



# 2019

21-23 JUNE

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

# MASCC/ISOO

Annual Meeting on Supportive Care in Cancer

[www.mascc.org/meeting](http://www.mascc.org/meeting)

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# Conflict of Interest Disclosure

Camilla Zimmermann, MD, PhD, FRCPC

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.



# Effects of a Palliative Care Intervention on Clinical Outcomes in Patients With Advanced Cancer

The Project ENABLE II Randomized Controlled Trial

Marie Bakitas, DNSc, MEd  
Kathleen Doyle Lyons,  
Mark T. Hegel, PhD  
Stefan Balan, MD  
Frances C. Brokaw, MD  
Janette Seville, PhD  
Jay G. Hull, PhD  
Zhongze Li, MS  
Tor D. Tosteson, ScD

ORIGINAL ARTICLE

## Early Palliative Care for Patients with Metastatic Non-Small-Cell Lung Cancer

Jennifer S. Temel, M.D., Joseph A. Greer, Ph.D., Alona Muzi  
Emily R. Gallagher, Ph.D., Sonal Admane, M.B., B.S.,  
Michael M. Dahlin,  
William F. Pirl,  
David J. Lynch, M.D.

Original Research

Systematic versus on-demand early palliative care: results from a multicentre, randomised clinical trial

Marco Maltoni<sup>a</sup>, Emanuela Scarpi<sup>b,\*</sup>, Monia Dall'Agata<sup>b</sup>,  
Leonel C. Raffaella Bertè<sup>d</sup>, Daris Ferrari<sup>c</sup>,  
Claudia Brogna<sup>f</sup>, Roberto Bortolussi<sup>g</sup>, Leonardo Trentin<sup>h</sup>,  
Lorenzo I. Sara Pini<sup>i</sup>, Alberto Farolfi<sup>i</sup>, Andrea Casadei Gardini<sup>i</sup>,  
Enrico B. Dino Amadori<sup>i</sup> on behalf of Early Palliative Care Italian  
Group (EPCISG)

THE LANCET  
2014; 383: 1721-30

## Early palliative care for patients with advanced cancer: a cluster-randomised controlled trial

Camilla Zimmermann, Nadia Swami, Monika Krzyzanowska, Breffni Hannon, Natasha Leighl, Amit Oza, Malcolm Moore, Anne Rydall,  
Gary Rodin, Ian Tannock, Allan Donner, Christopher Lo



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## 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<sup>1,2</sup>, Morten Aagaard Petersen<sup>1</sup>,  
Anette Damkier<sup>3</sup>, Mette Asbjørn Neergaard<sup>4</sup>,  
Jan Bjoern Nielsen<sup>5</sup>, Lise Pedersen<sup>1</sup>, Per Sjøgren<sup>6</sup>,  
Annette Sand Strömberg<sup>6</sup>, Tove Bahn Vejlgård<sup>7</sup>,  
Christian Gluud<sup>8</sup>, Jane Lindschou<sup>8</sup>, Peter Fayers<sup>9,10</sup>,  
Irene J Higginson<sup>11</sup> and Anna Thit Johnsen<sup>1,12</sup>



## Effect of early and systematic integration of palliative care in patients with advanced cancer: a randomised controlled trial

Gaëlle Vanbutsele, Koen Pardon, Simon Van Belle, Veerle Surmont, Martine De Laat, Roos Colman, Kim Eeckloo, Veronique Cocquyt, Karen Geboes,  
Luc Deliens

### Summary

**Background** The benefit of early integration of palliative care into oncological care is suggested to be due to increased psychosocial support. In Belgium, psychosocial care is part of standard oncological care. The aim of this randomised controlled trial is to examine whether early and systematic integration of palliative care alongside standard psychosocial oncological care provides added benefit compared with usual care.

Lancet Oncol 2018; 19: 394-404  
Published Online  
February 2, 2018  
[http://dx.doi.org/10.1016/S1473-0245\(18\)30060-3](http://dx.doi.org/10.1016/S1473-0245(18)30060-3)





# Cancer EPC Trials: Summary

Outcomes	Bakitas et al, 2009	Temel et al, 2010	Zimmermann et al, 2014	Bakitas et al, 2015	Maltoni et al, 2016	Temel et al, 2016	Groenvold et al, 2017	Vanbutsele et al, 2018
QOL	+	+	+	=	+	+	=	+
Physical Symptoms	=	+	+	=	+	na	=/+ (nausea)	=
Depression	+	+	na	=	=	+	=	=
Patient satisfaction with care	na	na	+	na	=	na	na	na
Caregiver outcomes	= burden	na	+ satisfaction with care = QOL	+ mood = QOL	na	+ mood =/+ QOL	na	not yet reported
EOL care/ service use	=	+	na	=	+/=	na	na	na
Survival	=	+	na	+	na	na	=	=



Kavalieratos et al. JAMA 2016, Haun et al. Cochrane 2017, Gaertner et al. BMJ 2017, Hui et al. Ca Cancer J Clin, 2018



# ASCO Clinical Guideline

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  $\geq 6$  months, recruited from Lung, GI, GU, Breast and Gyne outpatient clinics
- Outcome measures completed at baseline, 2, 4, 6 months (primary endpoint)



**2019**

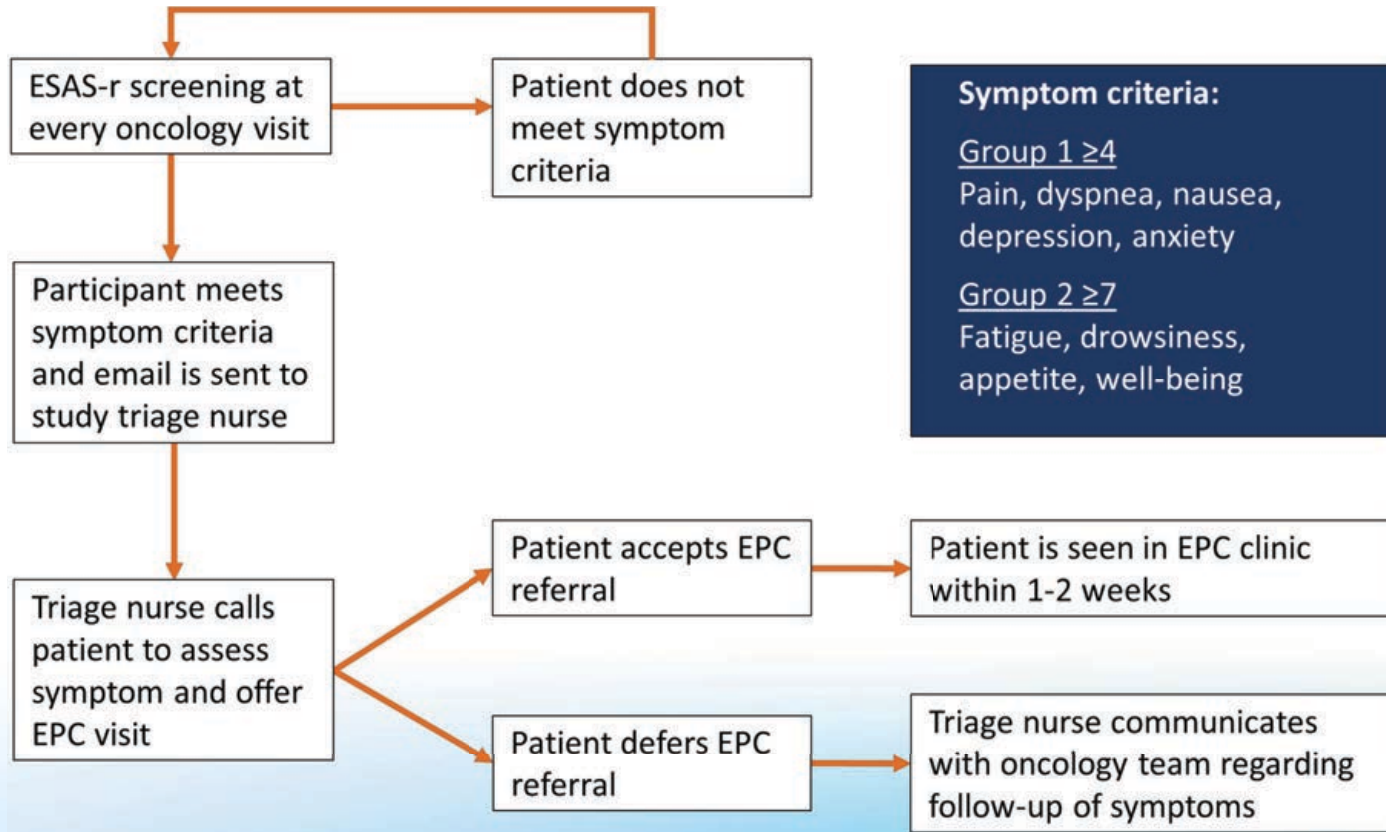
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# STEP Intervention



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# ESAS-r

## Your Symptoms Matter



Edmonton Symptom Assessment System-Revised  
(ESAS-R)

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

No Pain	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Pain
No Tiredness <i>(Tiredness = lack of energy)</i>	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Tiredness
No Drowsiness <i>(Drowsiness = feeling sleepy)</i>	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Drowsiness
No Nausea	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Nausea
No Lack of Appetite	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Lack of Appetite
No Shortness of Breath	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Shortness of Breath
No Depression <i>(Depression = feeling sad)</i>	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Depression
No Anxiety <i>(Anxiety = feeling nervous)</i>	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Anxiety
Best Wellbeing <i>(Wellbeing = how you feel overall)</i>	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Wellbeing
No Other Problem <i>(for example constipation)</i>	0	1	2	3	4	5	6	7	8	9	10	Worst Possible



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# 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.  $\geq 100$  patients accrued in 12 months
- ii.  $\geq 70\%$  complete screening for  $\geq 70\%$  of visits
- iii.  $\geq 60\%$  of those for whom a call is triggered meet at least once with the EPC team
- iv.  $\geq 60\%$  complete measures at each endpoint

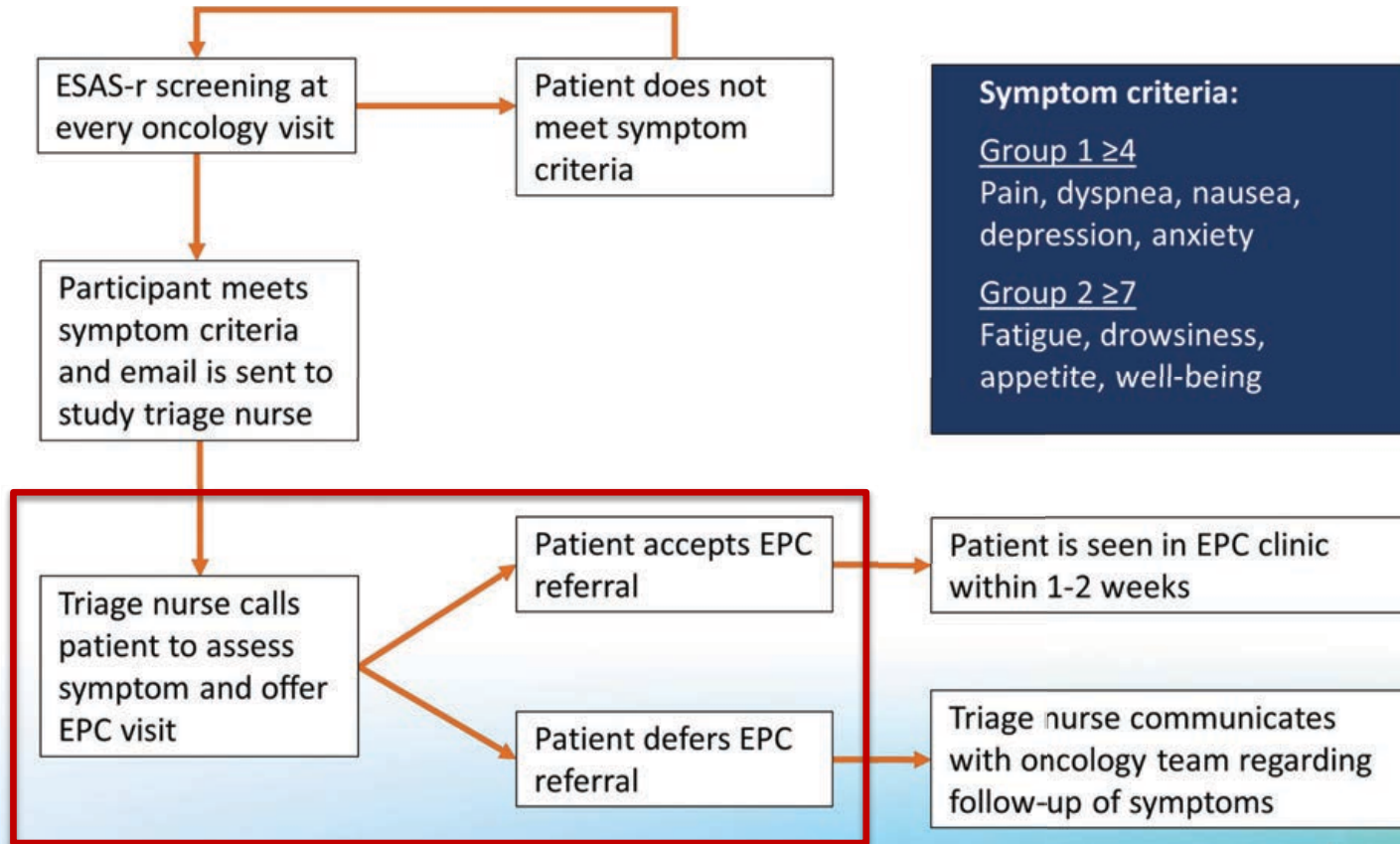


# Results - Feasibility

- ✓ From Nov 2016 to Jan 2018, **116** patients enrolled
- ✓ **77%** (89/116) completed screening for  $\geq 70\%$  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



## Symptom criteria:

### Group 1 $\geq 4$

Pain, dyspnea, nausea, depression, anxiety

### Group 2 $\geq 7$

Fatigue, drowsiness, appetite, well-being



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# 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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