

Medical assessment of adverse health outcomes in Dutch childhood cancer survivors; a nationwide project; SKION LATER Q2008 study: long-term psychosocial consequences of childhood cancer

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Aims of SKION LATER Q2008-Psychosocial: 1. Survivors - to assess emotional functioning, generic and survivor-specific QoL, and executive functioning (< 18 years), and to compare with siblings and norm data; - to assess determinants of emotional...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON47868

Source

ToetsingOnline

Brief title

SKION LATER Q2008-Psychosocial

Condition

- Other condition
- Adjustment disorders (incl subtypes)

Synonym

late effects of treatment for childhood cancer

Health condition

kwaliteit van leven

Research involving

Human

Sponsors and support

Primary sponsor: Stichting Kinderoncologie Nederland

Source(s) of monetary or material Support: Quality of life gala en Kika; mogelijk KWF kankerbestrijding

Intervention

Keyword: late effects, pediatric oncology, psychology, psychosocial factors

Outcome measures

Primary outcome

QoL(generic and survivor-specific), emotional functioning, anxiety, depression, PTSS, psychosocial predictors, namely: 1) Survivors < 18jaar: - emotional functioning (SDQ) - generic QoL (PEDSQL) - health status (EQ-5d-Y) - developmental milestones (part of LVJV) - disease cognitions (part of CCSS) - self-esteem (part of Kidscreen) - impact of cancer (BBSC) - anxiety (ZBV-K) - PTSS (CRIES) 2) Survivors >= 18 jaar: - emotional functioning (GHQ-28) - generic QoL (TAAQOL) - health status (EQ-5d-Y) - developmental milestones (part of LVJV) - disease cognitions (ZCL) - self-esteem (Rosenberg Self-Esteem Scale) - impact van kanker (IOC-YA) - anxiety and depression (HADS) - PTSS (SRS-PTSS) 3) Siblings < 18jaar: - emotional functioning (SDQ) - generic QoL (PEDSQL) - health status (EQ-5d-Y) - self-esteem (part of Kidscreen) 4) Siblings >= 18jaar: - emotional functioning (GHQ-28) - generic QoL (TAAQOL) - health status (EQ-5d) - self-esteem (Rosenberg Self-Esteem Scale) - anxiety and depression

(HADS) - PTSS (SRS-PTSS) 5) Parents: - emotional functioning (GHQ-28) - health status (EQ-5d) - PTSS (SRS-PTSS) - cognitions about the child's disease (ZCL) - parenting stress (NOSIK) - perceptions of child's disease (Child Vulnerability Scale) - executive functioning child <18jaar (BRIEF) (For more details see appendix)

Secondary outcome

n/a

Study description

Background summary

Survivors The diagnosis and treatment of childhood cancer is a dramatic event that could influence physical and psychosocial functioning long time after treatment has been terminated. The literature about the long-term psychosocial consequences of childhood cancer yielded contradictory results. In many studies overall mean adjustment has been found to be near normal levels. Most survivors seem to cope well with the cancer experience and positive outcomes, for example resiliency or posttraumatic growth, were found. The results of other studies, on the other hand, suggested that survivors suffer more from depressive, anxiety and posttraumatic stress symptoms than the general population. Furthermore, a growing body of evidence suggests that more subtle or specific areas may be adversely affected in long-term survivors. Studies of paediatric psycho-oncological outcomes consistently identify a group of children and family members (estimated 25-30%) who do not cope well with the cancer or who have personal, family and social difficulties. Considering the previous, research limited to psychopathology or generic HRQoL in survivors is inadequate. It is of utmost importance to gain clear understanding of survivor-specific QoL issues such as disease-related worries and positive outcomes. In addition, research on psychosocial determinants of the psychosocial consequences of childhood cancer is recommended strongly because few clear medical risk factors for diminished psychosocial functioning have been traced until now, with the exception of CNS-tumours, bone-tumours and radiotherapy. Moreover, identification of psychosocial risk and protective factors will enable care-providers to provide optimal support to patients and survivors. Parents and siblings Childhood cancer exerts also considerable strain on the parents and siblings. More research is needed to gain insight in

the long-term consequences of childhood cancer for parents and siblings.

Study objective

Aims of SKION LATER Q2008-Psychosocial: 1. Survivors - to assess emotional functioning, generic and survivor-specific QoL, and executive functioning (< 18 years), and to compare with siblings and norm data; - to assess determinants of emotional functioning, generic and survivor-specific QoL 2. Siblings - to assess emotional functioning and generic QoL, and to compare with norm data; - to assess determinants of emotional functioning and generic QoL. 3. Parents - to assess emotional functioning, and to compare with norm data; - to assess determinants of emotional functioning.

Study design

The study involves a cross-sectional study of a retrospective nationwide cohort of 5-year survivors of childhood cancer (diagnosed 1960-2001) in the Netherlands. We estimate that the total cohort will include 7000 survivors. For SKION LATER Q2008-Psychosocial parents and siblings will also be approached. Survivors, their parents and siblings will be asked to complete several validated questionnaires concerning QoL(generic and survivor-specific), emotional functioning (incl anxiety, depression, PTSS) and determinants of QoL and emotional functioning. (see appendix) Data of the survivors will be compared with data of siblings and with norm data. Parental data will be compared with norm data. Data of siblings will be compared with norm data.

Study burden and risks

There are no risks for the participants. The survivors will be invited for the Q2008 SKION LATER study close to a visit to the LATER out patient clinic. The burden depends on the age of the survivor because this determines the number of questionnaires to be completed for SKION LATER Q2008-Psychosocial (see appendix).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

All patients who were treated for childhood cancer (before age 18) in one of the Pediatric Oncology Centers between 1960 and 2001 and who survived for at least 5 years after diagnosis will be included in the SKION LATER study.

Participating centres are located in Amsterdam (VU University Medical Center (VUMC)), Groningen (Children's Cancer Center/ University Medical Center Groningen (UMCG)), Rotterdam (Rotterdam Erasmus MC-Sophia (REMC-S), Nijmegen (University Medical Center Nijmegen (UMCN)), Leiden (Leiden University Medical Center (LUMC) and Utrecht (Princess Máxima Center for Pediatric Oncology (PMC)).

Exclusion criteria

diagnosis of childhood cancer with survival less than 5 years, age at diagnosis >17 years or diagnosis while residing in foreign country; no ability to read/write in Dutch

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	04-05-2016
Enrollment:	11800
Type:	Actual

Ethics review

Approved WMO	
Date:	15-04-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	02-02-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	05-02-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	05-01-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	06-10-2016

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-06-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-05-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-08-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL34985.018.10