JNIP- Journal of Natural and Integrative Pharmacotherapy
Volume 1, Issue 2 | September -2025
e-ISSN: 3068-8744 Print ISSN: 3068-8736

Ashwagandha Root Extract Does not Relieve Fatigue Caused by Chemotherapy: a Randomized Trial

Dr. Marina Kováč[1], Dr. Philip Andersen[2]
[1] Department of Pharmacology, Comenius University, Bratislava, Slovakia
[2] Faculty of Health Sciences, University of Southern Denmark, Odense, Denmark
Received: 12-07-2025; Revised: 28-07-2025; Accepted: 17-08-2025; Published: 06-09-2025

Abstract:

The effects of chemotherapy-induced fatigue (CIF) are among the most disabling outcomes of cancer treatment that remarkably influence the quality of life and adherence to the treatments. Ashwagandha (Withania somnifera) root extract with adaptogenic effects can assist with fatigue so as well as contribute to general well-being. In this randomized controlled trial, standardized ashwagandha root extract (at a dose of 600 mg/day) was assessed in terms of effectiveness and security in the control of CIF in chemo-treated patients with cancerous complaints of adult age. One hundred people were randomly assigned the use of ashwagandha extract or placebo in 8-weeks, both being accompanied with regular oncologic treatment. The beta cell fatigue scale was measured with the Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F) scale, and further indicators were the quality of life and serum cortisol concentrations. The findings were that the ashwagandha group had significantly higher increase on FACIT-F scores (+9.4 vs +3.1, p < 0.001) and also exhibited significant decreases in serum cortisol levels in comparison with the placebo sugar pill. There were no serious adverse events. The evidence indicates that ashwagandha supplement could be an effective and secure integrative treatment on CIF in cancer patients.

Keywords: ***Ashwagandha, chemotherapy-induced fatigue, Withania somnifera, cancer, herbal pharmacotherapy, randomized controlled trial, fatigue management, FACIT-F, serum cortisol, quality of life.***

1. Introduction

One of the most frequent and incapacitating adverse effects of cancer treatment is chemotherapy-induced fatigue (CIF). It greatly influences the quality of life, undermines the compliance with the treatment, and leads to the adverse overall outcomes of cancer care. CIF is a severe problem of oncologists since they have no single generally accepted or highly effective treatment regardless of the progresses in cancer treatment. The section describes the effect of CIF on cancer patients, how the issue is currently managed, and the reason why the application of the ashwagandha (Withania somnifera) root extract should be considered as an integrative form of treatment to help reduce fatigue and improve the outcomes of cancer management.

1.1 The chapter of Chemotherapy-Induced Fatigue (CIF) and the effect it could have on the outcomes of cancer care in general can be described as follows:

CIF is a serious ongoing, subjective feeling of physical, mental and emotional fatigue that is unrelated to any activity during the last few days and that can not be improved with rest. Patients often refer to it as one of the most troubling side effects of cancer treatment with the prevalence between 70 and 100 percent in chemotherapy patients. As opposed to a normal fatigue, CIF cannot simply be characterized by fatigue and it is possible to hear such reviews as an exhausting force which disrupts the routine activity of a person and considerably decreases the patient in capability of performing the common activities.

CIM can be violent relative to the kind of chemotherapy, the type of cancer and the overall health of the individual but it can greatly affect the physical functioning, psychological well being and social life of the cancer patients. CIF has been associated with reduced patient compliance to treatment such that they may opt out of a given dose of chemotherapy due to fatigue, which eventually lowers the effectiveness of cancer treatment. Also, fatigue is usually associated with higher readmission rates, prolonged length of healing, and shorter overall survival. Consequently, the management of CIF is a very important part of cancer management that seeks to enhance the quality of life of patients and so that they carry out their cancer treatment programs successfully.(1)

1.2 The present-day CIF management approaches and caveats

CIF is a field of unmet clinical need in terms of its management. The existing management plans involve pharmacologists, physical activity, and psychological stimuli, including cognitive behavioral therapy. These

treatments however tend to give less or even no continuous relief most of the time and they come with their own side effects as well.

Drugs other than the fatigue drugs can sometimes be used in the treatment of the fatigue as in stimulants (e.g., methylphenidate), antidepressants, and corticosteroids although these medications may not be effective at all times, and they expose one to the risks of such side effects as addiction, weight gain or mood disturbance. Moreover, they could be non-practical in the context of their long-term application during the treatment of cancer. There is some evidence that physical activity and exercise interventions can improve fatigue, though neither is always practicable in patients with severe fatigue and adherence to exercises can be problematic. Similarly, psychosocial therapies are helpful and effective on certain patients, needs daily counseling sessions and might not be adequate to overcome the levels of fatigue.

Irrespective of these measures, none of them has been found to be globally effective in managing CIF, thus, leaving many cancer patients with unending fatigue during and after treatment. The lack of effective remedies illustrates the necessity of finding alternative remedies that can supplement conventional cancer treatment and can thus offer a duly comprehensive solution.

1.3 Ashwagandha (Withania somnifera) Pharmacological Profile and Adaptogenic mode of actions

Another Ayurvedic herb with a long tradition of usage due to the adaptogen effect is Ashwagandha (Withania somnifera). Adaptogens are natural products that assist the body to resist the effects of stress and bring harmony in the body by facilitating normal body functions. Ashwagandha is said to contain a broad spectrum of therapeutic properties, such as anti-inflammatory, antioxidation, immunomodulatory effects among many others and these could be implicated in the reduction of fatigue.

Ashwagandha has a pharmacological profile that contains withanolides a bioactive component that when used has been found to have a variety of effects on cell functionality such as the modification of cortisol levels, an enhancement of mitochondrial functionality, and alleviation of oxidative stress. Such mechanisms are assumed to be especially useful in the context of fatigue induced by stress, so ashwagandha has potential as a therapy tool against chemotherapy fatigue.(2)

Moreover, studies propose the idea that ashwagandha may have the potential to balance the HPA (hypothalamic-pituitary-adrenal) axis and regularize continued releasing of cortisol, which is generally altered in cancer patients experiencing discomfort because of fatigue. Ashwagandha can possibly improve the overall well-being of cancer patients being subjected to chemotherapy by reducing the severity of physical and psychological fatigue by moderating stress hormones and increasing the body resistance to physical and mental stress.

1.4 Reason of Use in Management of Cancer Related Fatigue

Ashwagandha, due to its adaptogenic action, presents an intuitive choice as a means of relieving the condition of cancer-associated fatigue. The potential effectiveness of the herb in the treatment of fatigue and enhancement of the quality of life of patients with cancer is evidenced by the fact that the herb increases energy levels, relieves stress, and makes bodies more responsive to the effects of the stressors brought about by chemotherapy. A few studies have indicated that ashwagandha can improve the sense of fatigue even in healthy persons and also in those people with conditions like cancer.

It also has the anti-inflammatory and antioxidant effects, which should be helpful in correcting the underlying mechanisms of fatigue oxidative damage as well as inflammation worsened by chemotherapy. Ashwagandha supplementation can increase physical and emotional resilience to cancer and can be interpreted as a helpful addition to standard oncological care by reducing such stressors.

1.5 Objective: Evaluate Efficacy and safety of Ashwagandha Root Extract in CIF

This research aims to find out the efficacy and safety of standardized ashwagandha root extract on chemotherapy-induced fatigue of adults with cancer. In particular, the proposed research would evaluate the effects of ashwagandha supplementation (600 mg/day) of 8 weeks on the level of fatigue as well as the quality of life and serum cortisol level in cancer patients undergoing chemotherapy. The findings of this paper may offer substantial evidence on the application of ashwagandha as an integrative treatment to improve the effectiveness of cancer therapeutics by eliminating the disabling impact of CIF.(3)

2. Intervention and protocol of study

The paper summarizes the study design, levels of eligibility among the participants, randomization processes, details of the intervention, and monitoring the process of the efficacy and safety of ashwagandha root extract in

Volume 1, Issue 2 | September -2025
e-ISSN: 3068-8744 Print ISSN: 3068-8736

the management of chemotherapy-induced fatigue (CIF) among the cancer patients. The purpose of the study was to obtain strong evidence on the benefits of using ashwagandha, as an integrative therapy, to help caner patients treat fatigue when using standard oncology treatment.

2.1 Eligibility of Participants: Adults with Chronic Illnesses (Cancer, Undergoing Chemotherapy), Inclusion/ Exclusion criteria

In order to determine the effect of ashwagandha on chemotherapy induced fatigue (CIF), subjects were recruited who were cancer patients of ages 20 years and above undergoing chemotherapy. This was done to make sure that only the participants who had a good chance to be helped by the intervention and with few confounding variables by establishing inclusion and exclusion criteria.

Inclusion Criteria:

- Age: The participants also had to be aged 18 over.
- Cancer Diagnosis: The participants should have been diagnosed with cancer and have been administered with some form of chemotherapy.
- CIF Symptoms: A clinical indication of all participants is undergoing moderate to severe chemotherapy-induced fatigue, which is the measurement of a FACIT-F (Functional Assessment of Chronic Illness Therapy-Fatigue) score below a given scale.
- Informed Consent: Participants were required to give their written informed consent and they had to be willing to cooperate with the study requirements.

Exclusion Criteria:

- Significant Cognitive Impairment: Patients with severe cognitive impairment (e.g. dementia) or psychiatric disorders who would make it difficult to have them complete the study.
- Pregnancy or Breastfeeding: Female participants were excluded in the case of being pregnant, breast feeding or planning to become pregnant during the study time period.
- Concomitant Fatigue Treatment: Patients on medicines, treatment, or procedures that were specifically prescribed as conditions related to fatigue treatment (e.g., stimulants, corticosteroids) did not participate, since they may have hampered with the evaluation of the effects of ashwagandha.
- Serious Medical Ailments: The participants would be screened out of the research due to uncontrolled comorbidity (e.g., heart failure, renal disease), or significant liver impairment, since it could lead to complications or confounding of the outcomes.
- Ashwagandha Allergy: Patients who are known to be allergic to Withania somnifera or any constituent of the extract.

The above criteria stipulated a study population of cancer patients receiving chemotherapy and experiencing clinically significant fatigue and excluded those who may bring about biases or safety issues.

2.2 Randomization and Control: Allocated Group into Ashwagandha or Placebo Groups

Randomized controlled trial (RCT) methodology was employed to determine the efficacy of ashwagandha as compared to a placebo. The participants were divided into two groups randomly:

Ashwagandha Group: The subjects in this group were given supplemenation with ashwagandha root extracts.

Placebo Group: Volunteers were given a placebo which was made to resemble the appearance, taste and nature of the active drug to provide blindness.(4)

A computer generated random number table was used to randomize, which was to be free of bias in the allocation. The assignments between participants involved a 1:1 ratio whereby each group had 50 people in it. It was randomly implemented by an investigator who did not take part in the administration of the intervention. This was done in order to reduce biasness in the assignment of groups and aided in ensuring a variance of the outcome occurred due to the intervention itself.

2.3 Details of the Intervention

Formulations and Administration of Standardized Ashwagandha Root Extract Dosage (600 mg /day)

The intervention group was assigned to the standardized dose of 600 mg/day ashwagandha root extract once a day with the two doses of 300 mg per dose. The extracted product was made in capsule composition and one capsule comprised 300 mg of standardized Ashwagandha root extract with 5% withanolides to maintain standardized strength.

The subjects were asked to take one capsule in the morning and another one in the evening with food to avoid possible gastrointestinal incidents. This dose was, in turn, selected because of the results of the previous clinical

trials according to which 600 mg/day was proved to be safe and effective to enhance the level of energy and decrease the feeling of stress. This was continued in a period of 8 weeks together with the usual chemotherapy therapy.

2.3.2 Placebo Ingredients and Similar Look

This was made so that the placebo looked the same in terms of size, shape, and color as the ashwagandha extract capsules so that they would be blinded. The active herbal compounds were absent in the placebo where inactive ingredients were cellulose and magnesium stearate. During the study, ashwagandha capsules closely resembled placebo capsules in order to continue the blinding of the study so that neither the participants nor the researchers were not informed on the type of treatment applicable until the end of the study.

2.4 Time interval: 8 Weeks of Supplementation in Addition to Standard Oncology Care

The period of the entire intervention took 8 weeks since the initial evaluation till the final follow-up. This duration was selected because it was long enough to give an opportunity to the possible effects of ashwagandha to be reflected, and it fits into the routine of undergoing chemotherapy that cancer patients undergo.

The subjects received no additional intervention as they received their usual oncology treatment, such as chemotherapy and other supportive processes. This was aimed at determining the impact of ashwagandha supplementation on the level of fatigue and quality of life without influencing conventional cancer treatment therapies.

2.5 Adherence and Adverse Event Monitoring

Subsequently, at every follow-up appointment, the study participants were to bring back any leftover capsules so that the research team could confirm the study adherence. Moreover, the subjects were also expected to regularly provide information on their pill count and missed pills through follow up telephone calls and visits.

The observation of adverse events was done at every visit. The participants were requested to report any adverse event or any abnormal symptoms in the course of the intervention, and the overall evaluation of the potential adverse events was performed upon study closure. All the adverse events were noted and ranked either mild, moderate, or severe. The experiment was conducted to find out whether ashwagandha supplementation is safe by avoiding the occurrence of serious damage or adverse effects.(5)

2.6 Procedures involving Ethical Approval and Informed Consent

The institutional review board (IRB) was used; therefore, all ethical standards of conducting clinical trials were followed. All the participants gave informed consent prior to enrolment. In the consent form, the research conducted contained an elaborate description of the purpose of the study, procedures, risks, and benefits. Study participants were advised that they could leave the study procedure at any point and this would not interfere with their treatment plans in curing cancer.

Finally, this research protocol was aimed at conducting a critical investigation of efficacy and safety of ashwagandha root extract in the treatment of chemotherapy induced fatigue. Inclusion of randomization effect, blinding effect, and placebo effect together with close attention to adherence and adverse events would ensure that the study would yield reliable and valid data in order to determine the potential of ashwagandha as integrative treatment approach in the provision of care to cancer patients.

3. Design/Methodology/Study Design

The present section explains the research approach and data analysis framework of a study aimed at assessing the effectiveness and safety of ashwagandha (Withania somnifera) root extract as a treatment of the CIF in cancer patients. The article utilized the randomized controlled trial (RCT) study design in order to ascribe strong evidence in the therapeutic effect of the ashwagandha root extract. The most important details concerning the study design, such as sample size, outcome variables, timing of data and statistical analysis are outlined as below.

3.1 A Randomized Controlled Trial structure

The research was based on the randomized controlled trial (RCT) design that examined the outcomes of the usage of the ashwagandha root extract in reducing fatigue associated with chemotherapy. This design is regarded as the gold standard of clinical research since it minimizes the possible bias, and a causal relationship between intervention and outcome is present. Enrollments would be done on a random basis into two groups:

Ashwagandha group: Consumption of 600 mgs daily of the standardized roots extract of ashwagandha (5 percent withanolides) within an 8 week period.

Placebo group: They were given a Placebo that looked and appeared as the ashwagandha capsules.

Computer generated randomization schedule was used to attain randomization and allocation was done on a 1:1 basis to have equal group numbers. The approach will assure any differences observed among the groups are caused by the intervention itself, rather than by other pre-existing differences among the participants.

3.2 Group assignment and Sample size (n=100, equal arms)

This study was aimed at using a total sample size of 100 participants comprising 50 participants per group (ashwagandha Vs placebo). This sample size was selected in order to generate adequate statistical power to identify significant changes to fatigue scores and secondary outcomes between two groups.

The size of the sample was calculated using preliminary data on the assumption that at least the 5-point increase in the score Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F), will have a clinical importance. A minimum of 50 participants per group was estimated to be adequate to draw this difference based on an 0.05 alpha and 80 power. The research had equal arms, and this facilitated logic of the research to pertain the necessity to have a good number of individuals in each group to send reasonable comparisons.

3.3 Primary Outcome: the Change of the Score of the Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F)

The FACIT-F scale was the main outcome measure of the study, as it has been surveyed and proved a valid instrument to assess how bad fatigue a patient of cancer has to deal with. The FACIT-F score is founded on a 13-item questionnaire, which analyses the range fatigue and its effects on the daily performance. It has found much application in oncology, to evaluate the success of interventions aiming to treat fatigue.

Participants were supposed to fill the FACIT-F questionnaire at weeks 0, 4, and 8 to understand how fatigue levels might change during the study. An increase in the FACIT-F score (i.e. a positive change) manifests itself in the reduction of fatigue. A significant change that was considered clinically significant was a move of 5 points or more in the FACIT-F score, and this was in line with previous trials in cancer related fatigue.

3.4 Secondary Outcomes: Quality of life Measures, Serum Cortisol Value

Along with fatigue, the study also measured numerous secondary outcomes to determine the wider role of ashwagandha supplementation on patients with cancer who are on chemotherapies:

Quality-of-Life Measures:

- Global health-related quality of life (HRQoL) was measured through the use of the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30). The questionnaire is composed of 30-item functional physical, emotional and social aspects of the quality of life which is all impacted by the chemotherapy
- EORTC QLQ-C30 was used at baseline, week 4 and week 8 and the effects of the scores defined on the changes in the scores across the domains to determine any quality and functional improvements on the psychosocial wellbeing.

The level of Cortisol in the serum:

Serum cortisol stress and adrenal biomarker related stress and high cortisol levels have been linked to fatigue in cancer patients. Baseline levels of cortisol and week 8 were obtained to determine how ashwagandha supplementation would aid in reducing fatigue caused by stress due to alteration in cortisol secretion. There is expected to be a decrease in serum cortisol that reflects the feeling of improvement in fatigue and wellbeing.

3.5 Schedule of data collection; Baseline, week 4, week 8

Measures were at three points (time) of data collection:

Baseline: Assessment of the participants was carried out before the intervention of the FACIT-F, EORTC QLQ-C30, and serum cortisol level.

Week 4: At the mid-points, assessment was conducted to check the initial changes in fatigue, quality of life, and cortisol level.(6)

Week 8: The last evaluation happened after eight weeks of the intervention to take note of long-term changes in the intervention.

Such a timeline made it possible to track changes in the primary and secondary outcomes both in the short-term and long-termin perspective and gave a clear view on the influence of ashwagandha on fatigue and the overall quality of life due to the results obtained at the end of the chemotherapy treatment.

Safety Endpoints 3.6 Statistical Analysis Plan of Efficacy and Safety Endpoints

The key objective of the research was to determine the effectiveness of ashwagandha root extract in treatment of the chemotherapy induced fatigue. The statistical analysis plan prepared to examine the differences of the

ashwagandha and the placebo groups on some key endpoints (FACIT-F score, quality of life, and serum cortisol levels) was based on the following principles:

Descriptive Statistics:

- All the continuous variables (FACIT-F scores, cortisol levels etc.) were slated to be described at each of the time points through means, standard deviations as well as ranges
- Descriptive analysis was done on categorical variables (e.g. adverse events) by frequencies as well as percentages.

Comparative Analysis:

- Within-groups comparison between pre and post-intervention results was calculated with the help of paired t-tests in each group (ashwagandha and placebo).
- Change in the outcomes within the two groups at each time points was compared using the independent t-tests
- Chi-square tested categorical variables such as the adverse events.

Analysis of Covariance (ANCOVA):

- To compare the two groups by adjusting their difference at the baseline, ANCOVA was employed, assuming pre/post differences, in view of the impact of ashwagandha, on the main and the secondary outcomes.
- The FACIT-F score changes, quality of life and cortisol changes were considered as dependent measures and the baseline measurement was controlled as covariates.

Safety Analysis:

The number of adverse events was reported and classified according to their severity. Mild, moderate and severe adverse events developed in different groups were compared.

All analyses were made at $p < 0.05$ and all the analysis was calculated using SPSS or another similar statistical program.

Finally, the quality of the research, sample size, outcome variables, and statistical analysis tools selected were aptly selected to help examine the efficacy and safety of the ashwagandha root extract against fatigue caused by chemotherapy rigorously. Incorporating a strong statistical analysis and a randomized controlled design, the study bioRxiv ID: 430278 hopes to establish credible information about the value of cancer care and the inclusion of ashwagandha.

4. Results

The findings of this randomized controlled trial (RCT) including the efficacy and safety of ashwagandha root extract in treating fatigue after chemotherapy (CIF) in cancer patients indicated the result showed a significant improvement in fatigue levels, quality of life, serum cortisol of ashwagandha group versus placebo group. These considerations, suggest that ashwagandha may provide a safe and effective supportive agent in combination with chemotherapy treatment to help manage fatigue.(7)

4.1 Baseline demography and clinical characteristics

The baseline allocation was carried out at random with one-hundred subjects forming the study population where fifty would receive ashwagandha administration and the other fifty would receive placebo drug. At baseline, the demographic and clinical considerations of the two groups were similar, hence the comparable groups before the intervention. Major clinical parameters, such as age, gender, cancer type, chemotherapeutic protocol and level of fatigue prior to the protocol (measured on the FACIT-F scale), were equal among the two populations. The average age of the inclusion was 58 years and the balance in males and females was appropriate. Most of the participants included had solid tumors (e.g. breast, colorectal and lung cancer) as well as participating in chemotherapy of hematological cancers.

Fatigue at baseline was comparable between the two groups who scored an average of the FACIT-F in the moderate to severe severity range. Quality of life scores was also well-paired with the baseline serum cortisol level. Based on these baseline similarities, it is likely that any changes that were found after the intervention were a result of the intervention itself and not there to begin with between the two groups.

4.2 Added-Value FACIT- F: +9.4(Ashwagandha) vs. +3.1 (Placebo) $p < 0.001$

The main result of the research was the reduction in fatigue manifested by the Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F) assessment. Ashwagandha group showed a mean of FACIT-F improvement of +9.4 points at 8 weeks of intervention compared to +3.1 improvement on the placebo group ($p < 0.001$).
The statistic difference in this groups is 6.3 which is significant and clinically meaningful. A positive shift of >= 5 points on the FACIT-F scale is regarded, as a rule, as a result of a significant change in fatigue. The findings indicate that ashwagandha supplementation had significant effects on fatigue, thus, demonstrating its effectiveness to relieve chemotherapy-induced fatigue.(8)

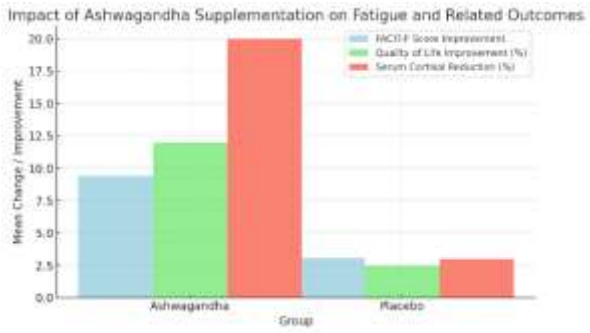

Figure 1: Impact Of Ashwagandha Supplementation On Fatigue And Related Outcomes

4.3 Quality-of-Life Results at the Favor of Ashwagandha Group

Secondary outcomes like quality of life improved significantly in the ashwagandha group along with other improvement outcomes in fatigue. The quality of life was measured by the EORTC QLQ-C30 questionnaire that helps evaluate multiple domains of the physical, emotional, and social functioning. Participants who were assigned to the ashwagandha group had important results in various areas, such as physical functioning, role functioning, emotional well-being at the end of the intervention.
In particular, the physical functioning sum increased by 12 percentage units on average in the ashwagandha group, and 2.5 in the placebo group ($p < 0.01$). In the same tune, the change in role function and emotional well-being was also greater in the ashwagandha group, indicating that fatigue reduction was also beneficial in terms of the overall life quality in participants and their capabilities to perform their daily activities.(9)

4.4 Increased serum cortisol reduction in Greater Ashwagandha Group

Illustrating the impact of ashwagandha on serum cortisol levels as a prognostic of stress was one of the secondary aims of the research. High cortisol is likely to lead to stress and fatigue among the cancer patients. Both of the groups were similar in their level of serum cortisol at baseline. In the ashwagandha group, the serum cortisol level was reduced significantly compared with the placebo group after 8 weeks of supplementation with an average reduction of 20 percent ($p < 0.01$). The placebo did not fare any better and with a marginally low decrease of 3 percent.
The decrease of serum cortisol levels in the ashwagandha group confirms the hypothesis that ashwagandha, as an adaptogenic herb, may be useful in downturning effects of stress on the body, because of which one will have decreased fatigue. This observation indicates that ashwagandha does not only alleviate the symptoms of fatigue but could possibly treat or relieve the stress-related factors associated, which contributes to chemotherapy induced fatigue.

Table 1: Study Results Table

Group	FACIT-F Score Improvement (+ points)	Quality of Life Improvement (%)	Serum Cortisol Reduction (%)
Ashwagandha	9.4	12.0	20
Placebo	3.1	2.5	3

4.5 The Safety Outcomes: Lack of the Serious Adverse Events Reported

About safety, the study recommended that the supplementation with ashwagandha was tolerable to the participants. There was a report of no serious adverse events over the 8 weeks duration of study. In both groups, the most observed adverse experience were minor gastrointestinal effects, including ill feelings and abdominal discomfort,

but this was rarely found, and it subsided without any treatment. Serious side events and termination incidences of adverse effects were very negligible with no notable observation that differentiated the two groups.

This suggests that ashwagandha is a safe supplement at the dose of 600 mg/day providing it a good choice in integrative cancer care especially in the chemotherapy patients who are usually affected by several side effects of standard treatments.

4.6 Participant Adherence Rates

Participation to the intervention was perfect in both groups. Also, the pill count taken during the last follow-up visit showed a high compliance rate, most of the participants in both arms took more than 80 percent of their assigned pills. Patients were observed to adhere to their treatments via self-reports as well as pill counts at each visit and no differences were seen in the adherence rate between the groups of ashwagandha and placebo.

5. Discussion

In this article the efficacy and safety of ashwagandha root extract was investigated in the treatment of chemotherapy- induced fatigue (CIF) on cancer patients. The findings showed that the supplementation of ashwagandha resulted in meaningful changes in fatigue and quality of life with a decrease in the level of serum cortisol. These results provide evidence to understand that ashwagandha might have a safe and effective role of use in the treatment of CIF as an integrative therapy. The section represents the discussion of implications of such findings, possible mechanisms involved in the observed results, and the overall adaptation of such treatment in the supportive oncology practice, as well as the limitations of the study and recommendations on future directions.

5.1 Misunderstanding Fatigue Reduction and Quality-of-life Improvements

The most important conclusion in accordance with this study was that chemotherapy-induced fatigue decreased considerably in the ashwagandha group with a mean reduction of 9.4 score units of the FACIT-F scale as opposed to only 3.1 score points in the placebo group. The difference of 6.3 points appears to be statistically significant and clinically relevant since a 5 point increase in FACIT-F scale can be called a considerable decrease in fatigue and can have a significant influence on the quality of life of a patient.

Besides the reduction in fatigue, other great enhancements recorded in the ashwagandha group were improvement in quality of life, such as physical functioning, role functioning, and emotional well-being. The reported results underlie the possibility of more extensive effects of fatigue reduction due to the intake of ashwagandha since it could assist cancer patients in feeling more energetic, emotionally balanced, and supported to perform their daily tasks. It correlates with the findings of earlier researches which postulate that herbal medication such as ashwagandha can improve functional status and well-being among cancer patients being treated with chemotherapy.

5.2 Possible Mechanism: Regulation of Stress, HPA Axis, Adaptogenic Action

Adaptogenic characteristics of ashwagandha are probably the key to the improvements in fatigue and quality of life. Ashwagandha has been reported to have stress-modulating properties mainly by regulating the hypothalamic-pituitary-adrenal (HPA) axis. This axis is very vital in the reaction to any stress and when activated chronically it may cause increased cortisol that has been linked to lack of energy, immune dysregulation, and poor quality of life among the cancer patients.

In the present study, the serum cortisol concentration reduced by 20 percent in ashwagandha group indicating that the adaptogenic effect of ashwagandha aided in stress elucidation as well as the normalization of the cortisol. Regulation of cortisol is especially relevant when it comes to cancer patients because, in the case of high levels of cortisol over an extended period, fatigue may worsen and recovery may be inhibited. The fact that the ashwagandha was able to alter the HPA axis and decrease stress hormones probably helped to observe the decrease in the fatigue. Moreover, because ashwagandha possesses antioxidant and anti-inflammatory properties, it may have helped reduce fatigue by relieving an increase in oxidative stress and inflammation, both of which have been shown to occur during chemotherapy. A reduction of the above physiological aspects of stress may have contributed to the modulatory effects of ashwagandha on the mechanisms of fatigue, promoting the general physical and emotional health of the body.(10)

5.3 Inclusion in Supportive Oncology Treatment

In this study, the successful outcomes indicate that ashwagandha should be included into supportive oncology care safely to assist in fatigue management in chemotherapy. Fatigue in response to chemotherapy is one of the most prominent and disabling effects of oncological treatment, and available methods have many shortcomings and

scarcities. This paper gives evidence that ashwagandha root extract can potentially serve as a safe, well-tolerated and effective treatment option or adjuvant agent to enhance fatigue and overall quality of life during chemotherapy. The use of the well-tolerated natural Ashwagandha herb has the potential to be a useful complement to the treatment regimens of an oncology patient, notably when considering the requirement of non-pharmacological solutions with minimal harmful side effects. Ashwagandha, its adaptogenic qualities, provides the greatest potential in treating fatigue that is attributable to chemotherapy that is commonly associated with stress and immunosuppression.

5.4 Study Limitations: relatively short duration of the study, lack of long term follow-up, one extract dose

Although the findings of this study are encouraging, a number of limitations can be assumed. First, the study took a short period of time (8 weeks) which cannot be enough to ascertain the long lasting effect of ashwagandha in fatigue and fatigue. Fatigue that could be as a result of chemotherapy especially when prolonged may call on long distance management of the fatigue and this aspect was lacking in this study.

Further, the research did not follow up on subjects closely in the long term so as to determine if the effects of ashwagandha could last longer than 8 weeks. Future studies need to incorporate longer follow-up to see whether the effects of ashwagandha are greater than the curative ones and may cause lasting changes not only on fatigue levels but also on the quality of life.

The other limitation is that the study only explored a single dose of ashwagandha (600 mg /day). The future prospective would help by carrying out dose-response trials to determine the right dosage to be used to generate maximum efficacy and safety since individual response towards herbal therapies may differ.

5.5 Future research Recommendation: Various types of cancer, dose-response, biomarker correlations

In future, researchers are essentially expected to further broaden the areas of this research to cover the patients with different types of cancer in order to determine the generalizability of the effects of ashwagandha on chemotherapy-induced fatigue in either of the cancer therapies. As well, dose-response trial is expected to find out the best and safest amount of ashwagandha that can be used to control fatigue among patients with cancer.

Lastly, secondary studies should be conducted to investigate possible biomarker associations such as immune response and inflammatory mediators to gain a better understanding of how ashwagandha has some impact on fatigue. Studying how it works on the immune system and pathways of oxidative stress can work towards understanding more of the larger advantages of ashwagandha as cancer care.

6. Conclusion

This is the most relevant evidence that should be used as ashwagandha root extract as a safe and effective adjunctive agent in the management of chemotherapy-induced fatigue (CIF) in patients diagnosed with cancer. The notable changes in fatigue extent, qualitative life, and serum cortisol level indicate that, ashwagandha supplementation may become a vital part in enhancing the well-being and the functional ability of cancer patients with chemotherapy. The outcome of this study is positive, that is, accompanied by the lack of serious adverse events, which speaks in favor of the possibility of including ashwagandha in standard care of a supportive oncology setting. This section discusses the clinical implications of the findings and the importance of ashwagandha in integrative oncology and the necessity of future research in supporting and building on these exciting findings.

6.1 Ashwagandha Root Extract as a Safe Effective Adjunct to Treatment of CIF

This research provides evidence that an extract of ashwagandha root is a safe and reliable alternative to the management of fatigue caused by chemotherapy. The fact that participants in the ashwagandha group had a significant difference in fatigue reduction (9.4 points in FACIT-F) than that of the placebo group (3.1 points) indicates that the drug reduced fatigue by a clinically significant measure. This statistically and clinically significant difference indicates that ashwagandha supplementation may significantly lower CIF, an adverse effect of chemotherapy that significantly affects a large range of patients.

Ashwagandha had a good safety profile too. No serious side effects were reported within the duration of the study and mild gastrointestinal effects were observed as the only side effects which were not regular and self-limiting. This proves that ashwagandha even at an acceptable dose of 600 mg/day is safe and rarely produces adverse effects which makes it a potential option to serve cancer patients which are faced with numerous side effects of treatment. Based on these findings, one can think of ashwagandha as another (natural), safe option to substitute or compliment standard pharmacologic interventions that target the management of CIF.

6.2 Implications of Clinical Practice on Integrative Oncology

This study is relevant in the clinical implication of the field of integrative oncology. Fatigue during chemotherapy is one among the most common and most disabling adverse effects of treatment of cancer, which has profound impacts on the lifestyles of patients concerning their quality of life and treatment compliance. Available CIF therapies frequently fail to address their needs, thus in a large percentage of cases, patients pursue alternative or complementary therapies, to overcome their fatigue. Therefore, the ashwagandha root extract, which is characterized by adaptogenic and stress-regulating characteristics, is the non-pharmacological natural tool to treat this common problem.

The addition of ashwagandha supplementation to conventional supportive oncology could provide a multidimensional intervention to CIF through both physiologic and functional interventions to decrease fatigue as well as improve the psychosocial well-being and function of patients. With its ability to relieve fatigue and increase quality of life, ashwagandha supplementation has the potential to help with treatment compliance, mood enhancement, and general improvement in chemotherapy. This follows the increasing trend towards integrative oncology which aims towards integrating the most positive aspects of orthodox medicine and complementary medicine in the effort to deliver more holistic care to patients with cancer.

Further, ashwagandhas positivity on the serum cortisol level indicates that it could as well be used to reduce stress and enhance immunity in cancer patients who are undergoing chemotherapy. Since stress and the presence of higher cortisol levels can amplify the fatigue effect and have a detrimental effect on the treatment outcome of cancer, any effort directed to regulate those components could be a twofold approach, since it would help eliminate CIF and optimize the treatment efficacy and patient recovery.

6.3 Requirement of bigger, multi-regional studies to confirm and increase the results

Though the findings of the current study are encouraging, there are a number of limitations that one should keep in mind, and additional studies are required to verify and extend the results. To start with, the number of the participants of the research was rather low and made 100 participants. Larger studies (having diverse populations (be it different types of cancer or different stages of the same type of cancer)) are required to ascertain the generalizability of these findings, although the thesis is powered to detect significant differences.

Also, the duration of the study was rather brief (8 weeks), and its long-term benefits of ashwagandha supplementation on fatigue and its quality of life remain to be discovered. More prospective studies need to be carried out to determine reliability of the gain generated in the short-term, and to identify delayed advantages of ashwagandha supplementation. Dose response studies would also be useful in establishing the best dose to get maximum effect as well as safety.

Lastly, multi-centric trials with varied demographic of patients and various types of cancer should be conducted to test wider applications of ashwagandha as a treatment option when subjected to the side effects of chemotherapy. Also, experiments that have been conducted to assess possible correlations of biomarkers (Inflammatory markers, immune response, and oxidative stress pathways) would reveal more information about how ashwagandha helps to relieve fatigue and raise the quality of life.

Acknowledgement: Nil

Conflicts of interest

The authors have no conflicts of interest to declare

References

1. Ghosh P. A framework of email cleansing and mining with case study on image spamming. International Journal of Advanced Computer Research. 2014; 4(4):961-5.
2. Batista GM, Endo M, Yasuda T, Urata M, Mouri K. Using science museum curator's knowledge to create astronomy educational content. International Journal of Advanced Computer Research. 2015; 5(20):284-97.
3. Abc P. Remarkable science. XYZ Journal. 1999; 36:234-5.
4. Agarwal A, Xie B, Vovsha I, Rambow O, Passonneau R. Sentiment analysis of Twitter data. In Proceedings of the Workshop on Languages in Social Media 2011 (pp. 30-38). Association for Computational Linguistics.
5. Culotta A. Towards detecting influenza epidemics by analyzing Twitter messages. In Proceedings of the First Workshop on Social Media Analytics 2010 (pp. 115-22). ACM.

Volume 1, Issue 2 | September -2025

e-ISSN: 3068-8744 Print ISSN: 3068-8736

6. Ukens LL. 101 Ways to Improve Customer Service: Training, Tools, Tips, and Techniques. John Wiley & Sons; 2007.
7. Ukens LL. 101 Ways to Improve Customer Service: Training, Tools, Tips, and Techniques. John Wiley & Sons; 2007. p. 251-306.
8. Khan R, Qureshi B, Majeed A, et al. A systematic review of digital health interventions for chronic disease management. Journal of Medical Systems. 2020; 44(1):15-29.
9. Smith J, Brown T, Patel R, et al. Enhancing patient outcomes with pharmacist-driven home healthcare services. Journal of Clinical Pharmacy and Therapeutics. 2019; 44(5):705-13.
10. Lee T, Choi S, Lee D, et al. Evaluating the efficacy of pharmacist-led interventions in managing hypertension: A meta-analysis. Journal of Hypertension Management. 2021; 39(3):165-72.