

# Evaluation of a support program for cancer survivors in older age

<b>Submission date</b> 07/08/2025	<b>Recruitment status</b> Not yet recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 11/08/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 11/08/2025	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Rapid advances in early detection, modern therapies, and demographic changes have led to an increasing number of older people surviving cancer. Meanwhile, the majority of cancer survivors are  $\geq 70$  years old. Cancer and its intensive treatment can have a significant physical and psychosocial impact on survivors' quality of life. Elderly survivors show an increased risk of an unfavorable course due to complex interactions between the aging process, concomitant diseases and the consequences of the cancer and its treatment. Due to the reduced physical reserves of elderly cancer survivors and their increased susceptibility to stressful events, the aging process is often accelerated, resulting in reduced physical and cognitive performance and mental well-being. In addition, the resources of elderly people and their specific support needs are often not included in the treatment. To ensure a better long-term survival, it is necessary to have follow-up care programs that are designed for a person's age, health risks, and available support, focusing on both cancer care and overall health. The IMPULS-A program addresses these needs by improving access to the networking of regional care services and providing individualized support for elderly cancer survivors. This study will evaluate whether the care program is effective and useful.

### Who can participate?

Cancer survivors aged  $\geq 70$  years with an expected lifespan of  $\geq 3$  years, residing within a 100 km radius of the National Center for Tumor Diseases (NCT) in Heidelberg, with support needs. Patients' relatives may also take part in the study if interested.

### What does the study involve?

Study candidates are screened to assess their biopsychosocial support needs. If support is needed, they will be enrolled in the study. If no needs are identified, they will not be included in the study at that time but will be screened every six months. If support needs are later identified, they will be included in the study then.

Participants are randomly allocated either to the intervention group, receiving the IMPULS-A program or to the control group, receiving standard care.

Participating patients will be asked to complete a questionnaire at three measurement time points: at the beginning of the study (T0), 9 months after the start (T1) and 18 months after (T2). In addition, participants in the survivorship program are screened at study inclusion and every 6

months with regard to existing needs and asked whether they have any support requests. If needs are identified, a care navigator provides appropriate counselling/treatment services and coordinates them with the patient's personal preference. If complex needs are identified, the Care Navigator may present the case to an interdisciplinary survivor board to facilitate coordinated, cross-professional care.

What are the possible benefits and risks of participating?

Participants allocated to the intervention group may benefit from personalized support through the survivorship program. Support from psycho-oncological services is available if needed. There are no risks of physical injury or harm.

Where is the study run from?

National Center for Tumor Diseases (NCT) Heidelberg (Germany)

When is the study starting and how long is it expected to run for?

April 2023 to August 2028

Who is funding the study?

Deutsche Krebshilfe (Germany)

Who is the main contact?

Dr. med. Till Joahnnnes Bugaj, Impuls-A@med.uni-heidelberg.de

## Contact information

### Type(s)

Principal Investigator

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## **Additional identifiers**

### **EudraCT/CTIS number**

Nil known

### **IRAS number**

### **ClinicalTrials.gov number**

Nil known

### **Secondary identifying numbers**

German Cancer Aid reference number: 70116185

## **Study information**

### **Scientific Title**

IMPlmentation of a sUpport program for Long-term cancer Survivors in older Age

### **Acronym**

IMPULS-A

### **Study objectives**

The primary hypothesis is that compared to the control group, the intervention group shows better health literacy 18 months after randomisation. Health literacy is defined as the extent to which elderly cancer survivors feel sufficiently informed to actively do something for their health and feel competent in the medical system.

Secondary hypotheses are that the intervention group will show higher digital health literacy, higher quality of life and resources, higher use of support services, lower use of emergency care,

and higher patient satisfaction than the control group after 18 months. In addition, acceptability, appropriateness, and feasibility of the survivorship care model will be assessed as secondary outcomes.

### **Ethics approval required**

Ethics approval required

### **Ethics approval(s)**

Approved 27/11/2024, Ethikkommission der Medizinischen Fakultät Heidelberg (Ethics Committee of the Medical Faculty of Heidelberg) (Alte Glockengießerei 11/1, Heidelberg, 69115, Germany; +49 6221 56 26460; ethikkommission-l@med.uni-heidelberg.de), ref: S-692/2024

### **Study design**

Multicentre interventional randomized controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

GP practice, Hospital, Other

### **Study type(s)**

Efficacy

### **Participant information sheet**

### **Health condition(s) or problem(s) studied**

Cancer survivors in older age

### **Interventions**

Participants will be randomized into one of the two arms:

1. IMPULS-A program: participants undergo a screening every 6 months to assess their needs and willingness for support. If needs are identified, appropriate counseling/treatment options will be recommended, and participants will be assisted with referrals, primarily to existing services close to their home. Complex cases are reviewed by an interdisciplinary Survivor Board.
2. Treatment as usual (control intervention): participants receive the current standard treatment for long-term survivors. This means that some of the participants will also use support services, but will not be systematically and individually informed about them.

Randomisation will be done using REDcap (a web application for building and managing online surveys and databases).

### **Intervention Type**

Behavioural

### **Primary outcome measure**

Health literacy measured using the Health Literacy Questionnaire (HLQ) subscale 2: "Having sufficient information to manage my health" at 18 months after randomization (T2)

### **Secondary outcome measures**

1. Digital health literacy measured using the Health Literacy Survey 2019–2021 (HLS19-DIGI) at 18 months after randomization (T2)
2. Quality of life measured using an abridged version of QLQ-SUR73 at 18 months after randomization (T2)
3. Psychosocial resources measured using the PR-26 at 18 months after randomization (T2)
4. Satisfaction with the medical treatment (measured using the PACIC-S11) at 18 months after randomization (T2)
5. Effects on preventive health measures and the use of care (measured using an abridged version of FIMA) at 9 months after randomisation (T1) and 18 months after randomization (T2)
6. Acceptability, appropriateness and feasibility of the survivorship care model (measured respectively with the Acceptability of intervention measure (AIM), the Intervention appropriateness measure (IAM) and the Feasibility of intervention measure (FIM)) at 18 months after randomization (T2) by participants in the intervention group and their relatives. Practitioners will complete the assessment at the times of "first patient in" and "last patient out"
7. Support needs of relatives in the long-term survival phase (measured with SCNS P&C) at 18 months after randomization (T2)

### **Overall study start date**

18/04/2023

### **Completion date**

15/08/2028

## **Eligibility**

### **Key inclusion criteria**

Inclusion criteria for patients:

1. Expected life expectancy > 3 yrs. as assessed by the treating oncologist
2. Increased support needs
3. Ability to give consent
4. Written informed consent

Inclusion criteria for relatives:

1. A person named by the patient as a relative who knows about the cancer
2. Minimum age  $\geq 18$  years
3. Ability to give consent
4. Written informed consent

Inclusion criteria for practitioners:

1. Belonging to the professional group of doctors, psychologists, physiotherapists, and sports scientists
2. Actively involved in patient care
3. Ability to give consent
4. Written consent

### **Participant type(s)**

Patient, Health professional, Carer

**Age group**

Senior

**Lower age limit**

70 Years

**Sex**

Both

**Target number of participants**

n=724

**Key exclusion criteria**

Exclusion criteria for patients:

1. Patients who can no longer care for themselves
2. Insufficient knowledge of written and spoken German
3. Factors that foreseeably severely restrict adherence to treatment (e.g. dementia and/or severe cognitive impairment, significant hearing and/or visual impairment)

Exclusion criteria for relatives:

Insufficient knowledge of written and spoken German

**Date of first enrolment**

15/08/2025

**Date of final enrolment**

15/02/2027

## **Locations**

**Countries of recruitment**

Germany

**Study participating centre**

**National Center for Tumor Diseases (NCT) Heidelberg**

Im Neuenheimer Feld 460

Heidelberg

Germany

69120

**Study participating centre**

**Geriatric rehabilitation, Agaplesion Bethanien Hospital Heidelberg**

Rohrbacher Straße 149

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Germany  
69126

**Study participating centre**  
**Radiotherapy Landau**  
Weissenburger Str. 3  
Landau  
Germany  
76829

**Study participating centre**  
**GRN MVZ gGmbH Sinsheim**  
Alte Waibstadter Str. 2b  
Sinsheim  
Germany  
74889

**Study participating centre**  
**MVZ Radiation Therapy and Nuclear Medicine Weinheim GmbH**  
Röntgenstraße 3  
Weinheim  
Germany  
69469

**Study participating centre**  
**Radiotherapy Neustadt**  
Stiftstraße 15  
Neustadt  
Germany  
67434

**Study participating centre**  
**North Baden Cancer Counseling Center**  
Im Neuenheimer Feld 105  
Heidelberg  
Germany  
69120

**Study participating centre**

Various oncology specialist practices in Baden-Württemberg, Hessen and Rhineland-Palatinate  
Germany

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## Sponsor information

### Organisation

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### Sponsor type

Hospital/treatment centre

### Website

<https://www.klinikum.uni-heidelberg.de/>

### ROR

<https://ror.org/013czdx64>

## Funder(s)

### Funder type

Research organisation

### Funder Name

Deutsche Krebshilfe

### Alternative Name(s)

Stiftung Deutsche Krebshilfe, German Cancer Aid

### Funding Body Type

Private sector organisation

### Funding Body Subtype

Other non-profit organizations

**Location**  
Germany

## **Results and Publications**

### **Publication and dissemination plan**

Publication in a high-impact journal. Dissemination of the results at congress meetings.

### **Intention to publish date**

31/07/2029

### **Individual participant data (IPD) sharing plan**

The data-sharing plans for the current study are unknown and will be made available at a later date

### **IPD sharing plan summary**

Data sharing statement to be made available at a later date