Evaluating the feasibility and outcomes of implementing PanCareFollowUp Care as usual care in four European Countries: a prospective cohort study

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21449

Bron
NTR

Verkorte titel
PCFU Care-Cohort

Aandoening

Late effects in survivors of childhood cancer.

Ondersteuning

Primaire sponsor: Princess Máxima Center, Utrecht, the Netherlands
Overige ondersteuning: European Union, Horizon 2020

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Given the short study period and the expected variety in health-related outcomes, we have refrained from a health-related outcome as the primary outcome measure, and chosen instead a cognitive-behavioural patient-reported outcome, namely empowerment. The change in empowerment will be measured by the Health Education Impact Questionnaire (HEIQ) including 32 items and six constructs: social Integration and support, health service navigation, constructive attitudes and approaches, skill and technique acquisition, emotional distress, and self-monitoring and insight. This study has a before-after design, where each survivor serves as their own control.

Toelichting onderzoek

Achtergrond van het onderzoek

The 5-year survival for children with cancer increased from 30% in the 1970s to more than 80% at present. There are up to 300,000 childhood cancer survivors in Europe and this number is increasing. Years after treatment, childhood cancer survivors are at high risk for developing health and psychosocial late effects, resulting in excess morbidity and mortality compared the general population. The impact on the quality of life (QoL) of survivors and their families, as well as the societal and economic burdens, are significant. However, these impacts can be reduced by long-term survivorship care to detect treatable disease at an early phase and start timely interventions to preserve health, improve QoL, as well as coordinate specialised care and empower survivors. Implementing follow-up care, especially for young adult and adult survivors of childhood cancer, has proven challenging across Europe. These survivors have left paediatric care and most of them have no opportunity to visit experts in survivorship care.

To improve survivorship care for these survivors across Europe, PanCareFollowUp will conduct a prospective cohort study to assess effectiveness, value, cost effectiveness and feasibility of the PanCareFollowUp Care intervention, a person-centred approach to survivor follow-up care based on international clinical guidelines for surveillance of late effects. Ensuring that the PanCareFollowUp Care intervention is used in the real world is paramount to achieving enduring improvements to survivorship care. Hence, the project includes the development of materials to support sustainable maintenance and replication of the PanCareFollowUp Care intervention. The PanCare network will become the guardian of the intervention after the project, ensuring that the intervention materials are openly available, sustainably maintained and widely shared.

Doel van het onderzoek

We hypothesize that the Care intervention is both feasible and effective in increasing empowerment of childhood cancer survivors.

Onderzoeksopzet

To meet the objectives of the PCFU Cohort Study, data will be collected from participating survivors and HCPs involved in providing the PCFU Care Intervention at five moments during a period of six months. These measuring moments are linked to the PCFU Care Intervention that distinguishes the following three steps:
1. Preparation of the visit of survivor at the clinic
2. Visit at the clinic
3. Follow-up call by a HCP after the clinical visit

Considering this, the data of the PCFU Cohort Study will be collected at five time points (T1-T5) including the following measuring moments:
T1: 2-8 weeks before scheduled clinical visit of the survivor
T2: Clinical visit of survivor
T3: 2-6 weeks after clinical visit during follow-up call of HCP with survivor
T4: 1 week after follow-up call at T3
T5: 6 months after clinical visit at T2

Onderzoeksproduct en/of interventie

PCFU Care is a person-centered care approach developed in the Netherlands to meet the needs of adult survivors of childhood cancer, of whom many experience (either physical or psychological) late effects of their childhood cancer or treatment, which may also impact their social wellbeing and participation in society. PCFU Care consists of a PCFU visit at the clinic, prepared by both the survivor and the health care professional involved in PCFU Care, and tailored follow-up care. Before their visit at the clinic, survivors provide information about their health by completing the Survivor questionnaire; health care professionals prepare a Treatment summary. The use of these instruments belong to standardized PCFU Care. During and after the visit, additional diagnostic tests may be performed. A follow-up call with the survivor will take place two to six weeks after the clinical visit and, if agreed with the survivor, any follow-up care will be provided in accordance with the PCFU intervention manual.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Aged 16 years or older
2. Diagnosed with cancer before the age of 19 years
3. At least 5 years from cancer diagnosis
4. At least one year off-treatment (also applying to treatment of secondary tumours, benign tumours, skin cancers)
5. Treated with chemotherapy and/or radiation therapy for childhood cancer
6. Not having received complete follow-up care (as described in PCFU Intervention Manual)
7. Signed informed consent according to local legislation

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Being unable to answer the questions of the PCFU-Cohort study questionnaires (not even with help from another person) because of severe mental sequelae or insufficient mastery of language used.
2. Currently in treatment for secondary malignancy or relapse of primary malignancy.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2020
Aantal proefpersonen:	800
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	24-09-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8918
Ander register	European Union : 824982

Resultaten

Samenvatting resultaten
Results of the cohort study will be published in peer-reviewed journals.