Streamlined Geriatric and Oncological evaluation based on IC Technology for holistic patient-oriented healthcare management for older multimorbid patients - TWOBE study

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PRIMARY OBJECTIVE: to evaluate the effectiveness of the GerOnTe, ICT-based, integrated care pathway to improve patient 6-month quality of life, in Belgium and the Netherlands.SECONDARY OBJECTIVES• Evaluate the effectiveness of the GerOnTe patient-...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON53890

Source
ToetsingOnline

Brief title
GerOnTe TWOBE

Condition

- Other condition

Synonym
cancer, comorbidity

Health condition

Borst-, long-, prostaat- en colorectale kanker

Research involving
Human

Sponsors and support

Primary sponsor: Universitaire Ziekenhuizen Leuven (UZ Leuven)
Source(s) of monetary or material Support: European Union research and innovation funding programme;Horizon 2020

Intervention

Keyword: geriatrics, holistic, oncology, technology

Outcome measures

Primary outcome

PRIMARY ENDPOINT

Quality of life assessed by the EORTC QLQ-C30 questionnaire at 6 months after

GerOnTe inclusion using 3 derived scores of the QLQ-C30 questionnaire:

• Normalized global health status score

• Normalized score of the physical functioning scale

• Normalized score of the emotional functioning scale

Secondary outcome

SECONDARY ENDPOINTS

1. Quality of life

• The 3 normalized QLQ-C30 scores at baseline 3, 9 and 12 months

• Normalized scores of QLQ-C30 scales/items (role functioning scale, cognitive

functioning scale, social functioning scale, fatigue scale, nausea scale, pain

scale, dyspnea item, insomnia item, appetite loss item, constipation item,

diarrhea item and financial difficulties item) at baseline, 3, 6, 9 and 12

months.

• Scores of QLQ-ELD14 scales/items (mobility scale, worries about others scale, future worries scale, maintaining purpose scale, burden of illness scale, joint stiffness item, family support item) at baseline, 3, 6, 9 and 12 months

2. Survival: Overall survival at 12 months and progression-free survival (the time from study treatment initiation to the first occurrence of disease progression or death, whichever occurs first).

3. Patient autonomy, frailty and weight evolution

• Dependence score of the Activities of Daily Living scale (Katz ADL) at baseline, 3, 6, 9 and 12 months,

• Proportion of patients living at home at 6 and 12 months,

• Number of completed chair stands in 30 seconds (Chair stand test) at baseline, 3, 6, 9 and 12 months,

• Score of the Clinical Frailty Scale at baseline, 3, 6, 9 and 12 months,

• Grade of performance status, measured by ECOG-PS at baseline, 3, 6, 9 and 12 months,

• Weight at baseline, 3, 6, 9 and 12 months.

4. Patient anxiety: Score of Hospital Anxiety and Depression Scale (HADS) at baseline, 3, 6, 9 and 12 months.

5. Proportion of patient institutionalized and number of unscheduled hospitalisations per participants at 6 and 12 months.

6. Cost per life years gained (CEA, derived from survival/progression-free survival), cost per QALY gained (CUA, using utility assessed through normalized scores of EQ-5D-5L questionnaire collected at baseline, at 3, 6, 9 and 12 months after inclusion) and incremental cost-effectiveness ratios (ICERs) obtained by a cost-utility and a cost-effectiveness analysis.

7. Caregiver burden in health, psychological well-being, finances, social life and relationship with patient, using the Zarit Burden Interview at baseline, 3, 6, 9 and 12 months

8. Patient reported overall experience of person-centred coordinated care measured through the Person-Centred Coordinated Care Experience Questionnaire (P3CEQ) at 6 and 12 months.

9. Patient, physician and health-care-professionals-reported overall satisfaction with the ICT of the GerOnTe system: Score derived from the mHealth App Usability Questionnaire (MAUQ) for standalone mHealth Apps using the patient version for patient satisfaction and the provider version for physician and health care professional at 6 and 12 months after inclusion.

10. GerOnTe patient-centred system implementation and usage evaluated at 6 months (use of the Holis Patient App measures, for instance: number and frequency of connections to the app by patients; number of web-based meetings

with APN by site)

Study description

Background summary

The heterogeneity of older patients in terms of health status, physical functioning and intrinsic capacity makes their evaluation complex. In those aged 65 to 84, the proportion of patients with multimorbidity is as high as 65% and rises to 81% in those aged 85 or older. Currently, in Europe, acute-hospital care is mainly single-disease oriented. As a result, coexisting morbidities are often under-evaluated and under-managed, leading to inappropriate drug prescriptions, avoidable hospital admissions, delays in treatment and ultimately to suboptimal care and unnecessary cost overruns. Moreover, because of different health organisations, management of older multimorbid patients varies from one country to the other while we know that the structure of health system organisation has a strong impact on patients* health status. Finally, none is currently structured to absorb the demographic increase of older patients.

People with multimorbidity have reduced quality of life and impaired health outcomes and experience a significant impact of disease burden and an increased risk of death that current disease-centred management, which impacts patients* quality of life and quality of care, cannot manage.

Disease-centred approach is not appropriate to manage these patients. Change to a patient-centred approach will simplify care pathways, secure management and treatment decision making and decrease healthcare costs. It will be a real breakthrough for daily practice with multiple impacts that must be quantified.

The clinical model behind GerOnTe is to regroup all health professionals taking care of a multimorbid patient, into a common care coordination pathway: the Health Professional Consortium (HPC). The HPC will (i) centralise the decisions, aligning them to the patient*s priorities, (ii) be assisted by an advanced practice nurse (APN) as case manager, and (iii) be facilitated by HolisTM GV data exchange, personalised for each patient. Patients will be stratified in order to determine their dominant disease, thus the appropriate HPC. Patient-centred health management by the HPC with availability of real time, hospital- and patient-based data will foster timely decision enabling avoidance of unnecessary procedures and treatments leading to reduction in number of ineffective treatments, complications and unscheduled hospitalisations, concerted treatments of multimorbidities, and to more patients staying at home thanks to self-management related reduction of dependence.

The whole approach will be co-designed with patients, informal care givers and health professionals. Cancer is an excellent model to develop this approach in multimorbid patients because it is frequent and commonly associated with other morbidities in older patients but also because of its major impact on patients* general status and coexistent diseases. Cancer already benefits from a multidisciplinary management model that GerOnTe will enhance, strengthening exchange of holistic data, role of primary care and case management. GerOnTe will also provide new country-specific guidelines and best practices for implementation across Europe and for improved management of older multimorbid patients including improved quality of life and independent living at decreased costs.

Study objective

PRIMARY OBJECTIVE: to evaluate the effectiveness of the GerOnTe, ICT-based, integrated care pathway to improve patient 6-month quality of life, in Belgium and the Netherlands.

SECONDARY OBJECTIVES
• Evaluate the effectiveness of the GerOnTe patient-centred system to:
o Improve quality of life at 3, 9 and 12 months,
o Improve patient survival and progression-free survival at 12 months,
o Improve patient autonomy at 3, 6, 9 and 12 months,
o Reduce patient anxiety at 3, 6, 9 and 12 months,
o Reduce patient unscheduled hospitalisations and patient institutionalisations at 6 and 12 months,
• Assess the cost-utility and cost-effectiveness of the GerOnTe intervention versus standard of care up to 1-year post-inclusion (3, 6, 9 and 12 months after inclusion),
• Evaluate caregiver burden in health, psychological well-being, finances, social life and relationship with patient at 3, 6, 9 and 12 months,
• Evaluate patient-reported overall experience of the GerOnTe intervention at 6 and 12 months,
• Evaluate patient and health care professionals reported overall satisfaction and acceptability of the GerOnTe intervention at 6 and 12 months,
• Analyze the implementation and use of the GerOnTe patient-centred intervention by patients and health care professionals

Study design

Study design is a stepped wedge randomized controlled trial. Clusters will be participating hospitals, comprising eight investigating sites in total.
Patients included at each *step* are different individuals. The first *step* is a reference measurement where none of the clusters will implement the intervention. The investigating sites will be randomly drawn to determine the order in which they will implement the intervention, by *steps* of two months.

Each centre engaged to participate needs to participate till the end of the trial. A centre commitment to participate will be requested before each centre involvement to avoid centre withdrawal after the start of the trial.

Intervention

The intervention will include the following components:
• A health professional consortium (HPC) for each patient, which will work together to make recommendations regarding oncologic treatment and non-oncologic interventions, at baseline and in the course of treatment. This will be in addition to the usual multidisciplinary tumour board (MTB) which will provide oncologic treatment recommendations based on the usual oncologic work-up.
• An advance practice nurse (APN) as case-manager, who will be the primary contact person for the patient during the oncologic treatment and subsequent follow-up
• A baseline patient evaluation consisting of a comprehensive geriatric assessment by a geriatrician or APN, which will focus on general health status, comorbidities and intrinsic capacity. Baseline documentation of patient preferences and priorities will be done by the APN.
• A health care professional dashboard called Holis Dashboard, which will provide a structured presentation of patient and tumour information, both during the decision-making phase as well as during treatment and follow-up, according to the standard consensus dataset. Dashboard data will be made available selectively to all health care professionals of the HPC.
• A patient application called Holis Patient Application, which will allow for monitoring of symptoms and signs of destabilised comorbidity or functional decline during and after treatment, with additional self-management library with recommendations for how the patient can deal with issues or for contacting their health care providers in case of symptoms requiring urgent intervention.
• Additional data that will be collected every 3 months are quality of life questionnaires (EORTC QLQ-C30/QLQ-ELD14/EQ-5D-5L), autonomy questionnaire (Katz ADL), anxiety/depression questionnaire (HADS), patient-related outcomes questionnaire (perceived benefit, treatment objectives, tool satisfaction) and possible revision of patient*s treatment objectives.

Study burden and risks

Very minimal risks to the patient. Possible increased focus on side effects due to daily use of HolisTM GV Patient App which may cause anxiety.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Inclusion criteria

General inclusion criteria
1. Age >= 70 years old.
2. New or progressive cancer (breast, lung, colorectal, prostate) fulfilling the tumour specific criteria.
3. Estimated life expectancy greater than 6 months.
4. At least one moderate/severe multimorbidity inclusion criteria other than current cancer (see separate list under 5.3).
5. Patients must be willing and able to comply with study procedures.
6. Voluntarily signed and dated written informed consents prior to any study specific procedure.
7. QLQ-C30 Quality of Life Questionnaire fully completed at baseline, before inclusion.

Tumour specific inclusion criteria

8. Specific inclusion criteria for breast cancer:
8.1. Non-metastatic breast cancer (M0):

• No prior treatment for the current breast cancer.
• All 3 criteria required:
o Clinical staging: cT2-3-4 Nany, or cTany N1-2-3,
o The cancer specialist considers* surgery,
o The cancer specialist considers* radiotherapy and/or chemotherapy.
8.2. Metastatic breast cancer (M1): Both criteria required:
• The cancer specialist considers* chemotherapy or PARP-inhibitors or mTOR-inhibitors / PIK3CA inhibitors; Previous endocrine therapy +/- CDK4/6 inhibitors is allowed,
• The patient received maximum 1 prior line of chemotherapy for metastatic disease.
**consider* implies that this treatment may be a treatment option for this patient in this particular setting. If at a later point, a different treatment choice is made, the patient remains eligible.

9. Specific inclusion criteria for colorectal cancer:
9.1. Non-metastatic colorectal cancer (M0):
• No prior therapy for the current tumour in the recruiting hospital.
• At least one of the 3 criteria required:
o The cancer specialist considers* surgery,
o The cancer specialist considers* radiotherapy,
o The cancer specialist considers* chemotherapy.
9.2. Metastatic colorectal cancer (M1):
• The cancer specialist considers* first line systemic therapy and/or radiotherapy (+/- surgery). No previous chemotherapy allowed except adjuvant/perioperative chemotherapy stopped for more than 12 months.
**consider* implies that this treatment may be a treatment option for this patient in this particular setting. If at a later point, a different treatment choice is made, the patient remains eligible.

10. Specific inclusion criteria for lung cancer:
10.1. Non-metastatic lung cancer (M0):
• No prior therapy for the current tumour in the recruiting hospital
• At least one of the 3 criteria required:
o The cancer specialist considers* surgery (patients considered for treatment with percutaneous thermoablation alone are not eligible),
o The cancer specialist considers* radiotherapy (except SBRT),
o The cancer specialist considers* systemic therapy. Possible systemic therapies are chemotherapy and/or immune therapy and/or targeted therapy. Patients only considered* for monotherapy with anti-EGFR TKI or somatostatin analog are not eligible.
10.2. Metastatic lung cancer (M1):
• The cancer specialist considers* first or second line systemic therapy. Possible systemic therapies are chemotherapy and/or immune therapy and/or targeted therapy. Patients only considered* for monotherapy with anti-EGFR TKI or somatostatin analog are not eligible.
**consider* implies that this treatment may be a treatment option for this

patient in this particular setting. If at a later point, a different treatment choice is made, the patient remains eligible.

11. Specific inclusion criteria for prostate cancer:
11.1. Non-metastatic prostate cancer (M0): one of the following:
• First diagnosis M0 prostate cancer (no therapy received yet for prostate cancer): at least one of the 2 criteria required:
o The cancer specialist considers* radiotherapy,
o The cancer specialist considers* hormone therapy (ADT +/- combination Abiraterone and Prednisone).
• Salvage treatment M0 prostate cancer (received prior surgery at least 6 months before):
o The cancer specialist considers* radiotherapy (+/- ADT)
• Non-metastatic castration resistant prostate cancer:
o The cancer specialist considers* treatment intensification (ADT + Enzalutamide or Apalutamide or Darolutamide).
11.2. Metastatic prostate cancer (M1):
• The cancer specialist considers* treatment with Abiraterone or Enzalutamide or Apalutamide or Docetaxel or Cabazitaxel or PARP-inhibitors or Lutetium PSMA.
**consider* implies that this treatment may be a treatment option for this patient in this particular setting. If at a later point, a different treatment choice is made, the patient remains eligible.

Protocol: page numbers 24-28

Exclusion criteria

1. Mental illness/cognitive impairment that limits ability to provide consent or complete trial procedures.
2. Participating to an interventional clinical trial with a non-registered anticancer drug or to another geriatric intervention trial.
3. Patients and caregivers are unable or unwilling to use ICT-devices (tablet, computer, smartphone) or the Internet according to protocol.
4. Patient already included in this study.

Protocol: page number 26

Study design

Design

Study type: Interventional

Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2024
Enrollment:	360
Type:	Anticipated

Medical products/devices used

Generic name:	HolisTM GV
Registration:	No

Ethics review

Approved WMO Date:	11-11-2022
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	24-03-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT05423808
CCMO	NL81897.100.22