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A Substance Use Decision Aid for Medically-at-Risk Adolescents: Results of a Randomized Controlled Trial for Cancer-Surviving Adolescents

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Abstract

Background—Adolescent survivors of childhood cancer engage in risky behaviors.

Objective—This study tested a decision aid for cancer-surviving adolescents aimed at difficult decisions related to engaging in substance use behaviors.

Methods/Intervention—This RCT recruited 243 teen survivors at three cancer centers. The cognitive-behavioral skills program focused on decision making and substance use within the context of past treatment. Effects at 6- and 12-months were examined for decision making, risk motivation, and substance use behaviors using linear regression models.

Results—The majority (90%) of the teen cancer survivors rated the program as positive. There was an intermediate effect at 6 months for change in risk motivation for low riskers; but, this effect was not sustained at 12 months. For quality decision making, there was no significant effect between treatment groups for either time point.

Conclusions—The overall program effects were modest. Once teen survivors are in the program and learn what quality decision making is, their written reports indicated adjustment in their perception of their decision-making ability; thus, a more diagnostic baseline decision-making measure and a more intensive intervention is needed in the last six months. With two out of three teen participants dealing with cognitive difficulties, the data suggest that this type of intervention will continue to be challenging, especially when 90% of their household members and 56% of their close friends model substance use.

Implications for Practice—This effectiveness trial utilizing late effects clinics provides recommendations for further program development for medically-at-risk adolescents, particularly ones with cognitive difficulties.

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Keywords

Cancer-Surviving Adolescents; Decision Making; Substance Use

Introduction

The continuing improvement in survival from pediatric cancer with contemporary treatment is one of the most gratifying results in all aspects of cancer care and research. The 5-year survival rate, which averages 80% for all pediatric cancers,[1] is encouraging, but tempered by the long-term health consequences affecting the majority of survivors. Childhood Cancer Survivor Study investigators reported that of 10,397 adult survivors of childhood cancer, 73.4% had at least one chronic condition and 27.5% had a severe or life-threatening condition.[2] It is well known that substance use may alter clinical status, amplifying late effects of irradiation and chemotherapy and resulting in pulmonary damage, cardiovascular abnormalities, and liver dysfunction. An additional risk is the occurrence of second cancers, with lifestyle choices such as smoking and alcohol use contributing greatly to this problem.[3] To facilitate early identification of cancer/cancer treatment late effects and promote healthy lifestyle in childhood cancer survivors, the Children's Oncology Group (COG) organized exposure-based recommendations in 2003 for health screening and counseling related to type of cancer, type of treatment, and risk behaviors to avoid; several modifications have now been presented with the 2008 version now available online.[4] A decision aid that has been tested for substance use behaviors would be an asset to implementing the "health protective counseling" component of the COG Guideline recommendations.

Teen survivors of childhood cancer do engage in substance use. Based on a model depicting poor quality decision making as a predictor of increased substance use risk behaviors, shortcuts in adherence to quality decision-making criteria have been reported by the majority of teen cancer survivors in three small cohorts compared in 2007 as well as a 2009 cohort.[5–8] Of 243 cancer-surviving adolescents evaluated in the 2009 cohort from three cancer centers across the U.S., half also reported engaging in at least one type of substance use (cigarettes, alcohol, or marijuana).[8] Similarly, in a sample of 307 adolescent cancer survivors, nearly one in three had smoked.[9] Comparing multiple risk behaviors (tobacco, alcohol use, illicit drug use, or sexual behavior) of these same 14–20 year old teen survivors with their 97 sibling controls, the rates were generally equivalent.[10]

In a recent CCSS study of evaluating health behaviors of 2,022 survivors who were younger than age 18 upon entry in the cohort, childhood attention deficits were found to be a significant predictor of adult cigarette smoking (for both lifetime and current smoking.)[11] In another CCSS investigation, impairment of executive function was found to be a significant predictor of current smoking in 8,383 adult survivors.[10] Lifetime smoking among 307 adolescent survivors of childhood cancer was significantly associated with five predictors (peer smoking, smokers in the household, binging, suicidal behavior, and no history of cranial irradiation [CRT]).[9] Significant predictors of lifetime substance use (cigarettes, alcohol, or marijuana) for 243 cancer-surviving adolescents were older age, *current* school problems, lack of resiliency, and negative modeling by household members and peers.[8] For

these 243 teen survivors, 187 (90%) had either one or more household members engaged in some type of substance use and 123 (56%) had a close friend who engaged in some type of substance use. Risk motivation as a surrogate for resiliency to social influence to engage in substance use continues to be a common predictor across these studies, specifically the behaviors of parents and peers as role models.[8,.9,12]

Most agree that the *central executive*, defined as that portion of the brain that includes the functions of self-regulation, flexibility, response inhibition, planning, and organization of behavior, is integral to quality decision making. [13] Executive function allows one to imagine or think in the abstract as a means of weighing future consequences, controlling impulses, and planning behavior based on judgment; thus, the frontal lobe is critical for decision making. According to Giedd and colleagues, adolescent brains may not be fully developed until the mid-20s.[14–16] Geidd used magnetic resonance imaging on healthy boys and girls, ages 3–27 years, and found that the dorsolateral prefrontal cortex, where decision making occurs, is still maturing for a decade past puberty. Geidd states that adolescent brains go through "explosive changes during the teen years," which are just beginning to be understood.[15,p.83] He connects adolescent morbidity and mortality directly to poor decision making and risky behavior as an outcome of the brain's ability to assess rewards; but acknowledges that more data are needed to confirm this relationship.[16] Indeed, the delayed maturation of adolescent brain development in combination with cognitive late effects from cancer/cancer treatment, may create an even greater potential risk for cancer-surviving adolescents and supports the need for specialized programs beyond the school environment. *According to Geidd,"…the teen brain is not a defective adult brain…but the enormous plasticity of the brain makes adolescence a time of great risk and great opportunity."*[16,*p.341*]

Making decisions about engaging in substance use risk behaviors may be especially difficult for many adolescent cancer survivors due to cognitive late effects from cancer/cancer treatments impacting central nervous system function (e.g., CRT, intrathecal chemotherapy, high-dose systemic antimetabolite therapy) in combination with social influences. In a meta-analysis of 28 studies, researchers found that the long-term neurocognitive effects of childhood acute lymphoblastic leukemia suggested both global and specific areas decline with contemporary treatment.[17] A review of empirical literature by Bhatia and Constine related to late morbidity of childhood cancer also reports that neurocognitive sequelae in survivors, such as subtle attention and executive function deficits, continue to appear after treatment.[18] Some researchers have estimated that as many as 40% of survivors of childhood cancer may have neurocognitive deficits due to cancer and treatment.[19] These long-term neurocognitive sequelae are more likely to occur in survivors of acute lymphoblastic leukemia and brain tumors.[20]

Because adolescent survivors are at greater than normal risk for physical, psychological, and social problems than the general population, they must continue to be vigilant in monitoring their health. A scientific working conference sponsored by the National Institutes of Health and St. Jude Children's Research Hospital, "Tobacco Control Strategies for Medically At-Risk Youth," was held in 2005 at St. Jude in Memphis, TN. This interdisciplinary consortium concluded that the point of entry for these vulnerable adolescents for prevention-based programs should be subspecialty clinics due to their chronic or life-threatening

disease.[21] Specific tobacco control strategies were also delineated for these medically at-risk youths, including decision making and tailored programs. The long-term follow-up programs available at most cancer centers are the subspecialty clinics that typically address the impact of risky health behaviors in the context of post-therapy health promotion counseling of childhood cancer survivors.

Decision aids are in use with many populations, but especially those with cancer. *Decision aids* are defined as tools that help prepare patients to participate or make decisions relevant to their personal health status, and generally use specific health information related to the decision being considered.[22,23] These decision aids have included a variety of formats, including decision boards, interactive videos, workbooks, and computer programs. They are interactive, requiring a balancing of the pros and cons of a difficult decision and seem to be most effective when they are tailored to the individual patient. For example, a method of rationally weighing alternatives, the decisional balance sheet procedure by Janis and Mann, two decision theorists, has been used in health care for some time; this is a method of weighing the pros and cons for oneself and others for consequential decisions, which then helps an individual become more aware of one's own values and the values of those they care about.[24,25]

The broad goal for the research reported in this paper is to enhance care related to risk behaviors for adolescent survivors of childhood cancer. The major objective of the study was to test further a decision aid for adolescent survivors of childhood cancer that is aimed at difficult decisions related to engaging in substance use risk behaviors. The specific aims were: (1) To test the hypothesis that cancer-surviving adolescents who receive a cognitive-behavioral skills program in the clinic setting to enhance decision-making skills (framed within the context of engaging in substance use risk behaviors and their interaction with late effects of cancer/cancer treatment) will report increased quality decision making 6- and 12-months post-intervention compared with the usual care group; and (2) To test the hypothesis that cancer-surviving adolescents who receive a cognitive-behavioral skills program will report (a) maintained or lowered inherent risk motivation and (b) maintained or lowered risk behavior status (in smoking, alcohol consumption, or illicit drug use) 6- and 12-months post-intervention compared with the usual care group.

Background

Most specialty care clinics provide educational information related to the disease and medication regimens quite well, and ongoing research shows they continue to try to improve in this area, including care of survivors of childhood cancer. However, such programs in specialty clinics tend not to concentrate on "processes" to change patient behaviors, such as improving decision-making skills.[21,7] They generally assume that decision making is sufficiently taught in schools and in homes, but statistics from national health surveys verify that this is not the case.[21,7] Based on this premise, a substance use decision aid was developed for adolescents.[26] This decision aid allows healthcare professionals to "drive home the message of risk" to adolescents who are medically at-risk with chronic health disorders by framing substance use in the context of not only worsening their underlying disease process, but also the possibility of dangerous interactions with their prescribed

medications, in addition to the well-known long-term health risks for substance use for any individual, such as lung cancer. It is based on the Janis and Mann theory of decision making and a classic change theory by Hersey and Blanchard, as well as a conceptual model developed by Hollen that provides a clinical profile model to predict decision making, risk behaviors, and quality of life.[24,25,27,5,6]

In a 2-site,12-month camp pilot study with 64 cancer-surviving adolescents, ages 14–19 years of age, the decision aid was able to significantly improve decision making in the intervention group with an 8% change at 12 months ($p = 0.001$). There was a significant change at one month post-intervention, which waned a bit at 6 months, but the effect was sustained at 12 months.[28] This finding was similar to the results of a St. Jude tobacco study with delayed effects at 12 months by Tyc and colleagues.[29] An additional 6-month pilot study with 55 cancer-surviving adolescents was conducted to test the intervention in a clinic vs. camp setting to prepare for a larger definitive study with a more diverse sample and more diverse settings.[30] Although it was expected that statistical significance would not be reached because the initial power analysis determined a need for 62 cases per group for .80 power to detect a difference, analysis was conducted to support an NIH grant application. Data from the pilot study indicated varying results when assessing changes in decision making (DMQS) from baseline to 6 months by whether or not the subject engaged in risk behavior at the time of study entry. Group equivalence was obtained, with no significant differences in baseline measurements of age, gender, abstract reasoning ability, or parental education and family income level. Analysis of the subgroup of subjects who engaged in no risk behaviors at study entry (n=30) indicated an estimated difference of 0.5 (se 1.1), p=0.65, in the change of DMQS scores from 0 to 6 months for the usual care group compared with the enhanced care group. The estimated change of DMQS scores from 0 to 6 months was 0.3 and 0.8 for the usual care group and the enhanced care group, respectively. Analysis of the subgroup of subjects who engaged in at least one risk behavior at study entry (n=25) indicated an estimated difference of –1.5 (se 1.1), p=0.18, in the change of DMQS scores from 0 to 6 months for the usual care compared to enhanced care group. The estimated change of DMQS scores from 0 to 6 months was 0.4 and −1.1 for the usual care group and the enhanced care group, respectively. Based on these findings, this current study was approved.

Methods

Design/Setting

This prospective, randomized controlled trial (RCT) tested a decision aid for adolescent survivors of childhood cancer, assessing immediate (6 months) and sustained (12 months) changes post-intervention. The intent of the decision aid is to help adolescent survivors improve their decision-making skills by considering tailored decision context related to potential or actual late effects of cancer/cancer treatment and substance use interaction that only the health care professional can provide. Three pediatric oncology clinics (St. Jude Children’s Research Hospital in TN; Long Beach Medical Center in CA; and Hackensack University in NJ) enrolled 243 cancer-surviving adolescents, ages 14 to 19 (up to the 20th birthday).

This was primarily a Web-based study, which had online stratification by risk level. Teen cancer survivors were randomized to either an enhanced care or usual care treatment group by computer-based randomization. Data were collected during a semi-structured interview for the baseline and 12-month clinic visits using a laptop, with measures at 6 months collected off site from the teen's home/library computer. Three surveys within a software program (Survey.NET) were used to obtain the outcome measures: decision making, risk motivation, and risk behavior status (smoking, alcohol consumption, illicit drug use).

A stratified block randomization design was used in which strata were determined by two stratification variables (clinical site and risk behavior status). For baseline risk behavior, stratification levels were low risk vs. high risk (low risk = none with score = 0; high risk = one or more with score of ≥ 1). As a randomization variable, Hollen created a *high risker index* (HRI), a 7-item computer-assisted index, to identify adolescents at risk for substance use. This baseline index identified teens reporting poor quality decision making and engaging in one or more risk behaviors, by self-report, medical record review, or urine biomarker (1=positive or refused urine cotinine; 0=negative). Each behavior was dichotomized: *smokers* (1=any use in past 30 days; 0=nonsmokers); *alcohol use* (1=monthly or more frequent use in the past year; 0=no alcohol use); and *illicit drug use* (1=any use of at least one type of street drug in the past year; 0=no street drug use). Initial content validity was obtained by a panel of four experts in adolescent risk behaviors, and reliability was obtained by hand scoring 72 HRIs and matching results with the software scoring program results; adjustments were made until a perfect correlation was reached.

Intervention

Components of the intervention (decision aid) included five modules on decision making, smoking, alcohol/drug use, an interactive substance use module, and a health status module (Table 1). This comprehensive decision-skills program has several unique features such as it (a) teaches a psychological theory related to quality decision making as an easy-recall method during decision situations, (b) provides application of the theory using a tailored decisional balance sheet for values clarification of their decisions related to substance use, and (c) provides information about cancer/cancer treatment late effects. Tailored substance use risk behavior counseling was delivered by nurse practitioners at baseline and again at 9-months for high riskers in the intervention group. CD-ROM components of the intervention, with live action videos delivered at baseline, were delivered as electronic "*e*-boosters" at 2-, 4-, 6-months, and a telephone booster at 9-months to maintain contact prior to the final study visit at 12 months. The intervention involved approximately 7.5 contact hours (including the battery of measures at three timepoints) with the teen over 12 months to complete the study. As an intentional control, the usual care group received standard care and a sham CD-ROM related to study skills. Additionally, a website was created that provided the teens in three states access to online surveys at the three timepoints and the study coordinators access for data entry and the software program to determine the randomization strata using the HRI. Web-based support was available to the teens and study coordinators.

Sample/Procedures

A sample of 243 adolescent survivors of childhood cancer (and one parent per teen) was recruited through consecutive enrollment at the three late effects clinics. These teens, ages 14–19 years, were survivors of childhood cancer who had a history of cancer diagnosed between birth and 12 years, had been disease-free for *at least* five years, and had no treatment during the previous two years. Any eligible participant with physical or emotional concerns and/or known significant cognitive deficits that warranted exclusion from the study was not approached.

The *Enhanced Care/Intervention Group (EC Group)* received the decision aid (CD-ROMs) at baseline, which also included a one-on-one counseling session by the clinic nurse practitioner using a "tailored" Substance Use Risk Behaviors Facts Sheet related to the linkage of late effects of cancer/cancer treatment to substance use risk behaviors (smoking, alcohol use, and illicit drug use). The counseling session was expanded in a 9-month telephone call for high riskers. The EC group received contact at an initial visit, at the time of three home boosters (2, 4, 6 months), a 9-month timepoint to maintain contact and an additional booster for high risk adolescents, and at the next 12-month annual visit for final assessment. The three electronic CD-ROM home booster ("*e*-boosters") information was mailed to the teen and each had a telephone contact to keep the teen engaged. A follow-up form was completed by the site study coordinator after each contact to ensure compliance. A hard copy of the workbook, which included the balance sheet exercises, was mailed in the same packet as the CD-ROM at the 2-month timepoint, but completed online using an encrypted study ID. All measures for the teen were obtained online at the three timepoints, but baseline was facilitated using a semi-structured method to give examples if needed (a method that had worked well in previous studies in this program of research) and a 12-month exit interview for closure.

The *Usual Care Group (UC Group)* received usual care, which generally includes interactions with the health care provider about the following: survivorship education, such as the teen survivor's concerns of recurrence, second malignancies, late effects of cancer/cancer treatment, growth and development issues, and support to assist the survivor in putting past events into perspective. Adolescents in this group *did not* receive any oral, written, or recorded information related to decision making or the protocol (except St. Jude reviews substance use in their standard program). Participants received a neutral sham CD-ROM on study skills on a laptop computer at the baseline visit in order to match the modules and procedures of the treatment group. Teens in the UC group received the intervention at the 12-month visit as a "delayed" intervention *after* the final outcomes measures were completed, with the nurse practitioner reviewing the Substance Use Risk Behavior Facts Sheet as part of the final study closure visit.

The *accompanying parent* completed a brief battery of self-report measures at the initial visit only. Risk behaviors for their other household members were completed by proxy by this parent attending the initial study clinic visit.

Study Measures

A well-tested battery of measures has been used for this program of research. These included:

Medical Record Review Form (MRRF)—A four-page record review captured information on the history of the disease (including level of severity, type of therapy, dose and route of administration of treatment, and age at time of initial treatment). An additional indicator of cognitive function was determined from the medical record and scored dichotomously (0 = no problems; 1 = special education, general academic problems, subject difficulty, and dropout status).

Family Information Form (FIF)—A one-page, 6-item multiple-choice form was completed by the accompanying parent for sociodemographic data (including the parent's gender, marital status, age, educational level, occupation, and family income level), *and parent's perception of current status of academic achievement for teen survivor.*

Shipley Institute of Living Scale (SILS)—A classic cognitive measure by Shipley was used to assess abstract ability in relation to weighing future consequences.[31] This brief estimator of current intellectual functioning has two subtests: (a) vocabulary portion - choosing which of four listed words means the same or nearly the same through 40 items, and (b) abstract reasoning - filling in the numbers or letters of 20 completion items that logically complete a given sequence. Each subtest takes 10 minutes to administer by a trained paraprofessional. Executive function impairment was reported as limited abstract reasoning ability using a cut off score of less than 40 as stated in the manual. Normative data are available in the manual.

The Decision Making Quality Scale (DMQS)—A 7-item Likert rating scale developed by Hollen was used to assess the degree to which a participant adheres to seven quality decision-making criteria during consequential decision making.[32] For adolescents, Hollen adapted Janis and Mann's[24,25] seven criteria as: (1) searches for three or more choices; (2) takes into account values and goals desired; (3) weighs the pros and cons of consequences; (4) finds more information about the pros and cons when needed; (5) thinks about new information and what experts say, even if against the first choice; (6) reviews choices carefully before making a final choice; and (7) makes detailed plans with backup plans. The DMQS asks the respondent to consider, "How true do you think these statements are about your decision making for important choices (not everyday ones)?" and offers four ordinal level, Likert response choices: not at all true = 0, not very true = 1, somewhat true = 2, and very true = 3. The range of scores is 0–21, with higher scores reflecting greater adherence to quality criteria during consequential decision making. Based on the underpinning theory, cutoff scores have been published as: non-quality decision making (0–14 points) and quality decision-making (15–21 points).

Risk Motivation Questionnaire (RMQ)—This measure captures the motivation for an adolescent to engage in or abstain from a risk behavior. Ryan developed the RMQ based on previous scales developed by Ryan and Connell in the achievement and prosocial or moral

domain.[33,34] The RMQ is a 48-item survey that samples level of motivation for engaging in or avoiding three domains of risk behaviors: cigarette smoking, drinking alcohol, and street drug use. Sixteen items apply to each target behavior, with eight items representing reasons why one might engage in the risk behavior, and eight reasons why one would not. Each reason is rated on an ordinal 4-point, Likert scale from “not at all true” = 1 to “very true” = 4. For example, the alcohol total motivation score is obtained by subtracting the alcohol positive score from the alcohol negative score. An alcohol RMQ total score > 0 is interpreted as desirable in that it indicates that the teen’s attitude is more negative than positive toward drinking.

Periodic Assessment of Drug Use Among Youth (PADU)—Developed by Barnes et al, this self-report 50-item survey instrument for adolescents was used to assess frequency and amount of risk behaviors.[35,36] For the modeling, three subscales were used: *smoking risk* (average number of cigarettes per day/30 days multiplied by 12 months to obtain past year); *alcohol use risk* (average number of drinking occasions/past year multiplied by average number of drinks of beer, wine, or liquor at one time); and *illicit drug use risk* (number of times used illicit drugs/past year). A 3-item subscale was added, asking the teen to report by proxy if his/her closest friend engages in smoking, alcohol use, or recreational drug use more, the same, or less than he/she does. Parents also completed this measure about their own risk behaviors and, by proxy, the behavioral status of their household members who engaged in substance use. The PADU has been used in several representative school samples from the state of New York, which included more than 27,000 adolescents in each sample, thereby providing substantial normative data.

A *urine cotinine assessment for tobacco use***,** a biochemical marker for active smoking, was used to control bias in self-reporting by high-risk adolescents and to identify high-risk adolescents. The QuickScreen^{TM} One-Step Rapid Nicotine Test (distributed by Craig Medical) detected cotinine in human urine at a cut-off sensitivity level of 200 ng/ml, the established standard for determination of tobacco and nicotine use by the U.S. Department of Health and Human Services and World Health Organization.

A *Teen Study Pledge* was created for the study to control for teens discussing the intervention with one another and was used as a contract with both teen and parent signatures. This form also provided a statement that those teens in the usual care group, who did not receive the Substance Use Risk Behaviors Facts Sheet, Decision-Making CD-ROM, and workbook as part of their program in the study, would receive these at the 12-month visit and that the clinic nurse practitioner would review the Risk Behavior Facts Sheet as part of the final study closure visit.

Protocol/Study Checklists—Two short checklists developed by the coordinating center PI for this study, were completed by the clinic nurse practitioner to document adherence to the protocol care components to ensure compliance. The two forms are: the usual care group (10 items), and the enhanced care group (11 items). The one additional item in the enhanced care group reflects the degree of adherence to the Risk Behavior Facts Sheet tailored to the teen’s specific treatment. All checklists used a 4-pt. Likert scale (not at all true = 0; very true = 3). A similar checklist, completed by the study coordinator, ensured that all instruments

were appropriately completed at each time interval. A brief follow-up checklist was also completed by the study coordinator and verified by the study team to document the teen's compliance to the home boosters.

The *Teen Exit Interview Form* consisted of a short exit interview form for the enhanced care group. The two components were: Part I documents the teen's perception of the degree of clarity to which the Substance Use Risk Behavior Facts Sheet was presented by the clinic nurse practitioner. This part used a simple 3-item checklist. Part II, an 8-item program evaluation component, was developed by the coordinating center PI to document the teen's perception of meeting eight programmatic outcome criteria related to the decision aid program. These criteria address eight outcomes: (1) understanding of the basic decision-making theory, (2) ability to explain the theory to another, (3) belief that the theory was useful, (4) ability to take steps to make an important decision, (5) belief that the computer CD-ROMS were helpful, (6) helpfulness of the workbook, (7) recommendation to another based on interest of the program, and (8) recommendation to another based on helpfulness of program. A 4-pt. Likert scale was used (not at all true = 0; very true = 3). A short debriefing form was used to ensure consistent closure for all participants.

Analyses

All data analyses were performed using SAS (version 9.2). An overall significance level of $\alpha = 0.05$ was used for all statistical tests; all tests were two-sided. For attrition analysis as well as baseline group comparisons between the intervention and usual care groups, t-tests or Chi-square tests were used to detect differences. Basic summary statistics were calculated overall, by risk group (those who engage in one or more risk behaviors at baseline and those who did not), and by treatment group (usual and enhanced care) within each risk group. *Cognitive difficulties* were defined by multiple variables: 1) *late effects* by medical record extraction (0=no; 1=yes, any type); 2) *executive function impairment* as limited abstract reasoning ability (0=none; 1= limited abstract reasoning, with cut off score of less than 40 for the adult Shipley abstraction quotient); and 3) *current school problems* by both parent report and medical record extraction (0=no problems;1=special education, general academic problems, subject difficulty, and dropout status). Descriptive statistics were also used to summarize the *teen's evaluation of the intervention* at the 12-month end-of-study timepoint.

A mixed general linear model was used to assess the effectiveness of this decision aid for adolescent survivors of childhood cancer. *Group membership* (measured by a dichotomous variable), *time* (the two measurement points of 6-months and 12-months), and the *interaction of group membership and time* (to determine whether either group shows a greater change over time) were used as predictors. Maintained status and lowered status were both captured in the multi-level modeling. A positive effect of the intervention was interpreted as *reduction* in the number of cigarettes or *continuation of non-smoking status*, and similar outcomes stated for alcohol and illicit drug use. Immediate effects (6-month follow-up) and sustained effects (12-month follow-up) were chosen to capture intervention boosters throughout the year. Planned contrasts, measured by a dichotomous variable, were used to examine group differences at each time point for treatment group and high/low risker status.

Two original stratification factors (clinical site and risk group) and *inflator status* were factors in the analyses. *Clinical site*, defined as three late effects clinics, was included as a stratification factor because St. Jude Children's Research Hospital offers review of substance use in their standard program within their late effects clinic. *Risk group* was a stratification factor to control for differences in substance use education and known geographical differences in substance use. The last factor was *inflator status,* added to define those at baseline who had 15 or higher on DMQS (representing a self-report of quality decision making) yet also reported engaging in one or more risk behaviors at baseline. With so many in this last category, they were retained and not deleted from the analyses.

Planned contrasts for the total group of teens in the treatment group (EC group) were also examined for *clinical site* and *cognitive ability*, controlling for inflator status only, as risk status was not of interest for subgroups. These two subgroups were dichotomized as: (1) *clinical site* because of the diversity at each site (1= St. Jude had its own prevention program which included smoking = 1; 0 = Long Beach and Hackensack did not); and (2) *cognitive difficulties* (see definition above).

RESULTS

Participants

*A summary of accrual, attrition and evaluable cases within the two randomized groups by cancer center is presented (*Table 2*).* Of the 243 participants, there were 213 (88%) with evaluable data in the two treatment groups (102 for enhanced care; 111 for usual care); thus, the accrual goal was met and the evaluation goal of 80% was met.

With a target goal of 240 adolescent survivors of childhood cancer from three cancer centers from across the U.S., 243 teens were enrolled in this cohort, called the 2009 Cohort. In a presenting clinical profile for this 2009 cohort of 243 adolescent survivors of childhood cancer, baseline characteristics are described for adolescents from three regions of the U.S. (Table 3). This cohort presents a fairly typical demographic profile to previous studies in this program of research, with a fairly even distribution between genders and the majority being Caucasians from intact families and high incomes. Within this 2009 cohort of cancer survivors, the mean age at diagnosis was 5.1 (range 0–14 years) and 126 (52%) were diagnosed before age five. The most prevalent diagnosis was acute lymphoblastic leukemia for 98 (40%) of the adolescent cancer survivors. In examining cognitive late effects in this 2009 cohort, 39 (16%) had a history of cranial irradiation (CRT) of 1800 Gy or more and 55 (23%) had a history of dexamethasone therapy. All teen survivors had cognitive testing at baseline using the Shipley cognitive test. Among 54 cases, those with a diagnosis of brain tumor or those with a history of CRT as examples for those expected to have cognitive late effects, 5 (9.3%) had executive function impairment using the Shipley cognitive test. As noted on their medical records, 35 (14%) had late effects but causing no impairment to learning and 27 (11%) had late effects causing impairment to learning. Two out of three teen participants had cognitive difficulties using medical record extraction and parent report (total 160; 66%); this held true at each clinical site (Hackensack University, 49 teens, 69%; Long Beach, 39 teens, 85%; St. Jude, 72 teens, 58%). For this 2009 cohort, 187 (90%) parents reported one or more household members engaged in some type of substance use and 123

(56%) teens reported that they had a close friend who engaged in some type of substance use. Using the computerized high risker index at baseline to identify those reporting poor quality decision making and engaging in one or more risk behaviors by self-report, by medical record review, or urine biomarker, 74 (34%) of the 213 evaluable cases were categorized as *low riskers* at baseline and 141 (66%) were identified as *high riskers*.

The attrition analysis revealed cases lost to follow-up were similar across all three sites and allocation to treatment group remained fairly equal across sites as well (Table 4). There were 30 attrition cases (12%) over the 12-months follow-up period and 8 cases (3%) withdrew over the course of the study. The primary reasons for refusal were multiple studies to choose from or no time in schedule. There were no significant characteristic differences between those lost to follow-up and those who remained in the study according to baseline report of substance use by the teen. In the latest of the two pilot studies, more teens dropped out (almost 3:1) who reported one or more risk behaviors at baseline (30%) than those who reported no substance use risk-taking behaviors (9%). To compare this group of 243 teens with that pilot sample, dropout status was defined as those with no DMQS at the 12-month timepoint; attrition again occurred almost 3:1 in those reporting one or more risk behaviors (73%) at baseline than those who reported no substance use risk behaviors (27%). There was no significant difference in attrition between these two groups by risker status.

Overall, adherence (thoroughness of completion) of the online intervention boosters for those in the enhanced care group was better than expected, ranging from 90–99% at the various timepoints (Table 5). If a teen took the time to do the booster, they generally understood according to the quick quiz for comprehension, which was evaluated by a panel of three research team members using “somewhat true” or “very true” scoring. However, some teens were late in compliance; but, this was not considered reason for exclusion because the timepoints were arbitrarily chosen and lateness is typical for adolescents. Of the 102 evaluable enhanced care cases with 12-month DMQS data, a panel of three research team members concurred that 64 (63%) teens completed all three *e*-boosters as specified in the protocol; 64 (82%) teens completed two; and 92 (90%) teens completed at least one.

Treatment Fidelity

There was close monitoring throughout the study using checklists, data monitoring, and emphasis on establishing rapport with the teens. The intervention included a remediation booster at the 9-month timepoint for the high riskers. This booster by the nurse practitioner repeated the one-on-one tailored counseling related to the Risk Behavior Facts Sheet and enhanced by discussing how some teens deal with the need for monitoring late effects of treatment. Reports revealed that in general the nurse practitioners found the teens to be more communicative at the second contact and were more responsive to the interventionist. Lastly, high riskers among the survivors of brain tumors were delayed in receiving the counseling due to an error related to non-common diagnoses; but, this was corrected prior to final administration of the outcome measures.

Intervention Outcomes

The outcomes are presented for both an *immediate* effect (6-months) and a *sustained* effect (12-months) for quality decision making, risk motivation, and substance use risk behaviors. Two planned contrasts were randomized treatment group (usual care; enhanced care) and baseline risk group (high/low). Mixed linear regression models were used to estimate the effect of the treatment with each modeling strategy, including the baseline measure, site, risk group, inflator status, treatment effect, and with interaction terms of site by risk group and treatment by risk group. The results were consistent for the 12-month analysis when limited to teen survivors with complete data.

Decision Making—Unexpectedly, one third (36%) of the adolescent survivors were considered *inflators* of their baseline decision-making score (defined as those who rated themselves as quality decision makers at baseline, but also reported engaging in substance use, followed by decreased decision scores at 12 months). For quality decision making, there was no effect between treatment groups for either follow-up timepoint of 6- and 12 months. Similarly, there was no effect at either timepoint for high/low risk group (Table 6). Once teen survivors are in the online program and learn what quality decision making is, based on learning a decision theory, their written reports in the workbooks stated they adjust their perception of their decision-making ability.

Risk Motivation—In examining immediate effects (6-month timepoint) for risk motivation (Table 6), the intervention resulted in a significant effect (p=0.04) between treatment groups for the total score as well as for the alcohol (p=0.02) and illicit drug (p=0.02) subscales. Unexpectedly, there also was a trend toward significance for the total score (p=0.06) for low riskers at 6 months.

Substance Use Risk Behaviors—After examining the proportions of those who showed change, substance use behavior was not included in the models at the 6- or 12-months timepoints (Table 6).

Planned Contrasts—The total group of teens in the treatment group (EC group) was also examined for subgroup differences (clinical site and cognitive ability, controlling for inflator status only, as risk status was not of interest for subgroups). There was no differential effect between these subgroups.

Evaluation of Intervention by Participants—The exit evaluation for the enhanced care group was conducted with a survey as well as an exit interview by the nurse practitioner and study coordinator (Table 7). The majority of the teens rated the program favorably, with almost all evaluation criteria above 90% (for the combined scores of “somewhat true” and “very true” response options).

DISCUSSION

At baseline, substance use risk behaviors by these adolescent survivors were found to be high and comparable to cohorts of teens previously studied.[8] These data indicate that adolescent cancer survivors are taking unacceptable risks with their health and underscores

the need for substance use counseling interventions. Study results demonstrate that some immediate change in substance use motivation can occur even through a modest intervention, but that sustaining these results over a longer period may require more intensive approaches and consistent follow-up. Yet, there are many implications generated from this study for research and practice.

The first study aim testing the hypothesis that cancer-surviving adolescents who receive a cognitive-behavioral skills program to enhance decision-making skills (framed within the context of engaging in substance use risk behaviors and their interaction with late effects of cancer/cancer treatment) will report increased quality decision making 6- and 12-months post-intervention compared with the usual care group was not supported. It would appear from the results of this 2009 cohort that the intervention was not effective for changing decision making, although the program was rated favorably by the teens. Unexpectedly, one third (87 cases; 36%) of the teen cancer survivors inflated their decision-making scores at baseline. *This had not been the case* in the Hollen et al camp study with 64 cancer-surviving adolescents in which the research team was able to significantly improve decision making in the intervention group with an 8% change at 12 months.[28] There was a significant change at one month post-intervention, which waned at 6 months, but was sustained at 12 months, resulting in similar results to that of St. Jude smoking study by Tyc with delayed effects at 12 months.[29] Based on these prior results, the investigators intensified the program; yet, once teen survivors are in the program and learn what quality decision making is, then their written reports often stated that they adjusted their perception of their decision-making ability. Although more feasible for cognitive impairment, the DMQS may not be sensitive enough as a baseline measure of decision making or the published minimally important differences for the DMQS need to be reexamined; a more diagnostic decision measure, the DMQI, may need to be considered in future studies.[8]

The second study aim testing the hypothesis that cancer-surviving adolescents who receive a cognitive-behavioral skills program will report maintained or lowered inherent risk motivation and maintained or lowered risk behavior status (in smoking, alcohol consumption, or illicit drug use) 6- and 12-months post-intervention compared with the usual care group was not supported. There also was no differential effect between the planned contrasts (clinical site or cognitive ability), but the limited sample may have presented a type II error. However, there was an intermediate effect (6 months) for change in risk motivation for low riskers; but, no sustained effect (12 months). The investigators had decided that all of these medically at-risk teens had the potential to benefit from the intervention, not just those engaged in substance use. Teen survivors who identified themselves as low riskers at baseline may be those who benefited most from this intervention. In the Hollen et al. camp study, the analysis of subgroups also found an increase in decision-making scores for the low-riskers, those teens not engaged in risk behaviors at baseline, in the intervention group.[28] Similarly, in a recent survey of 65 high schools across the U.S. that had implemented a successfully tested substance use program, the Project Towards No Drug Abuse (TND), one year follow-up found a marginally significant effect in lowering marijuana use. In that study, significant program effects on illicit drug use were found for baseline non-users only and not for the two program conditions.[37] A similar school-based program for substance use in 83 school districts (N =

10, 434), Take Charge of Your Life, had a negative impact on baseline non-users.[38] with a follow-up study unable to determine what went awry.[39] Thus, a case continues to be made from this study that teen cancer survivors who identify themselves as low riskers should not be eliminated from a structured program to enhance quality decision making because a decision aid such as this provides a "life tool" by teaching the basis of the theory of better decision making by Janis and Mann [24,25] and because risk behaviors have an upward trajectory for many teens.

Interestingly, there were changes in risk motivation but not decision making. The Janis and Mann theory [24,25] predicts decision-making behavior for consequential decisions – those which are emotionally-laden and motivationally driven in which perceived losses exist no matter which alternative is chosen. The main premise of the theory is that stress affects decision making and high-level cognitive processes (e.g., abstract thinking to weigh future consequences) are needed for quality decision making. The most effective range of stress is the intermediate range (too little or too much reduces adherence to quality decision-making procedures). According to the theory, three preconditions (the amount of risk from consequences, hope for finding a better solution, and time pressure to make a serious decision), precipitate a degree of stress, thus affecting the type of decision-making style an individual tends to use. The decision-making style chosen ultimately leads to quality or non-quality decision making. Based on the theory, risk of consequences was captured by the one-on-one counseling session using the Risk Behaviors Facts Sheet; but, more emphasis may be needed in helping teen survivors understand the effects of peer pressure affecting perceived losses. In the previous study in the camp setting, this was captured by positive peer interaction with older teen survivors, which may be a worthy approach to supplement counseling by the nurse practitioner and the online DVD context for substance use. Peer counseling as a part of a multicomponent program for smoking cessation has been used successful with survivors of childhood cancer in the past as well as other context and may be an important addition.[40]

A limitation that most likely affected the internal validity of the study was more variability or potential for smaller effect size in the outcome variables than expected from the pilot studies, even though there was no differential effect based on clinical site or those with cognitive difficulties. The diagnosis of brain tumors had not been included in prior pilot studies in this program of research. As this higher observed variability was an outcome, sample size was not expanded to account for this increase in variability and may have resulted in a type II error. Specifically, with two out three teen survivors dealing with cognitive difficulties, these data suggest that this type of substance use intervention will continue to be challenging, especially when 90% of the household members modeled substance use of some type as did 56% of their closest friends.[8] These findings emphasize the importance of attending to substance use as a family-based issue and suggest that interventions that target risk-taking behaviors among survivors consider the family context and environment. Based on what is known about cognitive late effects and the findings extracted from the medical records and parent report related to *current* school problems, the Shipley cognitive test was not useful as a formal cognitive test for identifying executive function deficit in this cohort of teen survivors. Future studies with adolescent survivors of

childhood cancer should consider use of the CCSS-Neurocognitive Questionnaire, adapted from the Behavior Rating Inventory of Executive Function. [11]

The feasibility of conducting this study in three busy late effects clinics at regional cancer centers across the U.S. was successful for the most part. The a priori completion rate was set at 80% by the statisticians; yet, for this 2009 cohort of cancer-surviving adolescents, there was an 88% completion rate. In addition, the teen cancer survivors continue to rate the program as acceptable, with the majority (over 90%) rating all evaluation criteria positively with responses “somewhat true” and “very true” by this cohort (Table 7). One third (37%) of these evaluable cases did not complete all three-boosters as specified in the protocol; yet, they completed the study at the12-month follow-up timepoint at the time of their annual evaluation. Of the 102 evaluable cases in the enhanced care group, dropouts occurred almost 3:1 in those reporting one or more substance use risk behaviors at baseline than those who reported no substance use risk behaviors similar to the last pilot study. Applying Janis and Mann’s decision theory,[24,25] the teens who were engaged in risk behaviors at baseline may have been “risky stickers” who did not want to change their decision making or risk behaviors and, thus, dropped out. Hasse has also presented that poor adherence or compliance to treatment by adolescents with cancer can be due to the teen constructing their own worldview of illness and treatment.[41]

Although the completion rate and the ongoing positive evaluation by the teens from the pilot studies to this effectiveness trial is encouraging, adherence needs to be continually monitored. Online programs that do not interfere with school commitments need to be provided as the primary reason for refusal was limited time. Substance use content is important but teens liked the live-action media of teens their age and typical situations as context. Adherence to the protocol over a year needs further development, such as more online substance use CD-ROMs (now DVDs) in the last six months to maintain interest. The quick quizzes have now been put online immediately following each booster with questions that only can be answered if the booster is watched and comprehended. Whether these are too difficult for those with cognitive difficulties needs review based on the results of this study. It also may be that the incentive for adherence can be more interaction/rapport by telephone with the nurse practitioner, who reported that the teens were more communicative at the 9-month booster. Given the familiarity with social media, use of cell phone, and now apps, use of newer technologies may be more appealing to teen survivors and provide an opportunity for health care providers to stay in more frequent contact with their patients, thus allowing greater intensity of intervention and follow-up sessions.

In addition to the media emphasis of some substances, such as tobacco use, an external validity threat for this type of study may include societal change in attitudes toward alcohol use, especially when 90% of the household members modeled substance use of some type. Recent figures show the decline in substance since the late 1990s and early 2000s has slowed or stalled, with young people using more alcohol than tobacco or illicit drugs.[42,43]

In summary, the overall effects of this intervention were modest; but, again the program was rated highly by the teen survivors. According to the school literature and early theorists, attitude change must precede behavioral change. If risk motivation is, indeed, linked by a

change in attitude, then again it can be said that the program may have "a dampening effect on the upward trajectory for substance use if longer follow-up were planned, as this path is well-known to increase for both age and gender in the general population" (**G. M. Barnes, personal communication, May 15, 2012**). Indeed, many interventions may be efficacious in controlled clinical trials, but lack sustainability in real-world effectiveness applications.[37,44] Nonetheless, this effectiveness trial, within the real-world scenario of several survivor clinics across the U.S., can provide some important recommendations for further program development for medically-at-risk adolescents. For adolescent cancer survivors who want to be like their peers and parents, the challenge remains, particularly for those dealing with cognitive difficulties. Health professionals providing interventions during the survivors' adolescent years need to continue to try to develop creative, engaging, and effective interventions for improving decision making related to substance use risk behaviors within the context of late effects from cancer/cancer treatment for this medically at-risk population. Enhancing decision making may be one approach to better outcomes for cancer-surviving teens; but, a combination of strategies will likely be needed.

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References

1. Jemal A, Siegel R, Ward E, Hao Y, Xu J, Thun MJ. Cancer statistics, 2009. CA Cancer J Clin. 2009; 59:225–249. [PubMed: 19474385]
2. Oeffinger KC, Mertens AC, Sklar CA, Kawashima T, Hudson M, Meadows M. Chronic health condition in adult survivors of childhood cancer. New Engl J Med. 2006; 355:1572–1782. [PubMed: 17035650]
3. Bhatia S, Sklar C. Second cancers in survivors of childhood cancer. Natl Rev Cancer. 2002; (2):124–132.
4. Children's Oncology Group. Late effects screening guidelines (2008; Version 3.0, March). Retrieved July 5, 2011, from http://www.survivorshipguidelines.org
5. Hollen PJ. A clinical profile model to predict decision making, risk behaviors, and quality of life of cancer-surviving adolescents: Part I. Cancer Nurs. 2000; 23(4):247–257. [PubMed: 10939172]
6. Hollen PJ. A clinical profile model to predict decision making, risk behaviors, and quality of life of cancer-surviving adolescents: Part II. Cancer Nurs. 2000; 23(5):337–343. [PubMed: 11037953]
7. Hollen PJ, Hobbie WL, Donnangelo SF, Shannon S, Erickson J. Substance use risk behaviors and decision-making skills among cancer-surviving adolescents. J Pediatr Oncol Nurs. 2007; 24:264–273. [PubMed: 17827492]
8. Hollen PJ, Tyc V, Shannon S, Donnangelo SF, Hobbie W, Hudson M, Smolkin M, Petroni G. Factors related to decision making and substance use in adolescent survivors of childhood cancer. Under review.
9. Kahalley LS, Robinson LA, Tyc VL, Hudson MM, Leisenring W, Stratton K. Risk factors for smoking among adolescent survivors of childhood cancer: A report from the childhood Cancer Survivor Study. Pediatr Blood Cancer. 2012; 58:428–434. [PubMed: 21618409]

10. Klosky JL, Howell CR, Li Z, Foster RH, Mertens AC, Robison LL, Ness KK. Risky health behavior among adolescents in the Childhood Cancer Survivor Study Cohort. Journal of Pediatric Psychology. [Advance Access published March 16, 2012]
11. Kahalley LS, Robinson LA, Tyc VL, Hudson MM, Leisenring W, Stratton K, et al. Attentional and executive dysfunction as predictors of smoking within the Childhood Cancer Survivor Study cohort. Nicotine Tob Res. 2010; 12(4):344–354. [PubMed: 20154054]
12. Hollen PJ, Hobbie WL, Finley SM. The relationship of resiliency to decision making and risk behaviors of cancer-surviving adolescents. J Pediatr Oncol Nurs. 2001; 18(5):188–204. [PubMed: 11588760]
13. Eslinger, PJ. Conceptualizing, describing, and measuring components of executive function: A summary. In: Lyon, GR., Krasnegor, NA., editors. Attention, memory, and executive function. Baltimore: Paul. H. Brooks; 1996. p. 367-395.
14. Geidd J, Blumenthal J, Jeffries NO, Castellanos FX, Liu H, Zijdenbos H, et al. Brain development during childhood and adolescence: A longitudinal MRI study. Nature Neuroscience. 1999; 2(10): 861–863. [PubMed: 10491603]
15. Geidd JN. Structural magnetic resonance imaging of the adolescent brain. Annals NY Academy Sci. 2004; 1021:77–85.
16. Geidd JN. Linking adolescent sleep, brain maturation, and behavior. J Adoles Health. 2009; 45(4): 319–320.
17. Campbell LK, Scaduto M, Sharp W, Dufton L, Van Slyke D, Whitlock JA, Compas B. A meta-analysis of the neurocognitive sequelae of treatment for childhood acute lymphocytic leukemia. Pediatr Blood Cancer. 2007; 49:65–73. [PubMed: 16628558]
18. Bhatia S, Contine LS. Late morbidity after successful treatment of children with cancer. Cancer J. 2009; 15(3):174–180. [PubMed: 19556899]
19. Krull KR, Gioia G, Ness KK, Ellenberg L, Recklitis C, Leisenring W, Huang S, Stovall M, Robison LL, Zeltzer L. Reliability and validity of the Childhood Cancer Survivor Study Neurocognitive Questionnaire. Cancer. 2008; 113(8):2188–2197. [PubMed: 18792068]
20. Nathan PC, Patel SK, Dilley K, Goldsby R, Harvey J, Jacobsen C, Kadan-Lottick N, McKinley K, Millham AK, Moore I, Okcu MF, Woodman CL, Brouwers P, Armstrong FD. Guidelines for identification of, advocacy for, and intervention in neurocognitive problems in survivors of childhood cancer: a report from the Children's Oncology Group. Arch Pediatr Adolesc Med. 2007; 161(8):798–806. [PubMed: 17679663]
21. Tercyak KP, Britto MT, Hanna KM, Hollen PJ, Hudson MM. Prevention of tobacco use among medically at risk children and adolescents: Clinical and research opportunities in the interest of public health. J Pediatr Psychol. 2008; 33:119–132. [PubMed: 18165219]
22. O'Connor AM, Stacey D, Entwistle V, Llewellyn-Thomas H, Rovner D, Holmes-Rovner M, et al. Decision aids for people facing health treatment or screening decisions. Cochrane Db Syst Rev. 2003; 3(2):CD001431.
23. O'Connor AM, Bennett C, Stacey D, Barry MJ, Nananda F, Eden KB, et al. Do patient decision aids meet effectiveness criteria of the International Patient Decision Aid Standards Collaboration? A systematic review and meta-analysis. Med Decis Making. 2007; 27:554–574. [PubMed: 17873255]
24. Janis, IL., Mann, L. Decision making: A psychological analysis of conflict, choice, and commitment. New York: The Free Press; 1977.
25. Janis, IL., Mann, L. A theoretical framework for decision counseling. In: Janis, IL., editor. Counseling on personal decisions: Theory and research on short-term helping relationships. 1982. p. 47-48.
26. Hollen PJ. Intervention booster: Adding a decision-making module to risk reduction and other healthcare programs for adolescents. Journal of Pediatric Health Care. 1998; 12:247–255. [PubMed: 9987255]
27. Hersey, P., Blanchard, K. Management of organizational behavior. Englewood Cliffs, NJ: Prentice Hall; 1969.

28. Hollen PJ, Hobbie WL, Finley SM. Testing the effects of a decision-making and risk-reduction program for cancer-surviving adolescents. Oncol Nurs Forum. 1999; 26:1475–1486. [PubMed: 11064879]
29. Tyc VL, Rai SN, Lensing S, Klosky JL, Stewart DB, Gattuso J. Intervention to reduce intentions to use tobacco among pediatric cancer survivors. J Clin Oncology. 2003; 21:1366–1372.
30. Hollen, PJ. Supported by the Oncology Nursing Society Foundation. 2004. A pilot study to test a shortened decision-making intervention for cancer-surviving adolescents. Unpublished data
31. Zackary, RA. Shipley Institute of Living Scale: Revised manual. Los Angles, CA: Western Psychological Services Publishers; 1986.
32. Hollen PJ. Psychometric properties of two instruments to measure quality decision making. Res Nurs Health. 1994; 17:137–148. [PubMed: 8127994]
33. Ryan RM, Connell JP. Perceived locus of causality and internalization: Examining reasons for acting in two domains. J Pers Soc Psychol. 1989; 57(5):749–761. [PubMed: 2810024]
34. Hollen, PJ., Ryan, RM. Decision making, risk motivation, and risk-taking behaviors of adolescents. 1990. Unpublished data
35. Barnes GM, Welte JW. Patterns and predictors of alcohol use among 7–12th grade students in New York State. J Stud Alcohol. 1986; 47(1):53–62. [PubMed: 3485740]
36. Barnes GM, Welte JW, Dintcheff BA. Decline in alcohol use among 7–12th grade students in New York State, 1983–1990. Alcohol Clin Exp Res. 1993; 17:797–801. [PubMed: 8214417]
37. Rohrbach LA, Sun P, Sussman S. One-year follow-up evaluation of the Project Towards No Drug Abuse (TND) dissemination trial. Prev Med. 2009; 51(3–4):313–319.
38. Sloboda Z, Stephens RC, Stephens PC, Grey SF, Teasdale B, Hawthorne RD, Williams J, et al. The Adolescent Substance Abuse Prevention Study: A randomized field trial of a universal substance abuse prevention program. Drug and Alcohol Dependence. 2009; 102(1–3):1–10. [PubMed: 19332365]
39. Teasdale B, Stephens PC, Sloboda Z, Grey SF, Stephens RC. The influence of program mediators on eleventh grade outcomes for seventh grade substance users and nonusers. Drug and Alcohol Dependence. 2009; 102(1–3):11–18. [PubMed: 19345519]
40. Emmons KM, Puleo E, Park E, Gritz ER, Butterfield RM, Weeks JC, Mertens A, Li FP. Peer-delivered smoking counseling for Childhood Cancer Survivors increases rate of cessation: The Partnership for Health Study. Journal of Clinical Oncology. 2005; 23(27):6516–6523. [PubMed: 16116148]
41. Haase JE, Phillips CR. The adolescent/young adult experience. J Pediatr Oncol Nurs. 2004; 21(3): 145–149. [PubMed: 15296043]
42. Centers for Disease Control and Prevention. Smoking and Tobacco Use. Youth and Tobacco Use. Fact Sheets. 2011. Retrieved January 30, 2012, fromhttp:/lwww.cdc.gov/tobacco/data_statistics/fact_sheets/youth_data/tobacco_use/index.htm
43. National Center for Chronic Disease Prevention and Health Promotion. Alcohol & Drug Use. Healthy Youth! Health Topics. 2010. Retrieved April 28, 20’12, fromhttp://www.cdc.gov/healthyyouth/alcoholdrug/
44. Grady PA. News from NINR: Translational research and nursing science. Nurs Outlook. 2010; 58:164–166. [PubMed: 20494692]

Table 1

Overview of Components of Interactive Decision Aid for Adolescents

"DecisionKEYS for Balancing Choices" [Formerly, "Choices for Tomorrow: Decision Making as a Life Tool"]

Learning Objectives and Reinforcement Strategies: By the end of the reinforcement component of the program, adolescents will: (1) acquire an understanding of not only the "how to" (procedures) but also the "why" (outcomes) of quality decision making; (2) recognize the need for quality decision making for consequential decisions faced by adolescents, especially for personal health concerns and lifestyle behaviors of smoking, alcohol consumption, and illicit drug use; (3) apply an easy recall method – the theory of better decision making – to understand and evaluate their own decision making and that of others; (4) prepare "Right for Me" choices as a part of self-care; and (5) use quality decision making as a life tool to enhance their early and late quality of life. Teaching/learning strategies include: (1) repetition, with standardization of content by CD-ROMs; (2) memory aids in the workbook to break down the parts of the decision-making process; (3) practice in the context of adolescence; (4) application to real world problems (risk behaviors) of the adolescent; and (5) multimodal approaches to content at a variety of times for reinforcement.

1. Decision-Making Module ©: A 17-minute video (now CD-ROM) on decision making will be used to teach a quality process to the teen. This module also includes a short curriculum for the healthcare professional. The intent of this live-action, color video is to teach an easy-recall method for making lifestyle and other health-related decisions. This method includes the basics of a psychological theory, the Janis and Mann (1977) conflict model of decision making, which has successfully been taught to teen survivors and their healthy peers in the Hollen's previous studies. A cameo spot in the video includes an introduction by one of the theorists, Dr. Leon Mann, University of Melbourne, Australia. Characteristics of the video, depicting 17 decisions (including engaging in smoking as well as alcohol and street drug use), include cultural diversity within the illustrations and live actors, diverse positive role models, appealing musical score, and digital video effects to stimulate interest. A special feature that appeals to teens is the illustrated and easy-to-remember names for five decision-making styles. Several other highlights of the module that were adapted from Janis and Mann are the balance sheet procedure for evaluating the pros and cons of a risky decision and 7 points for grading decision making. The workbook includes key components of the decision theory, such as the decision-making styles with their illustrations, as well as the balance sheets (self-checking technique) for practice during home assignment. This module has been developed/tested by the PI. Shown in full at initial visit and as booster. Script reading level = 7th grade level, using Flesh-Kincaid readability index.
2. Smoking Module: An 11-minute, award-winning video for grades 7–12 will be used to provide insight into why some teens start smoking and why it's so hard for them to stop. This live-action, color video, "Smoking: The Burning Truth" from Sunburst, a Houghton Mifflin Company, uses teen interviews to drive home the message of health consequences to smoking behavior. Facts are presented, such as the effect of nicotine on the body organs, and that those most likely to smoke are those whose parents smoke or friends smoke. Converted to CD-ROM.
3. Alcohol/Drug Use Module: A 10-minute portion (2 vignettes) from an award-winning video for grades 7–12 will provide meaningful adolescent context for alcohol use, the most prevalent risk behavior for teens. A live-action, color video, "Teens, Drugs, and Peer Pressure" from Sunburst, provides insight into the consequences of party drinking on interpersonal relationships as well as shows role playing of refusal strategies for drugs by two teens. Portion shown at initial visit; shown in full (18 min.) as booster. Converted to CD-ROM.
4. Interactive Substance Use Module: A 30–60 minute researched-based, interactive CD-ROM for grades 7–12 provides practice in deciding how to handle difficult situations with substance use, such as alcohol and marijuana. This module, "On the Road" from Will interactive, Inc., enables students to make choices about drug use by "playing it out before they live it out" and discover for themselves that good decisions result in good outcomes, while poor ones can lead to disaster. Teens can take as much time as they like, choose as many different paths as they like (or repeat) in the comfort of own home or library.
5. Health Status Module: A 15-minute face-to-face, tailored discussion with the health professional that includes using the Risk Behavior Facts Sheet ©, developed by Hollen, Hobbie, and Hudson (2006), and helping the teen to identify "Right for Me" (RFM) choices that consider one's past medical history. The concept of RFM choices was coined to support teens with special needs in responding comfortably with pre-chosen responses when pressured by peers. Estimated at 7th grade reading level.

Table 2

Summary of Accrual, Attrition and Evaluable Cases within Randomized Groups by Cancer Center

Study Status	Site #1 (Hackensack Univ)	Site #2 (Long Beach Med Ctr)	Site #3 (St. Jude)	Total
Total Accrual	71	46	126	243
Total Attrition (Lost)	9 (13%)	7 (15%)	14 (11%)	30 (12%)
Total Evaluable	62 (87%)	39 (85%)	112 (89%)	213 (88%)
Low Risk	19	12	41	72
High Risk	43	27	71	141
Evaluable EC Cases [a]	29 (85%)	19 (83%)	54 (86%)	102 (85%)
Evaluable UC Cases [b]	33 (89%)	20 (87%)	58 (92%)	111 (90%)

[a] Enhanced care group or treatment.

[b] Usual care group or comparison group.

Table 3

Presenting Sociodemographic and Disease-Related Characteristics for 243 Cancer-Surviving Adolescents from Three Regions in the U.S.

Characteristic		14–19 Years (N = 243)
Age (Years)	M (SD)	16.3 (1.6)
Ages 14–16		135 (56%)
Ages 17–19		108 (44%)
Sex	*f (%)*	
Males		115 (47%)
Females		128 (53%)
Race/Ethnicity	*f (%)*	
Caucasian		176 (72%)
African American		24 (10%)
Latino [a]		28 (12%)
Asian/Asian American		8 (3%)
Native American		1 (0%)
Other		6 (2%)
Family Income < $50,000 [b]	*f* (%)	68 (33%)
Intact Families [c]	*f* (%)	168 (78%)
Age at diagnosis	*M (Range)*	5.1 (0–14)
Before 5 years of age at diagnosis	*f (%)*	126 (52%)
Cranial irradiation (1800 Gy or more)	*f (%)*	39 (16%)
Methotrexate (intrathecal; high dose systemic)	*f* (%)	116 (48%)
Dexamethasone therapy	*f* (%)	55 (23%)
Learning late effects	*f* (%)	27 (11%)
Academic problems [d]	*f* (%)	*160 (66%)*
Household substance use	*f* (%)	*187 (90%)*
Peer substance use (close friend)	*f* (%)	*123 (56%)*
Diagnosis		
Acute lymphoblastic leukemia	*f* (%)	98 (40%)
Acute myelogenous leukemia	*f* (%)	7 (3%)
Hodgkin lymphoma	*f* (%)	7 (3%)
Non-Hodgkin lymphoma	*f* (%)	15 (6%)
Sarcoma	*f* (%)	21 (9%)
Embryonal	*f* (%)	48 (20%)
Brain tumors	*f (%)*	29 (12%)
Other	*f* (%)	18 (7%)

[a] Hispanics may be of any race. As assessed, ethnicity overrode race.

[b] Some missing data for emancipated adolescents.

[c] Parents married and family together.

[d] Parent report and medical record extraction; one case missing.

Table 4

Clinical Profile of Adolescents Lost to Follow-up Compared to Those Who Completed the Study

Characteristic	Lost to Attrition (n = 30)	Completed Study (n = 213)
Age (older; ≥ 16 years)	24 (80.0%)	133 (62.4%)
Sex (Males)	18 (60.0%)	97 (45.5%)
Race (Caucasian)	23 (76.7%)	153 (71.8%)
Intact Families [a,b]	21 (75%)	147 (78.6%)
<5 Years of Age at Dx	16 (53.3%)	110 (51.6%)
Diagnosis		
Acute lymphoblastic leukemia	9 (30.0%)	89 (41.8%)
Embryonal	7 (23.3%)	41 (19.2%)
Brain Tumors	4 (13.3%)	25 (11.7%)
Other	10 (33.3%)	58 (27.2%)
Academic Problems [c]	12 (40.0%)	52 (24.4%)
Engaging in ≥ 1 Risks	19 (63.3%)	103 (48.4%)

[a] Parents married and family together.

[b] Emanicpated teens excluded in intact families.

[c] Parent report and medical record extraction.

Table 5

Adherence to Intervention Boosters at Study Timepoints

Study Group	2-Month Booster (n = 95)	4-Month Booster (n = 83)	6-Month Booster (n = 89)	High Risker 9-Month Booster [a] (n = 51)
2009 Cohort Intervention Group [b]	90 (95%)	75 (90%)	88 (99%)	48 (94%)

Frequencies of “somewhat true” and “very true” to intervention boosters; judged by panel of three.

[a] Booster delivered again to high riskers as remediation by nurse practitioner.

[b] n = 102; not all completed within arbitrary time window of one month.

Table 6

Summary of Intervention Outcomes of Decision Aid for Adolescent Survivors of Childhood Cancer

		6 Months Follow-up			12 Months Follow-up		
Outcome	**Model Factor** [a]	**Model Est**	**SE**	**P-value**	**Model Est**	**SE**	**P-value**
Decision making (DMQS)	Total DMQS (E-U)	−0.13	0.43	.77	−0.14	0.38	.72
	Low Risk (E-U)	−0.03	0.69	.97	−0.22	0.63	.73
	High Risk (E-U)	−0.23	0.52	.66	−0.06	0.45	.89
	TX=U (Avg. over HR)[b]	15.94	0.33	-	16.25	0.29	-
	TX=E (Avg. over HR)[b]	15.81	0.33	-	16.11	0.29	-
Risk motivation (RMQ)	Total RMQ (E-U)	5.75	2.84	.04*	−1.56	2.66	.56
	Low Risk (E-U)	8.63	4.56	.06**	−3.37	4.35	.44
	High Risk (E-U)	2.88	3.37	.40	0.25	3.06	.94
	TX=U (Avg. over HR)[c]	26.64	2.33	-	32.25	2.18	-
	TX=E (Avg. over HR)[c]	32.40	2.21	-	30.69	2.09	-
RMQ – Cigarettes	Total Subscale (E-U)	1.22	1.01	.23	−0.69	0.93	.46
	Low Risk (E-U)	1.78	1.61	.27	−1.32	1.52	.38
	High Risk (E-U)	0.66	1.20	.59	−0.05	1.07	.96
	TX=U (Avg. over HR)[d]	9.64	0.83	-	11.67	0.77	-
	TX=E (Avg. over HR)[d]	10.86	0.79	-	10.98	0.74	-
RMQ – Alcohol	Total Subscale (E-U)	2.77	1.15	.017*	0.56	1.08	.61
	Low Risk (E-U)	4.47	1.84	.016*	0.15	1.75	.93
	High Risk (E-U)	1.06	1.37	.44	0.97	1.26	.44
	TX=U (Avg. over HR)[d]	7.18	0.87	-	8.15	0.81	-
	TX=E (Avg. over HR)[d]	9.95	0.86	-	8.71	0.80	-
RMQ – Illicit drugs	Total Subscale (E-U)	2.59	1.14	.024*	−0.82	0.97	.40
	Low Risk (E-U)	4.35	1.82	.018*	−1.05	1.58	.51

		6 Months Follow-up			12 Months Follow-up		
Outcome	**Model Factor** [a]	**Model Est**	**SE**	**P-value**	**Model Est**	**SE**	**P-value**
	High Risk (E-U)	0.82	1.37	.55	−0.59	1.12	.60
	TX=U (Avg. over HR)[d]	10.02	0.98	-	13.02	0.84	-
	TX=E (Avg. over HR)[d]	12.60	0.97	-	12.20	0.81	-

[a]Model-based estimates: adjusted for outcome value at baseline, site, risk group, site*risk group interaction, treatment group, treatment group*risk group interaction, and inflator status.

TX=Treatment Group; E=Enhanced Care; U=Usual Care; HR=Risk Group.

[b]Estimates at 6 and 12 months assume baseline DMQS equal to 16.

[c]Estimates at 6 and 12 months assume baseline RMQ equal to 30.

[d]Estimates at 6 and 12 months assume baseline RMQ components equal to 10.

*p<.05;

**p<.10

Table 7

Intervention Exit Evaluation by Cancer-Surviving Adolescents in 2009 Cohort Among Enhanced Care Group (n = 100 [a]) at Study Exit

Evaluation Criteria	*f* (%)
Clear description of possible late effects of my cancer treatment was presented	94 (94%)
Clear description of the Substance Use Risk Behavior Fact Sheet was presented	98 (98%)
Clear description of risk behaviors to avoid, based on possible late effects of my cancer treatment was presented	98 (98%)
Understand the basic decision-making theory	95 (95%)
Believe the decision-making theory can be useful	98 (98%)
Can explain the decision-making theory to others [b]	90 (91%)
Able to take steps to make an important decision	98 (98%)
Perceived the decision-making CD-ROM program as helpful	95 (95%)
The decision-making program was interesting	86 (86%)
The decision-making program was helpful	97 (97%)

Frequencies of “somewhat true” and “very true” to intervention evaluation criteria.

[a] Lost to follow-up = 10; withdrew = 8; missing value = 1.