



Rasmus Blechingberg Friis



Danish Research Center for  
Lung Cancer



Danish Cancer Society



AARHUS  
UNIVERSITY

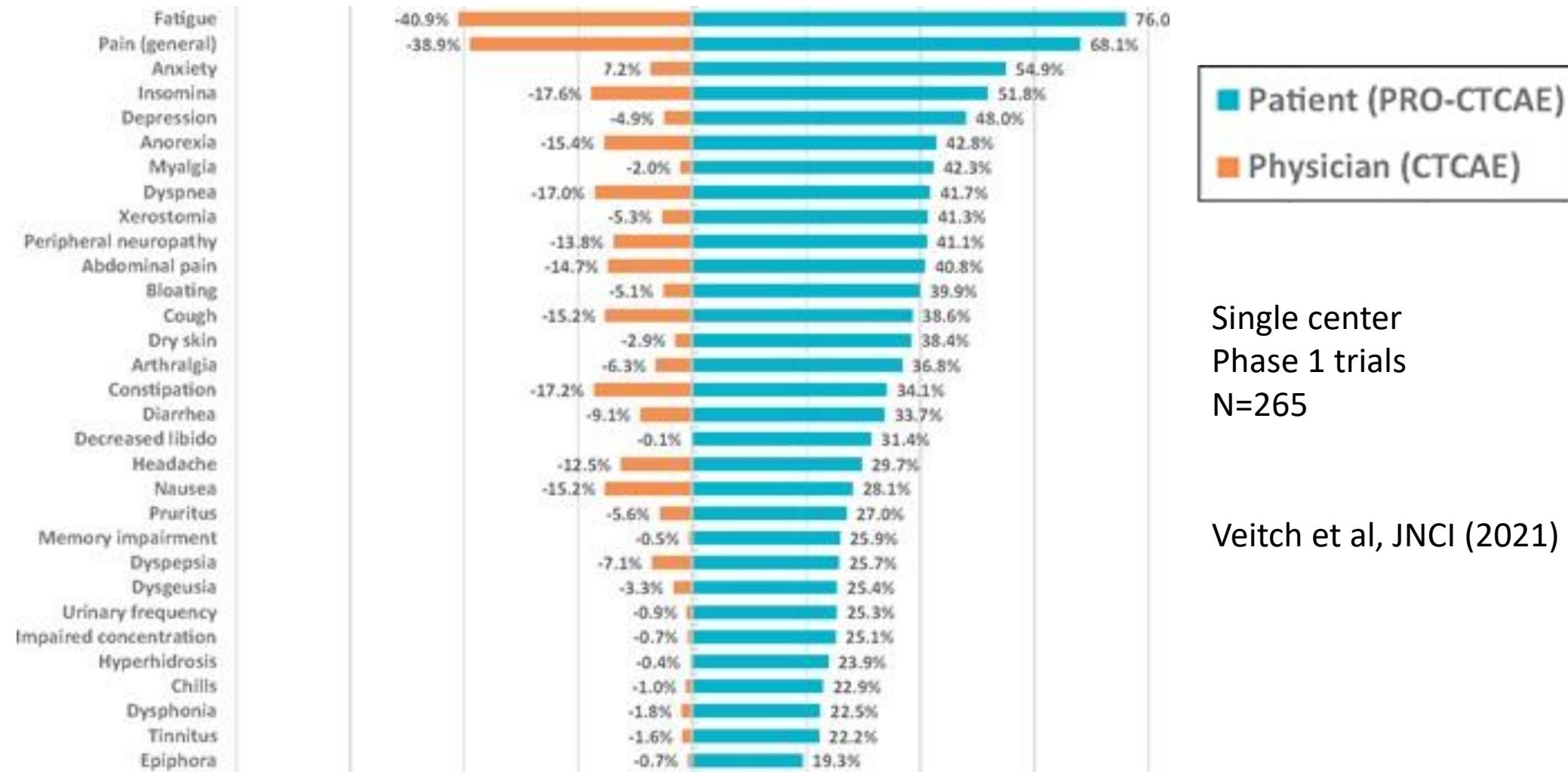
**midt**  
Central Denmark Region

# Patient Reported Outcomes

*“a report that comes directly from the patient about the status of a patient's health condition without interpretation of the patient's response by a clinician or anyone else”*

FDA

# Klinikere underrapporterer og overser patienters symptomer



# Ugentlig symptom-monitorering øger overlevelsen

## RCT

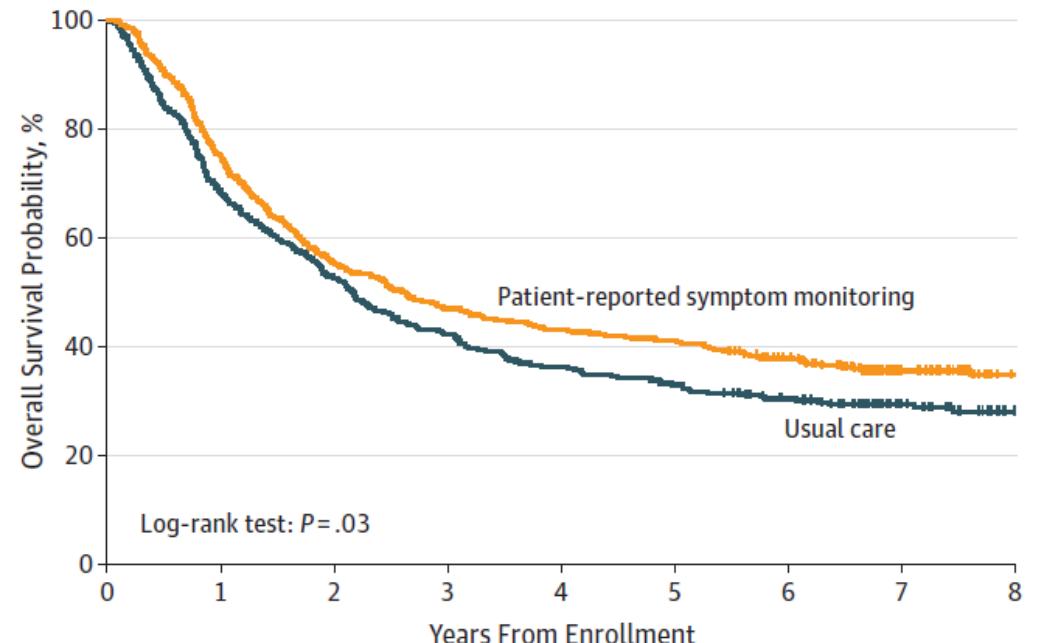
- Symptom-monitoring vs SOC
- 30 % with lung cancer
- n=766

## 1-year Overall Survival:

75% vs 69% ( $P = .05$ )

## Hazard Ratio

0.83 (95% CI, 0.70-0.99),  $p = .04$ )



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

*Basch et al, JAMA (2017)*

# Endnu større effekt for patienter med lungekræft

## RCT

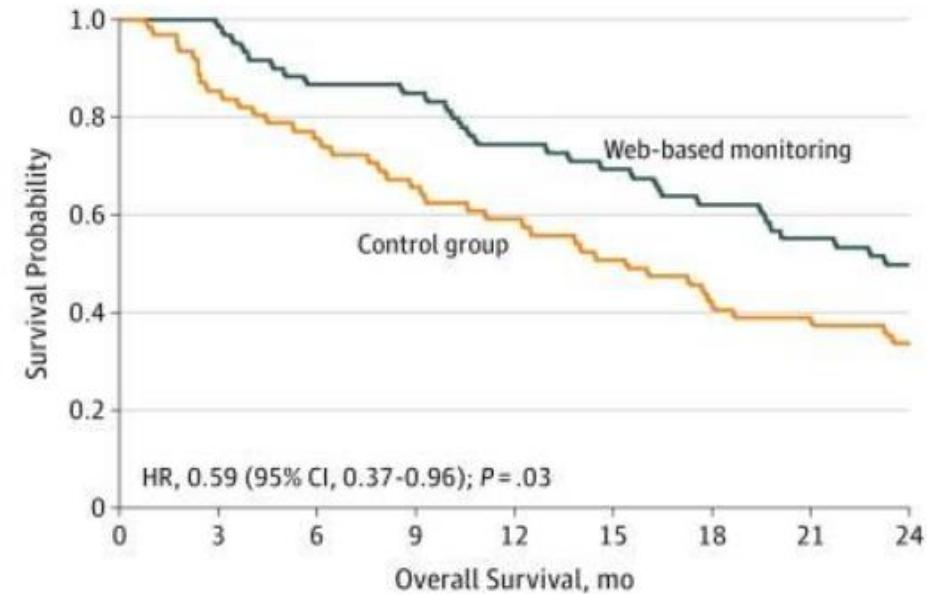
- Symptom-monitoring vs SOC
- Lung cancer
- n=121

## 1-year Overall Survival

75% vs 56%

## Hazard ratio

0.59 (95% CI, 0.37- 0.96), p = .03



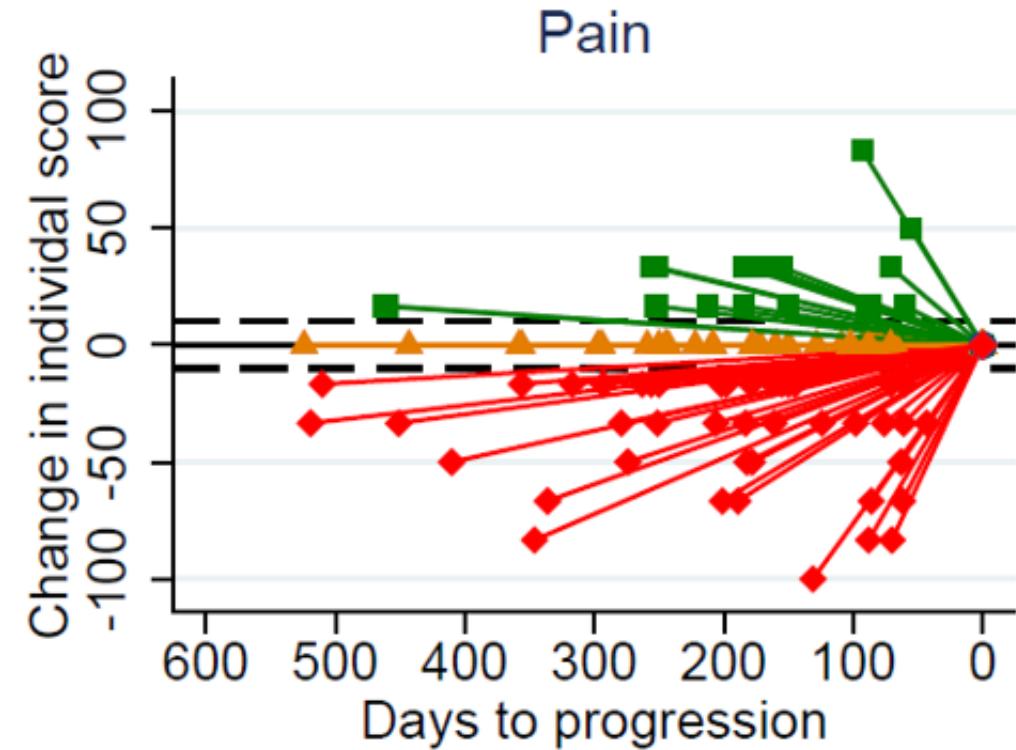
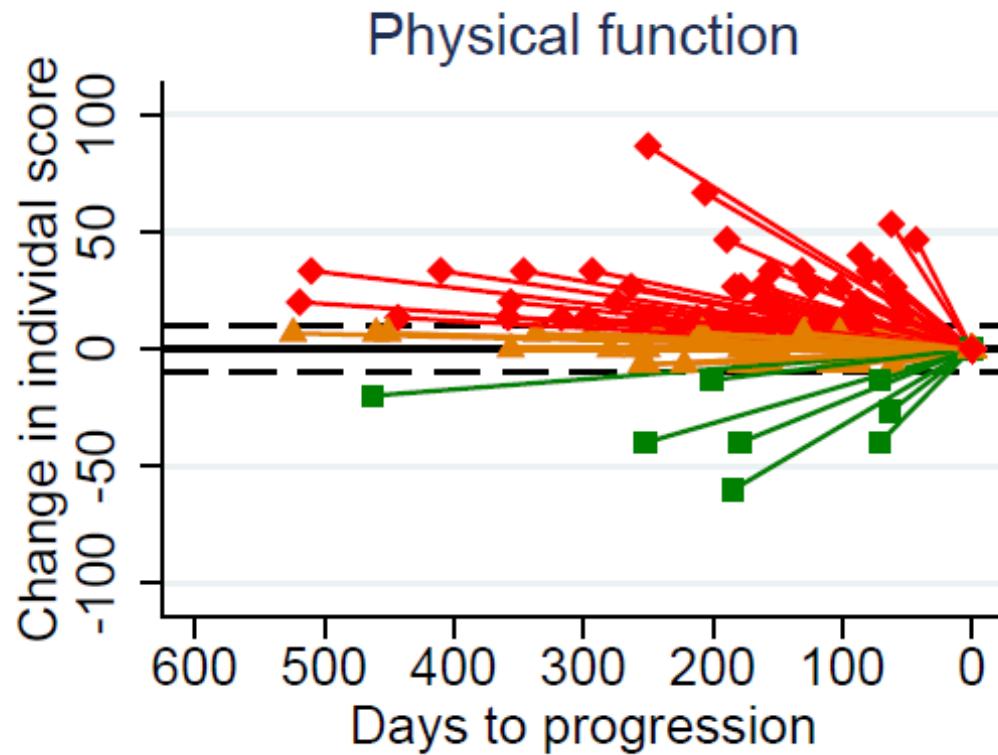
	No. at risk									
	Web-based monitoring	60	60	51	48	43	39	35	31	27
Control	61	52	45	38	34	29	24	22	19	

*Denis et al,  
JNCI (2017), JAMA (2019)*

# Forklaringer på overlevelsesgevinsten

- Tidlig opsporing af sygdoms-progression
- Early palliative care
- Bedre håndtering af bivirkninger / komplikationer

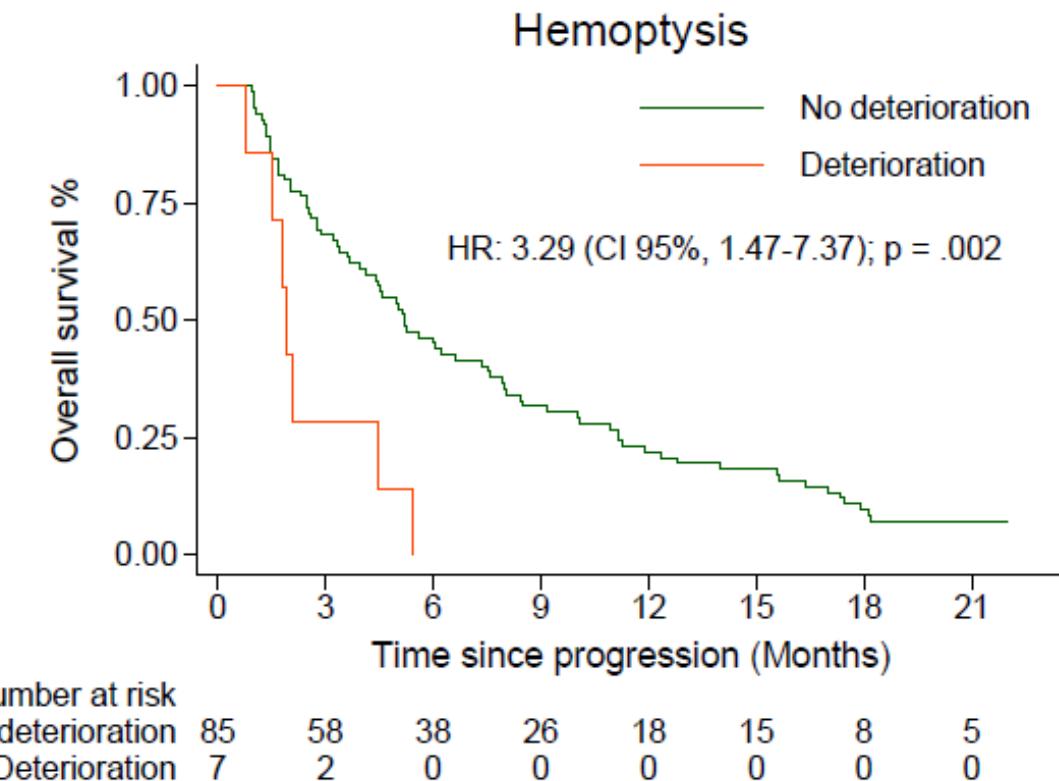
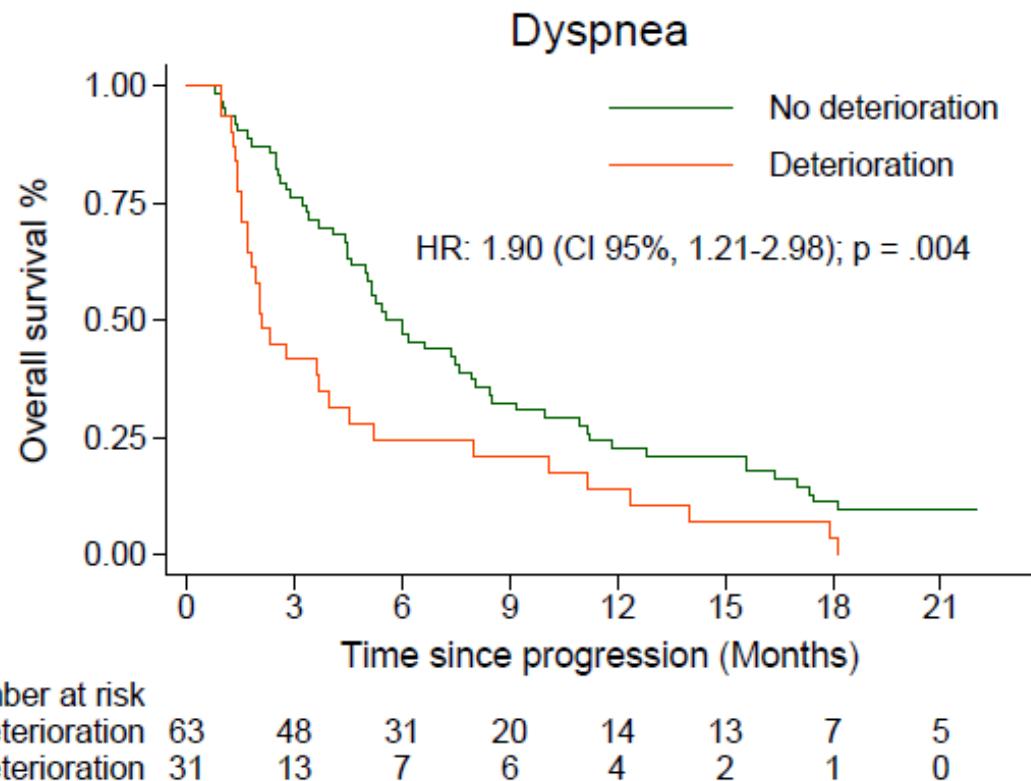
# De fleste patienter har symptomforværring igennem behandlingen



- - - Minimal Important Diff (MID): >10 points change from baseline to progression

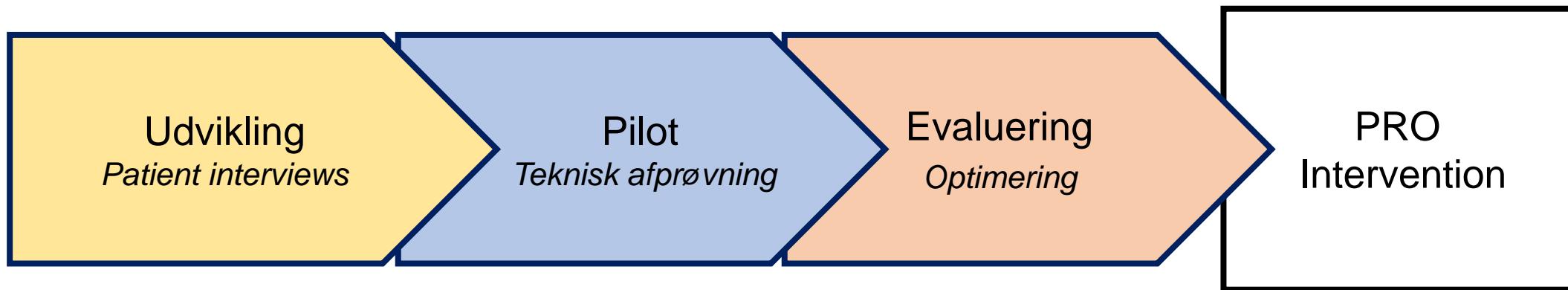
Rød: Forværring; Orange: Stabil; Grøn: Forbedring

# Symptomforværring er forbundet med dårlig prognose

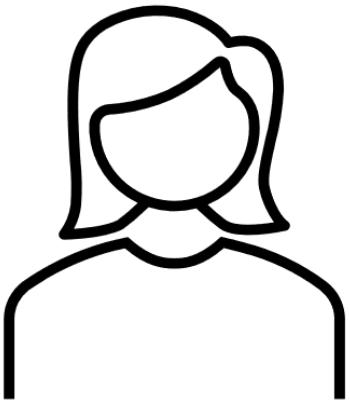


# Pilot studie

Udvikling af PRO interventionen

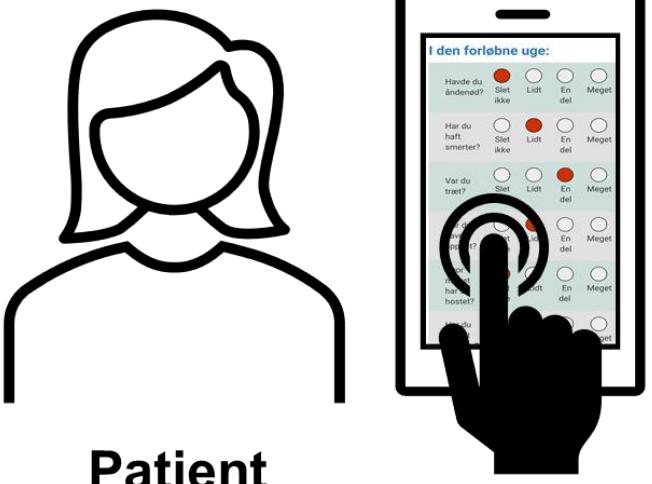


# Interventions-armen

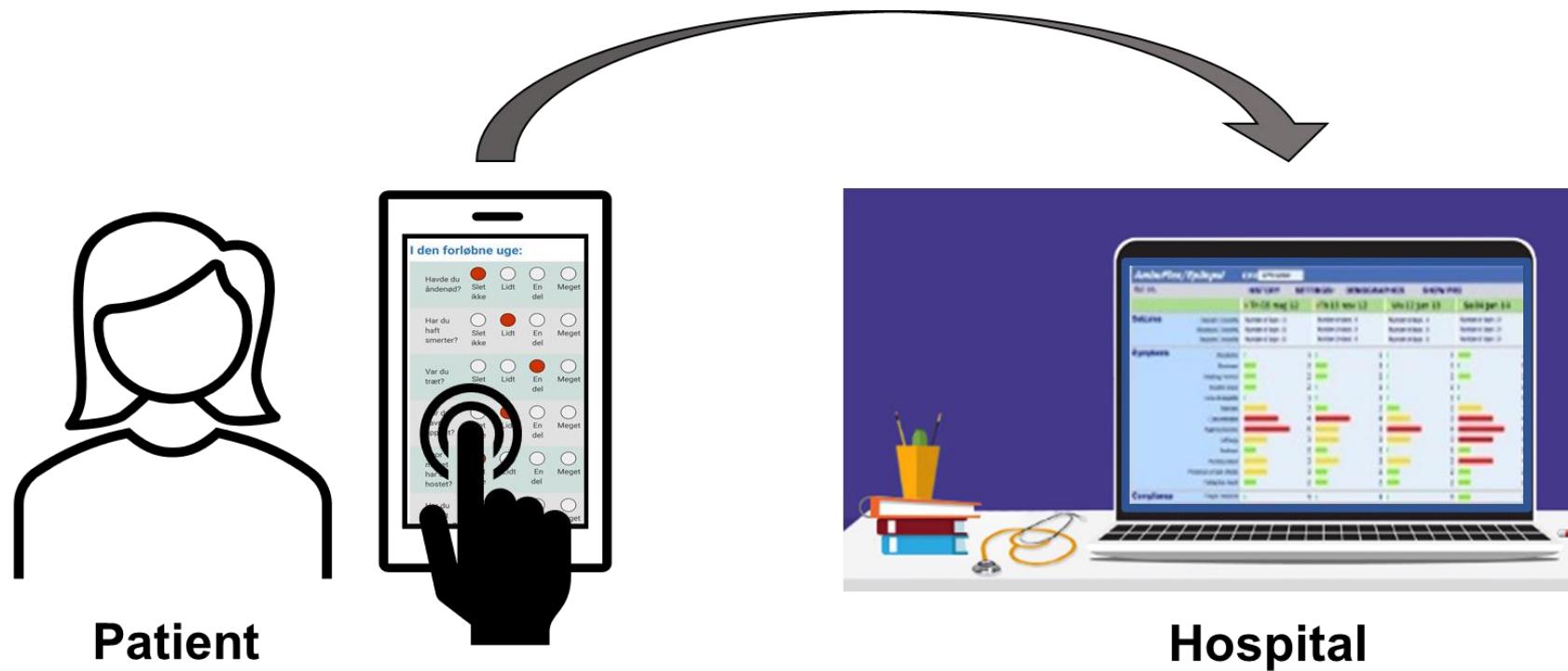


**Patient**

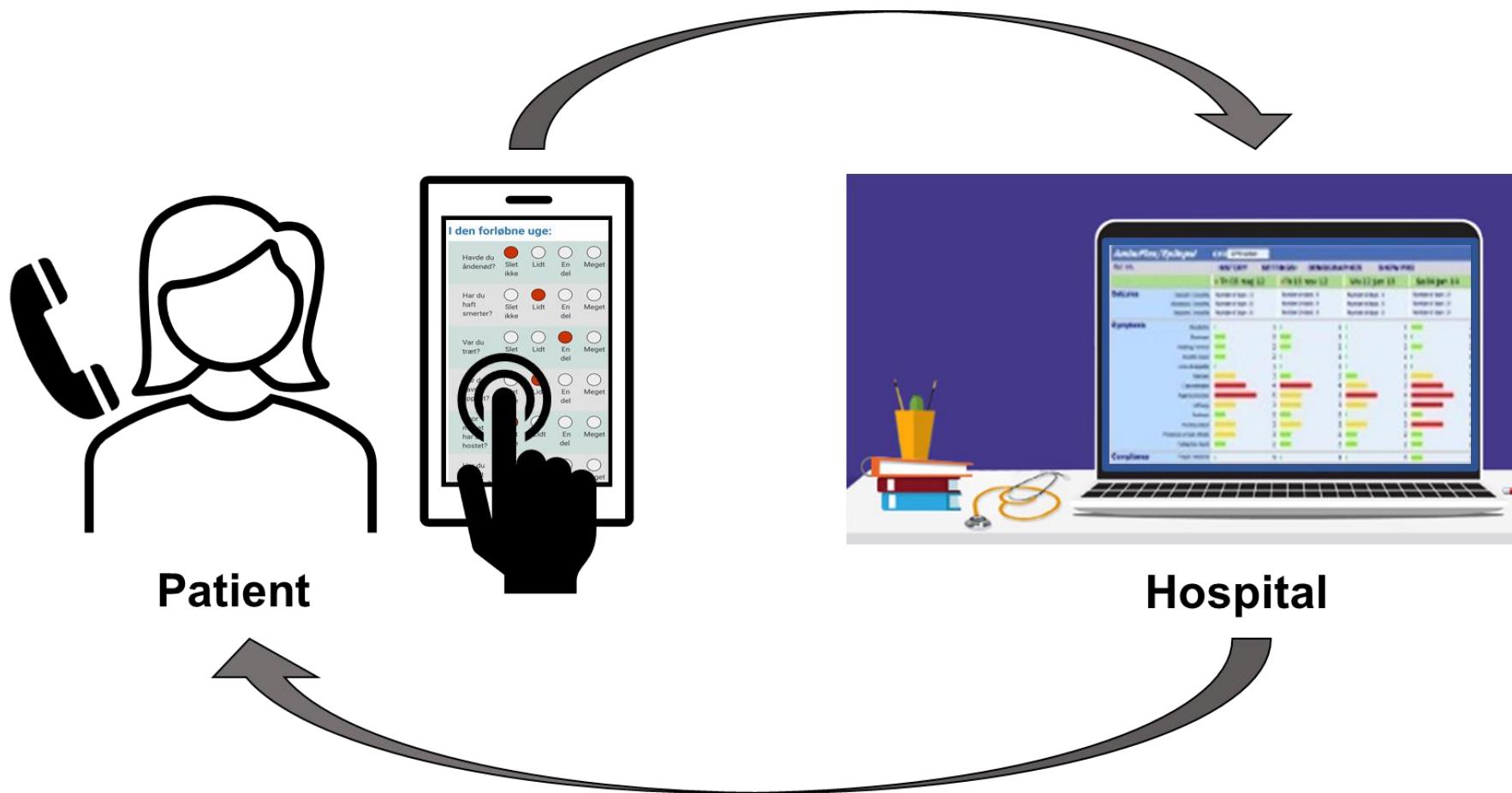
# Interventions-armen



# Interventions-armen



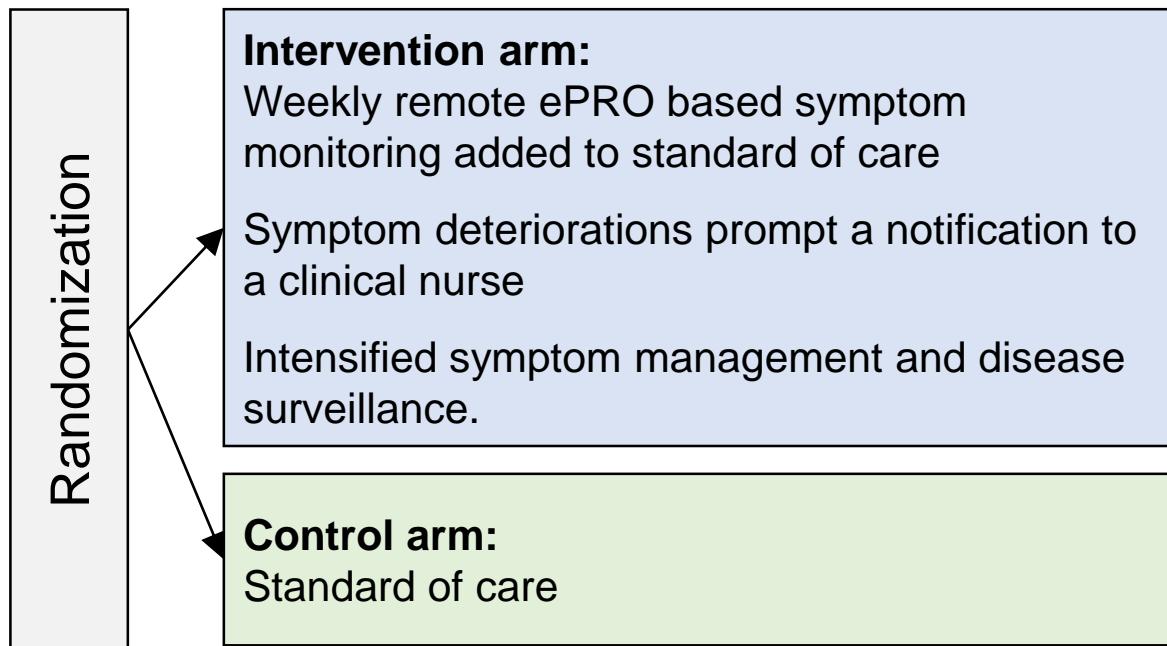
# Interventions-armen



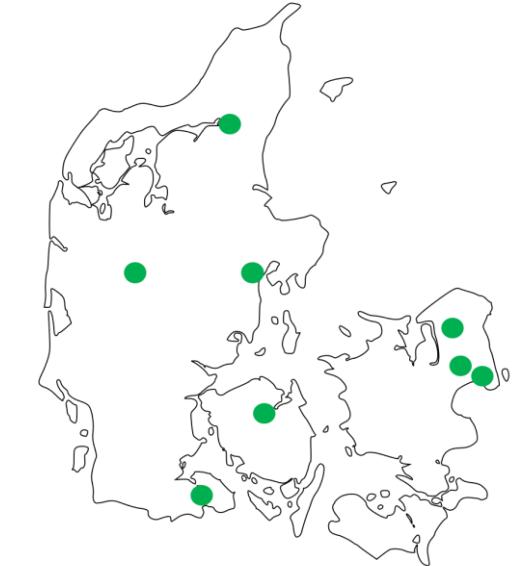
# Study design: National RCT



KEY ELIGIBILITY CRITERIA	
Stage III/IV lung cancer	
Palliative treatment	
Non-progressive disease after induction treatment	
Internet access	



*ClinicalTrials.gov Identifier: NCT03608410*



**Primary endpoint:**

Overall survival

**Secondary endpoints:**

HRQoL: EORTC QLQ-C30 / LC13, HADS (bimonthly)

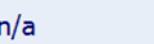
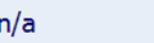
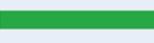
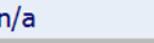
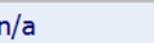
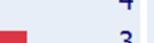
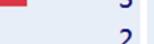
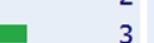
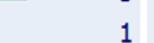
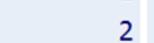
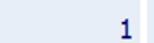
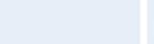
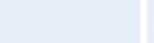
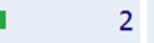
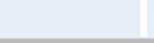
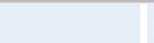
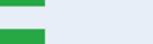
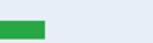
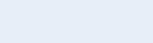
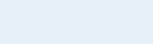
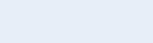
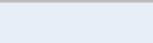
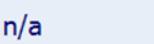
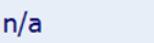
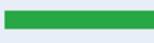
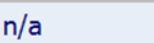
ECOG performance status

Second-line treatment

Health economics: EQ-5D-5L

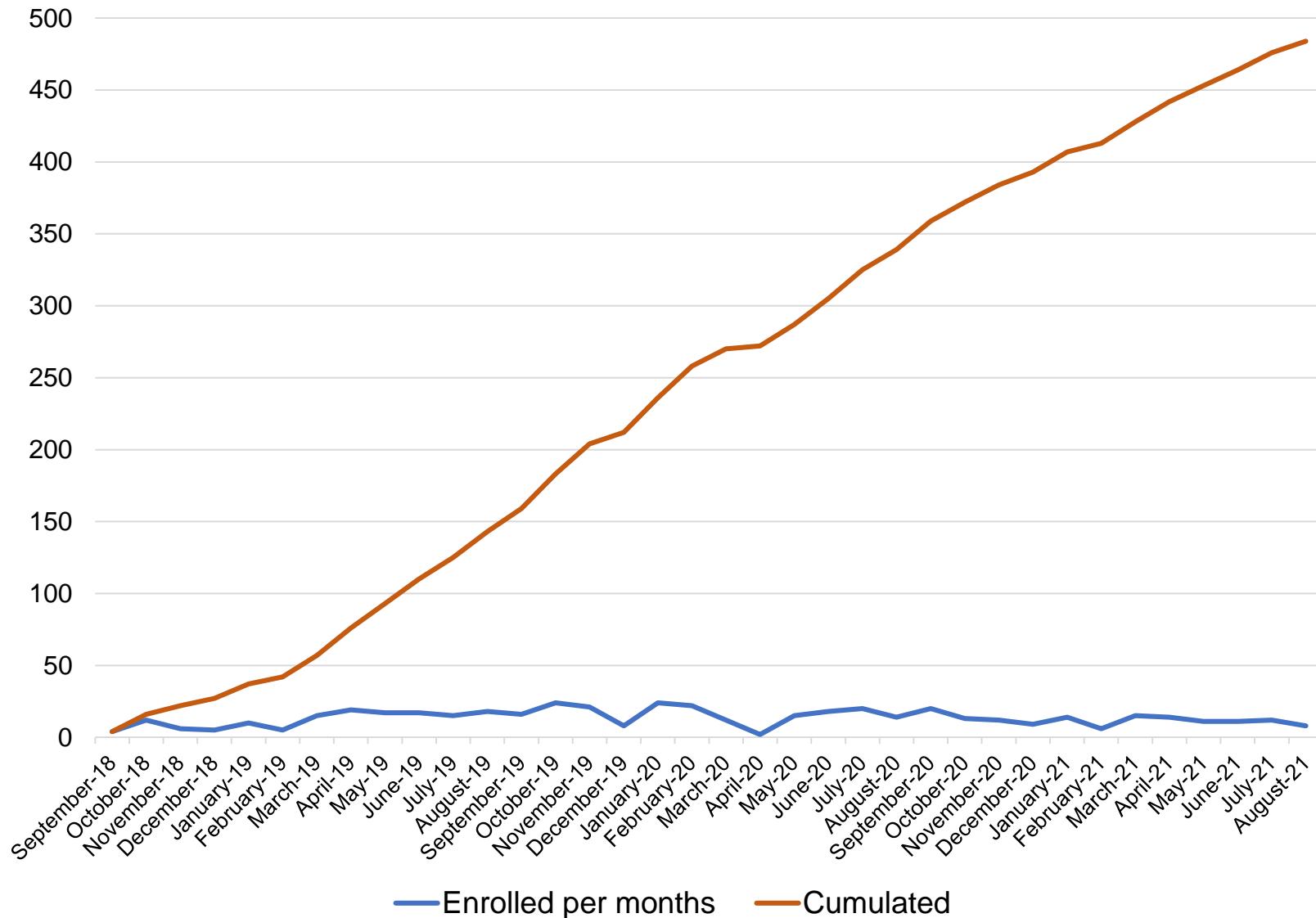
# PRO interventionen

Pneumonia

	Vis fra dato..	Fr 26 okt 18	Fr 02 nov 18	Sø 11 nov 18	To 15 nov 18	To 22 nov 18
Symptomer	Samlet helbred Åndenød Smerte Træthed Savnet appetit Hostet Hostet blod Hæshed Hævelse ansigt Knude Andre symptomer	          	          	          	          	          
Målinger	Temperatur Vægt Vægtændring	n/a Antal kg: 86 Kg ift første vægt: -1	n/a Antal kg: 86 Kg ift første vægt: -1	n/a Antal kg: 86 Kg ift første vægt: -1	n/a Antal kg: 86.5 Kg ift første vægt: -0.5	n/a Antal kg: 86 Kg ift første vægt: -1

Progression

# Recruitment completed (n=494)



# Perspektiver

- Forbedret livskvalitet / symptom kontrol?
- Forlænget overlevelse?
- Klinisk implementering?
- PRO i kommende studier...



# Spørgsmål?

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