






A randomized controlled trial of a distress screening, consultation, and targeted referral system for family caregivers in oncologic care

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Abstract

Objective: Distress screening is standard practice among oncology patients, yet few routine distress screening programs exist for cancer caregivers. The objective of this study was to demonstrate the feasibility, acceptability, and preliminary efficacy of Cancer Support Source-Caregiver™ (CSS-CG, 33-item), an electronic distress screening and automated referral program with a consultation (S + C) to improve caregiver unmet needs, quality of life, anxiety, depression, and distress relative to Enhanced Usual Care (EUC; access to educational materials).

Method: 150 caregivers of patients with varying sites/stages of cancer were randomized to S + C or EUC and completed assessments at baseline, 3-months post-baseline, and 6-months post-baseline. A subset of participants ($n = 10$) completed in-depth qualitative interviews.

Results: S + C was feasible: among 75 caregivers randomized to S + C, 66 (88%) completed CSS-CG and consultation. Top concerns reported were: (1) patient's pain and/or physical discomfort; (2) patient's cancer progressing/recurring; and (3) feeling nervous or afraid.

Differences between groups in improvements on outcomes by T2 and T3 were modest ($d_s < 0.53$) in favor of S + C. Qualitative data underscored the helpfulness of S + C in connecting caregivers to support and helping them feel cared for and integrated into cancer care.

Conclusions: S + C is feasible, acceptable, and yields more positive impact on emotional well-being than usual care. Future studies will examine programmatic impact among caregivers experiencing higher acuity of needs, and benefits of earlier integration of S + C on caregiver, patient, and healthcare system outcomes.

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KEYWORDS

cancer, distress screening, family caregivers, oncology, psychosocial, psycho-oncology, referral, unmet needs

1 | INTRODUCTION

Approximately 6 million Americans are family caregivers to patients with cancer.¹ They provide physical, emotional, and financial support, and increasingly perform complex medical and nursing tasks, often without formal training or education.² More recently, the COVID-19 pandemic highlighted caregivers' immense responsibilities for patient care, often in isolation.³ Such responsibilities put caregivers at high risk for psychiatric and medical morbidity, including anxiety, depression, poor immune function, cardiovascular disease, and sleep disturbances.⁴⁻⁷ Unsurprisingly, caregivers commonly report having a poor quality of life (QOL).⁸

In this setting, the benefits of psychosocial support can be profound. Distressed caregivers report great interest in supportive services.⁹ Despite the documented need and high demand for support,⁹⁻¹¹ however, only about 1 in 4 caregivers access psychosocial care. Reported barriers to accessing care include scheduling limitations, time constraints, lack of knowledge of resources, not wanting to "bother" the patient's medical team, and believing they would be inappropriately placing their needs above those of the patient.^{12,13}

In oncology centers, distress screening has become a standard practice among patients, yet few routine distress screening programs exist for caregivers. Among patients, distress screening has been shown to identify unmet needs and facilitate triage to appropriate services¹⁴ and is associated with benefits including fewer hospitalizations, emergency room visits, and prescriptions filled.^{14,15} While the Institute of Medicine¹⁶ and National Comprehensive Cancer Network (NCCN)¹⁷ recognize that psychosocial screening, referral, and follow-up are necessary for quality cancer care, existing distress screening programs fail to address the needs of family caregivers.^{18,19} Distress screening for caregivers would address many existing barriers to psychosocial service use and extend benefits experienced by patients to their vulnerable caregivers.

Given the well-documented association between caregiver well-being to patient care, outcomes,²⁰ and distress levels,²¹ protocols are needed to identify caregivers at risk for distress and triage them to necessary support. In a step towards that goal, we sought to demonstrate the feasibility, acceptability, and preliminary efficacy of a comprehensive distress screening program for caregivers. The CancerSupportSource™-Caregiver (CSS-CG)²² is a validated electronic distress screening and automatic referral system designed to address the unique concerns of cancer caregivers.²² Here we sought to evaluate the benefits of pairing CSS-CG with a follow-up consultation on caregiver unmet needs, QOL, anxiety, and depression.

2 | METHOD

2.1 | Participants and recruitment

Participants were family caregivers to patients of Memorial Sloan Kettering Cancer Center (MSK) and took part in the study between May 2019 and May 2022. Initially, participants presented to the Josie Robertson Surgery Center (JRSC), an outpatient surgical center, on the day of the patient's surgery and caregivers were approached by nursing staff once patients went into surgery and provided written informed consent. During COVID-19 lockdown, recruitment shifted to several inpatient floors at the Main Hospital and the Bone Marrow Transplant (BMT) Clinic, where caregivers were identified via patient records, and consented verbally over the phone and then enrolled by study staff. Across settings, eligible caregivers were ≥ 18 years old, self-identified as the primary caregiver, and fluent in English. Exclusion criteria included cognitive difficulties or medical illness that precluded participation and caring for a patient undergoing a prophylactic procedure. Only one caregiver was recruited per patient. For caregivers consenting remotely, assessments were sent through secure email.

2.2 | Procedures

Caregivers ($N = 150$) were randomized 1:1 into either Screening + Consultation (S + C) or Enhanced Usual Care (EUC) following completion of baseline measures. Participants were randomized by method of random permuted block without any stratification. The randomization sequence was generated using our institution's established software and caregivers were assigned to a group automatically upon enrollment and completion of the baseline assessment. Participants completed self-reported surveys via REDCap at baseline (T1), 3-months post-baseline (T2) and 6-months post-baseline (T3). Caregivers randomized to S + C completed the web-based CSS-CG within 1 week of completion of T1. A subset ($N = 10$) of these S + C participants completed semi-structured interviews at T2. We chose this sample size as we estimated that it would allow for thematic saturation.²³

2.3 | Interventions

2.3.1 | CancerSupportSource-Caregiver screening plus consultation (S + C)

The CSS-CG, developed by Cancer Support Community (CSC), is a validated electronic distress screening and automatic referral

system designed to address the unique concerns of cancer caregivers. We implemented a 33-item version of CSS-CG; caregivers rate how concerned (0 *Not at all* to 4 *Very seriously*) they are and how they would prefer these concerns be addressed.²² Concerns include their own self-care needs, emotional well-being, and caregiving tasks, as well as concerns about the patients' well-being. Two scores were derived: an overall caregiver distress score calculated as the sum of the level of concern across the 33 items (range: 0–132, with higher scores indicating greater distress); and a depression risk subscale summing four items, with a score ≥ 5 indicating risk for clinically significant depression.²⁴

During screening, if an item was rated as low (i.e., “Not at all” or “A little”), caregivers could request pertinent educational materials. If an item was rated as a higher concern (i.e., “Moderately,” “Seriously,” or “Very Seriously”), caregivers could request to speak with someone about that need (i.e., receive a referral) and/or receive information. CSS-CG incorporates health system/institution-specific information, and referral sources within MSK were designated to address each problem area. As of June 2020, an additional 6 items that specifically addressed COVID-19-related distress were added, plus COVID-19-specific resources.

Upon CSS-CG completion, study staff sent caregivers a report which provided item-level feedback including caregivers' greatest concerns and their depression risk status. Participants meeting criteria for depression risk were assessed within 24 h by a licensed clinical psychologist for imminent self-harm and given a referral to the MSK Counseling Center. For each item a participant requested educational materials, a brief educational summary was provided, along with links to tailored MSK and CSC educational materials. For each item a participant requested to speak with someone, the nurse liaison or study staff called to further evaluate support needs and provide additional information and referrals. Approximately 3–6 days after CSS-CG completion, all S + C participants were contacted by nurses (at JRSC) or Clinical Research Coordinators (CRCs, at the Main hospital) for a consultation call to review the report, assess change in distress and modify (add/remove/change) referrals as appropriate, and identify and problem solve barriers to accessing requested referrals.

2.3.2 | Enhanced usual care (EUC)

Caregivers randomized to EUC were instructed on how to access the MyMSK portal Caregiver Resources page, including links to MSK caregiver educational materials, contact information for psychosocial services (e.g., Caregivers Clinic at MSK), and external resources (e.g., educational materials and services through CSC, American Cancer Society). If caregivers did not wish to enroll in MyMSK, they were sent an email with abbreviated referral material.

2.4 | Outcome measures

2.4.1 | Caregiver well-being

Unmet needs were assessed using the 39-item National Comprehensive Cancer Network (NCCN) Problem List.²⁵ The number of endorsed problems (“yes” in past week, including today) were summed to compute domain-specific need (Practical, Family, Emotional, Spiritual/Religious, and Physical); total need was calculated as the sum of all needs across domains.

Global distress was measured using the NCCN Distress Thermometer (DT),²⁶ a visual analog scale ranging from 0 (*None*) to 10 (*Extreme*). Frequency of caregivers meeting the DT cutoff for clinically significant distress (scores ≥ 4) were determined.

Quality of life was assessed through the Functional Assessment of Cancer Therapy—General Population (FACT-GP), a 21-item self-report measure of general health-related QOL²⁷ with four subscales (physical, social/family, emotional, and functional well-being) that result in separate index scores and a summed overall score. Items were rated on a 5-point scale (0 *Not at all* to 4 *Very much*), with higher scores indicating better QOL.

Anxiety and depressive symptomatology were assessed using the Hospital Anxiety and Depression Scale (HADS),²⁸ a 14-item self-rated questionnaire with separate depression and anxiety subscales. Subscale scores range from 0 to 21 (8–10: mild; 11–14: moderate; 15–21: severe); scores for the entire scale range from 0 to 42, with higher scores indicating more distress.

2.4.2 | Healthcare utilization

Use of supportive care services at MSK and use of external professional resources, including CSC's Cancer Support Helpline, at any time in the past was evaluated by caregiver self-report. Items were rated and recoded for analysis: (1) no healthcare need (“Have not used & have no need”); (2) unmet healthcare need (“Have not used but would like to”); and (3) met healthcare need (“Have used & would like to use more” or “Have used but now have no need”). Two frequencies were calculated from these items: *number of unmet healthcare needs* and *number of met healthcare needs*.²⁹

2.4.3 | Post S + C interview

Semi-structured interviews were conducted with a subset of S + C participants to elicit evaluations of the process, barriers to follow-up, and recommendations for improvement. Six interviews were conducted by CRCs, audio recorded, and transcribed. Four interviews were conducted by nurses who took detailed notes to record participants' responses.

2.5 | Statistical methods

2.5.1 | Feasibility of S + C

Feasibility was described as (1) the percentage of eligible caregivers out of all approached, (2) the percentage of caregivers enrolled out of all eligible, (3) the percentage of caregivers completing study measures (and CSS-CG, if randomized to S + C) at baseline, (4) the percentage of caregivers completing CSS-CG who completed a consultation call, (5) the mean number of days between screening and consultation, and (6) the percentage of caregivers completing T2 and T3 measures. Differential completion rates were examined using χ^2 test of contingency tables for categorical variables and independent samples t-tests for continuous variables. In qualitative interviews, we asked about barriers to connecting to care if referrals were generated via S + C.

2.5.2 | Preliminary efficacy of S + C

Descriptive statistics were calculated for sociodemographic variables, CSS-CG, and all outcome measures. Preliminary efficacy of S + C for reducing unmet needs and improving QOL, anxiety, depression, and global distress was tested using a random effects modeling framework. Separate models were assessed for each outcome. Continuous outcomes utilized a linear model with identity link, and the dichotomous outcome (i.e., DT cutoff) utilized a logistic model. Data from all time points were included in a single model, with parameter contrasts designed to compare T2 to T1 and T3 to T1, and random per-person and per-site intercepts to account for correlation of multiple observations. Use of supportive care services was dichotomized and differences by randomization arm was tested by comparing T2 frequencies using a series of Chi-square tests.

2.5.3 | Acceptability of S + C

In qualitative interviews, we explored acceptability of S + C by asking about positive aspects of the S + C procedure, persisting barriers to psychosocial service use, and recommendations for improvement. Thematic analysis of interview transcripts and notes from unrecorded interviews was conducted as follows: (1) identifying concepts in text and assigning labels (codes), (2) collapsing codes into categories (themes), and (3) axial coding of data within each theme, facilitating a rich description.^{30,31} Themes illustrated below use exemplar quotes from interview transcripts only.

The study opened on 02/25/2019, and the last follow-up assessment was completed on 04/19/2022. The target sample size of 200 enrolled caregivers was chosen based on a target analytic sample size of 150 at follow-up (allowing for up to 25% attrition), but enrollment stopped early due to administrative reasons unrelated to efficacy. An analytic sample size of $n = 150$ provided 80% power to detect at least a $d = 0.46$ (medium) standardized effect size on the

primary outcome of unmet needs. Analyses were based on group of assignment, regardless of fidelity of delivery. All study procedures were approved by the MSK Institutional Review Board (#18-539), the study conformed to the US Federal Policy for the Protection of Human Subjects, and was registered on clinicaltrials.gov with identifier NCT03856086.

3 | RESULTS

Sociodemographic characteristics and baseline measures of participants completing T1 assessments are presented in Table 1. Two thirds of participants were female (66%), most were non-Hispanic (90%), White (84%), and employed (60%). The majority (70%) were the spouse/partner of the patient for whom they were providing care and had provided care constantly since the patient's diagnosis (64%). There were no significant differences in any baseline measures between study arms.

3.1 | Feasibility

Of 394 caregivers approached, 191 were eligible to participate (48%). Of these, 150 enrolled (79%), and 136 (91%) completed the baseline (T1) assessment. Among the 75 caregivers randomized to S + C, 71 (95%) completed the CSS-CG, of whom 66 (93%) completed the consultation call, which occurred on average 12 days-post T1 (range 2–51). Ninety-eight (65%) caregivers were recruited in person at JRSC, and 52 (35%) remotely from the Main Hospital and BMT Service.

Regarding follow-up assessments, a significantly greater proportion of caregivers randomized to S + C ($n = 49$, 65%) than EUC ($n = 36$, 48%) completed T2 ($p = 0.048$), with no significant difference in completion at T3 ($n = 44$, 59% of S + C caregivers and $n = 37$, 49% of EUC caregivers). Of the 69 caregivers who did not complete T3, 4 (6%) became bereaved, while the remaining 65 (94%) were lost to follow-up. Feasibility metrics are summarized in Figure 1.

3.2 | CSS-CG

Among participants randomized to S + C, at baseline the average total score on the CSS-CG was 28.5 (19.9), which corresponds to a concern rating between *not at all* and *slight* levels of concern. Regarding depression risk assessed by the CSS-CG, at baseline 26 participants (38%) met the risk threshold for clinically significant depression, though once evaluated by a licensed clinical psychologist, none required urgent care in the MSK Counseling Center.

In Supplemental Table S1, we present caregivers' concerns reported using CSS-CG. The top three concerns (% endorsing the concern as moderately/seriously/very seriously concerning) were: the patient's pain/physical discomfort (61%); the patient's cancer progressing or coming back (60%); and feeling nervous or afraid

TABLE 1 Baseline caregiver characteristics (N = 136).

Characteristic	n (%)	Characteristic	n (%)
Randomization		Employment	
EUC	65 (48%)	Employed	82 (60%)
S + C	71 (52%)	Self-employed	11 (8%)
Gender		Out of work >1 year	6 (4%)
Male	46 (34%)	Out of work <1 year	2 (1%)
Female	90 (66%)	A homemaker	6 (4%)
Relationship		A student	2 (1%)
Parent	9 (7%)	Retired	26 (19%)
Spouse/Partner	95 (70%)	Unable to work	1 (1%)
Child	23 (17%)	Children in home	
Sibling	6 (4%)	0	90 (66%)
Other	3 (2%)	1	19 (14%)
Hispanic/Latino		2	14 (10%)
Yes	11 (8%)	3	7 (5%)
No	122 (90%)	4	1 (1%)
Refused/Missing	3 (2%)	Missing	5 (4%)
Race		Annual HH income	
Asian	5 (4%)	<\$25,000	2 (1%)
Black or African American	9 (7%)	\$25,000 - \$35,000	4 (3%)
White	114 (84%)	\$35,000 - \$50,000	7 (5%)
Other	6 (4%)	\$50,000 - \$75,000	8 (6%)
Don't know/Not sure	1 (1%)	\$75,000 or more	100 (74%)
Refused	1 (1%)	Don't know/Not sure	8 (6%)
Relationship status		Refused/Missing	7 (5%)
Single	13 (10%)	Providing cancer care?	
Married	101 (74%)	No	13 (10%)
Divorced	5 (4%)	Yes—constantly since dx	87 (64%)
Widowed	2 (1%)	Yes—on and off since dx	32 (24%)
Separated	2 (1%)	Yes—recently began again	4 (3%)
Committed relationship	12 (9%)	Do you live with the patient?	
Refused	1 (1%)	Yes, all of the time	93 (68%)
Education		Yes, since initial cancer dx	9 (7%)
HS/GED	9 (7%)	No	33 (24%)
Some college	22 (16%)	Missing	1 (1%)
College grad	104 (76%)	FACT-GP	62.9 (13.3)
Refused	1 (1%)	Physical well-being	21.1 (3.3)
Age, M (SD)	52.3 (14.0)	Social well-being	15.2 (4.0)
NCCN problem list, M (SD)	7.6 (6.0)	Emotional well-being	11.7 (3.4)
HADS anxiety, M (SD)	8.1 (4.6)	Functional well-being	14.9 (5.7)

(Continues)

TABLE 1 (Continued)

Characteristic	n (%)	Characteristic	n (%)
HADS depression, M (SD)	5.2 (4.1)	Unmet needs	1.7 (1.8)
CSS-CG, M (SD) [n = 69]	28.5 (19.9)	Met needs	0.6 (1.1)
CSS-CG depression, n (%)	26 (38%)		
NCCN DT (global distress), M (SD)	5.4 (2.7)		

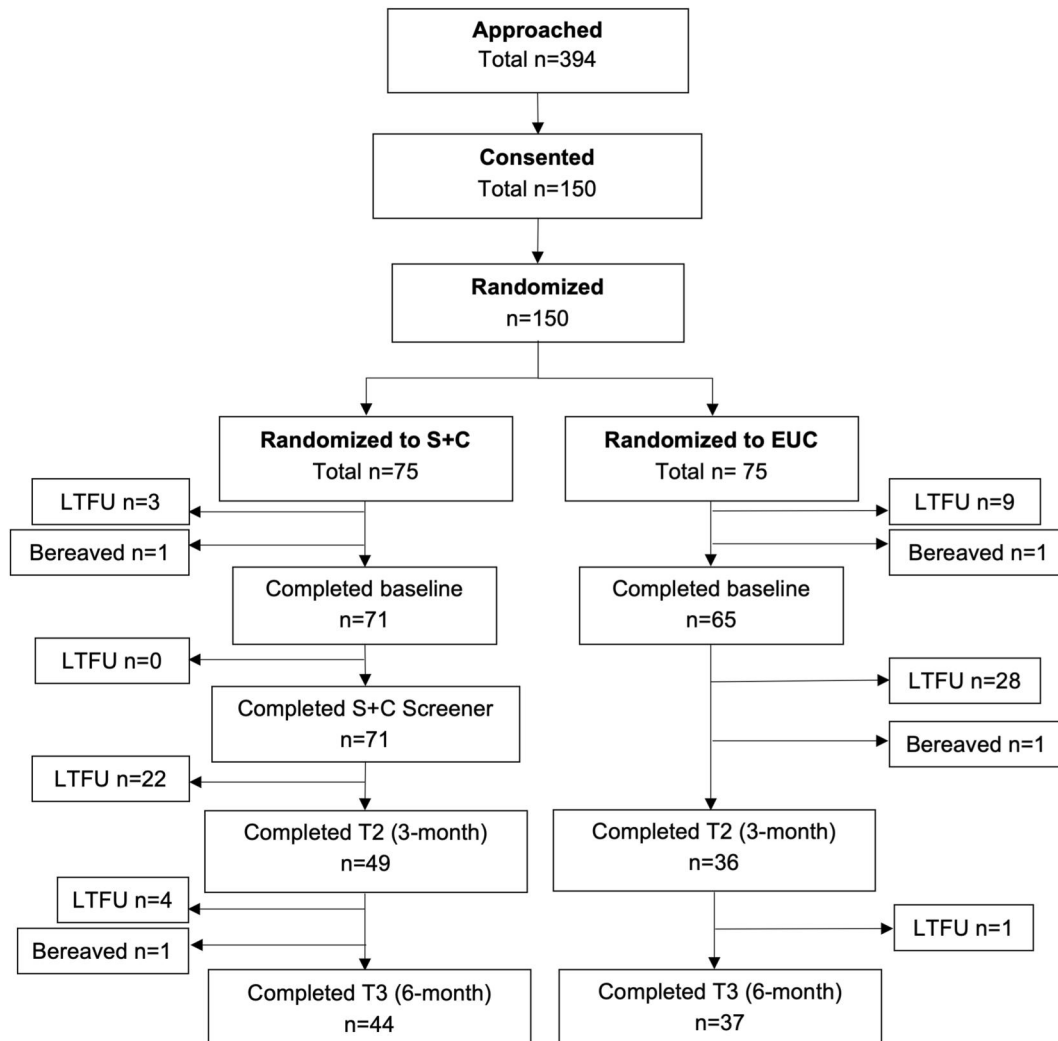


FIGURE 1 Consort diagram.

(43%). Among those rating items moderately to very seriously concerned, top concerns for which referrals were requested were relationship problems with the patient (83%), managing symptoms or side effects of treatment (54%), coordinating medical care for the patient (47%), and the patient's eating and nutrition (47%). Concerns for which caregivers most frequently requested information were as follows: the patient's cancer progressing or coming back (30%), the patient's pain and/or physical discomfort (28%), and changes in the patient's mood or behavior (23%). Finally, concerns that generated the most referrals overall (% requested to talk with a staff member) were the patient's pain and/or physical discomfort (16%), the

patient's cancer progressing or coming back (13%), and the patient's eating and nutrition (13%).

In terms of COVID-19 concerns, among the 30 participants recruited during lockdown, moderate or greater concern was reported by 57% regarding the risks of COVID-19 to the patient, and by 43% regarding the risks of COVID-19 to themselves. Among those reporting moderate or greater concerns, 50% requested additional information and staff contact regarding their ability to access food and other household necessities due to COVID-19, and 50% requested additional information about the patient's ability to access necessary cancer treatment or other medical care due to COVID-19.

3.3 | Healthcare utilization

Psychosocial service use is summarized in Supplemental Table S2. There were no significant differences in services used across arms at baseline. Overall, participants reported little service utilization (i.e., responding "Have used and would like to use more" or "Have used but now have no need"), with utilization ranging from only 4% ($n = 6$) for the CSC's Helpline to 10% ($n = 13$) for Integrative Medicine. Regarding desire for services (i.e., responding "Haven't used but would like to" or "Have used and would like to use more"), 40% ($n = 54$) of caregivers wanted to use the MSK Counseling Center, 40% ($n = 54$) wanted to use the CSC's Helpline, 39% ($n = 53$) wanted to use MSK Integrative Medicine, 28% ($n = 27$) wanted to connect with Social Work, 11% ($n = 15$) with Chaplaincy, 19% ($n = 26$) with Patient Financial Services, and 23% ($n = 30$) with any other type of support available.

3.4 | Effects of S + C

Participants more likely to complete T2 were caregivers assigned to S + C ($p = 0.048$), married to the patient ($p = 0.01$), White ($p = 0.02$), reported no children in the home ($p = 0.02$), and had provided care constantly since diagnosis ($p = 0.01$). However, the mixed-effects model methodology incorporates all available data and thus accommodates this differential attrition. A total of 140 caregivers had at least one of the baseline measures completed to be included in analysis; sample sizes for the mixed-effects models varied between 136 and 140.

Table 2 summarizes change scores by arm. p -values are based on the timepoint-specific time-by-arm interaction term in a mixed effects model with a per-caregiver intercept and main effects of time (3-month vs. baseline; 6-month vs. baseline) and intervention arm (S + C vs. EUC). Caregivers randomized to S + C demonstrated significantly improved

TABLE 2 Change scores by arm.

	S + C		EUC		Effect size Cohen's d	p-value
	n	Δ (SD)	n	Δ (SD)		
Baseline to 3-month follow-up						
FACT-GP total	50	-1.2 (8.6)	37	-3.3 (11.0)	0.22	0.24
Physical well-being	50	0.5 (2.4)	38	-0.4 (2.8)	0.35	0.11
Social well-being	50	-1.3 (4.3)	38	-1.3 (3.5)	0.01	0.97
Emotional well-being	50	-0.1 (2.5)	38	-0.4 (3.2)	0.09	0.59
Functional well-being	50	-0.2 (4.0)	38	-1.2 (3.8)	0.25	0.23
NCCN Problem list	50	-1.4 (3.8)	38	-0.3 (5.6)	0.24	0.25
HADS anxiety	49	-0.6 (3.6)	35	0.0 (3.8)	0.16	0.47
HADS depression	46	-0.2 (3.6)	34	0.5 (3.2)	0.22	0.33
Unmet needs	50	-0.9 (1.5)	38	-0.6 (1.7)	0.18	0.35
Met needs	50	-0.1 (0.6)	38	-0.1 (1.8)	0.01	0.86
NCCN DT (global distress)	50	-1.5 (2.6)	36	-1.3 (2.5)	0.08	0.70
Baseline to 6-month follow-up						
FACT-GP total	43	-1.7 (9.6)	37	-3.0 (8.5)	0.15	0.34
Physical well-being	44	0.2 (2.7)	37	0.1 (3.0)	0.04	0.94
Social well-being	44	-2.9 (3.9)	37	-2.1 (3.2)	0.24	0.44
Emotional well-being	43	1.3 (2.7)	37	-0.2 (2.8)	0.53	0.01
Functional well-being	44	-0.1 (4.2)	37	-0.8 (3.6)	0.19	0.29
NCCN Problem list	44	-1.5 (4.6)	37	-1.1 (4.5)	0.08	0.58
HADS anxiety	44	-1.5 (3.7)	36	-0.8 (3.0)	0.21	0.35
HADS depression	43	-0.6 (3.2)	36	0.1 (3.1)	0.20	0.37
Unmet needs	44	-1.0 (1.7)	37	-0.7 (1.8)	0.15	0.59
Met needs	44	0.2 (1.3)	37	0.0 (1.7)	0.14	0.53
NCCN DT (global distress)	44	-2.3 (2.4)	37	-1.5 (3.1)	0.29	0.15

emotional well-being on the FACT-GP (Cohen's $d = 0.53$, $p = 0.01$) compared to those randomized to EUC from T1 to T3. There were no significant differences over time in any other outcomes, though changes from T1 to T2 were all in the expected direction.

Regarding variations in psychosocial service use at T2 and T3, EUC caregivers reported greater unmet healthcare need (23%) for Integrative Medicine Services at T2 than S + C participants (6%, $p = 0.03$; see Supplemental Table S2). There were no other significant findings and overall service utilization at both T2 and T3 remained low, ranging from 1% for Chaplaincy at T2 to 16% for Social Work at T3.

3.5 | Acceptability

Qualitative interviews were conducted with 10 S + C caregivers (Supplemental Figure S1) to explore acceptability of the S + C process, though data were analyzable from only 7. Although not statistically significant, compared to those not included in interviews, qualitative interview participants appeared less diverse (with respect to race and ethnicity; 90% were White and non-Hispanic), with higher education (90% college graduates) and income (80% reporting annual household income greater than \$75,000), had a mean HADS Anxiety that was 1.1 points higher, and had a DT rating of 1.5 points lower. While caregivers described the overall process positively, none sought additional services. This was often attributed to feeling like psychosocial services were unnecessary; however, others described needing help but feeling too overwhelmed by caregiving responsibilities to follow through with service use. For example, one participant (*Caregiver 3*) stated, "It wasn't on my mind because I had so much to do taking care of [patient]."

Participants reported that S + C could be more helpful with further tailoring to address caregiver-specific needs. For example, some felt confused by screening questions that asked about concerns regarding the patient (e.g., "I sort of felt that a lot of questions didn't apply to me. [It] seemed like they were more for the patient" (*Caregiver 2*)). Others felt the screening was delivered too early in their caregiving trajectory and wished they could have participated later when their distress and support needs might be greater.

Nonetheless, nearly all caregivers reported feeling supported or less alone after the S + C process. For example, *Caregiver 1* stated, "The notion that somebody cares, even if it's the hospital, about how you're doing is really powerful, and that's probably what I took away from this the most." Even without using the services, caregivers reported being comforted just knowing support was available. One caregiver described how the screening helped them realize that caregiving may impact their well-being and inspired them to monitor their mental health.

4 | DISCUSSION

Screening caregivers for unmet needs and connecting them to support is not part of current standard oncologic care. Nonetheless, we were able to successfully enroll caregivers to this trial, and our

promising response rate indicates the feasibility of integrating caregiver engagement with standard nursing protocols and meeting caregivers *when* and *where* it is convenient: 79% of caregivers who were eligible enrolled in the trial. This rate is higher than prior clinical trials enrolling caregivers at the same institution,^{32,33} as well as national trials enrolling caregivers,³⁴ and may reflect the limited active involvement required and lack of symptom-related eligibility requirements. Moreover, 88% of caregivers randomized to S + C completed the consultation call, lending further support to the feasibility and acceptability of S + C procedures. These metrics were supported further from qualitative interviews in which caregivers reflected positively on the efficiency, flexibility, and structure of the S + C process.

In terms of efficacy, there were modest improvements in emotional well-being among S + C versus EUC participants, a finding that points to the potential benefits of this distress screening and consultation protocol. Indeed, data from qualitative interviews supported this idea: despite not using any supportive services because of the screening, caregivers reported S + C helped them feel supported, less alone, and acknowledged. Simply engaging caregivers in the S + C protocol combatted feelings of neglect and helped participants to feel seen and valued.

There were a range of concerns reported by caregivers randomized to S + C, the most common of which were patient focused. For example, concern about the patient's physical pain/discomfort and their cancer progressing/recurring were top concerns for which caregivers most frequently requested information and referrals. Moreover, given the devastating effects of COVID-19 on immunocompromised patients, participants reported greater concern about the risk of COVID-19 to the patient than to themselves. While areas of caregiver-specific concerns were endorsed (e.g., balancing caregiving with other demands, worry about the future), they were less frequently identified than those that were patient-focused. This pattern is consistent with a recent validation study for the 18-item version of the CSS-CG³⁵ and make sense given caregivers' role in supporting patient wellbeing. Concurrently, many caregivers also endorsed self-focused concerns and desired support for these needs. Given this, support for caregivers should be multifaceted and both assist them in meeting the healthcare needs of patients as well as managing their own distress.

4.1 | Study limitations

Participants were primarily non-Hispanic White, highly educated, and earned a high household income, reflecting the population typically seen at MSK but ultimately restricting the generalizability of findings. Given well-documented disparities and high levels of distress among low-income caregivers of color,^{36,37} our future work will expand recruitment sites to ensure the feasibility, acceptability, and efficacy of S + C for underrepresented racial/ethnic groups. Participants were also overwhelmingly women, though this sample composition is not significantly different from other US trials. Nonetheless, future trials will oversample men and gender

nonconforming caregivers to examine whether gender moderates outcomes. Moreover, only 7 of 10 qualitative interviews were analyzable, limiting our ability to derive rich thematic analysis. Future studies should involve a greater number of caregivers in qualitative assessments. An additional limitation is the challenge we face in research in delineating feasibility of study procedures versus feasibility of the intervention under examination. Importantly, despite many areas of concerns endorsed on CSS-CG, our participants reported relatively low levels of distress, anxiety, and depression. Future studies are needed to examine the programmatic impact of S + C among caregivers experiencing higher acuity of needs, and the benefits of earlier integration of S + C on caregiver, patient, and healthcare system outcomes. Future trials should also evaluate the benefits of repeated screening over time, as acuity of caregiver distress—and subsequently, psychosocial needs—often increases over time.^{38,39}

4.2 | Clinical implications

Our findings have important clinical implications for healthcare teams that interface with family caregivers. Clinicians can advocate for the integration of screening via the CSS-CG into standard practice to help facilitate the early identification of family caregivers in need of psychosocial services. This implementation of CSS-CG and a follow-up consultation will assist family caregivers to feel recognized and supported by healthcare teams, and more likely to reach out for support if needed in the future. More broadly, in the context of our already burdened healthcare system, the information and referrals built into the CSS-CG will allow the unmet information and educational needs that are so common among family caregivers to be rapidly addressed without adding further responsibilities to healthcare teams.

5 | CONCLUSIONS

Our data bring to life what psychosocial oncology professionals experience in practice: distress screening and the provision of information and referrals is itself an intervention, and the implementation of distress screening protocols for caregivers has the potential to transform their experience. These findings align with the 2022 National Strategy to Support Family Caregivers, which set as a priority the identification of caregivers and the development of services and supports to address their profound unmet needs. The future implementation and dissemination of the S + C protocol represents one mechanism through which the goals of the National Strategy can be realized.⁴⁰

AUTHOR CONTRIBUTIONS

Allison J. Applebaum: Conceptualization, methodology, data analysis, writing—original draft and review and editing. **Elizabeth Schofield:** Data curation and analysis, original draft review and editing. **Amanda**

Kastrinos: Qualitative data curation, original draft review and editing. **Rebecca Gebert:** Data curation, original draft review and editing. **Mia Behrens:** Data curation, original draft review and editing. **Morgan Loschiavo:** Data curation, original draft review and editing. **Kelly M. Shaffer:** Original draft review and editing. **Marcia Levine:** Conceptualization, original draft review. **Aimee Dannaoui:** Conceptualization, original draft review. **Courtney Bellantoni:** Conceptualization, original draft review. **Melissa F. Miller:** Conceptualization, methodology, data analysis, writing—original draft and review and editing. **Alexandra K. Zaleta:** Conceptualization, methodology, data analysis, writing—original draft and review and editing.

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CONFLICT OF INTEREST STATEMENT

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DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

ETHICS STATEMENT

All study procedures were approved by the MSK Institutional Review Board (#18-539), the study conformed to the US Federal Policy for the Protection of Human Subjects and was registered on clinicaltrials.gov with identifier NCT03856086.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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