

PROMs in routine clinical practice : Evidence on the impact of routine use of HRQOL tools on patient care

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Sistema Socio Sanitario

Regione
Lombardia



Disclosure

I have no actual or potential conflict of interest in relation to this presentation



Outcomes in Cancer care

- With improved cancer treatment modalities, the number of people living with cancer and of cancer survivors is rising.
- Survival and detection of recurrence are still the main pillars of cancer care follow-up.
- However patient-centred outcomes, such as health-related quality of life (HRQoL), functional impairment, pain, psycho-social aspects, are factors of great significance for patients.
- Monitoring patient-centered outcomes is then needed to get the whole picture of cancer burden and treatment outcomes.



PROMS application

- PROMs in clinical practice (micro level-patient level)
- PROMs in quality improvement and clinical research (meso level-group level)
- PROMs in population surveillance and health policy (macro level-population level)



PROMS application

- PROMs in clinical practice (micro level-patient level)
“as an intervention”:
Physical and psycho-social symptom screening followed by intervention
- PROMs in quality improvement and clinical research (meso level-group level)
- PROMs in population surveillance and health policy (macro level-population level)



Impact of PROMs as intervention: what is the evidence?

Literature reviews on routine PROMs use in health care published from late 1990s until today, identify an heterogeneous body of evidence :

- Intervention and assessment systems
- Study design
- Sample size
- Population
- Outcome

..... heterogeneous results

(Ishaque et al 2019)



Impact of PROMs as intervention: what is the evidence in cancer care?

Focus on systematic reviews of controlled trials in cancer care (up to 2019)

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JOURNAL OF CLINICAL ONCOLOGY

REVIEW ARTICLE


What Is the Value of the Routine Use of Patient-Reported Outcome Measures Toward Improvement of Patient Outcomes, Processes of Care, and Health Service Outcome in Cancer Care? A Systematic Review of Controlled Trials

Grigorios Kotronoulas, Nora Kearney, Roma Maguire, Alison Harrow, David Di Domenico, Suzanne Croy, and Stephen MacGillivray

Supportive Care in Cancer (2021) 29:573–593
<https://doi.org/10.1007/s00520-020-05695-4>

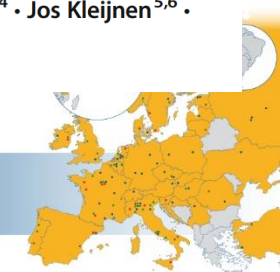
REVIEW ARTICLE

Patient outcomes, patient experiences and process indicators associated with the routine use of patient-reported outcome measures (PROMs) in cancer care: a systematic review

Caitlin Graupner^{1,2}  · Merel L. Kimman³ · Suzanne Mul¹ · Annerika H. M. Slok⁴ · Danny Claessens⁴ · Jos Kleijnen^{5,6} · Carmen D. Dirksen³ · Stéphanie O. Breukink^{1,2}



Organisation of European Cancer Institutes - EEIG



Summary of evidences up to 2019

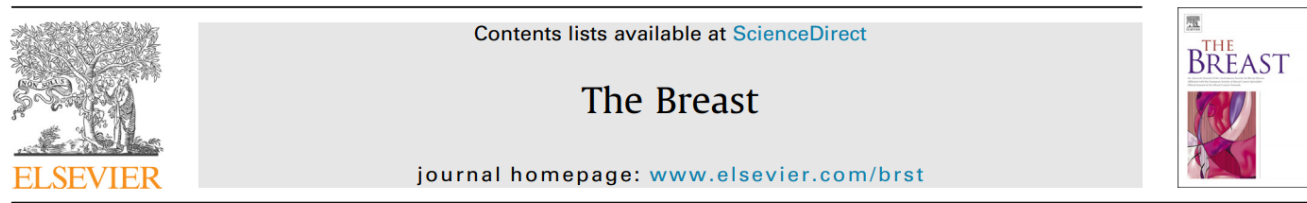
- Predominantly positive findings (at times not statistically significant) were found in the use of a PROM in daily cancer care.
- There is a trend towards better outcomes in specific symptoms, HRQoL, and patient-physician communication.
- Patient satisfaction with care did not improve significantly, possibly owing to the presence of ceiling effects
- Effect sizes shown are low to moderate (complex interventions)



Summary of evidences since 2020 controlled trials



Fjell et al. (The Breast 2020)



Reduced symptom burden with the support of an interactive app during neoadjuvant chemotherapy for breast cancer – A randomized controlled trial



Maria Fjell ^{a,*}, Ann Langius-Eklöf ^a, Marie Nilsson ^{a,b,c}, Yvonne Wengström ^{a,d}, Kay Sundberg ^a

^a Karolinska Institutet, Department of Neurobiology, Care Sciences and Society, Division of Nursing, Stockholm, Sweden

^b Karolinska University Hospital, Function Area Social Work in Health Care, Stockholm, Sweden

^c Stockholm County Council, Academic Primary Health Care Center, Stockholm, Sweden

^d Karolinska University Hospital, Cancer Theme, Stockholm, Sweden

Study design	RCT- 2 University hospital
Target population	Breast cancer patients planned for NACT
Sample size	149 pts (1:1)
Intervention	ePROM with feedback
Outcomes	symptom burden-HRQOL



Fjell et al. (The Breast 2020)

ePROMs group achieved:

- less overall symptom distress ($p < .004$).
- higher emotional functioning on EORTC QLQ-C30 ($P < .008$)
- lower scores in the total MSAS ($p < .033$).
- effect size ranged between 0.26 and 0.34



Absolom et al. (JCO 2021)

original report

Phase III Randomized Controlled Trial of eRAPID eHealth Intervention During Chemotherapy



Kate Absolom, PhD^{1,2}; Lorraine Warrington, PhD¹; Eleanor Hudson, MSc³; Jenny Hewison, PhD, MSc²; Carolyn Morris, BA⁴; Patricia Holch, PhD^{1,5}; Robert Carter, HND, OND¹; Andrea Gibson, RGN^{1,6}; Marie Holmes, MSc¹; Beverly Clayton, RGN¹; Zoe Rogers, MSc¹; Lucy McParland, MSc³; Mark Conner, PhD⁷; Liz Glidewell, MA, PhD, MSc²; Barbara Woroncow, MA⁸; Bryony Dawkins, MSc²; Sarah Dickinson, BSc¹; Claire Hulme, MA, PhD^{2,9}; Julia Brown, MSc³; and Galina Velikova, MD, PhD^{1,6}

Study design

RCT –single centre

Target population

variuos cancer diagnoses

Sample size

508 pts (1:1)

Intervention

ePROM + feedback + alerts

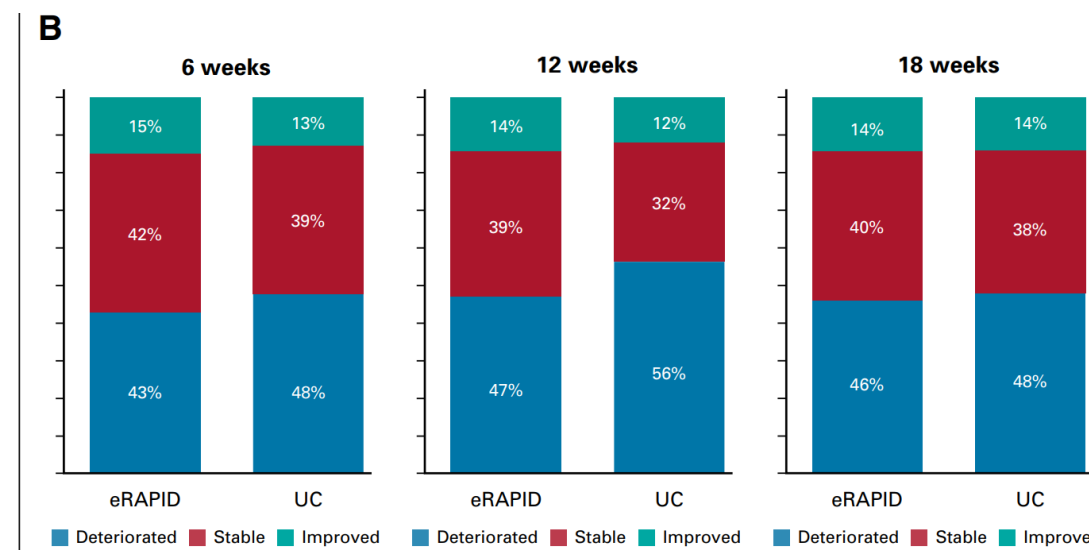
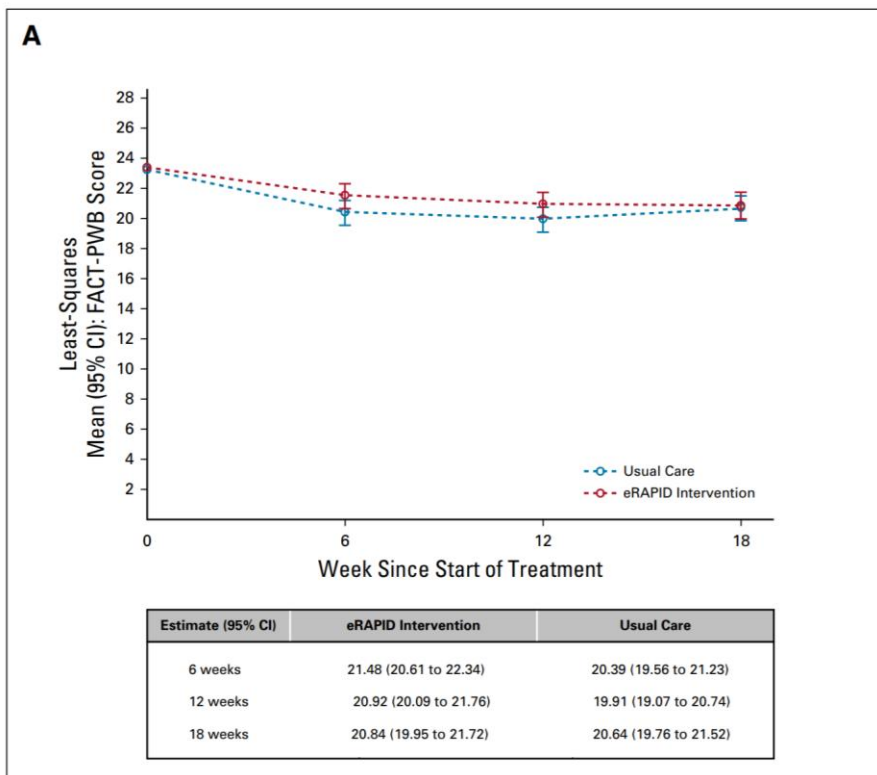
Outcomes

phys WB -HRQOL



Absolom et al. (JCO 2021)

Symptom Monitoring: An eHealth Intervention During Chemotherapy



Maguire et al. (BMJ 2021)

RESEARCH

 OPEN ACCESS

 Check for updates

Real time remote symptom monitoring during chemotherapy for cancer: European multicentre randomised controlled trial (eSMART)

Roma Maguire,¹ Lisa McCann,¹ Grigorios Kotronoulas,² Nora Kearney,³ Emma Ream,⁴ Jo Armes,⁴ Elisabeth Patiraki,⁵ Eileen Furlong,⁶ Patricia Fox,⁶ Alexander Gaiger,⁷ Paul McCrone,⁸ Geir Berg,⁹ Christine Miaskowski,¹⁰ Antonella Cardone,¹¹ Dawn Orr,¹² Adrian Flowerday,¹³ Stylianos Katsaragakis,⁵ Andrew Darley,¹⁴ Simone Lubowitzki,⁷ Jenny Harris,⁴ Simon Skene,¹⁵ Morven Miller,¹ Margaret Moore,¹ Liane Lewis,¹⁶ Nicosha DeSouza,¹⁷ Peter T Donnan¹⁷

Study design	RCT –international multicentre
Target population	non-metastatic various cancer diag.
Sample size	829 pts (1:1)
Intervention	ePROM with feedback + alert + recommend
Outcomes	symptom burden-HRQOL



Maguire et al. (BMJ 2021)

The analysis showed between group differences in favour of ePROMs

- Total symptom burden score (-0.15 , $P < 0.001$)
- Global distress index (-0.21 , $P < 0.001$)
- Psychological symptoms (-0.16 , $P < 0.001$)
- Medium effect sizes (around 0.5)




Pappot et al. (Breast Cancer 2021)

Breast Cancer (2021) 28:1096–1099
<https://doi.org/10.1007/s12282-021-01244-x>

ORIGINAL ARTICLE



Clinical effects of assessing electronic patient-reported outcomes monitoring symptomatic toxicities during breast cancer therapy: a nationwide and population-based study

Helle Pappot^{1,2}  · Christina W. Baeksted^{1,2} · Aase Nissen¹ · Ann Knoop² · Sandra A. Mitchell³ · Jane Christensen¹ · Niels Henrik Hjollund^{4,5} · Christoffer Johansen^{2,6}

Study design	cluster RCT -11 oncol. Dep.
Target population	breast cancer patients (adjuv. chemoth.)
Sample size	682 pts (1:1)
Intervention	ePROM with feedback
Outcomes	treatment adjustment-hospitalization



Pappot et al. (Breast Cancer 2021)

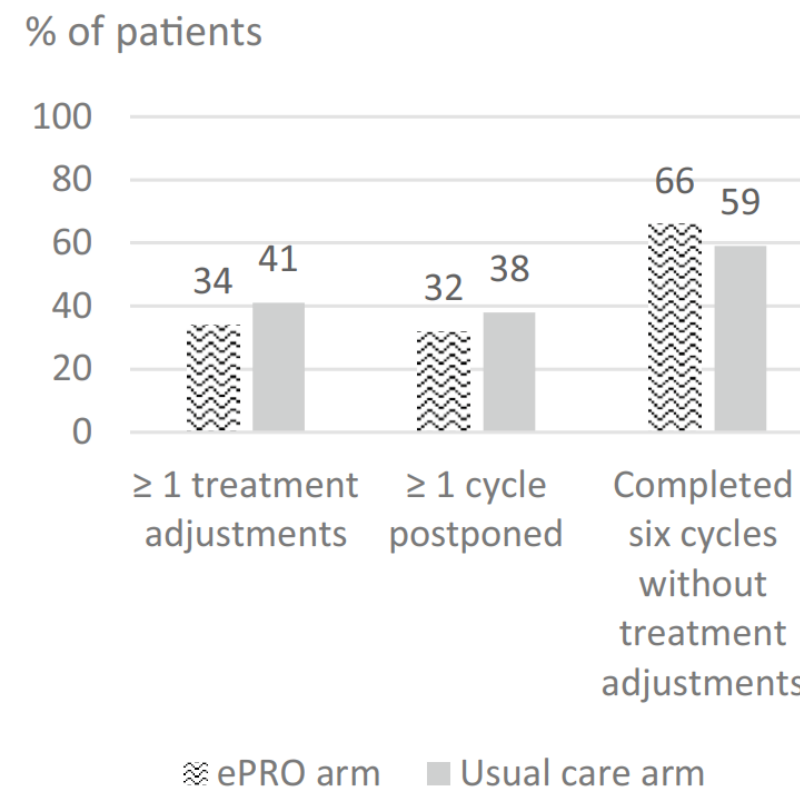
	ePRO (n=347) n (%)	Usual care (n=335) n (%)	Odds Ratio (OR) for patients in the ePRO arm compared to the usual care arm ¹
Treatment adjustments²	118 (34.0)	136 (40.6)	OR=0.75, 95% CI:0.54-1.05, p=0.095 ³
Hospitalization	89 (25.6)	75 (22.4)	OR=0.90, 95% CI:0.60-1.35, p=0.616 ³
Febrile neutropenia	31 (8.9)	35 (10.4)	OR=0.72, 95% CI:0.40-1.28, p=0.257 ³

*Number of patients with minimum one event of febrile neutropenia/hospitalization/treatment adjustment during six cycles of chemotherapy

¹OR for having at least one event of treatment adjustment/hospitalization/febrile neutropenia

²Dose reduction or change of treatment regimen

³A generalized linear mixed model taking into account the cluster randomization was used. Models were adjusted for age and treatment regimen



Mir et al. (Nature Medicine 2022)



Digital remote monitoring plus usual care versus usual care in patients treated with oral anticancer agents: the randomized phase 3 CAPRI trial

Olivier Mir^{1,2}✉, Marie Ferrua¹, Aude Fourcade¹, Delphine Mathivon^{1,2}, Adeline Dufлот-Boukoba^{1,2}, Sarah Dumont³, Eric Baudin⁴, Suzette Delaloge³, David Malka³, Laurence Albiges³, Patricia Pautier³, Caroline Robert³, David Planchard³, Stéphane de Botton⁵, Florian Scotté², François Lemare¹, May Abbas², Marilène Guillet¹, Vanessa Puglisi^{1,2}, Mario Di Palma^{1,2} and Etienne Minvielle^{2,6}

Study design	RCT
Target population	metastatic cancer patients (oral anticancer treat.)
Sample size	559 pts (1:1)
Intervention	ePROM with feedback+ <u>nurse navigator</u>
Outcomes	relative dose intensity + HRQOL+toxicity...



Mir et al. (Nature Medicine 2022)

Patients in the experimental arm showed:

- Higher dose intensity (93.4% versus 89.4%, $P=0.04$).
- Improved patient experience (Patient Assessment of Chronic Illness Care score, 2.94 versus 2.67, $P=0.01$)
- reduced days of hospitalization (2.82 versus 4.44 days, $P=0.02$)
- decreased treatment-related grade ≥ 3 toxicities (27.6% versus 36.9%, $P=0.02$).



Bash et al. (JAMA 2022)

Research

JAMA | **Original Investigation**

Effect of Electronic Symptom Monitoring on Patient-Reported Outcomes Among Patients With Metastatic Cancer A Randomized Clinical Trial

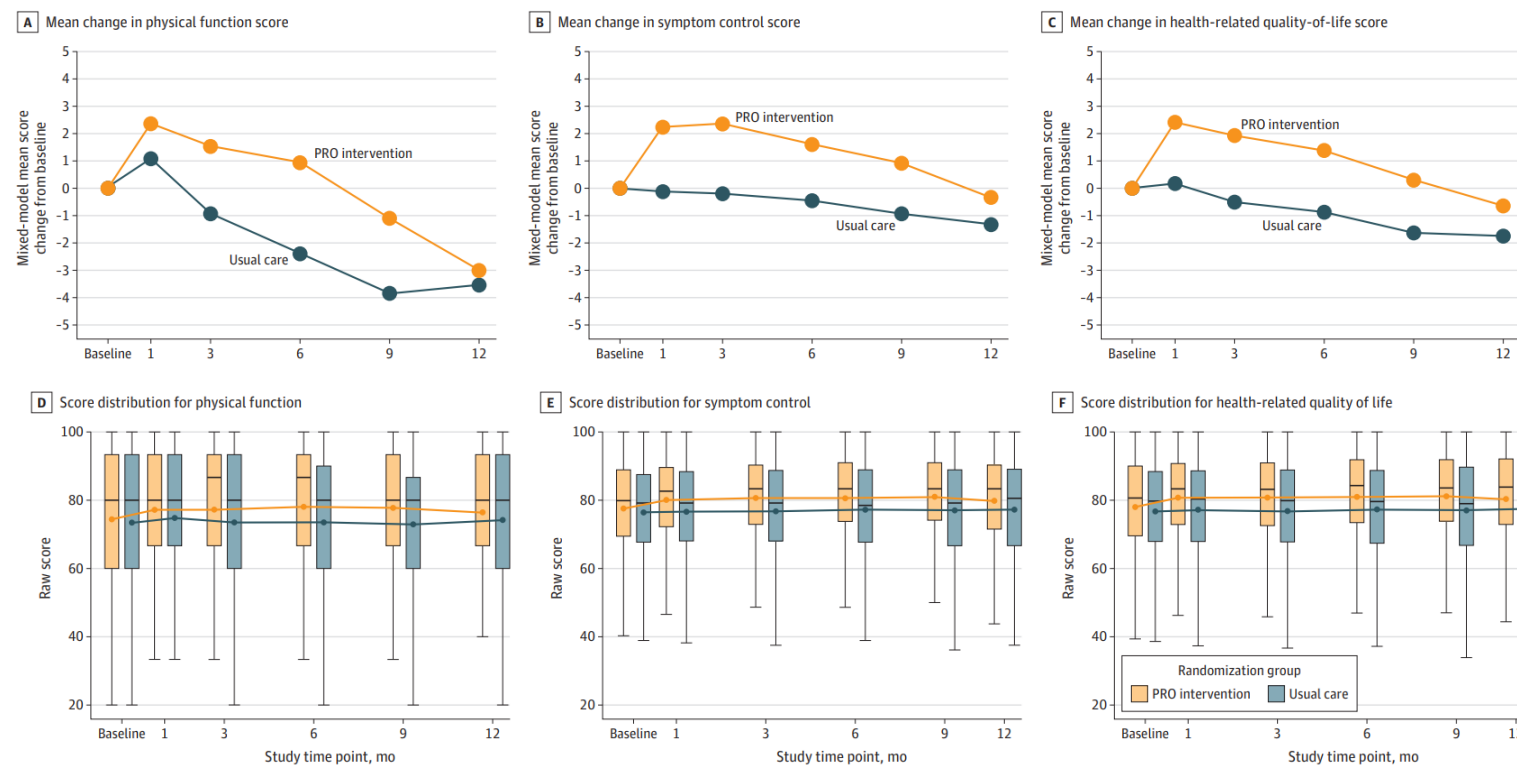
Ethan Basch, MD, MSc; Deborah Schrag, MD, MPH; Sydney Henson, BS; Jennifer Jansen, MPH; Brenda Ginos, MS; Angela M. Stover, PhD; Philip Carr, MPH; Patricia A. Spears, BS; Mattias Jonsson, BA; Allison M. Deal, MS; Antonia V. Bennett, PhD; Gita Thanarajasingam, MD; Lauren J. Rogak, MA; Bryce B. Reeve, PhD; Claire Snyder, PhD; Deborah Bruner, PhD; David Cella, PhD; Lisa A. Kottschade, MSN; Jane Perlmutter, PhD; Cindy Geoghegan, MA; Cleo A. Samuel-Ryals, PhD; Barbara Given, PhD; Gina L. Mazza, PhD; Robert Miller, MD; Jon F. Strasser, MD; Dylan M. Zylla, MD; Anna Weiss, MD; Victoria S. Blinder, MD; Amylou C. Dueck, PhD

Study design	cluster RCT - community oncology practice serv.
Target population	metastatic cancer patients
Sample size	1191 pts (1:1)
Intervention	ePROM with feedback
Outcomes	(survival) phys func, symptom, HRQOL



Bash et al. (JAMA 2022)

Figure 2. Score Distribution and Model-Based Mean Change From Baseline at Each Assessment Time Point for Physical Function, Symptom Control, and Health-Related Quality of Life



Evidence of the impact on survival

Bash et al JAMA 2017

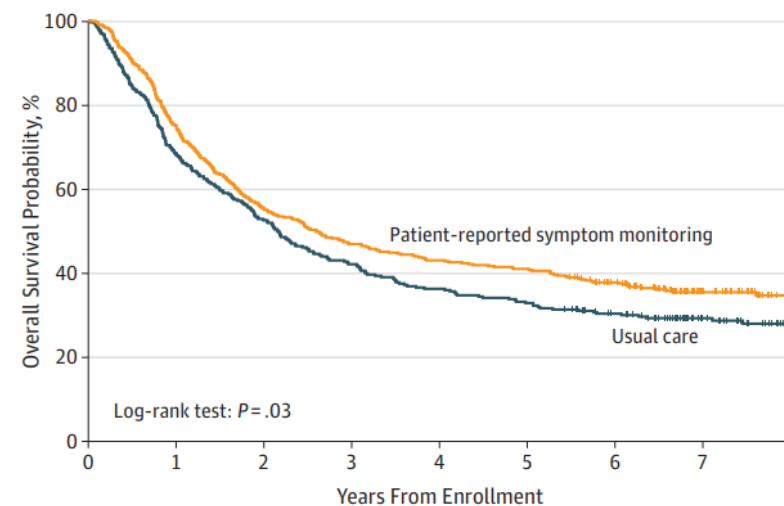
Letters

RESEARCH LETTER

Overall Survival Results of a Trial Assessing Patient-Reported Outcomes for Symptom Monitoring During Routine Cancer Treatment

**Median overall survival
31.2 vs 26.0 months
(p = .03)**

Figure. Overall Survival Among Patients With Metastatic Cancer Assigned to Electronic Patient-Reported Symptom Monitoring During Routine Chemotherapy vs Usual Care



No. at risk	0	1	2	3	4	5	6	7	8
Patient-reported symptom monitoring	441	331	244	207	190	181	148	65	33
Usual care	325	223	171	137	118	107	89	50	27



Evidence of the impact on survival

Denis et al JAMA 2019

Letters

RESEARCH LETTER

Two-Year Survival Comparing Web-Based Symptom Monitoring vs Routine Surveillance Following Treatment for Lung Cancer

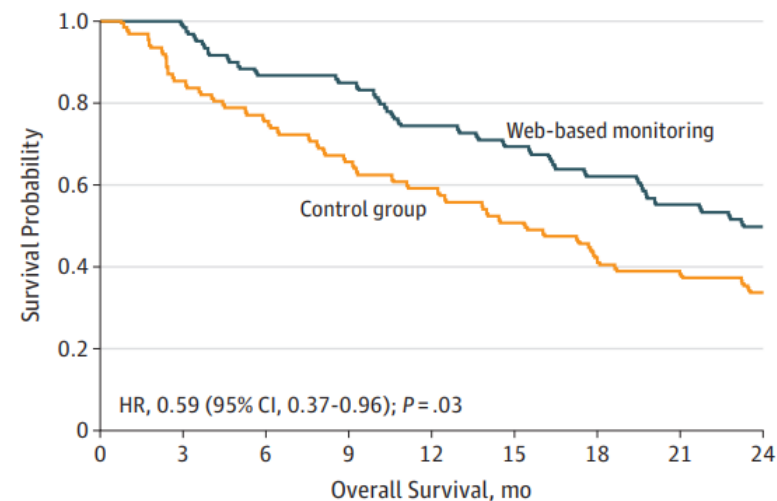
Symptom monitoring via weekly web-based PROs following treatment for lung cancer compared with standard imaging surveillance (3 to 6 months)

The trial was stopped for benefit at 60% of enrolled pts

**Median overall survival
22.5 vs 14.9 months
(p = .03)**

Figure 2. Kaplan-Meier Curves for the Overall Survival (OS) Analysis

A Intention-to-treat analysis



No. at risk	0	3	6	9	12	15	18	21	24
Web-based monitoring	60	60	51	48	43	39	35	31	27
Control	61	52	45	38	34	29	24	22	19



Summary of evidences since 2020 population based studies



Cancer Care Ontario routine symptom screening

- In 2007, Cancer Care Ontario implemented a program of routine symptom screening with the Edmonton Symptom Assessment System (ESAS) for ambulatory oncology patients attending clinics around the province.
- ESAS assesses 9 common cancer symptoms on a scale of 0 to 10.
- The programme is ongoing and allows the collection of a very huge amount of data every day



Population based studies

original contributions

CARE DELIVERY ReCAP

Check for updates

Impact of Standardized Edmonton Symptom Assessment System Use on Emergency Department Visits and Hospitalization: Results of a Population-Based Retrospective Matched Cohort Analysis

Lisa Barbera, MD, MPA^{1,2,3,4}; R
Nicole Mittmann, PhD⁵; Qing L

Original research

The impact of routine Edmonton symptom assessment system use on receiving palliative care services: results of a population-based retrospective-matched cohort analysis

DOI: 10.1002/cam4.3374

ORIGINAL RESEARCH

Cancer Medicine WILEY

The impact of routine Edmonton Symptom Assessment System (ESAS) use on overall survival in cancer patients: Results of a population-based retrospective matched cohort analysis

Lisa Barbera^{1,2,3,4} | Rinku Sutradhar^{1,2} | Hsien Seow^{1,5} | Nicole Mittmann³ | Doris Howell⁶ | Craig C. Earle¹ | Qing Li¹ | Deva Thiruchelvam¹

Compared to non exposed, patients exposed to ESAS :

- were 8% less likely to visit the ED and 14% less likely to be hospitalized
- were more likely to receive palliative care (cum inc 28% vs 21%).
- had a higher probability of survival (HR: 0.48, 95% CI: 0.47-0.49)



Conclusions

- Evidences from both CT and RWD indicate that digital monitoring of patient centered-reported outcomes in routine clinical practice showed benefits in terms of
 - symptom control, and quality of life
 - emergency department visits, PC activation
 - survival
- In a number of studies effect sizes are low to moderate but more positive effect were seen when feedback is provided to patient and/or health care professional.



Conclusions

..... yet systematic PROM collection is not widely implemented in routine oncology practice

- We need to agree upon and share implementation best practices
 - Short and relevant questionnaires
 - Training and engagement of patients and personnel
 - ePROMs integrated into the EMR (seamless integration into workflow)
- Resources are needed: we need more evidences on cost effectiveness
- Impact on research



Thank you

