A multicenter randomized controlled trial (RCT) for the effectiveness of Comprehensive Geriatric Assessment (CGA) with extensive patient coaching on quality of life (QoL) in older patients with solid tumors receiving systemic therapy

G-oncoCOACH study

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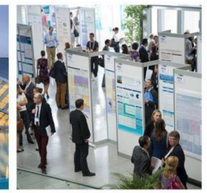
Conflict of Interest Disclosure

I declare the following conflict(s) of interest:

Pfizer, speaker





Background / Aim

- CGA = internationally recommended in the care for older patients with cancer (e.g. guidelines ASCO, SIOG, NCCN).
- CGA = process including geriatric screening (e.g. G8), geriatric assessment, recommendations, interventions, follow-up.

To evaluate the **effectiveness of CGA** coordinated by a geriatric team combined with intensive patient coaching versus CGA coordinated by an oncology team (= standard of care) on **QoL** in older patients with solid tumors receiving systemic therapy.

Methods

- G-oncoCOACH study = multicenter RCT (clinicaltrials.gov = NCT04069962)
- two academic Belgian hospitals (UZ Leuven / UZ Brussel)

- Eligibility criteria:
  - 70+ years,
  - solid tumor,
  - systemic therapy with curative or non-curative intent (first / second-line),
  - physician-estimated life expectancy >6 months.

Methods

CGA at baseline, 3, 6, and 12 months

Control Group

CGA coordinated by the oncology team (= standard of care)

Intervention Group

CGA coordinated by the geriatric team

G-oncoCOACH intervention

Additional individual counseling: 2 / 4.5 / 8 / 10 months

Intensive patientcoaching

Motivational interviewing

To increase patient compliance / To strengthen patient empowerment

By improving self-efficacy / By supporting self-management of age-related problems

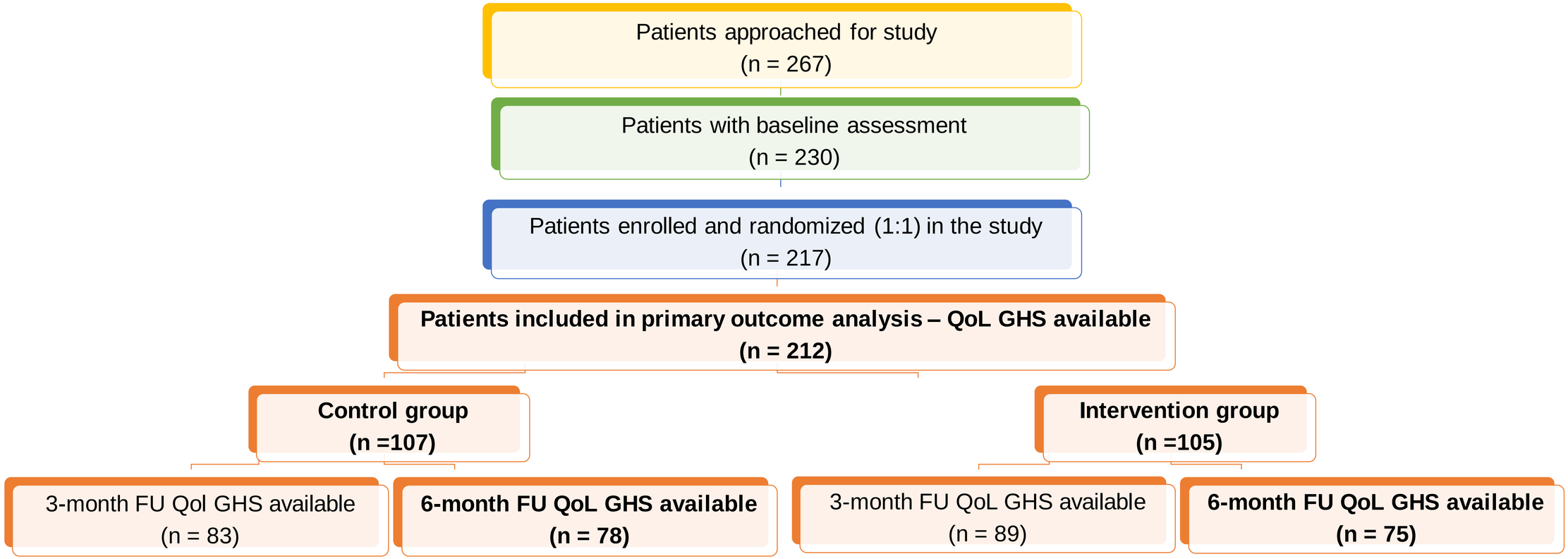
Methods

- **Primary endpoint:**
  - global health status (GHS) of the European Organisation for Research and Treatment of Cancer (EORTC) Qlq – C30
  - at 6 months after start of systemic therapy

- **Treatment group allocation:**
  - by minimization on tumor type, intent of systemic therapy, age, hospital and result on the G8 screening tool

- **Statistical analysis:**
  - Sample size calculation: >195 (≥10 points QoL change at 6 months) for 80% power at 2-sided 5% significance level
  - After exclusion of multicollinearity: analysis of the change in QoL GHS between baseline and 6 months follow-up with a mixed model

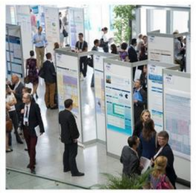
Results: flow-chart



Results

- Inclusion period: 10/2019 to 9/2021
- Follow-up period: till 9/2022
- Mean age (range): 76.8 years (70-96)
- Sex: female (n=111; 52.4%)
- 3 most common tumor types
  - digestive (n=65; 30.7%)
  - thorax (n=44; 20.8%)
  - urogenital (n=33; 15.6%)
- Systemic therapy: mostly non-curative intent (n=145; 68.4%)

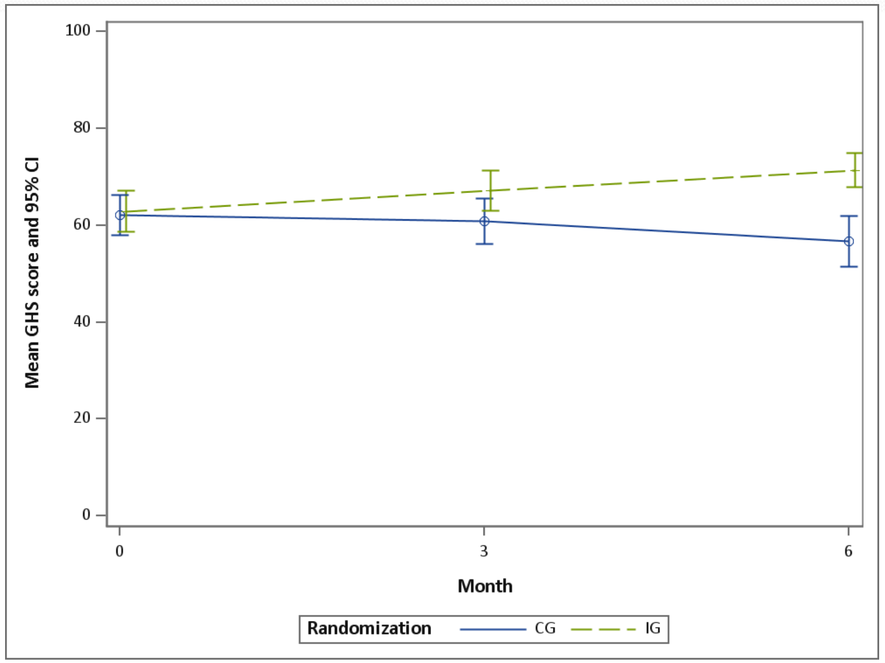




Results

- Mean observed values (unadjusted) and confidence interval (CI) of the EORTC QoL GHS for:
  - baseline, 3, and 6 months
  - both treatment arms

- CG and IG difference in change of adjusted* EORTC Qlq-C30 GHS
  - 6 months versus baseline
  - 12.8 points in favor of the IG (95%CL 6.7-18.8; p<0.0001)
    - CG: decline of 8.2
    - IG: improvement of 4.5



Legend: CG = control group; IG = intervention group

***Analysis adjusted for**: age, sex, ECOG-PS, G8, ADL, IADL, falls history, pain, fatigue, MMSE, GDS, polypharmacy, CCI, intent of systemic therapy, tumor type, diagnosis setting, 'randomization group * follow-up month'.

Conclusions / Take-Away

CGA coordinated by a geriatric team combined with extensive patient coaching improves QoL GHS in older patients with cancer compared to CGA coordinated by an oncology team.

Secondary endpoints (e.g. QoL at 12 months, patient satisfaction, severe systemic therapy-related adverse events, unplanned readmissions, survival) under analysis.

Conclusion

- CGA in geriatric oncology:
  - Detects previously unknown geriatric problems,
  - Influences treatment decisions,
  - Tailored geriatric interventions,
  - Prognostic and predictive value (e.g. survival),
  - Improved communication / shared-decision making process,
  - Reduced chemotherapy-related toxicity,
  - Improvement of functional status-related outcomes,
  - Improvement of likelihood of treatment completion,
  - Improved quality of life.

Source: Mohile et al, JAMA Oncology, 2020; Orum et al, JGO, 2021; Lund et al, BJO, 2021; Li et al, JAMA Oncology, 2021; Mohile et al, Lancet Oncol, 2021; Nipp et al, JGO, 2022; Soo et al, Lancet, 2022; Puts et al, JCO, 2023; Hamaker et al, JGO, 2022

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