

Contents lists available at ScienceDirect

Journal of Exercise Science & Fitness

journal homepage: www.elsevier.com/locate/jesf

The effect of a 12-week combinational exercise program on CD4 count and mental health among HIV infected women: A randomized control trial

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ARTICLE INFO

Article history:

Received 19 June 2017

Received in revised form

29 October 2017

Accepted 2 February 2018

Available online 9 February 2018

Keywords:

Exercises training

Mental health

CD4 count

HIV infected women

ABSTRACT

Background/objective: There are conflicting results regarding the effects of exercise on immune function of HIV positive patients. Exercise can also be beneficial to psychological functioning of the patients. The purpose of this study was to determine the impact of a 12-week aerobic and resistance exercise training program on mental health and CD4 counts among female HIV+ patients.

Methods: This clinical trial was conducted between September and December 2013. Forty participants (women age range 20–40) were carefully selected from 240 HIV-positive women referred to Voluntary Counseling and Treatment Center (VCT) and randomly assigned to either exercise (80 min of aerobic and strength training while receiving the VCT's routine services) group (n = 20) or control (received the VCT's routine services only) group (n = 20). To assess their mental health status, all participants completed GHQ28 questionnaire. Blood samples were collected to measure CD4 and T-cell counts at baseline and at the end of the 12-week intervention.

Results: From a sample of 40 women with HIV infection, the data of 30 participants [experimental group (14) and control group (16)] were analyzed (participation rate 75%). The results indicated that after the intervention program, a significant difference in CD4 cell counts was found between the two groups (P = 0.01). With regard to mental health, after performing intervention, significant improvement in all subscales including anxiety disorder, social function, depression and mental health's total score was observed in the exercise compared to the control groups (P < 0.001).

Conclusion: Exercise training can be included in health care services in order to improve the mental health status of women with HIV infection. No effect on CD4 count was detected.

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Introduction

AIDS is a communicable disease that can affect many aspects of affected individual's health including immune system. One of the most important effects of HIV on immune system is a gradual but

significant drop in CD4 count which makes these patients vulnerable to opportunistic infections such as tuberculosis.^{1,2} Indeed, AIDS is recognized by a dramatic reduction in the count of T-lymphocytes (T-helper), which play a crucial role in the immune system.^{3,4} (see Fig. 1)

HIV invade CD4 cells and make them to produce more copies of the virus. A person with HIV infection may feel well and show no symptom, whereas each day millions of CD4 cells are getting infected and demolished by the virus.¹ In clinical terms, if CD4 count falls below 250 to 200, treatment with anti-HIV drugs is

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required. This is because at this stage the risk of AIDS-related illnesses is high.^{1,5} On June 21st, 2013, the Iranian ministry of health reported that a total number of 26556 Iranians are living with HIV infection, of whom, 10.4% were women, and 46.1% had 25–34 years of age when acquired the infection.^{6,7} However, it is believed that the real number of people living with HIV/AIDS is underestimated and the actual figure is five times higher.⁸

Poor mental status and reduced courage and self-confidence cause HIV-infected individuals have less social and physical activities.^{9,10} Physical activity is suggested to be beneficial to chronic disease patients¹¹ and HIV infected patients as based on the results of a research,⁹ both aerobic and resistance exercises increase aerobic capacity and improve functional ability,¹¹ body composition and physiologic parameters such as muscle strength, endurance, time to fatigue, and, flexibility in HIV/AIDS patients.^{12,13} However, another study provided negative results with respect to the effects of exercise on immune function in people with HIV infection.¹⁴

Regarding CD4 count, the results of few studies revealed a significant change in CD4 counts among HIV infected patients with regard to physical activity¹⁵ whereas, other authors reported no significant change in this regard.^{16,17} A recently published meta-analysis could not approve any significant effect of exercise on the count of CD4 among HIV patients.¹⁸

In addition to the serological changes, HIV-infected patients suffer from psychological disorders e.g.; depression, panic disorders, dysthymia and generalized anxiety disorder.¹⁹ Previous studies have shown that regular exercise is beneficial to psychological functioning²⁰ and has been used successfully to treat psychological conditions such as depression and anxiety that are common in people

with HIV.²¹ For example, aerobic exercise is suggested to reduce the severity of depression.²² Both aerobic and resistance exercises are also found to decrease the level of anxiety over an 8-week period.²³

In a clinical trial on HIV⁺ patients, the participants achieved significant physical and psychological improvements after 12 weeks of aerobic exercises with moderate intensity.¹⁴ In another study, sixty HIV infected adults participated in a randomized controlled trial of a supervised 12-week aerobic exercise program. The results indicated that depressive symptoms were significantly improved in exercise group.²⁴

The present study examined the effects of a combinational exercise on the immune function and mental health status of a group of HIV infected female participants. The purpose of this study was to determine the impact of a 12-week aerobic and resistance exercise training program on mental health and CD4 counts of the participants.

Materials and methods

Settings

The protocol of this 12-week randomized controlled trial was reviewed and approved by the ethics committee of Shiraz University of Medical Sciences (approval state: 4500). Between September and December 2013, 40 HIV infected women who were registered with the center for behavioral disease counseling, run by Shiraz University of Medical Sciences, were enrolled. Using block randomization method, the patients were allocated to either intervention or control groups. Women in both control and

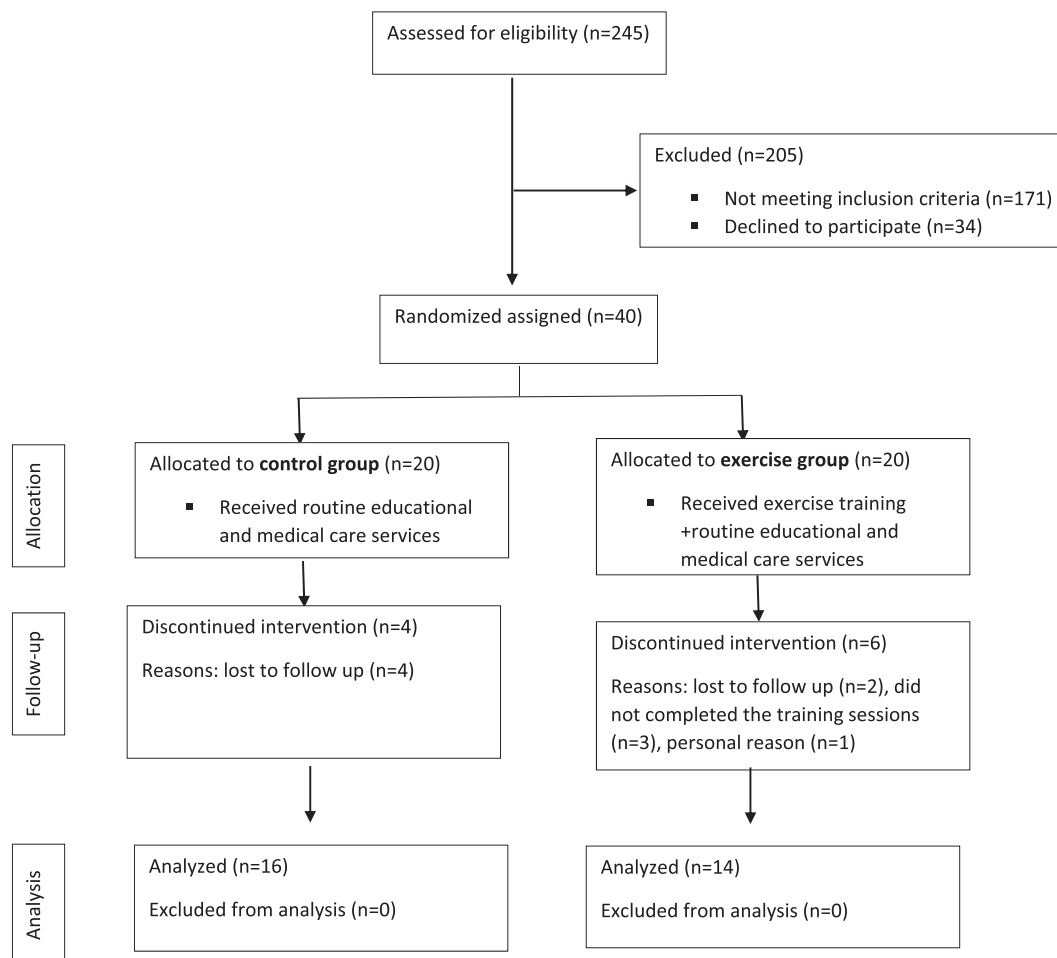


Fig. 1. Study flow diagram.

intervention groups received routine monitoring and consult services.

Inclusion criteria

All participants were between 20 and 40 years of age with no current or history of major chronic conditions or inflammatory or orthopedic diseases (e.g. arthritis, stroke, myocardial infarction and cancer). In addition, the participants were non-smoker and not being regularly exercising (≥ 3 days per week for 20 min per session) for at least 6 months prior to the study recruitment.

Exclusion criteria

The participants were not included if they had any plan of being away for more than 2 weeks in the next 9 months, had lost more than 10% of body weight during the last 12 weeks and taking corticosteroids or anabolic steroids. All participants were informed of the trial plan before recruitment and literate patients read and signed informed consent and verbal consent was obtained from illiterate patients.

Intervention Protocol

Participants were randomly assigned to two groups of intervention and control. The consulting center provides the registered patients with a wide range of social and medical services including training sessions for health and medical cares of the participants and their families. As the result, the participants in both intervention and control groups were involved in different types of social events provided by the center. The randomization was conducted based on block randomization with size two. The patients in the study groups were not to be blinded to their group assignment due to the merit of the intervention (exercise). However, neither the laboratory staff nor the interviewers or the statistician were aware of group assignment of the participants. All participants were invited to take the medical and mental tests based on a predefined schedules assuming the physiological and mental time dependent changes are randomly distributed in the study participants irrespective of their assigned group.

Women in intervention group attended an exercise training program, 3 times a week for 12 weeks. Women in both control and intervention group received routine monitoring and consult services. The exercise sessions were managed and supervised by a physiotherapist in alternate week days. The program included a warm-up session with stretching, light jogging and flexibility movements for 20 min followed by 45 min of aerobic exercise on a stationary bicycle at 40–45% of the maximal heart rate. The third session included a set of strengthening exercises: open and bending the elbow, shoulder press, bench press, knee and leg extension and partial abdominal flexion. Three sets of 8 repetitions were performed for all strengthening exercises using workload of 50–55%. The workload increased 5% after each two weeks, but aerobic exercise was fixed during the 12 weeks. Sessions finished with a cool-down and stretching period of 5–15 min. Before the study intervention, 5 ml blood samples were obtained and the serum were separated. CD4 count was measured using flow cytometry method with Partec kit.

To measure health status of the participants, GHQ28 (Goldberg & Williams 1988) was used. The questionnaire was used before and after the intervention program to assess the participants' physical and mental status. The responses are rated on a 4-point Likert scale ranging, from 'less good than usual' to 'much worse than usual'. The items cover different aspects of individual's life providing four subscales: somatic, anxiety, social dysfunction and depression. The

score for each subscale ranges between 0 and 21 points and the score for overall severity ranges from 0 to 84 and the cut-off point is 21, and higher individual's score indicates the better their health status.²⁵ The overall score of each participant is the sum of the four subscales. The validity and reliability of the GHQ is well established before.^{26,27}

The GHQ-28 consisted of 4 subscales: somatic symptoms, anxiety and insomnia, social dysfunction, and severe depression.²⁵ In this questionnaire, the items 1 to 7 were examine somatic symptoms, the items 8 to 14 were related to anxiety and insomnia, and the items 15 to 21 and 22 to 28 were related to social dysfunction and severe depression respectively.

Statistical analysis

Mean and standard deviation were used as the main indices of descriptive statistics. Independent sample *t*-test and Chi-square test used to compare baseline measures between intervention and control groups. Pair *t*-test was used to compare changes in the study measures within the study groups. Statistical analysis was conducted assuming two-sided 5% level of significance. STATA (version 12) package was used to analysis the data.

Results

At the end of the 12-week exercise program, the data of 30 participants (Control group: 16, Experimental Group: 14) were analyzed. Ten (25%) were excluded because they either had not completed the exercises training sessions or they refused to provide the post-test blood sampling. The mean [\pm SD] age of the participants in experimental and control groups were 30.2 [\pm 4.7] and 28.5 [\pm 5.2] respectively ($p = 0.09$). Most of the patients were infected through sexual relationship with their spouse ($n = 26$). The characteristics of patients are presented in Table 1.

The mean of the GHQ-28 scores at the baseline for total study participants was 29.7. According to Table 2 at the baseline total GHQ score in experimental group was 27.84 [\pm 9.48] and for control group was 31 [\pm 12.07]. Anxiety among experiment group was 5.92 [\pm 4.46] which was no significantly from controls 6.3 [\pm 4.19]. Also severe depression was seen more in experiment group 4.84 [\pm 2.76] compare to controls 6.6 [\pm 4.25] $p < 0.05$.

Table 2 summarizes the differences of pre and post intervention measures of CD4 count, GHQ score and other interested indexes. Accordingly, although with a smaller absolute value, CD4 count in the experimental group had a significant reduction ($P = 0.01$) compared to the control group ($P = 0.09$). On the other hand, the results indicated that the intervention group had significant

Table 1
Characteristics of the study patients at baseline.

	Experimental group (N = 14)	Control group (N = 16)	P-Value
Age (y)	30.2 \pm 4.7	28.5 \pm 5.2	0.09*
Body mass index (kg/m²)	23.4 \pm 4.6	24.1 \pm 3.2	0.23*
Marital status			
Never married	2 (14.3)	1 (5.8)	0.15*
Married	5 (35.7)	10 (64.7)	
Divorced	3 (21.4)	1 (5.8)	
Other	4 (28.6)	4 (23.5)	
Education			
Illiterate	1 (7.1)	3 (17.7)	0.24*
Under diploma	5 (35.7)	9 (52.9)	
Diploma	3 (21.4)	1 (5.8)	
University degree	4 (28.6)	4 (23.6)	
CD4 Count (cells/mm³)	526.07 \pm 261.17	548.45 \pm 273.9	0.67*
TOTAL GHQ	27.84 \pm 9.48	31 \pm 12.07	0.34*

P-values are based on **t*-test or χ^2 -square.

Table 2
Descriptive statistics of CD4 counts and GHQ components of the study participants before and after intervention.

Variables	Group	Mean \pm SD		P-value
		Baseline	Post-test	
CD4 count (cells/mm ³)	Experiment	526.07 \pm 261.17	495.57 \pm 149.37	0.01
	Control	548.45 \pm 273.9	491.18 \pm 284.48	0.09
Somatic symptoms	Experiment	7.23 \pm 3.47	4.00 \pm 2.41	0.02
	Control	6.5 \pm 3.66	6.60 \pm 4.22	0.65
Anxiety	Experiment	5.92 \pm 4.46	3.61 \pm 2.33	0.13
	Control	6.3 \pm 4.19	6.20 \pm 4.29	0.64
Social dysfunction	Experiment	10.15 \pm 3.34	7.46 \pm 2.60	0.05
	Control	10.6 \pm 2.91	10.40 \pm 3.13	0.48
Severe depression	Experiment	4.84 \pm 2.76	2.69 \pm 1.44	0.02
	Control	6.6 \pm 4.25	7.60 \pm 5.38	0.37
Total GHQ score	Experiment	27.84 \pm 9.48	17.07 \pm 6.71	0.01
	Control	31 \pm 12.07	30.80 \pm 14.28	0.73

*Pair T-test.

Table 3
Change in CD4 Counts and GHQ Components in intervention and control group after 12-week exercise program.

Variables	Group	Mean \pm SD	P value ^a
		Post-test	
CD4 Count (cells/mm ³)	Experiment	495.57 \pm 149.37	0.33
	Control	491.18 \pm 284.48	
Somatic symptoms	Experiment	4.00 \pm 2.41	0.02
	Control	6.60 \pm 4.22	
Anxiety	Experiment	3.61 \pm 2.33	0.07
	Control	6.20 \pm 4.29	
Social dysfunction	Experiment	7.46 \pm 2.60	0.02
	Control	10.40 \pm 3.13	
Severe depression	Experiment	2.69 \pm 1.44	0.008
	Control	7.60 \pm 5.38	
Total GHQ score	Experiment	17.07 \pm 6.71	0.005
	Control	30.80 \pm 14.28	

^a Independent samples T-test.

Table 4
The correlations between CD4 and anxiety, BMI and GHQ.

	CD4	BMI	Anxiety	GHQ ^d
CD4	1.0	–	–	–
BMI	0.301	1.0	–	–
Anxiety	–0.476 ^b	0.650	1.0	–
GHQ	0.721 ^a	0.422	NA ^c	1.0

^a Correlation is significant at the 0.05 level (2-tailed).

^b Correlation is significant at the 0.01 level (2-tailed).

^c NA: not applicable.

^d Total score.

improvement for subscales of social dysfunction ($P = 0.05$), somatic symptoms ($P < 0.02$), severe depression ($P = 0.02$) and total GHQ score ($P = 0.01$). No significant change was found for the study indexes in the control group.

The absolute changes in the study indexes are compared between experiment and control groups and the results are shown in Table 3. Accordingly, no significant difference in the reduction of CD4 counts was observed between the control and experimental groups ($p = 0.33$). The mean of total score of GHQ components for control and experimental group at post-test stage was 30.80 and 17.07 respectively, suggesting a significant improvement in general health status of the participants due to the intervention ($P = 0.005$). Also, Table 4 present the correlations between CD4, GHQ and other study variables.

Discussion

The present study examined the effects of a 12-week exercise program on CD4 and mental health of HIV positive female patients. The findings of the present study demonstrated no significant difference in the reduction of CD4 cell count but significant improvement in mental health in the experimental compared to the control groups. According to pre-post analyze of change, the patients who underwent a 12-week exercise, experienced less drop in CD4 count. However, possibly due to the high variation in CD4 counts and small sample size, the smaller rate of reduction in the intervention group was not statistically significant when compared to the controls. The intervention and control group both declined in CD4 count over time. It is important to note that may be there is a time effect for both groups, but since they are not statistically different from each other, it's not appropriate to conclude that the intervention (exercise) was the cause of the CD4 decline. However, the results show that exercise training had beneficial effect on important indexes such as, social dysfunction, severe depression and total GHQ score. There are a few studies which their published results were in line with the results of current study. In contrast to the results of few other studies, current study could not find any significant effect of exercise on prevention of CD4 count reduction.²⁸

The effect of exercise on CD4 count is still under debate, as few studies suggested that exercise programs may increase the CD4 count, whereas others found no significant association.²⁹ For example, Yar'zever et al., found significant improvement in CD4 cell counts in the experimental compared to the control groups.¹ O'brien suggested that these findings should be interpreted cautiously because of small sample sizes and methodologically differences between studies.²⁹ A meta-analysis that included most of the trials, reported no significant difference in change of CD4 count for patients in the exercise intervention group compared with the non-exercising control group.¹² Poton using a recent meta-analysis examined the effects of resistance training in HIV-infected individuals and reported a potential moderate effect of such intervention on CD4 count.³⁰

The present study suggested beneficial effects of a 12-week exercise program on total GHQ and its subscales, namely: somatic symptoms and severe depression, but no beneficial effect was found on anxiety and social dysfunction. Depression and anxiety are the main psychological conditions which their associations with exercise have been assessed in interventional studies on HIV+ patients. Few studies have been conducted to verify the effects of exercise on psychological parameters of special populations groups, demonstrating improvement in the levels of depression and anxiety among HIV patients. For example, Rodrigo et al. and Neidig et al. suggested that a 12-week exercise program can improve mental disorders in HIV+ patients.^{24,28} Similarly, a study by Hand et al., suggested that physical activity improves physiological and physiological conditions such as, endurance, anxiety and depression among patients with HIV.³¹ Other studies showed that exercise and physical activity reduce fatigue, anxiety and depressed mood and improved quality of life in HIV patients.³²

The preset study had some limitations including no participants were blinded to their assignments because of the nature of the intervention (exercise). In addition, due to the limited sample size and large standard deviation of CD4 counts, the study was not able to detect a significant effect of intervention on the dropping rate of CD4 count.

To sum up, although our study was not able to show any effect of exercise on CD4 counts but the program had positive effects on physical and mental health of HIV positive female patients.

Conclusion

Aerobic and resistance exercises had positive effect on physical and mental health of HIV positive female patients. Physical activities improved the quality of life in these patients via decreasing anxiety disorder, social dysfunction and depression. Although this study failed to find any significant association between CD4 counts and aerobic and resistance exercises, the positive effect of the exercises on different aspects of health of HIV infected patient was considerable.

Compliance with ethical standards

Source of funding

The present study was financially supported by Shiraz University of Medical Sciences, Shiraz, Iran (No: 94–7481).

Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Ethical approval was obtained from Shiraz University of Medical Sciences ethical comity.

Informed consent

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

Conflicts of interest

All members of the study declare that they have no conflicts of interest.

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