

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

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

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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? |
|---|----------|--------------|------------|----------------|-----------------|
| <a href="#">Participant information sheet</a> |          |              | 25/05/2016 | No             | Yes             |
| <a href="#">Protocol article</a>              | protocol | 01/12/2016   |            | Yes            | No              |
| <a href="#">Abstract results</a>              | S6       | 27/07/2017   | 14/06/2023 | No             | No              |