ISRCTN14717755 https://doi.org/10.1186/ISRCTN14717755

Evaluation of a support program for cancer survivors in older age

Submission date
07/08/2025

Recruitment status
Recruiting

Registration date
11/08/2025

Overall study status
Ongoing

Last Edited
28/08/2025

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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 ≥ 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 ≥ 70 years with an expected lifespan of ≥ 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 Joahnnes Bugaj, Impuls-A@med.uni-heidelberg.de

Contact information

Type(s)
Principal investigator

Contact name
Prof Hans-Christoph Friederich

Contact details
University Hospital Heidelberg
Im Neuenheimer Feld 410
Heidelberg
Germany
69120
+49 (0) 6221 56-8774
Hans-Christoph.Friederich@med.uni-heidelberg.de

Type(s)
Public

Contact name
Dr Till Johannes Bugaj

Contact details
University Hospital Heidelberg
Im Neuenheimer Feld 410
Heidelberg
Germany

69120
+49 (0) 6221 56-8774
Till.Bugaj@med.uni-heidelberg.de

Type(s)
Scientific

Contact name
Dr Beate Wild

Contact details
University Hospital Heidelberg
Im Neuenheimer Feld 410
Heidelberg
Germany
69120
+49 (0) 6221 56 8663
beate.wild@med.uni-heidelberg.de

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
German Cancer Aid reference number: 70116185

Study information

Scientific Title
IMPlementation 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-I@med.uni-heidelberg.de), ref: S-692/2024

Study design
Multicentre interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Cancer survivors in older age

Interventions
Current interventions as of 28/08/2025:

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.
Participants are randomised in a 1:1 ratio into the two groups. The randomisation is stratified by age (< or ≥ 80 years), sex, and time since (first) cancer diagnosis (< or ≥ 5 years).

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

_____

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

Key secondary outcome(s))
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)

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 ≥ 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

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
70 years

Sex
All

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
Heidelberg
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

Sponsor information

Organisation
University Hospital Heidelberg

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

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