Pilot intervention study aimed at reducing stress in parents of children undergoing SCT

Published: 17-04-2008
Last updated: 11-05-2024

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON32023

Source
ToetsingOnline

Brief title
Surviving SCT competently: a pilot interventionstudy

Condition

- Other condition
- Leukaemias

Synonym
cancer stem cell transplantation

Health condition

beenmergtransplantatie

Research involving
Human

Sponsors and support

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

Intervention

Keyword: parents, pediatric, SCT, stress

Outcome measures

Primary outcome

The parents* and child's socio-demographic and clinical data (gender, age, level of education) will be recorded during the first round of questionnaires at baseline. Clinical information will include the primary disease and the nature of treatment given. After the final session, participant satisfaction with the intervention (both the structure and content) will be recorded through a short evaluation form.

Several questionnaires will be used to measure the effects of the intervention:

The Pediatric Inventory for Parents (PIP) is a 42-item self-report questionnaire that measures illness- related parental stress. Each item is rated on two 5-point Likert-type scales. The first assesses the frequency of each stressor; the second scale assesses how difficult the issue has been for the parent in the last week. Adequate internal consistency (α =.80-.96) and construct validity of the PIP have been reported (Streisand et al., 2001). A Dutch version has recently been developed by Jantien Vrijmoet-Wiersma (2007, in preparation).

The Nijmeegse Parental Stress Index, shortened form NOSIK, measures parental stress associated with raising children in general. The reliability of the NOSIK lies between .92 and .95. The NOSIK differentiates well between clinical and non-clinical groups (de Brock et al., 1994) and is widely used (e.g. Thomas et al., 2004).

The State Trait Anxiety Index (STAI), state and trait version measures both the transitory emotional condition of stress and the general inclination towards anxiety of the respondents. Dutch norm group data are available (van der Ploeg et al., 2000), as well as information about reliability and validity. Internationally, the STAI is widely used to measure anxiety (e.g. Seligman et al, 2004)

The General Health Questionnaire (GHQ), 12-item version, is a self-report measure of psychological symptoms that can be used as a general measure for psychological distress (Jackson, 2007). The psychometric properties of the Dutch version of the scale are reported to be highly satisfactory (Koeter and Ormel, 1991).

The Impact of Events Scale (IES) is a 20 item self-report questionnaire measuring symptoms of posttraumatic stress, i.e. avoidance and intrusions. The questionnaire was designed by Horowitz et al. (1979) and is widely used. The Dutch version shows good validity and reliability (Brom & Kleber, 1985).

The Ziekte Cognitie Lijst, ouderversie (ZCL-O) is an 18-item questionnaire covering cognitions that parents can have about their child*s illness. There are three scales: helplessness, acceptance and disease benefits. The questionnaire was originally developed for adult patients, but adapted for parents of children with a chronic disease. Psychometric qualities of the original questionnaire are acceptable (Evers et al., 1998). The parent version is currently under study.

Assessment will take place two weeks before admittance (T1), one week before SCT (T2) and six months after discharge (T3).

Secondary outcome

not applicalbe

Study description

Background summary

Stem cell transplantation (SCT) in children has become increasingly sophisticated and as a consequence mortality rates have decreased (Broers et al., 2000). In addition to a wide range of medical and socio-emotional stressors associated with a life threatening illness, SCT represents a severe stressor with possible disruption for the child and the entire family. The lengthy hospitalization in isolation, the experiences of physical discomfort, the uncertainty of outcome as well as the fear of death are stressors associated with this treatment (Pot-Mees, 1989). Furthermore, the children and their families have to cope with several possible outcomes that may vary from a cure and normality to chronic graft-versus-host disease (GVHD), relapse, or the death of their child (Barrera et al., 2000).
Watching one*s child undergo transplantation can be a very traumatic experience for parents and can potentially lead to the development of long-term psychological distress responses (Manne et al., 2004, Rini et al., 2004). Parents may be at risk for emotional problems like anxiety (Barrera et al., 2000), depression (Manne et al., 2001), posttraumatic stress symptoms like

intrusions and avoidance (DuHamel et al., 2004, Manne et al., 2004) and various other stress reactions, particularly during the early period from pre-admission through three weeks post SCT (Phipps et al., 2005, Streisand et al., 2000, Dermatis & Lesko, 1990). Other researchers have found longer lasting psychological effects in a percentage of mothers, ranging from 20% of the mothers who classified for a psychiatric diagnosis 18 months after the diagnosis of a malignancy in their child (Manne et al., 2004).
Maternal post-SCT anxiety and depression scores have been found to correlate strongly with their children*s quality of life, as well as with symptom severity at 6 months post SCT (Barrera et al., 2000). Mothers who are most at risk are younger and show high levels of anxiety and depressive symptoms at the time of transplantation (Manne et al, 2003). Mothers who are depressed may not be able to attend optimally to the needs of their children. They are generally less affective towards others, have a decreased ability to make decisions and have a negative perception towards the future (Nelson, 1997).
Until now only one intervention program, aimed at reducing stress in parents of children undergoing stem cell transplantation, has been piloted (Streisand et al., 2000). The intervention -scheduled within 1 week of the child*s admission to the SCT unit- included a one 90-minute session with mothers only, including three components: education, relaxation and communication. Mothers in the intervention group reported the use of significantly more intervention techniques than mothers in the control group. However, there were no differences in stress levels between the two groups, possibly because the intervention involved only one session.
Given the scarcity of intervention research in the SCT population, it is necessary to look at the accomplishments of intervention studies involving parents of children with cancer. A number of these studies have yielded positive effects on parent distress and parent adjustment, according to a recent meta-analysis (Pai et al., 2006). One of the promising intervention studies was conducted by Anne Kazak et al. (2004, 2005). She designed a programme called SCCIP-ND (Surviving Cancer Competently Intervention Program), for parents of newly diagnosed children. The focus of the program is on understanding how beliefs about cancer and its treatment influence caregivers and to help family members anticipate on the impact of cancer on the family. The intervention has been piloted on 38 families (half of which served as a control group) and is currently delivered to more than 120 parents. First results are supportive of the value and challenges of developing evidence-based family interventions in pediatric psychology (Kazak et al., 2005).

Study objective

The objective of this study is to adapt and pilot an existing psychological intervention program (SCCIP-ND, mentioned above) to alleviate anxiety and distress and to prevent PTSS in parents of pediatric patients who are receiving stem cell transplantation.
Research questions to assess feasibility:
1. Acceptability: Is it possible to implement the intervention? Does it seem

relevant and doable? Was the intervention acceptable to the participants?
2. Recruitment and retention: Can a representative sample be recruited? What is the participant rate and what can be said about dropouts?
3. Time line: can the intervention session take place as planned?
4. Preliminary outcomes: within the context of a small pilot study, what evidence is there for the likely effects of the intervention on primary outcomes?

Study design

Pre-test interventie posttest design.

Since more than one year all parents at the SCT-ward are asked to fill in a booklet of questionnaires (primary outcomes) at three moments in time: two weeks before admittance (T1), two weeks after SCT (T2) and six months after discharge (T3).
These parents will serve as the control group.

Starting in june 2008, the inclusion of intervention group parents start: All parents of children undergoing SCT will be approached one month before admittance of their child. They will be assessed at the same time points as the control group parents. There is no randimization; all parents of children with a malignancy will be included.
Intervention takes place from one week pre-admittance to four months after discharge.

Intervention

Parents (as couples) will be asked to participate in the study one month before admittance by the physician. Assessment takes place two weeks before admittance, 14 days after SCT and six months after discharge. Parents in the intervention group will receive four psychotherapy sessions. The first session will be held at home, two weeks prior to admittance. The second session will take place during the SCT- admission period on day -7 (1 week before the SCT itself). One month and four months after discharge, parents take part in sessions 3 and 4 in the outpatient*s clinic. These sessions serve as booster sessions, which can assist in the maintenance of intervention outcomes (Pai et al., 2006).
Parents are taught to recognize the strengths and weaknesses of their own coping strategies and -if necessary- to change their cognitions and behaviour in order to alleviate stress and decrease anxiety. Psycho-education and relaxation skills training will also be standard ingredients of the sessions. Lastly, we will use filmed family discussions of parents that have already been through the SCT-experience, with the purpose of learning through modelling. The sessions are manualized and carried out by the research assistant (a trained junior psychologist) to avoid bias. Training and coaching of the research

assistant will be done by Jantien Vrijmoet, who is specialized in cognitive behavioural therapy. The manual used in the SCCIP-study of Anne Kazak (intended for parents of newly diagnosed children with cancer) will be adapted to use in this specific population. Treatment fidelity is obtained through working with manualized sessions, and at random audio taping of the sessions.

Study burden and risks

not applicable

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Parents of children undergoing SCT with a malignant disease.
Sufficient knowledge of the Dutch language

Exclusion criteria

Parents of children who are no longer eligible for SCT. Children with a relapse, children without an appropriate donor.
Parents of children who die during the transplant period.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2008
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL21013.058.07