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# Goal-Focused Emotion-Regulation Therapy (GET) in Young Adult Testicular Cancer Survivors: A Randomized Pilot Study

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## Abstract

**Background** Young adult testicular cancer survivors experience adverse impacts after treatment. We developed Goal-focused Emotion-regulation Therapy (GET) to improve distress symptoms, emotion regulation, and goal navigation skills.

**Purpose** This pilot study examined GET versus an active control intervention in young adult survivors of testicular cancer.

**Methods** Seventy-five eligible survivors treated with chemotherapy were randomized to receive GET or Individual Supportive Listening (ISL). Study acceptability, engagement, and tolerability were examined, and intervention fidelity and therapeutic alliance were compared between arms. Preliminary efficacy was evaluated by effect sizes for between-group changes in primary (anxiety and depressive symptoms) and secondary (career confusion, goal navigation, and emotion regulation) outcomes from baseline to immediately and 3-month post-intervention.

**Results** Among the 38 men randomized to GET, 81.1% completed all study sessions compared with 82.4% of the 37 men assigned to ISL. Fidelity to the intervention was 87% in GET. Therapeutic alliance was significantly higher among those receiving GET versus ISL. Participants exhibited a medium group-by-time effect size with greater reductions in depressive ( $d = 0.45$ ) and anxiety ( $d = 0.29$ ) symptoms for those in GET versus ISL, with a similar pattern at 3 months for depressive ( $d = 0.46$ ) and anxiety ( $d = 0.46$ ) symptoms.

**Conclusions** GET is a feasible and acceptable intervention for reducing adverse outcomes after testicular cancer for young adults. Observed effect sizes preliminarily suggest meaningful change, though should be interpreted with caution in small samples. GET may be a developmentally-matched behavioral approach to improve psychosocial function in this cancer group.

**Clinical Trial information** Clinicaltrials.gov, NCT04150848. Registered on October 28, 2019.

## Lay summary

Young adult testicular cancer survivors experience adverse impacts after treatment. Goal-focused Emotion-regulation Therapy (GET) was developed to improve distress symptoms, emotion regulation, and goal navigation skills. The aim of this pilot study was to examine GET versus a control intervention in young adult survivors of testicular cancer. Seventy-five survivors were randomly assigned to GET or Individual Supportive Listening (ISL). Indicators of acceptability, engagement, and tolerability were examined, and intervention fidelity and therapeutic alliance were compared between groups. Between-group changes in primary (anxiety and depressive symptoms) and secondary (career confusion, goal navigation, and emotion regulation) outcomes from baseline to immediately and 3-month post-intervention were examined. Among GET participants, 81.1% completed all study sessions compared with 82.4% of those receiving ISL. Fidelity to the intervention was 87% in GET. Therapeutic alliance scores were significantly higher among those receiving GET. Participants exhibited greater reductions in depressive and anxiety symptoms for those in the GET versus ISL, with a similar pattern observed for changes at 3 months for depressive and anxiety symptoms. GET is a feasible and acceptable intervention for reducing adverse outcomes after testicular cancer for young adults.

**Keywords** Testicular cancer · Emotion regulation · Young adults · Psycho-oncology · Survivorship · Biobehavioral

## Introduction

The development of effective interventions that prevent, control, and eliminate the adverse effects of cancer in young adult survivors was identified as a public health priority over a decade ago [1], yet, there is limited progress in identifying evidenced-based behavioral interventions [2, 3]. Testicular cancer is among the most prevalent non-skin cancer among men in late adolescence and young adulthood and rates of new cases have been rising on average one percent each year over the last decade [4], significantly more among young adult Hispanic White men (compared with non-Hispanic White men) [5]. Advances in multimodal therapy afford young men with testicular cancer survival rates upwards of 95%, underscoring the importance of research focused on long-term survivorship [6].

Testicular cancer survivors often face both psychological and physical impact from potential loss of a reproductive organ and long-term functional impacts of chemotherapy, radiation therapy, and/or surgery [7, 8]. Long-term sequelae are more severe and persistent in those receiving chemotherapy, and include peripheral neuropathy, hypogonadism, infertility, fatigue, secondary malignancies, long-term hearing loss and tinnitus, sexual dysfunction, cognitive impairment, and cardiovascular disease [9–11].

Testicular cancer survivors also incur a notable psychosocial impact [12–16]. The prevalence of moderate to high anxiety ranges from 17% to 41% across studies and clinically significant depression is as high as 5%–20% [7, 8, 17–21]. Poorer psychological outcomes are elevated among survivors who are of younger age, single, unemployed, living alone, of low socioeconomic status, suffering from comorbidities, and using passive self-regulation strategies (e.g., avoidance) [8]. Documented concerns include body image disruption, social relationship difficulty, fertility and sexual distress, masculinity threat, loss of agency, and worry about the future [7, 9, 19, 21, 22]. About two-thirds of testicular cancer survivors report unmet survivorship needs [22–25], most commonly relating to psychosocial supportive care, survivorship information, distress management, fertility, relationships, and self-image [24–26]. Occupational problems are also common and include career confusion, financial difficulty, and changes in career goals [27–29].

There is significant need for developmentally appropriate behavioral interventions to decrease the psychological, physical, and social impact of diagnosis and treatment. Meeting these needs is challenging, as men (particularly younger men) tend not to seek professional help for distress [30]. There is increasing evidence that men are reluctant to seek professional help due to “traditional” masculine attitudes [31], highlighting the need to develop interventions that are both accessible and acceptable to men. Moreover, very few studies have focused on testicular cancer survivors specifically. These have largely included nonrandomized pilot trials have been published that focus on testicular cancer survivors [32, 33], and neither has been specific to young adults. These include an expressive writing intervention ( $N = 28$ ) [32] and feasibility testing of an e-tool to reduce psychological distress ( $N = 25$ ) [33, 34]. A critical limitation of these trials has been the failure to identify developmentally matched targets of intervention or modifiable biobehavioral processes with potential to alter clinically relevant outcomes. Young adult testicular cancer survivors are notably absent from the research base and continue to experience unmet survivorship needs.

A meta-synthesis of qualitative studies [35] investigating the accessibility and acceptability of support interventions for those with long-term conditions including cancer found that self-regulation interventions may be particularly more acceptable, as they enable control over managing distress (promoting self-sufficiency and independence).

Young adult testicular cancer survivors identify the key self-regulatory processes of *goal adjustment* and *emotion regulation* after cancer as critical to their health-related quality of life [36]. In fact, adjustment to challenged goals may be particularly critical when cancer occurs in early adulthood [37, 38]. Goals reflect one’s key priorities and most valued aspirations [39]. Cancer diagnosis and treatment present circumstances that challenge the pursuit and achievement of meaningful and developmentally timed life goals (e.g., pursuit of dating/sexual relationships, values-driven occupational pursuits, independence) [40–42]. Such challenges can lead to actual or perceived blockage to goals. Cancer-related goal disturbances are associated with chemotherapy receipt and a host of behavioral and psychological symptoms, including depression, fatigue, pain, and cognitive complaints [43]. Concerns about the achievement of life goals are especially distressing for young adult survivors [44, 45], who are negotiating greater autonomy across life domains and are oriented toward achievement of future goals.

Building from such basic behavioral science, we developed Goal-focused Emotion-regulation Therapy (GET) as an individually delivered intervention aimed at reducing the adverse impacts of testicular cancer treatment among young adults. GET focuses on improving self-regulation in the form of skills to navigate challenged life goals and cancer-related emotions [46]. GET is a six-session intervention delivered over 8 weeks to enhance self-regulation through improved goal navigation skills, improved sense of meaning and purpose, and better ability to regulate specific emotional responses. GET has a strong theoretical base. Foremost, it draws heavily from the principles of Hope Therapy [47], with an emphasis on goal navigation skill building. Components of Hope Therapy have been used successfully in cancer survivorship interventions [48]. This includes work on goal setting with a focus on assessing progress toward achieving specific, realistic, and measurable goals. Patients identify value-derived goals (i.e., goals for the most important domains of one’s life) and ones sufficiently important to sustain movement toward them in the short-term future. They discuss their goal possibilities, providing a forum to ensure that goals are manageable and consistent with identified values. Patients learn strategies to refine their goals (e.g., approaching goals rather than avoiding obstacles, defining markers of progress), generate pathways to goals, and address potential obstacles and blockages. Additionally, goals provide the context for demonstrations of agentic thinking (e.g., I will be able to do this) and interventions to increase agentic thinking. Specific attention is given to career/education-related goals. Emotion regulation components include basic cognitive restructuring skills, cognitive distancing, and coping efficacy skills. In addition to applying Hope Theory [49] to guide goal navigation skill building, targets for change and specific intervention techniques have integrated Stress and Coping Theory [50] and Emotion Regulation Theory [51] to underscore core emotion-regulation components and Self Determination Theory [52] to build agency and mastery.

GET has been found to be feasibly delivered to this patient population, acceptable, safe, and with potential to invoke clinically meaningful impact on psychological distress in a small ( $N = 6$ ) proof-of-concept study [53]. In addition to establishing feasibility and acceptability of study procedures, this formative work yielded a refined intervention manual for GET and support the selection of primary and secondary measures. The current pilot study aimed to further evaluate feasibility of GET in a randomized controlled design with young adult testicular cancer survivors who completed chemotherapy. Extending from establishment of proof-of-concept, the focus will be on examination of acceptability, engagement, tolerability, fidelity to the intervention, group comparisons of therapeutic alliance, and participant satisfaction. GET has been shown to favorably impact stress and immune biomarkers [54]; the current study will report preliminary effects on primary and secondary psychosocial outcomes.

## Methods

### Trial Design

This was a randomized, controlled, repeated-measures pilot trial approved by the institutional review boards at the University of California, Irvine (#2018-4676) and Memorial Sloan Kettering Cancer Center (#16-491).

### Participants

Young adults treated by chemotherapy for testicular cancer were identified via chart review or by clinical referral at a large urban Comprehensive Cancer Center. Potential participants were recruited by direct approach in clinic by a study recruiter, via informational letter, or by direct referral from the medical team. Individuals were screened by a research assistant for eligibility in person or on the telephone. Eligible patients were between the ages of 18 and 39 years, had a confirmed diagnosis of testicular cancer (any stage), completed chemotherapy within 2 years prior, and had English fluency. Participants were also screened to exhibit suboptimal self-regulation as evidenced by a score of 1.8 or below on the Goal Navigation Scale [7] or a score of 4 or greater on the Distress Thermometer (DT) [55]. The Goal Navigation Scale of the Cancer Assessment for Young Adults (CAYA), which has been designed and validated for young adult men with testicular cancer [7], measures goal navigation skill, while the DT is a single-item visual analog screening tool for psychological distress with a 0–10 range in which a score of 4 or greater signals significant distress levels. All potential participants were informed of their access to on-site counseling services.

Men were excluded if they had a lifetime history of severe mental illness (i.e., schizoaffective disorder, schizophrenia, psychosis), active suicidality, presence of a disorder that compromises comprehension (e.g., dementia), or a self-reported medical condition or substance use (i.e., cigarettes or excessive alcohol use) known to confound biomarker assessments [56].

Participants were enrolled between November 2018 and February 2021.

### Sample Size

Sample size determination balanced realistic recruitment estimates and sample requirements for planned analyses and recommendations for pilot research [57–59]. Our target sample

size was 50 young adults; thus, we aimed to recruit 75 men to accommodate attrition.

### Procedures

Following written informed consent procedures, participants were randomly assigned by a study coordinator using a block 10 randomization strategy into either GET or Individual Supportive Listening (ISL) to ensure that the intervention groups would be balanced.

ISL has been used successfully as a time/attention control condition in psychotherapeutic trials of cancer survivors [60] and in our preliminary work [53, 54]. Following assignment, participants completed questionnaires via a secure HIPAA-compliant online platform. Some participants also underwent assessment for stress and immune biomarkers, which is described elsewhere [54]. Participants repeated questionnaires after the last intervention session and again 3 months later.

All study patient-reported outcomes were completed online to reduce any potential influence from research staff. Given that informed consent described the different study arms, participants were unaware of their group allocation; however, because either condition involved more than standard care, all participants knew they were receiving an intervention that could offer potential impact. Additionally, the research staff who reminded participants to complete study measures online were unaware of study condition. However, identical communication procedures and protocols were followed. Participants were given \$50 at each data collection point.

### Intervention Delivery

All intervention sessions were delivered by a trained mental health interventionist with a minimum of master's-level training. Both conditions consisted of six sessions delivered over 8 weeks. According to the original study design, sessions were delivered in person. However, in compliance with Covid-19 safety protocols, intervention sessions after March 2020 were delivered via video call.

### GET

GET is a manualized behavioral intervention. Sessions and at-home exercises focus on identifying value-derived goals and learning skills to navigate a process of sustained movement toward them in the short-term future. Goal-focused self-regulation skills include establishing manageable and values-driven goals, goal refinement, generating pathways toward goal fulfillment, and managing blocked or challenged strivings. GET is designed to foster agentic thinking and includes training in goal-related cognitive restructuring and emotion-regulating coping skills.

Each of the six sessions is 60 min in length. The first four sessions were scheduled weekly, and the final two sessions were separated by 2 weeks to provide time for skill application in real time. Specifically, session topics include a review of cancer-related experiences and influences on goal pursuits, psychoeducation regarding emotions, skills, and values (Session 1), values clarifications and emotional awareness (Session 2), achievability of goals, cognitive skills training (Sessions 3), goal pathway mapping, navigating blocked goals and redirecting energy (Sessions 4), goal motivation and agentic actions, self-care behavior (Session 5), and goal pursuits moving forward (Session 6). Participants are given structured at-home exercises via a workbook that were designed to facilitate skill acquisition that reinforce session

topics and foster skill building between sessions. Each session began with a review and discussion of the between-session, at-home exercises.

## ISL

ISL is a widely used supportive approach in psychosocial oncology [61], and was adapted for use with young adult testicular cancer survivors. ISL relies on supportive listening with a focus on the use of genuineness, unconditional positive regard, and empathic understanding. The overall approach emphasized maintaining focus on the cancer experience and supporting participants in the “here and now” by creating a sense of being understood [61]. Unlike GET, there were no at-home exercises, skill-building goals, or manualized psychoeducational components.

## Measures

### Acceptability, engagement, and tolerability

Descriptive measures of acceptability, session engagement, and tolerability were computed. Acceptability is defined in terms of uptake as the percentage of eligible men who consent to participation. To further quantify acceptability, participants were asked to rate the helpfulness of the intervention skills, number and length of sessions, homework assignments, and therapist interactions on a response scale from 1 (did not help at all) to 5 (extremely helpful). In addition, they rated the likelihood they would recommend this intervention to a friend with testicular cancer. Responses ranged from 1 (not at all) to 5 (extremely).

Engagement in the intervention is reported as the rate of patients completing the intervention sessions for both arms. Tolerability is reported as the percentage of men who complete study procedures in both arms.

### Fidelity to the intervention

A treatment integrity coding system was developed to assess the degree to which study interventionists adhered to the treatment protocol. Two independent raters evaluated audio-recordings of each session of both intervention arms for treatment adherence in terms of process and content using the developed tools.

### Therapeutic alliance

Participants completed the Working Alliance Inventory-Short Form (WAI-SF) [62] at the immediate post-intervention assessment timepoint, which assesses the perceived strength of the treatment alliance. The WAI-SF includes 12 items (e.g., “My interventionist does not understand what I am trying to accomplish in therapy”; “I feel that my interventionist appreciates me”) on a response scale ranging from 1 (never) to 7 (always). Cronbach’s alpha was 0.88.

### Outcome measures

Self-reported primary and secondary outcome measures were administered at baseline, immediately post-intervention, and 3 months later, unless otherwise specified.

The primary outcomes for this pilot RCT were quantification of anxiety and depressive symptoms measured by the Hospital Anxiety and Depression Scale (HADS) [63]. The HADS is a 14-item self-administered questionnaire, with 7 items assigned to each the HADS-Anxiety (HADS-A) and HADS-Depression (HADS-D) subscales. Each item is rated

on a 4-point response scale (from 0 to 3). Subscale scores are categorized to indicate the level of anxiety or depression experienced where scores of less than 8 are categorized as normal, scores of 8–10 as borderline, and scores of 11–21 as clinically notable. Cronbach’s alpha ranged from 0.79 to 0.89 for HADS-D and from 0.81 to 0.88 for HADS-A.

Secondary outcomes included several self-report measures reflecting core GET processes including goal navigation, career confusion, and emotion regulation. Goal navigation capacity was measured by the Cancer Assessment for Young Adults (CAYA-T) [7]. Goal navigation capacity includes elements of goal setting, goal clarification, goal adjustment, and goal initiation. The scale is composed of five items (e.g., “I am able to identify goals in my life,” “I know what steps to take to make progress toward my goals,” and “I am able to redirect my energy when I feel my life isn’t going in the right direction”). Participants indicate how often each item is true of them over the past 7 days on a 3-point response scale ranging from 0 (None of the time) to 2 (Much or most of the time). Cronbach’s alpha ranged from 0.78 to 0.81.

Career confusion was measured by the Career Thoughts Inventory (CTI) Global. The CTI [64] is a 48-item self-administered instrument that measures an individual’s level of dysfunctional thinking in career decision-making and career problem-solving. Items are rated on a 4-point Likert scale ranging from 0 (strongly disagree) to 3 (strongly agree). CTI total score reflects three core aspects of career confusion: decision-making confusion (difficulties with initiating or sustaining a career choice), commitment anxiety (difficulties with making a commitment to a career choice), and external conflict (difficulties with balancing one’s ideas with the ideas of others). Due to a technical error preventing administration of the CTI at the 3-month follow-up, only baseline and post-intervention CTI scores are available. Cronbach’s alpha ranged was 0.85 and 0.88 and baseline and post-intervention, respectively.

Finally, two emotion regulation processes, cognitive reappraisal and expressive suppression, were measured by the respective subscales of the Emotion Regulation Questionnaire (ERQ). The ERQ is a widely used 10-item scale designed to measure respondents’ tendency to regulate their emotions. Respondents answer each item on a 7-point Likert-type scale ranging from 1 (strongly disagree) to 7 (strongly agree) [65]. Cronbach’s alpha ranged from 0.79 to 0.89 for cognitive reappraisal and from 0.85 to 0.87 for expressive suppression.

## Demographic and clinical information

Demographic information, past/current psychosocial service use, support needs, intervention preferences, and perceived barriers were assessed through Likert-scale ratings and open-ended items. Additional demographic and clinical data, including testicular cancer-related treatment information, were assessed via medical record review and via self-report. In addition, medical comorbidities and physical health symptoms were recorded; comorbidities were assessed by the Charlson Comorbidity Index (CCI) [66]. The CCI results in a weighted score in which a score of zero indicates no present comorbidities and a higher score is indicative of more medical comorbidities.

## Data Analysis

Descriptive statistics were computed to report participant characteristics and summarize indicators of study acceptability,

engagement, and tolerability. Fidelity to the intervention and therapeutic alliance scores were also compiled and compared between treatment arms. Chi-square and *t*-tests were used to compare completion rates between groups.

Given the pilot study was not powered to detect significant differences between groups in outcome variables, only effect sizes (Cohen’s *d*) are reported. Cohen’s guide for interpreting effect sizes is *d* = 0.2, small effect; *d* = 0.5, medium effect; and *d* = 0.8, large effect. Analysis of covariance was used to identify between-group differences in the primary and secondary outcome variables. Group assignment and scores at baseline were used to predict post-intervention and 3-month post-intervention scores. Time since chemotherapy, ethnic minority status, and medical comorbidities were considered as potential covariates. In accord with intention-to-treat principle, multiple imputation was used to impute missing values within SPSS using the automatic method selection function.

## Results

### Sample Characteristics

As depicted in Fig. 1, 212 young adults were approached for participation. Of these, 75 (35.4%) consented to participate. Thirty-eight were randomly assigned to receive GET and 37 to receive ISL. Table 1 outlines the baseline characteristics for both study arms. The mean age of the sample was 28.3 years old (*SD* = 4.6). The majority of participants were White,

non-Hispanic (65.7%), and 19.7% were Hispanic. Men identified as single (32.9%), or married or in a committed partnership (54.0%). Most men had a college or graduate degree (80.3%) and were employed full time (64.5%).

The average time from completion of chemotherapy to study entry was 11.6 months (*SD* = 10.0). All participants underwent surgical intervention, including orchiectomy (100%) and retroperitoneal lymph node dissection surgery (55.3%). Few participants (7.9%) reported any medical comorbidities on the CCI, with 97.4% reporting one or zero. Therefore, CCI was not statistically controlled. There were no statistically significant differences between study arms on participant demographics, as shown in Table 1, at baseline. However, the GET arm did have a *qualitatively* higher percentage of Hispanic participants.

At baseline, average depressive symptoms were in the normal range (*M* = 5.33, *SD* = 3.84); however, 15% reported symptoms in the moderately high/borderline range and 10.7% reported depressive symptoms in the range of possible clinical significance. The average anxiety symptoms were just above the moderately high/borderline range (*M* = 10.35, *SD* = 4.23) with 52% reporting anxiety symptoms at levels with possible clinical significance.

### Acceptability, Engagement, and Tolerability

Among eligible men approached for participation, 43.4% enrolled in the trial. Among those receiving GET, 81.1%

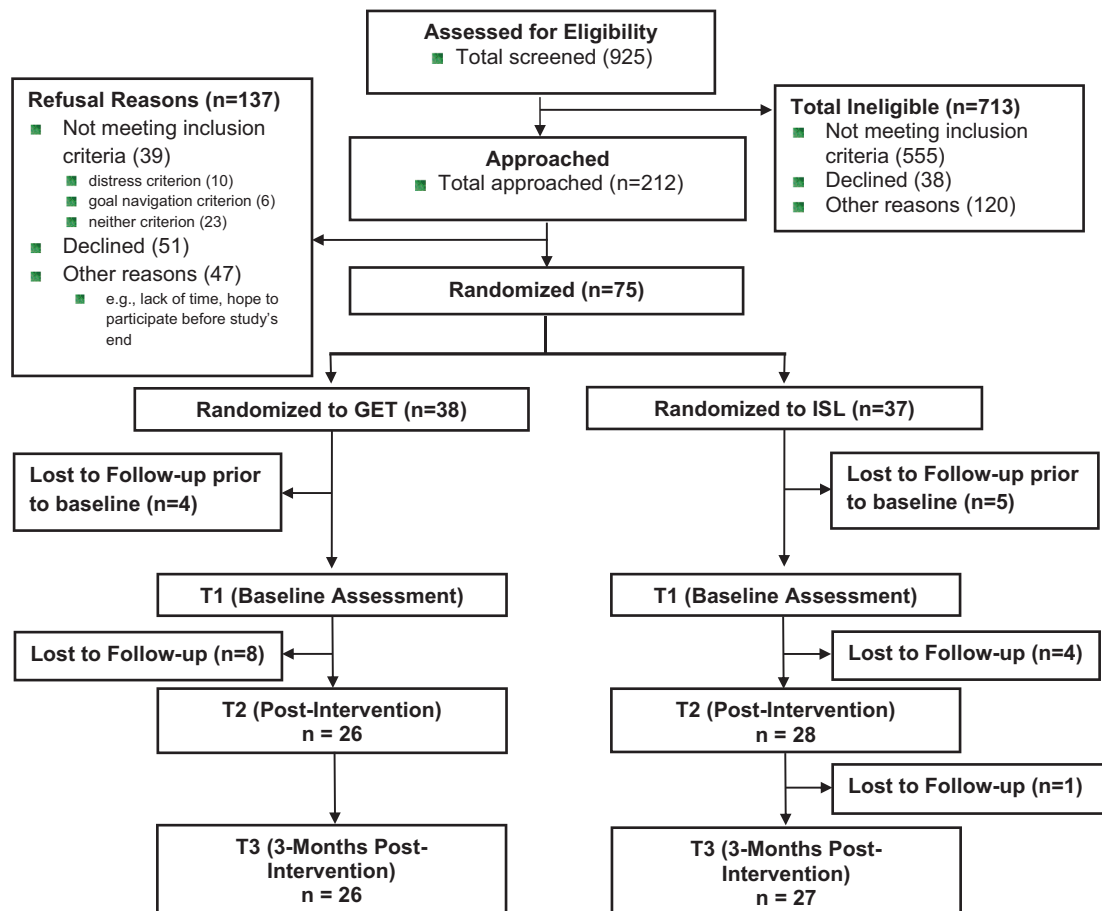


Fig. 1. CONSORT flow chart.

**Table 1** Young Adult Testicular Cancer Survivors, Demographics by Group

	GET ( <i>n</i> = 38)	ISL ( <i>n</i> = 37)
Age, years ( <i>M</i> , <i>SD</i> ; range)	28.2, 4.5; 20–39	28.5, 4.7; 22–39
Ethnicity (%)		
White (non-Hispanic)	63.2	70.3
Hispanic/Latino	26.3	13.5
African American/Black	5.3	5.4
Asian	5.3	5.4
Native American/Alaskan Native	2.6	2.7
Other	0.0	2.7
Education (%)		
High school/GED	5.2	5.4
Some college	5.3	10.8
2-Year college degree	7.9	0.0
4-Year college degree	44.7	51.4
Graduate	23.7	21.6
Household income (%)		
\$15,000 or less	5.3	8.1
\$15,001–\$30,000	2.6	16.2
\$30,001–\$45,000	7.9	5.4
\$45,001–\$60,000	7.9	10.8
\$60,001–\$75,000	23.7	5.4
\$75,001–\$100,000	13.2	13.5
\$100,001 or more	26.3	27.0
Sexual orientation (%)		
Straight	76.3	83.8
Gay or bisexual	10.5	5.4
Relationship status (%)		
Single	31.6	35.1
Committed/partnered	34.2	32.4
Married	21.1	21.6
Employment (%)		
Employed full time	63.2	67.6
Employed part time	10.5	10.8
Medical leave/disability	2.6	0.0
Unemployed	10.5	16.2
Time since chemotherapy completion ( <i>M</i> months, <i>SD</i> )	11.5, 10.6	11.6, 9.5
RPLND surgery ( <i>n</i> , %)	22, 57.9	20, 54.1
Distress rating ( <i>M</i> , <i>SD</i> )	5.2, 2.4	5.4, 2.1

*Note.* Some categories do not equal 100% due to missingness. *GET* Goal-Focused Emotion-regulation Therapy; *ISL* Individual Supportive Listening; *RPLND* retroperitoneal lymph node dissection.

completed all study sessions (vs. 82.4% in the ISL arm). Completing more sessions was significantly correlated with greater level of prior education ( $r = .27, p < .05$ ), but not correlated with other demographic or clinical variables including baseline levels of depressive or anxiety symptoms. Also, 63.2% of those assigned to GET and 67.6% of those assigned to ISL completed all study procedures. Excluding participants who did not initiate any study sessions, 72.7% of those in GET and 73.5% of those in ISL completed all study procedures.

As shown in **Table 2**, GET participants rated the helpfulness of the intervention skills in the moderate to high range, which

**Table 2** Intervention Ratings

	GET <i>M</i> ( <i>SD</i> )	ISL <i>M</i> ( <i>SD</i> )	<i>t</i>	<i>p</i>
Helpfulness ratings				
Intervention skills	4.13 (0.90)	3.40 (1.35)	−2.35	.011
Number of sessions	3.75 (0.79)	3.57 (1.25)	−0.66	.258
Length of sessions	3.88 (0.95)	3.83 (1.12)	−0.148	.441
Homework	3.13 (1.26)	2.36 (1.60)	−1.94	.029
Therapist interactions	4.75 (0.61)	4.47 (0.90)	−1.38	.087
Recommendation				
Likelihood to recommend intervention	4.50 (0.72)	4.50 (0.82)	0.000	.500

*Note.* The possible range on all item was 1–5. *GET* Goal-Focused Emotion-regulation Therapy; *ISL* Individual Supportive Listening.

was significantly higher than in ISL. Also, the number of and length of intervention sessions and homework exercises were rated in the moderate range of helpfulness. Participants rated therapist interactions in the high helpfulness range in both groups and were very likely to recommend the intervention to a friend with testicular cancer in both groups.

### Intervention Fidelity

Raters were determined to achieve >80% inter-rater reliability. Across the six GET sessions, average fidelity scores ranged from 75% to 98.5%. In ISL session, the average percentage of instances in which interventionists engaged in off-manual therapeutic techniques was infrequent (range across sessions: 0%–18%).

### Therapeutic Alliance

Working alliance scores were significantly higher among those receiving GET ( $M = 6.19, SD = 0.74$ ) versus those assigned to ISL ( $M = 5.59, SD = 1.32$ ) [ $t = 2.02, p < .05$ ], suggesting that strong rapport and a relatively robust working alliance were established in GET.

### Change in Outcome Measures

#### Psychological distress

At baseline, average depressive and anxiety symptoms were 5.82 ( $SD = 3.17$ ) and 10.61 ( $SD = 3.94$ ), respectively, for those in the GET arm and 4.85 ( $SD = 3.69$ ) and 10.09 ( $SD = 4.56$ ), respectively, for those assigned to ISL.

At the post-intervention assessment, there were greater reductions in depressive (Cohen's  $d = 0.45$ ) and anxiety symptoms (Cohen's  $d = 0.29$ ) for those in the GET group than ISL. Medium effects were further observed for changes at the 3-month assessment for both depressive (Cohen's  $d = 0.46$ ) and anxiety symptoms (Cohen's  $d = 0.46$ ) that favored the impact of GET.

#### Secondary outcomes

At baseline, average goal navigation was 1.35 ( $SD = 0.39$ ) and 1.43 ( $SD = 0.48$ ) for those in the GET and ISL arms, respectively. Regarding emotion-regulation, average cognitive reappraisal was 4.44 ( $SD = 1.64$ ) and 4.71 ( $SD = 1.11$ ), respectively, for those assigned to GET and ISL; average

expressive suppression was 3.39 ( $SD = 1.43$ ) and 3.71 ( $SD = 1.29$ ), respectively, for those assigned to GET and ISL.

At the post-intervention assessment, the GET group, as compared with the ISL group, reported greater gains in goal navigation skills at post-intervention (Cohen's  $d = 0.20$ ) and at 3 months (Cohen's  $d = 0.41$ ). In addition, the GET group as compared with the ISL group, reported small to medium effects for emotion regulation skill including greater cognitive reappraisal (Cohen's  $d = 0.35$ ) and lower expressive suppression (Cohen's  $d = 0.35$ ). However, medium to large effect sizes were observed with a similar pattern of changes at the 3-month assessment for both greater cognitive reappraisal (Cohen's  $d = 0.59$ ) and lower expressive suppression (Cohen's  $d = 0.46$ ) with GET.

Finally, at baseline, average career confusion was 17.24 ( $SD = 24.29$ ) and 15.06 ( $SD = 31.55$ ) for those in the GET and ISL arms, respectively. GET was associated with a greater pre–post reduction in career confusion compared with ISL (Cohen's  $d = .41$ ).

See [Supplementary Tables 1 and 2](#).

## Discussion

Young adults with poorer goal navigation skills and emotion-regulation abilities may be vulnerable to worse adverse psychosocial outcomes when facing cancer-related life goal challenges. However, there are currently no behavioral interventions to promote targeted elements of self-regulation that are matched to the challenges experienced by testicular cancer survivors in young adulthood. The aim of this pilot study was to evaluate the GET intervention and examine its preliminary impact on measures of psychological distress, emotion regulation, and goal-related processes versus an active supportive listening control (i.e., ISL).

Generally, those receiving GET found the intervention (and the control intervention) tolerable with a high majority completing all study sessions in both arms. Likewise, though to a lesser extent, the majority completed all study procedures including follow-up assessments. Despite adherence being adequate, there may be an opportunity in future work to enhance retention efforts following intervention completion during the follow-up assessment period. Various strategies might be considered in future trials including more frequent post-intervention communication between the study team and enrolled participants, the use of a brief booster session, or stepwise, graduated monetary incentive schedule. Increasing the proportion of enrollment among eligible men approached for participation should be a goal in future studies.

Although no criteria were identified a priori for determining acceptability or tolerability, pragmatically  $\geq 50\%$  of the young adult testicular cancer survivors reporting elevated distress and/or lower goal navigation skill in screening agreeing to participate in GET would equate to a large number of participants in a subsequent trial, particularly given the lack of accessible and developmentally targeted treatments. The participation rate of 43.4% in this study suggests the need to enhance recruitment in a larger trial. The current study relied on clinic-based recruitment methods. However, it might be that survivors are more amenable to behavioral intervention in slightly later phases of survivorship when close connection to clinical care has diminished. Also, recruitment for the current study relied on patients of a large comprehensive cancer

care center with presumably high levels of resources and care options. Patients in smaller care settings may have less opportunity for behavioral intervention and may therefore be more likely to participate.

Clinical observations of strong therapeutic relationships between interventionists and participants were supported by ratings of working alliance, which were higher among GET participants than those in ISL. Although all study interventionists were trained to engage in empathic, warm, and validating communication, it may be the targets of GET foster a relationship of shared therapeutic goals. Confidence in this possibility is strengthened by the relatively high intervention fidelity ratings in GET sessions and relatively low instances of therapeutic drift in ISL sessions.

The examination of patterns of change in primary and secondary measures in this pilot randomized trial were encouraging and provide some indication that the GET intervention might work to mitigate distress in this young adult survivor group and enhance emotion- and goal-related self-regulation skills. On average, participants reported reductions in symptoms of depression and anxiety from baseline to post-intervention of medium effect sizes, with improvements maintained or enhanced at 3-month post-intervention. Results focused on aspects of feasibility and examination of effects sizes for changes in primary and secondary measures. Results of pilot trials should be considered in context and understood as not necessarily reflecting the “true” effect of the intervention once it is optimized and delivered in a larger trial [67]. Considerations of effect sizes should not imply statistically significant group-by-time effects.

GET also demonstrated promising trends in key emotion regulation and goal navigation outcomes relative to ISL, with sustained and continued to change at 3 months. These outcomes are targeted processes of the GET intervention. This pattern of results not only suggests that GET has the potential to affect change in these outcomes, but provides the foundation for future mechanistic studies to confirm that goal- and emotion-regulation are processes of change for clinical outcomes. Finally, although only pre–post changes in career confusion were able to be assessed in this study, our preliminary results suggest GET might be a useful intervention in occupational goal pursuits.

Facility (or deficit) in navigating the pursuit of goals during and after cancer has unique relationships with one's maintenance of a sense of life purpose, as well as engagement in the regulation of difficult emotional responses to the demands and uncertainty of cancer [68]. Given strong associations between goal attainment and subjective well-being among young adults [69, 70], increasing the focus on goal-navigation skill building may further optimize intervention effects. A larger randomized trial is needed to build from these preliminary results to determine overall efficacy and clinical impact.

These results must be considered in light of several limitations. The small sample size, although adequate for pilot studies, should not be mistaken for trials designed to establish efficacy. The notable advantage is that this study provides critical opportunity to optimize and refine GET. Thus, the pilot nature of this analysis establishes effect size estimates and patterns of change rather than statistical significance. Also, this study included a useful 3-month follow-up period; however, the possibility that further change occurred over time remains. A future trial should include a longer follow-up period.



The context of the sample should also be considered. All participants received medical treatment at a large urban comprehensive cancer center, reported a relatively high annual household income, were relatively well educated, and had high levels of full-time employment. Such factors may reflect relatively high overall functioning which could also be related to how individuals engaged with and benefited from GET. More feasibility testing may be needed in subgroups of patients with increased diversity. Also, 12 individuals never initiated intervention sessions after completing baseline assessments. Although in two instances in which a cancer recurrence or new cancer diagnosis was the determinant, the reasons for lack of initiation in these cases are unknown. Future trials should enhance strategies for participant commitment prior to consent. Finally, due to Covid-19-related safety protocols, 21 participants received the intervention via video call. Although we detected no notable differences in assessed measures, intervention response, demographic factors, or clinical variables, the impact of the pandemic may have influenced results.

Despite limitations, this is the first pilot randomized controlled trial to demonstrate an impact of GET on reductions in psychological distress and enhancements in core self-regulatory processes among young adult survivors of testicular cancer. In fact, these results reached several milestones identified for declaring efficacy in phase IIb pilot trials of behavioral interventions [71] including demonstrating feasibility of the trial protocol (e.g., recruitment plan, an estimate of dropout rates from both treated and control conditions), estimating the range of effect from treatment and control conditions that will be attained on primary outcomes, and that a behavioral intervention produces a clinically significant signal on the behavioral risk factor above a relevant control intervention. Thus, these results, taken together with preliminary feasibility and biomarker studies [53, 54] position GET as a promising intervention ready for phase III testing.

Given the paucity of behavioral interventions for this population, it is challenging to contextualize these findings in the context of similar interventions. However, a focus on disrupted goal pursuits among young adult survivors is emerging as a focus on behavioral intervention. For instance, Berg et al. [72] piloted a goal-focused intervention in a sample of young adults with various cancer diagnoses and also concluded that a focus on skills related to goal pursuits after cancer is a promising clinical direction warranting further research to establish efficacy and optimize scalability.

Considering the adverse health impact of testicular cancer and lack of appropriate and developmentally matched behavioral interventions tailored to young adults, these findings provide preliminary evidence to underscore further research with the goal of discovering whether GET and goal-focused interventions alter the negative adverse psychological effects of cancer and cancer treatment in this population.

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## Compliance with Ethical Standards

**Authors' Statement of Conflict of Interest and Adherence to Ethical Standards** Authors Michael A. Hoyt, Ashley Wei-Ting Wang, Raymond Carrillo Ceja, Jennifer S. Cheavens, Michael A. Daneshvar, Darren R. Feldman, and Christian J. Nelson declare that they have no conflict of interest. Samuel A. Funt has received research support from AstraZeneca, Genentech/Roche, is a consultant/advisory board member for Merck, and owns stock in Urogen, Allogene Therapeutics, Neogene Therapeutics, Kronos Bio, ByHeart, 76Bio, Vida Ventures, Doximity, and Inconovir.

**Authors' Contributions** Michael A Hoyt, PhD (Conceptualization: Lead; Data curation: Lead; Formal analysis: Lead; Funding acquisition: Lead; Investigation: Lead; Methodology: Lead; Project administration: Lead; Supervision: Lead; Writing – original draft: Lead; Writing – review & editing: Lead), Ashley Wei-Ting Wang, PhD (Data curation: Supporting; Project administration: Supporting; Writing – original draft: Supporting; Writing – review & editing: Supporting), Raymond Carrillo Ceja (Data curation: Supporting; Project administration: Supporting; Writing – review & editing: Supporting), Jennifer S Cheavens, PhD (Methodology: Supporting; Writing – review & editing: Supporting), Michael A Daneshvar, MD (Project administration: Supporting; Writing – original draft: Supporting; Writing – review & editing: Supporting), Darren R Feldman, MD (Investigation: Supporting; Methodology: Supporting), Samuel A Funt, MD (Methodology: Supporting; Project administration: Supporting; Writing – original draft: Supporting; Writing – review & editing: Supporting), and Christian J Nelson, PhD (Conceptualization: Equal; Funding acquisition: Equal; Investigation: Equal; Methodology: Equal; Project administration: Equal; Supervision: Equal; Writing – original draft: Supporting; Writing – review & editing: Supporting)

## Transparency Statement

- *Analytic plan preregistration*: The analysis plan was not formally preregistered.
- *Analytic code availability*: Analytic code used to conduct the analyses presented in this study are not available in a public archive. They may be available by emailing the corresponding author.
- *Materials availability*: Materials used to conduct the study are not publicly available.

## Data Availability

Deidentified data from this study are not available in a public archive.

## Supplementary Material

Supplementary material is available at *Annals of Behavioral Medicine* online.

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