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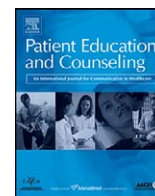
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Educational/Counseling Model Health Care

Effects of a cognitive behavioral self-help program and a computerized structured writing intervention on depressed mood for HIV-infected people: A pilot randomized controlled trial

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ABSTRACT

Objective: The aim of the present study was to examine whether low-resource, cost-effective intervention programs can be effective in improving depressed mood in people with HIV. The efficacy of a cognitive-behavioral self-help program (CBS) and a computerized structured writing intervention (SWI) were tested in a pilot randomized controlled trial.

Methods: Participants were members of a patient organization. They completed a pretest and posttest. The questionnaire included the HADS. Participants were randomly allocated to CBS ($n = 24$), SWI ($n = 25$) or a waiting list condition (WLC, $n = 24$). To evaluate changes in the continuous outcome measure, a 3×2 (group \times time) repeated measures ANCOVA was performed. Also, an ANCOVA was performed using change scores.

Results: Respondents who followed the CBS improved significantly compared to the WLC. However, for people in the SWI condition no significant improvement on depression was found.

Conclusion: This pilot study suggests that a low-resource, cost-effective CBS program seems to be effective in reducing depressed mood in people living with HIV.

Practice implications: Because self-help programs can be delivered through regular mail or the internet, a high number of people could be reached while overcoming geographical and social barriers to treatment.

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1. Introduction

Nowadays many people living with HIV are successfully treated through strict adherence to HAART. However, HIV-positive individuals continue to experience psychological distress from disease-specific and general life stressors associated with living with a chronic, highly stigmatized, disease [1]. Consequently, HIV-positive individuals may be at increased risk of developing psychological disorders. Mood disturbances are often viewed as one of the most common psychiatric symptoms reported by HIV-positive individuals [2–4]. Furthermore, HIV-positive individuals

with psychiatric disorders have been found to be at greater risk for poor adherence to antiretroviral therapy and for HIV-related morbidity [1,3,5–7]. Consequently, improvement of well-being for people living with HIV is a major treatment goal.

A number of psychological programs have been developed for people living with HIV. The majority of these interventions employ cognitive-behavioral intervention (CBI) techniques (see review studies: [8–12]). Several review studies have been performed, showing that all programs involved group-based or individualized face to face contact, and consisted of multiple sessions [8–12]. Overall, psychological interventions for HIV-infected persons significantly improve mental health and quality of life [8–11]. There is limited evidence suggesting intervention effects on CD4+ counts and viral load [10–12].

A disadvantage of these intervention programs is their high costs and the demands they place on patients as well as their professionals in terms of arranging and scheduling visits. The aim

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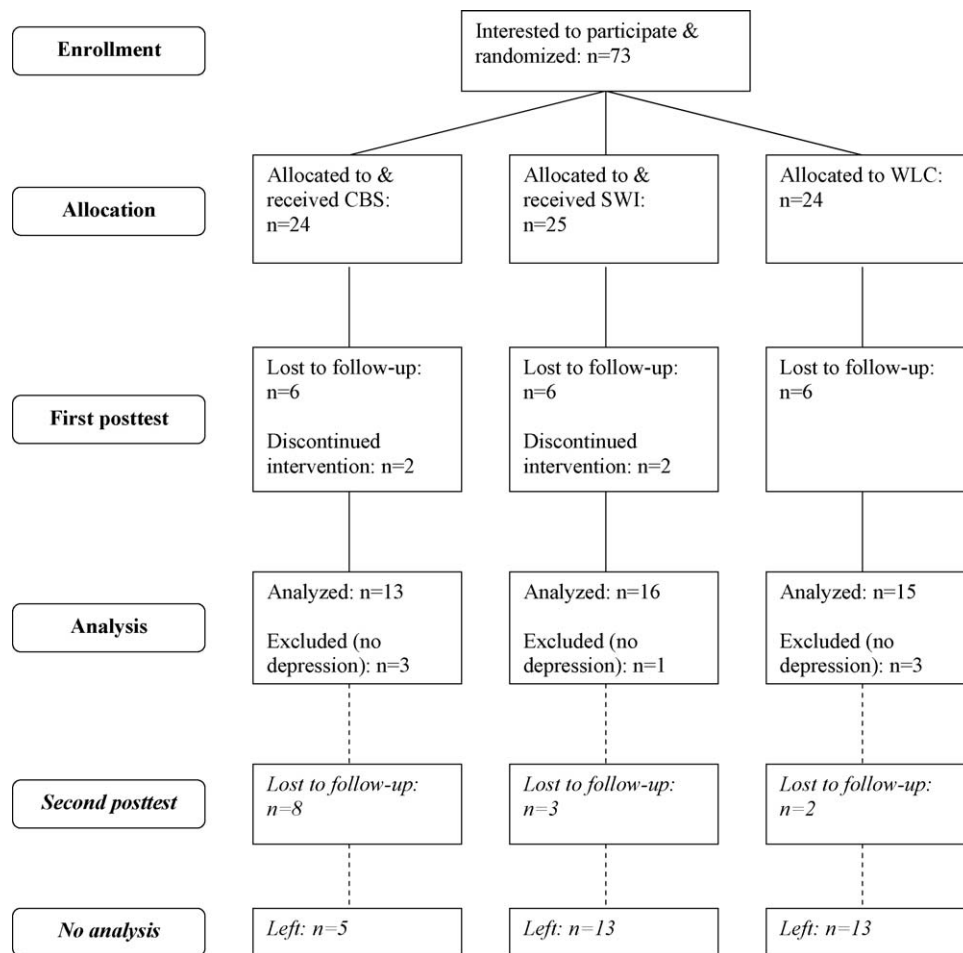


Fig. 1. Flow diagram of participant flow through the pilot study.

of the present study was to examine whether less resource-demanding and more cost-effective intervention programs can also be effective in improving depressed mood in people living with HIV. The efficacy of a cognitive-behavioral self-help program (CBS) and a computerized structured writing intervention (SWI) were tested in a pilot randomized controlled trial. Both interventions were expected to be effective in improving depressed mood, compared to a waiting list control group (WLC).

2. Methods

2.1. Procedures

Participants were recruited among members of the Dutch national organization for people living with HIV through a direct mailing and a call for participation on the Web page of the organization. People who were interested in following a self-help program could send an email to the researchers. After giving informed consent, participants completed the pretest through an especially designed secured website. Next, participants were randomly allocated based on a computer-generated list of random numbers. Respondents who were allocated to the CBS condition received the self-help program at home by regular mail. Respondents who were allocated to SWI were referred to a website. After completion of the program and again 2 months later participants completed the first and second posttest through the secured website. After completing the second posttest, participants in the WLC condition were offered participation in one of the intervention programs. Because not enough respondents filled in

the questionnaire at second posttest, these data are not further included in the present article.

2.2. Participants

A total of 73 persons with HIV were interested to participate in the study and filled in the baseline questionnaire before allocation to either CBS, SWI, or WLC. Fig. 1 shows a flow diagram (including the second posttest which will not be further part of the present article). In the analysis participants who reported none or only one depressive symptom at baseline (according the HADS, see Section 2.3) were excluded, because the interventions were designed to be effective for people with emotional problems. In addition, participants who reported that they did not do any part of the self-help program or who did none of the writing assignments were excluded. Actually, people who remained in the study missed no more than one of the writing assignments. The final sample did not differ from the people who dropped out or were excluded from the analyses on any of the demographic and HIV characteristics, except for viral load ($\chi^2 = 9.36$, d.f. = 1, $p < 0.01$). In the final sample the majority of the respondents (80%) had an undetectable viral load, while in the dropout/excluded group fewer people (45%) reported to have an undetectable viral load.

The mean age of the people who participated was 49 years. The majority was male, single and had no children. Most respondents reported to be homosexual and on average people knew about their HIV-positive status for 10 years (for more information see Table 1).

Table 1
Demographic and HIV characteristics for participants in CBS, SWI and WLC.

	Total (n=44)	CBS (n=13)	SWI (n=16)	WLC (n=15)
<i>Demographic characteristics</i>				
Mean age ± SD, years	49.48 ± 8.15	45.62 ± 6.55	55.31 ± 6.86	46.60 ± 7.43***
Gender, n (%)				
Male	39 (88.6%)	11 (84.6%)	15 (93.8%)	13 (86.7%)
Female	5 (11.4%)	2 (15.4%)	1 (6.2%)	2 (13.3%)
Educational level, n (%)				
Lower	16 (37.2%)	5 (38.5%)	4 (26.7%)	7 (46.7%)
Higher (college/university)	27 (62.8%)	8 (61.5%)	11 (73.3%)	8 (53.3%)
Marital status, n (%)				
Single	30 (69.8%)	9 (69.2%)	13 (81.2%)	8 (57.1%)
Married/cohabiting	13 (30.2%)	4 (30.8%)	3 (18.8%)	6 (42.9%)
<i>HIV characteristics</i>				
Mean time since diagnosis + SD, years	10.27 ± 6.29	7.69 ± 4.27	11.00 ± 7.57	11.73 ± 5.96
Viral load, n (%)				
Undetectable	35 (79.5%)	10 (76.9%)	11 (68.8%)	14 (93.3%)
Detectable	9 (20.5%)	3 (23.1%)	5 (31.2%)	1 (6.7%)
CD4 count, n (%)				
Lower than 500	19 (43.2%)	5 (38.5%)	8 (50.0%)	6 (40.0%)
Higher than 500	25 (56.8%)	8 (61.5%)	8 (50.0%)	9 (60.0%)
HAART medication, n (%)				
Yes	23 (52.3%)	7 (53.8%)	7 (43.8%)	9 (60.0%)
No	21 (47.7%)	6 (46.2%)	9 (56.2%)	6 (40.0%)

*** $p \leq .001$.

2.3. Measures

2.3.1. Depressive symptoms

Depressive symptoms were measured by the depression subscale of the Hospital Anxiety and Depression Scale (HADS: [13,14]). The HADS is a reliable self-report instrument [14]. In the present study the alpha-reliability of the depression subscale was 0.85 at pretest and 0.89 at posttest.

2.3.2. Demographic and HIV characteristics

Demographic information, time since diagnosis, CD4 cell count, viral load and use of medication were measured by means of self-report.

2.4. Study conditions

2.4.1. CBS

The self-help program was based on cognitive behavioral therapy. The content of the program was developed after the completion of a study on predictors of psychological well-being among people living with HIV [15,16]. The findings of this study suggested that intervention programs for people with HIV should focus on the content of thoughts and bringing about effective cognitive change, combined with working on goal adjustment. In the same study a needs assessment was performed. Respondents reported a high need for relaxation (60%) and finding new goals in life (60%). In addition, 50% reported a need for learning coping skills for living with HIV.

The self-help program consisted of a workbook, a work program and a CD-rom. Participants were asked to work on the intervention 4 days a week (1 h/day) for a period of 4 weeks. In the first week participants were asked to do mindfulness-based relaxation exercises, and to continue these exercises in the following 3 weeks. In the second and third week participants learned to identify and change irrational cognitions and to practice counter-conditioning. In the fourth week, they were guided to formulate a realistic, concrete goal and to improve their self-efficacy to reach this goal.

2.4.2. SWI

Emotional disclosure through writing has been demonstrated to improve a range of objective health markers (for reviews, see: [17–20]), and to reduce levels of various psychological symptoms, including depression [21]. Promising results have also been found for people with HIV [22]. Combined with the fact that writing assignments typically comprise no more than 30 min of writing on 3–5 days, makes it a low-resource and cost-effective intervention program.

In the present study participants completed four weekly 30-min writing assignments over a period of 4 weeks. In each writing assignment, participants were instructed to describe their deepest thoughts and feelings regarding their HIV-positive status or any other emotionally significant topic. Participants were instructed to pay special attention to issues that they had not previously disclosed to others. All writing assignments were completed through a website that was especially designed for the present study.

2.4.3. WLC

Participants on the waiting list did not receive any intervention. They were offered the interventions after completion of the study.

2.5. Statistical analyses

Baseline differences in demographic and HIV characteristics, and symptom severity between completers and dropout/excluded respondents at posttest were evaluated with independent *t*-tests and chi-square tests.

Baseline group differences in demographic and HIV characteristics, and symptom severity were examined with chi-square tests and one-way between-subjects ANOVAs to determine baseline equivalence of the study conditions.

To evaluate the changes in the continuous outcome measure, a 3×2 (group \times time) repeated measures ANCOVA was performed with group as a between-groups factor and time as a within-subjects factor, and with significant baseline measures set as the covariates. Also, an ANCOVA was performed, using the change

Table 2

Observed baseline and posttest depression scores for participants in self-help CBS, SWI and WLC.

	CBS (n = 13)	SWI (n = 16)	WLC (n = 15)	ANCOVA results ^a
Baseline	7.31 ± 4.53	8.13 ± 4.22	8.00 ± 3.32	Time: $F(1,40)=0.01$; $p=0.926$
Posttest	4.69 ± 4.05	7.06 ± 4.81	7.73 ± 3.88	Group × time: $F(2,40)=2.46$; $p=0.098$

^a Age as covariate.**Table 3**

Average change score (and SD) between posttest and baseline depression scores.

CBS (n = 13)	SWI (n = 16)	WLC (n = 15)	CBS vs. WLC		SWI vs. WLC	
			Mean difference	[CI]	Mean difference	[CI]
-2.62 (2.79)	-1.06 (3.13)	-0.27 (2.49)	-2.37 [*]	[-4.56 to -0.18]	-0.62	[-2.98 to 1.75]

^{*} $p < .05$.

score between posttest and baseline depression as outcome measure, and the following pre-defined contrasts were tested: CBS vs. WLC, and SWI vs. WLC. In this way, more insight was obtained in the effectiveness of each treatment group.

3. Results

3.1. Baseline equivalence

No differences in baseline symptom severity (see Table 2 for depression scores) were observed between participants in CBS, SWI and WLC ($F[2,41]=0.17$; $p=0.85$). Demographic and HIV characteristics did not differ between the two treatment groups and the control group, except for age (Table 1). The Post-hoc Tukey test showed that the SWI differed significantly from both the CBS and WLC conditions. The CBS and the WLC condition were similar with regard to age. Respondents in the SWI condition were of significant older age compared to the other two conditions.

3.2. Outcome

In a repeated measures ANCOVA with age as covariate, no main effect for time was observed (Table 2). The interaction effect between time and group was not significant, but a trend was observed. To examine this finding further, the differences in average change score from baseline to posttest depression between the conditions were tested. A significant difference was observed between the CBS vs. WLC condition (Table 3), indicating that respondents who were in the CBS improved significantly compared to people on the WLC. No significant difference was found between SWI and WLC.

4. Discussion and conclusion

4.1. Discussion

The present study examined the efficacy of two low-resource and cost-effective intervention programs in treating depressed mood in people living with HIV. Respondents who followed the CBS improved significantly compared to the WLC immediately post intervention. However, for people in the SWI condition no significant improvement on depression was found.

The efficacy of group-based or individualized face to face CBI programs for people living with HIV have been shown by earlier studies [8–12]. The presents pilot study demonstrated that HIV-positive individuals who received a self-help program at their home address and worked on relaxation, cognitive change and life goals for 4 weeks, reported significantly fewer depressive

symptoms after completion of the program, compared to people on a waiting list.

In the present study the SWI seemed to have no effect on depressed mood compared to the WLC. This is not in line with an earlier study in which promising results for the effects of structured writing were found for people with HIV [22,23]. Future studies should examine individual differences and the influence of increasing the frequency of sessions.

However, there is no one best treatment for every patient [24]. Future studies should focus on which HIV-infected persons benefit from which type of treatment.

There are several limitations. First, the sample size is rather low. This limits the possibility of analyzing differential effects between subgroups of participants. In addition, in the present study we were unable to evaluate the longer term effects of the interventions due to low follow-up rates. Studies with large sample sizes should be conducted. Additional effort should be undertaken to retain respondents in the study, especially at longer follow-up. Another limitation is the generalizability. Compared to the Dutch population with HIV [25], the present study group was relatively old. Whether we can generalize to younger people remains to be studied. Furthermore, in the present pilot study we assessed and randomized participants before eligibility criteria were assessed. This was done in order to include as many people as possible, but may have led to a higher dropout rate and consequently to a rather selected subsample of the overall randomized group. In the final sample the majority of the respondents (80%) had an undetectable viral load, while in the dropout/excluded group fewer people (45%) reported to have an undetectable viral load. Future studies should examine how people with unfavorable health conditions can participate and benefit from minimal interventions.

4.2. Conclusion

Respondents who followed a low-resource, cost-effective CBS program improved significantly on the amount of depressive symptoms compared to the WLC. People in the SWI condition showed no significant improvement on depression. However, it is important that future studies focus on which HIV-infected persons benefit from which type of treatment.

4.3. Practice implications

Given the growing prevalence of HIV, effective mental health interventions are urgently needed. The present study suggests that a low-resource, cost-effective self-help program can be effective in treating depressed mood in people living with HIV. Because self-help programs can be delivered through regular mail or through

the internet, a high number of people could be reached while overcoming geographical and social barriers to treatment [26].

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