ISRCTN41201864 https://doi.org/10.1186/ISRCTN41201864

Evaluating the feasibility, acceptability and potential effectiveness of complex nursing intervention focused on quality of life assessment on advanced cancer patients with palliative care needs

Submission date 12/09/2016	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 26/09/2016	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 30/01/2018	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Palliative care is an approach that improves the quality of life of patients and their families facing the problems associated with life-threatening illness. One of the most important challenges in palliative care is determining how patient' needs are defined and assessed. Palliative care interventions are usually delivered late when symptoms are uncontrolled, resulting in deteriorating quality of life. The aim of this study is to test the effectiveness of quality of life measurement in terms of patients' quality of life and related management actions taken by palliative care staff. It is predicted that patients being cared for by hospice staff who measure quality of life with an easy-to-use questionnaire will have better quality of life compared with patients being cared for by staff who provide traditional care (no quality of life measurement).

Who can participate?
Palliative care team members and adult patients at the two participating hospices

What does the study involve?
Quality of life measurement is introduced into one of the hospices selected at random. Palliative care staff are interviewed in order to collect their point of view about quality of life measurement in palliative care, and receive a 3-hour education and training session about quality of life measurement in palliative care. Patients are asked 10 questions that assess their quality of life. Patients and staff at the other hospice continue with traditional clinical practice.

What are the possible benefits and risks of participating?
All patients in the study will benefit from regular quality of life assessment. This may improve the recognition of patients' needs and overall care for all participants. The trialists are not aware of any disadvantages or risks of joining this study.

Where is the study run from?
1. IRCCS AOU San Martino - IST (Italy)
2. Gigi Ghirotti Hospice (Italy)

When is the study starting and how long is it expected to run for?
February 2014 to September 2017

Who is funding the study?
European Oncology Nursing Society

Who is the main contact?
Dr Gianluca Catania
gianluca.catania@edu.unige.it

Contact information

Type(s)
Public

Contact name
Dr Gianluca Catania

ORCID ID
http://orcid.org/0000-0002-0862-071X

Contact details
Via Pastore, 1
Genova
Italy
16132
+39 (0)10 353 8589
gianluca.catania@edu.unige.it

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A phase II quasi-experimental trial evaluating the feasibility, acceptability and potential effectiveness of complex nursing intervention focused on quality of life assessment on advanced cancer patients with palliative care needs

Acronym
INFO-QoL

Study objectives
Our primary hypothesis is that patients who will be cared for by hospice staff that have implemented a nurse-led complex INtervention FOcused on Quality of Life Measurement (INFO-QoL) measurement, will have a significantly better Quality of Life (QoL) compared with patients cared for by staff that provide traditional care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
IRCCS AOU San Martino – IST Regional Ethics Committee, 23/07/2015, ref: #335REG2014

Study design
Quasi-experimental non-equivalent comparison group before/after design

Primary study design
Interventional

Secondary study design
Mixed method trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Palliative care (advanced stage cancer patients)

Interventions
This is a multicentre two-stage study. The study will be conducted on a convenience sample of two hospice units of the urban district of Genoa in the North of Italy: the Gigi Ghirotti Bolzaneto Hospice is a 12-bed nonprofit hospice (Gigi Ghirotti Hospice – Association for Research and Treatment of Pain and Palliative Care), and the Maria Chighine Hospice is a 12-bed public hospice (IRCCS AOU San Martino – IST - Teaching Hospital and Cancer Research Centre). In both of these hospice units, healthcare professionals were educated and trained in PC and communication in end-of-life care and used the Liverpool Care Pathway. According to the definition of the European Association for Palliative Care, “they admit patients in their last phase of life when treatment in the hospital is not necessary and care at home or in nursing home is not possible” (Radbruch and Payne, 2009). The National Health System covers all or part of the costs of the care for the public and nonprofit hospice, respectively. The hospice staff of the Ghirotti Hospice includes 1 physician, 10 nurses and 6 nursing assistants, and the Maria Chighine Hospice includes 3 physicians, 12 nurses and 7 nursing assistants.

The study sample will be constituted of 39 multidisciplinary hospices' members and a sample of 46 advanced cancer patients admitted to hospices during the implementation of the intervention.

The modelling phase will be conducted through a qualitative approach:
1. Semi-structured face-to-face interviews to explore hospice nursing staff members' experiences, and their role in implementing a nurse-led intervention focused on QoL measurement
2. Focus groups with nursing staff members to explore their perspective about a draft version of the INFO-QoL received a week before the scheduled focus groups sessions
3. A questionnaire survey to assess staff knowledge on QoL in PC

The exploratory trial will have a quasi-experimental non-equivalent comparison group before /after design. This design will enable the researcher to pilot the components and methods, and the feasibility of the intervention (the INFO-QoL), assess its acceptability in practice, and whether the INFO-QoL is delivered according to the study protocol. It will also offer the opportunity to determine potential effectiveness of the INFO-QoL in improving patient QoL.

To partially address selection bias, the INFO-QoL will be introduced randomly into unit 1 (intervention unit) while patients and staff in unit 2 (comparison unit) will continue with traditional clinical practice. By gathering pre-test data, the equivalence of the two groups on antecedent variables can be compared before introducing the independent variable.

The unit of randomization is the hospice unit. To prevent performance bias before randomly allocating the experimental intervention in one of the two units, the collection of pre-test data will occur within a three-month period in both units before making any change. Subsequently, to reduce the selection bias, the INFO-QoL will be implemented randomly in "unit 1" (intervention units), while patients and staff in "unit 2" (comparison unit) will continue with the standard clinical practice.

Randomization will be performed independently by using a computer-generated sequence. The randomization procedure will be centralized and managed by an independent statistician at the coordinating centre of the study. All study investigators, personnel, and participants will be unaware of the randomization procedure.

Intervention Type
Other

Primary outcome measure
Patient QoL (potential effectiveness) assessed using the Italian version of the Palliative Outcome Scale (POS) before (period I: 3 months) and after (period II: 3 months) the intervention

Secondary outcome measures
1. Patient management, evaluated using an adapted version of the composite patient management score by Detmar et al. (2002). All QoL-related management actions taken by staff for patients are calculated by summarizing all the actions taken. Data is collected from medical and nursing charts and ad hoc documentation, which comprises the terminology included in the QoL tool (i.e., the POS) to collect actions delivered to patients for each of impaired QoL dimensions resulting from the POS score.
2. Acceptability of the study, evaluated in terms of number of patients accepting to participate in this study.

2.1. Acceptability of the intervention from the patients' perspective. Once the delivery of the intervention is completed, acceptability is examined using an ad hoc semi-structured questionnaire. Patients are asked to appraise the intervention in terms of appropriateness and usefulness in collecting their own needs using a QoL tool and to suggest ways to enhance its acceptability and to identify any missing elements (Sidani & Braden, 2011).
2.2. Acceptability of the intervention from the staff's perspective. Acceptability is assessed using an ad hoc semi-structured interview including five open questions. After implementing the intervention – at the end of a 3-month period – staff members' acceptability is explored in terms of relevance, appropriateness and usefulness in addressing QoL of palliative care patients. To enhance the completeness and acceptability of the intervention, staff members are asked to suggest ways to modify any aspects of the intervention and their professional views on maintaining the INFO-QoL as a standard for the unit. Preliminary to staff interviews, a fundamental overview of QoL as main focus of palliative care, the intervention (i.e. the INFO-QoL) is provided, and then staff are asked to answer the following questions:
1. How would you comment on the relevance of the intervention in addressing palliative care patients' QoL?
2. How would you overall appraise the intervention in terms of its appropriateness in addressing palliative care patients' QoL?
3. How would you overall appraise the intervention in terms of its usefulness in addressing palliative care patients' QoL?
4. Would you suggest ways to modify any components and/or activities of the intervention?
5. Would you maintain the INFO-QoL as a standard for the unit?
3. Feasibility of the intervention, measured in terms of time taken to organize and perform the intervention, and to train professionals on QoL. Also, deviations from the procedures, and uncompleted measurements and the reasons are recorded through structured professionals' self-reports – checklists (fidelity of intervention). In addition, professionals are asked to rate their competence and level of confidence in delivering the intervention at different points in time.
4. Feasibility of the study, assessed in terms of time taken to obtain patient's informed consent and recruitment and patient drop out rates.

Overall study start date
01/02/2014

Completion date
01/09/2017

Eligibility

Key inclusion criteria
1. All the PC team members within the two hospices during the modeling and feasibility phase
2. Adult patients (aged >=18 years) newly admitted to hospice units during the 6-month period of the feasibility phase (pre-test= 3 months; post-test= 3 months)

Participant type(s)
Mixed

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
46 patients

Key exclusion criteria
1. Patients too ill to receive the intervention
2. Unable to give informed consent either due to cognitive impairment or because they are unable to understand Italian

Date of first enrolment
07/12/2015

Date of final enrolment
01/05/2017

Locations

Countries of recruitment
Italy

Study participating centre
IRCCS AOU San Martino - IST (Hospice Unit)
Largo Rosanna Benzi 10
Genova
Italy
16132

Study participating centre
Gigi Ghirotti Hospice
Piazza Pastorino 3
Genova
Italy
16162

Sponsor information

Organisation
University of Genoa (Università di Genova)

Sponsor details
Via Pastore 1
Genova
Italy
16132
+39 (0)10 353 8589
gianluca.catania@edu.unige.it

Sponsor type
University/education

Website
https://unige.it/

ROR
https://ror.org/0107c5v14

Funder(s)

Funder type
Charity

Funder Name
European Oncology Nursing Society

Alternative Name(s)
EONS

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The trialists plan to publish the study protocol and then the results of the study. Study results will be presented in local and international conferences.

Intention to publish date
01/09/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		19/06/2014	26/09/2016	No	Yes
Protocol article	protocol	13/11/2017		Yes	No