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Revie : pilot study of an intervention that aims to promote the dignity of persons with advanced cancer

Submission date	Recruitment status	[_] Prospectively registered
04/05/2016	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/05/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/06/2023	Cancer	

Plain English summary of protocol

Background and study aims
A new life review intervention (programme) "Revie " for adults with advanced cancer has been developed. It consists of sharing significant events about a person's life history and supporting personal development by focusing on positive changes that have occurred since being diagnosed with cancer. Based on this information, a booklet is created, in which photos, poems, or another important text can be included. Once completed, the booklets are given to the participants. The focus of the intervention is to help patients approach the end-of-life in a more positive and dignified way. It can contribute to personal development and a better overall level of satisfaction with life. This study aims to evaluate the feasibility of Revie .

Who can participate?
Adults (aged 18 or older) with advanced cancer.

What does the study involve?
The intervention involves a patient having two sessions with a nurse. In the first session (which takes one hour) the patient is asked to share significant events in their life, discuss their concerns about death and dying, their vision of life and their relationships and focus on positive changes that have occurred since the cancer diagnosis. Drawing on this information, a booklet is created. In the second session (15-30 minutes), this booklet is presented, completed, and finalized. Patients can include photos, poems, or another text that they deem important. Once completed, the booklets are given to the participants.

What are possible benefits and risks for participating?
Patients may benefit from the intervention by promoting dignity, increasing their personal development an overall life satisfaction. The risk of adverse events during the intervention is estimated to be low. Nevertheless if a distress is perceived, the person can benefit from a consultation by a psychologist.

Where is the study run from?
Geneva University Hospital (Switzerland)

When is the study starting and how long is it expected to run?
August 2013 to January 2017

Who is funding the study?
HES-SO University of Applied Sciences and Arts Western Switzerland, School of Health Sciences, Geneva (Switzerland)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
15-037

Study information

Scientific Title
Revie : the influence of a life review intervention including a positive, patient-centered approach towards enhancing the personal dignity of patients with advanced cancer. A study protocol for a feasibility study using a mixed method investigation

Acronym
Revie

Study objectives
To evaluate the feasibility and preliminary efficacy of a novel intervention, Revie , to promote the dignity of patients with advanced cancer

Ethics approval required
Old ethics approval format

Ethics approval(s)
Swiss Ethics Committees on research involving humans, Geneva, 04/06/2015, ref: 15-037

Study design
Pilot pre-post feasibility study using a mixed method approach, i.e. an embedded concurrent design with both quantitative and qualitative parts.

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Advanced cancer patients, palliative care

Interventions
Life review intervention using a patient-centered positive approach. The intervention encompasses two sessions between a nurse and a patient. In the first session (60 minutes) the participant is firstly asked to share significant events in his life and secondly personal development is supported by focusing on positive changes that have occurred since the cancer diagnosis. In this first intervention five domains are addressed, namely:

1. Reflecting on the patient's life story and specific significant events;
2. Focusing on the positive changes that have occurred since the disease diagnosis;

3. Patients telling their values and vision of life and their relationship with others;
4. Discussing significant issues,
5. Discussing the patient's deepest concerns and their thoughts about death and dying.

Drawing on this information, a booklet is created. In the second session (15-30 minutes), this booklet is presented, completed, and finalized. Patients can include photos, poems, or another text that they deem important. Once completed, the booklets are given to the participants.

Intervention Type
Behavioural

Primary outcome(s)
1. Number of participants recruited: timepoint: end of recruitment: May 2016
2. Intervention retention rates. timepoint: end of recruitment: May 2016
3. Acceptability of the intervention for patients: semi-directed interview about the process and questionnaire about acceptability (T2 post- intervention)
4. Acceptability for nurses delivering the intervention in terms of fidelity (adherence structured content), resources mobilized, and practice change. Diary , focus group and questionnaire end of recruitment: May 2016

Key secondary outcome(s))
1. Sense of dignity, with The Patient Dignity Inventory (PDI) questionnaire (T0 baseline + T2 post intervention)
2. Post traumatic growth, with The Post-Traumatic Growth Inventory (PTGI) (T0 baseline + T2 post intervention)
3. Satisfaction with life, with The Satisfaction with Life Scale (SWLS) (T0 baseline + T2 post intervention)

Completion date
30/01/2017

Eligibility

Key inclusion criteria
1. Adults (aged 18 years or older) with advanced cancer (T3 or T4, or the presence of metastases)
2. Adequate health status to participate in the study, as determined by clinical consensus between nurses and physicians
3. Able to cognitively understand
4. Consent to inclusion in the study

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 years

Sex
All

Key exclusion criteria
1. Patients diagnosed with cognitive disorders related to memory loss or disturbances of speech that would not allow for a constructive exchange,
2. with insufficient command of the French language to complete the study questionnaires.

Date of first enrolment
15/04/2015

Date of final enrolment
30/04/2016

Locations

Countries of recruitment
Switzerland

Study participating centre
University Hospital Geneva (Hôpital Universitaire de Genève)
Geneva
Switzerland
122 Genève 14

Sponsor information

Organisation
University Institute of Training and Care Research (IUFRS) (Institut Universitaire de Formation et de Recherche en Soins)

ROR
https://ror.org/029ma5383

Funder(s)

Funder type
University/education

Funder Name

HES-SO University of Applied Sciences and Arts Western Switzerland, School of Health Sciences, Geneva, Switzerland

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/12/2016		Yes	No
Abstract results	S6	27/07/2017	14/06/2023	No	No
Participant information sheet			25/05/2016	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes