

# Identifying, Recruiting, and Enrolling Adolescent Survivors of Childhood Cancer into a Randomized Controlled Trial of Health Promotion: Preliminary Experiences in the Survivor Health and Resilience Education (SHARE) Program

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**Objective** To report on the identification, recruitment, and enrollment of adolescent survivors of childhood cancer into an ongoing randomized controlled trial (RCT) of health promotion. **Methods** A total of 244 adolescents were contacted by mail and telephone to assess their trial eligibility. Data were collected with respect to each adolescent's demographics and trial recruitment efforts (frequency and intensity of telephone call contact); exclusion and randomization status were tracked throughout. **Results** Thirty-one percent of adolescents were ultimately randomized in the trial and 69% were excluded from randomization (13% were ineligible, 33% refused to participate, 22% were unreachable or nonresponsive, that is, did not respond to trial mailings or telephone calls, and less than 1% were withdrawn prior to randomization). Among all eligible adolescents, the trial's consent rate was 49%. Adolescents excluded owing to refusal resided the farthest away from the intervention site and experienced the least amount of telephone call contact time. The primary reasons for trial refusal were lack of interest in health promotion (28%) and lack of time to participate (23%). **Conclusions** Health promotion RCTs among adolescent survivors of childhood cancer may help prevent and control the onset and severity cancer-treatment-related late effects. However, trial success may be contingent upon tracing nonresponsive adolescents and reducing and eliminating barriers to participation.

**Key words** cancer survivorship; health behavior; health promotion; randomized controlled trial.

Thanks to decades of progress in childhood cancer detection and treatment, the number of survivors of childhood cancer in the United States is growing. Among children and adolescents, the 5-year survival rate across all cancer sites is 79% and the 10-year survival rate is 75% (American Cancer Society, 2004; Centers for Disease Control and Prevention, 2004). This is a remarkable increase over the 56% of children and adolescents who were expected to be alive 5 or more years after a cancer diagnosis during

the early 1970s (Centers for Disease Control and Prevention, 2004). Much of this progress comes as a result of conducting randomized controlled trials (RCTs) at established childhood cancer treatment and research centers and the formation of childhood cancer cooperative groups to facilitate RCTs aimed at improving survival (Liu, Krailo, Reaman, & Bernstein, 2003; Reaman, 2004).

With respect to outcomes of interest to pediatric psychologists working with survivors of childhood cancer,

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the full benefits of RCT methodologies have yet to be realized. Among the negative outcomes related to cancer and its treatment during childhood, both physical (i.e., second cancers, poor bone health, cardiovascular problems, infertility) and psychological outcomes (i.e., adjustment problems, disruptions in social functioning, cognitive impairment) may be targets for RCTs involving behavioral interventions (Eiser, 2004). To date, pediatric psychology RCTs in childhood cancer populations have primarily intervened upon psychological outcomes (Barakat et al., 2003; Kazak et al., 2004; Sahler et al., 2002); fewer attempts have been made to intervene upon behaviors related to adolescent survivors' health and the prevention and control of negative physical outcomes (Hudson et al., 1999; Tercyak et al., 2004; Tyc et al., 2003). Examples of these behaviors include engaging in cancer screening, adhering to an annual follow-up visit schedule after cancer treatment has ended, consuming a balanced and nutritious diet, maintaining an appropriate weight, engaging in moderate physical activity, and refraining from tobacco use, alcohol consumption, and excessive sun exposure (Children's Oncology Group, 2004). These and other health behaviors are receiving intense research scrutiny in adults who have survived childhood cancer (Emmons et al., 2003; Hudson et al., 2003; Kadan-Lottick et al., 2002; Yeazel et al., 2004), with the intent of delivering health promotion interventions to improve long-term outcomes.

The epidemiology of health-promoting and health-compromising behaviors among children and adolescents who have survived cancer is poorly understood. This is due, in part, to a lack of focus on behavioral epidemiology in most studies of cancer survivorship, and especially those involving youth. The data that are available suggest that pediatric cancer survivors often use tobacco and alcohol just as frequently as do their peers who have never been treated for cancer (Haupt et al., 1992; Hollen & Hobbie, 1996). Data from Emmons et al. (2003) also suggests that over one-half of young adult survivors of childhood cancer who smoke are addicted to nicotine. Further, young adult cancer survivors report rates of sedentary lifestyles similar to those in the general population (Mulhern et al., 1995). Taken together, these data underscore the importance of health promotion interventions in this special population.

Health promotion interventions among children and adolescents require identifying many survivors of childhood cancer, recruiting them, and (ultimately) enrolling them into RCTs and following them for extended periods of time. Accomplishing these objectives in a thorough and timely manner is vitally important to

the health and well-being of childhood cancer survivors, but complicated by several unique and considerable limitations. First, given the rarity of cancer in childhood, multiple recruitment sites are often necessary to identify large numbers of potential trial subjects. Doing so usually requires substantial resources. Though the existence of childhood cancer cooperative groups partly overcomes this limitation, their trial emphases have been survival and cognitive impairment and not health promotion (Reaman, 2004). Second, though the literature suggests that medical record review is a viable mechanism by which to identify eligible individuals who have survived childhood cancer (Mertens et al., 2004), patient privacy rules limit the extent to which these data may be accessed and utilized. Third, even when survivors are identified, intense recruitment and enrollment efforts are required on the part of the trial (Mertens et al., 2004). These efforts may include direct mailing to last known addresses, direct telephone call contact, use of public directory information resources, and intensive tracing services. Limited time and resources may permit that only some of these efforts take place. Finally, unlike trials conducted with adults, RCTs involving children bear greater burdens with respect to informed consent. This is determined by the level of risk posed to subjects. At minimal, it usually involves presentation and discussion of a written informed consent form and obtaining written assent from both the child and at least one parent. The readability, understandability, and clarity of consent forms used in childhood cancer research are not always appropriate (Fernandez et al., 2003; Grossman, Piantadosi, & Covahey, 1994). This increases the time and effort placed on both the principal investigator to explain the trial in plain language, and on subjects to ask questions or clarify points to avoid confusion. In the end, these limitations may also impact trial enrollment.

At present, very little information exists on methods by which to identify, recruit, and enroll survivors of childhood cancer into health promotion RCTs and reasons for trial exclusion because of refusal. Hudson et al. (1999) offer one of the few descriptions of such methodology. They described how adolescent attendees at an annual late effects clinic at a cancer treatment and research center were approached in person; 86% consented to the trial were immediately randomized and then completed a baseline assessment prior to an intervention delivered as part of the usual care received on that day. Among adolescents excluded from the trial due to refusal, 57% lacked interest in health promotion and 22% objected to trial participation requirements. More

information of this type could be beneficial in planning and implementing future RCTs.

In light of these issues, this report focuses on experiences identifying, recruiting, and enrolling adolescent survivors of childhood cancer into an ongoing RCT of health promotion—the Survivor Health and Resilience Education (SHARE) Program. SHARE is an RCT designed to test the efficacy of health education and health behavior counseling to intervene upon lifestyle and health behavior outcomes in adolescents who have survived cancer (Donze & Tercyak, ). Participants in SHARE complete a detailed baseline assessment via telephone (two telephone calls lasting approximately 30–40 min each) and are asked to maintain a behavioral record for several days. Following completion of the baseline, participants are randomly allocated to either the intervention or a waitlist control condition. Participation in the intervention involves attending a 3- to 4-hour group session and completing up to three telephone booster calls. The group session is theory-based, manualized, and its content focuses on medical late effects of cancer survivorship and healthy behaviors associated with cancer-risk reduction, prevention, and health promotion (e.g., diet and nutrition, exercise and physical activity, tobacco control, sun protection, adherence to long-term follow-up). Outcome assessments are completed at 1 and 3 months after the end of treatment.

At the outset of this research, it was expected that a large number of adolescents could be identified as potentially eligible for this RCT and that direct contact with adolescents' parents would be key to recruitment (Mertens et al., 2004). With respect to trial enrollment, it was anticipated that at least 70% of adolescents screened as eligible would ultimately be randomized. This estimate was lower than an estimate derived from a clinic-based trial, given the difference in methods used (86%; Hudson et al., 1999). Among those excluded from randomization due to refusal, lack of interest in health promotion was expected to be cited most frequently (Hudson et al., 1999).

## **Method**

### **Participants**

A total of 244 adolescents were assessed for eligibility to participate in this RCT. Trial eligibility included both male and female adolescents between the ages of 11 and 21 years who were previously treated for any form of oncologic malignancy, were one or more years off of treatment for cancer, were one or more years cancer-free, and able to comprehend and speak English. Those

suffering from renal insufficiency or end stage renal disease or currently taking a thiazide diuretic, and those suffering from a pervasive developmental or other major psychiatric disorder precluding valid informed consent, were ineligible.

### **Measures**

The project director compiled and maintained a master file containing the following information about each adolescent.

### **Demographics**

Adolescents' date of birth, age, gender, race, home address, and telephone number were maintained. Using zip code, a median area household income variable was created as a gross index of socioeconomic status. Using home address, a distance variable was created reflecting the number of miles between the adolescents' home and the trial's single intervention site.

### **Recruitment and Enrollment Process**

Detailed telephone call contact logs were maintained for each adolescent indicating the total number of calls made to the adolescent and received by the project director from each adolescent (call frequency), as well as the length of time of each telephone call (call intensity).

### **Trial Status**

Each adolescent's trial status was tracked according to Consolidated Standards of Reporting Trials (CONSORT) guidelines and criteria (Stinson, McGrath, & Yamada, 2003). These were (a) assessed for eligibility, (b) excluded from randomization because of not meeting the inclusion criteria, trial refusal, and nonresponse, and (c) randomized. Among adolescents who were excluded from randomization because of trial refusal, an open-ended follow-up question immediately asked their parents to provide a reason for refusal. Reasons were subsequently coded into seven categories by two independent raters. Among the primary reasons offered for refusal, the coding scheme achieved 88% accuracy, indicating good interrater reliability. Coding discrepancies were later resolved by consensus.

### **Procedure**

All procedures were reviewed and approved by the institutional review boards at the participating sites. Two pediatric cancer treatment and research centers located within the same mid-Atlantic city served as recruitment sites for this trial. These sites are located less than 5 mi away from each other, provide inpatient and outpatient

services to large and diverse populations, and have active pediatric hematology–oncology clinical programs, including follow-up/aftercare and late effects programs for childhood cancer survivors. From these sites, tumor registries were used to identify adolescents who were or had been patients at each site and who might have been eligible for the trial. Over the course of approximately 18 months, parents of these adolescents were mailed a letter to their last known address from their adolescent's treating oncologist introducing the trial and referring to an enclosed trial brochure and informed consent/assent form for additional information. Parents were asked to respond to the mailing by contacting the trial's project director via telephone or an addressed stamped reply card to indicate if they were or were not interested in learning more about the trial on their adolescent's behalf. Parents were informed that if they did not respond to the letter within a specified period of time that their contact information would be forwarded to the trial so that appropriate follow-up could take place.

If parents responded by contacting the trial and expressed an interest in their adolescent participating, eligibility screening was conducted and, if eligible, informed consent/assent were obtained. If parents were not interested in having their adolescent participate, reasons for refusal were obtained.

The project director subsequently initiated telephone calls to all nonresponding adolescents' parents to confirm their receipt of the mailing and to learn if they were or were not interested in the trial. Procedures for screening, consent, or refusal were then conducted as described above.

To promote timely and accurate distribution of outgoing mailings, first class postage and return service were used. Return service from the US Postal Service allows customers to request an address update and forwarding address on any undeliverable item. All undeliverable items returned with return service information were promptly mailed again. For all undeliverable items, local and national Internet-based public directory information resources were used in an attempt to obtain an updated address and telephone number. Useful resources included <http://www.knowx.com> and <http://whitepages.com> for online address, reverse address, telephone number, and reverse telephone number lookups.

In addition to recruitment by direct mailing, two indirect methods were used as well. These were placement of trial brochures in pediatric hematology–oncology clinic waiting room, and announcement of the trial to local community organizations that serve childhood cancer

survivors. However, these indirect recruitment methods yielded few adolescents.

### Statistical Analysis

The first step in the data analysis plan was to tabulate the total number of adolescents falling into each trial group based upon CONSORT criteria. The next step was to describe, using univariate statistics, total sample and group characteristics. The final steps were to examine between- (using analysis of variance, ANOVA and chi-square statistics) and within-group differences. For the within-group analysis, data were limited to reasons for trial refusal offered by parents of adolescents within that group only.

### Results

As shown in Figure 1, a total of 244 adolescents were contacted to determine their eligibility for study. Of those 244, 31% (75/244) were ultimately randomized to one of two treatment conditions and 69% (169/244) were excluded from randomization—13% (31/244) did not meet study eligibility criteria, 33% (81/244) refused to participate, 22% (53/244) were unreachable or nonresponsive, and less than 1% (4/244) were consented but later withdrawn prior to randomization due to missed eligibility. Among all adolescents who were and may have been eligible (i.e., those who refused to participate, were unreachable or nonresponsive, were withdrawn prior to randomization, and were randomized;  $n = 213$ ), the trial's consent rate was 37% (79/213). Among all adolescents assessed as eligible to participate (i.e., those who refused to participate, were withdrawn prior to randomization, and were randomized;  $n = 160$ ), the trial's consent rate was 49% (79/160).

### Univariate Statistics

Descriptive statistics for adolescents by their overall randomized and excluded status are presented in Table I.

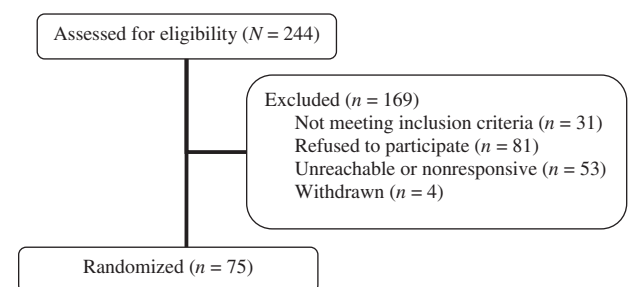


Figure 1. Participant flow diagram.

**Table I.** Descriptive Statistics by Randomization and Exclusion Status

	Total (n = 209)	Randomized (n = 75)	Excluded (refusal, n = 81)	Excluded (nonresponse, n = 53)	Test statistic
Age [M (SD)] (years)	14.7 (2.7)	14.2 (2.4)	14.8 (2.6)	15.3 (3.2)	$F(2, 206) = 2.68, p = .07$
Gender					
Male [n (%)]	104 (50)	36 (48)	35 (43)	33 (62)	$\chi^2(2) = 4.80, p = .091$
Female [n (%)]	105 (50)	39 (52)	46 (57)	20 (38)	
Race					
White [n (%)]	147 (70)	56 (75) <sup>a</sup>	61 (75) <sup>b</sup>	30 (57) <sup>a,b</sup>	$\chi^2(2) = 6.42, p = .04$
Black [n (%)]	32 (15)	9 (12)	10 (12)	13 (25)	
Hispanic [n (%)]	13 (6)	4 (5)	2 (3)	7 (13)	
Asian [n (%)]	10 (5)	3 (4)	5 (6)	2 (4)	
Other [n (%)]	7 (3)	3 (4)	3 (4)	1 (2)	
Income [M (SD)] (\$)	70,984 (23,680)	73,131 (23,851)	71,816 (22,551)	66,673 (24,988)	$F(2, 206) = 1.24, p = .29$
Site					
1	135, 67	49, 69	59, 71	30, 57	$\chi^2(2) = 3.21, p = .20$
2	68, 34	22, 31	23, 29	23, 43	
Distance [M (SD)] (mi)	30.0 (25.0)	25.5 (23.9) <sup>c</sup>	35.8 (27.6) <sup>c,d</sup>	23.5 (20.0) <sup>d</sup>	$F(2, 206) = 5.21, p = .006$
Call frequency [M (SD)]	4.3 (2.6)	3.9 (2.2) <sup>e</sup>	3.2 (2.5) <sup>f</sup>	6.6 (1.60) <sup>e,f</sup>	$F(2, 205) = 29.3, p = .0001$
Call intensity [M (SD)] (min)	23.4 (16.8)	32.5 (15.9) <sup>g,h</sup>	14.2 (14.2) <sup>g,i</sup>	24.4 (14.3) <sup>h,i</sup>	$F(2, 205) = 40.5, p = .0001$

Study N = 244. Adolescents assessed as ineligible (n = 31) or withdrawn (n = 4) are not shown. Percents do not total 100 due to rounding. Values with identical superscripts differ significantly ( $p < .05$ ).

Among randomized adolescents and adolescents excluded because of trial refusal or nonresponse, the average age was 14.7 years, one-half of adolescents were female, 70% were White, and on average they resided in areas with a median household income around \$71,000; two-thirds of adolescents were drawn from Site 1 and tended to reside around 30 mi from the intervention site. Across the three groups, the project director made or received a total of 897 telephone calls and spent a total of 4,865 min (81.1 hr) in telephone call contact. On average, each adolescent received four telephone calls ( $Mdn = 4$ , range = 0–11) regarding participation in the trial and the project director spent about 23 min in telephone call contact ( $Mdn = 20$ , range = 0–90) with each adolescent.

Among the 75 randomized adolescents only, a review of their medical records indicated the following types of cancer diagnoses: 52% (n = 39) leukemias, 16% (n = 12) nervous system tumors, 12% (n = 9) kidney or liver tumors, 9% (n = 7) lymphomas, 7% (n = 5) sarcomas, and 4% (n = 3) other. Regarding treatments received, the following were noted: 39% (n = 29) chemotherapy only, 21% (n = 16) chemotherapy and surgery, 19% (n = 14) chemotherapy and radiation, 13% (n = 10) chemotherapy, radiation, and surgery, and 8% surgery only (n = 3), radiation only (n = 2), or radiation and surgery (n = 1). On average, these adolescents were 5.3 years old ( $SD = 3.9$  years) at diagnosis and 7.2 years old

( $SD = 4.1$ ) at end of treatment. The  $M$  ( $SD$ ) time since treatment began was 9.0 (3.4) years and 7.1 (3.5) years had elapsed since treatment ended.

### Between-Group Differences

Analysis of variance modeling did not suggest differences between groups with respect to age or income. However, it did suggest between-group differences regarding distance and telephone call contact. Specifically, Tukey's studentized range testing (which controls for the type 1, experimentwise, error rate) indicated that adolescents excluded from the trial due to refusal resided the farthest away from the intervention site compared to adolescents in the other two groups. Not surprisingly, adolescents excluded because of nonresponse had the most frequent number of telephone call contacts. With respect to the amount of time spent in telephone call contacts, adolescents excluded because of refusal had the lowest intensity, followed by those excluded because of nonresponse, followed by those who were randomized.

Chi-square testing did not suggest these three groups differed from one another with respect to their gender distribution or differences by trial site. Thus, there were equal numbers of males and females in each group and equal representation by each site in the trial. However, the racial distribution was not even. Specifically, there were more subjects from non-White backgrounds

in the group excluded due to nonresponse than in either of the other two groups. Follow-up chi-square tests did not suggest Site x Race effects on randomization or exclusion.

### Within-Group Differences

Within the group of adolescents excluded from the trial owing to refusal, reasons were offered for refusal by 98% (79/81) of adolescents via their parents. These data are presented in Table II. The most frequently offered reasons, cited by approximately 64% of parents, were that the child was not interested in a health promotion trial for childhood cancer survivors and that adolescents were too busy to participate. The remaining 5 reasons reflected lack of interest in the trial on the part of parents, vague and nonspecific reasons (categorized as 'Other'), distance to the intervention site, concerns that stress and trauma once associated with the child's cancer experience would be reactivated by trial participation, and postponement of trial enrollment.

### Discussion

This report focused on experiences identifying, recruiting, and enrolling adolescent survivors of childhood cancer into an ongoing RCT of health promotion. The results suggest that the majority of adolescents assessed for eligibility were excluded from randomization due to either refusal to participate or nonresponse.

Reasons for refusal were primarily lack of interest in health promotion and lack of time; those who refused tended to reside the farthest from the intervention site. Findings regarding reasons for refusal are consistent with those of a prior RCT with a similar focus (Hudson et al., 1999). Differences between observed rates of randomization may have been due to differences in methodology. Hudson et al. (1999) conducted a clinic-based trial, whereas the present trial was nonselect with respect to late effects clinic attendance. The benefit of conducting a nonclinic-based trial is that it increases the

likelihood that those who do not attend clinic will participate; the challenge is then identifying, recruiting, and enrolling these adolescents outside the clinic setting.

The results reported herein can be compared to those of other RCTs focused on health promotion with adolescents in pediatric settings. One way to compare across trials is to examine the proportion of adolescents randomized out of the total number of adolescents screened for eligibility. At 31%, randomization into the SHARE Program was lower than randomization reported by DiClemente et al. (2004) for a pediatric HIV prevention intervention, by Patrick et al. (2001) for a pediatric nutrition and physical activity intervention and by Stevens et al. (2002) for a pediatric risk behavior prevention intervention. Hudson et al. (1999) reported randomizing 86% of adolescent cancer survivors for a health promotion intervention. However, randomization in the process of Hudson et al. (1999) occurred prior to an annually scheduled follow-up visit at a late effects clinic.

The data suggest several important points. First, when planning to conduct a RCT of health promotion with this population in a nonclinic-based setting, sample size calculations should be based upon highly conservative randomization estimates so as not to result in an underpowered trial. Second, adolescents' lack of interest in health promotion could be because of low awareness of, and knowledge deficits about, cancer treatment-related late effects and the role of behavior in promoting health. To the extent that the trial's recruitment efforts, including trial brochure, highlight late effects this may facilitate trial participation. Third, today's busy adolescents who anticipate difficulties making time to participate in the trial and are prone to refuse based upon this anticipation may benefit from flexible trial enrollment and the option to enroll at a later time. Finally, as distance to the intervention site may be a subtle barrier to trial participation, multiple, geographically dispersed, and mobile intervention sites located closer to (and ideally less than 35 mi from) where adolescents reside might also facilitate trial participation; telephone, telemedicine, electronic/remote access, or Internet-based interventions could also be explored, though these would likely depend on available and accessible technology in survivors' homes. Interestingly, data collected from adolescents' parents do not confirm that distance to the intervention site is a highly salient barrier. Nevertheless, it most likely had an overall impact and may have been an implicit aspect of being "too busy." Stress and trauma associated with cancer was not cited very often as an explicit reason for refusal either. The small

**Table II.** Primary Reasons for Trial Refusal Offered by Parents ( $n = 79$ )

	n (%)
Adolescent not interested	28 (35)
Adolescent too busy	23 (29)
Parent not interested	8 (10)
Other	8 (10)
Distance to trial	4 (5)
Stress/trauma associated with cancer	4 (5)
Would consider trial at a later date	4 (5)

Percents do not total 100 due to rounding.

but significant portion who are concerned about reactivation of, or continue to experience, posttraumatic stress could be counseled and referred.

Other issues to consider here include the use of focus groups (prior to initiating the trial) and the use of incentives/tokens of appreciation (once the trial is in progress). Regarding focus groups, they can be informative by identifying possible benefits and barriers to trial participation among prospective volunteers. Once identified, the benefits should be emphasized and barriers reduced and eliminated. Focus groups may also be informative by helping researchers learn more concise ways to explain the purpose of the trial, and to more effectively communicate the importance and relevance of the trial to potential volunteers, their families, and their communities. To the extent that potential volunteers understand that the researchers are studying relevant issues will bode well for trial enrollment (Stinson, McGrath, & Yamada, 2001). Regarding incentives, they can be used to acknowledge participants' time and effort to complete trial requirements (e.g., baseline and outcome measurements). This is routinely done in nonintervention studies of biobehavioral aspects of adolescent health, such as completing surveys or providing biospecimens (Audrain, Tercyak, Goldman, & Bush, 2002). However, caution is warranted in the potential use and misuse of incentives (especially monetary incentives) that are explicitly or implicitly linked to adolescents' willingness to participate in the trial (Martinson et al., 2000).

Regardless of adolescents randomization and exclusion status, it is clear that these RCTs require a significant investment in personnel time and trial resources to recruit and enroll subjects. In this trial, the equivalent of approximately 2 full workweeks were spent in telephone contact calls alone. The majority of these contacts occurred during nontraditional working hours (i.e., evenings, weekends). The importance of persistence and follow-up in attempting to directly contact families by mail and telephone cannot be understated.

Finally, it is important to comment on adolescents who were excluded due to nonresponse. In some cases, their addresses and telephone numbers could not be verified. In other cases with verifiable information, telephone privacy managers who blocked "unwanted" calls were an impediment. Nevertheless, principal investigators should plan on 1 in 5 adolescents requiring an unusually high call frequency and intensity with the distinct possibility of not receiving a response. This group may consist of a higher portion of non-White adolescents. As recruitment and enrollment of underserved

minorities into RCTs is a priority, the use of extensive tracing may be necessary. Story et al. (2003) recruited over 200 African American girls into an obesity prevention RCT. To do so, they employed mailings, flyers, radio announcements, and group presentations. The investigators attributed their success, in part, to utilizing multiple recruitment strategies and developing trusting relationships in the community. These findings are similar to those among RCTs conducted with adults, where minority accrual may be facilitated by community outreach and culturally-appropriate recruitment materials (Fouad et al., 2004).

There are clinical implications of this research as well. Specifically, that multiple patient communication mechanisms should be put into place that facilitate the sharing of new information or discoveries impacting survivorship. Toward this end, follow-up/aftercare and late effects programs for childhood cancer survivors should seek to maintain complete contact information for each of their patients. This would include patients' full names and any aliases, as well as the full names of patients' parents, their permanent addresses, home, work, and mobile telephone numbers, and e-mail addresses (if available). These programs could periodically update their patients' contact information during each appointment, or on a periodic basis (e.g., annually) via mail or telephone. In observance of patient privacy rules, programs should seek-out the appropriate authorization to share or disclose protected health information as warranted. Maintaining regular contact with patients through mailed or e-mailed newsletters, websites, or by hosting mailing list servers, newsgroups, or forums could also be valuable patient communication mechanisms. Patients and parents could subscribe to a discussion list, and other subscribers' discussions would be distributed to all list members. Many Internet sites host these lists for little or no cost (e.g., Yahoo!); information about local and national electronic discussion groups are also available through organizations that serve childhood cancer survivors (e.g., Candlelighters Childhood Cancer Foundation, National Childhood Cancer Foundation).

The limitations of reporting on these outcomes include the lack of more in-depth data regarding demographic and medical characteristics of adolescents, particularly those excluded from randomization. For example, individual-level socioeconomic status indicators could not be collected in a systematic manner from all adolescents. However, an area-based socioeconomic status indicator was available. This approach has successfully been used in prior child health research

(Krieger et al., 2003). Further, date and type of cancer diagnosis and treatment and time since treatment ended could not be uniformly ascertained for nonconsenting adolescents. It is possible that one or more of these variables could also impact trial enrollment. The limitations encountered by this RCT are applicable to most (if not all) RCTs and other investigations seeking to contact former patients who have survived childhood cancer (Mertens et al., 2004). Although, as demonstrated by this report, reasonable steps can be taken to collect and utilize available data. Finally, the presence of problem behavior was not a prerequisite to trial enrollment and the trial was open to all comers. Had the presence of problem behavior been included among the trial's eligibility criteria, more targeted and persuasive communications could have been used to enhance recruitment and enrollment. However, this advantage would likely have been offset by the greater number of excluded adolescents no longer eligible to participate. The decision to accept as many adolescents as possible was in keeping with the purpose and design of SHARE.

In sum, health promotion RCTs among adolescent survivors of childhood cancer may help prevent and control the onset and severity of cancer treatment-related late effects. However, trial success may be contingent upon tracing nonresponsive adolescents and reducing and eliminating barriers to participation. More frequent and in-depth reporting and exchange of information regarding ways to effectively identify, recruit, and enroll trial participants would be beneficial in this and other pediatric populations.

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