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ORIGINAL REPORT

Randomized Controlled Trial of Family Therapy in Advanced Cancer Continued Into Bereavement

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ABSTRACT

Purpose
Systematic family-centered cancer care is needed. We conducted a randomized controlled trial of family therapy, delivered to families identified by screening to be at risk from dysfunctional relationships when one of their relatives has advanced cancer.

Patients and Methods
Eligible patients with advanced cancer and their family members screened above the cut-off on the Family Relationships Index. After screening 1,488 patients or relatives at Memorial Sloan Kettering Cancer Center or three related community hospice programs, 620 patients (42%) were recruited, which represented 170 families. Families were stratified by three levels of family dysfunction (low communicating, low involvement, and high conflict) and randomly assigned to one of three arms: standard care or 6 or 10 sessions of a manualized family intervention. Primary outcomes were the Complicated Grief Inventory-Abbreviated (CGI) and Beck Depression Inventory-II (BDI-II). Generalized estimating equations allowed for clustered data in an intention-to-treat analysis.

Results
On the CGI, a significant treatment effect (Wald χ^2 = 6.88; df = 2; P = .032) and treatment by family-type interaction was found (Wald χ^2 = 20.64; df = 4; $P <$ .001), and better outcomes resulted from 10 sessions compared with standard care for low-communicating and high-conflict groups compared with low-involvement families. Low-communicating families improved by 6 months of bereavement. In the standard care arm, 15.5% of the bereaved developed a prolonged grief disorder at 13 months of bereavement compared with 3.3% of those who received 10 sessions of intervention (Wald χ^2 = 8.31; df = 2; P =.048). No significant treatment effects were found on the BDI-II.

Conclusion
Family-focused therapy delivered to high-risk families during palliative care and continued into bereavement reduced the severity of complicated grief and the development of prolonged grief disorder.

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INTRODUCTION

An important clinical goal is to support the families of patients with advanced cancer and eventually assist them in bereavement. Two broad approaches are used: educational and instrumental support to caregivers[1] and psychosocial care to the family as a whole.[2] The latter is more challenging—to be truly responsive to a family's needs.[3,4] The well-functioning family, with effective communication and mutual support, has low psychosocial morbidity[3-6] and can be aided by a single meeting during palliative care to define treatment goals.[7] Families with more complex needs, however, warrant early recognition and continued support to prevent morbid outcomes.[5,6,8] Oncology has not had an evidence-based model for such family-centered care.

To address this problem, we developed a method of screening patients with advanced cancer and their families to define their relational functioning.[9] This permits differentiation of well-functioning families from those at risk of poorer outcomes. As proof of concept, we conducted a randomized controlled trial (RCT) of the efficacy of family therapy delivered to at-risk palliative care families.[10,11] This model, Family-Focused Grief Therapy (FFGT), significantly reduced distress, optimized social adjustment, and reduced rates

of clinical depression in bereavement for those family members most distressed during palliative care. This preventive model of support for families who are usually considered challenging delivered beneficial outcomes.[12]

To replicate this work, we screened a cohort of 1,809 American patients and confirmed our ability to recognize families at risk.[13] Three patterns of family relationships are found in these families: low communication (21%), low involvement (5%), and high conflict (6%).[13] We then conducted a three-arm, multicenter RCT that randomly assigned families to receive standard care (SC) or six sessions or 10 sessions of FFGT. In this paper, we report the main outcome findings for bereaved family members.

PATIENTS AND METHODS

Study Design and Participants

Our RCT design stratified families by severity of family dysfunction and randomly assigned families across three intervention arms. Family members received follow-up at 6 and 13 months of bereavement. Primary outcomes were the Complicated Grief Inventory, Abbreviated (CGI) and the Beck Depression Inventory II (BDI). The study was registered with clinicaltrials.gov in December 2007.

Participants. We screened patients with a survival prognosis of less than 1 year (on the basis of judgment of the treating oncologist) and their relatives for individual perceptions of relational functioning using the Family Relationships Index (FRI).[5,9] Eligibility criteria were perception by one family member of reduced relational functioning, defined by an FRI of ≤ 9 out of 12 or a cohesion subscale < 4; geographic accessibility to treatment; children age 12 years or older who were able to complete questionnaires; and willingness of at least three family members, including the patient with cancer, to attend therapy.

Sites. Participants were recruited between January 2006 and December 2011 from Memorial Sloan Kettering Cancer Center (n = 540), Calvary Hospital (n = 46), Visiting Nursing Service of New York (n = 22), and Beth Israel Hospice Service (n = 12). The protocol was approved by each site's institutional review board for the conduct of ethical research.

Random Assignment and Masking

Random assignment was conducted independently by the Memorial Sloan Kettering Cancer Center protocol participant registration system. Masking was not possible for the research assistants who collected outcome data, because the longitudinal relationship with participants helped sustain retention to follow-up assessments.

Procedures

Participants were screened in outpatient clinics or homes for hospice care. When individual consents and baseline data were completed, families were randomly assigned to SC or to six or 10 therapy sessions.

The FRI is a well-validated, 12-item scale with good sensitivity to detect families that carry members with distress, depression, and poor coping.[14,15] Families with low communication have FRI scores of 8 to 9; low involvement families have FRI scores of 5 to 7; high conflict families have FRI scores of 0 to 4.[4,5,10]

Interventionists came from the disciplines of social work, psychology, and psychiatry and were trained to deliver the manualized FFGT therapy. Sessions were audio-recorded, and 69% (327 of 474 available audio-recordings) were independently coded by three blinded assessors by using the FFGT fidelity measure.[11] Peer group supervision

of therapists was conducted weekly by study leaders (D.W.K., T.I.Z., M.L., L.L.), who received fidelity ratings from coders. We demonstrated our ability to train 32 therapists to competently deliver this intervention.[16]

FFGT has been described in two books.[17,18] Families tell the story of illness. Therapists explore each family's communication, cohesiveness, and conflict resolution alongside family values, beliefs, roles, and expectations. The same FFGT model was applied in both six- and 10-session arms.

Therapy occurred once per week for the first two meetings, then 2 weeks later for the third meeting, 1 month later for the fourth, 2 months after that for the fifth, and 3 months later for the sixth and final session.

Outcomes

The CGI is derived from its well-validated, longer version[19,20] and identifies the grief symptoms proposed as criteria for prolonged grief disorder (PGD). Cronbach's α was .885. Eleven items evaluate the frequency and intensity of grief symptoms on a five-point Likert scale. Caseness for PGD is determined by disabling separation distress; psychosocial or occupational dysfunction; and at least five of nine symptoms that prove impairment or that are experienced daily for at least 6 months of bereavement.[21]

The BDI-II[22] is a well-validated, 21-item measure of depressive symptoms. Cronbach's α was .911. A threshold of 20 or greater corresponds to moderate and severe depression and was used to designate caseness.[23]

Follow-up assessments were conducted at 6 and 13 months after death; the latter was used to avoid confounding by the anniversary of the death. When the patient improved and outlived the prognosis (17 patients [13%] did not die), CGI could not be completed; BDI was completed at 6 and 13 months after therapy.

Statistical Analysis

We used an intention-to-treat approach. The primary end points were CGI and BDI scores assessed from bereaved family members at 6 and 13 months after death. Statistical power was calculated a priori, by assuming family size of three members, intraclass correlation of 0.1 between members, and type 1 error rate of .05. With clustering into three levels of family functioning, 55 families per strata would provide 80% power for two-sided tests to detect an effect size of .33 on the BDI on the basis of the 2006 trial.[11]

Generalized estimating equations (GEE) were used to account for the hierarchical (correlated) outcomes, including two repeated-measures outcomes per person (6 and 13 months), and for persons nested within families.[24] An exchangeable working correlation was assumed so that different family members shared the same within-family correlation. The GEE modeled the outcome reported by the bereaved family members nested within family clusters, adjusting for fixed effects of site, family type (three FRI categories), random assignment (SC or six-session or 10-session FFGT), time (6 and 13 months), and a two-way interaction between family type and random assignment. The BDI analysis included baseline BDI scores as covariates. Postbereavement BDI and CGI scores were also dichotomized into clinical cases, and a similar GEE model was fitted. An identity link function was used for continuous outcomes (BDI and CGI scores), and logit was used for binary outcomes (BDI and CGI cases). Statistical hypothesis tests were based on the Wald χ^2 test. Adjusted P values were calculated to control for multiple statistical tests by using the simulated linear step-up method of Benjamini and Hochberg (1995)[25] or by using empirically simulated results that exceed the fifth percentile of the 20,000 simulated distributions. Simulated multiple comparison adjustments have the advantage of not requiring statistical assumptions that may not be tenable. All modeling of the clustered data was conducted with the GENMOD and MULTITEST procedures in the statistical software package SAS (Version 9.2; SAS Institute, Cary, NC).

RESULTS

Participation

From 1,488 eligible individuals, 620 (42%) consented, which represented 170 families (mean, 3.6 individuals per family). Common reasons for refusal were disinterest, satisfactory coping,

and preference not to meet as a family. As seen in the CONSORT diagram (Fig 1), 55 families were assigned to SC, 59 to six-session therapy, and 56 to 10-session therapy. A total of 91% (105 of 115 families) began therapy; retention rates were 82% (94 of 115 families) for completion of half, 64% (38 of 59 families) for completion of all six assigned sessions, and 50% (28 of 56) for completion of all 10 sessions.
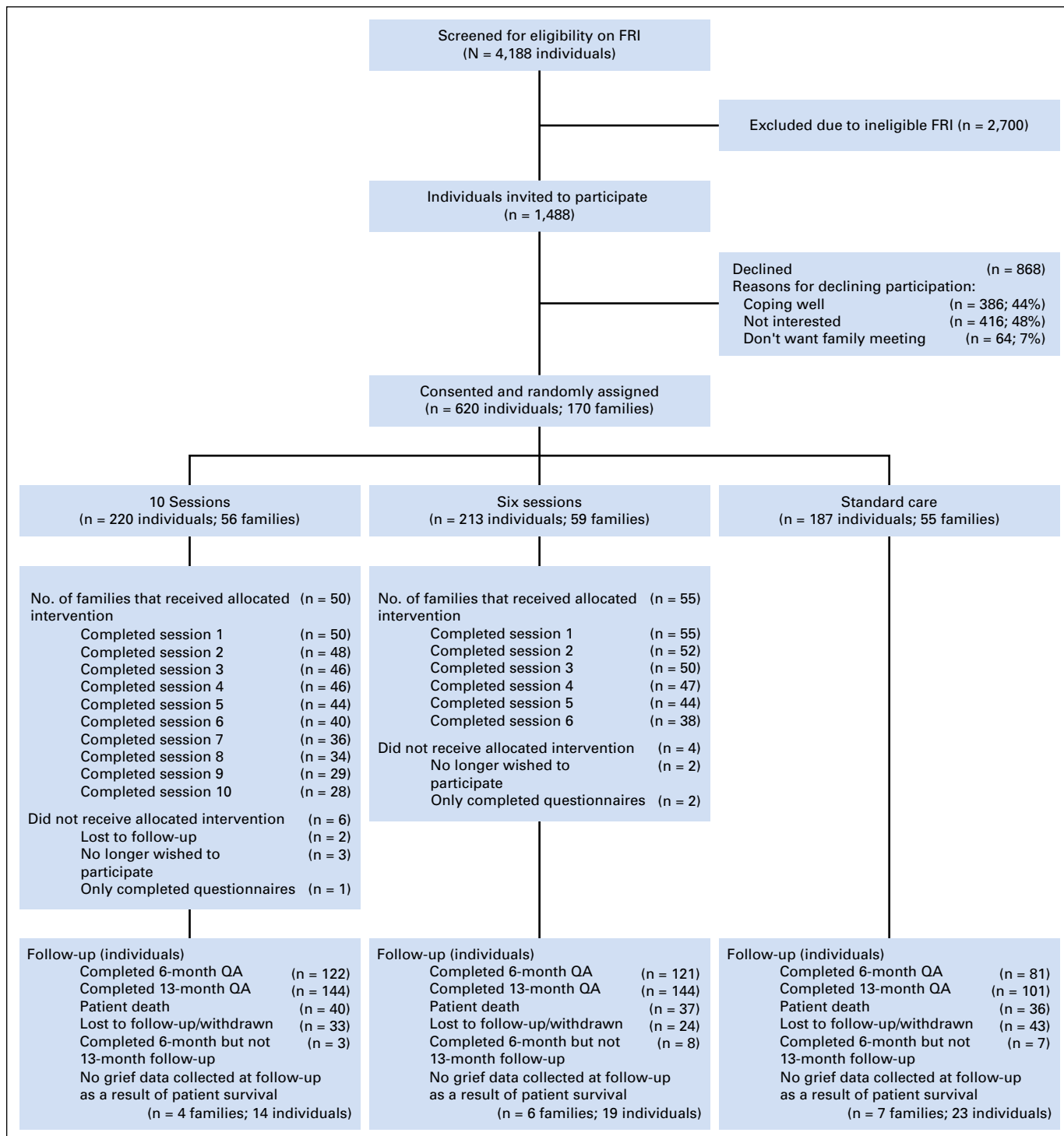
Screened for eligibility on FRI
(N = 4,188 individuals)

Excluded due to ineligible FRI (n = 2,700)

Individuals invited to participate
(n = 1,488)

Declined   (n = 868)
Reasons for declining participation:
  Coping well   (n = 386; 44%)
  Not interested   (n = 416; 48%)
  Don't want family meeting   (n = 64; 7%)

Consented and randomly assigned
(n = 620 individuals; 170 families)

10 Sessions
(n = 220 individuals; 56 families)

Six sessions
(n = 213 individuals; 59 families)

Standard care
(n = 187 individuals; 55 families)

No. of families that received allocated (n = 50)
intervention
  Completed session 1   (n = 50)
  Completed session 2   (n = 48)
  Completed session 3   (n = 46)
  Completed session 4   (n = 46)
  Completed session 5   (n = 44)
  Completed session 6   (n = 40)
  Completed session 7   (n = 36)
  Completed session 8   (n = 34)
  Completed session 9   (n = 29)
  Completed session 10   (n = 28)

Did not receive allocated intervention   (n = 6)
Lost to follow-up   (n = 2)
No longer wished to   (n = 3)
participate
Only completed questionnaires   (n = 1)

No. of families that received allocated (n = 55)
intervention
  Completed session 1   (n = 55)
  Completed session 2   (n = 52)
  Completed session 3   (n = 50)
  Completed session 4   (n = 47)
  Completed session 5   (n = 44)
  Completed session 6   (n = 38)
Did not receive allocated intervention   (n = 4)
  No longer wished to   (n = 2)
  participate
  Only completed questionnaires   (n = 2)

Follow-up (individuals)
  Completed 6-month QA   (n = 122)
  Completed 13-month QA   (n = 144)
  Patient death   (n = 40)
  Lost to follow-up/withdrawn   (n = 33)
  Completed 6-month but not   (n = 3)
  13-month follow-up
  No grief data collected at follow-up
  as a result of patient survival
                          (n = 4 families; 14 individuals)

Follow-up (individuals)
  Completed 6-month QA   (n = 121)
  Completed 13-month QA   (n = 144)
  Patient death   (n = 37)
  Lost to follow-up/withdrawn   (n = 24)
  Completed 6-month but not   (n = 8)
  13-month follow-up
  No grief data collected at follow-up
  as a result of patient survival
                          (n = 6 families; 19 individuals)

Follow-up (individuals)
  Completed 6-month QA   (n = 81)
  Completed 13-month QA   (n = 101)
  Patient death   (n = 36)
  Lost to follow-up/withdrawn   (n = 43)
  Completed 6-month but not   (n = 7)
  13-month follow-up
  No grief data collected at follow-up
  as a result of patient survival
                          (n = 7 families; 23 individuals)

Fig 1. Consort diagram of study participants. FRI, Family Relationships Index; QA, questionnaire

Table 1 shows participant characteristics. Patients were middle aged, and offspring were mostly young adults. The sample was mostly Judeo-Christian, half were employed, and 59% married. The major cancer types that affected patients were upper gastrointestinal, including pancreatic (n = 85 [65%]); melanoma (n =13 [10%]); lung (n = 10 [8%]); breast (n = 5 [4%]); and other cancers (n = 17 [13%]). Most patients underwent a surgical procedure (90%) and received chemotherapy (89%) or radiation therapy (40%).

Outcomes

In Table 2, for prolonged grief symptoms (ie, CGI), we examined the summary scores and found a treatment effect (P =.032) and a treatment by family-type interaction ($P < .001$; independent of time). To better understand this interaction, post hoc analyses (aggregated over time) showed that the interactional effect was explained by outperformance of SC by 10 sessions in low-communicating families versus in low-involvement families (adjusted $P < .001$) and in high-conflict families versus low-involvement families (adjusted $P = .039$). Additional post hoc analyses showed greater benefits from 10 sessions than from SC within low-communicating families; this difference emerged by 6 months (adjusted $P = .0104$) and was maintained at 13 months (adjusted $P = .017$). Within high-conflict families, a similar pattern was suggested; however, no difference was statistically significant. For BDI, no significant treatment effect or treatment by family-type interaction was found.

Table 1. Sociodemographic Features of Study Participants (N = 620)				
		No. (%) of Participants by Intervention Type		
Feature	Total No. (%) of Participants*	Standard Care	Six-Session Arm	10-Session Arm
No. of families	170	55	59	56
No. of individuals	620	187	213	220
Mean age, years				
Patients	130 (21.0)	55.07	52.81	58.47
Partners	112 (18.1)	57.70	54.80	60.35
Other relatives	378 (60.9)	33.83	37.58	40.98
Sex				
Female	372 (60.0)	108 (57.8)	130 (61.0)	134 (60.9)
Male	248 (40.0)	79 (42.2)	83 (39.0)	86 (39.1)
Marital status				
Married/cohabitating	369 (59.6)	111 (59.4)	124 (58.2)	134 (60.9)
Single	202 (32.6)	65 (34.8)	69 (32.4)	68 (30.9)
Separated/divorced	32 (5.2)	9 (4.8)	11 (5.2)	12 (5.5)
Widowed	17 (2.7)	2 (1.0)	9 (4.2)	6 (2.7)
Ethnicity				
Hispanic	68 (11)	26 (13.9)	11 (5.2)	31 (14.1)
Non-Hispanic	549 (88.5)	161 (86.1)	200 (93.9)	188 (85.5)
Race				
White	507 (81.8)	157 (84.0)	177 (83.1)	173 (78.6)
Black	61 (9.8)	14 (7.5)	24 (11.3)	23 (10.5)
Asian	20 (3.2)	6 (3.2)	5 (2.3)	9 (4.1)
Other	11 (1.8)	1 (0.5)	2 (0.9)	8 (3.6)
Religious status				
Catholic	243 (39.2)	84 (44.9)	64 (30.0)	95 (43.2)
Jewish	145 (23.4)	46 (24.6)	55 (25.8)	44 (20.0)
Christian	141 (22.7)	32 (17.1)	64 (30.0)	45 (20.5)
Other	39 (6.3)	9 (4.8)	11 (5.2)	19 (8.6)
None	50 (8.1)	15 (8.0)	18 (8.5)	17 (7.7)
Employment status				
Employed	313 (50.5)	87 (46.5)	99 (46.5)	127 (57.7)
Unemployed	89 (14.4)	34 (18.2)	29 (13.6)	26 (11.8)
Retired	89 (14.4)	20 (10.7)	35 (16.4)	34 (15.5)
Student	77 (12.4)	24 (12.8)	35 (16.4)	18 (8.2)
Disabled	52 (8.3)	22 (11.8)	15 (7.1)	15 (6.8)
Family type				
Low communicating				
Individuals	191 (30.8)	52 (27.8)	61 (28.6)	78 (35.5)
Families	53 (31.2)	17 (30.9)	17 (28.8)	19 (33.9)
Low involvement				
Individuals	313 (50.5)	102 (54.5)	110 (51.6)	101 (45.9)
Families	84 (49.4)	27 (49.1)	31 (52.5)	26 (46.5)
High conflict				
Individuals	116 (18.7)	33 (17.7)	42 (19.8)	41 (18.6)
Families	33 (19.4)	11 (20.0)	11 (18.7)	11 (19.6)

NOTE. Feature refers to that of the individual unless families are specified.
*Column numbers do not add up to full sample size in some categories because of missing data.

Table 2. Effects of Treatment, Family Type, and Treatment by Family-Type Interaction on Complicated Grief and Depression in Bereaved Family Members

Family Type and Treatment for Complicated Grief and Depression	Mean (SD) of Participants			Mean (95% CI)	Analyzed Effect[a]		
	Baseline	6-Month Bereavement	13-Month Bereavement	Post-Bereavement Model-Estimated Average 6-13 Months	Treatment	Family Type	Treatment by Family-Type at Average of 6-13 Months
CGI[b]					Wald χ^2 = 6.88; df = 2; P = .032	Wald χ^2 = 4.01; df = 2; P = .135	Wald χ^2 = 20.64; df = 4; P < .001[c]
Low communicating							
SC	NA[d]	23.6 (7.8)	22.5 (7.9)	23.16 (20.06 to 26.25)			
Six sessions		20.2 (9.5)	22.6 (6.6)	22.54 (20.18 to 24.90)			
10 sessions		17.6 (6.9)[e]	17.0 (6.9)[fg]	17.58 (15.25 to 19.91)[h]			
Low involvement							
SC	NA[d]	19.2 (7.0)	16.8 (6.4)	18.08 (15.60 to 20.56)			
Six sessions		19.9 (6.3)	19.0 (6.9)	19.59 (17.54 to 21.65)			
10 sessions		21.1 (7.9)	19.7 (6.9)	20.70 (18.37 to 23.03)			
High conflict							
SC	NA[d]	20.9 (8.1)	20.4 (9.8)	21.63 (17.40 to 25.87)			
Six sessions		20.7 (6.0)	18.1 (6.8)	20.19 (17.41 to 22.97)			
10 sessions		19.3 (8.3)[i]	17.1 (6.9)[j]	17.63 (14.40 to 20.85)[k]			
BDI[l]					Wald χ^2 = 1.00; df = 2; P = .608	Wald χ^2 = 8.47; df = 2; P = .0145	Wald χ^2 = 4.25; df = 4; P = .374
Low communicating							
SC	13.3 (7.7)	12.1 (10.6)	10.9 (11.2)	10.08 (6.77 to 13.39)			
Six sessions	13.6 (6.6)	11.6 (7.1)	12.8 (9.0)	11.24 (8.44 to 14.05)			
10 sessions	7.7 (7.1)	7.0 (6.8)	6.6 (6.5)	9.49 (6.89 to 12.10)			
Low involvement							
SC	12.2 (8.9)	11.5 (10.6)	8.8 (8.6)	10.26 (7.39 to 13.14)			
Six sessions	12.0 (8.6)	10.1 (7.7)	9.7 (9.1)	9.83 (7.27 to 12.39)			
10 sessions	14.3 (9.6)	13.6 (9.5)	11.0 (9.3)	11.02 (8.47 to 13.58)			
High conflict							
SC	16.8 (11.5)	12.4 (8.6)	11.9 (7.8)	8.82 (5.92 to 11.73)			
Six sessions	14.2 (9.6)	11.0 (7.1)	10.2 (9.8)	8.60 (5.78 to 11.43)			
10 sessions	10.3 (7.0)	6.0 (6.9)	5.7 (6.8)	7.01 (4.73 to 9.28)			

NOTE. Unless noted in the footnotes, all other post hoc pairwise comparisons were nonsignificant.

Abbreviations: BDI, Beck Depression Inventory II; CGI, Complicated Grief Inventory, Abbreviated; NA, not available; SC, standard care.

[a]Analyzed treatments were SC and six sessions or 10 sessions of family intervention. Treatment by family-type interaction on complicated grief was assessed with the CGI; BDI was used to assess depression

[b]CGI analysis used data from 416 family members nested within 151 families.

[c]To better understand the treatment by family-type interaction, we contrasted the treatment effect (10 sessions v SC, aggregating as per generalized estimated equations default over 6 and 13 months) between the following family types: low-communicating versus low-involvement families (−8.20; 95% adjusted CI, −12.32 to −4.08; adjusted P < .001); high-conflict versus low-involvement families (−6.63; 95% adjusted CI, −12.46 to −0.79; adjusted P = .039); high-conflict versus low-communicating families (1.57; 95% CI, −4.61 to 7.76; adjusted P =.618). A lower CGI score indicated a better outcome; thus, a negative score was the expected direction of contrast. In high-conflict families, the model-estimated treatment effect was −4 (17.63 minus 21.63), which, when contrasted against that of low-involvement families, yielded an overall estimate of −6.63 (−4 plus −2.62, after rounding). These post hoc analyses suggest that the treatment by family-type interaction resulted from greater benefits gained by low-communicating and high-conflict families than by low-involvement families in a comparison of 10-session interventions with SC. High-conflict families did not gain greater benefits than low-communicating families; their respective gains were similar.

[d]CGI not assessed prior to death of patient.

[e]Post hoc analyses, for CGI, within low-communicating families: at 6 months of bereavement, post hoc 10-session intervention compared with SC: mean estimated difference = −6.14 (95% adjusted CI, −11.32 to −0.97); adjusted P = .0104.

[f]Post hoc analyses, for CGI, within low-communicating families: at 13 months of bereavement, post hoc 10 sessions compared with six sessions: mean estimated difference = −4.96 (95% adjusted CI, −9.21 to −071); adjusted P = .009.

[g]Post hoc analyses, for CGI, within low-communicating families: at 13 months of bereavement, post hoc 10-session intervention compared with SC: mean estimated difference = −5.58 (95% adjusted CI, −10.60 to −0.56); adjusted P = .017.

[h]Post hoc analyses, for CGI, within low-communicating families at an average of 6 to 13 months of bereavement, post hoc 10-session intervention compared with SC: mean estimated difference = −5.70 (95% adjusted CI, −10.01 to −1.40); adjusted P = .004.

[i]Post hoc analyses, for CGI, within conflictual families: at 6 months of bereavement, post hoc 10-session intervention compared with SC: mean estimated difference = −4.43 (95% adjusted CI, −10.27 to 1.41); adjusted P = .228.

[j]Post hoc analyses, for CGI within conflictual families: at 13 months of bereavement, post hoc 10-session intervention compared with SC: mean estimated difference = −4.194 (95% adjusted CI, −11.690 to 3.302); adjusted P = .503.

[k]Post hoc analyses, for CGI within conflictual families: at an average of 6 to 13 months of bereavement, post hoc 10-session intervention compared with SC: mean estimated difference = −3.961 (95% adjusted CI, −10.60 to 2.68); adjusted P = .378.

[l]BDI analysis used data from 417 family members nested within 151 families; also, baseline BDI score was included as a covariate.

In Table 3, using the threshold for clinical cases on the CGI categorically, which represents a diagnosis of PGD, 15.5% family members showed caseness in SC, 12.1% in six sessions, and 3.3% in 10 sessions at 13 months of bereavement (P = .048). By combining moderate and severe levels of BDI caseness (see the Measures section) at 13 months of bereavement, the rate of clinical cases was 21% in SC compared with 11% after 10 sessions of FFGT (P = .07).

Table 3. Observed Clinical Cases in Prolonged Grief Disorder and Depression Among Family Members in Three Intervention Conditions Over Time

Caseness by Test and Time Point*	Family Members by Intervention Type % (No./Total No.)†			GEE Effect‡
	Standard Care	Six-Session FFGT	10-Session FFGT	
CGI				
Baseline§				Treatment main effect:
6-month bereavement	19.3 (11/57)	12.3 (13/106)	8.9 (9/101)‖	Wald χ^2 = 8.31; df = 2; P = .016; adjusted P = .048
13-month bereavement	15.5 (13/84)	12.1 (15/124)	3.3 (4/122)¶	
BDI				
Baseline	18 (23/125)	21 (33/156)	17 (26/155)	Baseline to 6 months:
				Wald χ^2 = 2.63; P = .105; adjusted P = .105
6-month bereavement	20 (15/74)	10 (12/116)	16 (19/116)	
13-month bereavement	21 (20/97)	14 (19/138)	11 (15/136)	Baseline to 13 months:
				Wald χ^2 = 3.92; P =.047; adjusted P = .0705

Abbreviations: BDI, Beck Depression Inventory II; CGI, Complicated Grief Inventory; FFGT, family-focused grief therapy; GEE, generalized estimating equations.
*CGI caseness applied criteria for prolonged grief disorder. BDI caseness was defined by combining cases with severe BDI scores of 29 or greater and moderate BDI scores of 20 or greater.
‡Test statistics were based on a GEE model of BDI caseness as a function of five covariates: study stratification factors (site and family type), treatment assignment, time (eg, 6 months v baseline), and a fifth covariate of a treatment-by-time interaction. The Wald χ^2 statistics were from the Wald test for the treatment by time-interaction (eg, for BDI, 6 months v baseline and 13 months v baseline; for CGI, 6 months v 13 months).
†Denominators differed because of varied family sizes and because of more surviving patients in the standard care arm (n = 7 surviving patients with 23 family members) than in the 10-session arm (n = 4 surviving patients with 14 family members) and in the six-session arm (n = 6 surviving patients with 19 family members).
§CGI data not collected before death.
‖Post hoc analyses at 6-month bereavement for 10-session FFGT versus standard care: odds ratio, 0.442; 95% adjusted CI, 0.129 to 1.380; adjusted P = .238.
¶Post hoc analyses at 13-month bereavement for 10-session FFGT versus standard care: odds ratio, 0.182; 95% adjusted CI, 0.043 to 0.773; adjusted P = .014.

DISCUSSION

FFGT reduced CGI for low-communicating and high-conflict families but not for low-involvement families. The findings were robust for low-communicating families, where real gains were evident by 6 months of bereavement. Ten sessions achieved more effects than did six sessions of therapy. The low-involvement families choose distance to cope and did not benefit from family therapy.

Attachment disorders are implicated as risk factors that predispose people to PGD, and family therapy, which opens up communication, targets these relational processes. FFGT did not prevent major depression, a diagnosis for which antidepressants may be more important. Of interest, therapy was delivered to families from a variety of cultural backgrounds with apparent effectiveness; clinical accounts of these have been published elsewhere.[26-28] The addition of FFGT to a comprehensive psychosocial care program can be argued to be cost effective, given that this is dispersed over 18 months and simultaneously reaches several family members.

In the real world, engagement of families is challenging, especially those featuring troubled relationships.[29] The 42% rate of acceptance of our invitation to participate is modest, but this response rate was limited by the burdens of research. It is noteworthy that 91% commenced family therapy, 82% completed half of the sessions, and 50% to 64% completed all of the sessions. These are satisfactory markers of the feasibility of the model, which was taught to 32 therapists who delivered it faithfully.[16] Our results do offer reassurance that it is worthwhile to target families who would be considered difficult.

A number of limitations exist with this complex study. Not all families completed their allocated sessions. Furthermore, our screening procedures relied on available patients and relatives and did not include perspectives of relatives who were less active in caregiving. Because nearly half of families who met FRI eligibility declined enrollment, our sample comprised help-seeking families who saw value in convening. The level of morbidity may be higher than evident here. Embedding family support into palliative care services may be necessary to overcome the barriers inherent in a clinical trial. Finally, power was based on testing the effect of the different doses of therapy rather than on a full interaction effect with family types. Family recruitment is challenging and restricts larger studies.

FFGT has helped to reduce PGD in families who might otherwise be difficult to care for. Given that bereavement is a major life event that results in morbid consequences for 20% of bereaved relatives,[30-33] this model of family-centered care shows considerable promise.

AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

Disclosures provided by the authors are available with this article at www.jco.org.

AUTHOR CONTRIBUTIONS

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GLOSSARY TERMS

psychosocial: the psychological (emotional) and social aspects of a disease and its treatment. Some of the psychosocial aspects of cancer are its effects on patients' feelings, moods, beliefs, the way they cope, and relationships with family, friends, and coworkers.

AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

Randomized Controlled Trial of Family Therapy in Advanced Cancer Continued Into Bereavement

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