Parental cancer and the family: Screening for psychosocial risk in parents and their children

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON56965

Source
ToetsingOnline

Brief title
PAT-parent study

Condition

- Other condition

Synonym
family adjustment, psychosocial problems

Health condition

psychosociale gevolgen van kanker

Research involving
Human

Sponsors and support

Primary sponsor: OLVG
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: cancer, children, parents, psycho-oncology

Outcome measures

Primary outcome

The reliability and (concurrent-, divergent-, en predictive) validity of the

PAT are the primary parameters/outcomes of the study.

Secondary outcome

Secondary study parameters/outcomes are:

- the agreement and possible differences between the PAT scores of mothers and

fathers, and between patients and partners

- the agreement and possible differences between PAT scores at two different

timepoints

- families' use of, and expressed need for, psychosocial care

Study description

Background summary

When a parent with minor children is diagnosed with cancer, this impacts the entire family. A substantial number
of parents and children show psychological problems in the short- or longer term. With early systematic screening, risk factors in families can be identified. By identifying these factors shortly after diagnosis, psychosocial care can be matched to the family*s risk level and needs. In this study, risk factors within the family are identified through an adapted version of the Psychosocial Assessment Tool (PAT; a psychosocial screening questionnaire). The study aims to evaluate the reliabity and validty of the PAT, through

questionnaire data collected from parents with cancer, their partners and children (ages 8 to 18). .

Study objective

The primary objective is to:
a) examine the reliability and validity of the adapted PAT.

Secondary objectives are to:
b) examine agreement and possible differences between PAT scores of mothers and fathers, and between patients and partners.
c) examine agreement and possible differences between PAT scores at two different timepoints.
d) to examine the relationship between PAT scores and families' use of psychosocial care.

Study design

This is an (observational) prospective cohort study in which both parents (patient and partner) are asked to complete the PAT at two timepoints (T1 = within four months after the cancer diagnosis; T2 = four months after the first timepoint). In addition, one parent per family will complete several validation questionnaires at both timepoints. At T2, one child per family (8 to 18 years old) is asked to participate. Children complete only some of the validation questionnaires; they do not complete the PAT.

Study burden and risks

The risks faced by participants in this study are next to nil. The burden of the study mainly covers the time it takes to complete the questionnaires (approximately 45-60 minutes per measurement time for parents and 30 minutes for children). A possible disadvantage of the study is that completing the questionnaires can evoke emotional reactions from the participants. Therefore, each participant is offered the possibility to have a telephone contact with a psychologist from the research team after completing the questionnaires. During this call, they can discuss any questions or concerns about the impact of parental cancer on the family, or emotional reactions to completing the questionnaires. Because it is also important to incorporate the child's perspective and to explore whether this perspective matches the PAT outcomes reported by the parent(s), children aged 8 to 18 years old are also asked to complete a number of questionnaires at T2 in this study.

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)
Children (2-11 years)

Inclusion criteria

To be eligible to participate in this study, a participant must meet the following criteria:
Patient
- The patient was newly diagnosed with cancer within the past 4 months
- The patient has at least one child aged 0 to 18 living at home
- The patient is receiving curative or palliative treatment, or this treatment is planned
- The patient is at least 18 years old

Partners

- Partner of a patient who has been diagnosed with cancer and has at least one child aged 0 to 18 living at home
- The partner lives with the patient
- The partner is at least 18 years old

Children (T2)
- The child has a parent who has been diagnosed with cancer
- The child is at least 8 and up to 18 years of age
- The child is living at home
Children with pre-existing psychosocial co-morbidity may participate in the study; this is not an exclusion criterion.

Participation of members from the same family.
Not all family members have to be willing to participate in the study. At least one of the parents (patient or partner) has to participate at T1. Thus, children cannot participate if neither of their parents participates at T1. However, a parent can participate if his/her partner does not want to participate in the study.

Exclusion criteria

A potential participant who meets any of the following criteria will be excluded from participation in the study:
• Patients, partners or children who do not have sufficient proficiency of the Dutch language to complete the questionnaires
• Ex-partners of patients who do not live with the patient
• Children (8-18 years old) of which neither of their parents participates at T1.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	10-08-2024
Enrollment:	200
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	12-07-2024
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL86294.100.24