ISRCTN14737915 https://doi.org/10.1186/ISRCTN14737915

Meaningful contextual communication in cancer care

Submission date
07/09/2021

Registration date
15/09/2021

Last Edited
15/09/2021

Recruitment status
Recruiting

Overall study status
Ongoing

Condition category
Cancer

☒ Prospectively registered
☐ Protocol
☐ Statistical analysis plan
☐ Results
☐ Individual participant data
☐ Record updated in last year

Plain English summary of protocol
Background and study aims
Contextual care is the continuous, ongoing process of identifying individual patient circumstances (their context) and, if necessary, modifying the plan of care to accommodate those circumstances. It is about essential patient needs that need to be addressed.
Being confronted with the reality of having advanced cancer may give rise to life questions, and subsequent struggles such as fear, anger, loss of independence, changing self-image, roles and relationships and failure to find meaning are frequently reported amongst patients.
This project will focus on increasing meaningful contextual communication between health care professionals (HCPs) and patients with advanced cancer, considering differences across Europe in both clinical and ethical aspects. The challenge addressed by this project is to develop an intervention founded on a European-wide set of central educational design principles, in order to increase the competence of specialised palliative care HCPs in meaningful contextual communication (what does it mean for this patient at this moment to live with his or her illness?), and as a result to increase QoL of patients with advanced cancer throughout Europe.

Who can participate?
Adult (over 18 years of age) patients with advanced cancer and their family caregivers under treatment of included multidisciplinary teams in palliative care.

What does the study involve?
An observational pre-study in which participants will randomly be invited for an interview or focus group.
A communication training for HCPs working in multidisciplinary teams for palliative care (5 steps in 5 months).
HCPs, patients, and their family caregivers will be interviewed before and after the communication training to assess impact of training.

What are the possible benefits and risks of participating?
Benefits: increased meaningful contextual communication, resulting in increased job satisfaction for HCPs, increased QoL for patients and family caregivers, increased cost-effectiveness.
Risks: None

Where is the study run from?
Radboud University Nijmegen Medical Centre (Netherlands)

When is the study starting and how long is it expected to run for?
September 2021 to June 2028

Who is funding the study?
EU (HORIZON-21)

Who is the main contact?
Dr Anne Wichmann (anne.wichmann@radboudumc.nl)

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
A mixed-method implementation study of a design-based educational intervention to enhance meaningful contextual communication in care planning with advanced cancer patients and their families across Europe

Acronym

onCOntext

Study objectives
The introduction of the onCOntext intervention will improve meaningful contextual communication.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Interventional uncontrolled pre-post study

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Increasing meaningful contextual communication between multidisciplinary palliative care teams, patients with advanced cancer and their family caregivers.

Interventions
The observational cross-sectional study in year 1 comprises of a comprehensive European-wide (The Netherlands, Belgium, Scotland, Switzerland, Poland, Turkey, Spain, Italy) qualitative current practice study amongst HCPs (N=80), patients with advanced cancer (N=80) and their family caregivers (N=80) on i) the perspectives on current practice regarding meaningful contextual communication in palliative care, its integration in care planning and serious late and long-term side effects; ii) how these stakeholders from different European cultures understand meaningful contextual communication in palliative care; iii) how HCPs define the concept 'meaningful contextual communication' and which 'language' they use for it; iv) what makes team-based learning in European palliative care work? For point iv, additionally two focus groups per country (total N=16) will be conducted with 10-15 stakeholders (total N≈200). It will take approximately a year.

The interventional pre- post effect measurement study in year 3 consists of i) prospective interviews conducted amongst HCPs (N≈150), patients (N≈150) and family caregivers (N≈150); ii) 4C coding of audio-recorded consultations (N≈320); iii) a structured retrospective after-death questionnaire study amongst HCP most involved in care (N≈800) and a family caregiver closely involved (N≈800), also about the patient*.
* all participating teams retrospectively report all deaths of patients over a three month period, about whom the HCP and family caregiver will also answer questions. Using a three-month period limits recall bias and has been tested previously.

Intervention Type
Behavioural

Primary outcome(s)

1. Observational pre-study: current practice, perspectives, cultures measured amongst HCPs, patients, family caregivers and relevant experts using interviews (N=80 per stakeholder group)

Main interventional study:
2. Experiences of HCPs, patients and their family caregivers with current care measured using interviews at baseline (T0) and 3-6 months post-intervention (T1)
3. Contextual communication measured in audio-taped consultations using 4C coding, at baseline (T0) and 3-6 months post-intervention (T1)

Key secondary outcome(s))

1. HCP competence measured using questionnaire (SCCS), at baseline (T0) and 3-6 months post-intervention (T1)
2. HCP job satisfaction measured using questionnaire (NEXT study), at baseline (T0) and 3-6 months post-intervention (T1)
3. Patient QoL measured using questionnaires (EQ5D-5L, FACIT-Sp, ICECAP-SCM) at baseline (T0) and 3-6 months post-intervention (T1)
4. Family caregiver burden measured using questionnaire (CRA) at baseline (T0) and 3-6 months post-intervention (T1)
5. Costs measured using consultation length and questionnaire (RUD) at baseline (T0) and 3-6 months post-intervention (T1)

Completion date

01/06/2028

Eligibility

Key inclusion criteria

Adult (>18 years of age) patients with advanced cancer and their family caregivers under treatment of included multidisciplinary teams in palliative care

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Patients with intellectual disabilities
2. Children

Date of first enrolment

01/06/2025

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
United Kingdom

Scotland

Belgium

Italy

Netherlands

Poland

Spain

Switzerland

Türkiye

Study participating centre
Radboud university medical center
Netherlands
6500 HB

Study participating centre
UEDIN
Edinburgh
United Kingdom
EH8 9AG

Study participating centre
UANTWERPEN
Antwerp
Belgium
2610

Study participating centre
UZ UNIVERSITY OF ZIELONA GORA
Poland
65–046

Study participating centre
PALLIATIVE HEALTH SERVICES ASSOCIATION
Türkiye
06520

Study participating centre
UNIBO
Italy
40126

Study participating centre
CENTRAL UNIVERSITY OF CATALONIA
Spain
08500 Vic

Study participating centre
UNIVERSITAET BERN
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3012 Bern

Sponsor information

Organisation
Radboud University Nijmegen Medical Centre

ROR
https://ror.org/05wg1m734

Funder(s)

Funder type
Government

Funder Name
European Commission

Alternative Name(s)
European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, EC, EU

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes