

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

Submission date 04/05/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 13/05/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 14/06/2023	Condition category Cancer	<input type="checkbox"/> Individual participant data

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 and 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?
Maria Goreti da Rocha Rodrigues

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

See additional files

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 measure

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

Secondary outcome measures

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)

Overall study start date

31/08/2013

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

N=40

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)

Sponsor details

Biopôle 2
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Lausanne
Switzerland
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+41 21 314 58 15
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Sponsor type

University/education

Website

<https://www.unil.ch/sciences-infirmieres/fr/home/menuinst/iufrs.html>

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**Publication and dissemination plan**

1. March 2016: submitted to be published in the journal Pilot and Feasibility Studies. : "Revue + 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"
2. September 2016: manuscript on the development of the intervention and link with the theoretical framework
3. November 2016: a manuscript on the results of the study

Intention to publish date

30/11/2016

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?
Participant information sheet			25/05/2016	No	Yes
Protocol article	protocol	01/12/2016		Yes	No
Abstract results	S6	27/07/2017	14/06/2023	No	No