



Original Article

EVIDENCE FOR NATUROPATHIC AND YOGIC INTERVENTIONS TO AUGMENT THE EFFECTS OF ART CARE AS AN ADJUVANT THERAPY - A PARALLEL MATCHED CONTROL STUDY

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ABSTRACT

Background Complementary and alternative medicine (CAM) is becoming a pillar in the rehabilitative efforts for many people living with HIV AIDS (PLWHA). The efficacy of naturopathic and yoga intervention, a CAM therapy is an area to be explored in rehabilitation of PLWHA. **Aim:** The present study, a parallel matched control study to was designed to compare the efficacy of naturopathic and yogic interventions as an adjuvant therapy with standard Antiretroviral Therapy (ART) to PLWHA. **Methods:** Twenty matched subjects were screened for the study based on the criteria: HIV positive subjects aged between 25 to 55 years, both sexes, no secondary infections, under ART care, last CD4 estimate done on June 2014. The intervention group (IG) underwent Naturopathic and yogic intervention along with ART in a HIV sanatorium for a month followed by periodical follow up and control group (CG) received only ART. The outcome measure was a change in CD4 count. **Results** After the end of 6 month, the IG showed significant changes CD4 cell count (p=3.96E-05). The CG also showed a significant improvement in CD4 cell counts (p= 0.024) but not of the same magnitude as of IG. An independent t-test between the groups has shown that the IG was more significant (p=0.047). **Conclusion** The improved levels of CD4 cells in the intervention group suggests that naturopathy and yoga can augment the efficiency of ART care and can be safely prescribed to PLWHA and prescribed as a adjuvant therapy.

KEYWORDS

HIV care, Naturopathy, Yoga, ART, CD4 count.

INTRODUCTION

Human Immuno Deficiency Virus (HIV) has turned out to be one of the most serious health and development challenges.^[1] Despite of substantial progress in the delivery of HIV prevention programs, HIV is still a worrying factor across the globe. Antiretroviral Therapy (ART), the standard medical care available for people living with HIV AIDS (PLWHA) has reasonably reduced the incidence of acquired immunodeficiency syndrome (AIDS)-related death and disease.^[2] However the adherence to ART and the life expectancy or improvement in quality of life in PLWHA is affected due to the negative lifestyle such as improper diet, addictions, sedentary lifestyle as well as behavioral attitudes like anxiety, phobia etc., The life expectancy can be improved by altering the lifestyle and behavioral changes in the PLWHA.^[3]

Naturopathy can be defined as a drugless, noninvasive, rational and evidence-based system of medicine imparting treatments with natural elements based on the theories of vitality, toxemia and the self-healing capacity of the body, as well as the principles of healthy living.^[4] Naturopathy treats the body by considering it as a complete unit.^[5] National

institute of Naturopathy (NIN) HIV sanatorium is a free residential facility in Pune, providing free integrative healthcare, accommodation, diet, and vocational training for HIV-positive individuals. Additionally the sanatorium provides specialized asymptomatic clinical care which includes naturopathy and yoga interventions along with counseling and education on HIV transmission and risk-reduction behaviors. It also offers routine clinical monitoring and assessment, nutritional assessment and counseling, promotion of good personal and household hygiene.^[6] A normal criteria to initiate ART care as well as for pragmatic prioritization of patients at highest risk for AIDS.² The defect in the immune system is characterized by a loss of lymphocytes (lymphopenia) as a result of selective deficiency of CD4+ T-cells. As a result of their CD4+ T-cell deficiency, AIDS patients have major defects in their cell-mediated immune responses.^[7] Currently there are less evidence available to show the efficacy of naturopathy interventions in HIV care. The present study is a parallel matched control trial aimed at comparing the changes in the CD4 count of PLWHA between

the subjects under standard ART and naturopathy & yoga with ART care.

MATERIAL AND METHODS

Study Location: The study was conducted as a parallel matched control study in two centers in Sathara District.

Ethics approval: The study was conducted in accordance with the international ethical standards the research protocol was approved by Institutional ethics committee of NIN. Informed consent was obtained from participants

Inclusion criteria:

Both males and females aged between 25 to 55 years with no secondary infections, who are under ART care were included in the study.

Exclusion criteria:

Patients under pre ART Care, concomitant infections and patients who are not under regular ART medication were excluded from the study.

Sample size:

Sample size (n=40)

Grouping:

The participants were divided in to two arms, Intervention arm (n=20), control arm (n=20).

Methodology:

A parallel matched control study was conducted in two centres in sathara district, Maharashtra. The intervention arm received naturopathic and yogic interventions along with the standard ART care at the HIV sanatorium of National institute of Naturopathy (NIN), Panchagani, Maharashtra. The control arm received standard ART care at District Civil Hospital, Sathara, Maharashtra.

Subjects: 9942 HIV infected subjects were screened to find matched control for 20 subjects in the intervention arm who have come to the center for their CD4 evaluation in June and expected date of periodic evaluation on January 2015. The intervention group was screened out of 114 subjects based on inclusion criteria. The matches were selected by the authors from the same ART centre were the intervention group is also undergoing ART care. The databases of the District Civil hospital were used to identify the matched controls and the subjects were screened according to the eligibility criteria. Both the group belongs to the same district, Sathara, Maharashtra. Both the arms were matched for age, sex, CD4 counts, and number of years of infection. The subjects were followed from July 2014 to January 2015.

Intervention:

The intervention arm received naturopathic and yogic interventions specially designed for HIV subjects for 30 days along with standard ART care as prescribed by ART center, District Civil Hospital, Sathara, Maharashtra. The subjects were asked to continue this naturopathy and yogic lifestyle changes post their stay at sanatorium. Follow-up and

counseling has been done through phone at an interval of 30 days for 5 months to ensure the adherence.

Counseling

Counseling is a key element of naturopathic treatment as it endows individuals to take greater control of their own health, happiness, and life path. Based on naturopathic principle the role of a doctor does not end at treating the patient, it accentuate doctor as a teacher (docere) who educate the patients, involve them in healing process and emphasize the importance of the doctor-patient relationship.^[8] Counseling was an integral part of the intervention plan to educate the patients about HIV transmission, principles of naturopathy treatment and how it influence the body functions.

Yoga:

Yoga practices have shown to reduce fear, anxiety,^[9] stress and depression which also enhances overall well-being.^[10] It includes loosening exercises, asanas (postures) like Standing asanas: Tadasan, Triyaka tadasan, Kati chakrasan. Supine asanaas: utanapadasan, Pavanamuktasan, Setu bandhasan, Prone asanas: Bhujangasan, shalabhasan, Dhanurasan. Sitting asanas: Paschimottanasan, Vakrasan, Gomukhasan. Pranayama (breathing techniques) such as nadishuddi,^[11] bhramari,^[12] kapalbhathi,^[13] and deep relaxation techniques. These techniques were not specifically standardized for PLWHA, but this was included in the treatment plan owing to the general effects of yoga in building physical and emotional wellbeing. In addition, morning and evening walk is also followed as routine, aimed to provide mild sunbath and air bath.

Naturopathy treatments:

Hydrotherapy, a naturopathic modality stimulates the body's natural healing mechanisms, which regulates the circulation of blood and lymph.^[8] The hydrotherapy treatment includes water packs at different areas of the body like forehead pack, abdominal pack, chest pack etc, mud packs, spinal baths, hip bath, hot foot and arm bath. Water used at various temperatures enhances blood flow, which is thought to help in eliminating algogenic chemicals, and facilitate muscle relaxation.^[14]

Forehead pack:

A cotton cloth made wet in cold water (18–24° C) is applied on the forehead after the hair and scalp have been thoroughly wet with cold water. This pack was given along with abdominal pack for 45 min once in a day. This helps in relieving chronic nasal catarrh, common cold as well as the rheumatic affections of the head.^[15]

Abdominal pack

Two cotton clothes 2–2 ½ m long and ½ m wide dipped in cold water (18–24° C) is wrapped around the abdomen after wringing out the excess water. After wrapping this, wrap a dry flannel or blanket of 1 m long and ½ m wide around the cotton cloth^[16] for 45 min once in a day. This helps in regulating blood

circulation in abdominal organs and improves the function of them.^[17]

Spinal bath

Hypothermic water bath, a hydrotherapy modality, which is the application of water, both topical and whole-body in 40°C for 30 min.^[18,19] This has shown to increase the CD8+ lymphocyte and natural killer cell count. This has been attributed to the increase in somatotropin production.^[18] Neutral spinal bath (34–35° C) is given for 15 min in a spinal bath tub, which is designed in such a way that the entire length of the spine from the nape of the neck to the lowest portion of the spine is immersed inside the water. The applications of water to the spine can influence all the spinal ganglias which are related to the sensory, heat, vasomotor, and secretory centers.^[20]

Hip bath/sitz bath

The sitz bath/hip bath (partial immersion bath of the pelvic region) is given in a specially constructed tub. The tub or basin was filled with enough water of temperature 55° F–65° F to cover the buttocks and hips so that the water reaches the level of the navel.^[21] Patients were asked to sit in the tub for 20 min.

Hot foot bath

It is given in small tub in which hot water (40–45° C) where the patient has to dip the legs up to the calf muscle in water and the patient is covered with a blanket to prevent the heat loss. This is given for 20 min once in a day before sleep. Warm

foot bath has shown significant effects in relieving fatigue and insomnia symptoms.^[22] This bath was provided intending to relieve stress and ensure good sleep.

Mud pack to abdomen

Immunocorrective effects of mud therapy have been demonstrated in a clinical-immunological study.²³ Mud pack was prepared with the clay which was grinded, sieved, mixed with cold water, and it was made with a consistency like soft dough. This mud was spread on a strip of cloth with the dimensions 20 cm × 10 cm × 2.5 cm. The pack was applied on the lower abdomen (from the navel to the pubis).^[23] The treatment was given for 20 min.

Raw juice therapy

The raw juice therapy was followed as a regular routine in which 200 ml of wheatgrass juice was served in empty stomach. Wheat grass is known for its high chlorophyll content which is homologous with the hemoglobin structure.^[24] This property of wheatgrass can help in blood building of the immune compromised individuals, and also it will help in alleviating the anemia which is prevalent in HIV individuals.

Diet therapy

There is a mutually aggravating relationship between malnutrition and infection.^[25] This signifies the need of a good diet rich in immune enhancers such as protein, vitamins, and minerals for the PLWHA. Other than the juice therapy the patients were provided with short vegetarian meals which

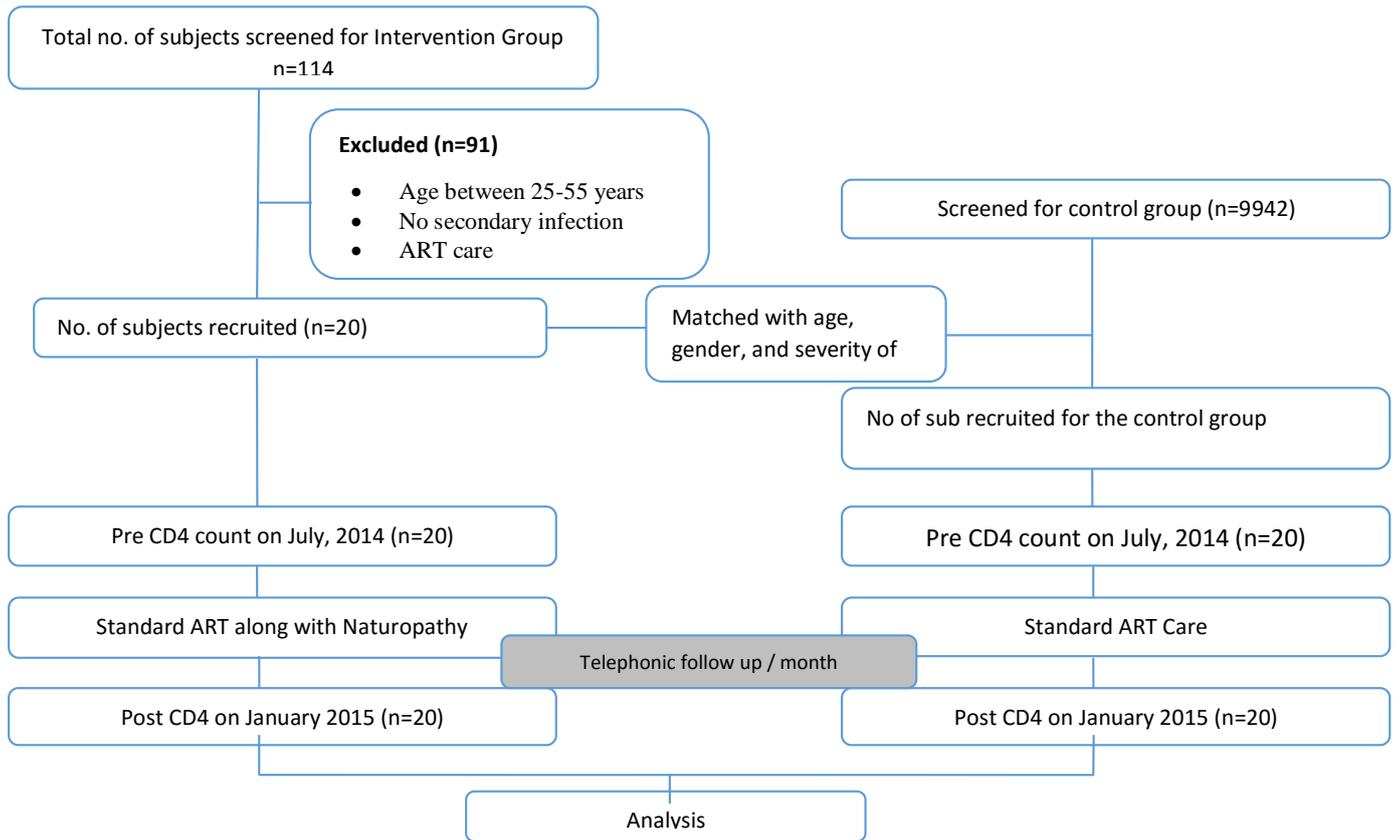


Figure 1 – Trial Profile

include fresh vegetable salads, fruits, fruit juices, dry fruits, sprouts, coconut milk, dry chapatti with cooked vegetables, and soups which are rich sources of proteins, vitamins and minerals.

Sun bath

Vitamin D which regulates calcium absorption and homeostasis [26] in the body may come both from dietary sources and from synthesis in the skin triggered by sun exposure, or more specifically ultraviolet B (UVB) irradiation. UVB sunlight exposure, rather than diet, has been reported as the main source for the majority of the population.[27] Participants were advised to take sun bath morning between 7.30 and 8.30 am and evening at 5.00–6.00 pm for 20 min, as a part of their daily routine. This could help in improving the immune status of the participants.

Whereas, Control group was only under standard ART care along with lifestyle counseling provided at the ART center, Sathara.

Parameters studied

The outcome measure was a change in the CD4 count. CD4 counts were measured for both intervention arm and control arm at the baseline and at the end of 6 months by using Alere Determine™ an immunochromatographic test at Sathara ART center.

STATISTICAL ANALYSIS

A paired t-test conducted within the group has shown significant changes in the interventional arm (p=3.96E-05) and control arm (p= 0.024). An independent t-test between the groups has shown that the intervention arm was more significant (p=0.047).

RESULTS

The trial profile is depicted in Figure 1.

Assessments were done using SPSS statistical software, version 20.0. A parallel matching was done for both the groups. Both the groups constitutes of 9 males (45%) and 11 females (55%). The other characteristics are shown in table 1.

Table 1. Summary of patient data at the baseline

Characteristics	Intervention arm (n = 20)	Control arm (n = 20)
Age (Years)	34.75 ± 5.4	34.65 ± 9.1
Males/Females Ratio	11/9	11/9
Average years of infection	4.7 ± 1.3	4.8 ± 1.9
Baseline CD4 count	271.85 ± 133.58 cells/mm3	297.7 ± 146.6 cells/mm3

DISCUSSION

HIV is a disease which encompasses lot of social stigma. ART, the gold standard care available, has been reported to have versatile patient attrition owing to factors like costs associated with the treatment, fear of side effects, long-term

harm to the body and perceived burden of being on life-long treatment.[28] The present study suggests that naturopathy and yogic interventions when used along with ART can enhance the CD4 cells count. This also shows that complementary medicine may have a role to play in the HIV care as it can reduce the drug dependency, but this fact has to be validated. Health homes like HIV sanatorium provides the patient to cultivate his multiple planes of being, as naturopathy by definition itself states that it treats person as a whole.[5] Previous studies from this sanatorium also has reported that naturopathy and yogic interventions has an affirmative effect on the CD4 counts [29] as well as quality of life.[6] But those studies lack control group which is a major limitation. To our knowledge this is the first study comparing naturopathy and yoga interventions with ART as an adjuvant therapy. However we have not made any attempt to study the subjective changes. Randomization also was not sought for which is another limitation of this study. Future studies should include larger randomized samples to draw more irrefutable results.

CONCLUSION

Naturopathy and yogic interventions as shown in this study enhance the effects of ART when used as an adjuvant therapy which suggests that (1) it can be safely and effectively employed in treatment regimen of PLWHA; (2) there is increase need of health sanatoriums like NINs HIV sanatorium which reshapes the mental, physical, moral and social planes of being altogether.

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