Phase 2 trial of Symptom screening with Targeted Early Palliative care (STEP) for patients with advanced cancer

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Annual Meeting on Supportive Care in Cancer
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Has no real or apparent conflicts of interest to report.
Background

- Early palliative care (EPC) delivered by specialized teams improves quality of life, and is recommended routinely for patients with advanced cancer, but may not be practicable.

Study objective

- To conduct a phase 2 trial of STEP, a novel intervention of targeted EPC based on symptom screening, to plan for a larger randomized controlled trial.
Randomised clinical trial of early specialist palliative care plus standard care versus standard care alone in patients with advanced cancer: The Danish Palliative Care Trial

Mogens Groenvold, Morten Aagaard Petersen, Anette Damkier, Mette Asbjoern Neergaard, Jan Bjorn Nielsen, Lise Pedersen, Per Sjogren, Annette Sand Strømgren, Tove Bahn Vejlgaard, Christian Gluud, Jane Lindschou, Peter Fayers, Irene J Higginson, and Anna Thit Johnsen.
## Cancer EPC Trials: Summary

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<td>Caregiver outcomes</td>
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<td>EOL care/service use</td>
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Inpatients and outpatients with advanced cancer should receive dedicated palliative care services, early in the disease course, concurrent with active treatment.

ASCO Clinical Guideline
Ferrell et al. J Clin Oncol 2017
Methods

• **Single arm trial** to determine feasibility of a larger phase III trial

• **Participants:** advanced cancer, ECOG 0-2, clinical prognosis ≥6 months, recruited from Lung, GI, GU, Breast and Gyne outpatient clinics

• Outcome measures completed at baseline, 2, 4, 6 months (primary endpoint)
**STEP Intervention**

- ESAS-r screening at every oncology visit
  - Participant meets symptom criteria and email is sent to study triage nurse
    - Triage nurse calls patient to assess symptom and offer EPC visit
      - Patient accepts EPC referral
        - Patient is seen in EPC clinic within 1-2 weeks
      - Patient defers EPC referral
        - Triage nurse communicates with oncology team regarding follow-up of symptoms
    - Patient does not meet symptom criteria
      - Symptom criteria:
        - **Group 1 ≥4**
          - Pain, dyspnea, nausea, depression, anxiety
        - **Group 2 ≥7**
          - Fatigue, drowsiness, appetite, well-being

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Your Symptoms Matter

Edmonton Symptom Assessment System Revised (ESAS-r)

Please circle the number that best describes how you feel NOW:

<table>
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<tr>
<th>Symptom</th>
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Worst Possible

Pain
Tiredness
Drowsiness
Nausea
Lack of Appetite
Shortness of Breath
Depression
Anxiety
Wellbeing
Other Problem
Outcome Measures

Quality of life
- QUAL-E: Quality of Life at the End of Life
- FACIT-Sp: Functional Assessment of Chronic Illness Therapy—Spiritual Well-Being

Symptom control
- ESAS-r-CS: Edmonton Symptom Assessment System-revised + constipation and trouble sleeping

Depression
- PHQ-9: Patient Health Questionnaire

Satisfaction with care
- FAMCARE-P16: FAMCARE patient satisfaction with care
Feasibility Criteria

i.  ≥100 patients accrued in 12 months

ii.  ≥70% complete screening for ≥70% of visits

iii.  ≥60% of those for whom a call is triggered meet at least once with the EPC team

iv.  ≥60% complete measures at each endpoint
Results - Feasibility

✓ From Nov 2016 to Jan 2018, **116** patients enrolled

✓ **77%** (89/116) completed screening for ≥70% of visits

✓ 59% (69/116) received a triggered call
  • of those **62%** (43/69) received palliative care
  • 3 further patients referred by oncologist

- Measure completion: **79%** (81/116) at 2 mo, **61%** (71/116) at 4 mo, **57%** (66/116) at 6 mo
Results: Outcomes

ESAS-r screening at every oncology visit

Participant meets symptom criteria and email is sent to study triage nurse

Triage nurse calls patient to assess symptom and offer EPC visit

Patient does not meet symptom criteria

Symptom criteria:
- Group 1 ≥4
  - Pain, dyspnea, nausea, depression, anxiety
- Group 2 ≥7
  - Fatigue, drowsiness, appetite, well-being

Patient accepts EPC referral

Patient is seen in EPC clinic within 1-2 weeks

Triage nurse communicates with oncology team regarding follow-up of symptoms

Patient defers EPC referral
Results - Outcomes

Compared those accepting and those declining palliative care when offered by the triage nurse. By trial end (6 months), patients who accepted palliative care had:

- better symptom control (ESAS-r-CS, p=0.02)
- less deterioration in mood (PHQ-9, p=0.003)
- similar QOL and satisfaction with care
Conclusions

• **STEP is feasible** for delivering early palliative care to patients with advanced cancer who have higher symptom burden

• More than half of patients with advanced cancer have moderate to severe symptoms

• Acceptance of the triggered early palliative care visit should be encouraged
Acknowledgments

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