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STUDY INFORMATION

Official Title of the Study: Bright IDEAS-Young Adults: Problem-Solving Skills Training to Reduce Distress among Young Adults with Cancer

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INTERVENTIONAL
RESEARCH PROTOCOL TEMPLATE
(HRP-503a)

STUDY INFORMATION

- **Title of Project:**
  Bright IDEAS-Young Adults: Problem-Solving Skills Training to Reduce Distress among Young Adults with Cancer

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- **Protocol Version and Date:**
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1.0 Research Design

1.1 Purpose/Specific Aims

The purpose of this project is to evaluate efficacy of Bright IDEAS, an evidence-based problem-solving skills training (PSST) program, as a supportive care intervention for adolescent and young adult (AYA) cancer patients compared with enhanced usual psychosocial care with 344 young adult patients newly diagnosed with cancer.

A. Objectives

We will evaluate the efficacy of Bright IDEAS-YA by examining changes in psychosocial outcomes from baseline to post-intervention (3 months) and follow-up (6, 12, and 24 months).

We will determine the extent to which changes in aspects of problem-solving ability mediate the intervention effects and examine relevant moderators.

B. Hypotheses / Research Question(s)

Aim 1: Evaluate the efficacy of Bright IDEAS-Young Adults on psychosocial outcomes.

Hypothesis 1: Participants who receive the Bright IDEAS-YA intervention will report lower depression, anxiety, and impairment in health-related quality of life over time than participants who receive usual psychosocial care.

Aim 2: Determine the extent to which problem-solving ability mediates treatment effects.

Hypothesis 2: The effects of the intervention will be mediated by improved positive problem orientation and rational problem-solving skills, and reduced negative problem orientation, impulsive style, and avoidant style.

Aim 3 (Exploratory): Examine moderators of treatment effects.

Sex, financial strain, and baseline unmet needs will be examined as potential moderators of treatment effects to identify subgroups who benefit most from this intervention.

1.2 Research Significance

Young adults with cancer diagnosed between the ages of 18 to 39 are increasingly recognized as a vulnerable group with unique emotional, social, and practical needs due to the intersection of cancer treatment and normal developmental processes.[1] Although a cancer diagnosis at any age is highly stressful, cancer diagnosis and treatment during the critical period of young adulthood is particularly challenging. A cancer diagnosis during this time can hinder the process of achieving desired developmental tasks in all life domains, including identity, education, career, financial independence, relationships, and starting a family.[2,3] These disruptions put young adults at particularly high risk of negative outcomes due to their underdeveloped problem-solving ability (i.e., capacity to find effective solutions to problems) and limited resources (i.e., less experience dealing with similar challenges, unstable social support). Ongoing concerns and unmet informational, emotional, and practical support needs are associated with increased emotional distress and poorer health-related quality of life.[2,4] A critical gap in the field is the lack of evidence-based interventions to address the unique concerns of the young adult population.

To address this clinical care gap, a behavioral intervention is needed that provides skills to manage the diverse and numerous stressors associated with a cancer diagnosis in the context of life transitions, addresses underdeveloped problem-solving ability characteristic of this age group, and is relatively simple to learn and use during the highly stressful time following cancer diagnosis. Problem-solving skills training is uniquely suited to fit this need, as it teaches a global life skill to help young adults address *any* concern, is tailored to individual needs, and is relatively simple to learn and use. Problem-solving skills training is an application of problem-solving therapy, which has accumulated a large body of evidence showing it successfully improves problem-solving ability, reduces negative affect, and improves health-related quality of life.[5678-1112-1512-1516 17138]

1.3 Research Design and Methods

Bright IDEAS-YA will be tested with young adult cancer patients in a two-arm parallel randomized controlled trial (RCT) of the intervention versus enhanced usual psychosocial care.

A. Research Procedures

Research staff will collect participants' contact information for tracking and study management. Following consent, baseline surveys (see section 1.9 Data Collection) will be administered online using DatStat, a HIPAA-compliant electronic data capture system. Research staff will either provide a tablet for patients to complete the online survey (paper copies will be available as back-up in the event of significant internet disruption) or email/text a link for completion. If a participant does not complete the baseline survey during an initial in-person visit, we will email a link for completion. After completion of the baseline survey, participants will be randomly assigned 1:1 to either the intervention or enhanced usual psychosocial care comparison group. The study biostatistician will determine a randomization scheme stratified by site, age group (18-29 vs. 30-39 based on definitions of emerging adults and young adults[18])using an undisclosed block size to balance group assignment within each site and age group. This schema will be uploaded to the DatStat program such that completion of the baseline survey will trigger assignment according to the schema via a message to study staff. Participants will then be notified of assignment via an automatic Welcome email through DatStat. For those assigned to the intervention group, study staff will assign a Bright IDEAS-YA trainer, schedule for the participant and trainer to meet at the patient's next medical visit or schedule a virtual meeting to complete the first Bright IDEAS-YA session, and mail/email Bright IDEAS-YA manual, worksheets and the list of resources from the NCCN adolescent and young adult patient guildeline.[19] For those assigned to the enhanced usual psychosocial care group, study staff will mail/email the list of resources from the NCCN adolescent and young adult patient guidelines.[19] All participants will also be mailed a small gift (e.g., Bright IDEAS stress ball) as a token of appreciation for their time and effort. Trainers will schedule all subsequent sessions directly with participants. All participants will be asked to complete surveys at 3 months (post-intervention), 6 months (3-month follow-up), 12 months (9-month follow-up), and 24 months (21-month follow-up). DatStat will send survey links and subsequent reminders via email/text according to the survey schedule. Study staff will also call and/or send text message reminders to participants to facilitate completion of online surveys as needed. All participants will continue to receive usual psychosocial care per institutional standards, as well as a standardized list of young adult-specific resources (see Enhanced Usual Psychosocial Care section). Usage of these services will be tracked via patient self-report at each survey. Participants will receive $25 for each of the first four surveys completed, and a $50 gift card for completing the final survey (up to $150 total).

B. Data Points

All participants will be asked to complete follow-up surveys at 3 months (post-intervention), 6 months (3-month follow-up), 12 months (9-month follow-up), and 24 months (21-month follow-up). Study staff will also collect data regarding participant completion of intervention sessions and trainer fidelity. Intervention sessions will be audio-recorded with participant permission for fidelity evaluation and trainer supervision.

C. Study Duration

The overall study will last 5 years. Each subject will participate for 2 years.

D. Endpoints

The primary endpoint will be the estimated change from baseline to 6 months in depression, anxiety, and psychosocial HRQOL (i.e., Social/Family Well-Being and Emotional Well-Being), selected to allow for examination of temporal mediation of problem-solving ability post-intervention. The changes from baseline to 3 months, 12 months, and 24 months will be considered secondary endpoints.

1.4 Preliminary Data

The Bright IDEAS intervention has demonstrated effectiveness in increasing problem-solving skills, decreasing distress, and reducing symptoms of depression and post-traumatic stress of caregivers who are managing their child's cancer treatment.[20-22] We developed Bright IDEAS-Young Adults (Bright

IDEAS-YA) to meet the needs of young adult patients during the critical months following a new cancer diagnosis. We used the Bright IDEAS acronym to remind participants of essential components of the intervention – fostering positive (vs. negative) problem orientation and using rational (vs. impulsive or avoidant) problem-solving skills. We completed a pilot study to gather data about the feasibility of using Bright IDEAS with AYA cancer patients (n=40). Analysis of the first 24 participants with complete data showed that patients reported a high satisfaction with the intervention (*M* = 4.6 out of 5, *SD* = 0.5). As expected, patients used Bright IDEAS-YA to solve a variety of problems across life domains, including: (1) coping with the uncertainty of cancer; (2) deciding to go back to school; (3) returning to work/figuring out career; (4) feeling isolated from friends; (5) eating healthy/losing weight; (6) dating with cancer; and (7) challenges moving back home with parents. Qualitative feedback indicated that participants found Bright IDEAS-YA to be easy to learn and use, emphasizing the systematic approach and structure as most helpful. They noted that it was a skill they learned and can now use going forward. Young adults also reported that having a supportive trainer teach the skill was valuable.

Results were promising, with moderate to large effects on problem-solving ability (particularly improved positive problem-orientation and rational problem solving and reduced negative problem orientation and avoidant style). We found small to moderate improvements in depression, anxiety, and emotional health-related quality of life (HRQOL). We concluded that Bright IDEAS-YA is feasible and acceptable, with promising results that suggest efficacy testing is warranted.

1.5 Sample Size Justification

Up to 344 YA patients newly diagnosed with cancer will be enrolled across sites. There are no exclusion criteria based on gender or race. We expect the percentage of male/female and minority race participants enrolled to reflect the distributions seen at three sites.

Power focused on Aim 1 and was calculated based on effect size estimates that incorporate both estimates of change in mean as well as standard deviations from our pilot data and compared against published data, assuming an intent-to-treat analysis. For the proposed study, we assume the standard deviation will be 70% of the pilot standard deviation, due to tightening of the eligibility criteria to exclude those with cancer recurrence and recruit within 4 months of first diagnosis. In addition, we assume that the control group will see 20% of the change in depression compared to intervention. This leads to a Cohen effect size of 0.26. Assuming 344 subjects with 30% dropout, we will have 85% power to detect an effect of intervention on the Depression score. Similar calculations demonstrate 82% power to detect an effect of intervention on Anxiety. If we observe a group difference closer to 3.22 for Depression, cited as clinically meaningful in previous literature,[23] then under the assumptions listed above, our Cohen effect size will be closer to 0.29 and our power for the primary outcomes will be higher. For HRQOL, pilot Cohen estimates of effect size and estimates from the literature with the assumptions above would yield a Cohen effect size of 0.32, which would yield a power of 95%.[2425]

1.6 Study Variables

A. Independent Variables, Interventions, or Predictor Variables

Bright IDEAS-YA Intervention: Bright IDEAS-YA is a manualized problem-solving skills training intervention conducted by a trainer who teaches the participant the Bright IDEAS stepwise approach to problem-solving and guides the participant through solving their own problems using the Bright IDEAS approach and worksheets. The intervention consists of six 45-minute one-on-one sessions held at the clinic/hospital, by telephone between a patient and a trainer, or via video-conference session on HIPPA compliant Doxy.me (https://doxy.me/), or another institutionally-approved telehealth platform (e.g. Rutgers Zoom, site-specific telehealth platforms). Sessions are held weekly. However, due to the changing demands of cancer treatment and side effects that sometimes cause patients to feel too ill to do a session as scheduled, we allow up to 12 weeks to complete the 6

sessions. During the first face-to-face or virtual session, participants will be introduced to the Bright IDEAS model and the participant manual that explains the approach and provides worksheets for systematically solving problems. "Bright" refers to the sense of optimism that is critical to finding constructive solutions to difficult challenges. The letters in IDEAS represent the five essential steps of the PSST problem-solving approach (see Figure 1): "I"= "Identify the problem"; "D"="Determine the options"; "E"="Evaluate options and choose the best"; "A"="Act"; and "S"="See if it worked." Sessions 2-5 involve using the model to work through challenges identified by the participant. Session 6 involves a summary of the model, discussion of how the participant can continue to use the skills learned after the sessions end, and solicitation of feedback regarding the program and the website/app. See Table 1 for overview of each session.

Table 1. Overview of Bright IDEAS-YA Intervention Sessions

Session	Goals/Activities	Mapping to Problem-Solving Ability
1	1. Establish rapport 2. Explain general rationale for Bright IDEAS-YA approach 3. Review the 5 steps – Identify, Define your options, Evaluate options and choose, Act, See if it worked 4. Establish basic expectations for participation	- Reframes stressors as challenges that can be overcome, enhancing positive problem orientation and reducing negative problem orientation. - Introduces 5-step approach, building rational problem-solving skills.
2-5	1. Review homework from last session 2. Work on a patient-identified problem using Bright IDEAS-YA worksheets 3. Identify homework for participant to use Bright IDEAS-YA between sessions	- Apply skills systematically to personal problems encourages self-efficacy to work through challenges (positive problem orientation), builds rational problem-solving skills, reduces impulsive responding, and prevents avoidance. - Homework and follow-up reduce avoidance.
6	1. Review and reinforce the elements of Bright IDEAS-YA 2. Elicit feedback about experience using Bright IDEAS-YA 3. Review "relapse prevention" – continue to use skills instead of returning to prior problem-solving strategies 4. Thank patient for their participation	- Reviewing success fosters self-efficacy and positive problem orientation. - Relapse prevention reinforces continued use of these skills to any challenge young adults encounter, including achieving normative life milestones.

Enhanced Usual Care Comparison Group: The Enhanced Usual Psychosocial Care group will complete surveys, receive the list of resources from the NCCN adolescent and young adult patient guildeline,[19] and receive usual psychosocial care per institutional standards. Usual psychosocial care generally consists of an initial social work consultation at the time of diagnosis, referral to necessary social resources such as transportation or financial assistance services according to patient needs, and optional supportive counseling or pastoral care if sought by the patient. Ongoing service use is determined by patient needs and preference. The standardized NCCN list of resources will be given to patients in both arms to control for awareness of young adult resources. Listed resources will include websites and organizations that provide informational (e.g., websites with information about young adult cancer treatment and side effects), emotional (e.g., young adult online support groups) and practical (e.g., transportation assistance, financial assistance) support services for young adults.

B. Dependent Variables or Outcome Measures

We will evaluate changes in the following outcomes: depression, anxiety, and health-related quality of life. See section 1.9B Study Instruments for details on each measure.

1.7 Drugs/Devices/Biologics

N/A

A. Drug/Device Accountability and Storage Methods
N/A

1.8 Specimen Collection

A. Primary Specimen Collection
N/A

B. Secondary Specimen Collection
N/A

1.9 Data Collection

A. Primary Data Collection

- **Location**: Surveys can be completed in a private space during a patient's routine treatment visit at each respective site or at home by the participant. The survey link will be emailed and/or texted to the participant, or a paper copy will be sent to their home address, if requested.
- **Process of Data Collection**: Surveys will be administered online using DatStat, a HIPAA-compliant electronic data capture system. For in-person administration, research staff will provide a tablet for patients to complete the online survey (paper copies will be available as back-up in the event of significant internet disruption). For at-home completion, research staff will email or text the link to the survey to participants, or, if preferred, a paper copies will be mailed to them with a postage-paid return envelope.
- **Timing and Frequency**: Surveys will be administered five times – once at baseline, then again at 3 months (post-intervention), 6 months (3-month follow-up), 12 months (9-month follow-up), and 24 months (21-month follow-up). We anticipate each survey will take approximately 25 minutes to complete.
- **Procedures for Audio/Visual Recording**: Participants will be asked to give permission to audio record the intervention sessions for evaluation of treatment integrity and supervision of the trainers. As part of the consent process, participants will be told that it is completely voluntary to agree to the recording and they can change their mind at any time. The trainer will also ask the patient if it is okay to record at the beginning of each session. It will not be considered a protocol violation if technical issues prevent or disrupt recording or a trainer forgets to record a session. Digital recordings will be transferred off of the audio recorders as soon as possible following each session to the study folder on a cloud-based file storage application for a secure storage, management and sharing of digital files (e.g., Rutgers OneDrive, site-specific approved platform), and then erased from the recorder. Recordings will be labeled with a subject number rather than any identifiable information. Session audio recording files may be securely transferred between members of the research team using Rutgers secure large file transfer service (LiFT) or site-specific secure file transfer methods.

- **Study Instruments**:
  - Social Problem-Solving Inventory-Revised Short Form (SPSI-R:S)[26] is a 25-item self-report measure of five theoretically-important constructs of everyday problem-solving, including positive problem orientation, negative problem orientation, rational problem-solving style, impulsive/carelessness style, and avoidant style. Summary scores ranging from 0-20 are computed for each subscale, as well as an overall score. A higher Total score indicates better problem-solving ability. The SPSI-R:S has demonstrated

strong reliability and validity estimates in our prior work[20,22,27] and other studies.[26]

- PROMIS Depression Short Form (v1.0 8a) and PROMIS Anxiety Short Form (v1.0 8a)[28] are 8-item measures of depressive symptoms and anxiety from the NIH Patient-Reported Outcomes Measurement Information System (PROMIS).[29,30] Respondents report symptoms on a 5-point rating scale from 1 (*never*) to 5 (*always*) in the past 7 days, with higher scores indicating higher levels of negative affect. These measures are scored using the online Assessment Center, which calculates a total raw score and translates it into a standardized T-score with a mean of 50 and standard deviation of 10. Depression items focus on affective and cognitive symptoms of depression (sadness, worthlessness, loss of interest) rather than somatic symptoms (change in sleep or appetite) to avoid potential confounding with medical conditions. The Anxiety scale focuses on fear (panic), anxious misery (worry, dread), and hyperarousal (tension, nervousness). These measures have demonstrated clinical validity and responsiveness to change.[31,32]
- The Functional Assessment of Cancer Therapy – General (FACT-G v4)[33] is a 27-item widely used and well-validated measure of health-related quality of life for adult cancer patients ages 18 and older. It yields an overall General Total score and four subscales: Physical Well-Being (PWB), Social/Family Well-Being (SWB), Emotional Well-Being (EWB) and Functional Well-Being (FWB). Respondents rate each item on 5-point Likert scale from 0 (*not at all)* to 4 (*very much)* in the past 7 days. Each scale is a summary of responses, ranging from 0 to 28 for PWB, SWB, and FWB, 0 to 24 for EWB, and 0 to 108 for General Total.
- Financial strain, a marker of socioeconomic status particularly relevant for young adults with cancer, will be measured using the Comprehensive Score for Financial Toxicity (COST),[34] an 11-item scale of financial toxicity associated with cancer treatment. Respondents rate each item on a 5-point Likert scale from 0 (*not at all)* to 4 (*very much)* in the past 7 days. The measure yields a total summary score, with higher scores indicating greater financial strain. It has demonstrated adequate internal reliability and face validity.[34] These items will be administered at baseline, 12 months, and 24 months. Given that young adults may demonstrate different levels of financial independence, those who indicate that they are not primarily responsible for paying for their medical care will respond to only two items regarding financial stress at baseline only. Those who indicate financial responsibility at baseline and everybody at 12 months, and 24 months follow-up, will respond to the full 11-item scale.
- Unmet needs and concerns will be measured using the Adolescent and Young Adult Oncology Screening Tool, which is an adapted version of the NCCN Distress Thermometer and problem checklist to include problems specific to young adults.[35] Participants first rate their distress on a 0-10 scale. Next, they are asked to check off areas of concern from the past week, including practical (e.g., housing arrangements, work, bills, transportation), family (e.g., parents, siblings, partner), emotional (e.g., sadness, isolation, guilt), social (e.g., isolation from friends, missing important events), physical (e.g., body image, sexual concerns, sleeping difficulty), and informational (e.g., understanding information, feeling involved in decision-making) needs. A total score from 0 to 51 is calculated. This checklist is used to prompt selection of problems to be addressed in the intervention for those assigned to receive the intervention.
- Demographic/Medical: Patients will report age, sex, independent living status, race, ethnicity, school/work status, health insurance coverage, marital status, whether he/she is a parent, and income. Potentially time-varying characteristics (i.e., school/work status, insurance status, income) will be repeatedly assessed at all follow-up surveys. Cancer diagnosis, date of diagnosis, and treatment received (e.g., chemotherapy, radiation, hematopoietic stem cell transplant), will be abstracted from the medical record by research staff. This information will be used to describe the sample and used as

covariates in the model (except for sex, which will be evaluated as a moderator). Observational research with adolescents and young adults found being on treatment and not being in school or working to be the primary drivers of distress rather than age, race, or cancer type.[36]

- Supportive Services Received will be measured via self-report where participants will check whether they have used or received services in the following categories: psychosocial support, informational and practical support, fertility or sexual health, physical/wellness services and integrative medicine services) since diagnosis (at baseline) or the prior survey (at 3, 6, 12, and 24 months). If they check yes, they will be asked to specify the service used.
- PROMIS Social Isolation –Short Form 4a is a four-item measure assessing perceptions of social isolation from the NIH Patient-Reported Outcomes Measurement Information System (PROMIS.) [29,30] Each question uses a 5-point rating scale from 1 (*never*) to 5 (*always*) in the past 7 days, with higher scores indicating higher levels of perceived isolation.
- Participant Satisfaction will be assessed using a 10-item questionnaire derived from the Multi-Dimensional Treatment Satisfaction Meausre[37] to assess utility of intervention-specific components (e.g., the user manual, worksheets), attitude towards the intervention, trainer competence, and perceived benefit attributable to the intervention, plus 3open-ended questions eliciting ideas for improvements. This questionnaire will only be administered at post-intervention to intervention arm only (3 months).
- Coronavirus Impact Scale[38] is a 12-item scale to assess how COVID-19 has changed a person's life (e.g., routine, family income, food access, medical and mental health access, access to family and friends, etc.) This will be administered at baseline.
- Treatment Integrity (TI) Checklists will be completed by a qualified member of the research team from any site. The reviewer will listen to the randomly selected session audio recording and complete a structured checklist specific to the manualized content of each session (separate checklists for session 1, 2-5, and 6).[22] Items rate the quality of therapeutic alliance (e.g., “trainer and participant clearly engaged, with good rapport, working together throughout session”), communication (e.g., “trainer uses a variety of techniques to clearly communicate that young adult is being listened to throughout session”), and fidelity to the treatment manual (e.g., “session includes application of Bright IDEAS-YA steps to a participant problem,” “trainer offers 3 or more strategies for relapse prevention”).
- **Internal Tracking** (completed by research team)
  - Eligibility Checklist: This checklist will verify eligibility and document reasons for non-participation.
  - Participant Progress Tracking: The Research Assistant at each site will be responsible for registering and tracking all participants at their site using DatStat, a HIPAA-compliant cloud-based software used for participant tracking, study flow, and administration of patient surveys. Each relying site will only have access to their own participant data to maintain confidentiality. DatStat automates study workflow to remind Research Assistants of upcoming or overdue study tasks (such as tracking of session and survey completion) and can directly email participants links to complete surveys and reminders according to the study schedule. This system also tracks participant incentives. DatStat also produces study flow charts to monitor recruitment and retention throughout the study.

- **Ethnographic Studies, Interviews, Or Observation**: For the supplemental work, semi-structured interview/focus group guides will be used to conduct the interviews.

- **Subject Identifiers**: We will collect participant name, address, telephone number, and email address for contact purposes throughout the study. Each participant will be assigned a participant ID number and we will keep a key linking the ID number to name for up to 6 years after the close of the study. We will collect MRN, date of birth, and date of diagnosis to abstract medical treatment data, calculate age, and calculate time since diagnosis. At the conclusion of the study, identifiers will be removed from the database and de-identified data kept indefinitely.

B. Secondary Data Collection

- **Type of Records**: Medical records will be accessed to abstract: date of birth, date of diagnosis, type of diagnosis to determine eligibility and describe the study sample. At the last survey follow-up, records will be accessed to document treatment(s) received, relapse status, comorbid psychological conditions, any documented social concerns, hospice referral, COVID-19 vaccination history, and use of psychosocial services. For those subjects who do not remain in the study until last follow-up due to various reasons (e.g., no longer interested, deceased, etc), data abstraction will occur at time subjects are exited from the study or as soon as practical.
- **Location**: Research staff with authorization to access medical records will access the medical records at each site using an authorized workstation to access the record.
- **Inclusion/Exclusion**: See Inclusion/Exclusion criteria in section 4.1C.
- **Data Abstraction Form(s):** See Data Abstraction Form.

1.10 Timetable/Schedule of Events

Arm	Baseline Survey & Randomization	Bright IDEAS-YA Sessions	3-month Survey	6-month Survey	12-month Survey	24-month Survey
Bright IDEAS-YA Intervention	X	X	X	X	X	X
Enhanced Usual Care Comparison	X		X	X	X	X

2.0 Project Management

2.1 Research Staff and Qualifications

The PI and research staff at each site will have the appropriate qualifications and training to conduct the study at each site.

Dr. Devine, the overall study PI, oversees the entire project. She is an expert trainer in Bright IDEAS and has trained other qualified individuals (e.g., graduate students, social workers, psychologists) to conduct the intervention. She will train and supervise all research assistants who will deliver the Bright IDEAS-YA intervention. All research assistants who will serve as trainers will be added via modification and approved as study staff in the IRB protocol prior to any patient contact. Each trainer will undergo a standardized Bright IDEAS training led by Dr. Devine. This training includes education about the foundations of the intervention, reviewing the instructor's manual with guidelines for each session, viewing videotaped training videos, and role-playing intervention sessions. Trainers do not have to be professional counselors but are required to complete this training prior to working with any participant. Trainers will also complete CITI, HIPAA, and other required research trainings.

Kristine Levonyan-Radloff, the project coordinator, has significant experience managing research studies and will meet at least weekly with Dr. Devine.

2.2 Research Staff Training

All staff is trained and compliant with CITI requirements to conduct research. Additionally, all staff will attend study start-up meetings to review the protocol, become familiar with study procedures and the proper conduct of the protocol.

2.3 Resources Available

All participants will be patients undergoing treatment at their respective cancer centers and will have access to usual psychosocial care as needed (e.g., social work and/or psychologist). All Site PIs are licensed psychologists who can assist patients in obtaining referrals as needed.

At the Rutgers Cancer Institute of New Jersey, participants will have access to social work and other psychological resources as needed. Dr. Devine is a psychologist and can make referrals for psychological resources if necessary.

2.4 Research Sites

Participant recruitment will take place at:

1) Rutgers Cancer Institute of New Jersey, New Brunswick, NJ
2) Memorial Sloan Kettering Cancer Center, New York, NY
3) Moffitt Cancer Center, Tampa, FL

IRB reliance agreements will be obtained and uploaded prior to engaging in research.

The University of Rochester will contribute intellectually to the research and access coded audio recordings to conduct treatment fidelity ratings but will not store any data or have access to any PHI or the code linking data and subject identifiers. A letter of cooperation is uploaded.

3.0 Multi-Center Research

Rutgers will serve as the IRB of Record for this multisite study. IRB reliance agreements will be obtained and uploaded prior to engaging in research.

Communication Plan. At the beginning of the project, Dr. Devine will host a three-hour virtual kick-off meeting using Webex videoconference to plan each site's action steps to initiate the project (i.e., finalization of protocol and timeline for regulatory submissions and hiring staff). Once each site has hired the personnel who will serve as Bright IDEAS-YA trainers, Site PIs, project coordinators, and interventionists will attend a 1.5-day in-person or remote training at Rutgers with Dr. Devine. The workshop training has been standardized based on prior Bright IDEAS clinical trials and the dissemination trial led by Co-I Sahler that taught mental health professionals how to use Bright IDEAS (R25CA183725). It involves didactic presentation of the skills needed to teach Bright IDEAS and the goals of each session, live and video-recorded demonstrations of these skills, and role playing with constructive feedback. Site PIs will conduct future trainings using this standardized approach for additional personnel as needed, with Dr. Devine available via videoconference to answer questions and provide feedback. All interventionists will be supervised regularly throughout the trial (See Treatment Integrity section). The PI will coordinate monthly phone calls with all co-investigators and study staff throughout the project to discuss enrollment, retention, data management, and implementation issues. Dr. Devine and the project coordinator will also hold weekly calls with site research staff to ensure compliance with study procedures and accrual targets.

4.0 Subject Considerations

4.1 Subject Selection and Enrollment Considerations

A. Method to Identify Potential Subjects

At each site, patients will be identified through electronic medical record review of active patients and by referrals from treating physicians/nurses/social workers. Research study staff will contact treating physicians or other qualified treatment team member familiar with the patients, to assess

medical eligibility of patients. If a physician or other treatment team member feels their patient is not suitable for participation, we will not approach the patient. Patients who pass initial screens will be approached in person by research staff during a routine medical visit or contacted by letter/phone or email (if available).

B. Recruitment Details

Trained research staff will approach potentially eligible patients during a routine medical visit or via letter/phone, or e-mail (if available). If in-person, study staff will hand out the study information sheet and flyer, explain the study, assess interest/eligibility, allow adequate time for review and discussion with family if needed, and obtain informed consent if patient is eligible and interested. If by letter/phone, study staff will mail study cover letter along with the study information sheet and flyer to explain the study and let them know they will be contacted by phone by a member of the study team to assess interest and eligibility. If patient's email address is available, an email will be sent to introduce the study and to let them know the study staff will follow-up with a phone call. Staff will be rigorously trained as to how to approach patients, introduce the study, communicate about confidentiality and voluntary participation, and engage in the process of informed consent in a culturally-competent way.[39] Recruitment scripts, cover letter, information sheet, e-mail wording and flyer are being uploaded for approval.

C. Subject Screening

A study staff member will screen interested patients during their initial contact. Study staff member will approach potentially eligible patients (i.e., within the age range and with initial physician/nurse/social worker's recommendation) in clinic, send a recruitment letter/email, or call, if not scheduled for a visit, using the Recruitment Script to explain the study and answer any questions from potential participants. If the patient is interested, study staff member will administer the Eligibility Checklist. If patient is eligible and willing to enroll in the study, the study staff member will continue the Consent process.

- **Inclusion Criteria**

  Participants will be eligible if:

  1) Current age 18-39 years
  2) Within 4 months of first* diagnosis of any cancer (*patients diagnosed previously with non-melanoma type of skin cancer treated with surgery only may also be included).
  3) Cancer is being treated with chemotherapy and/or radiation therapy and/or hematopoietic stem cell transplant (immunotherapy included)
  4) No documented or self-reported cognitive delay or impairment that would prevent completion of survey measures
  5) English-speaking

- **Exclusion Criteria**

  1) Life expectancy < 6 months per physician/treatment team report
  2) Treatment involves surgery only

4.2 Secondary Subjects

N/A

4.3 Number of Subjects

A. Total Number of Subjects

344

B. Total Number of Subjects If Multicenter Study

344

C. Feasibility

Each site has a large enough patient population to support recruitment of the target number of participants. Combined across sites, the estimated patient pool is 3,450 over 3 years; acceptance rates would have to fall below 10% to not meet accrual goals, which is highly unlikely given our acceptance rate of 66% in our pilot study.

4.4 Consent Procedures

A. Consent Process

- **Location of Consent Process**
  The consent process will take place during a patient's routine medical visit (in-person or telehealth), or via phone.
- **Ongoing Consent**
  The trainers conducting the intervention sessions will also be trained to check in with participants at each session their ongoing willingness to participate in the study. Each follow-up survey will begin with a paragraph of instructions reminding participants of the voluntary nature of their participation.
- **Individual Roles for Researchers Involved in Consent**
  The PI, project coordinator, or trained research staff member will obtain consent.
- **Consent Discussion Duration**
  We expect most initial consent discussions to take approximately 10 minutes. The trainers conducting the intervention sessions will also be trained to check in with participants at each session about their ongoing willingness to participate in the study.
- **Coercion or Undue Influence**
  The PI or trained research team member obtaining consent is not a part of the treating team and will clearly state that participation is voluntary and the decision to take part in the study or not will have no effect on the person's ongoing treatment or relationship with their treating team.
- **Subject Understanding**
  The PI or trained research team member obtaining consent will encourage questions and ask the participant to state in their own words their understanding of the research study, including risks, benefits, and voluntary nature of participation. The consent form will contain a few questions to assess understanding.

B. Waiver or Alteration of Consent Process

- **Waiver or Alteration Details**
  N/A
- **Destruction of Identifiers**
  N/A
- **Use of Deception/Concealment**
  N/A
  a. **Minimal Risk Justification**
     N/A
  b. **Alternatives**
     N/A
  c. **Subject Debriefing**
     N/A

C. Documentation of Consent

- **Documenting Consent**
  Informed consent will be obtained from every participant prior to beginning the study via online DatStat consenting (with electronic signature). In the event of internet disruption or technical difficulties, paper consent can be used. Signed consent forms can be securely downloaded from DatStat and stored in Rutgers BOX or as indicated in site-specific local context procedures.
- **Waiver of Documentation Of Consent (i.e., will not obtain subject's signature)**
  N/A

4.5 Special Consent/Populations

A. Minors-Subjects Who Are Not Yet Adults

- **Parental Permission**
  N/A
- **Non-Parental Permission**
  N/A
- **Assent Process**
  N/A
- **Documentation of Assent**
  N/A
- **Reaching Age of Majority During Study**
  N/A

B. Wards of the State

N/A

- **Research Outside of NJ Involving Minors**
  N/A

C. Non-English-Speaking Subjects

N/A

- **Process for Non-English-Speaking Subjects**
  N/A
- **Short Form Consent for Non-English Speakers**
  N/A

D. Adults Unable to Consent / Decisionally Impaired Adults

N/A

- **NJ Law-Assessment of Regaining the Capacity to Consent**
  N/A
- **Capacity to Consent**
  N/A
  a. **NJ Law-Selecting A Witness**
     N/A
  b. **Removing a Subject**
     N/A

4.6 Economic Burden and/or Compensation for Subjects

A. Expenses

There are no costs associated with this study.

B. Compensation/Incentives

Participants will receive a $25 gift card for each of the first four completed surveys, and a $50 gift card for completing the final survey, up to $150 total. Small token gifts, such as Bright IDEAS stress balls or sticky pads, will be sent as a thank you for participants' time and effort to promote retention in the study. Furthermore, to promote retention, study staff will mail yearly holiday cards to subjects on study.

C. Compensation Documentation

Research staff will maintain documentation of compensation in DatStat, which keeps records of the compensation sent electronically to participants.

4.7 Risks of Harm/Potential for Benefits to Subjects

A. Description of Risks of Harm to Subjects

- **Reasonably Foreseeable Risks of Harm**
  This study involves minimal risk. There are no physical risks or side effects associated with the study. Potential emotional risks of study participation include possible discomfort or distress associated with answering survey questions about current emotional functioning, problem-solving skills, financial strain, and health-related quality of life, or discussing personal challenges during problem-solving sessions. Attending in-person sessions may be seen as an inconvenience, but virtual visits are available and the trainer attempts to minimize burden by scheduling when the participant is already scheduled for a medical visit or offering virtual sessions as needed. There is also a risk of breach of confidentiality of data provided for research, but safeguards are in place to minimize risks (see section E. Minimizing Risks below). Based on our prior experience conducting research with cancer caregivers, the likelihood that participants in this study will experience such discomfort or distress is low.
- **Risk of Harm from an Intervention on a Subject with an Existing Condition**
  All participants will be undergoing cancer treatment and the intervention is targeted to address the needs of these individuals. Individuals with a concurrent or past mental health diagnosis are eligible to participate and trainers or the PI can make referrals for additional psychological treatment resources as needed if participants present with mental health concerns.
- **Other Foreseeable Risks of Harm**
  A possible loss of confidentiality could cause embarrassment for a participant but unlikely to cause any social harm or consequences given no collection of sensitive data.
- **Observation and Sensitive Information**
  N/A

B. Procedures which Risk Harm to Embryo, Fetus, and/or Pregnant Subjects
N/A

C. Risks of Harm to Non-Subjects
N/A

D. Assessment of Social Behavior Considerations
Participant distress will be systematically monitored in several ways. First, the study coordinator at each site will review patient reported distress on the baseline survey. Individuals who report elevated distress scores (i.e., ≥8 on 0-10 scale) will be assessed for safety, and if they express no intent to harm themselves, will be referred to clinical social work services. If there is concern about participant safety in the medical setting, the study will alert the treating clinical staff to initiate patient safety protocols and notify the site PI (licensed psychologist). If the participant is not at the medical center, research staff will coach them to go to their nearest emergency room for help and call 911 if needed. Second, interventionists will be trained to respond to patient distress at the time it occurs during intervention sessions, calling the Site PI (licensed psychologist) and referring to clinical social work services if needed. Third, study coordinators will review patient-reported distress at all subsequent surveys, intervening as above if elevated distress occurs and documenting procedures.

E. Minimizing Risks of Harm
Participants will be encouraged to contact the research team if they experience emotional discomfort or distress at any time during the study. All research staff will receive training to appropriately identify and handle instances when a patient would benefit from a referral (e.g., to a clinical social worker) for follow-up of emotional discomfort or distress.

To protect the confidentiality of participants, a series of security procedures will be undertaken. IRB and HIPAA regulations concerning confidentiality will be strictly enforced. All study personnel receive training and certification in human subjects protection and HIPAA regulations. Each study participant will be given a unique numeric identifier upon study entry. Names and other identifiable protected health information will not be stored in the same database as survey and

medical information. All computers used for research purposes adhere to the institution's requirements regarding password protection, data encryption, anti-virus protection, and intrusion detection. All Internet-based data communications will be encrypted. This includes transfer of electronic audio files between approved members of the research team for treatment fidelity and supervision purposes if needed. All hard copy study-related materials and data will be stored in locked file cabinets in the site PI's locked office.

- **Certificate of Confidentiality**
  This study is NIH-funded and therefore a Certificate of Confidentiality is automatically issued to protect the data collected.
- **Provisions to Protect the Privacy Interests of Subjects**
  Participants will only be approached by trained and authorized research staff. Physicians or other appropriate treatment team members will be contacted for permission to approach prospective participants that study staff deem eligible based on the inclusion criteria. If anyone feels their patient is not suitable for participation, we will not approach the participant.

F. Potential Benefits to Subjects

Participants randomized to the Bright IDEAS-YA intervention may benefit by improving problem-solving skills and reducing symptoms of anxiety, depression, and distress. Prior studies with caregivers of pediatric patients have demonstrated such benefits[20-22] but it is unknown if AYA would benefit from this training. Participants randomized to the Enhanced Usual Care arm may or may not benefit from obtaining the list of resources from the NCCN adolescent and young adult patient guideline.

5.0 Special Considerations

5.1 Health Insurance Portability and Accountability Act (HIPAA)

HIPAA language is included in the consent form. As part of this study the following identifiable and/or protected health information will be collected: name, address, phone number, date of birth, email address, date of diagnosis, and IP address (surveys completed on DatStat collect this data but IP address will not be downloaded with the survey data). We will not be disclosing individually identifiable health information unless required by law.

5.2 Family Educational Rights and Privacy Act (FERPA)

N/A

5.3 Code of Federal Regulations Title 45 Part 46 (Vulnerable Populations)

A. Special Populations

- Prisoners: N/A
- Neonates: N/A
- Neonates of Uncertain Viability: N/A
- Children: N/A
- Individuals with Impaired Decision-Making Capacity: N/A

5.4 General Data Protection Regulation (GDPR)

N/A

5.5 NJ Access to Medical Research Act (Surrogate Consent)

N/A

6.0 Data Management Plan

6.1 Data Analysis

Aim 1: Efficacy of the Bright IDEAS-YA intervention vs. enhanced usual psychosocial care will be evaluated assuming repeated measures linear models, using maximum likelihood estimation (MLE) (SAS Proc Mixed).[40] All randomized participants, regardless of the extent to which they completed the intervention, will be included in intent-to-treat analysis. The benefits of this approach include: (1) all available data can be included in analyses; (2) correlation between related measures and adjusted test statistics can be estimated; (3) time varying covariates (such as school/employment status, treatment status (on treatment vs. completed), utilization of usual psychosocial care) can be incorporated into the model; and, (4) the assumptions about missing data from Missing Completely at Random (MCAR) to Missing at Random (MAR) are relaxed. Site will be included as a fixed effect. The primary hypothesis is that participants in Bright IDEAS-YA will experience greater decreases in depression and anxiety and increases in HRQOL at the 6-month follow-up relative to participants in the enhanced usual psychosocial care condition. The primary endpoint will be the estimated change from baseline to 6 months in depression, anxiety, and psychosocial HRQOL (i.e., Social/Family Well-Being and Emotional Well-Being), calculated as linear contrasts of regression parameters using the main effect of time and the interaction between time and treatment group from the mixed linear model. The changes from baseline to 3 months, 12 months, and 24 months will be considered secondary endpoints. For HRQOL, we are particularly interested in 12-and 24-month follow-ups given that changes may take longer to accrue compared with distress symptoms. Sensitivity analyses will be performed to determine the robustness of conclusions.[41] Planned sensitivity analyses include: (1) analysis with and without adjusting for site; (2) per protocol analysis (excluding participants who did not complete at least 4 out of 6 intervention sessions, selected because it is expected that participants would have adequate exposure and practice with the Bright IDEAS model by four sessions); (3) adjustment for imbalance in baseline characteristics, if applicable; and (4) analysis to examine any differences by racial/ethnic subgroups.

Aim 2: Mediation analysis will be used to evaluate problem-solving ability as a mediating variable between the intervention and each of the outcomes while also allowing for a direct effect of intervention on outcome. Specifically, bootstrap approaches will estimate the proportions attributed to the direct effect and to the effect mediated through problem-solving using the R program package mediation.[42]

A small direct effect is expected due to a positive therapeutic effect of talking to the trainer. Problem-solving ability will be measured by the total scale score and five subscales (positive problem orientation, negative problem orientation, rational problem solving, impulsive-careless style, and avoidant style), which will each be considered individually as potential mediators.

Aim 3: Potential moderators, including sex, financial strain, baseline unmet needs, and baseline distress, will be tested individually in models including all possible interaction terms. We will allow for each moderator to interact with time, arm, and time x arm to determine if it modifies the relationship between intervention and outcomes. We consider this analysis exploratory to identify subgroups who may benefit differentially from this intervention. We expect that females and participants with greater financial strain, baseline unmet needs, and baseline distress will benefit more.

6.2 Data Security

Only authorized study personnel will have access to study data, and access to identifiable data will be limited to staff who need the data to interact with participants. Survey and medical data will be in a separate database from identifiable data (e.g., name, address, etc.). The link between subject name and ID will be destroyed 6 years after the close of the study; other study data will be kept indefinitely. All computers used for research purposes adhere to the institution's requirements regarding password protection, data encryption, anti-virus protection, and intrusion detection. All Internet-based data communications will be encrypted. Physical records will be stored in a locked filing cabinet with the PI's locked office at each site. For participants who consent to be contacted for future studies (to be requested at the end of the final survey at 24 month follow-up), the study team will store their contact information (i.e., first and last names, phone number, email address) as well as cancer history (i.e.,

diagnosis, date of diagnosis, and end of treatment date) separately from research data on the PI's secure One Drive, with access granted only to the PI, study coordinator, and limited authorized research staff. We will store this information for up to 10 years from date of consent, after which it will be destroyed by the Primary Investigator.

6.3 Data and Safety Monitoring

A. Data/Safety Monitoring Plan

This is a minimal risk study. The PI and study staff at each site will continuously monitor for any potential adverse events (AEs). Anticipated adverse events include participant distress related to the intervention sessions or breach of confidentiality. Participant distress will be monitored in several ways. First, the study coordinator at each site will review patient reported distress on the baseline survey, which is generally completed in person at the same time as a routine medical visit. Individuals who report elevated distress (i.e., score ≥8 on 0-10 scale) will be assessed for safety, and if they express no intent to harm themselves, will be referred to clinical social work services. If there is concern about participant safety in the medical setting, the study will alert the treating clinical staff to initiate patient safety protocols and notify the site PI (licensed psychologist). If the participant is not at the medical center, research staff will coach them to go to their nearest emergency room for help and call 911 if needed. Second, interventionists will be trained to respond to patient distress at the time it occurs during intervention sessions, calling the Site PI (licensed psychologist) and referring to clinical social work services if needed. Third, study coordinators will review patient-reported distress as soon as possible following completion of all subsequent surveys, calling the patient to assess for safety as above if elevated distress occurs, making appropriate referrals, and documenting procedures. The online survey will also contain contact information for the study coordinator if patients have any questions or concerns while completing the survey. All staff will be trained to maintain confidentiality of patient data. Study staff will report any AEs immediately to the PI. Dr. Devine and the investigative team, in consultation with the Data and Safety Monitoring Board, will be responsible for evaluating each AE, determining whether it is study-related, and assessing any change to the risk/benefit ratio.

All unexpected and/or serious adverse events (AEs) occurring during the active portion of the intervention or up to 30 days after the last intervention session will be reported to the RBHS IRB in accordance with IRB policy. The research team will review and discuss via teleconference any serious adverse events to ensure protections to the participants and discuss any modifications to the protocol. If modifications are needed, they will be submitted immediately according to standard IRB procedures. The PI will also conduct a quarterly review of safety and adverse events to be discussed during monthly all-investigator calls.

B. Data/Safety Monitoring Board Details

The PI will convene a Data and Safety Monitoring Board (DSMB) composed of a biostatistician, a behavioral scientist, and a physician who are not associated with the study. The committee will be responsible for oversight of patient safety and will meet yearly to review patient safety and trial progress. This review will include for each arm of the study: the number of patients enrolled, withdrawals, serious adverse events both expected and unexpected, and responses observed. A report with recommendations from the DSMB will be submitted annually to the RBHS IRB with the continuing review for the study.

6.4 Reporting Results

A. Individual Subjects' Results

N/A – results will be calculated on the aggregate data; no relevant data for sharing with subjects.

B. Aggregate Results

We will post aggregate results on clinicaltrials.gov for public viewing.

C. Professional Reporting

It is expected that the results of this research will be submitted for publication in a timely manner following the conclusion of the study. The PI and all co-authors must review any abstract or manuscript prior to submission.

D. Clinical Trials Registration, Results Reporting and Consent Posting

This trial will be registered at clinicaltrials.gov. Results will be reported and the approved consent form uploaded.

6.5 Secondary Use of the Data

We will make de-identified data available for sharing with other qualified researchers for secondary research. This is described in the consent form.

7.0 Research Repositories – Specimens and/or Data

N/A

8.0 Approvals/Authorizations

Rutgers will serve as the IRB of record for this study. Reliance agreements with the IRBs of participating sights will be obtained prior to commencing the research.

9.0 Bibliography

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