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A Randomized Clinical Trial of Accelerated Transition from Oncological Treatment to Palliative Care at Home

Per Sjøgren
Palliative Research Group, Department of Oncology, Rigshospitalet, Denmark

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Something's ironic in Denmark: An otherwise progressive welfare state lags well behind in care of patients at the end of life

James M. Hoefler^{a,b,c,d}, Tove Bahn Vejgaard^{a,e,f,g}

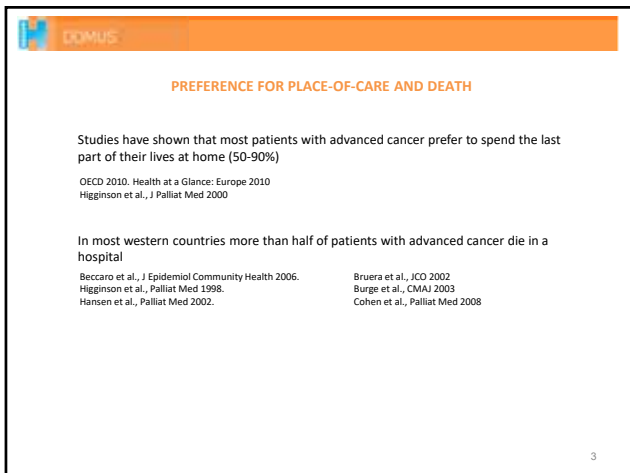
^a Medical Science, Pedersen College, Aarhus, DK, 2013, 100
^b Danish Institute for Study Abroad, Copenhagen N.C., 1451, Copenhagen, Denmark
^c Aarhus Regional Medical Center, Biomedical Ethics Committee, 3rd Avenue, Spring Hill, Larvik, SE, 1301, 104
^d Palliative Care Unit, Rigshospitalet, 1, 2140, Copenhagen, Denmark
^e Danish Association of Palliative Medicine, Fælledvej 10, 2100 Copenhagen, Denmark
^f Hospice Group, Danish, 3rd Avenue, Larvik, 1300, Larvik, Denmark
^g Hospice Group, Danish, 3rd Avenue, Larvik, 1300, Larvik, Denmark

ARTICLE INFO **ABSTRACT**

Keywords: Palliative care, Terminal care, Hospice care

Translational studies have been made in the last few decades with regard to the quality of palliative care available to patients at the end of life. But progress has not been uniform, with varying countries in the same region of the world. The objective of this study is to describe, in a comparative context, the current status of end-of-life palliative care in Denmark using quantitative research published in the past five years. This study's conclusions, based on a synthesis of the research, suggest that despite its well earned reputation as a generally progressive welfare state, Denmark tends to lag well behind its European neighbors when it comes to end-of-life care. Understanding the cultural forces that underlie this reality may help Danish health care professionals and policy makers overcome the barriers that stand in the way of providing state-of-the-art medical care to patients who suffer at the end of life.

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PREFERENCE FOR PLACE-OF-CARE AND DEATH

Studies have shown that most patients with advanced cancer prefer to spend the last part of their lives at home (50-90%)

OECD 2010. Health at a Glance: Europe 2010
Higginson et al., J Palliat Med 2000

In most western countries more than half of patients with advanced cancer die in a hospital

Beccaro et al., J Epidemiol Community Health 2006. Bruera et al., JCO 2002
Higginson et al., Palliat Med 1998. Burge et al., CMAJ 2003
Hansen et al., Palliat Med 2002. Cohen et al., Palliat Med 2008

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Preference for place-of-death among terminally ill cancer patients in Denmark

Mette Asbjørn Neergaard MD, PhD, GP Specialist Registrar^a, Anders Bonde Jensen MD, PhD (Consultant of Oncology)^b, Jens Sondergaard MD, PhD (Professor, Research Leader)^c, Ineta Sokolowski MSc, Statistician, Senior Researcher^d, Frede Olesen MD, DMS (Professor, Research Leader)^e and Peter Vedsted MD, PhD (Professor Research Leader)^f

^aThe Palliative Team, Department of Oncology, Aarhus University Hospital, Aarhus, Denmark, ^bDepartment of Oncology, Aarhus University Hospital, Aarhus, Denmark, ^cThe Research Unit for General Practice, Department for General Practice, University of Southern Denmark, Odense, Denmark and ^dThe Research Unit for General Practice, Aarhus University, Aarhus, Denmark

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Preference for place-of-death among terminally ill cancer patients in Denmark

Advancing home death is often seen as an important endpoint in palliative care, but no studies of the preferred place-of-death have yet been conducted in Scandinavia. Furthermore, we do not know if professionals' report on deceased patients' preference of place-of-death is a valid information. The aim of this study was to describe where terminally ill Danish cancer patients prefer to die and to

what most terminally ill cancer patients preferred home death (up to 86.7%). The reported preference for home death weakened as death approached (down to 68.8%). A linear regression was seen between relatives' and GPs' accounts of preference for place-of-death at the end of the palliative period (r 0.71) (also between relatives' and GPs' accounts (r 0.37). In conclusion, bereaved relatives (and GPs and GPs) report retrospectively that most terminally ill cancer patients wish to die at home. The preference weakened significantly as death approached. The agreement between relatives' and GPs' accounts on patients'

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Congruence between preferred and actual place of care and death among Danish cancer patients

Trine Brogaard *Research Unit for General Practice and Department of Family Medicine, Aarhus University School of Public Health, Denmark*

Mette A Neergaard *The Palliative Care Team, Department of Oncology, Aarhus University Hospital, Denmark*

Ineta Sokolowski *Research Unit for General Practice and Department of Family Medicine, Aarhus University School of Public Health, Denmark*

Frede Olesen *Research Unit for General Practice and Department of Family Medicine, Aarhus University School of Public Health, Denmark*

Anders B Jensen *Department of Oncology, Aarhus University Hospital, Denmark*

Abstract
Background: Meeting patients' preferences is an important outcome in palliative care. Aa Scandinavian study has reported systematically collected preferences from patients regarding place of care (POC) and place of death (POD). The extent of possible incongruence between patients' preferences and reality remains unknown.
Aim: The aim of this study was to describe patients' preferred POC and POD and changes in preferences over time and to evaluate congruence between preferences and reality. Furthermore, the aim was to search for predictive factors regarding patients' wishes and fulfillment of these.

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PLACE OF DEATH IN DENMARK

Place of death for cancer patients in Denmark:

- 57% died in hospitals
- 26% died at home

Dødsted og dødsårsager i Danmark 2007-2011

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Home-based specialized palliative care in patients with advanced cancer: A systematic review

MIE NORDEK, M.D.,^{1,2} EVA SOELBERG VADSTUUP, M.D., PH.D.,¹
PER NIELSEN, M.D., M.Sc.,^{1,2} AND GEANA PAULA RUIHTA, M.D., PH.D.,^{1,2}

¹Department of Oncology, Rigshospitalet, Copenhagen University Hospital, Copenhagen, Denmark
²Department of Clinical Medicine, Faculty of Health and Medical Sciences, Copenhagen University, Copenhagen, Denmark
³Multidisciplinary Pain Centre, Rigshospitalet, Copenhagen University Hospital, Copenhagen, Denmark

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ABSTRACT
Objective: Due to an urgent need for specialized palliative care (SPC) for patients with advanced cancer, an overview of available information on organization and outcomes of home-based SPC would be valuable. Our systematic review aims to give an overview of available information on the organization and outcomes of home-based SPC for patients with advanced cancer. Outcomes related to place of death, survival time, quality of life, performance status, and symptom management are included.
Method: A PRIO process search strategy consisting of terms related to cancer, palliation, and home care was employed. The search was conducted in PubMed, EMBASE, and Cochrane from January 1, 2000, to January 27, 2015. A hand search of the references lists of the included studies was also performed.
Results: A total of 7 articles (out of 2096 abstracts) were selected for analysis. Three additional studies were added to the hand search. Six observational and two interventional studies were

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HOME-BASED SPECIALIZED PALLIATIVE CARE IN PATIENTS WITH ADVANCED CANCER: A SYSTEMATIC REVIEW

Six observational and two interventional studies were evaluated:

- From 44 to 90% of the patients receiving home-based SPC died at home.
- Symptom control did improve over time (pain and dyspnoea)

Conclusion:
There is a lack of controlled clinical trials and organizational descriptions regarding home-based SPC for patients with advanced cancer

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CARING FOR FAMILY CAREGIVERS

Family caregivers may experience:

- Distress, poor HQoL, increased morbidity and healthcare utilization
- The prevalence of moderate to severe depression and complicated grief was 15% and 40%, respectively, at 6 months post-loss
- There is an increased awareness of the caregiver burden and interventions directed towards the patient-caregiver dyads

Song et al., Psycho-oncol 2012
Guldin et al., Support Cancer Care 2012
Guldin et al., Psycho-oncol 2013
Lee et al., Psycho-oncol 2015
Nipp et al., Ann Oncol 2016
Nielsen et al., Support Cancer care 2016

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Study Design	Randomized Controlled Trial Sample size: 340 in- and outpatients Balanced parallel-group randomization (1:1)
When and where	Cancer patients treated at the Department of Oncology, Rigshospitalet, Copenhagen University Hospital from June 2013 -> Spring 2017
Primary objective	To investigate whether an accelerated transition from oncological treatment to Specialized Palliative Care (SPC) enriched with a psychological intervention at home for patients with incurable cancer results in more patients reaching their preferred place of care and death.
Secondary objectives	To relieve the patients' symptoms To improve the patients' and the caregivers' quality of life To relieve the patients' as well as the caregivers' psychosocial problems To relieve the bereavement process among the closest relatives To prolong survival of patients To improve cooperation between professionals To analyze cost-effectiveness

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POWER CALCULATION

The primary purpose of this study is to increase the number of patients who die at home 15-20% (from 26% to 41-46%). With a power of at least 80%, and an effect difference of 15% at a significance level of 0.05, 170 patients are required in each study arm.

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INCLUSION CRITERIA

- Adult (at least 18 year old) cancer patients treated at the Department of Oncology, Copenhagen University Hospital
- Patients who want to spend as much time as possible in their own homes supported by a Specialized Palliative Team (SPT)
- Patients with incurable cancer
- Patients with no or limited antineoplastic treatment options or patients who resign antineoplastic treatment
- Patients living in the Capital Region, Denmark
- Written informed consent

EXCLUSION CRITERIA

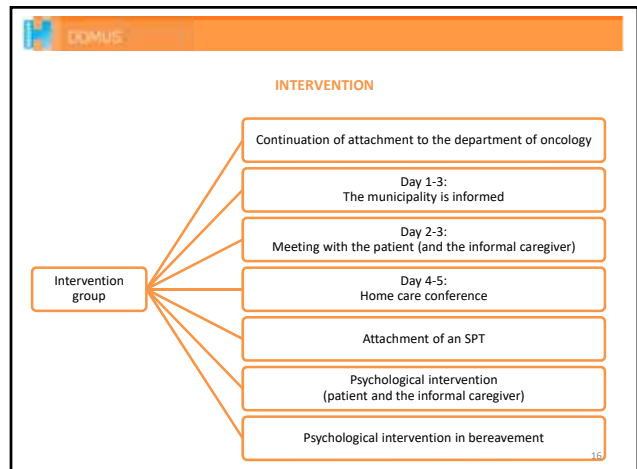
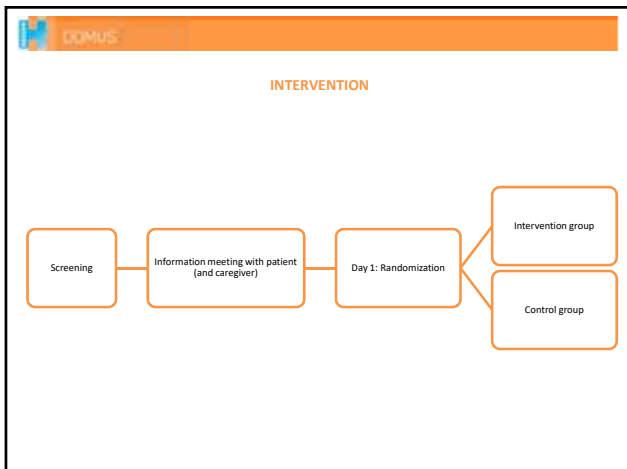
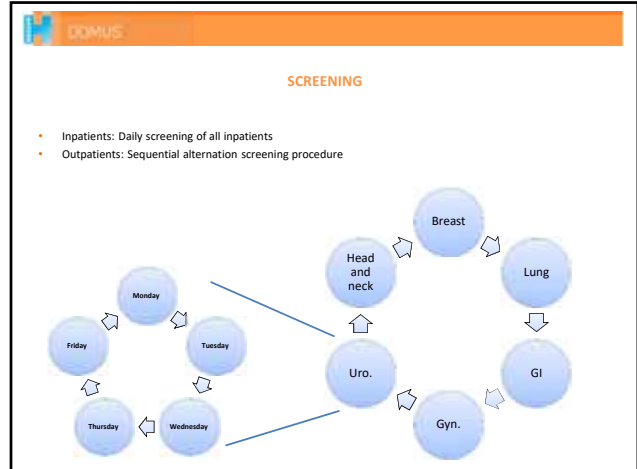
- Patients who have already been referred to an SPT
- Hospitalized patients who are not judged capable of being discharged home
- Patients who are admitted to other hospitals
- Patients who do not speak Danish well enough to answer the questionnaires
- Patients who are considered incapable of cooperating in the trial

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INCURABLE CANCER DISEASE AND LIMITED TREATMENT OPTIONS

Diagnosis	Limited treatment options
Breast cancer	Refractory to 3rd line treatment for metastatic disease
Lung cancer	Refractory to 1st line treatment for metastatic/advanced disease
Gastrointestinal cancers	Refractory to 1st line treatment for metastatic/advanced disease
Ovarian cancer / Uterine cancer	Refractory to 2nd line treatment for metastatic/advanced disease
Cervical cancer / Vulva cancer	Refractory to 1st line treatment for metastatic/advanced disease
CNS tumours	Refractory to concomitant /adjuvant chemotherapy
Prostate cancer / Bladder cancer / Penile cancer / Thyme cancer / Adrenal carcinomas	Refractory to 1st line treatment for metastatic/advanced disease
Cancer of unknown primary origin	Refractory to 1st line treatment for metastatic/advanced disease
Head and neck cancers	Refractory to radiotherapy or surgery with curative intent

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INTERVENTION- AND CONTROLGROUP		
	Intervention	Control
Contact to Health Care service	Continued treatment in department of oncology clinic and other health care services	Continued treatment in department of oncology clinic and other health care services
Specialized palliative care	Starting within 5 days with a home care conference	
Basic palliative care	Contact with the municipal home care/home nursing service within 5 days	
Psychologist	Min. 2 conversations with patients and closest relative(s) and thereafter when needed	
Needs assessment	Regular systematic assessment of symptoms and needs	

Treatment as usual but the option to be referred SPC if the need arises

ASSESSMENTS		
Patients	Closest relatives	Bereavement
<ul style="list-style-type: none"> Baseline 2, 4 og 8 weeks 6 months 	<ul style="list-style-type: none"> Baseline 2, 4 og 8 weeks 6 months 	<ul style="list-style-type: none"> 2 weeks after the patients death 2, 7, 13 and 19 months after the patients death
Symptoms and quality of life: <ul style="list-style-type: none"> EORTC-QLQ-C30 HADS ESAS-r SCL-92R 	Symptoms and quality of life: <ul style="list-style-type: none"> SCL-92R SF-36 'Caregiver burden': <ul style="list-style-type: none"> ZBI 	Symptoms and quality of life: <ul style="list-style-type: none"> SCL-92R SF-36 PSQI Grief: <ul style="list-style-type: none"> IDWL PG-13
Dyadic coping: <ul style="list-style-type: none"> DCI 	Dyadic coping: <ul style="list-style-type: none"> DCI 	Social support: <ul style="list-style-type: none"> mMOS-SS
Social support: <ul style="list-style-type: none"> mMOS-SS 	Social support: <ul style="list-style-type: none"> mMOS-SS 	Affiliation : <ul style="list-style-type: none"> ECR The experience of the patient's residence the last day

End-points

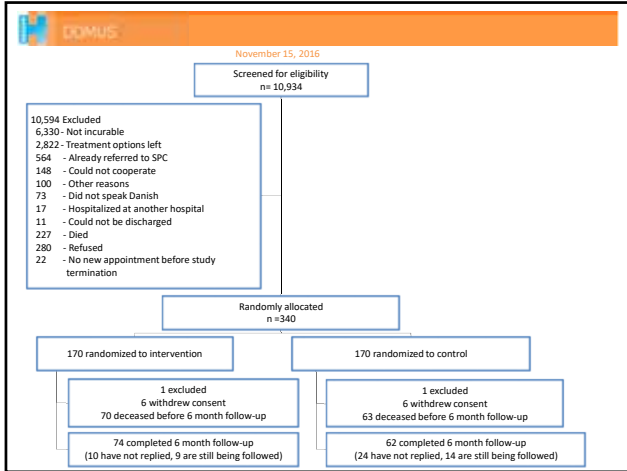
The primary outcome will be the patient's place of death/time spent: home, hospital, in-patient hospice unit, or nursing home.

Secondary outcomes:

- Survival, symptom development, psychosocial issues (e.g. psychological distress) and bereavement among relatives.
- The fast-track intervention lane will be assessed by a multi-perspective HTA (Health Technology Assessment) approach, focusing on organization, patient perceptions and health economics.

STATUS OF DOMUS

- 340 patients have been randomized
- 6 months follow-up is expected to close Marts 2017



CONSIDERATIONS

- National and international relevance
- Clinical applicability
- Organization of SPC in the future

RCTS IN SPECIALISED PALLIATIVE CANCER CARE

Author, journal, year	Country	Design	Cancer site	Sample size (intervention/control)	Duration	Primary aim	Effect	Secondary aim
Mahon et al., EJC 2016	Italy	RCT	1 site	207 107/200	Until death	• QoL ↑	• Physical symptoms ↓ • Depression ↓ • Anxiety ↓ • Overall survival ↑ • Resource use ↓ • Place of death ↓	
Tennel et al., unpublished 2016	USA Boston	RCT	1 site	275	22 and 24 weeks	• QoL ↑ • Mood ↓		
Grønmo et al., unpublished 2015	Denmark	RCT	6 sites	297 140/152	8 weeks	• QoL ↓	• Physical symptoms ↓ • Depression ↓ • Anxiety ↓ • Family ↓ • Survival ↓ • Satisfaction with care ↓ • (Economic) consequences ↓	
Bakula et al., JCO 2015	USA New Hampshire	RCT	6 sites	207 104/203	Until death	• QoL ↓ • Physical symptoms ↓ • Mood ↓ • 3 year survival ↑ 35%	• Overall survival ↓ • Resource use ↓ • Physical death ↓	
Zimmermann et al., The Lancet 2014	Canada	Cluster RCT	4 sites	455 228/233	16 weeks	• QoL after 3 months ↓	After 3 months • Physical symptoms ↓ • QoL ↓ • Satisfaction with care ↑ • Interaction between staff and patient ↓	After 4 months • QoL ↑ • Physical symptoms ↓ • QoL ↓ • Satisfaction with care ↑ • Interaction between staff and patient ↓
Tennel et al., NEJM 2010	USA Boston	RCT	1 site	331 77/74	22 weeks	• QoL ↑	• Depression ↓ • Survival ↓ • Aggravation of end-of-life care ↓ • Better documentation of resident preferences in electronic medical record	
Bakula et al., JAMA 2009	USA New Hampshire	RCT	4 sites	322 162/161	Until death	• QoL ↑ • Physical symptoms ↓ • Resource use ↓	• Overall survival ↓	
Jordhej et al., JCO 2001	Norway	Cluster RCT	3 SD sites	434 235/199	6 months	• QoL ↓ • Physical symptoms ↓ • Mood ↓ • Place of death: death at home ↑ 30%		

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RESEARCH TEAM

DOMUS is a collaboration between Rigshospitalet, Copenhagen University Hospital (RH), University of Copenhagen (KU), the Danish Cancer Society (KB), Knowledge Centre for Rehabilitation and Palliative Care (Repha) and The Danish Institute for Local and Regional Research (KORA).


DOMUS research consortium:
 Per Sjøgren, MD, DMSc (Study leader, RH, KU)
 Hans Von Der Maase, MD, DMSc (RH)
 Christoffer Johansen, MD, DMSc (RH, KB)
 Jakob Kjellberg, MSc (KORA)
 Helle Timm, MSc, PhD (PAVI)

Four PhD Fellows:
 Mie Nordly, Cand.scient.
 Kirstine Skov Benthien, Cand.scient.san.
 Annika v. Heymann-Horan, Cand.psych.

One student
 Kristina Rosengaard Holmenlund


Two project nurses:
 Lisbeth Grave Bendixen
 Helle Jensen

Two project psychologist:
 Cathrine Kingo
 Julie Ailing Skaarup

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 Kraftens Bekæmpelse

