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EFFECTIVENESS OF “PRIMARY BEREAVEMENT CARE” FOR WIDOWS: A CLUSTER RANDOMIZED CONTROLLED TRIAL INVOLVING FAMILY PHYSICIANS

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Thirty-one family physicians, from 19 primary care teams in Biscay (Spain), were randomly assigned to intervention or control group. The 15 intervention family physicians, after training in primary bereavement care, saw 43 widows for 7 sessions, from the 4th to 13th month after their loss. The 16 control family physicians, without primary bereavement care training, saw 44 widows for 7 ordinary appointments, with the same schedule. Outcome measures were collected at 4, 10, 16, and 24 months after the loss. A linear mixed model was used. No significant differences were found in favor of the intervention group on grief, and indeed control group widows experienced more improvement in somatization, general health, and general emotional outcomes.

Although bereavement is a natural process, the death of a loved one is one of the most stressful life events that a person can face (Dohrenwend, Krasnoff, Askenasy & Dohrenwend, 1994; Holmes & Rahe, 1967). Indeed, it is known to be associated with an increased risk of depression (Zisook & Shuchter, 1991), generalized anxiety and panic disorder (Jacobs et al., 1990), alcohol abuse (Maddison & Viola, 1968), greater use of medications (Parkes, 1964), sudden cardiac events (Kaprio, Koskenvuo & Rita, 1987), suicide (Kaprio et al.), prolonged grief disorder (Prigerson et al., 2009), and an increased demand for health resources (Parkes, 1964; Tudiver, Permaul-Woods, Hilditch, Harmina, & Saini, 1995), with the bereaved visiting their health centres 80% more often than general population (López, Ela, Bartolomé, Gómez, & García-García, 2001).

Family physicians (FP), according to some authors (Charlton & Dolman, 1995; García-García, Landa, Trigueros, Calvo, & Gaminde, 1996; Saunderson & Ridsdale, 1999; Woof & Carter, 1997), are the only specialists who, through their position in the health system and in the community, can give emotional support to the bereaved and simultaneously deal with the health problems associated with the bereavement process, without replacing other more traditional resources (family, friends, neighbours, religious leaders, etc.).

To date, there is insufficient evidence, given the heterogeneity of the studies, to agree on the best bereavement intervention (Allumbaugh & Hoyt, 1999; Kato & Mann, 1999), and even less in primary care (Woof & Carter, 1997), so each FP tends to care for bereaved people in a different way.

In response to this, we designed a standardized manual-based bereavement intervention for FPs, entitled Primary Bereavement

Care (PBC) (García-García, 2005; García-García & Landa, 2006; Landa & García-García, 2011), and set out to test its effectiveness. Our hypothesis was that, although all recently bereaved widows improve over time, those that received the PBC would improve more rapidly (García-García et al., 2007). Our aim was to evaluate the effectiveness of the PBC administered by FPs trained in its use, compared with the ordinary care administered by FPs with no PBC training, in terms of bereavement intensity, psychological discomfort, and quality of life, in a sample of recently bereaved widows (García-García et al., 2007). We concentrated exclusively on widows, because this is the bereavement process in which FPs are most commonly involved. In Spain, 44.5% of women over 65 are widows compared to 13% of men (Encuesta Población Activa, 2009), and they use primary care 10 times per year on average for the first 3 years after partner's death (López et al., 2001).

Methods

Design and Ethical Approval

The project was a cluster randomized controlled trial with two arms, control (CG) and intervention group (IG). FPs were the randomized units, and each FP saw a cluster of consecutively recruited widows who were monitored over the first 24 months after their partner's death. We chose a cluster design and randomized FPs instead of widows, to avoid having the same FP providing PBC to one widow and ordinary care to another, with the potential for contamination that would involve. The research protocol was approved by the Ethical Committee of Clinical Research of Cruces Hospital (Baracaldo, Biscay, Spain), study code CEIC 01/49 and record 12/01.

Study Setting and Participants

In Biscay in 2001, 120 FPs working for the Basque Health Service in Primary Care were invited to participate in the project on the basis of the following criteria: (a) showing interest in psychosocial aspects of Primary Care, (b) not working in the same Health Centre as the study researchers, and (c) not participating in any other clinical trial.

Through medical records and newspaper obituaries 123 widows were identified with the following inclusion criteria: (a) 70 years old or younger, (b) 3 months or less since partner's death, and (c) patients of any of the collaborating FPs; and exclusion criteria: (a) loss of a child in the previous three years, (b) loss of two or more close relatives in the previous year, (c) partner's death by suicide or AIDS, (d) current psychiatric problems (dementia, alcoholism or other drug addiction, and/or psychotic illness), (e) being bedridden, and/or (f) illiteracy.

Intervention Conditions

PBC (García-García, 2005; García-García & Landa, 2006; Landa & García-García, 2011) (see Figure 1) is a standardized bereavement intervention in primary care, summarized in a detailed PBC manual (available from the authors on request) drawn up by the research team and delivered by FPs trained in it. The PBC theoretical framework is based on counseling and bereavement theories (Parkes, Relf, & Couldricks, 1996; Worden, 1991; Wortman & Silver, 1989), the primary care model (Pendleton, Schofield, Tate, & Havelock, 1984; World Health Organization, 1978) and conceptualization of therapeutic "nonspecific" factors of psychotherapy (Grencavage & Norcross, 1990), adapted to our sociocultural environment (García-García, 1997). PBC is a face-to-face intervention that puts the accent on relational, emotional, and psycho-educational support. Intervention FPs received three PBC training meetings (7 hr each) just before the intervention, and five further meetings (also 7 hr each) during the intervention period (2, 6, 12, 18, and 30 months after the first meeting); and they saw each widow for seven PBC sessions of 45 min each (4, 4½, 5, 6, 8, 10, and 13 months after their partner's death), working with the material that the widows brought, but at the same time with the PBC agenda in their mind: integral care (biological, psychoemotional, psychosocial, and spiritual), a chronological scheme (past, present, and future), and the general and specific PBC techniques (Figure 1). The fidelity to the intervention was assessed using a "PBC control sheet," which the FPs completed at the end of every session with the widows. Control FPs were not trained in PBC and they saw each widow for seven ordinary appointments, with unspecified content and duration, but following the same schedule as the IG.

EXPLORATORY TECHNIQUES USED IN PBC	
<ul style="list-style-type: none"> • To explore general data • To explore family and social data • To explore background • To explore bereavement process data • To obtain a bereavement "profile" 	
INTERVENTION TECHNIQUES USED IN PBC	
GENERAL	SPECIFICS
<p><u>REFINO:</u></p> <ul style="list-style-type: none"> • R – RELATIONSHIP. Establishing good relationship with the bereaved is characterized by <ul style="list-style-type: none"> - having a strategy - being unidirectional - dealing with them as equals - trying to be genuine, natural, empathetic, respectful - keeping within the professional framework • E – EAR ("Lending an ear"). Active listening is <ul style="list-style-type: none"> - being attentive to both verbal and non verbal language - being focused on the present ("here and now") • F - FACILITATION. Facilitating is to encourage communication and emotional expression through <ul style="list-style-type: none"> - open questions - low reactivity - eye contact • I – INFORMATION. Informing is explaining the concept of Western grieving but at the same time the uniqueness or individuality of the process • N – NORMALISATION. Normalising is validating behaviors, feelings, and emotions of the bereaved • O – ORIENTATION. Orientating is guiding, suggesting, counselling, or even prescribing certain behaviors or rituals 	<p><u>Specific techniques typically used:</u></p> <ul style="list-style-type: none"> • Anticipating special dates and situations • Teaching problem solving decision making, and acquiring new skills • Prescription of rituals and/or "homework" • Talking about the life and death of the spouse (retelling it), and making it normal • Telling of dreams and presences • Therapeutic questions ('sounding out questions') • Avoiding current social topics • Psychological drugs and medical tests (blood tests, X-rays, and so on) • Detection of complications for potential referral <p><u>Specific techniques for special use:</u></p> <ul style="list-style-type: none"> • Telephone communication • Writing • Drawing • Self-help books • Building a photo album or creating a treasure chest of personal objects • Videos • Exercises of emotional expression • Pets • Internet chat rooms for the bereaved • The empty chair and role playing • Cognitive restructuring of unhelpful thinking patterns • Fantasies and guided visualisation • Metaphors

FIGURE 1 Standardization of the intervention group: The main techniques of Primary Bereavement Care (PBC).

Outcome Measures

The baseline questionnaire, the List of Threatening Experiences (LTE; (Brugha & Cragg, 1990), and Bereavement Risk Index (BRI; Parkes & Weiss, 1983), were administered at 4 months after the partner's death. The primary outcome measure, the Texas Revised Inventory of Grief (TRIG; Faschingbauer, 1981; García-García, Landa, Trigueros, & Gaminde, 2005) and

secondary measures, the Grief Experience Inventory (GEI; García-García, Landa, Trigueros, & Gaminde, 2001; Sanders, Mauger, & Strong, 1985), General Health Questionnaire–28 items (GHQ-28; Lobo, Perez-Echevarria, & Artal, 1986), and International Quality of Life Assessment Short Form–36 (SF-36; Alonso, Prieto, & Antó, 1995), were completed at home by the widows, before, during, and after intervention, and follow-up (4, 10, 16, and 24 months after the partner's death), in the presence of a trained interviewer.

The TRIG is a 5-point Likert-type grief questionnaire, composed of two scales: TRIG I Past (8 items, alpha coefficient: 0.77) and TRIG II Present (13 items, alpha coefficient: 0.86). The GEI is a 135 true/false item grief questionnaire; the GHQ-28 is a bimodal (scoring 0, 0, 1, 1) psychiatric screening questionnaire but is used in this project as an indicator of overall disturbance; and the SF-36 is a 3-point Likert-type, standardized (0–100 scoring algorithms), health-related quality of life questionnaire. In addition, the Inventory of Complicated Grief—Revised (ICG-R; Prigerson & Jacobs, 2001) was administered at 24 months after the partner's death.

Sample Size

The sample size was based on a total of 104 widows with the following assumptions: (a) an intracluster correlation coefficient (ICC) of 0.015 (Adams et al., 2004); (b) an average cluster size of 3 widows, (c) a standard deviation (*SD*) of 10.13 (*SD* inflated for the “design effect” = 10.43) in TRIG II (García-García et al., 2005); (d) a relevant clinical difference of at least 6.1 points in TRIG II (size effect = difference/*SD* = 6.1/10.13 = 0.6); (e) alpha of 0.05; (f) power of 80%; and (g) a dropout rate of 10%.

Randomization, Recruitment, and Blinding

Collaborating FPs were randomly and blindly assigned to CG and IG conditions. Collaborating FPs invited widows in their care—consecutively detected—to participate in the study, and, following explanation of what participation would involve, the widows were

recruited if they accepted and signed the consent form. At no stage did the epidemiologist, the interviewers, or the widows know to which group the collaborating FPs had been assigned.

Statistical Analysis

The differences between control and intervention FPs, and between control and intervention widows, were studied using chi-square and *t*-tests for categorical and continuous variables respectively. To compare the overall trend of outcome variables in CG and IG, over 24 months, mixed effects longitudinal models were used (SAS PROC MIXED version 9.1, SAS Institute, Cary, NC). These models included three levels of variability: Level 1 represents the initial score (intercept) and the monthly rate of change (time slope) each widow experienced during the study period; Level 2, level of widows, represents the association between the characteristics of the widows with the initial score and the monthly rate of change; and Level 3, level of FPs, represents the effect of the intervention and the association between the characteristics of the FPs with the initial score and the monthly rate of change. These models accounted for the longitudinal evolution of the repeated measurements of the results and the hierarchical structure of the data (repeated measurements for each widow and widows belonging to the same FP).

The effect of the time, the effect of the intervention, Intervention \times Time interaction, and the covariates of widows and FPs were included as fixed effects in the models. The analysis was adjusted for baseline characteristics of the FPs (bereavement training and years of practice) and widows (predictors: age, previous losses, duration of the relationship and BRI; and potential confounders: level of education, social class, morbidity and use of psychotropics). To simplify the model a backward, forward, and stepwise strategy with a likelihood ratio test ($p < .05$) was used, removing covariables and random effects that were not significant, in each scale.

The intervention effect was evaluated by testing the differences in the monthly rate of change attributable to the intervention (interaction between intervention and time slope $p < .05$) in each scale, between IG and CG. The intervention effect for the primary outcome measure (TRIG II Present) was also evaluated

for different subgroups in which the researchers hypothesized that the effect could be different (namely, according to widow age, duration of the relationship, morbidity, BRI, and LTE); for this an additional interaction between intervention, time, and these covariables was included in the model (significant level for subgroup analysis, $p < .01$). All analyses were by intention-to-treat and involved all the widows who completed the first assessment, just before intervention. All the statistical tests were two-sided, and $p < .05$ was considered significant.

Results

Participant Flow

Of the 120 FPs invited to participate, 39 accepted and were randomized, and 31 of these (16 CG and 15 IG), from 19 health centers in Biscay, collaborated with the project from start to finish, although 2 did not recruit widows (see Figure 2). No significant age and gender differences were identified between the 31 FPs who collaborated and the 8 who did not (see Table 1). Of the 123 widows detected (64 CG and 59 IG), 22 did not consent and 14 were not contacted, whereas 87 completed the first assessment and 77 of these the fourth. There were no significant age differences between the 22 widows who did not consent, the 14 not contacted, and the 87 who completed the first assessment. The only significant differences in baseline data between the 10 widows who did not complete the fourth assessment and the 77 who did, were that the duration of the final illness of their partner ($p = .0109$) and the number of the psychosocial problems ($p = .0007$) were slightly lower in the former. Except for there being more bereavement trained FPs in the CG ($p = .0233$), there were no differences in baseline data between control and intervention FPs. Similarly, except for control widows having a higher score in BRI ($p = .0155$), there were no differences in baseline data between control and intervention widows.

Measurement, Session, and Intervention Adherence

Of the planned four measurements per widow, 95% were carried out (CG: 97%, IG: 92%); and of the planned seven sessions per

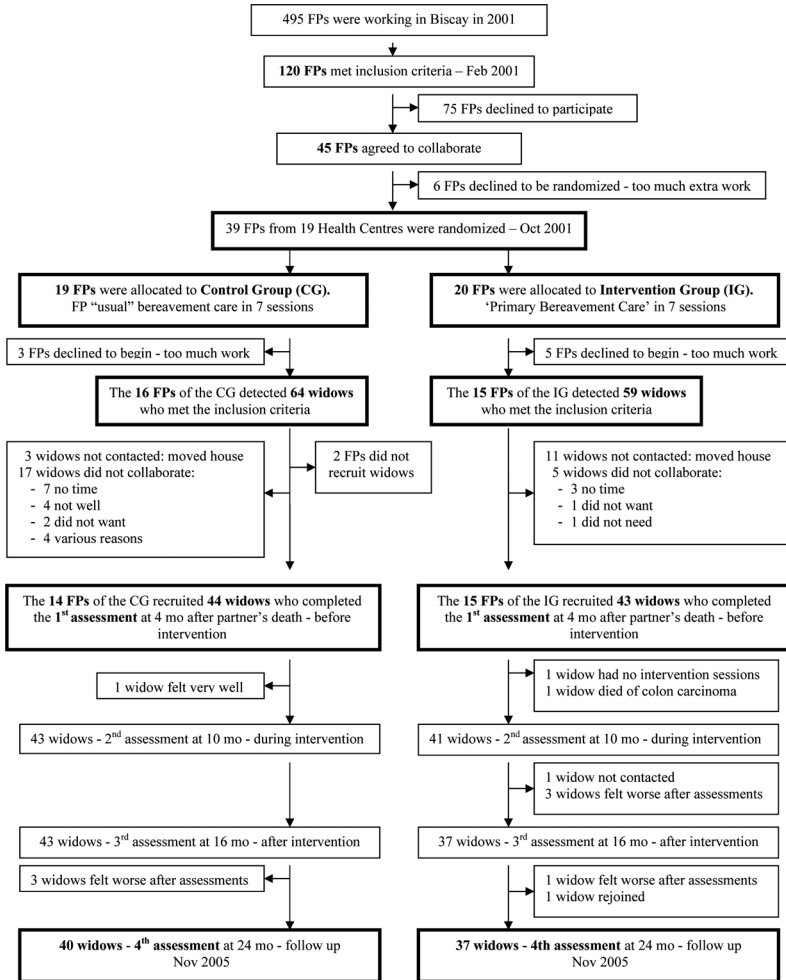


FIGURE 2 Flow chart of family physicians (FPs) and widows who participated throughout the study, Biscay 2001–2005. Feb = February; Oct = October; CG = Control Group; IG = Intervention Group; mo = months after partner's death; PBC = Primary Bereavement Care; Nov = November.

widow, 87% were conducted (CG: 86%; IG: 88%). The mean session duration was 21 min in CG and 44 in IG. Of the PBC general techniques (referred to by acronym REFINO), “relationship” and “ear”

TABLE 1 Baseline Characteristics of the Family Physicians and the Widows

Characteristic	Total	CG	IG	<i>p</i> values
Family physicians	(<i>n</i> = 31)	(<i>n</i> = 16)	(<i>n</i> = 15)	
Age (years), <i>M</i> (<i>SD</i>)	44.7 (5.4)	46.2 (4.5)	43.1 (6.0)	0.1116
Female sex, <i>n</i> (%)	19 (61.3)	10 (62.5)	9 (60.0)	0.8864
Work experience (years), <i>M</i> (<i>SD</i>)	14.5 (6.4)	14 (6.6)	15 (6.4)	0.6719
Current surgery (years), <i>M</i> (<i>SD</i>)	9.0 (6.9)	7.8 (6.4)	10.3 (7.4)	0.3190
Mental health training, <i>n</i> (%)	18 (58.1)	9 (56.3)	9 (60.0)	0.8325
Consultation training, <i>n</i> (%)	23 (74.2)	13 (81.3)	10 (66.7)	0.4331
Bereavement training, <i>n</i> (%)	11 (35.5)	9 (56.3)	2 (13.3)	0.0233
Widows	(<i>n</i> = 87)	(<i>n</i> = 44)	(<i>n</i> = 43)	
Age (years), <i>M</i> (<i>SD</i>)	59.0 (8.1)	59.6 (8.4)	58.4 (8.0)	0.5115
Educational level, <i>n</i> (%)				0.8900
Nonformal education	6 (6.9)	3 (6.8)	3 (7.0)	
Elementary	37 (42.5)	20 (45.5)	17 (39.5)	
High school non-completion	31 (35.6)	16 (36.4)	15 (34.9)	
High school completion	9 (10.3)	4 (9.1)	5 (11.6)	
Graduate degree	4 (4.6)	1 (2.3)	3 (7.0)	
Work status, <i>n</i> (%)				0.1374
Home duties	52 (59.8)	28 (63.6)	24 (55.8)	
Working out of home	24 (27.6)	8 (18.2)	16 (37.2)	
Retired	8 (9.2)	5 (11.4)	3 (7.0)	
Unemployed	2 (2.3)	2 (4.6)	0 (0)	
Disabled	1 (1.2)	1 (2.3)	0 (0)	
Social class, <i>n</i> (%)				0.6329
Executives	9 (10.3)	3 (6.8)	6 (14.0)	
Professionals and managers	16 (18.4)	10 (22.7)	6 (14.0)	
Semi-professionals	21 (24.1)	9 (20.5)	12 (27.9)	

Skilled trade	32 (36.8)	17 (38.6)	15 (34.9)	0.5603
Unskilled	9 (10.3)	5 (11.4)	4 (9.3)	
Family structure, n (%)				
Children >18 years	76 (87.4)	40 (90.9)	36 (83.7)	
Children <18 years	6 (6.9)	2 (4.6)	4 (9.3)	
No children	5 (5.8)	2 (4.6)	3 (7.0)	
Bereavement Risk Index, n (%) $n = 87$				0.0476
Low risk <12	12 (14.8)	3 (7.5)	9 (22.0)	
Moderate risk 13-18	47 (58.0)	22 (55.0)	25 (61.0)	
High risk ≥ 19	22 (27.2)	15 (37.5)	7 (17.1)	
Morbidity categories (CADGs modified), n (%)				
Acute	35 (40.2)	20 (45.5)	15 (34.9)	0.3148
Recurrent	28 (32.2)	15 (34.1)	13 (30.2)	0.7001
Unstable chronic	16 (18.4)	7 (15.9)	9 (20.9)	0.5456
Stable chronic	57 (65.5)	29 (65.9)	28 (65.2)	0.938
Psychosocial	24 (27.6)	11 (25.0)	13 (30.2)	0.5851
Psychiatric medication n (%)	26 (29.9)	13 (29.6)	13 (30.2)	0.8887
Previous losses n (%)	74 (85.1)	38 (86.4)	36 (83.7)	0.7296
LTE, $no.$ (%)	66 (75.9)	35 (79.6)	31 (72.1)	0.4167
First assessment (months), M (SD)	4.3 (1.0)	4.3 (1.1)	4.2 (1.0)	0.6413
Age of dead partner (years), M (SD)	62.5 (8.5)	63.6 (8.7)	61.4 (8.2)	0.229
Duration of relationship (years), M (SD)	34.9 (9.7)	35.0 (9.8)	34.7 (9.7)	0.8854
Duration of the last illness (months), M (SD)	22.7 (42.5)	26.9 (50.6)	18.4 (32.1)	0.3544
Place of death, n (%)				0.7537
Home	21 (24.1)	12 (27.3)	9 (20.9)	
Hospital	61 (70.1)	30 (68.0)	31 (72.1)	
Other	5 (5.8)	2 (4.6)	3 (7.0)	

Notes. CG = Control Group; IG = Intervention Group; CADG = Collapsed Ambulatory Diagnostic Group; LTE = List of Threatening Experiences in the previous 6 months excluding the partner's death.

were used in 100% of the sessions, “facilitation” and “normalization” in 95%, “information” in 89%, and “orientation” in 82%; and of the PBC specific techniques usually used, “anticipate dates” in 76%, “teaching problem solving” in 74%, “avoiding current social topics” in 73%, “recalling dreams” in 68%, and “sounding out emotional questions” in 61%.

Outcomes, Estimations, and Ancillary Analysis

Before the intervention (see Tables 2 and 3) control widows had significantly higher scores than the IG on nine of the 20 scales studied. During monitoring of the widows (Tables 2 and 3) no relevant clinical differences were found in unadjusted scores, and no significant statistical differences in the adjusted monthly rates of change (Intervention \times Time interaction), in favor of the IG. However, there were significant differences in the adjusted monthly rates of change contrary to the hypothesized effect, with a more favorable evolution of the CG, on three scales: GEI Somatization ($p = .0056$), GHQ-28 ($p = .0221$) and SF-36 Emotional Role ($p = .0356$).

Figure 3 shows unadjusted (Panel A) and adjusted TRIG II Present scores (Panel B) decreasing over time in a similar way in both groups. Adjusted scores (Panel B) show that the maximum difference between the GC and IG attributable to PBC, was of -2.8984 (95% CI: -5.9196 to 0.1228 , $p = .0599$) at 10 months after the partner's death, size effect (Cohen's d) = 0.3 (pooled $SD = 9.59$). The intervention effect was not modified by the baseline age ($p = .6990$), morbidity ($p = .6268$), BRI ($p = .3195$), or LTE ($p = .4932$) of the widows, nor by the duration of the relationship between the widows and their partners ($p = .6268$). The real power of the study was of 84% with a final sample size of 87 widows, irrelevant intracluster correlation coefficients (TRIG II Present ICC = 0.0258 , $p < .0001$), four measurements, multivariate adjustments, and a longitudinal analysis capacity to detect as significant ($\alpha = 0.05$) a difference of 5.75 (size effect = 0.6) in the TRIG II Present at 10 months after the partner's death. At 24 months after their partner's death, four and two widows, in the CG and IG, respectively, suffered from complicated grief according to the ICG-R.

TABLE 2 TRIG, GEI, and GHQ-28 Unadjusted Scores by Groups, and Adjusted Monthly Change Rates Attributed to Intervention (Intervention \times Time Interaction)

Outcome measures	CG ($n=44$) ^a <i>M</i> (95% CI)	IG ($n=43$) ^a <i>M</i> (95% CI)	<i>p</i> value	Intervention \times Time ^b mean (95% CI)	<i>p</i> value
TRIG					
I-Past, range 8–40					
4 months	27.23 (25.07 to 29.39)	23.40 (21.21 to 25.58)	0.0151	0.29 (–0.30 to 0.88)	0.3324
10 months	25.47 (23.06 to 27.87)	23.63 (21.17 to 26.10)	0.2937		
16 months	24.86 (22.41 to 27.31)	21.62 (18.98 to 24.27)	0.0778		
24 months	25.68 (23.34 to 28.01)	23.11 (20.68 to 25.54)	0.1338		
II-Present, range 13–65					
4 months	57.07 (54.38 to 59.75)	53.54 (50.82 to 56.25)	0.0693	–0.44 (–1.14 to 0.26)	0.2229
10 months	52.14 (49.32 to 54.96)	47.88 (44.99 to 50.77)	0.0388		
16 months	48.81 (45.61 to 52.02)	44.86 (41.41 to 48.32)	0.0994		
24 months	45.95 (42.59 to 49.31)	44.68 (41.18 to 48.17)	0.6019		
GEI					
Despair, range 0–18					
4 months	10.80 (9.33 to 12.26)	8.49 (7.01 to 9.97)	0.0303	0.08 (0.00 to 0.16)	0.0534
10 months	9.30 (7.87 to 10.73)	7.20 (5.73 to 8.66)	0.0438		
16 months	7.93 (6.48 to 9.39)	6.84 (5.27 to 8.41)	0.3126		
24 months	7.50 (6.00 to 9.00)	6.19 (4.63 to 7.75)	0.2304		
Anger/hostility, range 0–9					
4 months	3.80 (3.08 to 4.51)	3.56 (2.83 to 4.28)	0.6454	0.00 (–0.04 to 0.04)	0.9897
10 months	3.65 (2.94 to 4.36)	2.98 (2.25 to 3.70)	0.1881		
16 months	3.35 (2.64 to 4.05)	3.00 (2.24 to 3.76)	0.5051		
24 months	3.30 (2.60 to 4.00)	2.86 (2.13 to 3.60)	0.3961		

(Continued)

TABLE 2 Continued

Outcome measures	CG ($n=44$) ^a M (95% CI)	IG ($n=43$) ^a M (95% CI)	ρ value	Intervention \times Time ^b mean (95% CI)	ρ value
Guilt, range 0-6					
4 months	0.86 (0.56 to 1.17)	1.00 (0.69 to 1.31)	0.5316	-0.01 (-0.03 to 0.01)	0.5119
10 months	0.65 (0.36 to 0.94)	0.68 (0.39 to 0.98)	0.8793		
16 months	0.63 (0.36 to 0.90)	0.62 (0.33 to 0.91)	0.9748		
24 months	0.60 (0.36 to 0.84)	0.54 (0.29 to 0.79)	0.7335		
Social isolation, range 0-7					
4 months	3.27 (2.69 to 3.85)	2.81 (2.23 to 3.40)	0.2731	0.02 (-0.01 to 0.05)	0.3055
10 months	2.67 (2.16 to 3.19)	2.41 (1.89 to 2.94)	0.4846		
16 months	2.56 (2.08 to 3.04)	2.41 (1.89 to 2.92)	0.6674		
24 months	2.20 (1.68 to 2.72)	2.03 (1.49 to 2.56)	0.6453		
Loss of control, range 0-9					
4 months	5.77 (5.17 to 6.37)	5.44 (4.83 to 6.05)	0.4441	0.01 (-0.03 to 0.05)	0.4529
10 months	5.42 (4.78 to 6.05)	4.78 (4.13 to 5.43)	0.1671		
16 months	5.14 (4.62 to 5.66)	4.84 (4.28 to 5.40)	0.4340		
24 months	4.98 (4.33 to 5.62)	5.03 (4.36 to 5.69)	0.9112		
Rumination, range 0-12					
4 months	6.16 (5.49 to 6.82)	5.56 (4.89 to 6.23)	0.2101	-0.01 (-0.05 to 0.03)	0.5817
10 months	5.72 (5.03 to 6.41)	4.90 (4.20 to 5.61)	0.1022		
16 months	5.37 (4.75 to 5.99)	5.16 (4.49 to 5.83)	0.6476		
24 months	5.73 (5.03 to 6.42)	4.95 (4.22 to 5.67)	0.1253		

Depersonalization, range 0–8					
4 months	5.91 (5.35 to 6.47)	5.44 (4.87 to 6.01)	0.2488	–0.03 (–0.07 to 0.01)	0.1001
10 months	5.40 (4.74 to 6.05)	4.49 (3.82 to 5.16)	0.0567		
16 months	5.00 (4.35 to 5.65)	4.27 (3.57 to 4.97)	0.1318		
24 months	5.05 (4.40 to 5.70)	3.97 (3.29 to 4.65)	0.0260		
Somatization, range 0–20					
4 months	9.11 (7.94 to 10.29)	6.67 (5.48 to 7.87)	0.0048	0.08 (0.02 to 0.14)	0.0056
10 months	8.02 (6.84 to 9.20)	5.78 (4.57 to 6.99)	0.0100		
16 months	7.19 (6.08 to 8.29)	5.57 (4.37 to 6.76)	0.0513		
24 months	6.40 (5.21 to 7.59)	5.97 (4.74 to 7.21)	0.6210		
Death anxiety, range 0–11					
4 months	6.61 (5.92 to 7.31)	5.37 (4.67 to 6.07)	0.0141	0.01 (–0.04 to 0.06)	0.8227
10 months	6.35 (5.65 to 7.05)	5.27 (4.55 to 5.99)	0.0350		
16 months	6.16 (5.39 to 6.93)	4.86 (4.04 to 5.69)	0.0249		
24 months	5.78 (5.00 to 6.55)	5.24 (4.43 to 6.05)	0.3493		
GHQ-28, range 0–28					
4 months	12.07 (9.81 to 14.33)	7.86 (5.58 to 10.14)	0.0108	0.69 (0.63 to 0.75)	0.0221
10 months	6.61 (4.64 to 8.59)	4.40 (2.39 to 6.40)	0.1208		
16 months	4.18 (2.77 to 5.59)	2.28 (0.85 to 3.70)	0.0624		
24 months	3.48 (1.86 to 5.09)	2.72 (1.09 to 4.35)	0.5141		

Notes. TRIG = Texas Revised Inventory of Grief; GEI = Grief Experience Inventory; GHQ-28 = General Health Questionnaire-28 items; CG = Control Group; IG = Intervention Group; CI = Confidence Interval; 4 month = preintervention; 10 month = during intervention; 16 month = post-intervention; 24 month = follow-up.

^aHigher scores indicate more severe grief or psychological discomfort.

^bMonthly change rates attributed to intervention (Intervention × Time interaction): negative values are favorable to intervention.

TABLE 3 SF-36 Unadjusted Scores by Groups, and Adjusted Monthly Change Rates Attributed to Intervention (Intervention \times Time Interaction)

Outcome measures	CG ($n = 44$) ^a M (95% CI)	IG ($n = 43$) ^a M (95% CI)	ρ value	Intervention \times Time ^b	ρ value
Physical functioning, range 0–100					
4 months	67.73 (61.45 to 73.00)	77.56 (71.21 to 83.90)	0.0312	-0.03 (-0.46 to 0.41)	0.8801
10 months	73.02 (65.81 to 80.23)	80.73 (73.75 to 88.11)	0.1411		
16 months	73.02 (65.86 to 80.19)	79.46 (71.74 to 87.18)	0.2275		
24 months	73.38 (65.87 to 80.88)	81.35 (73.54 to 89.16)	0.1466		
Role-physical, range 0–100					
4 months	48.86 (36.11 to 61.61)	76.16 (63.27 to 89.06)	0.0036	-0.76 (-1.84 to 0.12)	0.1179
10 months	50.58 (37.09 to 64.07)	73.17 (59.36 to 86.99)	0.0224		
16 months	60.47 (47.81 to 73.12)	76.35 (62.71 to 89.99)	0.0932		
24 months	68.13 (55.22 to 81.03)	75.68 (62.25 to 89.10)	0.4218		
Bodily pain, range 0–100					
4 months	54.82 (45.83 to 63.80)	63.58 (54.49 to 72.67)	0.1763	-0.02 (-0.64 to 0.76)	0.9458
10 months	53.84 (44.74 to 62.93)	66.24 (56.93 to 75.56)	0.0615		
16 months	60.51 (51.72 to 69.31)	77.11 (67.63 to 86.59)	0.0126		
24 months	64.35 (54.79 to 73.91)	75.97 (66.03 to 85.92)	0.0975		
General health, range 0–100					
4 months	56.55 (50.74 to 62.35)	64.37 (58.50 to 70.24)	0.0628	-0.31 (-0.62 to 0.17)	0.1063
10 months	59.33 (53.00 to 65.65)	66.07 (59.59 to 72.55)	0.1422		
6 months	62.63 (56.56 to 68.69)	68.03 (61.49 to 74.56)	0.2317		
24 months	62.05 (55.71 to 68.39)	63.03 (56.44 to 69.62)	0.8320		

Vitality, range 0–100						
4 months	36.93 (30.30 to 43.56)	45.35 (38.64 to 52.05)	0.0794	–1.46 (–3.39 to 0.17)	0.0794	0.0989
10 months	49.19 (42.06 to 56.32)	52.07 (44.77 to 59.37)	0.5751		0.5751	
16 months	50.35 (44.40 to 56.30)	55.54 (49.13 to 61.95)	0.2409		0.2409	
24 months	49.88 (44.00 to 55.75)	57.97 (51.86 to 64.08)	0.0609		0.0609	
Social functioning, range 0–100						
4 months	62.50 (53.57 to 71.43)	68.02 (58.99 to 77.06)	0.3899	1.21 (–1.45 to 3.72)	0.3899	0.4311
10 months	65.41 (56.09 to 74.72)	83.54 (74.00 to 93.07)	0.0083		0.0083	
16 months	78.78 (71.67 to 85.89)	91.22 (83.55 to 98.88)	0.0203		0.0203	
24 months	76.25 (68.83 to 83.67)	87.50 (79.78 to 95.22)	0.0397		0.0397	
Role-emotional, range 0–100						
4 months	29.55 (16.48 to 42.61)	53.49 (40.27 to 66.70)	0.0122	–1.11 (–2.20 to –0.05)	0.0122	0.0356
10 months	46.51 (33.09 to 59.94)	72.36 (58.61 to 86.11)	0.0090		0.0090	
16 months	66.67 (54.10 to 79.23)	75.68 (62.13 to 89.22)	0.3346		0.3346	
24 months	62.50 (48.38 to 76.62)	65.77 (51.08 to 80.45)	0.7504		0.7504	
Mental health, range 0–100						
4 months	37.98 (31.54 to 44.41)	47.91 (41.40 to 54.41)	0.0338	–1.17 (–2.63 to 0.47)	0.0338	0.1154
10 months	50.23 (43.91 to 56.55)	55.46 (48.99 to 61.93)	0.2532		0.2532	
16 months	53.40 (47.59 to 59.20)	60.03 (53.77 to 66.28)	0.1258		0.1258	
24 months	57.20 (51.24 to 63.16)	62.16 (55.96 to 68.36)	0.2540		0.2540	

Notes. SF-36 = International Quality of Life Assessment Short Form-36; CG = Control Group; IG = Intervention Group; CI = Confidence Interval; 4 months = preintervention; 10 months = during intervention; 16 months = postintervention; 24 months = follow-up.

^aHigher scores indicate better quality of life related to health.

^bMonthly change rates attributed to intervention (Intervention × Time interaction): positive values are favorable to intervention.

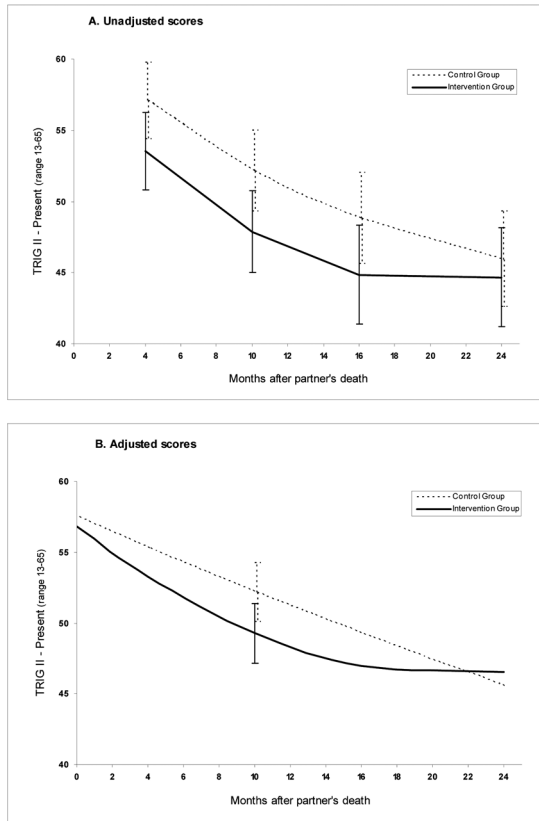


FIGURE 3 Texas Revised Inventory of Grief (TRIG) II Present unadjusted (Panel A) and adjusted (Panel B) scores decreasing over time in an almost parallel 'deckchair evolution' in the control and intervention group.

Discussion

PBC as applied by intervention FPs was no more effective in improving the process of bereavement in recently bereaved widows than the usual care given by control FPs. These results and the effect size (0.3) of our intervention accord with most reviews of the effectiveness of bereavement interventions (Allumbaugh & Hoyt, 1999; Currier, Neimeyer, & Berman, 2008; Forte, Hill, Pazder, & Feudtner, 2004; Kato & Mann, 1999; Neimeyer & Currier, 2009; Wimpenny et al., 2006;

Wittouck, Van Autreve, De Jaegere, Portzky, & Van Heeringen, 2011; Woof & Carter, 1997).

We want to emphasize that widows in the CG even scored significantly better on three scales, which means that some widows in the IG may not have improved as much as they might have if they had not received the intervention. An earlier “review of reviews” about bereavement interventions (Jordan & Neimeyer, 2003) similarly concluded that “perhaps the central finding of these reviews is that grief counselling does not appear to be very effective, most probably because many of the people who received it would do just as well (and perhaps in some cases better) without it” (p. 781). This statement seem to be equally applicable in our case—the more intervention the worse the outcome. At present this is a controversial issue (Currier et al., 2008; Hoyt & Larson, 2010; Larson & Hoyt, 2007; Lilienfeld, 2007; Neimeyer, 2010; Schut, 2010; Wimpenny et al., 2006), but we believe that bereavement intervention, as in any other treatment, has its indications, “doses,” and adverse effects.

It was also surprising that we did not detect better outcomes in widows at risk, as shown in other studies (Currier et al., 2008; Wimpenny et al., 2006), and that adherence to PBC did not modify the number of widows who went on to develop complicated grief. In short, our randomized controlled trial, despite the substantial training in bereavement care provided to intervention physicians, raises significant questions about the routine incorporation of such procedures in the primary care context.

Strengths and Limitations

The design of the current study incorporated many strengths. The intervention had a theoretical framework, was carefully manualized and fidelity was assessed via ongoing monitoring. Moreover, statistical power was sufficient (84%) to detect clinically relevant effects, and there was high measurement and protocol adherence, as well as retention of project participants.

However, some limitations also should be acknowledged. The FPs rather than the widows were randomly allocated, and widow baseline scores were not identical, which could be interpreted as a potential selection bias, but another possibility is that intervention FPs intervened from before the death and in the first 3

months thereafter. In any case, the analysis was adjusted to account for baseline differences.

Although control FPs had seven ordinary appointments with the widows under their care, they were not constrained from focusing their patients' responses to bereavement, thereby creating a possible confound, and this natural relational responsiveness to distress could have helped widows even if the physicians did not enter into their experiences in depth. On the other hand, PBC was oriented to address certain feelings and realities of the widows (vulnerability, hopelessness, etc.), which could cause more discomfort, as reflected on some scales. Thus, PBC could be felt to be meddling by some widows. We also suspect that control FPs were learning and improving their responsiveness as they delivered care to the widows, each widow being "learning opportunity." Observing Trig II Present scores over time (Figure 3), a "deckchair shape" can be seen, with bereavement intensity dropping faster at the beginning, until at some point, around 14–16 months, a kind of plateau is reached, after which it then stabilizes until 24 months. If the natural evolution of bereavement is to return to a similar situation to the general population, that is, there is a "floor effect," then when intervention widows reach this point it is impossible to see further improvement. These limitations could mask the differences between the two groups, and in this situation it would be particularly difficult to demonstrate any effect of PBC.

Conclusion

Early manual-based bereavement intervention in widows, provided by FPs trained in PBC, does not produce better outcomes than usual care provided by FPs not trained in PBC, with the same appointment schedule, and on some measures, may actually worsen patient outcomes. These findings are likely to be applicable to a wide range of widows in primary care. These findings lead us to believe that an ideal bereavement intervention model in primary care would use FPs trained in basic bereavement care, willing to discuss feelings with bereaved people at their request, rather than as a matter of course to all bereaved patients. That is, care would be provided a more selective basis, using a less formal intervention than PBC—essentially a minimal and natural responsiveness in cases of normal grief, deeper assessment, and

intervention in high risk cases (e.g., violent death bereavement, the loss of a child), and much deeper intervention in complicated grief, when referral to a mental health specialist could be indicated.

Further refinement of the type of the intervention (well-defined theoretical framework, a detailed intervention manual, etc.), the “dose” (depth of intervention, time and number of sessions, etc.) and to whom it should be delivered (in light of known risk factors, at the patient’s request, or in response to clear complications), is required to enable us to propose the most appropriate intervention for each bereaved person.

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