Erasmus MC
University Medical Center Rotterdam

Cancer Institute

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Health-related quality of life a prospective cohort study in phase I oncology trial participants[1]

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[1]In press by the European Journal of Cancer Care

Disclosure presentation

X	No (potential) conflict of interests	
X	1. Relations that could be relevant for the meeting	
X	2. Sponsorship or research funds	
X	3. Payment or other (financial) remuneration	
X	4. Shareholder	
X	5. Other relation	

Casus

- Sarah
- 57 years
- Ovarian carcinoma
- BRCA 1 mutation
- Married, 3 children & 4 grandchildren
- Options:
  1. Chemotherapy
  2. Phase I trial with PARP inhibitor, ABT-767[1]

Image by James Jardine; © Diane van der Biessen

[1]Van der Biessen et al 2018 Investigational New Drugs

Outline

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- Introduction
- Aim
- Methods
- Results
- Conclusion
- Clinical implications

Introduction

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- Phase I clinical trials
  - Safety profile and dose of new drug or combination of drug
- Palliative patients with cancer
  - Without standard treatment options
  - Specific mutation
  - In good health
- Ethical dilemma
- Prepare & inform adequatly

Aim

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- The potential relation of **health related quality of life** (HRQoL) to eligibility for phase I trial participation
- Assess changes during participation
  - HRQoL
  - Hope
  - Coping strategies

Methods

- Observational descriptive prospective cohort study
- $\geq$ 18 years
- Speak and read Dutch
- Approved by the Institutional Review Board
- Three timepoint
  - Pre-consent
  - Start phase I trial
  - First evaluation

Sarah at pre-consent

- Recurrence at CT scan
- WHO 1
- Works part-time, babysitting grandchildren
- Disease symptoms
  - Mild pain, constipation
  - Rising CA125
- Gives consent to
  - Phase I
  - Patients' perspectives study

Methods - Questionnaire

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- EORTC QLQ-C 30

- Five functional scales
  - ‘Do you have any trouble taking a long walk?’
  - ‘Did you worry?’
  - ‘Were you limited in doing either your work or other daily activities?’
  - ‘Have you had difficulty remembering things?’
  - ‘Has your physical condition or medical treatment interfered with your family life?’

Methods Questionnaire

- EORTC QLQ-C 30
- Three symptom scales:
  - Fatigue
  - Nausea & vomiting
  - Pain
- Six single items: dyspnoea, insomnia, loss of appetite, constipation, diarrhoea, and financial impact
- *Hope* → *Herth hope index*
- *Coping*
  - *Assimilation and accommodation coping-scale*
  - *Locus of control questionnaire*

Methods - statistics

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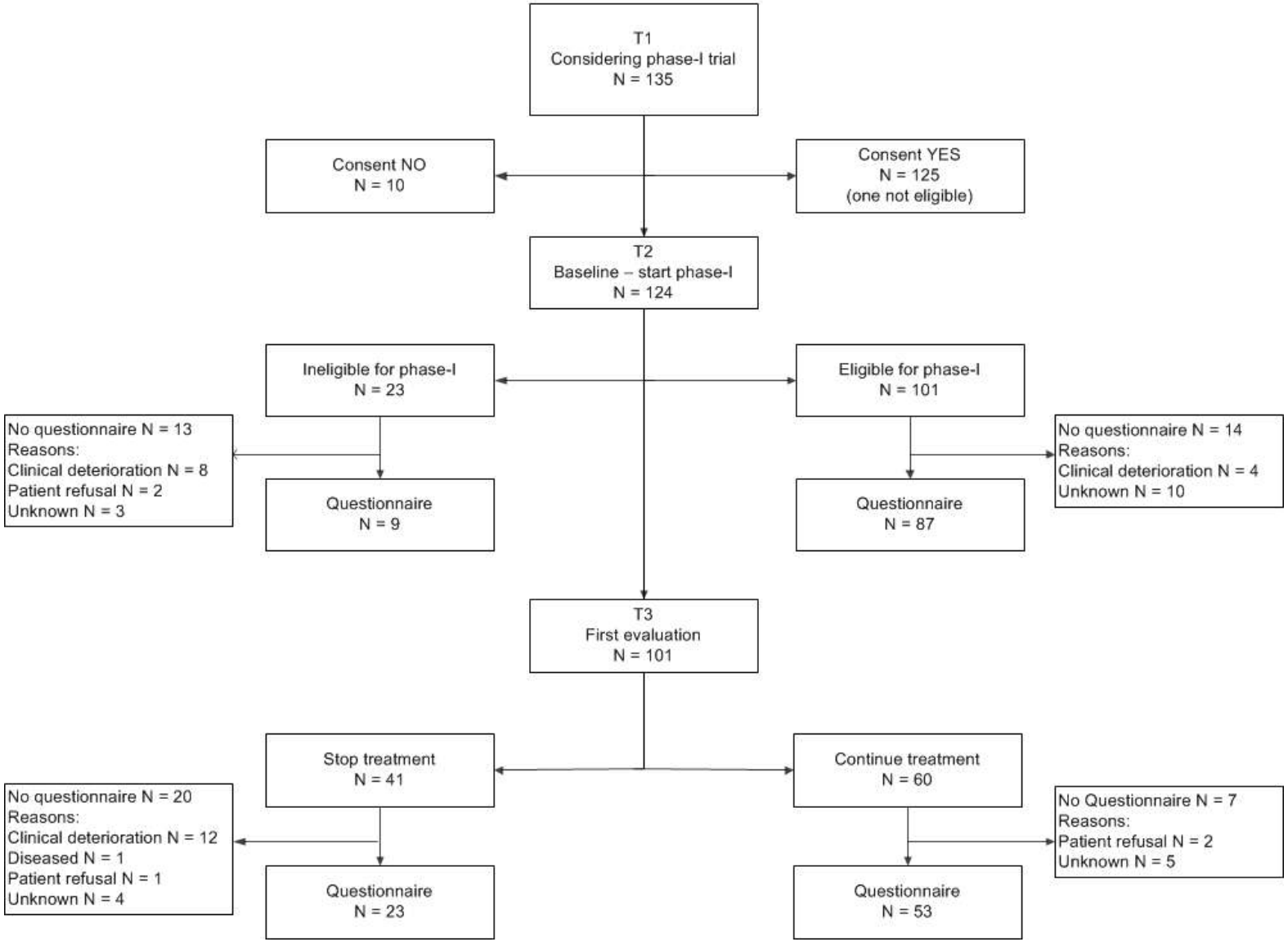
- Descriptives
- Differences between eligible versus non-eligible patients
  - Non-parametric Mann-Whitney U test & univariate logistic regression
- Differences between patients continuing versus stopping participation
  - Factorial repeated-measures ANOVA
- Overall survival by Kaplan-Meier method

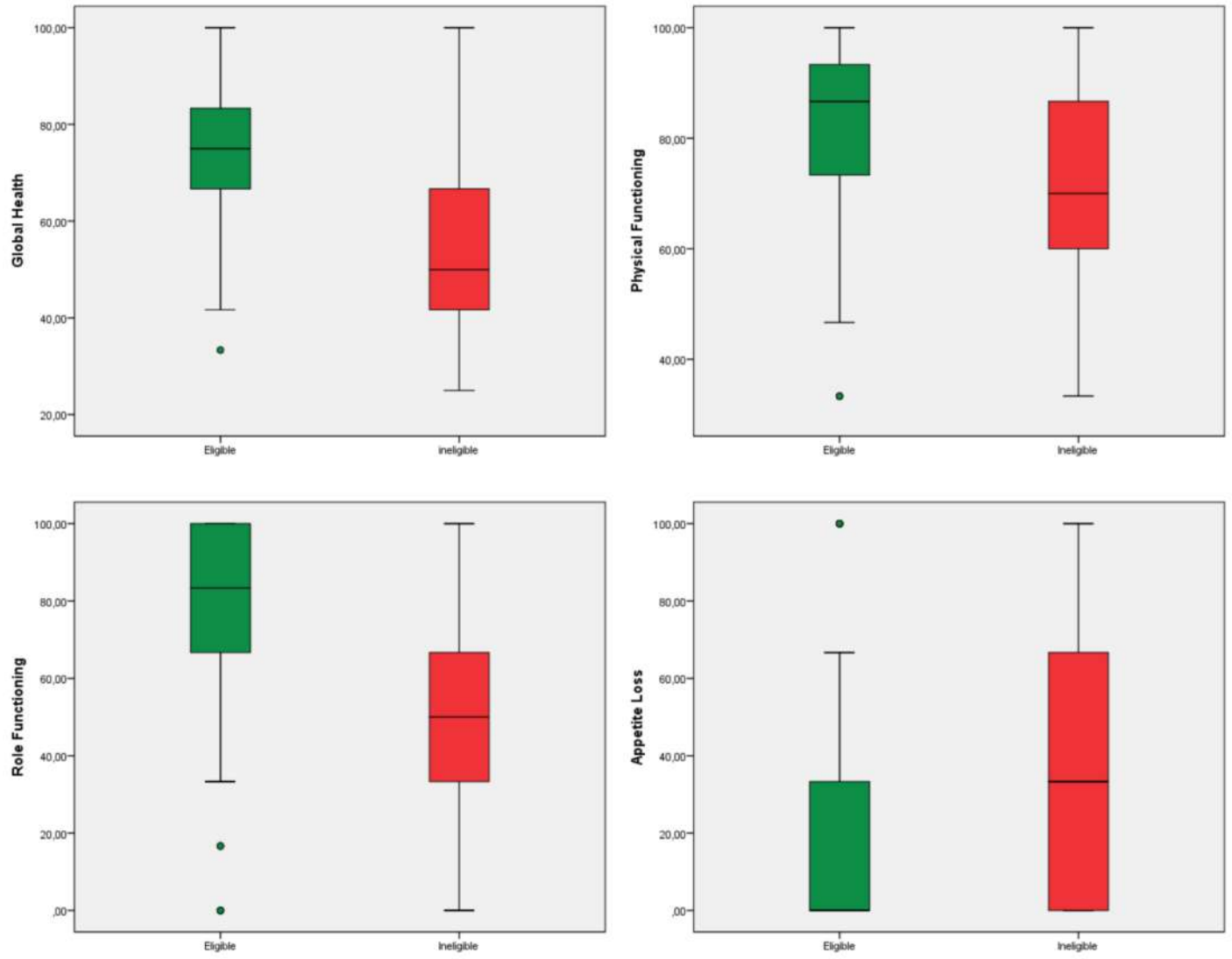
Sarah at start of phase I trial

- Eligible for participation
- WHO 1
- Still works and baby sits
- Disease symptoms
  - Mild pain, constipation
  - Anorexia, lost 1 kilogram
- Further rise of CA125

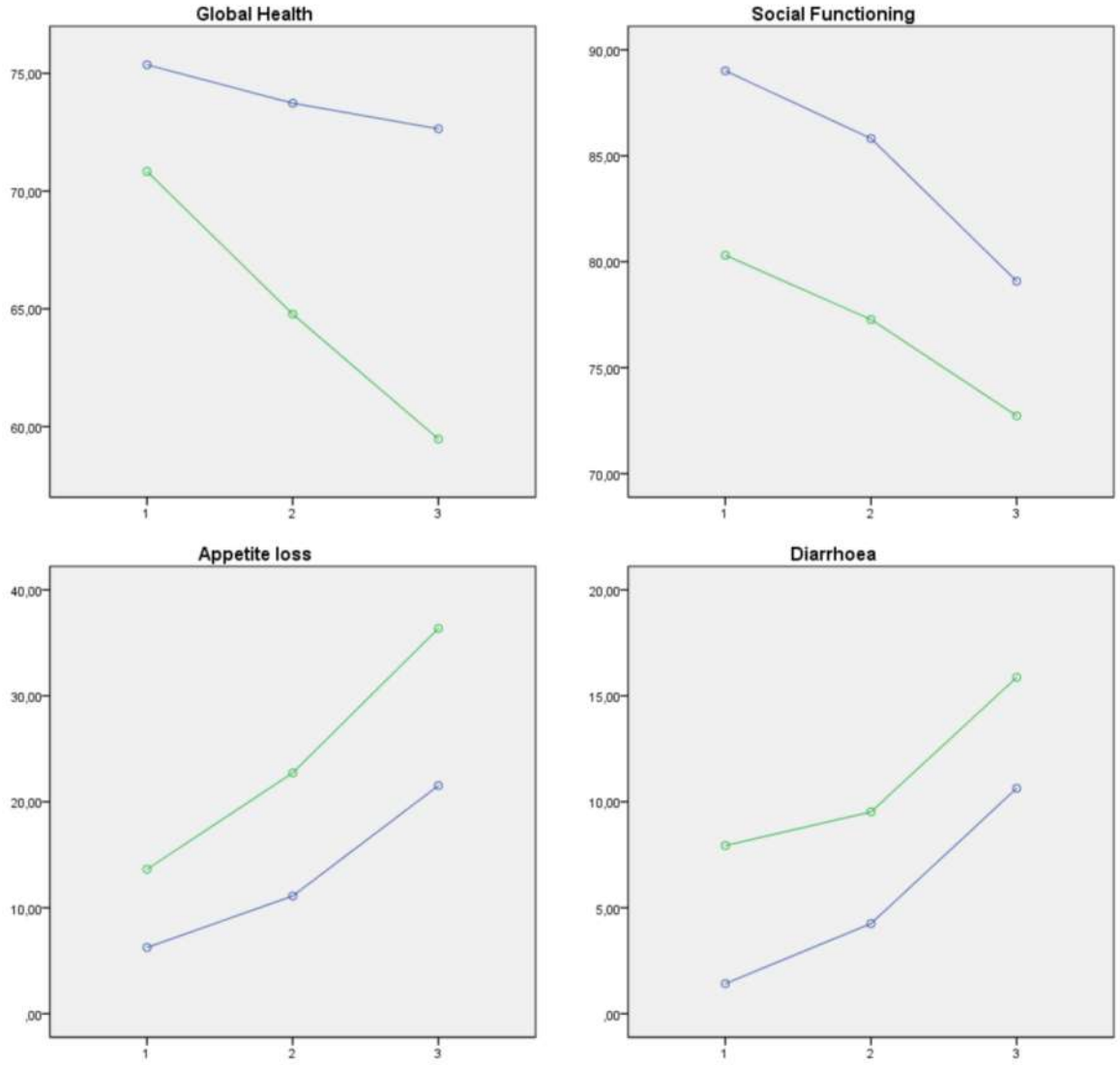
Results – consort flow chart



Results - Eligible versus non-eligible patients



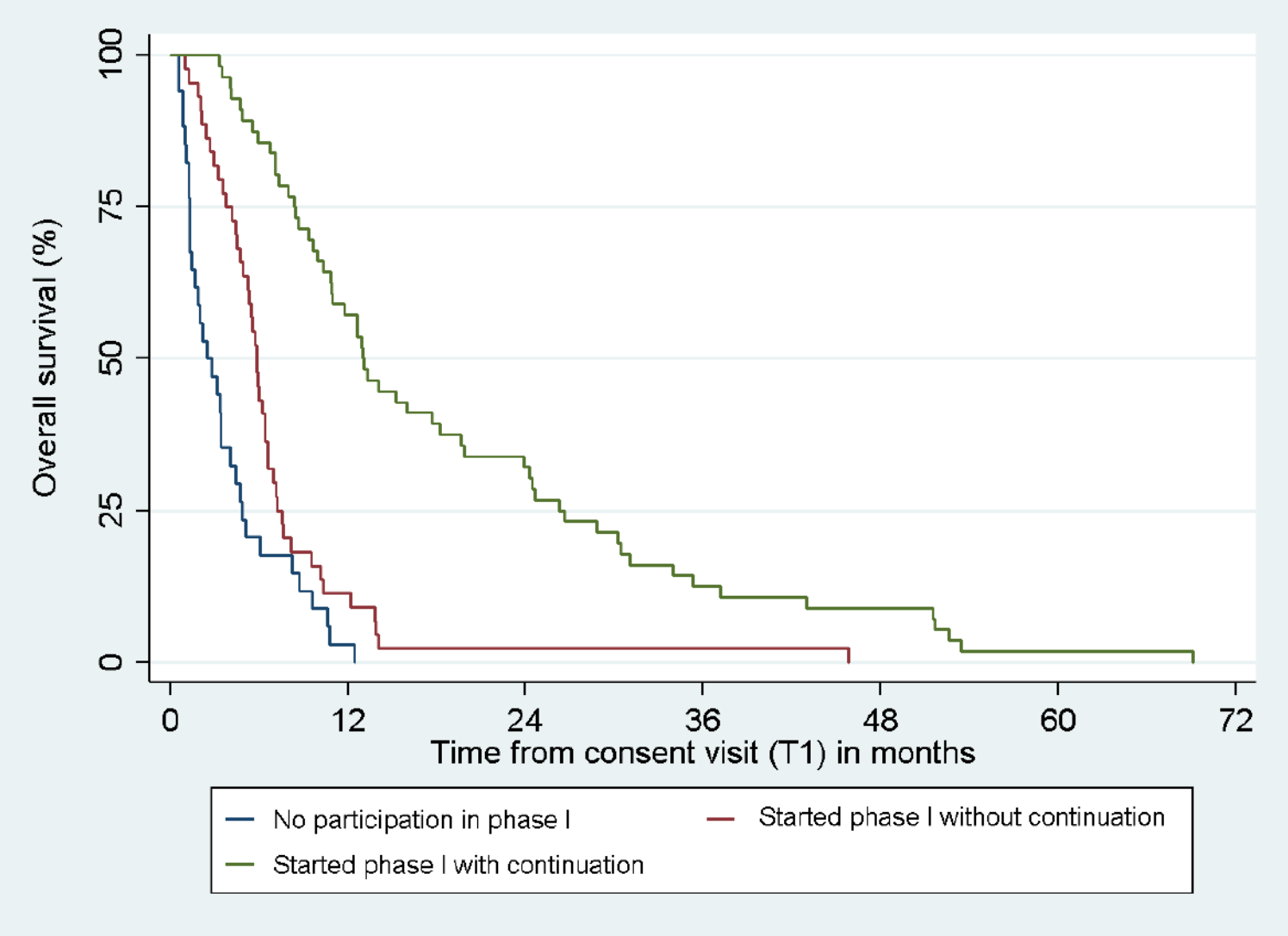
Results – continuing versus stopping participation



Sarah after first evaluation

- Side-effects
  - Nausea 2 – under control by anti-emetics
  - Anemia gr 2 & fatigue g 2– resolved by dose reduction
- Respons
  - CT scan and CA125
- Pain and constipation resolved
- Work and babysitting under stress

Results – survival by Kaplan-Meier



Conclusions

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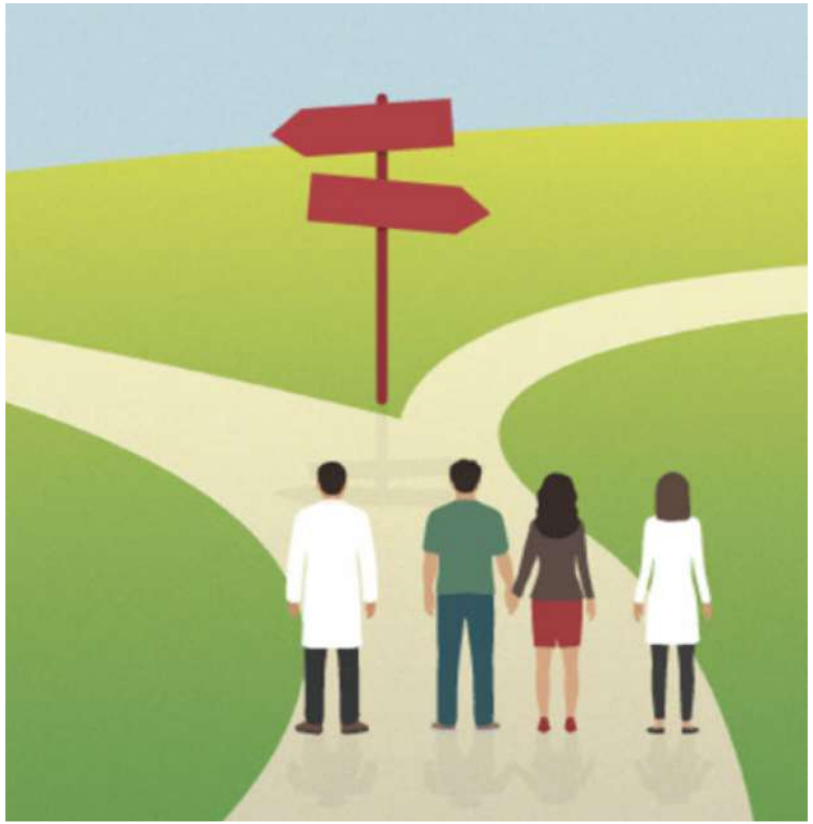
- Good HRQoL outcomes are related with
  - Eligibility
  - Prolonged trial continuation
- Social functioning is affected in all patients on trial
- Global health → appetite loss and diarrhea

Clinical implications



- Maintenance and support of HRQoL is challenging
- PROs may be of use
- Integration of palliative care cq advanced care planning
- Communicate about goals, needs and values

Thanks

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- The patients
- The phase I team
- The autheurs of this manuscript

Hoping for a New Horizon

- Defence of my thesis
- Wednesday 31th of October
- 11.30
- Professor Queridozaal
- Erasmus MC