


PAPER

A randomized control intervention trial to improve social skills and quality of life in pediatric brain tumor survivors

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Abstract

Background To determine if a group social skills intervention program improves social competence and quality of life (QOL) in pediatric brain tumor survivors (PBTS).

Methods We conducted a randomized control trial in which PBTS (8-16 years old, off therapy for over 3 months) were allocated to receive social skills training (eg, cooperation, assertion, using social cognitive problem solving strategies, role playing, games, and arts and crafts) in 8 weekly 2-hour sessions, or an attention placebo control (games and arts and crafts only). Outcomes were self-reported, proxy-reported (caregiver), and teacher-reported using the Social Skills Rating System (SSRS), to measure social competence, and the Pediatric Quality of Life (PedsQL4.0, generic) to measure QOL at baseline, after intervention, and at 6 months follow-up. At baseline, SSRS were stratified into low and high scores and included as a covariate in the analysis.

Results Compared to controls ($n = 48$), PBTS in the intervention group ($n = 43$) reported significantly better total and empathy SSRS scores, with improvements persisting at follow-up. The PBTS in the intervention group who had low scores at baseline reported the greatest improvements. Proxy and teacher reports showed no intervention effect.

Conclusions Participating in group social skills intervention can improve self-reported social competence that persisted to follow up. The PBTS should be given the opportunity to participate in social skills groups to improve social competence.

KEYWORDS

brain tumor survivors, evidence-based practice, oncology, pediatric cancer, randomized controlled trial, social competence, social skills intervention

1 | BACKGROUND

Survival of children with brain tumors has increased in recent years, but at a high cost of physical, neurocognitive, and social competence deficits.¹⁻³ Reports of social competence deficits in pediatric brain tumor survivors (PBTS) include having fewer friends than controls, being socially withdrawn, or victimization.⁴⁻⁶ Social competence is an umbrella concept encompassing the ability to achieve personal goals through social interactions across situations; includes social behavior, adjustment, performance, and social skills.^{3,7,8} Social skills refers to goal-directed, situationally appropriate behaviors (greetings) used to gain acceptance

by peers and others.⁹ Social competence and social skills deficits in PBTS may persist into adulthood, negatively affecting integration within society.^{4,10,11} These deficits may affect quality of life (QOL) during and after treatment and persist into adulthood.¹²⁻¹⁴ Tumor location and type,¹⁵⁻¹⁹ as well as cranial irradiation,^{6,20,21} and personal characteristics such as neurocognitive^{20,22} and executive functioning^{23,24} may be associated with social outcomes in PBTS. Limited information exists, however, on how to improve social competence in this population.

Social skills training interventions may prevent or reduce social competence deficits and improve QOL. Extensive efforts have been made to rehabilitate personality changes (including cognitive and social

behavioral dimensions) in children and adults after traumatic brain injury.^{9,25} Limited research has been conducted to develop social skills training interventions and evaluate their effectiveness with PBTS. Earlier work targeted a small group of boys attending a camp where skills such as assertiveness were fostered. Participants and parents completed satisfaction questionnaires.²⁶ Another small study used a manualized social skills program, standardized measures, and included teacher reports.²⁷ This early work suggested beneficial effects of social skills intervention for PBTS.

We previously developed an innovative, manualized, group social skills intervention program (SSKIP) that focused on teaching social-cognitive problem solving and social skills necessary for social interactions with peers and others.²⁸ We have tested SSKIP's feasibility and self- and proxy-reported preliminary outcomes of social competence and QOL.²⁹ The SSKIP was also pilot tested using a small comparison group, teacher reports, social problem solving, and social performance as preliminary outcomes.^{30,31} These initial studies led to this project.

The primary objective of this randomized control trial (RCT) was to determine if the SSKIP was associated with improved self-reported, proxy-reported, and teacher-reported social competence when compared to a placebo group. The secondary objective was to determine if SSKIP was associated with improved self-reported and proxy-reported QOL. Time effect was examined to evaluate change over time and initial social competence levels were examined as confounders.

2 | MATERIALS AND METHODS

2.1 | Participants and procedure

Participants were recruited from 4 sites: Sickkids Hospital, Toronto; London Health Sciences Centre, London; Alberta Children's Hospital, Calgary; and BC Children's Hospital, Vancouver, Canada. Participants were (1) diagnosed with a brain/spinal tumor; (2) off treatment for at least 3 months (the exceptions were 1 placebo and 3 intervention participants, medically stable, with low grade gliomas, who were receiving low dose chemotherapy for an extended period); (3) 8-16 years of age at enrollment; (4) fluent in English; and (5) spending more than 50% of school day in a regular classroom. Exclusions: those with severe neurocognitive deficits (defined by at least 50% enrollment in a special classroom) or severe psychiatric/developmental disorder (eg, autism). Following institutional ethics approval (IRB No. 1000029463) at each site, potential participants were identified from a patient database. Informed consent and assent as appropriate were obtained.

2.2 | Design

This was a parallel group, superiority RCT with concealed and balanced allocation, to 2 arms: a social skills intervention group or an attention placebo group. Randomization was stratified by age (≤ 12 years vs > 12 years), gender, and the weekday the child could participate (2 options); and conducted centrally by 2 researchers, who were blind to participants' identity, generating random numbers by flipping a coin. Participants were told the study was evaluating 2 different interventions, but the identity of the child's group was not disclosed. Families were discouraged from talking about their participation with other families.

Enrolled participants completed a brief neurocognitive battery prior to randomization. Outcome assessments were completed at baseline

(before session 1), at the end of the intervention (week 8) and 6 months later. Teacher ratings were completed 3-6 months post intervention.

3 | INTERVENTION STRATEGIES

Common characteristics of intervention and placebo groups were (1) eight 2-hour weekly sessions; (2) games and crafts, snack time, homework, and a graduation ceremony. Treatment fidelity was tested previously.²⁵ In this study, fidelity was monitored during weekly debriefing sessions between group facilitators and supervisor, and by reviewing "field notes" completed for each session by an independent observer. All facilitators received training specific to the groups they were assigned and were supervised at each site by a clinical psychologist, who was trained by the PI. At each recruitment cycle, actual groups of 3-6 participants were run for either the intervention or placebo group.

3.1 | Social skills intervention group

The active ingredient was the social skills training, manualized SSKIP program, described earlier.^{28,29} Briefly, the first 6 sessions focused on one of 6 social skills: (1) Friendship making; (2) Cooperation; (3) Managing teasing and bullying; (4) Conflict resolution; (5) Empathy; and (6) Assertion. Session 7 consisted of extensive review of the 6 social skills and Session 8 was wrap-up and graduation ceremony. Throughout the sessions, social interaction was encouraged among participants, integrating the skills learned in the group. The format of each session consisted of (1) Pre-activity, with the theme of the day. Participants could start working on the activity as soon as they arrived (approximately 10 minutes). (2) Homework discussion and praise to motivate participants to practice the skills learned in the previous session (approximately 10-15 minutes). (3) Training of the new social skill: introduction, questions and description of the skill, specific steps (depicted in drawings), and role playing. Role playing of the skills was the favorite step of skill learning, enacting brief skits and dressing up accordingly; (4) Main activity. This involved doing a craft or playing a game using the new skill. For example, for "managing teasing and bullying," the main activity was playing "bully bingo," a game created with cards of pictures of how to deal with bullies. Finally, (5) Homework assignment: practicing the new skill outside the group.

3.2 | Attention placebo group

Facilitators followed the attention control manual, with sessions planned around benign themes. For example, if the theme for that session was "summer fun," participants made a poster about summer activities, played summer-themed charades, and discussed the fun things they had planned for the summer holidays. Facilitators did not have access to the social skills training manual and structured activities used in the SSKIP.

4 | MEASURES

The primary outcome was the Social Skills Rating System (SSRS; self-report [for children over 6 years], parent proxy, and teacher

versions).²⁷ The SSRS provides age-normed and gender-normed total standard score and 4 social skills subscale scores: cooperation; assertion; self-control; and responsibility (or empathy for the child form). The SSRS assesses social behavior that impacts on peer interactions and acceptance.³² Thus, in this study the total standard score is operationalized as a measure of social competence rather than just an aggregation of social skills. The SSRS has adequate reliability and validity; and compared to other measures of social competence, it provides the most comprehensive data with this population.³³ Higher scores represent better social competence. For analyses, SSRS scores at baseline were stratified into low and high, using the median split value, as potential confounders of intervention. The QOL was the secondary outcome and was assessed using the Pediatric Quality of Life Inventory (PedsQL4.0 generic)³⁴ self-report and parent-proxy. The PedsQL is reliable and valid in pediatric cancer patients, and it yields a total score and 4 subscale scores: physical, emotional, social, and school functioning. Higher scores represent better QOL.

Satisfaction (what they liked best about the group) was assessed using a self-developed satisfaction questionnaire.²⁹

The SSRS and PedsQL were completed by PBTS and caregivers at baseline, end of the 8-week intervention, and 6 months later. Teachers completed the SSRS 3-6 months postintervention. The PBTS and caregivers who had difficulties understanding a question were assisted.

4.1 | Descriptive variables

The medical and demographic information collected is presented in Table 1 and included gender; age at study and at diagnosis; diagnosis and tumor location, time since diagnosis and since last treatment; treatment information (cranial irradiation; surgery; chemotherapy; and various treatment combinations); caregiver age, education, ethnicity, family income, and marital status. A neurocognitive battery was conducted at baseline and included an assessment of intelligence (Wechsler Abbreviated Scale of Intelligence),³⁵ and executive functioning (Behavior Rating Inventory of Executive Functions—parent version).³⁶

5 | SAMPLE SIZE ESTIMATION

Sample size was calculated using the minimum clinically important difference for the primary outcome measure, the SSRS. Based on preliminary work,²⁹ we assumed that an improvement of 5 points on the total SSRS score with a standard deviation of 11 points was considered clinically significant. Hence, sample sizes of 42 per group were needed to achieve 80% power to detect a clinical difference of SSRS from baseline to end of intervention (week 8) difference assuming a 10% loss to follow up and 5% level of significance.³⁷

6 | STATISTICAL ANALYSIS

Descriptive analyses were performed to check for normality and describe the sample. Self-reports and proxy-reports were compared to each other and to normative values. Data were analysed under an "intent to treat" strategy. Multivariable analyses with a mixed effects model were used to examine the intervention effect (intervention vs

control group), controlling for initial score levels (high/low), time since diagnosis (see below), and accounting for collinearity over time. Generalized linear contrasts (linear functions of the estimated parameters) were used to estimate within group change (eg, baseline to post intervention) and between group differences. If the total standard scores showed an intervention effect, the subscales were also examined. Teacher data were analysed using *t* test for independent samples. Finally, data from the satisfaction questionnaire were tabulated for frequency and percentages, including comments provided by 3 open-ended questions (eg, suggestions for future groups and challenges to participation); Fisher exact test were calculated comparing intervention and control groups. *P*-value and confidence intervals are reported for group differences; effect size, partial eta squared (η^2) are also reported. Cohen's³⁸ benchmark for η^2 are small ($\eta^2 = 0.01$), medium ($\eta^2 = 0.06$), and large ($\eta^2 = 0.14$) effects. All *P*-values were 2-sided and *P* < .05 was considered a significant difference. Statistical analyses were performed using SAS Version 9.4.

7 | RESULTS

7.1 | Descriptive statistics

Recruitment occurred between March 2012 and January 2015 (see CONSORT flow chart, supplementary material). In total, 234 PBTS were eligible; 95 families (41%) consented to participate; 100 families declined participation (distance to the center and schedule conflicts [*n* = 45]; too busy [*n* = 33]; or not interested [*n* = 22]). Participants and nonparticipants did not differ significantly on age, gender, and distance from the centre. There were, however, more patients with a diagnosis of medulloblastoma in the nonparticipant group (33% vs 21%). Additionally, 38% of the nonparticipants indicated the centre was "too far" or "too hard to get to". Ninety-one PBTS received the allocated treatment, 43 in intervention group, and 48 in placebo group. Group attendance was high (83.7% and 79.2% in intervention and placebo, respectively). Retention rates were 91.5% and 81% at 8 weeks and 6-month postintervention. Table 1 presents the characteristics of the sample at baseline. The 2 groups were similar except for longer time since diagnosis in the control than the intervention group (*P* < .05). Self-reported standard SSRS scores were significantly higher than caregiver proxy reports in both groups at baseline and end of intervention (*P* < .001), and follow-up (*P* < .05). Self-standard and proxy standard SSRS scores were significantly higher than normative values at baseline in both groups (*P* < .001; *P* < .05, respectively).

7.2 | Intervention outcomes

7.2.1 | Self-reports

A significant group effect in the adjusted self-reported SSRS standard scores was found, indicating higher scores in the intervention group than in the control (95% CI = 0.59-16.33; $F_{1,52} = 4.65$, *P* = .036, $\eta^2 = 0.082$). The PBTS in the intervention group who reported low-standard SSRS scores at baseline showed significant improvement after the intervention and continued to improve their scores at follow-up (95% CI = 0.47-14.27; $F_{1,52} = 4.60$, *P* = .037, $\eta^2 = 0.082$); see Figure 1. The PBTS in the intervention group with high scores at

TABLE 1 Sample characteristics at baseline

	Experimental		Control	
Child characteristics	N (%)	M (SD)	N (%)	M (SD)
Age (years)	43	11.56 (2.79)	48	10.91 (2.74)
Time Since Dx (years)*	43	5.70 (3.17)	48	4.35 (2.80)
Time Since Last Tx (years)	36	4.76 (3.12)	46	3.52 (2.66)
Male Gender	19 (44.2)		28 (58.3)	
Diagnosis				
Low-grade glioma	19 (44.2)		20 (41.7)	
Medulloblastoma	8 (18.6)		11 (22.9)	
Ependymoma	2 (4.7)		8 (16.7)	
Craniopharyngioma	4 (9.3)		3 (6.3)	
Other	10 (23.3)		6 (12.5)	
Brain Tumor Location				
Supratentorial	14 (32.6)		10 (20.8)	
Suprasellar	10 (23.2)		12 (25.1)	
Infratentorial	15 (34.9)		22 (45.8)	
Cranial Irradiation Therapy				
Whole brain	15 (34.9)		13 (27.1)	
Focal	7 (16.3)		15 (31.3)	
None	21 (48.8)		20 (41.7)	
Treatment				
Surgery Only,surgery/chemo	16 (37.2)		16 (33.4)	
Surgery/radiation, chemo/radiation, surgery/chemo/radiation	21 (48.8)		27 (56.3)	
Chemo Only,Other	6 (14.0)		5 (10.4)	
IQ (Full scale)		94.21 (16.35)		95.83 (17.10)
Executive Function (GEC)		57.12 (12.06)		54.52 (12.64)
Self-report SSRS—Total SS		111.14 (14.76)		106.50 (18.33)
Self-report PedsQL—Total		71.11 (16.83)		71.84 (14.68)
Caregiver proxy-report SSRS—Total SS		94.18 (17.42)		101.40 (15.55)
Caregiver proxy-PedsQL—Total		63.88 (18.30)		66.13 (15.31)
Caregiver characteristics				
Age (years)		43.16 (6.11)		43.40 (6.44)
Education (years)		14.70 (2.08)		14.89 (1.75)
Male gender	10 (23.3)		9 (18.8)	
Ethnicity—White	29 (67.4)		28 (58.3)	
Black	1 (2.3)		4 (8.30)	
Asian	5 (11.6)		10 (20.8)	
Other, Mixed	8 (18.6)		6 (12.5)	
Marital Status				
2-caregiver household	36 (83.7)		36 (75.0)	
Other (e.g., single)	7 (16.3)		12 (25.9)	
Family Income				
≤\$50 000	13 (30.3)		18 (37.5)	
\$50 001-\$99 999	19 (44.2)		15 (31.3)	
≥\$100 000	11 (25.6)		15 (31.3)	

* $P < .05$

SSRS = Social Skills Rating Scores

PedsQL = Pediatric Quality of Life Scores

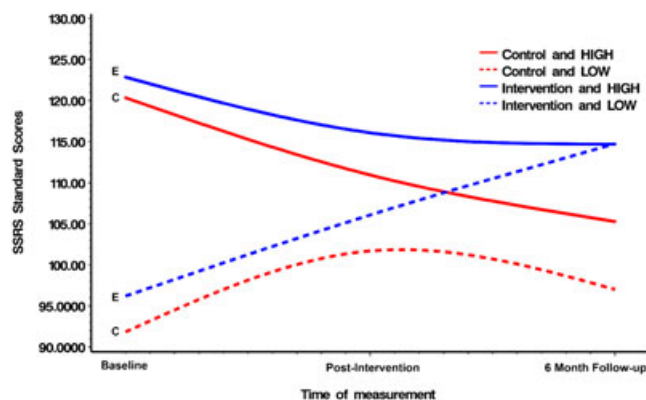


FIGURE 1 Adjusted self-reported SSRS total scores for the intervention and control groups, stratified as high and low at baseline. SSRS, Social Skills Rating System

baseline did not differ significantly from controls after the intervention and at follow-up. Their scores, however, remained stable over time while the scores of the controls tended to decrease over time.

There was also significantly higher empathy subscale scores (95% CI = 0.02-2.57; $F_{1,47} = 4.18$, $P = .046$, $\eta^2 = 0.082$) in the intervention group compared to controls. The PBTS in the intervention group who had low scores at baseline improved their scores compared to the control group at postintervention ($P < .05$) and remained consistently better at follow-up; see Figure 2.

Regarding the self-reported secondary outcome, PedsQL, we found no significant intervention effect with or without adjustment ($P > .05$); data not shown.

7.2.2 | Caregiver proxy reports

The proxy mean standard SSRS scores for the intervention ($m = 96.16$, $SD = 16.20$) and control groups ($m = 102.48$, $SD = 16.53$) did not differ significantly at the end of intervention or at follow-up ($m = 98.42$, [$SD = 17.65$]; 102.50 [15.67]) ($P > .05$). There was a significant mean effect of high vs low levels of standard SSRS scores regardless of the intervention (95% CI = 9.53-23.61; $F_{1,61} = 22.18$, $P < .0001$, $\eta^2 = 0.267$). Thus, caregivers who rated their children as having high (or low) scores at baseline continued to rate them the same way after

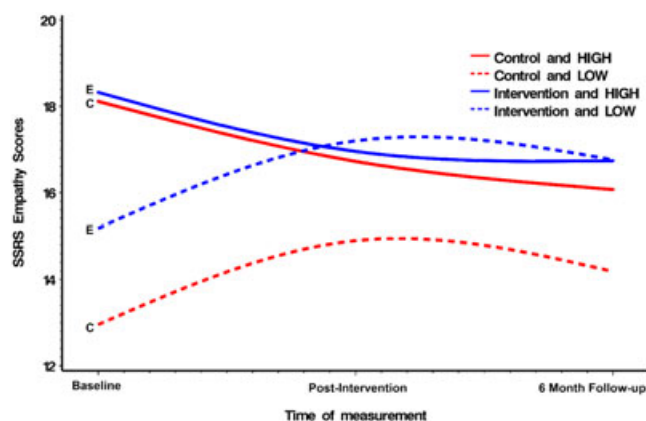


FIGURE 2 Adjusted self-reported SSRS empathy scores for the intervention and control groups, stratified as high and low at baseline. SSRS, Social Skills Rating System

the intervention and at 6 months follow-up; see Figure 3. Regarding the proxy secondary outcomes, PedsQL results, like the self-report, did not show significant differences between the groups nor did they show improvement over time (data not shown).

7.2.3 | Teacher reports

The teachers' mean total SSRS scores for the intervention ($m = 96.69$, $SD = 12.85$) and control groups ($m = 99.90$, $SD = 11.31$) did not differ significantly ($P > .05$).

7.3 | Participant satisfaction

Self-report. The PBTS in both groups reported benefits from creative activities, and talking with other kids with similar experiences. More PBTS in the intervention than in the control group wrote comments about enjoying talking/meeting with other kids (74% vs 26%; $P = .009$), engaging in problem solving (100% vs 0%; $P = .008$) and role playing (83% vs 17%; $P = .05$). On the other hand, more PBTS in the control group than in the intervention commented about enjoying games (82% vs 18%; $P = .001$) and all fun activities (100% vs 0%; $P = .002$).

Caregiver reports. More caregivers in the intervention than the control group expressed that "everything was great" (62% vs 38%; $P > .05$) and that they would like more feedback regarding the sessions (71% vs 29%; $P > .05$). Regarding challenges for participation, only caregivers in the intervention group identified child's sickness (eg, fatigue and headaches), and caregivers in both groups identified traffic, transportation, and distance as major challenges.

8 | DISCUSSION

This study examined the efficacy of the SSKIP, a group intervention program designed to improve the social skills (an important component of social competence) of PBTS. Given that validated interventions to address social skills deficits in PBTS are rare, this study provides an important contribution in the field. Using a RCT design, the adjusted standard SSRS and empathy scores for the intervention group were statistically and clinically significantly higher than the scores in the control group. This effect became clearer by examining the outcomes stratified by high vs low scores at baseline: The PBTS in the intervention group who had low scores at baseline significantly improved their scores postintervention and continue to improve at 6-month follow-up. In contrast, PBTS in the control group who had low scores at baseline slightly increased their scores postintervention but declined at follow-up. Regarding the high SSRS scores for the intervention and control groups at baseline, both declined postintervention but while the scores in the control group continued to decline at follow-up, the scores of the intervention group remained constant over time. Thus, examining the total SSRS scores stratified as high and low at baseline helped to better understand the intervention effect.

There are suggestions that psychosocial intervention should be provided mainly to those survivors who need it the most, because they are more likely to benefit from it.²⁹ The tendency of children with cancer to minimize their social and emotional adjustment challenges²⁹ makes it difficult to determine who is at the greatest social risk.

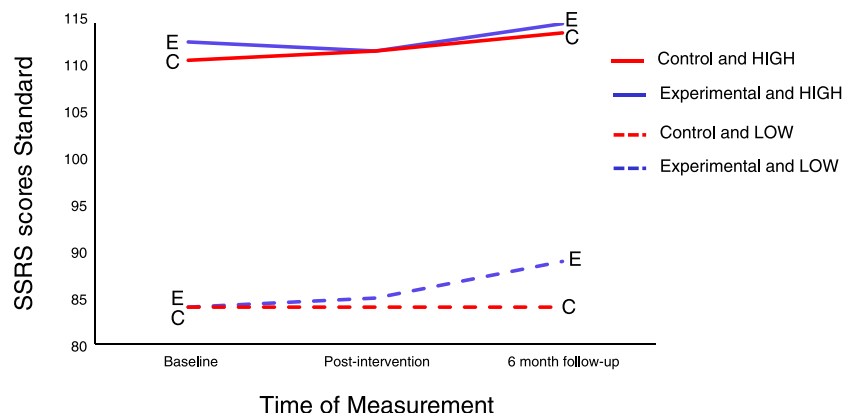


FIGURE 3 Adjusted caregiver-reported SSRS total scores for the intervention and control groups, stratified by high and low at baseline. SSRS, Social Skills Rating System

Stratifying the sample at baseline into high and low SSRS provided an alternative way to examine who benefited the most from this intervention.

Contrary to expectations from our previous research,^{29,30} proxy caregiver-SSRS or teacher-SSRS reports did not show intervention effects. Examination of the previous studies' methodology may clarify these inconsistencies. First, both previous studies had small samples. In the first one,³⁰ the size of the sample was adequate to test feasibility, its focus, but not to test intervention efficacy; the 2 preintervention and 2 postintervention designs did not rule out threats to validity; PBTS were accrued by referrals only after caregivers expressed concerns regarding their children's social difficulties. In the second study,³² a convenient comparison group (not interested in intervention) was added and the sample was too small (15 in the intervention group, 7 in the comparison group).²⁹ In both studies, parents and teachers knew that children were participating in a social skills intervention group. In contrast, in the current study, participants were randomly allocated (teachers and caregivers did not know which group was the intervention group) and the sample was larger. Thus, these methodological differences may explain the inconsistencies across studies.

The satisfaction self-reports and proxy reports provide some insights into the informants' perspective of group participation. The PBTS and caregivers in both groups generally perceived participation as beneficial, but more PBTS in the intervention than in the control group expressed enjoyment meeting and talking with other PBTS, or engaging in social problem solving and role playing. As well, more caregivers in the intervention group indicated everything was great, even though only caregivers in this group reported concerns of participants' fatigue and somatic problems such as headaches. These subtle differences could not be controlled by randomization and might have influenced rating of PBTS' social competence and QOL.

8.1 | Study limitations

Although the 41% response rate is disappointing, particularly for non-intervention research, it is considered adequate for randomized psychosocial intervention studies with rare and complex pediatric conditions, specifically brain tumors.³⁹ While psychosocial interventions and opportunities for social interaction are recognized as important for pediatric cancer patients,⁴⁰ they require time and commitment from caregivers and PBTS who are already stretched with daily

demands.³⁹ Transportation difficulties were a major barrier to accrual. Once families made the commitment to participate in the study, however, attrition was minimal (84% and 79% for intervention and control group, respectively). Alternative ways to offer SSKIP, including a combination of in person and online participation, may improve accrual.

The use of SSRS as the only measure of social competency, even when data were collected from 3 informants, is potentially limiting. Attempts were made to collect peer ratings using the revised class play, but school data collection proved to be unfeasible in the context of this study (eg, teacher labor strikes in 2 of the provinces; even when access was granted, teachers were not always receptive; the latter also impacted on teacher's completion of the SSRS). Finally, the absence of significant group differences with the caregiver and teacher data limits the strengths of the findings.

9 | CONCLUSIONS

This multisite RCT study involving 8-session social skills intervention for PBTS was successfully completed. In spite of multiple challenges and some limitations, the study was proven to be feasible. The efficacy of this intervention was supported by self-reports of improvements and maintenance of social skills ratings in the intervention group compared to the control group. The scientific rigor of this study strengthens the validity of the modest findings. The satisfaction data indicate acceptance by PBTS and caregivers of group participation, suggesting that simply providing the opportunity to meet as a group in a safe and fun environment is helpful to PBTS. However, survivors in the intervention group not only enjoyed being with and talking with other participants but reported appreciation for problem-solving social situations. Caregivers' comments regarding the child's daily health issues provide some insight for understanding caregivers' ratings. Future studies are encouraged to include peer ratings when assessing the efficacy of this intervention.

9.1 | Clinical implications

Although PBTS have been excluded from some studies in the past because of concerns regarding their understanding of the assessment instruments, they need to have the opportunity to report on their own social competence and QOL if they are able to attend an integrated classroom for at least 50% of the time. Making accommodations

for some of their disabilities (eg, difficulties with reading or writing) allows them to express their own views, which may or may not be different from those of their caregivers'. The PBTS' views of themselves are valuable in their own right. How they perceive themselves socially would determine how they behave towards others. Moreover, these results suggest that PBTS need to be given the opportunity to interact with peers as soon as they are able as recommended by the standards of care in pediatric psycho-oncology.⁴¹ Finally, the validation of SSKIP provides health care providers with a group intervention focused on social skills training to improve PBTS' social competence. This positive group experience may have long-term beneficial psychosocial effects such as improving dating and employment outcomes.

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CONFLICT OF INTEREST

The authors have declared no conflicts of interest.

TRIAL REGISTRATION NUMBER

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SUPPORTING INFORMATION

Additional Supporting Information may be found online in the supporting information tab for this article.

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