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Efficacy of a Group Medication Adherence Intervention Among HIV Positive Women: The SMART/EST Women's Project

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Abstract

This intervention sought to improve overall quality of life and health behavior in women living with human immunodeficiency virus (HIV). We contrasted the effect of a group cognitive behavioral stress management expressive supportive therapy (CBSM+) intervention plus a healthier lifestyles (HL) component with an individual educational/informational format plus HL on HIV-medication adherence. Women, n = 237, predominantly African-American and Latina, living with HIV were recruited from Miami, New York and New Jersey and randomized to group or individual conditions (ten weekly sessions) plus group or individual HL, i.e., four conditions. Women reported relatively high levels of adherence at baseline. Participants in any of the group conditions increased self-reported adherence and emotion-focused coping skills in comparison with individual participation. This study suggests that group interventions may be an important adjunct in increasing medication adherence for HIV positive women.

Keywords

Adherence; Anti-retroviral therapy; Women; Behavioral interventions; Psychosocial

Introduction

Adherence to human immunodeficiency virus (HIV) treatment regimens is critical to optimal disease management, yet rates of adherence to anti-retroviral (ARV) medications are frequently

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less than perfect and negatively affect long-term goals for disease management, including drug resistance, poor health outcomes and treatment failure (Paterson, Potoski, & Capitano, 2002; Paterson et al., 2000). Resistance to ARV therapy is the most significant limiting factor in the long-term efficacy of HIV pharmacotherapy, and it is a predictable consequence of reduced adherence to medication regimens (Boden et al., 1999; Carpenter et al., 2000; Hogg et al., 2001).

Adherence to medication regimens has been associated with clinically significant viral load reductions (Deeks, Beatty, Cohen, Grant, & Volberding, 1998). Most patients (81%) have complete viral suppression at greater than 95% adherence, compared with increasingly less (64%) at 90–95% adherence and only 50% at 80–90% adherence (Paterson et al., 2000). While controlled clinical trials of ARV therapy have demonstrated viral suppression below detectable limits when adherence reaches 95% or greater, adherence rates in clinical settings rarely surpass 50% (McPherson-Baker et al., 2000; Reiter, Stewart, & Wojtusik, 2000).

Adherence may be moderated or mediated by psychosocial and behavioral factors as well as the biological consequences associated with medication use (e.g., medication side effects). Social support for medication adherence has encouraged patients to follow their medical regimen (Remien et al., 2003), moderating levels of adherence in patients. In addition, beliefs about medication efficacy (Horne, Weinman, & Hankins, 1991; Remien et al., 2003), the cognitive demands of regimen complexity (Remien et al., 2003; Stone et al., 2001) and the association between strict adherence and benefit derived from medication (Malcolm, Ng, Rosen, & Stone, 2003; Remien et al., 2003) may also influence or mediate levels of adherence. Finally, mixed findings concerning patient knowledge about HIV infection and treatment and its relationship to adherence (e.g., Goujard et al., 2003; Simoni, Frick, Lockhart, & Liebovitz, 2002) suggest that knowledge itself may also be a necessary, but not sufficient, component of adherence.

This study of HIV positive women sought to assess whether a group cognitive behavioral stress management (CBSM+) intervention plus a health education intervention would significantly improve the adoption and maintenance of HIV-relevant health behaviors, including medication adherence. We hypothesized that a group CBSM+ (CBSM plus expressive supportive therapy) intervention would be more effective in improving HIV-specific health behaviors than the traditional health education model, an individual educational/ informational format. We also hypothesized that the group delivery format of the intervention would have an impact upon the application of the newly learned skills. Thus, we theorized that adherence would be influenced (mediated or moderated) by bio-psychosocial factors, i.e., medication side effects, cognitive functioning and psychosocial factors, i.e., coping strategies and group social support.

Methods

Participants and Procedures

The SMART/EST Women's Project II trial had a 2×2 factorial design resulting in four intervention groups (see Fig. 1). Each of the two phases of SMART/EST II was delivered in either a high or low intensity version (see Table 1). The study hypotheses were that the degree of participation in the high intensity group interventions would be related to improved health and health behaviors. For Phase 1, the high intensity intervention received ten group sessions of therapist-guided exercises in CBSM+. The low intensity intervention received ten sessions of a time-matched individual educational/informational format in which participants were shown segments of a video on stress management and received the written handouts from the group condition, but did not receive individualized instructions or attention. The time-matched low intensity intervention was developed as an alternative to a wait-listed control group given

the vulnerability of the study population. The ten-session intervention format has been previously described (LaPerriere et al., 2005).

For Phase 2, the high intensity intervention received six sessions of group behavioral exercises led by the therapist plus expert advice from a relevant professional (i.e., nutritionist, exercise trainer or pharmacist) depending on the content of the session. The low intensity intervention was shown segments of videos on medication adherence, nutrition and exercise and received the written materials of the group condition. The Phase 2 intervention has been previously described (Segal-Isaacson et al., 2006).

The formats differed by mode of presentation, but the sessions were similar in content; all information from the group session was presented in the individual session in both phases. The content of Phase 2 was designed as a separate component to follow the Phase 1 CBSM+ module, rather than interwoven within the CBSM+ module itself to test whether CBSM+ was a necessary precursor for participants to receive maximum benefit from the Phase 2 program.

Phase 2 Group Intervention Format—Phase 2 was a six-session, closed, structured group intervention meeting biweekly, 150 min per session, for 12 weeks. The group healthier lifestyles (HL) intervention addressed HIV-related health behaviors (medication adherence, nutrition, sexual risk behavior, exercise, substance use) and included relevant discussion material and problem solving exercises, e.g., memory aids to increase medication adherence. Both Phase 1 and Phase 2 groups used members and leaders as coping role models, encouraged emotional expression, provided the opportunity to seek emotional and instrumental social support, reduced feelings of helplessness through identifying areas where control was feasible, discouraged avoidance and encouraged planning as a coping strategy, and imparted knowledge about specific lifestyle issues to increase adherence to health promoting behaviors. Sessions included video, didactic and interactive formats.

The Medication Adherence module of Phase 2 also included a video of a pharmacist emphasizing the importance of high levels of medication adherence (i.e., >90%), the phenomenon of medication resistance, and addressing the most important reasons for non-adherence (e.g., forgetting, too busy, side effects).

Phase 2 Individual Educational/Informational Condition—Phase 2 individual participants received identical health education information (videos, handouts), session frequency and length to the intervention provided to the group participants. There was no interactive client–therapist component to this condition.

Beginning in 2000, women were recruited from the three major epicenters in the United States for women living with HIV/AIDS: Miami-Dade County, New York City and the New Jersey metropolitan areas. Candidates were drawn from hospital outpatient clinics, Community Health Centers/agencies and participant referrals, and were invited to complete an informed consent and screening assessments. Eligible post-screen participants were HIV positive English speaking women, 18 years or older, who completed psychosocial questionnaires, including an adherence assessment. Participants were requested to provide their primary care physician's approval for participation.

Participants, $n = 237$, had a mean time since HIV diagnosis of 8 ± 5 years, median time since diagnosis was 5 years, and mean age of 41 ± 8; the majority (83%) were African-American, 6% were South American, 5% white non-Hispanic and 6% Haitian or other. Most (68%) were unemployed, 10% were working part time, 5% full-time and 65% lived in a private residence or apartment. The primary routes of HIV infection were sexual contact (73%) and drug use (8%), 15% were not sure of the cause of infection. Many (47%) participants reported having

completed less than a 12th grade high school education, and the majority had drug (57%) and/or alcohol dependence (27%) histories. No site differences were found between the group and individual conditions on these demographic variables.

Exclusion criteria were limited to active psychosis, psychotic depression or current substance dependence. Of those consented, $n = 387$, 28% were temporarily or permanently excluded, 20% substance dependent, 36% major depression, 7% psychosis and 21% failure to appear for scheduled screening appointments.

Measures

Assessments were conducted by trained interviewers and were collected at baseline, 3 and 6 months. The 3-month measurement point immediately followed completion of the Phase 1 CBSM+ intervention and the 6-month measurement point occurred immediately upon completion of the Phase 2 health education intervention.

Adherence to ARV Medication—Adherence was measured by 4-day self-report using the ACTG (AIDS Clinical Trials Group) Questionnaire for Adherence to Anti-HIV Medications (4 days; Chesney & Ickovics, 1997). The mean number of pills per day was divided by the prescribed number using information regarding the medication regimen provided by the participant, to calculate an average adherence percentage. Frequency of medication-related experiences was measured using a Likert scale of never (0), rarely (1), sometimes (2) and often (3).

Viral Load—Blood samples were collected at baseline and all subsequent measurement timepoints using sterile evacuated tubes containing EDTA. The viral load was estimated via reverse transcriptase polymerase chain reaction using the Roche (Nutley, NJ, USA) Amplicor HIV Monitor ultrasensitive assay kit and the Biomerieux (Marcy l'Etoile, France) NucliSens HIV-1 QT assay kit as described in Barre-Sinoussi et al. (1983) and Kievits et al. (1991).

Due to high numbers of women reporting 100% adherence and undetectable viral load, the sample size for women on both ARVs and having detectable viral load was too small to permit reliable analyses. Among the current sample, viral load and adherence were not associated.

Coping with Stress—The COPE (Carver, Sheier, & Weintraub, 1989), a 38-item scale, was used to determine the strategies participants used to cope with AIDS-related stressors over the past month. The COPE has been used with varied medical populations (Ingledew, Hardy, Cooper, & Jemal, 1996; Cronbach's alpha $\geq .61$). COPE subscales are theoretically derived and measure preferential use of problem-focused and emotion-focused coping strategies. Eight subscales were selected to assess cognitive appraisal: active coping, planning, instrumental and emotional support, denial, social and behavioral disengagement, self-distraction, substance use and self-blame. "Active coping" has been associated with lower distress in several studies of patients with HIV.

Data Analyses

To test our hypotheses regarding the impact of group assignment on emotional support coping strategies and adherence, we used linear mixed-modeling analyses, including correlations, analyses of variance and regression analyses.

Results

There was no difference in adherence at baseline between conditions, $F(1, 176) = .01$, $P > .05$. Of the total sample, $n = 237$, only 75%, $n = 177$, reported an ARV prescription, 55% for

nucleoside reverse transcriptase inhibitors (NRTIs), 45% for non-nucleoside reverse transcriptase inhibitors (NNRTIs), 41% for protease inhibitors (PIs), 44% for combination therapies (comprising a combination of two or more NRTI, NNRTI, PI) and 3% using products under investigation. Eleven percent were on monotherapy, $n = 19$, 89% on combination therapy, $n = 154$, and 40% using a combination including a PI, $n = 69$.

The following analyses are based on the 177 participants who reported an ARV prescription, Miami $n = 90$, New York city/New Jersey $n = 89$; group condition, $n = 89$ individual condition $n = 90$. Participant retention rates at 6 months post-baseline were 72%; attrition was reported by participants as being due primarily to illness, change of residence, employment and scheduling difficulties.

It was hypothesized that the group CBSM+ intervention would enhance emotional support coping strategies and the group CBSM + GHL combination would increase self-reported adherence and reduce reasons for missing ARV doses.

Post-intervention Effects

To assess the dual treatment intervention design using all available data we conducted linear mixed-modeling analyses. This procedure allowed modeling of both treatment effects (CBSM + and GHL) and their interaction (CBSM+ × GHL).

Emotional Support Coping—The baseline and post-CBSM+ intervention emotional support outcomes were used to determine the impact of the CBSM+ intervention on emotional support coping. This analysis revealed an effect for the CBSM+ intervention, $F(1, 229) = 4.92$, $P < .05$, such that the group condition reported a mean emotional support ($M = 12.75$, SD = 3.17) nearly one point greater than the individual condition ($M = 11.51$, SD = 3.77). The post-GHL (i.e., 6 months after CBSM+) emotional support scores were then included in the analysis to examine the long-term effect of the CBSM+ intervention upon emotional support. The initial effect of CBSM+ intervention was maintained up to 6 months afterwards (group $M = 12.50$, SD = 3.0, individual $M = 11.89$, SD = 3.79), $F(1, 228) = 4.21$, $P < .05$.

ARV Adherence—At baseline there was no significant difference between the self-reported adherence level of those randomly assigned to the individual or the CBSM+ conditions $F(1, 176) = .43$, $P > 0.05$. Using only baseline and post-CBSM+ intervention adherence scores the mixed-model ANOVA was not significant. Using the post-CBSM+ adherence level as the pre-GHL adherence and the post-GHL adherence level as the follow-up, there was no significant effect of the GHL intervention. However, there was a significant interaction between the CBSM + intervention and the GHL intervention when using all timepoints (times 1, 2 and 3; i.e., Phase 1 × Phase 2 × time; timepoints 1, 2 and 3), $F(3, 226) = 2.66$, $P < .05$.

Ad-hoc two-group analysis of the effect of any group condition assignment upon adherence revealed a significant effect of group participation on self-reported adherence, $F(1, 114) = 4.44$, $P < .05$. Participation in the group condition of either intervention resulted in an increase ($M = 7\%$) compared to individual condition only (see Fig. 2). There was no additional benefit of double group over single group assignment, $F(1, 85) = .84$, $P > .05$. Effect sizes for main effects of an ANOVA F-test were small, CBSM+ = .07, GHL = .09, in contrast with moderate interaction effects, CBSM+ × GHL = .20, and any group effect sizes, .19.

Reasons for Missing ARV Dose—At baseline, the most frequent reason reported for non-adherence was side effects, the most common being fatigue, headache and peripheral numbness. We explored the reasons for missing ARV doses at the conclusion of the GHL intervention within each condition pair to determine how the GHL intervention increased adherence. Four reasons for often missing a dose were endorsed by those doubly assigned to

a group condition, forgetfulness (8%), pill burden (8%), fear of long-term effects (8%) and special instructions (4%). Those with no group experience endorsed almost all reasons for missing a dose. Any group experience resulted in fewer instances of missing a dose to avoid side effects than the individual condition, I–I, 12%, I–G, 10%, G–I, 5%, G–G 0%.

Mediation Analyses—An ad-hoc mediation model was hypothesized where the CBSM+ intervention, as the independent variable, explains more of the variance in adherence when mediated by emotional support coping than alone. Baron and Kenny (1986) provide three preconditions necessary to test a mediation model. The first pre-condition, a significant relationship between the independent variable and the mediator was successfully established in the group × time ANOVA above. However, the second precondition, a relationship between the independent variable (i.e., CBSM+ intervention) and the dependent variable (i.e., adherence), was not significant. Participation in the CBSM+ phase of the intervention was necessary but not sufficient to improve self-reported adherence over the 3-month interval. Participants who were assigned to the CBSM+ condition in the first phase and either of the GHL conditions improved adherence over the 6-month interval.

Discussion

We examined the impact of CBSM and HL interventions on adherence. Most women reported high levels of adherence at study entry. Participants with any group exposure, i.e., group CBSM or group HL interventions, had an increase in adherence, while participation in the information only condition showed no significant effect on adherence. In addition, the group intervention increased emotion-focused coping skills related to adherence.

The effect of the group condition on adherence may be due to social learning and emotional support as the interventions encouraged emotional expression and support as a way of coping with the virus. Lower levels of social support have been related to decreased adherence (Catz, Kelly, Bogart, Benotsch, & Mcauliffe, 2000; Gordillo, Del Amo, Soriano, & Gonzlez-Lahoz, 1999) and lack of support for medication adherence may discourage individuals from taking their medications (Remien et al., 2003). Thus, group participation coupled with emotional support appears to have provided the foundation for increased adherence.

Group participants reported a decrease in the number of reasons for missing medication (i.e., avoiding/feeling sick from side effects, disclosure, depression). Many maintained positive beliefs regarding the importance of medication, though the GHL intervention failed to reduce their concerns regarding the medication. Future interventions should address the influence of such concerns on medication adherence over time. Consistent with previous findings, health-related beliefs and attitudes (Malcolm et al., 2003; Remien et al., 2003; Wagner, Remien, Carballo-Dieguez, & Dolezal, 2002) and concerns (Remien et al., 2003; Sankar, Luborsky, Schuman, & Roberts, 2002) were related to the level of adherence.

Results suggest that HIV-related medication knowledge in combination with an environment of emotional expression and support improve medication adherence among HIV positive women. Previous studies have been inconclusive regarding the relationship between knowledge and adherence (Kalichman et al., 2001; Simoni et al., 2002). Knowledge may be necessary but not sufficient for adherence, while additional emotional support may provide a catalyst for the application of knowledge. Emotional support and expressive interventions have been found to have salutary effects on women with chronic illness (Spiegel & Yalom, 1981). The group provides a supportive environment in which specific issues or concerns related to HIV/AIDS can be openly discussed, emotions expressed and a sense of acceptance engendered among the participants. Acceptance, availability and nurturing have been found to be the most helpful aspects of emotional support (Pakenham, 1998). Group members may also have had

an opportunity for social comparison, which may have guided the adherence process in which participants become aware of the adherence behaviors and physical health of others in a similar situation (Bogart, Gray-Bernhardt, Catz, Hartmann, & Otto-Salaj, 2002). Results also suggest that while group sessions may be more challenging to develop at the clinic level, the more traditional health education model of handouts and videos may be insufficient to increase adherence in the population.

There are several limitations to the results of this study. A significant number of potential participants were excluded from the study due to distress or other related factors. This greatly limits generalizability to HIV positive women. Secondly, city differences were not considered in the analyses. In addition, the high rates of adherence reported by study participants limited analyses, as did self-report as a measure of adherence evaluation. Other measures of adherence, such as electronic drug monitoring or pill counts would provide additional supportive data. Although self-report measures are useful for assessing non-adherence (Catz et al., 2000; Paterson et al., 2002), some participants may overestimate their adherence level with self-report measures (Bangsberg et al., 2001; Paterson et al., 2002) or not consider themselves non-adherent when they modified their regimen (Hill, Kendall, & Fernandez, 2003). Additionally, the study presents an intensive intervention that may be more effective when provided in clinical settings; future research should evaluate its efficacy after translation to community settings. However, translational research should recognize the limitations to generalizability of the results in the broader community due to the exclusion criteria of depression and substance dependence, which may be more frequent in a community or clinic setting.

Group interventions for women living with HIV appear to play an important role in increasing medication adherence. Many interventions focus on the importance of increasing active coping skills and decreasing reliance on emotional coping; this study provides support for the role of emotional support for improving adherence among HIV positive women. Future research regarding HIV-related medication interventions for women should consider information presented in a supportive group environment. Community interventions that enable HIV positive women to interact with their peers in the acquisition and sharing of knowledge and experiences may be effective in coping with HIV.

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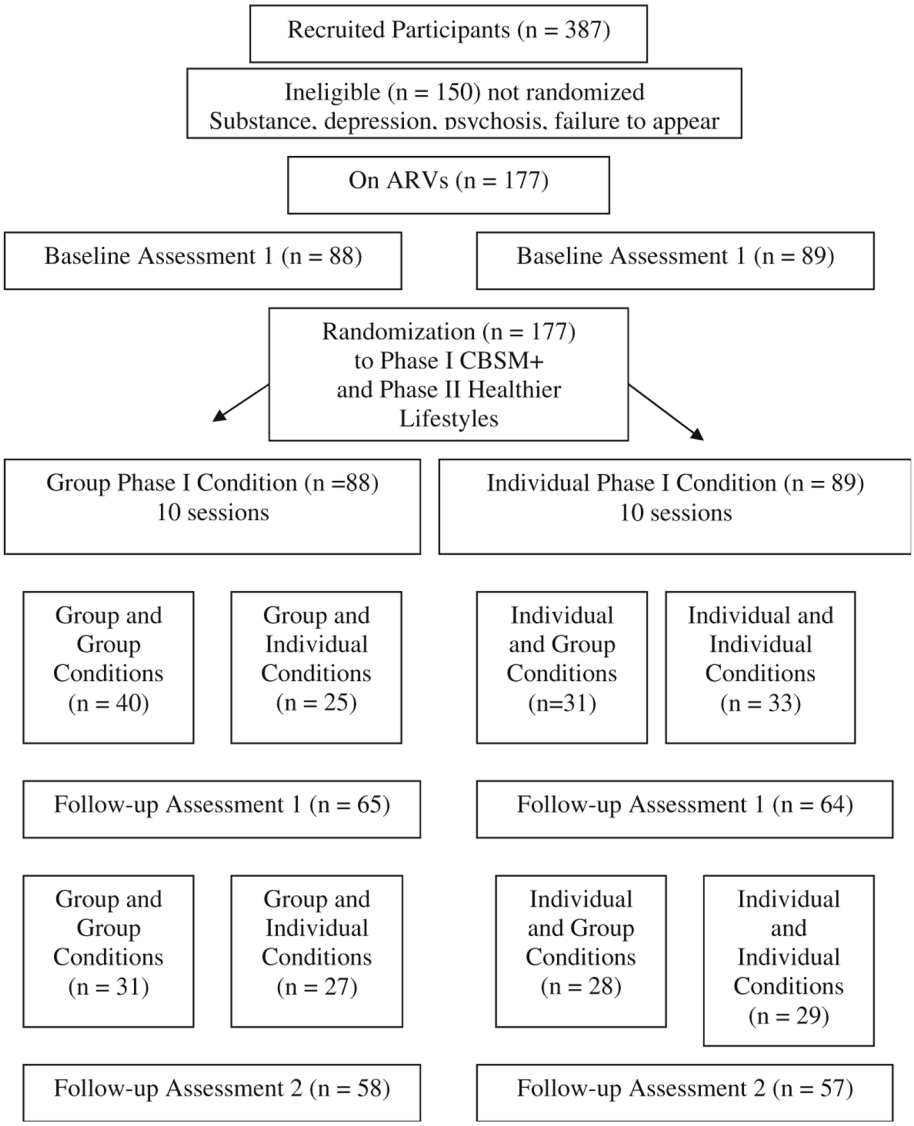

Fig. 1.
Flowchart of study participation and randomization—entire sample

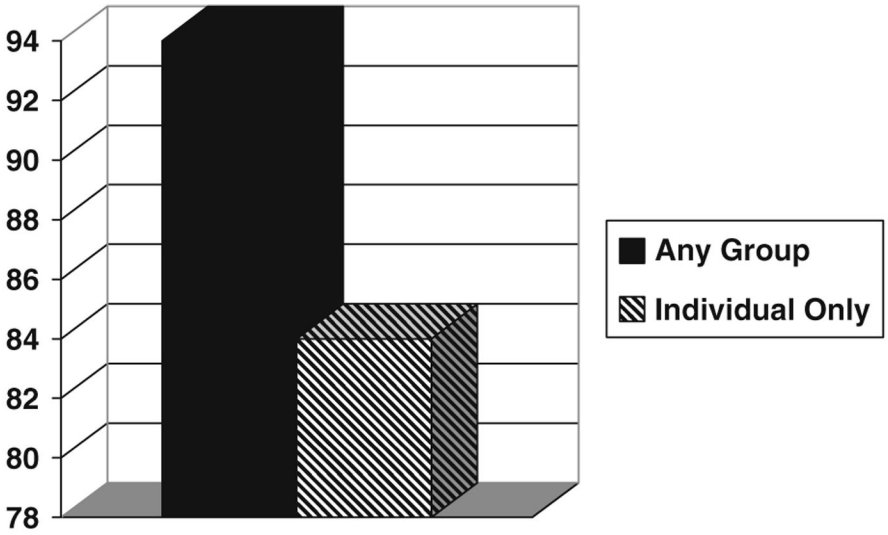

Fig. 2.
Percent adherent in combined group and individual conditions

Table 1

Combinations of intervention assignments for SMART/EST II

Phase 1 general CBSM skills	Phase 2 health behavior focused CBSM+
Low intensity individual educational/informational	Low intensity individual educational/informational
Low intensity individual educational/informational	High intensity facilitated group
High intensity facilitated group	Low intensity individual educational/informational
High intensity facilitated group	High intensity facilitated group