Physical and psychological sequelae of childhood cancer from diagnosis till 5-8 years after diagnosis

Published: 17-06-2015
Last updated: 19-04-2024

The current study is a continuation of the cohort 5-8 years post-diagnosis and aims to evaluate:1.The course of the nutritional status, and the related factors and consequences of malnutrition in survivors of childhood cancer until 5-8 years post-…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Observational non invasive

Summary

ID

NL-OMON43986

Source
ToetsingOnline

Brief title
Physical and psychological sequelae of childhood cancer

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
chilhood cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: benefit-finding, goals, nutritional status, quality of life

Outcome measures

Primary outcome

The main study parameters are nutritional status of the survivors and psychological adaptation of the survivors and their parents. In addition, factors related to nutritional status will be assessed such as dietary intake, physical activity, and medical late effects. Regarding psychological adaptation, goals, benefit-finding, psychological functioning and quality of life will be assessed.

Secondary outcome

dietary intake, eating problems, level of physical activity, quality of life optimism/pessimism, goals, benefit-finding, depressive symptoms, psychological functioning

Study description

Background summary

The current study builds forth on a longitudinal research project started in 2007 which looked into the physical and psychological sequelae of treatment in children with cancer during the first year post-diagnosis. This first part of the study indicated that problems with nutritional status among children with cancer were diverse. Undernutrition and overweight were frequently present and both had serious consequences for the chances of survival and quality of life of the children. In addition, part 1 demonstrated that children and parents were resilient and able to cope with the stressors brought by the disease.

Study objective

The current study is a continuation of the cohort 5-8 years post-diagnosis and

aims to evaluate:
1.The course of the nutritional status, and the related factors and consequences of malnutrition in survivors of childhood cancer until 5-8 years post-diagosis;
2.Dispositional optimism and pessimism, goals and benefit-finding and the association of these concepts with well-being in survivors of childhood cancer at 5-8 years post-diagnosis.

Study design

Longitudinal observational study, continuation of a prospective cohort study started in 2007.
The study consists of one measurement point 5-8 years post-diagnosis.

Study burden and risks

Respondents will receive questionnaires at home. The total time for answering the questionnaires will take 20 min for the survivors and 20 min for the parents. Respondents will wear an accelerometer (watch) for 7 consecutive days while they are at home. Measurements of nutritional status will be performed during regular follow-up visits to the outpatient department or during a homevisit (for those whose next regular follow-up visit is planned > 6months in the future). These measurements are largely part of routine care (except skinfold measurements and bio-electrical impedance), are all non-invasive and not burdensome. In addition, respondents will be interviewed about eating problems and personal goals. The estimated time for measurements and interview is 20 minutes. This means that the time for the regular follow-up visit will take 20 minutes longer than usual.
The risk of participation is negligible, no invasive procedures are performed and answering the questionnaires is not expected to cause any psychological discomfort. Given the nature of the study, no SAE*s are to be expected.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1

Groningen 9713 GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

In order to be elegible to participate, a subject must have (1) participated in part 1 of the cohort study (Peacannut 1) and (2) given written informed consent to use the data of Pecannut 1.

Exclusion criteria

patients receiving palliative care
insufficient command of the Ducth language

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-06-2015
Enrollment:	107
Type:	Actual

Ethics review

Approved WMO Date:	17-06-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	14-11-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
Other	NL17977.042.07
CCMO	NL53356.042.15