

WITHDRAWN: Effectiveness of a Cognitive-behavioral Group Therapy for Complicated Grief in Family Members of Patients With Cancer

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Research Article

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EDITORIAL NOTE:

The full text of this preprint has been withdrawn by the authors while they make corrections to the work. Therefore, the authors do not wish this work to be cited as a reference. Questions should be directed to the corresponding author.

Abstract

Introduction: complicated grief can affect a large number of individuals who have lost a relative due to cancer. **Objective:** to assess the efficacy of a cognitive-behavioral group therapy (CBGT) for complicated grief in those who have lost a relative due to cancer in comparison with a psychoeducational and emotional expression intervention (PSDEEI).

Method: 249 relatives of deceased cancer patients with complicated grief were randomly assigned to treatment with CBGT or PSDEEI. Complicated Grief (ICG), depression (BDI-II), hopelessness (BHS), anxiety (BAI) symptoms and general health (GHQ28) were assessed at pre-treatment, post-treatment, and follow-up at 6 and 12 months.

Results: the CBGT group improved significantly ($p < 0.001$), with the scores in ICG, BDI-II, BAI, BSH, and GHQ28 ($p < 0.001$) being higher than those for the PSDEEI group in each of the assessed moments, with high effect sizes: ICG ($\eta^2 = 0.16$), BDI ($\eta^2 = 0.10$), BAI ($\eta^2 = 0.06$), BSH ($\eta^2 = 0.21$) and GHQ28 ($\eta^2 = 0.21$). At the 12-month follow-up, the number of cases of complicated grief decreased by 81.1% for the CBGT group vs. 31.7% in the PSDEEI group.

Conclusions: The CBGT treatment is effective for complicated grief, for depression, anxiety, and hopelessness symptoms and for mental health, and is superior to PSDEEI treatment.

Introduction

Grief is a normal psychological process that occurs after the loss of a loved one. It is an experience characterized by longing, emotional distress, sadness, anxiety, and loss of meaning or purpose. Most people adjust well to the new situation within a six-month to two-year period. However, there is a significant percentage of people who present complicated grief, whose main symptoms include intense emotional grief, alteration of social, leisure and work activities and even physical health problems [1, 2]. Lunderdorff et al. (2017) reported that 9.8% (CI95%: 6.8-14) of people can present CG [3]. In the case of caregivers of cancer patients, a higher prevalence has been reported, specifically, Guldin et al. (2012) found percentages of 40% at 6 months, 28% at 13 months, and 27% at 18 months [4], and Zordan et al. (2019) reported that almost 20% had CG three years after the loss [5]. This justifies the importance of having effective psychological treatments for complicated grief.

Research results in recent years with randomized clinical trials regarding cognitive behavioral treatments have been very positive. Specifically, Rosner et al. (2014) [6], and Rosner et al. (2015) tested the efficacy of a cognitive behavioral intervention (CBT) of 20 to 25 sessions [7], Bryant et al. (2014) and Bryant et al. (2017) showed positive effects of a treatment of 10 CBT and four exposure therapy sessions [8, 9]. Wen et al. (2019) reported good results using metacognitive therapy [10]. Likewise, Lintz et al. (2014) found positive effects of CBT applied via the internet [11].

Furthermore, Shear et al. showed the efficacy of an intervention program of 16 sessions that proved its superiority with respect to interpersonal psychotherapy [12], and drug treatments [13], and that it is effective applied as a group therapy [14]. This is the most studied treatment program so far [15].

The data on the efficacy of these treatments for complicated grief must be confirmed in the specific case of family members of deceased cancer patients. The objective of the present study is to verify the efficacy of a cognitive behavioral group therapy (CBGT) treatment to reduce the symptoms of grief, anxiety, depression, and psychopathological symptoms in comparison with a psychoeducation treatment on grief and emotional expression (PSDEEI) in family members of cancer patients.

Method

Design

This study has an experimental design with two randomized groups, in which the effect of the intervention through a cognitive-behavioral group therapy (CBGT) is compared to a PEE in complicated grief, and symptoms of depression, anxiety, hopelessness and mental health in relatives of deceased cancer patients. Pre-treatment, post-treatment, and follow-up measures at 6 and 12 months after treatment were taken. The study took place between January 2018 and March 2020 at the La Paz University Hospital in Madrid. The project was approved by the ethical research committee of the La Paz University Hospital in Madrid.

Participants

The sample consisted of relatives of deceased cancer patients who had symptoms of grief and were referred to the Oncology and Palliative Care Unit of the Hospital Universitario La Paz by the Palliative Care and Primary Care units in Area 5 of Madrid. All participants carried out a clinical interview to confirm the presence of complicated grief symptoms. The inclusion criteria were the following: being over 18 years of age, speaking Spanish, having a family member who has died of cancer 6 months or more prior, availability to attend all assessment and/or treatment sessions, and scoring 25 or more in the Inventory of Complicated Grief. The exclusion criteria were: presenting psychopathological disorders or being under psychiatric treatment, substance addiction (according to the medical history), or undergoing any other grief treatments.

Two hundred and forty-nine relatives of deceased cancer patients met the inclusion criteria. A 48.7% were referred by the Palliative Care Units and 35.8% were referred by Primary Care in Area 5 of Madrid. Eighteen individuals in the experimental group did not complete the treatment and 35 individuals in the control group did not attend all the sessions and 8 did not fill in the questionnaires adequately. Therefore, the final sample consisted of 187 grieving

relatives, 106 in the experimental group and 81 in the control condition. The statistical power with this sample size is 0.99 (calculated by the Gpower program with an effect size of 0.25 and alpha of 0.05)

Procedure

After the selection and random assignment of the participants, groups of 8 to 10 relatives homogeneous in terms of age and type of loss were formed. Both treatments, CBGT and PSDEEI, were carried out, in both groups, by two clinical psychologists and were carried out across 16 weekly sessions, of 2 hours each, during a period of 4 months. All participants were assessed at baseline, one week after the end of treatment (post-treatment) and after 6 and 12 months of follow-up. The research was carried out in a period of 18 months, running three weekly intervention groups.

Experimental group

The treatment program is based on treatment programs that have been shown to be effective [14, 15]. The components of the treatment are the following: a) psychoeducation on grief and complicated grief; b) identifying and addressing cognitive, affective, physiological and behavioral manifestations, especially guilt; c) facilitating or favoring the acceptance of the reality of the loss, sharing personal experiences, reviewing the history of death, its implications and consequences, and searching for meaning/purpose; d) identifying and regulating emotion; e) improving self-care; f) facilitating optimal interpersonal functioning and communication; g) working on personal values and goals; h) Reviewing places and activities that are avoided; i) working with memories, images; j) imaginary conversations and letters to the deceased. Relaxation techniques, breathing, in vivo exposure and imagination, cognitive modification and behavioral activation were used.

Control Group

Groups of 8 to 10 people were formed following the same criteria as the experimental group. They received a total of 16 weekly sessions of 2 hours duration, just like the experimental group. The content of the sessions consisted of psychoeducation on grief and emotional ventilation.

Variables and Instruments

A semi-structured interview was carried out to collect sociodemographic data, referral data and clinical history, drug treatments, personal grief reactions, personal resources, and socio-family support.

The following instruments were used to measure the efficacy of the treatment:

- Beck Depression Inventory (BDI-II) (Spanish version) [16]. The cut-off point to consider high levels of depressive symptoms was 21 in the present study. A score between 0 and 13 would indicate a level of minimal depressive symptoms, between 14 and 19, mild, between 20 and 28, moderate, and between 29 and 63, severe.
- Beck Anxiety Inventory (BAI) (Spanish version) [17]. The cut-off point to consider high levels of anxiety symptoms was 21 in the present study. A score of 0-7 would indicate minimal anxiety, 8-15, mild anxiety, 16-25, moderate anxiety, and 26-63, severe anxiety.
- Beck Hopelessness Scale (BHS), Spanish adaptation [18]. The severity categories are as follows: 0-3- Mild hopelessness within the limit, 4-8 slight hopelessness, 9-14 moderate hopelessness, 15-20 severe hopelessness. In the present study, ≥ 8 was used as a cut-off point.
- Goldberg's General Health Questionnaire (GHQ28) [19,20]. It is a screening instrument that aims to detect psychological morbidity and possible cases of psychiatric disorders in contexts such as primary care or in the general population. It is a mental health assessment measure. Scores ≥ 6 were considered indicative of psychosocial problems.
- The Inventory of Complicated Grief (ICG – *Inventario de Duelo Complicado*, IDC in Spanish) [21,22]. The cut-off point to consider complicated grief was ≥ 25 at six months after death.

Data Analyses

The distribution of the qualitative variables was presented in the form of absolute and relative frequencies and the distribution of the quantitative variables was described by the mean and standard deviation or median and interquartile range, depending on the distribution of the data.

A univariate analysis was carried out to study the homogeneity of the two groups in terms of their sociodemographic characteristics and the baseline situation of the scales: to contrast the differences of the qualitative variables, the chi-square test was performed and to compare the differences between the quantitative variables, the Student's t test for two independent samples or the nonparametric Mann Whitney U test, depending on the distribution of the data.

To study the efficacy of the treatment, the development of the BDI, BAI, BHS, GHQ28 and ICG scales over time was analyzed by adjusting Linear Mixed Models including the treatment (Experimental vs Control) as a fixed factor and the measurement time as a repeated measures factor (Pretreatment, Posttreatment, 6 months, and 12 months). The Treatment x Time interaction effect was also included, with a variance matrix without structure. A statistically significant interaction effect indicated that the groups differed in their development. In the hypothesis tests for post-hoc comparisons, the Bonferroni correction for multiple comparisons was used. The eta-squared value for the interaction effect was also presented as a standardized measure of effect size. This statistic describes the proportion of total variability attributable to a factor.

All tests were considered two-tailed and a p-value less than 0.05 was considered statistically significant.

Results

The study sample was composed mainly of women, with a low educational level, aged close to 60 years, who had lost their husbands at least 6 months prior. No statistically significant differences were found in the sociodemographic characteristics of the patients, or in the time elapsed after death (see Table 1).

Table 1
Sociodemographic data and time (in months) since the loss.

	CBGT	PSDEEI	Total	p-value
Sociodemographic data	106	81	187	
Age mean (SD; range)	58 (15; 24-79)	59 (16; 21-80)	59 (15; 21-80)	0,794
Gender:				0,751
Male	19 (18%)	16(20%)	35 (19%)	
Female	87 (82%)	65(80%)	152 (81%)	
Education:				0,735
Primary	65 (61%)	51 63%	116 (62%)	
secondary	27 (26%)	18 (22%)	45 (24%)	
Higher education	14 (13%)	12 (15%)	26 (14%)	
Marital Status:				0,156
Married/couple	16 (15%)	5 (6%)	19 (10%)	
Single	12 (11%)	11 (14%)	25 (13%)	
Widowed	78 (74%)	65 (80%)	143 (77%)	
Relation to the deceased:				0,297
Spouse /Partner	78 (74%)	63 (78%)	141 (75%)	
Father / Mother	16 (15%)	14 (17%)	30 (16%)	
Son / Daughter	12 (11%)	4 (5%)	16 (9%)	
Months since the loss				0,85
Mean (SD)	7.62 (6.14)	6.4 (4.4)	7,13 (5.5))	
CBGT: Cognitive-Behavioral Group Therapy; PSDEEI: Psychoeducational and Expressive Emotional Intervention.				

Regarding the efficacy of the treatment, in all the measures, a statistically significant interaction effect was obtained that indicated the different development of each group. An improvement in the scores was observed with a decrease in both groups at temporal measurements, which was much greater in the experimental group. From the eta-squared values we can conclude that the interaction effect was larger in the GHQ28 and ICG scores, with 21% and 16% of attributable variability (see Table 2 and Figure 1).

Table 2
Development of depression, anxiety, hopelessness, general health, and grief. GLM model results.

GLM models RESULTS		Tests of Within-Subjects Effects				Models estimated means				Difference from baseline						
Outcome	Effect	df	F	Sig.	η^2	Time	CBTG		PSDEEI		Control		Experimental			
							Mean	SE	Mean	SE	Diff	CI95%	Diff	CI95%		
BDI	Time	2.4	208.4	<0.001	0.55	Pre	19.0	1.0	18.6	.7						
	Treatment*Time	2.4	18.7	<0.001	0.10	Post	17.3	.9	10.6	.7	1.7	-1	3.5	8.*	6.6	9.4
						6 m	13.1	.8	8.3	.6	5.9*	3.9	7.9	10.3*	8.7	11.9
						12 m	10.7	.7	6.6	.6	8.3*	6.1	10.5	12.1*	10.3	13.8
BAI	Time	1.7	203.2	<0.001	0.55	Pre	19.8	1.3	18.9	1.0						
	Treatment*Time	1.7	10.0	<0.001	0.06	Post	16.3	1.0	10.9	.8	3.5*	1.7	5.3	8*	6.6	9.4
						6 m	13.3	.8	8.4	.7	6.6*	4.1	9.1	10.5*	8.5	12.4
						12 m	10.6	.7	5.3	.6	9.2*	6.3	12.0	13.7*	11.4	15.9
BHS	Time	2.3	124.6	<0.001	0.42	Pre	10.5	.6	9.8	.5						
	Treatment*Time	2.3	15.6	<0.001	0.08	Post	9.7	.6	5.9	.4	.7	-4	1.8	3.8*	3.0	4.7
						6 m	8.1	.5	4.1	.4	2.4*	1.1	3.7	5.6*	4.6	6.7
						12 m	6.9	.5	3.2	.4	3.5*	2.1	5.0	6.6*	5.4	7.7
GHQ28	Time	2.1	377.0	<0.001	0.69	Pre	14.3	.7	16.0	.6						
	Treatment*Time	2.1	45.6	<0.001	0.21	Post	13.3	.7	8.6	.5	1.0	-2	2.3	7.5*	6.5	8.4
						6 m	9.3	.7	4.6	.5	5*	3.3	6.7	11.5*	10.1	12.8
						12 m	7.0	.5	2.6	.4	7.3*	5.5	9.0	13.5*	12.1	14.8
ICG	Time	2.3	284.4	<0.001	0.63	Pre	42.3	1.3	42.1	1.0						
	Treatment*Time	2.3	31.5	<0.001	0.16	Post	38.6	1.4	27.5	1.1	3.7*	.7	6.8	14.5*	12.1	16.9
						6 m	28.7	1.0	19.8	.8	13.6*	10.2	17.0	22.3*	19.6	24.9
						12 m	30.0	1.2	15.9	1.0	12.3*	8.6	16.0	26.1*	23.3	29.0

df: degree freedom; F: test F value; SE: standard error; Diff: difference; CI95%: confidence interval 95%

BDI: Beck Depression Inventory, BAI: Beck Anxiety Inventory; BHS: Beck Hopelessness Scale; GHQ28: General Health Questionnaire-28 items; ICG: Inventory of Complicated Grief. CBTG: Cognitive-Behavioral Group Treatment; PSDEEI: Psychoeducational and Expressive Emotional Intervention.

*p<0.05

In relation to the scores in the ICG, the CBGT group showed a decrease of 14.5 points (CI95%: 12.1-16.9) in the post-treatment, and the PSDEEI group exhibited a decrease of 3.1 points (CI95%: 0.4-5.9). The CBGT group reached normality values (<25) at 6 months, while the PSDEEI group maintained a high score for complicated grief symptoms at 12 months of follow-up.

In order to ease clinical interpretation, the results of the clinical case are presented, defined as complicated grief at each assessment time (see Table 3). In the post-treatment assessment, a percentage of complicated grief of 47% was reached in the CBGT group compared to 86% in the PSDEEI group, which represents a relative difference of 45%. In the 12-month assessment, 65% of those in the PSDEEI group still continued with complicated grief, while in the CBGT group, only 14% remained with complicated grief. Therefore, there was a 78% higher success rate in the CBGT group than in the PSDEEI.

Table 3
Presence of Complicated Grief.

ICG (>25)	Control	Experimental	Complicated Grief Ratio	IC95%	IC95%	Interpretation
Pre-treatment	81 (100%)	106 (100%)				
Post-treatment	70 (86.4%)	50 (47.2%)	0.546*	0.438	0.680	45%
6-month follow-up	47 (65.3%)	16 (15.1%)	0.231*	0.143	0.374	77%
12-month follow-up	42 (64.6%)	15 (14.2%)	0.219*	0.133	0.362	78%
ICG: Inventory of Complicated Grief						
*p<0.001						

Regarding the scores on the BDHI, in the post-treatment assessment, the CBGT group showed a mean decrease of 8 (CI95%: 6.5-9.5), while the PSDEEI group decreased 2 points (CI95%: 0.2-3.7). The CBGT group achieved a low mean for depression symptoms (BDHI <13) in the post-treatment assessment, whereas the control group reached those values later, at the 6-month follow-up.

Regarding the scores in the BAI, in the post-treatment assessment, the CBGT group showed a mean reduction of 8 (CI95%: 6.5-9.4), while the PSDEEI group decreased 2.9 points (CI95%: 1.2-4.6). The experimental group reached a mild mean of anxiety symptoms (BAI <15) in the post-treatment assessment, whereas the control group only reached this level later, at the 6-month follow-up.

Regarding the scores in the BHS, in post-treatment, the CBGT group had a mean reduction of 3.8 (CI95%: 3-4.7), while the PSDEEI group decrease was 0.5 points (CI95%: 0.4-1.5). The CBGT group achieved a low mean of hopelessness (BSH <8) in the post-treatment assessment, whereas the PSDEEI group achieved it later, at the 6-month follow-up.

Regarding the scores on the GHQ28, the differences at the post-treatment showed a significant decrease only in the CBGT group of 7.5 (6.8-8.4), while the mean score in the control group was similar to that for the pre-treatment assessment. The CBGT group reached normality values (<6) at the 6-month follow-up, whereas the PSDEEI group did not achieve normality values during the follow-up.

Discussion

The results of the present study show an optimal effectiveness of CBGT in reducing the mean symptoms of complicated grief (more than 26 points in the ICG from the pre- to the post-treatment). The percentage of cases of complicated grief at 12 months after the intervention was reduced by 81% in the CBGT group, compared to only a reduction of 32.7% of cases in the PSDEEI group.

Similarly, the CBGT was effective in reducing the symptoms of depression, anxiety, hopelessness, and psychopathology.

The results of the CBGT group are clearly superior to those obtained by the PSDEEI group.

The results on the efficacy of cognitive behavioral treatment are similar to those reported in individual treatment [6–7, 12, 13], and in group mode [14].

The main strength of the present study is that it is the first experimental investigation to test a cognitive behavioral group therapy treatment with relatives of deceased cancer patients for complicated grief using a large sample. Furthermore, the CBGT group showed superiority over the active treatment group: psychoeducational and emotional expression intervention.

It should be noted that the treatment has been applied in groups of 8 to 10 people, which has been shown to be highly effective. This is important because it enables efficacy of the psychological intervention for the mental health of the bereaved with a reduction in its economic cost.

Finally, the treatment has been effective in a sample of people with a low educational level. Bolen et al. (2011) pointed out that low educational level is a predictor of lower efficacy of cognitive-behavioral treatments for complicated grief [23]. Shear et al. could not verify the efficacy of the treatment for people with a lower educational level as their samples were composed of a greater number of people with a higher educational level [12, 13].

Limitations

Among the limitations of the present study, it should be noted that the sample has a higher representation of women, which is common in other studies, but this impairs the generalization of the results to the male gender.

It should be highlighted that most of the sample was composed of people whose loss had occurred 6 months prior to the start of the intervention, the efficacy of the intervention with losses occurring a minimum of a year prior to the treatment remains to be determined.

In the experimental group, there was a loss of 14.4% of participants, throughout the study, and in the PSDEEI group it was 35% loss. The number of dropouts is very small if one takes into account that they take place throughout the treatment and the one-year follow-up. Nevertheless, the loss is higher in the PSDEEI group.

Another important limitation is that the application of the treatments has been carried out by the same clinicians in both groups, as well as the administration of the assessment tests, which constitutes a research bias.

Conclusions

Complicated grief affects a considerable number of relatives of deceased cancer patients. Evaluation and treatment of complicated grief is an integral part of care. Cognitive behavioral group therapy treatment is effective for complicated grief, depression, anxiety, hopelessness, and psychopathological symptoms, and is superior to psychoeducational and emotional expression intervention. In addition, the effects are maintained at the 12-month follow-up. The fact that cognitive behavioral treatment is effective when applied in a group mode can reduce the cost of its application and make it more accessible to a greater number of people.

Declarations

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Competing Interests:

The authors have no relevant financial or non-financial interests to disclose.

Availability of data and material:

Available on request.

Code availability:

Not applicable

Author Contributions:

All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by MARIA ANTONIA LACASTA REVERTE and JUAN ANTONIO CRUZADO. The first draft and the final version of the manuscript was written by MARIA ANTONIA LACASTA REVERTE and JUAN ANTONIO CRUZADO. All authors read and approved the final manuscript.

Ethics approval:

The project was approved by the Ethical Research Committee of the La Paz University Hospital in Madrid, Spain.

Consent to participate:

Informed consent was obtained from all individual participants included in the study

Consent to publish:

All participants provided informed consent that the results would be published, maintaining the confidentiality of personal data, since only global data media and frequencies are published, not individual ones.

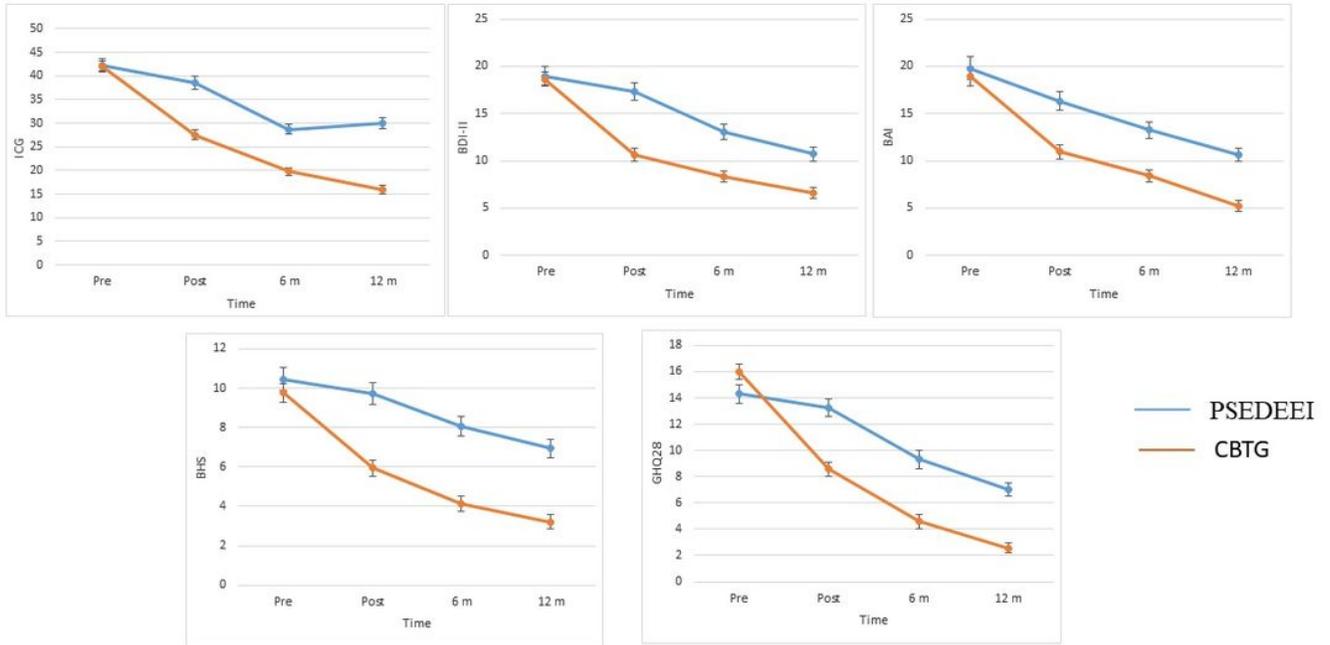
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Figures

Figure 1. Evolution of depression, anxiety, hopelessness and general health. Means and standard errors estimated by the GLM models.



BDI-II: Beck Depression Inventory; BAI: Beck Anxiety Inventory; BHS: Beck Depression Hopelessness; GHQ28: General Health Questionnaire-28 items; ICG: Inventory of Complicated Grief. CBTG: Cognitive Behavioral Therapy Group; PSEDEEI: Psychoeducational and Emotional Expression Intervention

Figure 1

See image above for figure legend.