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A randomized controlled trial of a group intervention for siblings of children with cancer: Changes in symptoms of anxiety in siblings and caregivers

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Abstract

Objective: This study assessed the effects of a group intervention—Siblings Coping Together (SibCT)—on siblings' and caregivers' anxiety symptoms compared to controls, and potential moderators.

Methods: Seventy healthy siblings of children on or off treatment (7-16 y old, 41 males) participated in a randomized controlled trial (RCT) with 2 arms/groups: SibCT (n = 41) and an attention control (CG) (n = 34). Both groups had eight 2-hour weekly sessions. EG followed SibCT's educational, social, and problem-solving activities. CG had planned games and crafts. Siblings and caregivers self-reported on anxiety symptoms at baseline, intervention end, and 3 months later. Multivariable mixed model analyses examined the intervention effect over time, and potential moderators (gender, on/off ill child's treatment).

Results: No main effects of group or time were found in sibling scores. A group × gender interaction ($P < .05$) indicated that in the intervention group female siblings reported less total anxiety symptoms than male siblings, with no significant gender differences in the control group. Caregivers' total anxiety symptoms declined over time ($P < .02$). A group × on/off treatment interaction in physiological/panic subscale ($P < .03$) indicated that when ill child was on treatment, caregivers of siblings in SibCT reported less anxiety compared with caregivers of CG.

Conclusions: There was no clear SibCT intervention effect. SibCT may benefit female siblings, and caregivers whose ill child is on active treatment. Contextual factors (gender) seem to influence psychosocial intervention in this population.

KEYWORDS

anxiety, childhood cancer, intervention, mental health, oncology, randomized control trial, siblings

1 | BACKGROUND

Childhood cancer diagnosis and treatment can result in psychological distress in siblings.[1-3] While the majority of siblings adjust well, a small subgroup experience elevated psychological distress.[1,2,4,5] More specifically, greater distress has been reported in siblings during the initial stages of the cancer treatment,[6] but some have reported elevated distress even years after diagnosis,[7,8] including alcohol abuse in adulthood.[9] Risk factors for poorer psychological distress in siblings include being female, relapse and impaired health in the child with cancer, and family difficulties.[4,7,8,10] These findings have led to

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recommendations for services for siblings.[11] Although psychosocial interventions for siblings of children with cancer have been documented since the 1980s,[7,12,13] controlled studies examining sibling outcomes are rare.

A manualized intervention program, Siblings Coping Together (SibCT),[14,15] was previously developed and pilot tested revealing significant reductions in siblings' anxiety post intervention.[14,15] Moreover, some trends were noted including older female siblings tending to have higher anxiety scores than younger females.[15] These findings, however, were limited by a small sample size and the lack of a control group.

Caregivers of children with cancer are also at risk for psychological distress.[16] Reports have documented symptoms of post-traumatic stress, anxiety, and depression, particularly during the early months of their child's treatment.[17-22] Some evidence-based interventions for caregivers shortly after diagnosis have been developed and evaluated with mixed results.[23-25] Whether interventions targeted at siblings of children with cancer might indirectly benefit their caregivers has not been previously examined.

This study investigated the efficacy of SibCT on symptoms of anxiety in siblings' self-reports (aim 1), and caregivers' self-reports (aim 2). It was hypothesized that compared to the CG, siblings in the intervention group and their caregivers (who completed assessments only) would report less symptoms of anxiety post intervention. The hypothesis regarding the caregivers is based on the assumption that caregivers of siblings in SibCT may note more positive changes in siblings' behavior than caregivers of siblings in CG. The potential moderating effect of siblings' age, gender, and baseline distress on outcomes was also examined (aim 3). We hypothesized that female siblings in the intervention would demonstrate a greater reduction in anxiety compared with male siblings and that siblings who presented with more symptoms of anxiety at baseline would have greater benefit after intervention. Finally, we explored, as potential moderators of caregiver's anxiety symptoms, whether or not the ill child was on treatment, and caregiver gender (aim 4). We hypothesized that caregivers of siblings who participated in SibCT when the ill child was on active treatment would have reduced anxiety compared with caregivers of siblings in the control group.

2 | METHODS

2.1 | Study design

This was a parallel group RCT with 2 arms and 3 measurement time points: baseline, upon completion of the intervention, and 3- to 4-month follow-up.

2.2 | Participants

Eligible participants were recruited from 2 tertiary Canadian pediatric cancer centers (Central and Western Canada) serving a large, urban and rural population. Inclusion criteria were as follows: (1) 7 to 16 years old siblings of children diagnosed with any type of cancer at least 3 months from diagnosis, or off treatment on follow-up; (2) the child with cancer was expected to live beyond 6 months post enrollment; and (3) a sibling and one caregiver spoke English fluently. Siblings diagnosed with a developmental or psychiatric disorder or who were receiving active psychological treatment at recruitment were excluded.

2.3 | Procedure

All procedures were approved by the institutional research ethics boards at the main site SickKids Hospital, Toronto, Canada (#1000028990) and Alberta Children's Hospital, Calgary (E-25054). This study was registered at ClinicalTrials.gov, US National Institutes of Health (# NCT02787330). Potential siblings were identified from hospital databases for pediatric cancer patients or referred by Hematology/Oncology (H/O)/Psychology staff and then screened by a research assistant for eligibility, family schedule, and availability during the week. Informed, written consent was obtained from each participant. Siblings were then assigned to 1 of 2 groups, stratifying by site, balanced by age and gender, and based on families' availability. After enough participants (>3 per group) were enrolled in each group (range of 3-6 siblings per group), blocked randomization of the groups to SibCT or CG was conducted centrally by 2 researchers, who were blind to participants' identity. Participants were told the study was evaluating 2 different group interventions, but the identity of the group was not disclosed. In total, there were 8 intervention and 8 control groups.

2.4 | Intervention

SibCT manualized intervention consisted of cognitive-behavioral, problem-solving sessions, using role-playing, arts and crafts, games, group discussions, and homework, planned around specific themes: (1) developing group rapport, getting to know each other; (2) medical education about cancer; (3) cancer in the family context; (4) siblings' personal experience with cancer; (5) relationships between healthy sibling and child with cancer; (6) school and peer relationships; (7) siblings' future; and (8) graduation, closure, and evaluation. The CG was designed to control for the effect of gathering together in a group and attention from the group facilitators. Instead of intervention components, CG sessions were planned around themes such as “Fun with Music” and “Fun with Art.” Both groups had eight 2-hour weekly sessions run by 2 trained facilitators (eg, psychologists and graduate students). A manual for the CG was also developed to assure fidelity and consistency across sites (available upon request).

2.5 | Outcomes

Anxiety symptoms were measured by the Multidimensional Anxiety Scale for Children (MASC).[26] The MASC consists of 39 items that comprise a total and 4 subscales: Physical Symptoms, Social Anxiety, Harm Avoidance, and Separation/Panic Anxiety. Test-retest reliability was 0.79 in clinical samples[26] and 0.88 in school-based samples.[27] Validity of the MASC has been demonstrated.[26] In the current sample, internal consistency estimates for the total MASC was 0.88, and for the subscales ranged from 0.64 for separation/panic to 0.84 for social anxiety. Caregiver anxiety symptoms were measured using the *Multidimensional Anxiety Questionnaire* (MAQ).[28] The MAQ consists of 40

items, yielding a total and 4 subscale scores (physiological-panic, social phobia, worry and fears, and negative affectivity). The MAQ has strong test-reset reliability (0.95 for the MAQ total scale, 0.90 to 0.93 for the subscales) and validity (0.96 for the MAQ total scale and 0.88 to 0.91 for the MAQ subscales). Internal consistency estimates for the total MAQ was 0.94, and for the subscales ranged from 0.61 for negative affectivity to 0.85 for social phobia. The total and the subscales T-scores (mean of 50 and SD of 10) for the MASC and MAQ were reported. T-scores ≥60 are considered elevated. Clinical information regarding the child with cancer (eg, diagnosis, time since diagnosis, and being on or off treatment) and demographic data regarding the family (eg, siblings' age and gender and caregiver's age and gender) were obtained at baseline.

2.6 | Statistical analysis

The sample size was calculated using the minimum clinically important difference. A minimum clinically important difference of 5 was estimated using half of the standard deviation (M = 50, SD = 10) for the MASC and MAQ scores, respectively. To achieve 80% power, with a significance level (alpha) of 0.05, it was estimated that 40 participants for each group or a total sample of 80 were required to test the intervention effect (SibCT vs CG).

Descriptive analyses were performed to check for normality and to describe the sample and outcome measures at each assessment point. Preliminary bivariate correlations, chi-square test, and analyses of variance (ANOVAs) were conducted to compare groups at baseline and select potential moderators for siblings' or caregivers' outcomes. Data were analyzed under an "intent-to-treat" strategy. Multivariable analyses with a mixed model and maximum likelihood estimation method were conducted to examine the intervention effect (SibCT vs CG) × time in siblings' anxiety scores (aim 1) or caregivers' anxiety scores (aim 2), separately. Within the model for siblings' outcomes, we examined gender as a moderator (aim 3), and within the model for caregivers' outcomes, we examined ill child's treatment status (on/off) and gender as moderators (aim 4). Each model estimated the parameters for main effects (aims 1 and 2) and the interactions to explore moderators for sibling outcomes (aim 3) and caregiver outcomes (aim 4). These analyses generated intervention effect (group), time effect, group × time interaction, and interaction terms with the potential moderators.

Potential moderators were included in the multivariable mixed model analysis based on correlations to the specific dependent variable. For example, total MASC was associated with sibling gender ($P = .04$), but not sibling age ($P > .1$); hence, age was not included as a potential moderator of sibling outcomes. Similarly, with caregiver MAQ scores, time since diagnosis and whether the ill child was on or off treatment were correlated to one another, but only on/off treatment was associated with total MAQ scores ($P < .05$). At baseline, a group × gender ANOVA on the MASC total scores found no significant main effects or group or gender, or group × gender interaction ($Ps > .05$). Also, the groups did not differ significantly on any other demographic, clinical, or outcome variables at baseline. An ANOVA on the total MAQ scores using gender and group at baseline yielded no significant group differences or interaction between group and gender for caregivers. A significant gender effect indicated that female caregivers had significantly higher anxiety scores than males ($F_{1,73} = 7.51$, $P < .01$). Thus, caregiver's gender and being on/off treatment were the variables considered in the multivariable analyses as potential moderators of caregiver outcomes.

Finally, a separate multivariable analysis was conducted with siblings' total MASC scores to test if those siblings who had greater anxiety scores at baseline would experience greater improvement after the intervention (aim 3). To do this, total MASC scores at baseline were dichotomized using the median split into low and high, and data on postintervention and follow-up was then used. *P* values are reported for significant differences. Using Cohen's benchmark, partial eta squared (η^2) are also reported for determining effect size: small ($\eta^2 = 0.01$), medium ($\eta^2 = 0.06$), and large ($\eta^2 = 0.14$). All *P* values were 2-sided, and $P < .05$ was considered a significant difference. Statistical analyses were performed using SAS Version 9.4.

3 | RESULTS

3.1 | Recruitment

Recruitment occurred between March 2012 and September 2014 (see CONSORT flow chart in the Supporting Information). Of the 289 siblings who were identified as potential participants, 229 were contacted, 158 (60%) verbally consented to participate, and 71 (25%) declined participation. Of those who verbally consented, 83 were later unable to participate due to scheduling difficulties. Seventy-five siblings (41 in EG, 34 in CG) received the allocated treatment. Participating siblings did not differ significantly from nonparticipants on age, gender, and distance from the center. Group attendance (defined as attending more than 75% of the sessions) was moderate to high (76% and 82% in EG and CG, respectively).[29] Retention rates were strong (93% and 87% at 8-wk and 3-mo follow-up).[29] Table S1 presents the characteristics of the sample at baseline.

3.2 | Descriptive data

3.2.1 | Sibling data

At baseline, the average sibling scores were within the normal range for anxiety symptoms (see Table S2). At baseline, 28% of males and 17% of females had elevated total MASC scores, but these percentages were not significantly different ($P > .05$).

3.3 | Efficacy of intervention

3.3.1 | Aim 1: siblings outcomes

No significant main effects of group or time, or group × time interaction were found on the MASC total or subscale scores.

3.3.2 | Aim 2: caregiver outcomes

A significant medium size effect of time was found for the MAQ total scores ($F_{2,126} = 4.05$, $P < .02$, $\eta^2 = 0.060$), indicating an overall reduction of anxiety symptoms overtime averaged across the 2 groups. This effect was also noticed in all the subscales (physiological-panic reactions, $F_{2,111} = 6.95$, $P < .001$, $\eta^2 = 0.111$; social phobias,

$F_{2,129}$ = 3.20, P < .04, η^2 = 0.048; worries and fears, $F_{2,136}$ = 3.64, P < .03, η^2 = 0.051; and negative affectivity, $F_{2,127}$ = 5.11, P < .01, η^2 = 0.074). No significant main effect of group or a group × time interaction was found.

3.3.3 | Aim 3: potential moderating effects on sibling outcomes

Gender

Multivariable analyses revealed a significant medium size effect of gender for total MASC scores: Sibling males (across groups and the three assessment times) reported higher scores than females ($F_{1,67}$ = 3.98, P < .05, η^2 = 0.069). The same pattern of gender differences was found in the subscales of harm-avoidance ($F_{1,82}$ = 18.50, P = .001, η^2 = 0.184), anxious coping ($F_{1,82}$ = 25.59, P = .0001, η^2 = 0.238), and panic-separation ($F_{1,73}$ = 6.80, P = .01, η^2 = 0.085), with medium to large effect sizes. A significant group × gender interaction was also found in the total MASC scores, with a medium effect size ($F_{1,67}$ = 4.37, P < .105, η^2 = 0.062). Compared with males, female siblings who participated in the intervention group reported significantly lower anxiety scores, averaged across the 3 assessment points (P < .005; see Figure S1). No differences were found between male and female siblings in the CG. There were no significant main effects of group or time, or interactions of group × time, gender × time, or group × time × gender in the total or subscale scores.

High/low anxiety scores at baseline

There was a large significant main effect of Hi/Lo scores in the total MASC, indicating that high or low scores at baseline continue the same pattern across assessment points and groups ($F_{1,68}$ = 25.57, P < .0001, η^2 = 0.278). There were no significant interactions with group or with time.

3.3.4 | Aim 4: potential moderating factors on caregiver outcomes

Gender

There was no significant main effect of caregiver gender, or interaction of gender × group, or gender × group × time.

Child with cancer being on/off treatment

No significant main effect for on/off treatment status was found for the total MAQ scores. However, a significant main medium effect size was found for on/off treatment status in the physiological/panic MAQ subscale ($F_{1,61}$ = 4.60, P < .04, η^2 = 0.070), indicating that caregivers' physiological/panic scores averaged across the 3 assessment points were higher when the ill child was on active treatment than when off treatment. No significant main effect of on/off treatment was found in any of the other MAQ subscales. There was also a significant group × on/off treatment interaction for the physiological/panic scores, with a medium effect ($F_{1,61}$ = 5.25, P < .04, η^2 = 0.079), indicating that caregivers of siblings in the intervention group whose ill child was on active treatment had significantly fewer panic reactions averaged across all 3 times compared with caregivers of siblings in the CG (P < .03). In contrast, when the ill child was off treatment, caregivers in both groups generally reported low panic anxiety symptoms and did not differ from one another (see Figure S2). There was no significant group × on/off treatment × time interaction with data from this or the other subscales or total MAQ.

4 | DISCUSSION

This study investigated the efficacy of the SibCT intervention program using an RCT with 2 arms, on self-reported symptoms of anxiety in siblings and caregivers. We also examined factors that may modify the effect of intervention including selected demographic and ill child's clinical variables. The hypotheses that compared to controls siblings' and their caregivers' anxiety scores would decrease after siblings participated in SibCT were not supported. Regarding gender as a moderator, the finding that females in the intervention group reported less anxiety symptoms than males (averaged across the 3 assessment time points) and no differences were found in CG, is promising. However, without a significant group × time × gender interaction, no moderation can be concluded.

Anxiety scores at baseline showed no significant gender differences, but scores averaged across time indicated significantly more anxiety symptoms in male siblings than females. Gender differences in distress among siblings of children with cancer have been inconsistently reported, but when they are reported, females are shown to be more distressed than males.[1,4,7,8,10] The question that arises is: why did female siblings who participated in group intervention report less anxiety symptoms than male siblings? During the intervention sessions, siblings discussed their feelings and problem-solved difficult situations in a safe, supportive environment. Female adolescents in the general population engage in more problem solving and seeking social support than males, whereas males report higher avoidance coping strategies than females.[30] It is possible that female siblings in this study found the group activities more in tune with their coping styles and hence more beneficial to them than did males. These intriguing findings and interpretations merit further investigation in future studies.

It is important to note that while the anxiety scores for siblings as a group were within the normal range at baseline, elevated scores continued to be elevated after intervention. Siblings may experience subclinical levels of distress related to the family demands of cancer treatment, as has been reported in several qualitative studies.[31,32] Subtle distress signs and behavioral changes may not be detected by instruments designed to assess clinical levels of anxiety. Subtle changes (eg, speaking up and better management of negative emotions) that may emerge after SibCT participation may reflect more subtle aspects of adjustment and coping.[33] Thus, the full impact of SibCT may become evident by complementing quantitative measures with qualitative methods, a future goal of our team.

Regarding the outcomes in caregivers, several important points emerged. First, although the main efficacy hypothesis was not supported, anxiety scores of caregivers in both groups significantly declined over time. Perhaps caregivers who enrolled their "healthy" child in the intervention project (regardless of group allocation) felt relieved by doing something for the child, "like a good parent," a concept previously coined for parents caring for children with cancer.[34] Second, findings indicating higher caregiver anxiety scores when the

ill child is on treatment, compared with when the ill child is off treatment, is consistent with previous studies.[19,35,36]

Third, the significant overall interaction of group × ill child's on/off treatment status suggests that when the ill child was on treatment (high stress level), caregivers of siblings in the intervention group experience less panic/anxiety symptoms compared with caregivers of siblings in the control group. Differences between the 2 groups of caregivers did not emerge when the ill child was off treatment. It is possible that these findings may be the result of caregivers noticing more positive, subtle changes in the siblings' behavior and mood when the sibling participated in the intervention. Thus, it appears that there are beneficial effects for caregivers to have the "healthy child" involved in SibCT intervention when they are in the middle of managing the ongoing cancer treatment for the ill child. This finding, however, may need further replication.

To summarize, this study has several strengths. One main strength is its rigorous use of methodology which includes an RCT design with a manualized intervention and standardized measures involving 2 sites representing 2 geographically diverse areas of the country, both with urban and rural populations. However, the efficacy of SibCT was not confirmed. The intervention effect may be conditional on siblings' gender (less anxiety symptoms in female vs male siblings who participated in SibCT), but this was inconclusive. Regarding caregivers, indirect effects of intervention (less anxiety symptoms) became evident if the ill child was on active treatment. The indirect effect of the intervention on caregivers' anxiety symptoms is a novel and important outcome that warrants further investigation. While this research is challenging, rigorous evaluations of new intervention programs for siblings of children with cancer can contribute to improving our knowledge base for providing effective supportive intervention for this population.

4.1 | Study limitations

Although the study had sufficient power for assessing the intervention effect, it might have been underpowered to examine the effect of potential moderators (sibling's gender, on/off treatment) on the intervention effect. Consequently, the interactions with gender (sibling data) and being on/off treatment (caregiver data) may be underestimations of their impact on the intervention. We faced recruitment challenges related to logistical problems (family's transportation difficulties and finding the right time and date suitable to all participants). These may have biased the sample towards participants who had less challenges to participation. Future studies should examine other ways to participate in groups such as face time and skyping to ensure greater enrollment. Perhaps instruments that were designed to detect clinical levels of psychopathology (as the one used in this study) are not able to detect subclinical changes in behavior related to intervention.

4.2 | Clinical implications

The results of this study suggest that attending to the psychological needs of siblings of children with cancer may benefit not only siblings but also caregivers, as a positive ripple effect in the family, particularly when the ill child is on active treatment. In addition to direct psychosocial support for caregivers of children with cancer,[19] providing psychosocial support for the "healthy children" may also provide caregivers with much needed relief to know that their other children are not being neglected. These findings support family-centered care in pediatric oncology.[37,38]

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CONFLICT OF INTEREST

The authors have no conflict of interest to declare.

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SUPPORTING INFORMATION

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