

# A Randomized Controlled Clinical Trial of a Bereavement Support Group Intervention in Human Immunodeficiency Virus Type 1–Seropositive and –Seronegative Homosexual Men

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**Background:** Bereavement is a severe and frequent stressor among those infected with human immunodeficiency virus type 1 (HIV-1) and those affected by the acquired immunodeficiency syndrome epidemic. This study examined the impact of a research-derived, semistructured, bereavement support group among HIV-1–seropositive and HIV-1–seronegative homosexual men having lost a close friend or intimate partner to the acquired immunodeficiency syndrome within the prior 6 months.

**Methods:** A total of 166 subjects (97 HIV-1 seropositive; 69 HIV-1 seronegative) were randomly assigned to groups of homogeneous HIV-1 serostatus or to their respective control group. Subjects were assessed at entry and at 10 weeks with psychosocial questionnaires, a semistructured interview for psychopathology, a medical history and physical examination, urine collection, and phlebotomy.

**Results:** For a composite score of psychological distress and grief as well as the distress component, scores were significantly lower after the intervention by analyses against baseline scores, with and without control variables for other factors affecting distress level. A significant reduction in grief level was found only in the analysis that included control variables. Control subjects showed no significant decrements in overall distress, although a significant decrement in grief level was observed.

**Conclusion:** A brief group intervention can significantly reduce overall distress and accelerate grief reduction in a sample of bereaved subjects unselected for psychopathology or at high risk for subsequent maladjustment.

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**B**EREAVEMENT IS A frequent, severe life stressor among individuals who are seropositive and seronegative for the human immunodeficiency virus type 1 (HIV-1). The prevalence of loss of a significant other to the acquired immunodeficiency syndrome (AIDS) was reported as 27% among 745 homosexual men in New York City, NY.<sup>1</sup> Over a 7-year study,<sup>2</sup> bereaved HIV-1–seropositive men reported the highest distress levels. Neugebauer et al<sup>3</sup> found no relation between loss-related depressive symptoms and diagnosed depressive disorder, although men with more losses did report more preoccupation with and searching for the deceased. Such persistent grief is not surprising, as grief is more specifically correlated with loss than is depressed mood. Indeed, recent research differentiating grief from bereavement-related depressed and anxious mood showed an 18% prevalence of unresolved grief in HIV-1–seropositive and –seronegative homosexual men.<sup>4</sup>

Although the majority of postbereavement depressive symptoms are tran-

sient,<sup>5,6</sup> there is a significant incidence of bereavement complicated by major depressive disorder,<sup>7</sup> and psychological distress is common in the year following loss.<sup>8</sup> Factors increasing postbereavement psychological distress that are particularly common in homosexual men infected with and affected by HIV include close aggregation of losses, discrimination, homophobia, lack of family support, forced disclosure, lack of recognition for financial benefits and medical care rights, and greater difficulties in resocialization.<sup>9</sup> Homosexual men as a population, then, were presumed to be at risk for adjustment difficulties following losses of loved ones to AIDS and to potentially benefit from our bereavement support group tailored to their specific loss issues.

Efficacy of brief group therapy has been demonstrated for the bereaved, generally,<sup>10,11</sup> and for depressed HIV-1–seropositive homosexual men, specifically.<sup>12</sup> Kelly et al<sup>12</sup> compared cognitive-behavioral and social support group interventions. A combination of these therapies, our bereavement support group highlights an integration of grief resolution and stressor management.<sup>13</sup> Our

## SUBJECTS AND METHODS

### SAMPLE

Of the 581 men screened, 197 were enrolled. Subjects were homosexual men, aged 18 to 65 years, who lost a close friend or intimate partner to AIDS during the prior 6 months and rated the loss with a significant, negative impact. English-language fluency was required for group participation and assessment. Recruitment was through local media advertisements, fliers in settings with homosexual clientele, and referrals from our community liaison group. Of the 384 screened but not enrolled, 216 did not meet trial entry criteria, 111 declined, and 57 were lost to follow-up contact. For decliners, the extensive study commitment required was the principal reason ( $n = 83$ ; 74.8%). Trial exclusion criteria were, in descending order: no loss of a significant other within 6 months, 87 (40.3%); prescribed medications at doses significantly affecting immune function (eg, daily use of oral corticosteroids), 54 (25.0%); CD4 cell count less than  $0.05 \times 10^9/L$  (50 cells/mm<sup>3</sup>) (related to expected longevity), 28 (12.9%); heterosexual preference, 16 (7.4%); current or recent (within the past 6 months) alcohol or substance dependence (as defined by the Structured Clinical Interview for *DSM-III-R*: Non-Patient Version for HIV Studies [SCID-NP-HIV<sup>17</sup>]), 9 (4.2%); lack of fluency in English, 6 (2.8%); other excluded psychopathological conditions (past or current major psychiatric disorder, eg, HIV-1-associated dementia, psychosis, bipolar disorder, major depressive disorder with melancholia), also defined by the SCID-NP-HIV,<sup>17</sup> 4 (1.8%); intravenous substance use within 2 years, 4 (1.8%); age, 3 (1.4%); surgery in prior 6 months, 3 (1.4%); smoking history of more than 50 pack-years (for study immune outcomes across the foregoing 3 criteria), 1 (0.5%); and participation in blinded clinical antiretroviral medication trials, 1 (0.5%). Subjects signed informed consent forms approved by our institutional review board and were then randomized using a sealed envelope. Subjects were encouraged to begin new antiretroviral regimens 1 month prior to enrollment, if they had not previously been prescribed antiretroviral medications or required regimen changes. Antiretroviral medication use was expected to remain constant throughout the trial, when appropriate.

### ASSESSMENT AND INTERVENTION PROCEDURES

There were 2 assessments (T1, baseline; T2, 10 weeks [at the conclusion of the intervention period]) consisting of self-report psychosocial instruments, standardized inter-

view for psychopathology and mood ratings, medical history and physical examination, urine collection, and phlebotomy.

To confirm serostatus, an HIV-1 antibody test was done at T1 (and at T2 for HIV-1-seronegative subjects) by enzyme-linked immunosorbent assay (Cambridge Biotech, Worcester, Mass). Reactive samples were repeated. Doubly positive samples were confirmed by protein immunoblot (Western blot) (Cambridge Biotech).

The bereavement support group intervention, as detailed elsewhere,<sup>13</sup> was partly adapted from prior research on support group intervention in patients with terminal breast cancer<sup>18,19</sup> and from a model of bereavement group techniques.<sup>11</sup> A 2-tiered, standardized protocol with 10 specific session topics focused on grief work (first tier) was used in continuous, repeating cycles in both the HIV-1-seropositive and HIV-1-seronegative intervention groups. Subjects entered the group condition at the first session available, across the contiguous 10-session cycles. Because of confidentiality of serostatus and differential implications of bereavement for one's mortality, HIV-1-seropositive and HIV-1-seronegative individuals attended separate group sessions. The intervention consisted of 90-minute, weekly sessions led by 2 cotherapists (J.E.B. and B.L.) experienced in supportive group psychotherapy for bereavement and lethal diseases. Therapists were trained on a specified protocol<sup>13</sup> using a weekly checklist for therapist behaviors, which was completed by the therapists and objective raters. (Such monitoring has been shown to improve the quality of group psychotherapy<sup>20</sup> and protocol adherence.) The second tier of the intervention focused on the SSC model predictors of psychological distress among HIV-1-seropositive and HIV-1-seronegative homosexual men—life stressors, social support, and coping style.<sup>14-16</sup>

In the community standard-of-care control condition, subjects were allowed to continue the level of psychosocial and medical care used prior to baseline (if used consistently 1 month or longer). Control subjects received 4 telephone calls during the 10-week period to assess clinical status. (Total call time was limited to 90 minutes.) Study staff avoided therapeutic interactions during calls and maintained a contact log documenting call content.

Grief level was measured by the Texas Inventory of Grief<sup>21</sup>—a 13-item, self-report measure of current feelings related to the loss qualifying for entry. An ad hoc complicated grief index consisting of 3 items quantifying intense, longer-term, unresolved grief was used, which is related in content to the Grief Resolution Index.<sup>22</sup> The items were (1) "I cannot accept this person's death"; (2) "Sometimes, I very much miss the person who died"; and (3) "Even

Continued on next page

stressor-support-coping (SSC) model dictates an additional triad of therapeutic foci: (1) accurate stressor burden appraisal, (2) effective social support utilization, and (3) adaptive coping strategy selection.<sup>13</sup> Hence, this intervention represents a unique meld of a bereavement support group with stressor management training.

The issue of relating bereavement sequelae to grief rather than depressed mood level is of increasing interest.<sup>14</sup> Our intervention previously demonstrated benefits on CD4 cell count, plasma cortisol level, and health care visit use.<sup>15</sup> This investigation tested whether our in-

tervention reduces a composite index of self-reported grief and overall distress. Intervention effects on a complicated grief index and clinically rated depression and anxiety were tested in secondary outcome analyses. Our SSC model<sup>14-16</sup> demands control for baseline life stressor burden, social support availability, and coping style.

## RESULTS

The subjects were generally in their late 30s, well educated, largely employed, and living alone (62.4%). More

now it's painful to recall memories of the person who died." This index was the sum of the item scores. The Profile of Mood States<sup>23</sup>—a widely used, standardized, 65-item, self-report adjective checklist—characterized subjects' overall distress over the prior week using a 5-point Likert rating scale. The sum of the depression-dejection, tension-anxiety, anger-hostility, fatigue-inertia, and confusion-bewilderment subscale scores minus the vigor-activity subscale score yielded the total mood disturbance (TMD) score. We used a grief-overall distress composite score based on the total grief and TMD scores, which was calculated as the sum of their standardized scores (Cronbach  $\alpha = .956$ ).<sup>24</sup> The Pearson product-moment correlation ( $r$ ) of the baseline total grief and TMD scores was +0.49; that of the composite score and total grief score was +0.87, and that of the composite with the TMD score was +0.86. The Structured Interview Guide for the Hamilton Anxiety and Depression (SIGH-AD) rating scale was used for clinical ratings of depression and anxiety used as secondary distress outcome measures to supplement the self-reported Profile of Mood States.<sup>25</sup> The SIGH-AD combines the 17-item Hamilton Rating Scale for Depression (HRSD)<sup>26</sup> and the 14-item Hamilton Anxiety Rating Scale (HARS).<sup>27</sup> Adapted for HIV-1-infected individuals, the SIGH-AD allowed for scores with and without exclusion of somatic items.

Checks for randomization failure were conducted for (1) sociodemographic characteristics (age, ethnicity, educational level, socioeconomic status, current employment status, and health insurance status); (2) baseline distress level for each aforementioned distress outcome measure; (3) mental and physical health service utilization (month prior to baseline); (4) sexual activity (new partners in the prior month, anonymous contacts in the prior month, and lifetime partners); and (5) SSC model distress predictors (negative life stressor count in the prior 6 months [from the Life Experience Survey, as previously modified]<sup>28,29</sup>; social support availability (number of persons [from the Social Support Questionnaire-6<sup>30</sup>]); and bereavement-specific, situational coping (active coping composite score, disengagement and denial composite score; focus on and venting of emotions score; and turning to religion score [as defined in prior work<sup>14-16,29</sup> from the Coping Orientations to Problems Experienced<sup>31</sup>]). Controls for other variables affecting distress were (1) loss characteristics (type of relationship [friend/partner]; being primary caretaker; relationship quality [modified Dyadic Adjustment Scale]<sup>32</sup>; time since loss; relationship length; extent of anticipation; and loss burden [prior 6 months and total due to AIDS]); (2) any lifetime Axis I and Axis II disorder defined by interviewers standardized

on an established protocol<sup>33</sup> (K.G.) comprised by the SCID-NP-HIV<sup>17</sup> and the Structured Clinical Interview for DSM-III-R—Personality Disorders (SCID II),<sup>34</sup> respectively (and used for the SIGH-AD above); (3) Centers for Disease Control and Prevention (CDC) disease stage<sup>35</sup>; (4) current constitutional symptoms; (5) neuropsychological impairment (minor cognitive-motor disorder [defined by history and physical examination results using American Academy of Neurology criteria]<sup>36</sup>; the Mini-Mental State Examination score<sup>37,38</sup>; and the Visual Scanning and Discrimination Speed Test (seconds)<sup>38</sup>; (6) baseline, self-reported frequency of use of caffeine, nicotine, alcohol, marijuana, psychostimulants, sedative or hypnotic medications or substances, hallucinogens, and opioids; (7) sleep deprivation (estimated sleep efficiency); (8) exercise frequency (total time in the prior week); (9) prescribed psychotropic medications (categorical indicator); and (10) nutritional status (serum albumin level<sup>39</sup>; plasma pyridoxine activity<sup>40</sup>; and serum cobalamin level),<sup>41</sup> as plasma pyridoxine activity<sup>42</sup> and cobalamin level<sup>43</sup> have been related to psychological distress in HIV-1-infected individuals.

## STATISTICAL METHODS

Statistics were computed using SAS V6.09 software (SAS Institute, Cary, NC).<sup>44</sup> Potential failures of randomization were examined by analysis of variance for serostatus, intervention condition, and their interaction. Potential confounders with distress outcomes were examined using Spearman rank-order correlations of confounders with changes in distress outcome variables. Variables demonstrating  $P < .20$  (to avoid type II error) were entered into multiple regression analysis on change in the relevant distress outcome. Only variables maintaining  $P < .20$  were included in the 2 (treatment/control)  $\times$  2 (HIV-1 seropositive/HIV-1 seronegative)  $\times$  2 (T1/T2) repeated-measures analyses of covariance (RANCOVAs) used for the hypothesis tests on the distress outcome measures at  $\alpha = .05$ . The primary distress outcome measure is the distress-grief composite score, and the secondary distress outcome measures are the ad hoc complicated grief index and the HRSD and HARS total scores. The model term of primary interest to test any differential effect of the bereavement support group intervention is the within-subjects intervention effect on levels of distress outcome variables at T1 and T2. Post hoc analyses examined the distress and grief components of the composite score, the HRSD and HARS excluding somatic items, and the effect of an intervention condition by HIV-1 serostatus interaction term.

than one third were of minority ethnicity (**Table 1**). Men who were HIV-1 seropositive were predominantly ( $n = 65$ ; 67.0%) at the early symptomatic clinical stage (CDC stage B), with a sizable minority ( $n = 25$ ; 25.8%) in the asymptomatic stage (CDC stage A) and few ( $n = 7$ ; 7.2%) at the late symptomatic stage (AIDS; CDC stage C). The baseline mean CD4 cell count for HIV-1-seropositive individuals showed a moderate level of immunological progression at  $0.366 \times 10^9/L$  ( $SD = 0.238 \times 10^9/L$ ); the mean was  $0.820 \times 10^9/L$  ( $SD = 0.242 \times 10^9/L$ ) for HIV-1-seronegative individuals. Baseline grief level was similar

to that in the first year of conjugal loss (**Table 2**).<sup>29</sup> Self-reported overall distress level was clinically significant although mild, compared with psychiatric outpatient clinic patients.<sup>23</sup> Clinical ratings of depressed and anxious mood (Table 2) were well below the ranges established for disorders.<sup>34,35</sup> On all distress outcomes, mean levels at T2 were lower than at T1 for the intervention conditions (Table 2). Likewise, decrements in distress were nearly uniform in controls, although always of smaller magnitude than those in intervention subjects. The median number of sessions attended was 9 in the HIV-1-

**Table 1. Sociodemographic Characteristics of the Sample\***

Characteristic	Randomized Sample (N = 197)†	Efficacy Sample‡			P
		Total Sample (N = 166)‡	HIV-1–Seropositive Subsample (n = 97)§	HIV-1–Seronegative Subsample (n = 69)	
Age, mean (SD), y	37.8 (9.0)	38.5 (9.3)	36.5 (7.7)	41.2 (10.6)	≤.01
Education, mean (SD), y	14.7 (2.2)	14.8 (2.2)	14.3 (2.3)	15.4 (1.9)	≤.01
Ethnicity, %					
European American	62.9	63.9	52.6	79.7	≤.01
Hispanic American	24.4	22.9	27.8	15.9	.28
African American	10.2	10.8	15.5	4.4	≤.05
Multiethnic	2.5	2.4	4.1	0.0	≤.05
Annual modal income, \$¶	20 000-29 999	20 000-29 999	20 000-29 999	30 000-39 999	≤.05
Unemployed, %	12.2	11.6	11.5	11.8	.95

\*HIV-1 indicates human immunodeficiency virus type 1. The HIV-1–seropositive subsample was significantly younger, less well educated, less frequently European American and more frequently African American, multiethnic, unemployed, and of lower income, although the magnitudes of these differences were greatest for ethnicity.

†The randomized sample was less frequently African American (10.2% vs 20.4%,  $\chi^2_1 = 9.34$ ,  $P < .01$ ), greater in educational level ( $t_{361} = 3.55$ ,  $P < .001$ ), and showed a nonsignificant trend to be slightly older ( $t_{361} = 1.92$ ,  $P = .06$ ) than those screened for randomization.

‡The sample size discrepancy between those randomized and those completing 10 weeks (the efficacy sample) was 31 subjects: subject dropout ( $n = 17$ ), T2 beyond 2-week time window ( $n = 6$ ), termination due to substance dependence not previously identified ( $n = 3$ ), missing outcome data ( $n = 3$ ), moved ( $n = 1$ ), and death ( $n = 1$ ).

§One HIV-1–seropositive subject subsequently tested seronegative and negative by the polymerase chain reaction technique. The subject was retained as seropositive; the subject's elimination did not affect results. There were no seroconversions between baseline and conclusion of intervention.

||Age alone was significantly different (younger) in the randomized vs the efficacy (ie, outcome test) samples ( $P < .005$ ).

¶ $n = 193$  for randomized sample;  $n = 161$  for total efficacy sample;  $n = 95$  for HIV-1–seropositive sample; and  $n = 66$  for HIV-1–seronegative sample.

**Table 2. Mean and Variability of Distress Outcome Measures by Time Point and Sample\***

Outcome Measure	Randomized Sample (N = 197)	Total Efficacy Sample (N = 166)		HIV-1–Seropositive Intervention Subsample (n = 53)		HIV-1–Seropositive Control Subsample (n = 44)		HIV-1–Seronegative Intervention Subsample (n = 39)		HIV-1–Seronegative Control Subsample (n = 30)	
		T1	T2	T1	T2	T1	T2	T1	T2	T1	T2
		Distress-grief composite index score	–0.001 (1.75)	0.001 (1.75)	–0.842 (1.83)	0.167 (1.69)	–0.924 (1.53)	–0.026 (1.94)	–0.496 (2.28)	0.084 (1.60)	–1.125 (1.68)
Overall distress score	45.9 (39.1)	45.5 (39.5)	34.2 (41.4)	48.3 (41.8)	32.8 (39.5)	47.6 (39.2)	49.0 (47.3)	49.0 (41.9)	23.5 (31.6)	33.0 (31.0)	28.9 (42.4)
Total grief score	31.8 (11.1)	31.9 (10.8)	26.0 (11.6)	32.9 (10.1)	25.4 (10.3)	31.1 (11.9)	25.6 (13.6)	31.8 (9.2)	25.9 (12.1)	31.5 (12.3)	27.5 (10.4)
Complicated grief index score	7.6 (2.7)	7.6 (2.7)	6.2 (2.8)	8.1 (2.6)	6.2 (2.5)	7.6 (3.0)	6.2 (3.0)	7.6 (2.4)	6.0 (2.8)	6.7 (2.7)	7.1 (2.7)
Hamilton Rating Scale for Depression score	7.7 (5.8)	7.7 (5.5)	5.4 (5.2)	7.7 (5.3)	4.9 (4.1)	8.8 (6.7)	6.5 (6.1)	7.5 (5.1)	4.8 (5.2)	6.4 (4.3)	5.2 (5.3)
Hamilton Anxiety Rating Scale score	6.9 (6.6)	7.0 (6.5)	5.1 (5.8)	7.0 (6.2)	4.8 (5.0)	8.5 (8.5)	6.9 (7.0)	6.4 (5.3)	3.8 (4.4)	5.7 (4.9)	4.6 (6.0)

\*Data are given as mean (SD). HIV-1 indicates human immunodeficiency virus type 1; T1, baseline; and T2, 10 weeks (at conclusion of the intervention period).

seronegative and 8 in the HIV-1–seropositive intervention conditions.

### COMPOSITE SCORE OF GRIEF AND OVERALL DISTRESS

The RANCOVA demonstrated a significant intervention effect ( $F_{1,156} = 9.09$ ,  $P = .003$ ) (Table 3), as did the simple repeated-measures analysis of variance (RANOVA) ( $F_{1,163} = 14.17$ ,  $P < .001$ ). For HIV-1–seropositive individuals, there were significant decrements for the intervention ( $F_{1,52} = 50.98$ ,  $P < .001$ ) and control conditions ( $F_{1,43} = 6.81$ ,  $P = .02$ ), with the intervention condition ef-

fect significantly greater ( $F_{1,95} = 6.99$ ,  $P = .01$ ). For HIV-1–seronegative individuals, the pattern was similar, with significant intervention ( $F_{1,38} = 44.38$ ,  $P < .001$ ) and control condition ( $F_{1,29} = 5.83$ ,  $P = .03$ ) effects. Again, the intervention effect was significantly greater than that of the control condition ( $F_{1,67} = 7.28$ ,  $P = .009$ ).

### OVERALL DISTRESS COMPONENT

The RANCOVA was statistically significant ( $F_{1,156} = 8.54$ ,  $P = .004$ ), as was the simple RANOVA ( $F_{1,163} = 14.65$ ,  $P < .001$ ). For HIV-1–seropositive individuals, distress was significantly decreased in the intervention ( $F_{1,52} = 11.86$ ,

**Table 3. Repeated-Measures Analyses of Covariance on Distress Outcome Measure Levels at T1 and T2 by HIV-1 Serostatus and Intervention Condition\***

Outcome Measures	HIV-1 Serostatus				Intervention Condition			
	Between (Mean)		Within (Change)		Between (Mean)		Test of Intervention Effect, Within (Change)	
	F	P	F	P	F	P	F	P
Primary distress outcome measures								
Distress-grief composite index score (with control variables)†	0.16	.69	0.74	.39	0.02	.88	9.09	.003**
Index component scale scores								
Profile of Mood States total mood disturbance score (with control variables)‡	0.84	.36	3.19	.08	0.50	.48	8.54	.004**
Texas Inventory of Grief score (with control variables)§	0.65	.42	0.22	.64	0.04	.84	4.23	.04††
Secondary distress outcome measures								
Ad hoc complicated grief index score (with control variables)	0.24	.63	0.06	.83	0.05	.83	5.16	.03††
Clinical rating scales of depression and anxiety								
HRSD total score (with control variables)¶	0.86	.36	2.56	.12	1.93	.17	0.95	.33
HARS total score (with control variables)#	2.58	.11	0.12	.73	3.09	.06	1.25	.27

\*T1 indicates baseline; T2, 10 weeks (at conclusion of intervention period); HIV-1, human immunodeficiency virus type 1; HRSD, Hamilton Rating Scale for Depression; and HARS, Hamilton Anxiety Rating Scale.

†Control variables were educational level, income in past month, Hispanic ethnicity, social support availability, presence of Axis II disorder, current alcohol use, and a missing data indicator. Each F statistic had df (1,156).

‡Control variables were age, Hispanic ethnicity, active coping frequency, presence of minor cognitive-motor disorder and of Axis II disorder, current alcohol use, and a missing data indicator. Each F statistic had df (1,156).

§Control variables were degree of loss anticipation, income in past month, African American ethnicity, mental health service use in past month, social support availability, active coping frequency, and a missing data indicator. Each F statistic had df (1,156).

||Control variables were degree of loss anticipation, African American ethnicity, income in past month, abnormal Visual Scanning and Discrimination Speed Test (>96 seconds), sedative or hypnotic substance use (including abuse of prescribed medication), active coping frequency, and turning to religion. Each F statistic had df (1,149).

¶Control variables were self-rated loss impact, African American ethnicity, physical health services used in past month, being employed, abnormal Visual Scanning and Discrimination Speed Test, abnormal Mini-Mental State Examination Score (<26), negatively rated major life stressor count over past 6 months, and the focusing on and venting of emotions score. Each F statistic had df (1,157).

#Control variables were self-rated loss impact, age, African American ethnicity, physical health services used in past month, presence of Axis I disorder, marijuana use, sleep efficiency, total exercise in past week, lifetime sexual partners, and the disengagement and denial score. Each F statistic had df (1,143).

\*\* .001 < P < .01.

†† .01 < P < .05.

$P = .002$ ) but not control ( $F_{1,43} = 0.09$ ,  $P = .77$ ) subjects, with posttreatment levels well below the clinically distressed range (mean = 32.8, SE = 5.4). The decrement was significantly greater than that in controls ( $F_{1,95} = 6.71$ ,  $P = .01$ ). For HIV-1-seronegative individuals, distress was significantly decreased in intervention ( $F_{1,38} = 22.52$ ,  $P < .001$ ) but not control ( $F_{1,29} = 0.73$ ,  $P = .40$ ) subjects.

### GRIEF COMPONENT

The RANCOVA demonstrated a statistically significant intervention effect ( $F_{1,156} = 4.23$ ,  $P = .04$ ), although the simple RANOVA showed a nonsignificant trend toward an effect ( $F_{1,163} = 2.86$ ,  $P = .09$ ). For HIV-1-seropositive intervention subjects, grief level was significantly decreased ( $F_{1,52} = 52.07$ ,  $P < .001$ ), as for control subjects ( $F_{1,43} = 20.75$ ,  $P < .001$ ), although the decrement was not significantly greater in intervention subjects ( $F_{1,95} = 1.66$ ,  $P = .21$ ). The same pattern was observed in HIV-1-seronegative intervention and control subjects.

### SECONDARY DISTRESS OUTCOMES

On the complicated grief index, the RANCOVA showed a significant intervention condition reduction ( $F_{1,149} = 5.16$ ,

$P = .03$ ), as did the simple RANOVA ( $F_{1,158} = 5.80$ ,  $P = .02$ ). Men who were HIV-1 seropositive showed a statistically significant decrease after intervention ( $F_{1,49} = 42.92$ ,  $P < .001$ ) with a lesser, but significant, decrease in controls ( $F_{1,42} = 12.72$ ,  $P < .001$ ), although the difference of changes across conditions was not statistically significant ( $F_{1,91} = 1.71$ ,  $P = .20$ ). Men who were HIV-1 seronegative showed a similar, significant intervention effect ( $F_{1,37} = 19.79$ ,  $P < .001$ ), although this was not observed in controls ( $F_{1,29} = 1.79$ ,  $P = .20$ ), and the contrast between conditions was statistically significant ( $F_{1,66} = 5.15$ ,  $P = .03$ ). For the HRSD and the HARS, there were no statistically significant differences on the RANCOVAs or simple RANOVAs (with or without somatic items), although a nonsignificant trend toward an effect in the RANCOVA on the HARS without somatic items was noted ( $F_{1,151} = 2.84$ ,  $P = .10$ ).

Additional post hoc analyses repeating the foregoing with the addition of an HIV-1 serostatus  $\times$  intervention condition interaction term demonstrated the same results; the interaction terms were not statistically significant in any analysis.

The primary hypothesis of an intervention effect (with controls) on the distress-grief composite score represents 1 statistical test (followed by post hoc exami-

nation of the composite's components). In contrast, the secondary hypothesis tests (with controls) represent multiple, independent statistical tests. The probability of obtaining the observed results of 1 significant effect on the 3 secondary distress outcome measures (the complicated grief index, the HARS total score, and the HRSD total score) by chance, with an  $\alpha = .05$ , may be expressed as  $[1 - (1 - \alpha)^3]^1 = 0.143$ . The Scheffé test was conducted to control for multiple comparisons on the secondary distress outcomes. The effect on the complicated grief index was retained on 1 of 3 mean contrast comparisons between intervention and control conditions ( $F_{1,155} = 2.67, P < .05$ ).

#### COMMENT

The bereavement support group intervention effectively reduced an index of dysphoria combining the stressor-specific, affective state of grief with overall distress, reflecting depression, anger, anxiety, fatigue, confusion, and lack of vigor. Compared with general dysphoria, grief reflects additional, loss-specific aspects of distress, such as yearning and loneliness. The intervention significantly reduced this comprehensive measure of bereavement-related distress for both HIV-1-seropositive and HIV-1-seronegative individuals, compared with control subjects, both when controlling for other influences on bereavement-related distress and in analyses with no additional controls. Among the control variables for the composite score, social support availability was associated with decreased distress levels, while personality disorder, Hispanic ethnicity, and current alcohol use were associated with higher distress levels. To our knowledge, this randomized controlled clinical trial represents the largest sample reported to date using such a design to determine either the effect of a bereavement support group intervention, generally, or the effect of psychotherapy interventions in HIV-1-infected and -affected individuals, specifically.

The tests on the components of the composite index differentiated intervention effects on general dysphoria from those on grief. The same pattern of consistent reductions and relevant control variables was observed for overall distress, suggesting that it contributed greatly to the composite index effects observed. Regarding the distress component of the composite, both HIV-1-seropositive and HIV-1-seronegative intervention subjects showed reductions in distress level below the clinically significant range of overall distress after the intervention. The distress levels of HIV-1-seropositive and HIV-1-seronegative controls did not change significantly, with the HIV-1-seropositive controls in the clinically significant range at T1 and T2. The primary analysis including control variables on the grief component of the composite demonstrated a statistically significant effect as well, although the uncontrolled analysis showed a nonsignificant trend toward a grief effect. The results suggest a degree of continuity between the factors mediating overall distress and grief. Among the control variables for grief were baseline social support availability and active coping style frequency. Both variables have been demonstrated in prior

SSC model<sup>45-47</sup> studies with HIV-1-seropositive and HIV-1-seronegative homosexual men to have ameliorating effects on overall distress generally<sup>14,16</sup> and were extended here to the setting of bereavement. A control for degree of loss anticipation was also required, as supported by early work on predictors of postbereavement adjustment.<sup>48,49</sup> As expected, the quantity of mental health services accessed at baseline was associated with less grief reduction, while higher socioeconomic status (and, presumably, access to additional resources) was associated with greater grief reduction. African American ethnicity was associated with less grief reduction, possibly due to the high level of stigmatization, discrimination, and isolation experienced by African American homosexual men.<sup>50</sup>

The extent of grief reduction merits attention. At baseline, each of the 4 trial conditions demonstrated grief means within 2.0 SEs ( $SE = 1.5$ ) of the norm (mean = 34.2) reported within 1 year following conjugal loss.<sup>21</sup> Yet, at T2, the grief means for each trial condition had decreased to a level of 4.5 or more SEs below this norm. Hence, the intervention response appeared to accelerate normal resolution of the grieving process also occurring in the control subjects. An additional contribution to lower grief and distress levels in control subjects could have been the contact related to trial participation. Further, control subjects were allowed to continue psychosocial treatment related to distress and grieving that had been ongoing prior to enrollment; hence, the test of the effect of this specific intervention is a stringent test against the background of a considerable breadth of other psychosocial interventions, taken generally.

Regarding the secondary distress outcomes, the complicated grief index score was significantly reduced in both HIV-1-seropositive conditions. For HIV-1-seronegative subjects, the intervention-associated reduction was statistically significant but that for the control subjects was not. Moreover, the contrast comparison between the 2 conditions was statistically significant. This suggests that the untreated HIV-1-seronegative individuals may be more susceptible to long-term bereavement adjustment difficulties than their HIV-1-seropositive counterparts, possibly due to differentially greater survivorship guilt among HIV-1-seronegative homosexual men.<sup>51</sup> This interpretation corroborates the rationale for 1 of the weekly intervention topics incorporating survivorship guilt into its title and provides empiric support for the validation of the inclusion of this grief work issue herein.

For clinically rated anxiety and depression, there were no significant intervention effects. This might be due to the relatively compressed range of variation observed on these measures in this sample, which was less distressed than a typical clinical population. In part, this sample characteristic was dictated by trial entry criteria, which allowed low levels of associated negative mood at entry. Hence, a limitation of this study is that the generalizability of these intervention results to a population with more severe distress and/or psychopathology remains to be established. Another limitation of the study involves the small proportion of HIV-1-seropositive subjects with advanced disease, which may

limit study generalizability to patients with full-blown AIDS.

Refocusing on this nonclinical sample, research to date outside of populations with HIV-1 infection has suggested that bereavement support group interventions are indicated only for individuals identified as "at risk" for poor, postloss adjustment,<sup>52</sup> although such interventions still may yield inconclusive results.<sup>53</sup> Risk factors for poor postloss adjustment include a "hostile" or "sullen" family atmosphere<sup>54</sup>; the presence or history of affective, alcohol, and/or psychoactive substance use disorders; low social support availability; and ongoing high distress levels.<sup>55</sup> "Hovering over" (or periodic assessment of) the bereaved has been suggested as a clinical strategy to monitor the potential need for intervention during the course of the grieving process.<sup>56</sup> Yet, the intervention results herein were statistically significant for a sample unselected for any established risk factors for poor, postloss adjustment or clinically significant distress levels, other than those associated with loss due to AIDS in the homosexual male population generally.<sup>9</sup> Properly identifying bereavement support group referrals in other HIV-1-infected and -affected populations (eg, women) may similarly justify resetting the target population to anyone experiencing the loss of a close friend or intimate partner due to AIDS.

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making. Capacity assessment by a professional independent of the research team should be required only for research that is categorized as more than a minor increase over minimal risk.

## CONCLUSIONS

Protection of vulnerable populations from undue or inappropriate research risk is of paramount importance. The devastating personal, family, and social cost of illnesses that interfere with decision-making capacity, however, must be recognized as well, along with the critical need for continued research to develop better methods of treatment and prevention. Well-intended recommendations for needed protective guidelines and regulations should be disentangled from stigmatizing bias, should apply to all persons with decisional impairment regardless of category, and should allow appropriate risk-benefit determinations.

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## Correction

**Error in Table.** In the original article by Goodkin et al titled "A Randomized Controlled Clinical Trial of a Bereavement Support Group Intervention in Human Immunodeficiency Virus Type 1-Seropositive and -Seronegative Homosexual Men," published in the January issue of the ARCHIVES (1999;56:52-59), an error occurred in Table 1 on page 55. The "Unemployed, %" variable refers only to the previous week, and the entries should have read: "for the randomized sample, 12.2%; for the total efficacy sample, 12.1%; for the HIV-1-seropositive subsample, 12.4%; and for the HIV-1-seronegative subsample, 11.6%;  $P = .88$ ." However, a more representative employment statistic would have been "Employed, full-time or part-time (past year), %." Therefore, the last row should have read as follows: "Employed (full-time or part-time, past year), %: for the randomized sample, 66.5%; for the total efficacy sample, 65.1%; for the HIV-1-seropositive subsample, 57.7%; and for the HIV-1-seronegative subsample, 75.4%;  $P \leq .02$ ." These corrected data support the statement made in the first footnote that the HIV-1-seropositive subsample was less frequently employed (as well as less well educated, less frequently European American, and younger).