Recruitment and Retention of Older Adolescent and Young Adult Female Survivors of Childhood Cancer in Longitudinal Research

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Conducting studies to test the efficacy of targeted interventions among childhood cancer survivors is an identified need to advance their care and to improve their health-related quality of life (HRQOL) (Finnegan et al., 2009; Kazak et al., 2010; Speechley, Barrera, Shaw, Morrison, & Maunsell, 2006; Zeltzer et al., 2008). Researchers across disciplines have identified subgroups of childhood cancer survivors at risk for poorer HRQOL (Hudson et al., 2003; Kazak et al., 2010; Zeltzer et al., 2009). Female survivors of childhood cancer are one subgroup of survivors at risk for poorer physical and psychosocial functioning after treatment (Armstrong, Sklar, Hudson, & Robison, 2007; Shankar et al., 2005; Wu et al., 2007; Zelter et al., 2009). Although conducting investigations among childhood cancer survivors is essential for promoting their physical and emotional well-being, recruitment can be a challenge.

Survivors of pediatric cancer are a challenging clinical population to recruit and retain as research participants (Hinds, Burghen, Haase, & Phillips, 2006; Patenaude & Kupst, 2005; Smith & Hare, 2004; Tercyak, Donze, Prahlad, Mosher, & Shad, 2006). The recruitment and retention of older adolescent and young adult (AYA) childhood cancer survivors for research studies may be even more challenging because of their developmental stage, lifestyle characteristics, and less frequent contact with pediatric oncology centers (Tercyak et al., 2006). The purpose of the article is to describe the planning and design of a longitudinal study to maximize the recruitment and retention of a sample of AYA female survivors of childhood cancer. The article also reports the multiple strategies and efforts of, as well as the challenges encountered by, the study team in the recruitment and retention of the survivors at the 18-month mark of the recruitment phase in a three-year study.

Van Mechelen and Mellenbergh (1997) posited that longitudinal studies provide the only method for directly studying the natural course of human growth and development. In addition, longitudinal studies are critical to measuring the short-term and long-term effects of intervention research. Regardless of the objective, longitudinal research involves the successive measurement of the same participants’ attributes at different points in time. Decisions in the design and planning of a longitudinal study involve the number of study participants, the use...
of a control group, the number of measurement times, the time between measurement points, type and number of measurement instruments, and methods of data collection and storage (Van Mechelen & Mellenbergh, 1997). Those design decisions, as well as careful attention in the development of the intervention, were considered by the principal investigator (PI) and study team. Design decisions were based on published literature describing recruitment issues with survivors of and patients with pediatric cancer, as well as developmental and lifestyle characteristics of young adult females thought to influence their interest and continued participation in a research study.

**Study Protocol**

**Intervention**

The randomized, attention control group study employed a hope intervention program aimed at improving AYA female survivors’ HRQOL. The study intervention was the Hope Intervention Program (HIP), developed and tested by Herth (2001). Several modifications to HIP and its delivery were made in an effort to recruit and retain AYA study participants. The aim of the HIP was to enhance hope using specific strategies in a small group interactional format delivered over eight sequential sessions (Herth, 2001). Although the original structure of HIP was maintained, modifications to the goals, content, and activities for each session were made. The modifications were based on research findings emphasizing that, for interventions to be meaningful and effective for AYA cancer survivors, they must be developmentally relevant in their content and mode of delivery (Murray, 2000).

Herth (2001) delivered HIP to adult patients with cancer on site at a specific healthcare institution, which required study participants to travel to the institution eight times. Expecting that level of travel commitment from AYA survivors and recruiting adequate numbers of AYA survivors at one site were not feasible in the current study. Hinds et al. (2006) pointed out that designated groups of pediatric patients with cancer are not easily accessible in sufficient numbers to conduct on-site or even limited-site studies. Access and recruitment issues pose even greater challenges for researchers in conducting on-site studies among childhood cancer survivors. Although still followed closely by the pediatric oncology team for late effects from treatment, childhood cancer survivors typically have less frequent contact with healthcare professionals because their treatment has been completed (Smith & Hare, 2004). Smith and Hare (2004) stated that the survivors usually do not return to the treatment facility where they initially received care, and often are lost to follow-up care. In addition, their focus has shifted to their busy lifestyles and integration back into school or work, which are age and developmentally appropriate.

Computer-based interventions can address the prohibitive factors of participating in research because of geographically distant locations, travel time, and costs (Hill, Weinert, & Cudney, 2006). For researchers, Web-based research is useful in obtaining information from individuals who are not easily accessible in sufficient numbers to conduct on-site or limited-site studies (Hinds et al., 2006). Hinds et al. (2006) pointed out that AYAs with cancer, similar to most individuals in this age group, are active users of Web-based technology and the use of chat rooms and other discussion forums to describe their experiences with cancer. Researchers involved with childhood cancer survivors recognized the need to use technology for meeting the long-term needs of childhood cancer survivors (Dalton, 2005; Tercyak et al., 2006). Internet-based clinical trials are now considered feasible (McAlindon, Formica, Kabbara, LaValley, & Lehmer, 2003).

Based on published literature (Lakeman, 1997; McAlindon et al., 2003; Thomas, Stamler, Lafreniere, & Dumala, 2000), HIP was delivered online using Web cameras and an interactive software program. Web cameras and the Wimba® software program allowed group participants to see and hear each other in real time, which maintained fidelity to the original HIP intervention protocol during each synchronous session. That technology fostered interaction among the group members and allowed an ongoing exchange of ideas and thoughts and the telling of stories. Interaction among study participants included live chats and text communication. The technology was not limited by geographic location. Web cameras and headsets with set-up instructions were mailed by the PI to participants’ homes at no cost to them.

Those strategies were pilot tested with a group of six female survivors of childhood cancer to ascertain the feasibility of delivering the intervention via an online method. Logsdon and Gohmann (2008) suggested that pilot studies can be invaluable in testing recruitment procedures, establishing costs of recruitment, and obtaining baseline data on study measures and demographic data. Evaluation data generated from the pilot study suggested that using a Web-based approach was effective in the delivery of the intervention as evidenced by participants’ evaluation of the program (Cantrell & Conte, 2008). Study participants’ comments suggested that the online sessions promoted intimate, meaningful, human-to-human interactions to foster hope and build a trusting relationship among group members (Cantrell & Conte, 2008).

**Control Group**

An attention control group design was chosen to decrease the threat of attrition, address the ethical concerns
related to participants committing to the study without receiving any benefit from their participation, and decrease the risk of confounding the outcome of the study as a result of participants simply receiving attention by being in the study. The control group received eight 75-minute online narrated presentations that discussed healthy lifestyle issues specific to young adult females. Topics addressed were sexuality, sexually transmitted infections, pregnancy, nutrition, alcohol and drug use, violence and date rape, women’s health issues, and a summary presentation that discussed general health and wellness.

Sample Size and Recruitment Strategies

A power analysis estimated a minimum total sample size of 160 early female survivors of childhood cancer. The sample size was calculated based on a power of 0.8, a medium effect size (d = 0.4), an alpha of 0.05, and a minimum correlation among repeated measures of 0.3 for repeated measures multivariate analysis of variance. An attrition rate as high as 25% was expected. The final sampling plan included an oversampling of 25% to ensure adequate power at each of the data collection points, resulting in a target sample of 200 participants. The 200 study participants were to be randomized to either the intervention (n = 104) or the attention control group (n = 96).

The inclusion criteria for eligible study participants included women aged 18–25 years, able to read and write English, and who had completed treatment for any type of childhood cancer, including bone marrow transplantation. The exclusion criteria were women childhood cancer survivors who had a documented history of psychopathology, cognitive impairment, or developmental delays not related to, or not a result of, their cancer experience, and women who did not have access to the Internet. Study participants were screened by nurse interventionists for their level of comprehension of the study and its procedures prior to the start of the intervention. Study participants were compensated $25 for their inclusion in the study.

Three designated pediatric oncology centers, each with an active survivorship program, were the data collection sites. Two sites were in the mid-Atlantic region of the country. One site in that region provides care for about 150 childhood cancer survivors in a follow-up survivorship clinic and enrolls about 30 new patients yearly; the second site in that region cares for about 500 survivors of childhood cancer and enrolls about 200 new patients into the pediatric oncology program yearly. The third recruitment site was in the Midwest and enrolls 100–150 new patients yearly and provides follow-up care for about 100 survivors.

In a review of three studies involving female adolescents, Logsdon and Gohmann (2008) concluded that choice of recruitment procedures and sites had major implications for the study budget, as well as adherence to the timeline established for the study. Knowing that AYAs are avid consumers of online information, an online homepage for the study was constructed. The current study’s homepage had two PowerPoint®-narrated presentations. One presentation was a short introductory presentation about the study and another provided a more detailed description of the study, eligibility requirements, time commitment, and consent process. The study team thought that the introductory presentation would allow interested participants an opportunity to preview the study and, for those who were seriously considering enrollment, the detailed presentation provided full disclosure of the study. The homepage provided the PI’s direct-contact e-mail address for interested survivors. Flyers and business cards, which also included the study’s homepage URL and the PI’s e-mail address, were developed, sent to all recruitment sites, and posted in each survivorship clinic. Although this measure was employed in an effort to recruit study participants, Teracyak et al. (2006) reported that the indirect recruitment method yielded few participants in the enrollment of adolescent survivors of childhood cancer for a randomized, controlled trial (RCT) of health promotion.

Databases at each recruitment site were searched for eligible survivors by an advanced nurse practitioner employed at each institution, and a letter that included information about the study’s homepage as the main direct-recruitment strategy was sent to those survivors by the designated recruiter at each institution. Motzer, Moseley, and Lewis (1997) identified 24 recruitment and retention strategies to enroll families in longitudinal clinical trials. Several of the strategies were adopted in the current study. Specifically, a grant-related logo was created, the front-loading of institution review board applications at Villanova University and at each recruitment site was done to avoid delays in the start of study participant recruitment, and a designated person at each recruitment site was established to identify eligible AYA participants for the study. Given those recruitment plans and the data from the evaluation of the pilot study (Cantrell & Conte, 2008), the study’s PI and the research team anticipated a robust response from eligible female survivors. In addition, Santacroce, Maccarelli, and Grey (2004) posited that in previous studies involving childhood cancer survivors, females were more likely to have more positive attitudes toward health care than males, and, therefore, more likely to participate in survivorship research than males.

Outcomes, Data Collection, and Storage

The outcome measures, the number of measurement times, and the intervals between measurement points for the study reflected Herth’s (2001) protocol. Study
outcomes included hope, HRQOL, and self-esteem. Pretest measurement of outcome variables and post-test measurement of study variables were conducted among participants in the intervention and control groups. Posttest measurement of the outcome variables was finished within one week of HIP being completed and then three and six months postintervention. Instruments to measure the outcome variables were specifically defined for AYA populations. Although the instruments were chosen based on their use, developmental relevance, and psychometric properties, attention to the total number of questions and the time to complete the instruments also were considered to avoid fatigue among study participants.

Fatigue among study participants in healthy and clinical populations is common when questionnaires require a substantial amount of time to complete. Because many of those survivors experience negative side effects from long-term treatment that affect their cognitive function and ability to concentrate for long periods of time, participant fatigue is a particularly important design consideration for HIP. Three instruments were used that had a combined total of 90 questions to answer and required an estimated 30 minutes total to complete. Hoerger (2010) reported that, in an online survey involving college students, 2% of those enrolled will drop out per 100 survey items included in the study. However, Hoerger (2010) reported that participant dropout in Internet-mediated research is not because of lengthy survey studies but, instead, related to the initial information provided, unanticipated survey content, or potential harm experienced during latter portions of survey studies because of the intensity of questions posed versus the fatigue factor.

Data were collected and stored using the online survey site SurveyMonkey™. The site was encrypted and met Health Insurance Portability and Accountability Act requirements. Because this was a small-scale study, a data- and safety-monitoring board was not needed to periodically review the data for any indicators of untoward effects; however, the PI and the consulting statistician deemed that this data collection and management plan would ensure the integrity of the data (Moody & McMillan, 2002). Links to the survey were sent directly to study participants at each measurement time. Reminder e-mails also were generated and sent if the questionnaires were not completed after one week. The data were recorded directly in an Excel® spreadsheet and housed on a secure server.

### Realized Outcomes

The design decisions involving the study intervention, including its content and mode of delivery, measurement of the study outcomes, and data collection procedures, did not produce any untoward issues. Study participants did not encounter any significant problems in using the Web camera or software program, or completing the online questionnaire. A member of the study team, other than the nurse interventionist moderating the session, was available online during each session to address any technology problems. If a session was missed by a study participant, most often it was because of a conflicting commitment. Every session was recorded and, if a session was missed by a study participant, they were provided the link to preview the recorded session on their own time. No study participant withdrew from the intervention arm of the study once they began HIP.

### Participant Recruitment and Retention

Despite the successes in other study design features, specifically the study intervention, including its content and mode of delivery, measurement of the study outcomes, data collection procedures, and the use of the Web-based technology for the intervention, significant issues were encountered in recruiting and retaining study participants. Specific to recruitment, the invitation sent to eligible participants at the three designated recruitment sites did not yield the expected enrollment of study participants. After four months, only four survivors had contacted the study’s PI and expressed an interest in participating. A number of alternative recruitment strategies then were implemented to broaden the pool of potential study participants (see Table 1). The most successful alternative

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<tr>
<th>Strategy</th>
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<tbody>
<tr>
<td>E-mail blasts sent by the directors of childhood cancer survivorship organizations</td>
<td>113</td>
</tr>
<tr>
<td>Postings on childhood cancer survivorship organizations’ Web sites</td>
<td>10</td>
</tr>
<tr>
<td>Flyers posted at three conferences for childhood cancer survivors</td>
<td>3</td>
</tr>
<tr>
<td>Flyers provided to attendees at an advanced practice pediatric oncology nurse conference</td>
<td>2</td>
</tr>
<tr>
<td>Letter and calls to college and university health centers and university health-promotion centers</td>
<td>–</td>
</tr>
<tr>
<td>E-mail blasts sent by the directors of childhood cancer survivorship camps</td>
<td>–</td>
</tr>
<tr>
<td>Postings on childhood cancer survivorship camps’ Web sites</td>
<td>–</td>
</tr>
<tr>
<td>Facebook paid advertisement</td>
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<tr>
<td>Facebook posting on childhood cancer survivorship sites</td>
<td>–</td>
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<tr>
<td>Advertisement on an online childhood cancer broadcasting show</td>
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N = 128
strategy in the recruitment of survivors was the result of an e-mail blast that was sent from the founder of a childhood cancer survivorship organization for young adults, a female survivor of childhood cancer, who endorsed the study and encouraged participation among the organization’s members.

At the 18-month mark into participant recruitment, 70 survivors had been enrolled in the study: 39 in the intervention group and 31 in the attention control group. A total of 43 study participants had completed the study, 29 from the intervention group and 14 from the control group, and 27 study participants dropped out of the study. Consequently, a 39% attrition rate was experienced. Reasons survivors gave for enrolling in the study but deciding not to participate in the intervention are listed in Table 2. Because of the significant attrition rate, if respondents in the control group completed the pretest and the post-test at the six-month mark, they were deemed as having completed the study. Among the 38 adult patients with cancer enrolled in the intervention group in Herth’s (2001) study, all completed the post-HIP questionnaires as well as those at the three- and six-month marks. Nine months after HIP was completed, Herth (2001) conducted a post-test measurement that 37 of the 38 participants completed.

A second issue related to recruitment and retention of study participants was that many of the survivors requested or assumed that they would be assigned to the intervention group (HIP group). That was compounded by a noticeably high attrition rate of study participants in the attention control group. Of the 31 study participants who were enrolled in the attention control group, only 14 completed the study, resulting in a 55% attrition rate. Although the participants’ time spent viewing the narrated presentations on healthy lifestyle was unable to be tracked and measured, their discontinuation in the study was evidenced by their lack of completing study measures at the designated collection times. Given that attrition rate, coupled with the decreasing number of eligible study participants enrolled in the study, the decision to change to a partial randomization design was made at the 10-month mark of participant recruitment. In a partial randomization design, eligible study participants only are enrolled in the intervention group.

Coward (2002) described how randomization in a study that involved women with breast cancer was not feasible and a partial randomization design then was used. Eligible study participants in Coward’s (2002) study also expressed a preference for a particular study group. An obvious concern with such a design is the bias introduced by the selection process that could weaken the internal validity of the study. However, Coward (2002) argued that, as study participants become more knowledgeable about research protocols, they may be unwilling to be passive participants of a research randomization process, and a partial randomization design may be the answer to the challenge of making randomization more acceptable to women and conducting studies with the adequate number of participants feasible.

### Discussion

#### Methodologic Issues

Methodologic issues encountered in longitudinal designs include threats to their internal, construct, external, and statistical conclusion validity (Van Mechelen & Mellenbergh, 1997). External and statistical conclusion validity threats were the known major threats that had operated in this study. Missing data points and the attrition of study participants posed two separate statistical conclusion validity threats to the findings of the current study. The threat posed by the existence of missing data will be addressed at the time of final data analyses using the mean substitution method of data imputation, which uses the total sample for a variable that substitutes for all the missing values for that variable. Known internal validity threats to longitudinal studies included attrition, testing, and history. In addition, low accrual of study participants can produce a biased sample, threatening the study’s internal validity (Bond Sutton, Erlen, Glad, & Siminoff, 2003). Therefore, attrition experienced in the current study is a serious threat to a study’s internal validity. Van Mechelen and Mellenbergh (1997) believed that attrition is a more serious threat than random missing data.

Colditz and Coakley (1997) suggested ways to reduce attrition, which included developing and maintaining a very strong study design and protocol, with careful consideration of the sample frame and sample size, maintaining a high response rate, and continuous monitoring and improvement of the survey and interview instruments. Young and Dombrowski (1989) reported

<table>
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<th>Reason</th>
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<tr>
<td>Unable to commit to the required time commitment</td>
<td>7</td>
</tr>
<tr>
<td>Dropped at last minute (no explanation provided)</td>
<td>5</td>
</tr>
<tr>
<td>Unable to be contacted with e-mail address provided</td>
<td>2</td>
</tr>
<tr>
<td>No consistent Internet</td>
<td>2</td>
</tr>
<tr>
<td>Death in family</td>
<td>1</td>
</tr>
<tr>
<td>Did not want to share information</td>
<td>1</td>
</tr>
<tr>
<td>Payment for participating was too low</td>
<td>1</td>
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</tbody>
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N = 19
that interactions among the study recruitment team and study participants profoundly affected the successful implementation of a research study involving 4,781 family-planning patients. Factors that contributed to greater study participant retention were (a) the study participants who enrolled were aware of the research study as integral to the family planning program, (b) trust had developed between study participants and the research staff doing the recruitment, and (c) participants were given flexibility regarding when follow-up contacts were made (Young & Dombrowski, 1989).

Cook and Campbell (1979) described external validity as the degree to which a study’s findings can be generalized across various people and settings and involve tests of psychological interactions, specifically selection and treatment, setting and treatment, patient history and treatment. Van Mechelen and Mellenbergh (1997) posited that the best guarantee for generalizing to people, settings, or times is the use of a stratified random cluster sample of people, settings, and times. Although the recruitment strategies were varied and could theoretically reach AYA female survivors across the country and from multiple treatment centers, the sample for the current study was a convenience sample that was susceptible to response biases. High bias and low representation are two well-known issues with that type of sampling (Cook & Campbell, 1979). In addition, although AYAs are, in general, avid users of the Internet, those who are active users (or have a computer) might be more likely to have access and respond to the online advertising about the study. The individuals who did respond and enroll in the study may have had their psychosocial functioning status less affected by childhood cancer as compared to those whose psychosocial functioning was more negatively affected (Hibbs, 1993). To address low enrollment rates, Tercyak et al. (2006) suggested that sample size calculations in RCTs involving childhood cancer survivors should be based on highly conservative randomization estimates so that the study would not be underpowered.

Butterfield, Yates, Rogers, and Healow (2003) have suggested that gatekeepers (site-based research facilitators) are critical for successful recruitment, such that a site-based research facilitator can be a strong determinant to successful recruitment. In 20 years of research among various adolescent samples in school settings, Yarcheski and Mahon (2007) recommended that researchers develop personal relationship networks to gain entry into school systems, refine their negotiation skills, and be ready to provide services to schools to secure access to adolescents. Although the study’s PI did form relationships with designated healthcare providers at the three recruitment sites and with the administrators of the childhood cancer survivorship organizations, the PI was not onsite with the sole objective to recruit the AYA female survivors. Although the designated healthcare providers at each recruitment site were invested in the project, their primary responsibility was in providing care to their patients. Logsdon and Gohmann (2008) recommended that, in the recruitment of female adolescents, the researchers seek data collection sites where clinical staff have continued contact with them.

**Participant Issues**

Ulrich et al. (2010) stated that timely recruitment and retention of study participants remained a leading problem in oncology clinical trials, even among the national oncology clinical trial cooperative groups, such that 80% of randomized clinical trials struggle with recruitment and retention issues. Because the current study was a smaller scale study compared to clinical trials involving cooperative groups, recruitment and retention of study participants were known challenges from the beginning of the project. Wants (1992) suggested that even in studies where few, if any, risks, existed, potential participants from vulnerable populations may feel that the research protocol and its requirements are too extensive or that the inconvenience of being in a study is too burdensome given the restraints of their illness and its treatment. Findings from the pilot study suggested that the study’s protocol was feasible for the six survivors involved, but perhaps the sample of six survivors was not representative of the population of AYA female survivors in regard to their physical and psychological abilities to participate in a research study, as suggested by the seven survivors consenting to be in the larger study, but dropping out once they became more aware of the time commitment. Lamb, Puskar, and Tusaie-Mumford (2001) reported that, despite conducting feasibility studies before implementing a major research project, unanticipated roadblocks occur when attaining adequate numbers for large studies.

Other barriers in AYA female survivors participating in longitudinal interventional research may be a reflection of the multiple demands on their time and resources, lack of trust of the researcher or research team, reticence to share personal information, or a lack of an understanding of their importance in research (Daunt, 2003; Ulrich, Wallen, & Grady, 2002). An option to address this challenge is peer recruiters. Howard and el-Mallakh (2001) have stated that peer recruiters have been effective in increasing participation enrollment in studies. Peer recruitment was conducted to some extent in this current study, but via online methods. Using peer recruiting strategies in face-to-face meetings on-site may be more effective.

**Conclusion**

Using empirical literature to construct this study for AYA female survivors of cancer resulted in successes in achieving certain goals of the study’s design, but not
in the recruitment and retention of adequate numbers of study participants. In general, an important factor to increasing the success in the recruitment and retention of AYAAs is the need for more research on effective strategies on how to recruit this population.

A reasonable number of publications describing issues of recruitment and retention of adolescents in research studies exist; however, very few focus on older adolescents and young adults. Tercyak et al. (2006) noted that very little information existed on methods to identify, recruit, and enroll survivors of childhood cancer for health promotion RCTs. Research investigations involving survivors of pediatric cancer require a significant investment in personnel time and resources for enrollment and recruitment of study participants (Tercyak et al., 2006). A critical need remains to recruit and retain subgroups at risk for poor long-term physical and psychosocial outcomes in research studies to maximize their HRQOL, particularly AYA childhood cancer survivors.

Implications for Nursing

Nursing professionals who provide care for AYA female survivors of cancer can be instrumental in recruiting them for intervention studies that may be beneficial for improving those survivors’ overall HRQOL. Pediatric oncology nurses who provide direct care for AYA female survivors of cancer often have long-term relationships with the survivors in which a bond of trust is developed. That trusting relationship has been identified as an important factor in study participant recruitment, and can facilitate recruitment and retention of AYA female survivors of cancer in longitudinal research studies. In addition, professional cancer nursing organizations can promote the participation of AYA female survivors of cancer in studies through media advertising.

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