

ORIGINAL ARTICLE

FAMily-Oriented Support (FAMOS): development and feasibility of a psychosocial intervention for families of childhood cancer survivors

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ABSTRACT

Background: We developed and tested the feasibility of a manualized psychosocial intervention, FAMily-Oriented Support (FAMOS), a home-based psychosocial intervention for families of childhood cancer survivors. The aim of the intervention is to support families in adopting healthy strategies to cope with the psychological consequences of childhood cancer. The intervention is now being evaluated in a nationwide randomized controlled trial (RCT).

Methods and design: FAMOS is based on principles of family systems therapy and cognitive behavioral therapy, and is delivered in six sessions at home. Families were recruited from all four pediatric oncology departments in Denmark after the end of intensive cancer treatment. We evaluated the feasibility of the intervention and of a RCT design for comparing the intervention with usual care. The evaluation was conducted among families enrolled in the study by tracking procedures and parents' evaluations.

Results: A total of 68 families (68 mothers, 60 fathers, 68 children with cancer and 73 siblings) were enrolled, with a participation rate of 62% of families. Fathers were highly represented (88% of families); also families with single parents (12%) and parents with basic education (7–12 years of primary, secondary, and grammar school education) were represented (12%). The dropout rate was 12% of families (all in the control group), and two families did not complete the intervention because of relapse. Evaluation by parents in the intervention group showed overall satisfaction with the format, timing, and content of the intervention.

Conclusion: The results indicate that the FAMOS intervention is feasible in terms of recruitment, retention, and acceptability. The effects of the intervention on post-traumatic stress, depression, anxiety, family functioning, and quality of life will be reported after the nationwide RCT has been completed.

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The long-term psychological effects on the parents of childhood cancer survivors (CCS) after diagnosis include anxiety and depression (in 20–30%), post-traumatic stress (in 21–44%), worry (in 33–75%), disease-related thoughts and feelings (in 13%) and decreased quality of life [1]. The health care system provides little systematic psychological support for such families, possibly because resources are prioritized for medical treatment and lack of evidence on how to provide psychosocial support.

According to the 'biobehavioral family' model, patterns of family relations, and the diversity of family members' reactions to childhood illness such as cancer can influence the physical and psychological well-being of children [2]. Relieving parents' distress may have a positive influence on their child's well-being and the way in which the whole family adapts to living with cancer, which indicates the efficacy of family-focused interventions [3].

We conducted a literature search and found 22 studies of varying methodological quality of interventions targeting

psychological symptoms in CCS and their families. The results suggest that the interventions improve to varying degrees the symptoms of post-traumatic stress, emotional problems, understanding of cancer, and coping strategies. Most of the studies targeted either CCS or CCS and their mothers [4], while siblings and fathers have received less attention. Only six studies addressed the psychological well-being of the family as a whole [3]; and only eight were randomized controlled trials (RCTs), of which five had more than 50 participants and one had 150 participants, including the whole family [5].

The development and delivery of interventions to the families of CCS present a number of challenges, such as meeting the needs of a whole family in terms of timing, age and psychological symptoms, and providing standardized psychosocial care for a diverse group of families. We developed the FAMily-Oriented Support (FAMOS) intervention to help families cope with psychological issues related to cancer. This is the first home-based psychosocial intervention for

the whole family that is delivered shortly after the end of intensive treatment of the child. The purpose is to help families cope with and prevent cancer-related psychological problems as soon as possible after the end of medical treatment. We define CCSs as children completing treatment for cancer or in maintenance treatment. The aims of the study reported here were two-fold. The first was to present the rationale and design of the FAMOS intervention, and the second was to evaluate the feasibility of the FAMOS intervention and of conducting a RCT, by evaluating: (1) recruitment into the trial in terms of participation and representativeness according to cancer type, treatment characteristics, family type, parent gender, and age of child; (2) retention and attrition in data collection; (3) participation and retention in the intervention; and (4) the acceptability of the intervention.

Methods

Study design

The development of the FAMOS intervention and evaluation of the feasibility of the study design and intervention were part of an ongoing nationwide RCT (clinical trial no.: NCT02200731 at clinicaltrials.gov and journal no: H-1-2013-073 at the National Committee for Health Research Ethics in Denmark).

Participants and procedures

Families of CCS were recruited at one of Denmark's four pediatric oncology departments (University Hospital Rigshospitalet, Aarhus University Hospital, Odense University Hospital or Aalborg University Hospital), which cover all cases of pediatric cancer in Denmark. The eligibility criteria for families of CCS were: CCS aged 0–6 years (except children who did not receive chemotherapy or radiotherapy, who were eligible up to the age of 18 years), who had ended intensive medical treatment within 0–4 months and who were not terminally ill; parents (single or couples including at least one biological parent) over 18 years who spoke Danish; and siblings of all ages. As another psychosocial intervention study was being conducted concurrently aiming at physical and social activity in children with cancer (clinicaltrials.gov no: NCT01772862), we were unable to invite families of CCS over six years, unless the patient did not receive chemotherapy or radiotherapy. We defined the date of end of intensive treatment according to cancer type: leukemia (1–2.5 years after diagnosis), non-Hodgkin lymphoma (one year after diagnosis) and solid tumors including brain tumors (one month after surgery or one month after chemotherapy). Children who received a stem cell transplant, independent of cancer diagnosis, were contacted three months after transplantation. The families of children who died or relapsed during the study were eligible to continue in the study.

Families were randomized 1:1 to the intervention group or to usual care and stratified by cancer type and pediatric oncology department. Usual care in Denmark often includes an invitation to one session with a hospital psychologist

during treatment and one session at relapse or death, but the support is not offered systematically and may vary according to department.

Rationale and design of the FAMOS intervention

The development of the FAMOS psychosocial intervention was inspired by the Surviving Cancer Competently Intervention Program (SCCIP) and SCCIP-ND (newly diagnosed) designed by Kazak et al. [5,6], which has been reported to be the most promising support program for the families of CCS [4]. SCCIP is a cognitive behavioral and family therapy intervention for adolescent survivors of childhood cancer and their families, with the aim of reducing distress in caregivers of CCS. It consists of a one-day family group intervention based on a manual, with separate sessions for the survivors, their fathers, their mothers, and their siblings. Evaluations of SCCIP have shown significantly less anxiety, arousal, and intrusive thoughts in CCS and their parents [5,7]. The aim of SCCIP-ND, which also combines cognitive behavioral therapy and family therapy but in three sessions with short videos, is to reduce distress in the caregivers of newly diagnosed CCS. For FAMOS, we adapted several concepts and techniques from SCCIP and SCCIP-ND to ensure sessions are specific for parents and children (Table 1). FAMOS was developed in Danish and will be translated into English when the study is completed.

Theoretical framework: family systems therapy and cognitive behavioral therapy

FAMOS draws on family systems theory, in which the family is viewed as a system of interrelated, interdependent individuals. Examining the family structure (single or divorced parents, blended families or siblings living alone) and the individual roles and states of mind of family members reveals factors that influence family coping, e.g. the members of a family that had difficulty in seeking support from each other before the cancer diagnosis might more intensely fear not being able to cope. Family functioning can be improved by working on their roles and functions in the system [8]. Cognitive behavioral therapy is the theoretical framework for targeting psychosocial issues in families of CCS by examining the associations between thoughts, feelings, and behavior (Figure 1). By integrating family system theory and cognitive behavioral therapy, the FAMOS intervention is expected to improve both individual well-being and family functioning with techniques to identify beliefs and reframe negative thoughts and behavior.

The specific aims of FAMOS are to:

- strengthen communication between parents and between parents and children;
- prevent maladaptive long-term psychological reactions to cancer in the family;
- reduce acute cancer-related psychological symptoms, such as post-traumatic stress, in the family; and
- strengthen family functioning and quality of life.

Table 1. Overview of the FAMOS program.

Session	Goal	Technique
Introduction	- Set the FAMOS program agenda - Review the family's history and experience at diagnosis - Establish goals for the whole program	
Session one: How cancer has affected us as parents and as a family	- Normalize and reduce cancer-related psychological symptoms - Help parents to identify cancer-related thoughts and behavior - Strengthen communication between parents, parent and partner or parent and child(ren)	- Video 1 - ABC model (SCCIP) - Family's road through cancer (SCCIP)
Session two: How we coped with cancer	- Introduce ways to cope in difficult situations - Learn how to adjust to life after cancer	- Video 2 4 steps to reframing (SCCIP) - Pros and cons of reframing
Session three: The family's future	- Understand the association between individual beliefs and family's future - Strengthen family functioning and quality of life	- Video 3 4 steps to reframing (SCCIP) - Family's future - Goal-setting techniques - Problem-solving techniques
Session four: Children's session: the family before, during and after cancer	- Normalize children's cancer-related thoughts - Learn how cancer can affect each individual in a family differently	- Unwanted guest (SCCIP) - Sky illustration - ABC model (SCCIP) 'Things I want to change' 'Things I want to throw away' - Family road through cancer (if relevant) (SCCIP)
Session five: Children's session: how to move on	- Learn to cope with difficult situations - Strengthen communication between parents and children	- ABC model and one technique: - Problem-solving - Goal-setting - Psychoeducation - Registering and identifying feelings chart
Booster: what have we learnt?	- Summarize the main goals of the intervention - Plan how to continue using the techniques at home	- ABC model (SCCIP) 4 steps to reframing (SCCIP) - Family's road through cancer (SCCIP)

The components of SCCIP included in FAMOS, with permission were: 'ABC model', 'Family's road through cancer' and 'four steps to reframing'. ABC: Adversity Beliefs Consequences; SCCIP: Surviving Cancer Completely Intervention Program.

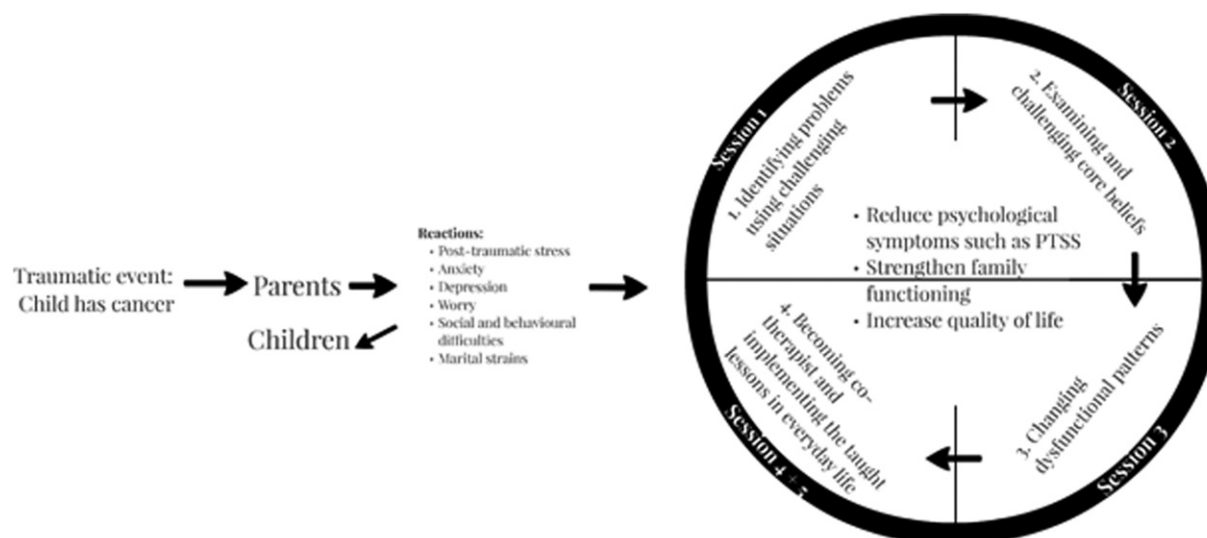


Figure 1. Process of change.

The intervention is designed for delivery at the homes of families of CCS shortly after the end of intensive treatment. Parents are the primary focus, and children and siblings over seven years are the secondary focus. The intervention comprises up to six sessions over a six-month period, of which three are for parents, two are for children age seven years or older and one is a booster session for the whole family to review the content of the sessions and techniques.

The minimum requirement for completing the intervention is that parents receive the three sessions. Children under seven years are not expected to participate actively in the sessions, as they cannot fully comprehend how cancer has affected them or their families. Even if children are too young for the intervention, it is important for parents to learn how to detect cancer-related distress symptoms. To accommodate families with children under seven years, we

offer two additional sessions for parents on teaching the techniques to their children so that they can use them every day. Thus, the psychologist teaches parents the purpose and application of the techniques and trains them to become co-therapists. The intervention can be adapted to the needs of each family, so that those that experience improvement can maintain the positive changes and values, while those that experience difficulties can learn to cope and adjust. Families of children who relapse or die have the option to continue the sessions during or after relapse treatment, depending on their need. We prepared a manual to ensure that the same intervention was offered to all families of CCS. The psychologist has a suggested script for each session, with examples of questions and scenarios, and a list of goals. Questions, scenarios, and techniques are proposed to engage the parents in the sessions. Psychologists with experience in cognitive behavioral therapy are trained in use of the FAMOS manual to ensure standardized delivery and are supervised by an external psychologist certified in supervision regularly to ensure that they have the knowledge and skills required to provide relevant support for each family.

Measures and outcomes

The measures of feasibility were examined descriptively, as the sample size precluded statistical analyses that would have reliable conclusions.

The study-tracking database was examined to determine the participation rate in the RCT, reasons for exclusion and reasons for refusal. Representativeness in terms of frequency and percentage distribution was determined according to gender (father; mother), parent's education (basic school or high school: 7–12 years of primary, secondary and grammar school; vocational education: 10–12 years; higher education, ≥ 13 years; and unknown), family type (single parent or a couple including at least one biological parent), age of parents (18–30, 31–40, 41–50, >50 years) and age of child (0–5, 6–12, 13–18 years) and gender of CCS and siblings (female, male), cancer type of CCS (acute lymphoblastic leukemia, acute myeloid leukemia, non-Hodgkin lymphoma, brain cancer or other solid tumor) and time since diagnosis (0–3, 3–6, 6–9, 9–12, 12–15, 15–18, >18 months) (Table 3).

Families were asked to fill-out questionnaires on a number of outcomes at baseline, and at six- and 12-month follow-up, however, we do not report on the questionnaire outcomes in this feasibility study as the trial is ongoing. The study-tracking database was used to determine the frequency and percentage distribution of participation and withdrawal at baseline and at six and 12 months, the numbers and percentages of sessions for parents and children attended, and reasons for attrition. We examined the acceptability of the intervention to parents at the six-month follow-up from their responses ('yes, maybe or no') to an evaluation form with 20 items, which was developed for this study. The items covered the format of the intervention, the relevance of the content

for the whole family and use of cognitive tools, videos, and information packages.

Results

Recruitment to the randomized controlled trial

Between August 2014 and August 2016, 109 eligible CCS were identified (Figure 2). From these, we recruited 68 families (participation rate, 62%), consisting of 128 parents (mean age, 36 years), of whom 68 are mothers and 60 are fathers, 68 are CCS (mean age, 3.8 years), and 73 are siblings in 50 of the families (mean age, six years). The characteristics of the families enrolled showed a high proportion of fathers ($N=60$; 88% of families); 12% were single parent families. The distribution of CCS by gender was even, and 12% of the 128 parents had basic education/high school (Table 2). The main cancers were leukemia (49%) and other solid tumors than brain tumors (35%); 60% of the CCS were included between one and two years after diagnosis. Of the 41 families that did not participate (Figure 2), 14 (34%) could not be contacted to obtain consent, six (15%) considered that they did not need intervention, and 21 (51%) said that they did not have the time or felt overwhelmed (not shown in figure).

Retention and attrition in the randomized controlled trial

Of the 68 enrolled families, four have not reached their six-month follow-up. Of the remaining 64, four (6%) dropped out before six months of follow-up, and three (5%) dropped out before the 12-month follow-up. The seven families that dropped out (12%) were all in the control group; the reasons they gave were being in the control group ($N=2$), death ($N=2$) or feeling overwhelmed ($N=3$). All the families in the intervention group continued in the RCT for the 12-month follow-up.

Participation and retention in the intervention

Thirty families have completed the intervention, and most (28; 93%) completed all the parent sessions (data not shown); two families did not complete the three parent sessions because of relapse of their child's cancer. Other reasons for having completed fewer than three sessions included death of the child or being uninterested in or ineligible for the children's sessions (Table 4). However, all these families were able to complete the follow-up.

Acceptability of the intervention to parents

The parents were generally satisfied with the intervention (Table 5), reporting high or moderate satisfaction with the separate sessions for parents and children ($N=43$; 72%), starting the intervention at the end of intensive medical treatment ($N=42$; 70%) and having sessions at home ($N=45$; 75%). Most parents ($N=44$; 73%) reported that they had learnt useful cognitive tools and many parents had used

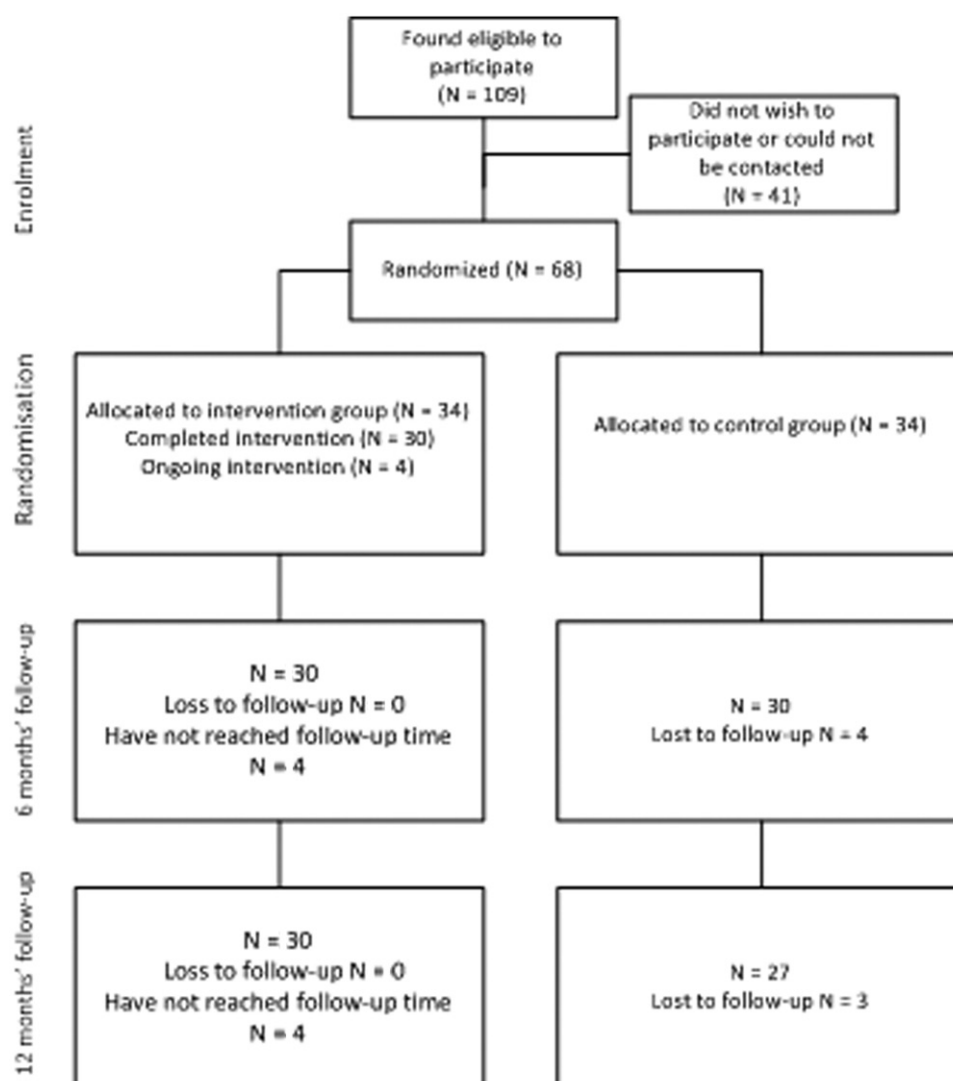


Figure 2. Flowchart of FAMOS randomized controlled trial.

the ABC tool after completing the intervention (N = 28; 47%) (Table 5).

Discussion

The results of the feasibility study of our home-based psychosocial intervention for families of CCS at the end of intensive medical treatment suggest that the FAMOS intervention is highly relevant, as the majority of families accepted the invitation. Furthermore, few families withdrew during follow-up, and parents were satisfied with the format, timing, and content.

The participation rate in the RCT was 62%, which was higher than those in previous studies of in-person interventions for families of children with cancer (40%) [6] and of couple-based interventions for cancer patients (49%) [9]. The reasons for non-participation included lack of need, time, and resources, which may indicate that the intervention is especially relevant for families with psychological symptoms at the time of inclusion and who have the resources to allow them to organize participation of the whole family in up to six sessions (Table 1). This reflects the challenges in

designing a therapeutic intervention for families of CCS, in which the patients, parents, and siblings have a wide variety of psychological symptoms [1,10]. As there is still no convincing evidence for the effect of screening before interventions, we did not screen for mental health problems before inclusion but designed an intervention that would be meaningful for families with widely different circumstances and difficulties. Non-participation might also have been related to the requirement of the RCT that questionnaires be filled in for the whole family.

The timing of the start of the FAMOS intervention was another challenge. In most families, cancer-related stress symptoms decrease naturally [11], while in others they increase [12,13]. Furthermore, the length of treatment for childhood cancers varies widely. We invited families after the completion of intensive treatment, as our pilot sessions indicated that families might de-emphasize their psychological needs while they are focusing on the medical treatment. The study shows that it is feasible and acceptable to invite families at this time. Interventions with even more flexibility, so that families could be included at any time after the cancer diagnosis, might be relevant; however, as the FAMOS

intervention was designed for family life after cancer, it is assumed that most treatment has been given. It would have to be adapted if this is not the case.

In previous studies, attrition in interventions for couples 3–8 months after diagnosis of cancer was reported to be 25–27% [9]. We had an attrition rate of 12% of families in the control group, which might indicate that it is difficult to fill in a questionnaire about family well-being knowing that it will not result in support. Future studies may address the important issue of attrition by using a waiting list design, in which the families in the control group are offered the same intervention after the trial has ended [14].

Table 2. Characteristics of families enrolled in the FAMOS randomized control trial (families N = 68, parents N = 128).

Characteristic	No. (%) of families
Family type	
Single mother	8 (12%)
Single father	0 (0%)
Married or cohabiting	60 (88%)
Parents' age (N = 128), mean (years: age range 18–51)	
Mean	
18–30	36.2
31–40	25 (20%)
41–50	80 (63%)
>51	21 (16%)
Missing	2 (<1%)
Parents' education level ^a (N = 128)	
Basic school or high school	16 (12%)
Vocational training	34 (27%)
Higher education	76 (59%)
Missing	2 (<2%)
Age of childhood cancer survivor (years: age range 0–12)	
Mean	
0–5	3.85
6–12	56 (82%)
13–18	12 (18%)
Childhood cancer survivor gender	
Female	39 (57%)
Male	29 (43%)
No. of siblings	
0	18 (26%)
1	31 (46%)
2	15 (22%)
≥3	4 (6%)
Diagnosis	
Acute lymphoblastic leukemia	30 (45%)
Acute myeloblastic leukemia	3 (4%)
Non-Hodgkin lymphoma	3 (4%)
Brain tumor	8 (12%)
Other solid tumor	24 (35%)

^aBasic school or high school: 7–12 years of primary, secondary and grammar-school education; vocational education: 10–12 years; higher education, ≥13 years.

Participation and retention in the intervention were high, perhaps because of the home-based design. We expected that home sessions would give families optimal support and flexibility, even during maintenance chemotherapy for leukemia, as they eliminate practical challenges such as hiring a babysitter or taking time off work. Also underlining the importance of accessibility to the families, pilot studies have also shown promising feasibility of cognitive behavioral-based online support for families of CCS [15,16]. We were also able to recruit families with basic education/high school and single parents, for whom home sessions may be especially helpful if they do not have social or financial support to travel for other types of treatment. Another reason for the high retention in the intervention might be the availability of a manual, which ensures a concrete program with specific goals, a timeframe, and tools to provide relevant help to families.

FAMOS is original in its focus on the entire family, including siblings and fathers, and we found that fathers also found it feasible to participate in the study. By adding the reactions and perceptions of siblings and fathers on how the family has been affected, a psychologist can identify the whole family's needs and target their issues more precisely. Including the whole family is also a challenge, however, in terms of including children only when relevant and providing age-appropriate sessions for children and siblings whose needs and understanding of the techniques may vary considerably. For instance, some children might consider the tools too childish and others too difficult [17].

Table 4. Completion of sessions among families in the FAMOS intervention (N = 30).

Intervention group	n (%)
Total of number of sessions	
1–2	1 (3%)
3–4	8 (27%)
5–6	21 (70%)
Children's sessions used	
0	18 (60%)
1	7 (23%)
2	4 (13%)
Missing	1 (<4%)
Reason for not completing the children's sessions	
Children are too young	15 (50%)
Relapse or death	2 (7%)
Not relevant	13 (43%)
Reason for not completing the parents' sessions	
Relapse	2 (100%)
Not interested	0 (0%)
Other	0 (0%)

Table 3. Time between diagnosis and inclusion (months).

Time between diagnosis and inclusion (months)	No. of families				
	Acute lymphoblastic and myeloblastic leukemia	Non-Hodgkin lymphoma	Brain tumor	Other tumor	Total
0–3	0	0	1	1	2%
3–6	0	0	0	6	9%
6–9	3	3	0	6	18%
9–12	1	0	0	5	9%
12–15	21	0	0	2	33%
15–18	1	0	1	0	4%
>18	7	0	6	4	25%

Table 5. Evaluation of FAMOS intervention (families N = 30).

Format of intervention	Mothers (N = 30) N (%)				Fathers (N = 30) N (%)				Total (N = 60) N (%)		
	Yes	Maybe	No	Missing	Yes	Maybe	No	Missing	Yes/maybe	No	Missing
Timing (after end of treatment) was appropriate	18 (60)	6 (20)	2 (7)	4 (13)	13 (43)	5 (17)	1 (3)	11 (37)	42 (70)	3 (5)	15 (25)
Sessions at home worked well for our family	21 (70)	5 (17)	0 (0)	4 (13)	17 (57)	2 (7)	0 (0)	11 (37)	45 (75)	0 (0)	15 (25)
Separate sessions for parents and children worked really well	16 (53)	9 (30)	0 (0)	5 (17)	14 (47)	4 (13)	0 (0)	12 (40)	43 (72)	0 (0)	17 (28)
We learnt useful tools	22 (74)	3 (10)	1 (3)	4 (13)	17 (57)	2 (7)	0 (0)	11 (37)	44 (73)	1 (2)	15 (25)
The program was useful for our family	17 (57)	4 (13)	5 (17)	4 (13)	13 (43)	5 (17)	1 (3)	11 (37)	39 (65)	6 (10)	15 (25)
We would recommend the FAMOS program to other families of childhood cancer survivors	20 (67)	6 (20)	0 (0)	8 (13)	17 (89)	2 (11)	0 (0)	11 (37)	45 (75)	0 (0)	15 (25)
Seeing videos of other families going through the same experience helped us to talk about our thoughts and feelings	17 (57)	4 (13)	4 (13)	9 (17)	16 (53)	1 (3)	2 (7)	11 (37)	38 (63)	6 (10)	16 (27)
<i>Use of cognitive tools after completing the program</i>											
	Mothers (N = 30) N (%)			Fathers (N = 30) N (%)			Total (N = 60) N (%)				
	Yes	No	Missing	Yes	No	Missing	Yes	No	Missing		
Use of 'roadmap'	9 (30)	17 (57)	4 (13)	4 (13)	14 (47)	12 (40)	13 (22)	31 (52)	16 (26)		
Use of information package	5 (17)	21 (70)	4 (13)	5 (17)	13 (43)	12 (40)	10 (17)	34 (57)	16 (26)		
Use of ABC model	19 (64)	7 (23)	4 (13)	9 (30)	9 (30)	12 (40)	28 (47)	16 (27)	16 (26)		

As most of the children in intervention group are too young to participate in the sessions, we taught parents to become 'co-therapists', by using the techniques at home. The parents must therefore be highly motivated and resourceful enough to use the techniques in everyday life. The results of the evaluation of the intervention suggest that it was well received.

Many of the parents used at least one tool after the end of the intervention, indicating the usefulness of cognitive behavioral therapy in the intervention. Problem-solving techniques have been proven to be the most effective in improving the mental health and behavior of parents after medical treatment of their children [18]. A potential benefit of extension of the FAMOS intervention to everyday life might be that parents continue to use the techniques after completing the intervention. Sahler et al. [19] showed that mothers who learnt problem-solving techniques continued to improve their mood, anxiety, and post-traumatic stress after the intervention.

Strengths and limitations

The main strengths of the intervention are that it is the first home-based psychosocial intervention for the whole family, delivered shortly after the end of medical treatment and built on the most promising psychotherapeutic techniques. Furthermore, this is the first study of a psychosocial intervention for families of CCS in a nationwide setting. In Denmark, all treatment of CCS is free of charge, and the nationwide setting implies systematic invitation of the families of CCS in all regions, independently of socioeconomic factors. These characteristics ensure the generalizability of this feasibility study as well as that of the results of the RCT. The randomized controlled design implies that we take into account changes in psychological symptoms due to natural recovery of families of CCS and those due to standard care. A possible limitation is restriction of the age of the children. Initially, we intended to include all children under 18 years; however, owing to a concurrent psychosocial intervention study, we are unable to invite children over six years, and the results should be generalized to families of CCS over six years with caution.

Conclusion

This study of the development and feasibility of the FAMOS intervention was part of an ongoing nationwide RCT, which is to include 150 families. The primary outcome of the study is post-traumatic stress symptoms in parents at six and 12 months of follow-up. Secondary outcomes include depression, anxiety, family functioning, coping strategies, quality of life, and communication between parents.

We have developed the first home-based psychosocial intervention for families of CCS after the end of intensive medical treatment. Our results suggest that the intervention is highly relevant to many families, with promising feasibility, including a high participation rate and satisfaction. Evaluation of the intervention in the RCT will reveal its effect on psychological outcomes.

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Disclosure statement

There is no conflict of interest.

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