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Exploratory analysis of treatment response trajectories in the Promoting Resilience in Stress Management (PRISM) Trial: models of psychosocial care

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Abstract

Objective.—Adolescents and young adults (AYAs) with cancer are at high risk of negative psychosocial outcomes. Promoting Resilience in Stress Management (PRISM), a novel, brief, skills-based intervention, has demonstrated efficacy in improving psychosocial well-being for AYAs. We utilized data from a recent randomized trial of PRISM versus Usual Care (UC) to categorize and explore group differences in change trajectories of Patient Reported Outcomes (PROs) over time.

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This trial has been registered at [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT02340884) (NCT02340884).

DATA MANAGEMENT AND SHARING

Our data cannot legally or ethically be released as our participants include minors, and they and their parents did not provide consent for data sharing.

CONFLICTS OF INTEREST

The authors have no conflicts of interest to report.

Methods.—100 English-speaking AYAs (ages 12–25) with cancer were randomized to PRISM versus UC. At enrollment and 6 months later, AYAs completed validated PROs measuring resilience (CDRISC-10), hope (Hope Scale), benefit-finding (Benefit and Burden Scale for Children), cancer-specific quality of life (PedsQL Cancer Module), and distress (Kessler-6). Patient response trajectories were categorized as “improved”, “consistently well”, “consistently at risk”, or “deteriorated” using Minimal Clinically Important Differences (MCIDs) or established measure cut-offs for all PROs. Positive response trajectories consisted of the first two categories (“improved”, “consistently well”) and negative response trajectories consisted of the latter two categories (“consistently at risk”, “deteriorated”).

Results.—Across all PROs, more patients in the PRISM arm “improved” in psychosocial well-being over time, and fewer PRISM recipients “deteriorated” over time. Across all PROs, a greater proportion of PRISM participants (vs. UC) experienced positive response trajectories. Across all PROs, a greater proportion of UC participants experienced negative response trajectories.

Conclusions.—PRISM shows evidence of both a prevention effect and an intervention effect. Thus, PRISM may serve as a viable prevention and early intervention model for psychosocial care.

Keywords

cancer; oncology; adolescent; young adult; preventive programs; psycho-oncology; quality of life; randomized controlled trial; resilience; psychosocial factors

BACKGROUND

Adolescents and Young Adults (AYAs; 12–25 years old) with cancer are at high risk of negative psychosocial outcomes, in part due to the disruption of normative developmental experiences and life transitions related to establishing independence and personal identity, navigating social and romantic relationships, and the pursuit of educational and vocational goals.^{1–5} Psychosocial outcomes among AYA cancer survivors are inferior to their younger pediatric and older adult counterparts, with significantly more psychological distress, poorer quality of life, and fewer positive health benefits.⁶

Positive psychological interventions have the potential to improve psychosocial outcomes, but few have been developed and tested with AYAs with cancer.^{7–9} Promoting Resilience in Stress Management (PRISM) is a novel, brief, developmentally appropriate, skills-based intervention targeting the “resilience resources” of stress management, goal setting, cognitive reframing (evaluating and reappraising negative cognitions and self-talk), and benefit finding (finding meaning and benefit from adversity).¹⁰ In a phase II randomized controlled trial (RCT) testing the efficacy of PRISM compared to psychosocial usual care (UC) in AYAs with cancer, PRISM was associated with improved patient-reported resilience, hope, benefit-finding, and cancer-specific quality of life and decreased psychological distress.^{11,12}

Previous publications of the phase II PRISM RCT focused on intention to treat analyses comparing change in total instrument scores of PRISM vs. UC, and PRISM was associated with moderate-to-large effect sizes.^{11,12} Here, we report results of a *post-hoc* exploratory analysis of the phase II PRISM RCT in which we examined and classified individual patient

responses of Patient Reported Outcomes (PROs) over time in order to better understand how and why PRISM works. Does PRISM: (a) improve psychosocial well-being over time; (b) prevent the deterioration of symptoms over time; (c) sustain patient well-being; or, is it some combination of these options?

METHODS

Design, setting, and participants

Eligible participants for the phase II, parallel, 1:1 RCT^{11,12} were enrolled between January 2015 and October 2016. Participants provided written informed consent and the Seattle Children's Hospital Institutional Review Board approved this study (IRB Protocol #: 15300). Participants were ages 12–25, English-speaking, and diagnosed with cancer 1–10 weeks prior to enrollment or ever diagnosed with progressive, recurrent, or refractory cancer, and receiving systemic chemotherapy.

Recruitment and randomization

Eligible participants were identified through clinic rosters and approached in inpatient or outpatient settings. Consecutive patients were enrolled until reaching a target enrollment of $n = 100$. After enrollment, participants were randomized 1:1 to UC alone or UC plus PRISM. Study staff were blinded to the randomization assignment until after enrollment; staff collecting outcomes data were blinded to assignment. After the four main sessions were completed, participants had the option to participate in once monthly brief “booster” sessions to practice PRISM skills.

Psychosocial UC

All participants received psychosocial UC which consisted of an assigned social worker who provided services ranging from behavioral health services to material and social needs for the AYA and his or her family throughout the study; access to multidisciplinary AYA and psychosocial teams; and, referrals to psychology, psychiatry, pain medicine, child life, chaplaincy, palliative care, school, physical/occupational therapy, and art/music therapy.

The PRISM Intervention

The PRISM intervention is as a novel, manualized, skills-based intervention based on resilience, stress, and coping theories and evidence-based interventions in other patient populations. PRISM's development, feasibility, acceptability, and efficacy has previously been described.^{10,11} PRISM was designed to be deliverable by bachelors or masters-level non-clinical professionals. Interventionists conducted four 30–50 minute, one-on-one sessions, approximately every other week.

PROs Measurements

At enrollment and 6 months later, patients completed a comprehensive assessment of AYA age-validated PROs. In previous publications^{11,12}, PRISM was associated with improvement in the following PROs:

Resilience.—The Connor-Davidson Resilience Scale (CDRISC-10) assesses inherent resiliency, personal problem solving, and approaches to adversity.¹³ Items are rated on a 5-point Likert scale, with higher scores indicating greater resilience. Total scores range from 0 to 40.

Hope.—The Hope Scale measures the overall perception that one's goals can be met and hopeful thought patterns.¹⁴ Items are rated on an 8-point Likert scale, with higher scores indicating greater levels of hopeful thought patterns. Total scores range from 8 to 64.

Benefit finding.—The Benefit and Burden Scale for Children assesses perceived potential benefits and burdens of illness.¹⁵ Items are rated on a 5-point Likert scale, with higher scores indicating greater benefit. Total scores range from 10 to 50.

Quality of life.—The Pediatric Quality of Life (PedsQL) Cancer Module measures cancer specific symptoms, worries, cognition, and communication.¹⁶ Total scores range from 0 to 100 with higher scores indicating better quality of life.

Distress.—The Kessler-6 Psychological Distress Scale (K-6) measures global psychological distress.^{17,18} Items are rated on a 5-point Likert scale, with higher scores indicating greater distress. Total scores range from 0 to 24. Previous studies suggest that scores ≥ 7 are consistent with elevated distress.

Analytic Approach to Patient Response Trajectory Categorizations

Individual patient response trajectories were categorized into four groups: “improved”, “consistently well”, “consistently at risk”, and “deteriorated”. Categorizations were defined using clinical cut-offs for K-6 (distress) and Minimal Clinically Important Differences (MCIDs) for all other PROs.

Distress.—K6 scores at baseline and follow-up were categorized dichotomously as “not distressed” = 0–6 or “distressed” = ≥ 7 according to established measure cut-off scores. Patient response trajectories from baseline to follow-up were categorized as: (a) “improved” = scores changed from “distressed” to “not distressed”; (b) “consistently well” = scores remained “not distressed”; (c) “consistently at risk” = scores remained “distressed”; or, (d) “deteriorated” = scores changed from “not distressed” to “distressed”.

All other PROs.—At baseline, PROs scores were categorized as: (a) “average” = within a range of mean \pm MCID, where MCID was defined as $1/2$ SD of the overall sample at baseline¹⁹; (b) “at-risk” = PRO score $<$ “average”; and, (c) “good” = PRO score $>$ “average”. Patient response trajectories from baseline to follow-up were defined as “stable” if the score change was \leq MCID, where MCID was defined as $1/2$ SD of the overall sample change. The “improved” category includes those who started with “at-risk” or “average” scores and had a score increase $>$ MCID, while the “deteriorated” category includes those with “good” or “average” baseline scores who had a score decrease $>$ MCID. The “consistently well” category includes those who started with “average” or “good” scores and remained “stable” over time, as well as those who started with “good” scores and had a score increase $>$ MCID over time. The “consistently at risk” category includes those who started with “at-risk”

scores and remained “stable” over time, as well as those who started with “at-risk” scores and had a score decrease $>$ MCID over time.

Across all PROs, “improved” and “consistently well” categories were defined as positive response trajectories, whereas “consistently at risk” and “deteriorated” categories were defined as negative response trajectories. Figure 1 provides a hypothetical visual representation of group categorizations. We used graphical representations and 95% confidence intervals to describe the proportion of participants with positive and negative trajectories in each study arm. P-values were not generated due to inadequate subsample sizes for this *post-hoc* exploratory analysis.

RESULTS

One PRISM participant was identified as ineligible immediately after randomization, and was unenrolled.¹¹ Of the 99 remaining participants, six UC participants and one PRISM participant did not complete the baseline survey. Participant characteristics at baseline are summarized in Table 1. Percent positive trajectories (95% Confidence Interval (CI) are summarized by study arm in Table 2. Patient response trajectory categorizations for each PRO are summarized by study arm in Figure 2.

Resilience.

PRISM arm patients were categorized as follows: 33% “improved”; 39% “consistently well”; 11% “consistently at risk”; and, 17% “deteriorated”. UC arm patients were categorized as follows: 13% “improved”; 34% “consistently well”; 24% “consistently at risk”; and, “29% substantial deterioration”.

More PRISM recipients “improved” (PRISM: 33% vs. UC: 13%), and fewer PRISM recipients “deteriorated” (PRISM: 17% vs. UC: 29%). A higher proportion of PRISM recipients had positive response trajectories, categorized as either “improved” or “consistently well” (PRISM=72%, 95% CI: 56–84 vs. UC=47%, 95% CI: 32–63).

Hope.

PRISM arm patients were categorized as follows: 39% “improved”; 39% “consistently well”; 11% “consistently at risk”; and, 11% “deteriorated”. UC arm patients were categorized as follows: 26% “improved”; 34% “consistently well”; 8% “consistently at risk”; and, 32% “deteriorated”.

More PRISM recipients “improved” (PRISM: 39% vs. UC: 26%), and fewer PRISM recipients “deteriorated” (PRISM: 11% vs. UC: 32%). A higher proportion of PRISM recipients had positive response trajectories, categorized as either “improved” or “consistently well” (PRISM=78%, 95% CI: 62–88 vs. UC=61%, 95% CI: 45–74).

Benefit finding.

PRISM arm patients were categorized as follows: 58% “improved”; 28% “consistently well”; 3% “consistently at risk”; and, 11% “deteriorated”. UC arm patients were categorized

as follows: 37% “improved”; 39% “consistently well”; 5% “consistently at risk”; and, 18% “deteriorated”.

More PRISM recipients “improved” (PRISM: 58% vs. UC: 37%) and fewer PRISM recipients “deteriorated” (PRISM: 11% vs. UC: 18%). A higher proportion of PRISM recipients had positive response trajectories, categorized as either “improved” or “consistently well” (PRISM=86%, 95% CI: 71–94 vs. UC=76%, 95% CI: 61–87).

Quality of life.

PRISM arm patients were categorized as follows: 39% “improved”; 42% “consistently well”; 8% “consistently at risk”; and, 11% “deteriorated”. UC arm patients were categorized as follows: 13% “improved”; 47% “consistently well”; 21% “consistently at risk”; and, 18% “deteriorated”.

More PRISM recipients “improved” (PRISM: 39% vs. UC: 13%), and fewer PRISM recipients “deteriorated” (PRISM: 11% vs. UC: 18%). A higher proportion of PRISM recipients had positive response trajectories, categorized as either “improved” or “consistently well” (PRISM=81%, 95% CI: 65–90 vs. UC=61%, 95% CI: 45–74).

Distress.

PRISM arm patients were categorized as follows: 31% “improved”; 39% “consistently well”; 17% “consistently at risk”; and, 14% “deteriorated”. UC arm patients were categorized as follows: 16% “improved”; 32% “consistently well”; 34% “consistently at risk”; and, 18% “deteriorated”.

More PRISM recipients “improved” (PRISM: 31% vs. UC: 16%), and fewer PRISM recipients “deteriorated” (PRISM: 14% vs. UC: 18%). A higher proportion of PRISM recipients had positive response trajectories over time, categorized as either “improved” or “consistently well” (PRISM=69%, 95% CI: 53–82 vs. UC=47%, 95% CI: 32–63).

CONCLUSIONS

AYAs with cancer are at risk of negative psychosocial outcomes and poor quality of life because a cancer diagnosis disrupts normative development. Positive psychological interventions may benefit this vulnerable disease population. PRISM is a first of its kind, brief, skills-based intervention designed and tested with AYAs for AYAs and has been shown to be feasible, acceptable, and efficacious. However, previous publications have focused on PRISM performance and effect sizes at the broad treatment arm level in comparison to UC. In order to parse apart how AYAs respond to both PRISM and UC, individual patient trajectories have proven to be illuminating.

The current *post-hoc* exploratory analysis provides a granular assessment of patient trajectories of change and showed that PRISM recipients (in comparison to UC) were both more likely to show improvement in psychosocial well-being over time, and less likely to deteriorate over time. Across all PROs, a greater proportion of patients in the PRISM arm experienced positive response trajectories, either improving or sustaining their well-being

over time. Across all PROs, a greater proportion of patients in the UC arm experienced negative response trajectories, either deteriorating or remaining at risk over time. The current study helps to shed light on how PRISM works, providing evidence that PRISM may be associated with both an intervention effect via improvement in psychosocial well-being, and a prevention effect via sustained patient well-being and preventing deterioration in symptoms over time. Thus, PRISM may be an appropriate intervention for all AYAs with a cancer diagnosis, even those patients who do not present with at-risk baseline PROs scores. Additionally, it is unlikely that intervention-participation factors such as number of sessions completed influenced treatment response as completion rates were uniformly high; 90% of PRISM participants completed all 4 sessions.¹¹

Progress has been slow in translating evidence-based psychosocial interventions into clinical treatment setting.²⁰ A practical challenge is that the standard duration of evidence-based psychosocial interventions such as cognitive behavioral therapy is 10–12 weekly 1-hour sessions. Such time commitments may be prohibitive for AYAs with cancer and their caregivers.²¹ Additionally, having a trained doctoral-level psychologist provide individual therapy to all cancer patients is infeasible due to personnel shortages.²² The result is inconsistent and delayed delivery of care, missed opportunities to prevent escalating distress, and a focus on emergent interventions for families in crisis. A potential solution is a stepped care model where brief treatments delivered by non-specialists such as PRISM serve as “entry level” care, and “stepped up” (advanced level) treatments delivered by social workers and psychologists is limited to those with determined psychosocial needs.²³

Study Limitations

Limitations of this analysis include that this report utilizes data from a phase II RCT that was not powered for these *post-hoc* analyses and subsample sizes for trajectories group categorizations were small. Thus, we could not test for statistical or clinical significance based on trajectories group categorizations for these *post-hoc* analyses; however, the range of the 95% CIs for positive trajectories was consistently higher in PRISM than UC across all PROs. Additionally, due to small sample sizes within trajectories subgroups, we were unable to conduct further analyses of subgroups to determine characteristics associated with patients who benefited the most (or least) from a prevention or intervention effect. Therefore, findings reported are considered preliminary, hypothesis-generating, and descriptive in nature. Generalizability of our findings are also limited as this is a single institution study conducted at an academic hospital, and we only included English-speaking patients because PRISM has only been validated in English. Additionally, we did not collect data on the timing and influence of medical variables such as disease progression and medical treatment which may interact with psychosocial PROs. Finally, the optimal timing and long-term durability of the PRISM intervention is unknown. These findings should be replicated in future longitudinal studies powered for this sub-analysis and in more diverse settings. Additionally, adequately powered future studies with larger sample sizes would benefit from responder analysis²⁴ to assess the clinical and statistical relevance of PRISM’s prevention and intervention effect.

Clinical Implications

In summary, PRISM may have the potential to both improve psychosocial outcomes for newly diagnosed AYA cancer patients and to protect against the deleterious psychosocial effects of cancer even for patients who do not initially present as at-risk; evidence of a prevention effect should further be explored and substantiated in future studies powered for this analysis. Future research with larger sample sizes should explore sociodemographic and clinical characteristics as predictors of positive and negative response trajectories, and trajectories subgroups. Future research will focus on the early implementation of PRISM in real-world clinical settings, training non-clinical professionals to deliver the intervention with fidelity, as our research group has done successfully in the past. This will expand access to psychosocial care for AYA cancer patients and their families, improving their psychosocial well-being and quality of life.

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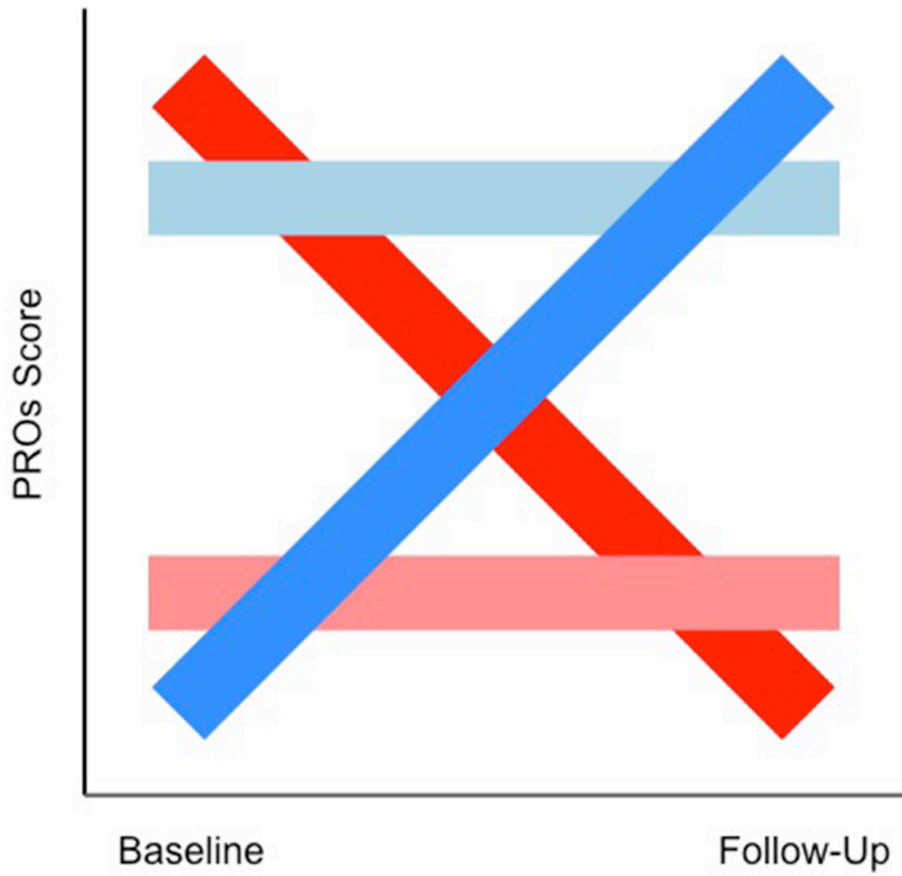


Figure 1.
Hypothetical visual representation of group categorizations

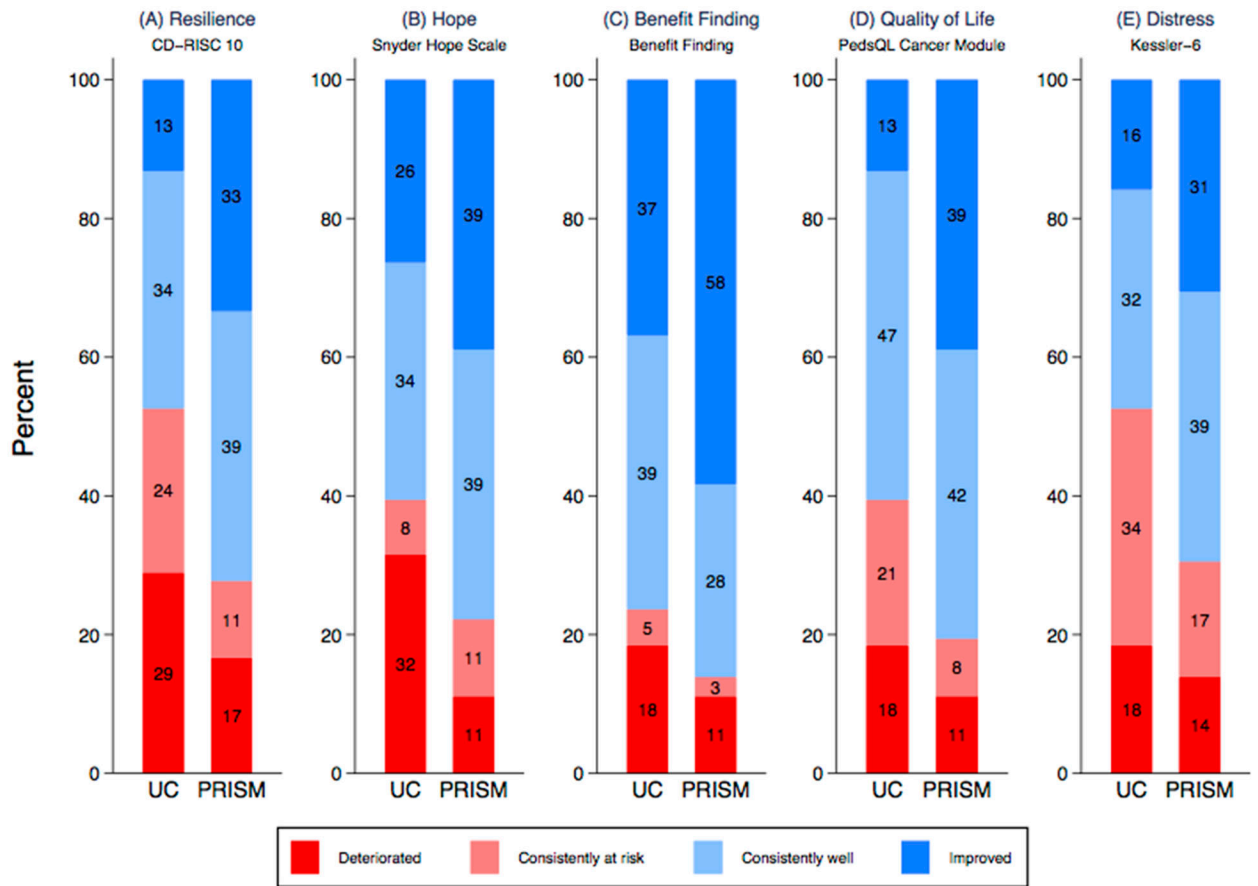


Figure 2.
Patient response trajectory categorizations for each PRO

Table 1.

Participant characteristics and instrument scores at the time of enrollment

Characteristic	UC (n = 44)	PRISM (n = 48)	All (n = 92)
	n (%)	n (%)	n (%)
Female	24 (55)	16 (33)	40 (43)
12–17 years old at enrollment	32 (73)	35 (73)	67 (73)
18–25 years old at enrollment	12 (27)	13 (27)	25 (27)
Non-White race	19 (43)	14 (29)	33 (36)
First language other than English	10 (23)	1 (2)	11 (12)
Leukemia/lymphoma	29 (66)	31 (65)	60 (65)
Central nervous system (CNS)	4 (9)	3 (6)	7 (8)
Non-CNS solid tumor	11 (25)	14 (29)	25 (27)
Advanced cancer at enrollment	14 (32)	10 (21)	24 (26)
Instrument Score	Mean (SD)	Mean (SD)	Mean (SD, MCID)
Resilience (CDRISC-10)	28 (5.8)	29 (6.2)	29 (6.0, 3.0)
Hope-Total (Hope Scale)	51 (8.1)	49 (8.4)	50 (8.3, 4.1)
Benefit Finding (Benefit and Burden Scale for Children)	37 (8.2)	34 (9.5)	35 (9.0, 4.5)
Cancer-specific quality of life (PedsQL Cancer Module)	65 (16.9)	66 (15.9)	65 (16.3, 8.1)
Global psychological distress (Kessler-6)	8 (4.8)	6 (4.5)	7 (4.7, 2.3)

Table 2.

Percent positive trajectories (95% CI) by study arm

	UC		PRISM	
	Percent	95% CI	Percent	95% CI
Resilience (CDRISC-10)	47	32–63	72	56–84
Hope-Total (Hope Scale)	61	45–74	78	62–88
Benefit Finding (Benefit and Burden Scale for Children)	76	61–87	86	71–94
Cancer-specific quality of life (PedsQL Cancer Module)	61	45–74	81	65–90
Global psychological distress (Kessler-6)	47	32–63	69	53–82

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