



The child facing a parent's cancer: a randomized study evaluating the effectiveness of a psychological intervention designed to support parenting.

Protocol

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1. Introduction.

In Belgium, more than 74,000 new cancers were diagnosed in 2014[1]. In the United States, it is estimated that 18% of adults diagnosed with cancer and 14% of patients in remission have dependent children under 18 years of age[2]. When faced with their parent's cancer, children experience more negative emotions (e.g., guilt, anger, sadness) as well as disease-specific fears (e.g., fear of uncertainty, fear of losing their parent)[3]. According to the literature, they are at greater risk of developing psycho-emotional difficulties (i.e., stress, anxiety, depression)[3-5] and of using mental health services more often in both childhood and adulthood[6]. The parental cancer experience has therefore an impact on children in the short, medium and long term. Maintaining a safe environment favorable to child development is likely to limit the impact of cancer[7]. The international group "Children of Somatically Ill Parents" (COSIP)[8] has also made recommendations to this effect.

Following a cancer diagnosis, nearly 10 to 50% of patients report high levels of psychological and emotional distress[9], which is comparable to those reported by their relatives[10, 11]. When patients and relatives are parents, they report specific concerns about the impact of the disease on their child and the support they need to provide[12]. Some parents are afraid to discuss the illness with their child, fearing to add additional distress to them[13]. Regardless of effective parenting skills, the distress of parents (sick or not) has also an impact on the feeling of parenting skills[14, 15]. As a result, some parents no longer feel able to meet their child's needs. This decrease in the sense of parental competence could be associated with difficulties in implementing some supportive behaviours such as communication and with difficulties in emotional regulation in this context. In addition, some parents report a lack of knowledge about supporting a child with a parent's cancer and therefore do not know how to approach cancer with their child[12]. Cancer therefore implies for sick and non sick parents, in addition to managing the physical and psychological impact of diagnosis and treatment, the development of new parental behaviours to be jointly implemented.

To meet these specific needs, many recommendations are made for parents, including brochures. Several interventions have also been created in various ways[16, 17]. Some interventions are specifically addressed to parents, others to children and some others to the whole family. Most oncology intervention studies around child or family support are qualitative studies that do not meet the scientific research criteria as described by "CONSORT"[18]. Nevertheless, despite the heterogeneity of the interventions and the quality

of the designs evaluating the interventions, the literature shows that they have a positive overall impact[16].

There are currently only a few randomized studies evaluating the effectiveness of a psychological intervention to support parenthood that focuses on helping the child in an oncological context and that is offered to significant caregiver of the child. As part of a randomized and controlled study, a psychological intervention to support parenting was developed at the Jules Bordet Institute. This intervention is offered to significant caregivers of a child who have questions about the support a child needs when confronted with a parent's cancer. This intervention aims to develop and reinforce these supportive behaviors. The intervention is intended to be flexible (to respond to the medical situation), relatively brief (four sessions) and open to the heterogeneity of families (e.g., reconstituted, divorced, extended family). Significant caregiver of the child can participate either in pairs (in dyads) or individually.

2. Objectives of the study.

The intervention is evaluated in a randomized controlled study. To do this, two conditions are compared. The first condition ("control" condition) consists in the delivery of an information booklet entitled "How to talk with the child about a parental cancer? A practical booklet on communication. "[23] which contains parental information and recommendations associated with supporting a child facing a parent's cancer. The second condition ("experimental" condition) consists, in addition to providing the same information booklet, of a psychological intervention focused on supporting the child who has a parent with cancer.

2.1. Primary Objective.

The main objective of this study is to test the contribution and effectiveness of a psychological intervention in relation to the delivery of an informational booklet regarding participants' communication with the child in the oncology context. This intervention should increase participants' sense of communicative competence and communication behaviors.

2.2. Secondary objectives.

The information booklet should more specifically improve participants' knowledge of how to support a child facing a parent's cancer. Psychological intervention should have an impact not only on the sense of communicative skills but also on the emotional regulating capacity

associated with participants' communication with the child and on participants' concerns about the child. When the intervention is carried out in a dyad, it should also improve mutual support between participants.

3. Method

3.1. Study Population

This intervention is offered to significant caregivers of a child between the ages of 3 and 18 who have questions about the support a child needs when confronted with a parent's cancer. In this study, the term "significant caregiver" refers to any person who provides significant practical, educational and emotional care to the child.

In order to respond to the heterogeneity of family and medical situations, each significant caregiver may decide to participate in the intervention alone or accompanied by a relative involved in the child's support.

The inclusion criteria for each participant are as follows:

- Participants must be of legal age (at least 18 years old);
- Participants must not have an acute psychiatric or neurological disorder that does not allow them to participate to the study and the intervention;
- Participants must have a sufficient command of French (speaking, writing and reading).

Participants cannot be included if:

- The child's parent with cancer is in a pre-terminal or terminal phase;
- The child's parent with cancer has died.

The sample size was calculated a priori to detect differences in the evolution of the two groups ("control" condition and "experimental" condition) between T1 and T2. A pilot study suggests a minimum expected effect size of 0.8 (effect size) if the GC remains stable. Under this double assumption, an overall population of 68 subjects (34 subjects in each group) will be required to achieve a level of significance (p) of 5% with a statistical power of 90%.

However, taking into account possible dropouts, the total recruitment sample should be 80 participants.

Regarding recruitment, as soon as a patient is identified by the team as having a child between 3 and 18 years of age, he or she is contacted to suggest the project. Information to identify and contact patients is taken from medical records. One study found that following or having recently followed chemotherapy or radiation therapy was associated with a higher level of

parental competence (Moore, 2015). In this way, a more systematic recruitment will be organised within the Jules Bordet Institute at the day hospital and in radiotherapy in agreement with the department heads. In addition, in order to facilitate families' access to the project, the study is being disseminated to front-line carers (doctors, nurses, psychologists, social workers, NOC, etc.) within the Jules Bordet Institute, Erasmus Hospital and also in other hospitals via the distribution of information sheets and oral presentations.

3.2. Description of the study.

This is a randomized longitudinal controlled study conducted at the Jules Bordet Institute site and at Erasmus Hospital (Figure 1). This study evaluates the effectiveness of a psychological intervention focused on helping children in the oncology context. Significant caregivers may participate alone or in dyads at the intervention. At the time of recruitment (T0), after checking the eligibility criteria, participants receive all the information associated with the study. As a first step, they are offered the opportunity to perform the dyad intervention. If this is not possible, participants have the opportunity to participate in an individual way. After this step of presenting the information, they sign a consent form for inclusion in the study. As soon as they are included, the participants (in dyads or individually) have a first evaluation time (T1) consisting of the completion of questionnaires and a semi-directive interview.

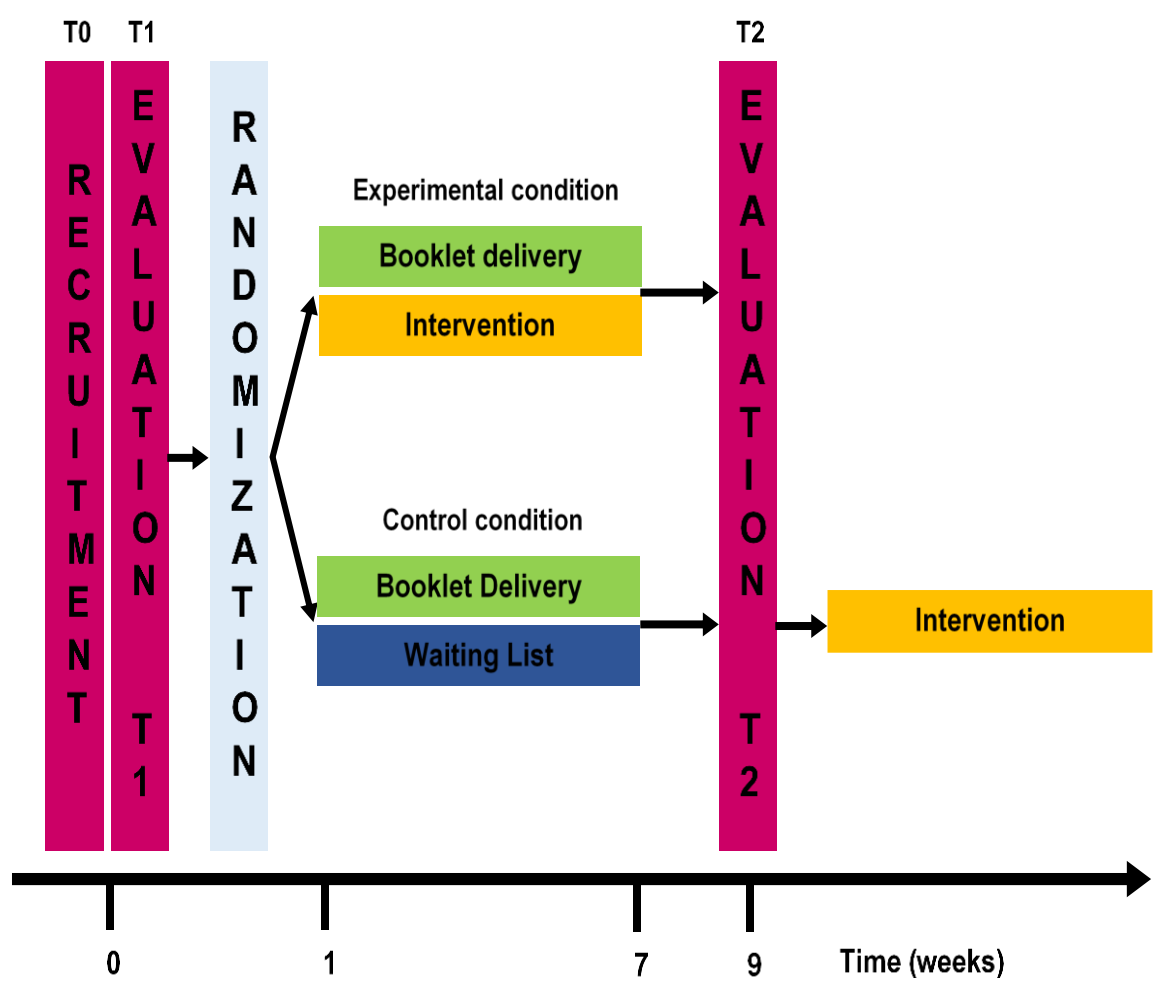
At the end of T1, all participants (experimental condition and control condition) receive an information booklet entitled "How to talk with the child about a parental cancer? A practical booklet on communication. "[23] which contains parental information and recommendations associated with supporting a child facing a parent's cancer.

After T1, each participant is directly randomly assigned to either the experimental or control condition. Randomization is done after the first evaluation so that evaluators and participants are not aware of the distribution at T1.

After receiving the information booklet, participants randomized to the experimental condition receive a brief parental support intervention consisting of four sessions. Fifteen days after the end of the intervention, these participants have a second evaluation (T2), again consisting of the completion of questionnaires and a semi-directive interview.

After receiving the information booklet, randomized participants in the control condition are placed on a waiting list. Nine weeks after the end of T1, these participants have a second evaluation time (T2) consisting of the completion of questionnaires and a semi-directive interview. They subsequently benefit from parental support intervention.

The entire study was manualized and standardized in order to best meet the methodological recommendations recommended by "CONSORT"[18].



Information booklet: "How to talk to your child about a parental cancer? A practical booklet on communication. » [23]

All participants (control and experimental conditions) receive an information booklet containing parental information and recommendations associated with supporting a child facing a parent's cancer. To address this theme, the booklet describes concepts related to child

development such as understanding the disease, reactions and needs. It also presents recommendations related to communication around the disease according to the child's age and development (*what to say to the child?* and *how to respond to the child?*). Finally, the booklet offers resources (e.g., books, websites, non-profit organisations) that are useful in this context.

3.3. Parental Support Intervention.

3.3.1. Objectives of the intervention.

While the information booklet mainly aims to increase the knowledge of significant caregivers about supporting a child facing a parent's cancer, the parental support intervention aims to develop and reinforce their behaviors associated with supporting the child in this context. The intervention aims to improve communication with the child by strengthening the sense of communicative competence and transmitting emotional regulation strategies. The dyad intervention also aims to strengthen mutual support between participants.

3.3.2. Content of the intervention.

This is a brief four-session parental support psychological intervention that can be done individually or in a dyad. The first session is dedicated to a global assessment of the medical and family situation, communication with the child, as well as to an identification and reinforcement of the participant's parental skills. The second session suggests to the participant to identify the reactions and needs of children in the context of the disease and based on concrete examples. A construction work of what can influence perception is carried out. The last two sessions are devoted to the participant's specific questions about communicating with his or her children in the context of the disease.

In general, emotional regulation techniques specific to parenthood are worked on during the session and reinforced by the transmission of a relaxation booklet. Parental competence is systematically supported and strengthened. The content does not change whether one is in a dyadic or individual intervention except that dyadic interactions and support are enhanced.

Our workers are trained in the management of families through their clinical practice within the activities of "Bordet'N Family". In order to increase the fidelity of intervention replication, future practitioners will also benefit from a training process that involves three stages: general theoretical training in intervention, practical training specific to the intervention and

supervisions scheduled after each session with an experienced psychologist. In addition, the workers are supervised by the study coordinator (Prof. Darius Razavi).

A quality control of the intervention is set up by an audio and video recording of the interventions. These records are regularly analyzed using an analysis grid created from the intervention manual to verify the standardization of the intervention.

3.4. Evaluation procedure and questionnaires.

This study includes 2 evaluation periods, T1 and T2, consisting of the completion of questionnaires and a semi-directive individual interview. The evaluation procedure includes a research interview which is structured in three parts. The entire research interview lasts approximately 1h30.

The first part focuses on supporting the child facing a parent's cancer. To do this, participants are asked to complete several questionnaires with specific reference to only one child in their circle. This child must face a parent's cancer and must be between 3 and 18 years old. If several children meet these criteria, the participant determines the one for whom he or she has the most questions about how to communicate with him or her about the disease. When it comes to dyads, participants agree on the choice of the child. The child identified serves as a reference during both T1 and T2 in order to standardize the assessment procedure as much as possible. Participants are invited to complete questionnaires describing the situation of the identified child, as well as questionnaires focusing on their parental concern and support for the child.

- Individual intervention:
 - The socio-demographic data of the identified child.
 - The relationship of the participant(s) to the identified child.
 - The medical context of the disease. Two versions of this questionnaire were created for the study: one for non-patient participants and one for sick participants.
 - The sense of communicative competence. A questionnaire developed specifically for the study was created from the theories of parental competence in oncology and self-efficacy theories[13-15, 19].
 - Communication with the child. The participant's communication with the child is assessed by a questionnaire specifically developed for the study. This questionnaire contains two

subscales: communication with the child and the emotional regulation associated with this communication.

- Concerns about the identified child. An adaptation of Muriel et al.'s Parenting Concerns Questionnaire (PCQ)[2] was developed for the study. Since the PCQ is an oncology patient questionnaire, one item has been removed so that all items can be adapted to all participants.

- The feeling of knowledge. The participants' sense of knowledge about the support to the identified child is assessed by a questionnaire specifically developed for the study. This questionnaire was created from the concepts developed in the information booklet.

- Dyad intervention:

- idem plus two questionnaires, the first evaluating the relationship with the person who supports them in relation to the child and the second evaluating the mutual support between the participants by means of a questionnaire specifically developed for the study.

The second part of the evaluation is a semi-directive interview with the researcher. Each participant will individually answer a serie of questions about communicating with the identified child. The semi-directive interview consists of a framework of open and semi-open questions structured around predefined themes concerning communication with the identified child: general communication with the child, the emotions aroused during these exchanges, the child's reactions, the elements facilitating and disrupting communication. The semi-directive interview is audibly recorded and transcribed.

The third part of the evaluation consists of the completion of questionnaires to collect a serie of descriptive information from participants:

- The socio-demographic data of the participant.

- The psychological background of the participant.

- The social difficulties of the participant. Social difficulties are assessed using the Social Difficulties Inventory (SDI-16)[20].

- The emotional state of the participant. Emotional state is assessed using the Hospital Anxiety and Depression Scale (HADS)[21];

- The emotional state of the identified child. The emotional state of the identified child is assessed using the Child Behavior Check List (CBCL)[22]. Two versions adapted to the age of the identified child are used: one for children between 3 and 5 years old and the other for children between 6 and 18 years old.

- Knowledge about children's understanding of the disease. Participants' level of knowledge about children's understanding of the disease is assessed using a questionnaire specifically designed for the study.

At T2, the evaluation procedure is similar to the one mentioned above. In addition, the use and relevance of the information booklet and the satisfaction with the intervention of participants of the experimental condition are assessed.

3.5. Statistical analysis.

Before evaluating the effectiveness of the parental support intervention, the data will be examined to verify sample distributions and outliers. In addition, control analyses will be carried out to compare participants of experimental conditions and controls during T1 and to compare participants who performed T1 and T2 and those who dropped out (T1 completed). A comparative analysis between the group that performed the dyad intervention and the group that performed the intervention individually will be conducted in order to identify any differences in profile. An analysis using a mixed linear model including random effects will be used to compare the evolution of participants from the experimental condition to the control condition and consequently test the effectiveness of the intervention. This analysis will be done separately for participants who performed the intervention individually and those who did it in dyads. As for the content of the semi-directive interviews, a content analysis will be carried out.

4. Ethical and regulatory aspects.

This study does not present any risk to the physical health of the participants. Only questionnaires (T1-T2 assessment procedures) and interviews (during the T1- T2 assessment procedures and parental support intervention) are used. No biological sampling is carried out.

Participation in the study does not exclude the possibility of benefiting from traditional psycho-social care. During the study, if significant emotional distress is observed in one of the participants, appropriate management will be offered. In addition, if the child's caregiver with cancer dies during the study, participants will be able to benefit from specific care.

Concerning recruitment, the psychologists who suggest the intervention have been made aware of the study. The team of workers and interviewers is composed of psychologists and

doctors of psychology trained in the specific clinical aspects of psycho-oncology and family management.

Participation in the study is voluntary and participants may decide at any time to terminate their participation without affecting the quality of their medical and psychosocial care. Participants are informed of the entire research project since the study does not require blind conduct. This information is included in the document "Information letter and informed consent of the participant" given to each participant. No remuneration is required to participate to the study, participants benefit from free access to the study. Participants in the control group are notified that they are receiving parental support intervention after the second evaluation time. Before inclusion in the study, they are asked for their free and informed consent in writing.

All data collected is encrypted and stored on hard disks not connected to the Internet and themselves encrypted. The anonymity of the participants is guaranteed by a codification of their identity. The correspondence file between the code and the identity of the participants is stored separately from the database. Access to these external hard disks is only possible to trusted persons who are part of the research team. The principal investigator guarantees that anonymity and confidentiality are strictly respected throughout the project.

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