0.4, 95% CI = 0.02 to 0.85, p = 0.040)

TABLE 2 | Patient characteristics and nursing staff distress at baseline.

NH patient characteristics:	**Intervention (n = 297)**	**Control (n = 248)**	***p*-Value for difference between groups**[a]
Age, mean (*SD*)	87 (7.7)	87 (7.2)	0.40
Women, % (*n*)	73% (216)	75% (186)	0.55
Cognitive function:			
MMSE[b] (0–30), Mean (SD)	10.4 (7.6)	11.4 (7.9)	0.17
No/questionable (≥26), *n* (%)	9 (3%)	9 (4%)	-
Mild (21–25), *n* (%)	21 (7%)	21 (9%)	-
Moderate (11–20), *n* (%)	107 (36%)	90 (36%)	-
Severe (0–10), *n* (%)	141 (47%)	96 (39%)	-
Neuropsychiatric symptoms:			
NPI-NH total NPS[c] (0–144), mean (SD)	17.9 (19.6)	17.6 (20.7)	0.54
Staff distress:			
NPI-NH[d] total staff distress (0–60), mean (SD)	7.3 (7.9)	6.8 (8.3)	0.33

Data are presented as mean; SD = standard deviation; n = number of patients. The assessment scales range are in the brackets. [a]*Examined by independent samples t-tests for normally distributed continuous variables, Mann–Whitney U-test for non-normal distributed continuous variables and Pearson* χ^2 *tests for categorical variables.* [b]*MMSE = Mini-Mental Status Examination, higher score shows better cognitive function.* [c]*NPI-NH total NPS = Neuropsychiatric Inventory- Nursing Home version -total Neuropsychiatric symptoms score, higher score shows more NPS.* [d]*NPI-NH total staff distress = Neuropsychiatric Inventory -Nursing home version total staff distress, higher score shows more total staff distress.*

TABLE 3 | Communication deliverables at baseline – month 4 and month 9.

	Baseline		**Month 4**		**Month 9**	
Communication types[a]:	**Intervention *N* = 297 % (*n*)[b]**	**Control *N* = 248 % (*n*)[b]**	**Intervention *N* = 250 % (*n*)[b]**	**Control *N* = 211 % (*n*)[b]**	**Intervention *N* = 214 % (*n*)[b]**	**Control *N* = 183 % (*n*)[b]**
Invitation to a conversation with the physician	19% (28) (RR = 49%)[c]	11% (15) (RR = 56%)[c]	18% (42) (RR = 96%)[c]	15% (27) (RR = 84%)[c]	21% (43) (RR = 96%)[c]	15% (25) (RR = 95%)[c]
Shared conversation with primary nurse	28% (39) (RR = 46%)[c]	29% (39) (RR = 45%)[c]	38% (89) (RR = 93%)[c]	19% (33) (RR = 81%)[c]	35% (70) (RR = 94%)[c]	25% (42) (RR = 93%)[c]
Monthly phone calls to the relatives	52% (72) (RR = 46%)[c]	44% (59) (RR = 54)%[c]	61% (147) (RR = 96%)[c]	54% (89) (RR = 79%)[c]	65% (133) (RR = 96%)[c]	64% (108) (RR = 93%)[c]
Contact with the family the last month	90% (131) (RR = 49%)[c]	91% (126) (RR = 56%)[c]	93% (224) (RR = 96%)[c]	84% (143) (RR = 81%)[c]	93% (192) (RR = 97)%[c]	90% (159) (RR = 97%)[c]
Documented communication	70% (88) (RR = 42%)[c]	59% (69) (RR = 47%)[c]	78% (176) (RR = 90%)[c]	57% (89) (RR = 74%)[c]	73% (138) (RR = 88%)[c]	65% (102) (RR = 85%)[c]

[a]The data collection form with different types of communication deliverables. [b]% (n) = percent of, and number of patients answering "yes" to each of the listed communication deliverables. [c]RR = response rate to each communication variable.

TABLE 4 | Characteristics of the proxy raters (staff participating in the data collection) (*n* = 117)[1].

Age, mean (SD)	42.3	(10.53)
Years of experience in health care, mean (SD)	17.5	(9.75)
Years of experience in this institution, mean (SD)	8.8	(6.65)
Female, *n* (%)	111	(95%)
Nationality		
Norwegian, *N* (%)	88	(75%)
Other European countries, *N* (%)	14	(12%)
South east Asia, *N* (%)	10	(9%)
Africa, *N* (%)	1	(1%)
Education level		
RN with additional education, *N* (%)	29	(25%)
RN	63	(54%)
LPN	23	(20%)
Other profession	2	(2%)

[1]Due to missing values on some items, the sum of percentages is not 100. RN = registered nurse; LPN = licensed practical nurse.

at month 4, while no changes were found – neither in the families' nor nurses' experience of satisfaction concerning the communication with the NH physician (**Table 6**).

We found a reduction in nursing staff distress in the intervention as compared to the control group at month 4 ($B = -1.8$, 95% CI = -3.1 to -0.4, $p = 0.012$) assessed by NPI-NH distress scale (**Table 5**).

DISCUSSION

During the study period of 4 months, conversations between family, patient, and the primary nurse increased in the intervention group as compared to controls. An intervention effect was found regarding increased satisfaction with communication on the part of both the nurses and the family. In addition, there was a reduction in nursing staff distress. However, the effect did not persist at follow-up assessment at month 9.

The outcomes in this study are of high clinical relevance, as they indicate that the COSMOS ACP intervention changed NH routines (i.e., increased the number of meetings and conversations) and enhanced staff competence. The increased satisfaction suggests that these changes were perceived as positive for both family and staff. This study did not focus on the traditional outcomes when introducing ACP (e.g., number of "do not resuscitate" or "do not hospitalize" orders, feeding tube); consequently, it is difficult to compare the results of the present study with previous research in NHs.

This study included a very old and frail population, with a high prevalence of dementia. Although frailty and cognitive decline is common among NH patients (Clegg et al., 2013), research indicates that it is beneficial to include people with dementia in shared conversations (Allen et al., 2003; Dening et al., 2011). This was also an important message in our education program (Aasmul et al., 2017), as it is crucial, both from an ethical and clinical point of view, to include both the patient and family in the communication process (van der Steen et al., 2014).

The lack of effect at follow-up suggests that staff support is necessary to maintain a good routine for ACP in NHs. Initiating ACP is demanding on staff members, who are advised to start the process of ACP early, aiming to build up relationships by carefully considering timing and receptiveness for all the involved (van der Steen et al., 2014). This requires both staff skills, and well-established institutional routines that promote ACP meetings (Hickman et al., 2016; Aasmul et al., 2017; McGlade et al., 2017). Our education and follow-up helped the nursing staff to develop skills to initiate ACP, while the intervention's focus on routines created a work setting that promoted such communication.

A previous study of the end-of-life care in Norwegian NHs, suggested that there is a need to involve the attending physicians and improve the communication abilities among staff (Gjerberg et al., 2011). In our study, we were successful in involving

TABLE 5 | Change in communication and staff distress.

	Baseline to month 4			Baseline to month 9			ICC[a] NH unit	ICC[b] Patient
	Within-group change		Intervention effect	Within-group change		Intervention effect		
	Intervention OR (95% CI)[c]	Control OR (95% CI)[c]	OR (95% CI)[c]	Intervention OR (95% CI)[c]	Control OR (95% CI)[c]	OR (95% CI)[c]		
Types of communication:								
Invitation to a conversation with the physician	0.9 (0.5, 1.5)	1.5 (0.7, 3.0)	1.7 (0.7, 4.1)	1.1 (0.6, 2.0)	1.4 (0.7, 2.9)	1.2 (0.5, 3.1)	–	0.13
Shared communication with the primary nurse	1.6 (0.9, 2.9)	0.4** (0.2, 0.8)	3.9** (1.6, 9.4)	1.3 (0.7, 2.4)	0.6 (0.3, 1.1)	2.3 (0.9, 5.5)	0.33	0.39
Monthly phone calls to the family	1.4 (0.8, 2.5)	1.4 (0.8, 2.5)	1.0 (0.5, 2.2)	1.9** (0.4, 1.9)	2.5** (1.4, 4.4)	0.8 (0.3, 1.7)	0.19	0.39
Contact with the family the last month	1.5 (0.5, 4.0)	0.2** (0.8, 0.6)	6.5* (1.6, 3.5)	1.3 (0.5, 3.7)	0.5 (0.2, 1.4)	2.7 (0.6, 11.4)	0.18	0.68
Documented communication	1.5 (0.8, 2.8)	0.7 (0.4, 1.3)	2.1 (0.9, 4.8)	1.1 (0.6, 1.9)	1.1 (0.6, 2.0)	1.0 (0.4, 2.3)	0.32	0.38
	B (95% CI)[d]	B (95% CI)[d]	B (95% CI)[d]	B (95% CI)[d]	B (95% CI)[d]	B (95% CI)[d]		
Total staff distress[e]	−1.4** (−2.3, −0.5)	0.4 (−0.6, 1.4)	−1.8* (−3.1, −0.4)	−0.9 (−2.1, 0.3)	0.6 (−0.7, 1.9)	−1.5 (−3.3, 0.3)	0.19	0.62

Both within and between group effects (intervention effect) from baseline to month 4 and from baseline to month 9 are provided for the entire study population. The staff reported whether the listed type of communication had been performed for each patient during the time period from baseline to month 4 and to month 9 (yes and no). [a]*Intracluster correlation on NH-units level.* [b]*Intracluster correlation on patient level.* [c]*Numbers indicate Odds Ratio for the topics of communication, where >1 equals an increase, and <a decrease.* [d]*Numbers showing changes given by coefficient and 95% confidence interval.* [e]*Staff distress assessed by Neuropsychiatric Inventory Nursing Home Version. *p-Value < 0.05; **p-value < 0.01.*

nurses, but found no increase in meetings with the physician or in satisfaction with communication with the physician. This might in part be because it was not mandatory for the physician to participate in the education seminar prior to the study. Indeed, Sharp et al. (2013) found that most physicians believed it was their professional responsibility to initiate discussions, but experienced difficulties achieving this due to limited time and lack of appropriate occasions (Sharp et al., 2013). Physicians also have limited formal training in end-of-life care, as part of their basic training (Gibbins et al., 2011; Fosse et al., 2017), and previous studies suggest a need for ACP education among physicians (Cavalieri et al., 2002; Dening et al., 2011).

We found a decrease in nursing staff distress in the intervention as compared to the control group. This is in line with previous studies, which have demonstrated a link between staff distress and staff competence in the NH setting (Aasmul et al., 2016). Increased knowledge may also empower staff members to cope with difficult symptoms (Hsu et al., 2007; Whitaker et al., 2014). The NPI-NH distress scale is associated with NPS (Wood et al., 1999; Selbaek et al., 2014). While this assessment is not optimal to uncover general staff distress, it is possible that the education and improved communication helped nursing staff to cope better with demanding symptoms of dementia. However, other variables which we had not encountered for, such as staff empathy, may have been a confounding variable. As discussed in a review by Wilkinson et al. (2017), there is evidence for a negative correlation between burnout and empathy (Wilkinson et al., 2017). Additionally, previous research suggests that other aspects such as organizational culture, the psychosocial environment and leadership affect both staff distress (Testad et al., 2010) and the implementation of ACP (Gilissen et al., 2017). To avoid potential disagreements in the NH units, the COSMOS ACP intervention aimed to clarify roles and responsibilities among staff, and involving the management. This may in turn have improved some aspects pertaining to the work environment.

TABLE 6 | Between-groups comparison regarding change in satisfaction with communication at month 4 among NH staff and family.

Communication assessed by:	Communication with family, B (95% CI)[a]	Communication with the primary nurse, B (95% CI)[a]	Communication with physician, B (95% CI)[a]
Nursing staff	1.9 (0.80, 2.91)**		0.9 (−0.57, 2.37)
Family		0.4 (0.02, 0.85)*	−0.1 (−0.47, 0.29)

[a]*Numbers showing the intervention effect by changes given by coefficient and 95% confidence interval. *p-value < 0.05; **p-value < 0.01.*

This study suggests that the NH staff had difficulties continuing with ACP conversations when follow-up by researchers ended. The external facilitation is found to be key in improving outcomes in NHs (Seymour et al., 2011; Moore et al., 2017). The concept of ACP is complex, and support and guidance of the staff may be necessary to enable the units to maintain ACP conversations as part of the NH routine. We argue that there is no easy fix in this matter; as Bing-Jonsson et al. (2016) has shown, education, guidance and support of nursing staff is greatly needed in the NH setting (Bing-Jonsson et al., 2016). We have previously detected the importance of engaging NH managers along with the staff, working hands-on with patients as an important facilitator in implementing ACP (Aasmul et al., 2017). However, it may appear that this is not enough to change the NH culture over time. In the COSMOS ACP intervention, researchers telephoned the units every second week to discuss challenges and solutions. We suggest that this type of mentoring was an important part of successful implementation, along with continued attention to regular education in the units and a clear distribution of responsibilities (Aasmul et al., 2017).

Strengths and Limitations

This study has a large sample size, with patients from different types of units, which promotes generalizability. The age and cognitive status in our study population reflects today's NH population, ensuring ecological validity. To achieve implementation of a multicomponent intervention, staff follow-up was constantly optimized during the process. The number of patients participating in the shared conversations were not registered particularly, however staff were encouraged to act with attention to timing and sensitivity toward the patient and family's current situation and understanding of the patient's health status. The researchers' close follow-up by both phone and written material allowed for a thorough evaluation of the ACP process and satisfaction among nursing staff and families. Even though, this was a cluster randomized controlled study, double-blinding was not possible. Instead, we maintained a single-blinded design, where the staff, patients, and family were not informed about group allocation. The staff, however, could deduce their group allocation if they were interested, because the NH management received information about the study, prior to the intervention.

The COSMOS trial combines several components in a multicomponent intervention. The complex design makes it more difficult to recognize whether we are measuring only the effect of ACP, or the effects of the combined components. However, we believe that the combination of these components represents the core level of care and treatment that should be expected in a modern care facility. By providing the multicomponent intervention, we ensured a minimum level of quality including ACP. It has been suggested that the extra attention from the staff (e.g., regular phone calls, discussions) contributes to increasing satisfaction among families, even if it does not measure the effect of ACP directly, it is a useful additional attribution (Sampson et al., 2011).

Implications for Clinicians and Policy Makers

This study demonstrates that nursing staff education and follow-up improves communication about care and treatment and increases satisfaction. Our results are of high importance to both policymakers and NH managers, as they demonstrate benefits of increasing competence in nursing staff. Education with ongoing support should be a priority, to ensure that we meet the needs of the NH population. The frailty and impaired cognitive function in the study population illustrates the need to educate and empower healthcare professionals to initiate the communication process early, preferably while the patient still has the capacity to make informed decisions. Importantly, a well-established ACP routine in NHs appears to require a close staff follow-up and a continued focus on education. Thus, it is timely to highlight the need for a standard of care, ensuring that NHs provide qualified ACP.

CONCLUSION

The study improved the frequency of communication and the satisfaction with communication among the patients' families and the nurses. Additionally, nursing staff distress was reduced in the intervention group. This might be related to the focus on staff knowledge and enhanced competence provided by the intervention. The intervention effect did not persist beyond the intervention period; thus, we suggest that sustaining ACP necessitated close follow-up and staff support.

AUTHOR CONTRIBUTIONS

BH developed the study idea and applied for funding. BH and EF designed the study protocol, while IA had a main role in the data collection. IA drafted the first version of the manuscript with supervision from BH and EF. Contribution to the subsequent drafts were provided by IA, BH, ES, and EF. All authors approved the final version of the manuscript.

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