The Effect of White Light on Fatigue Levels in Patients With Gynecological Cancer: A Double Blind Randomized Trial

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STUDY PROTOCOL

Study design and participants

This was a triple-blind randomized study. The study included two parallel groups consisted of 72 patients who met the inclusion criteria and were receiving outpatient chemotherapy for gynecological cancer. The sample size in this study was 72 subjects: 36 in the intervention group and 36 in the control group. This study was based on an effect size of 0.25, a first type error of 5%, and 80% power, relying on the results of a previous study that evaluated the effect of bright white light on the fatigue levels of patients with cancer.[16] Patients aged over 18 years, had a normal state of consciousness, had no communication disorders, did not work in the night shift, had a general fatigue level score of ≥1 according to the Brief Fatigue Inventory(1,2), and could perceive light were included in the study. Patients who had natural/artificial lenses, used medication that causes photosensitivity (tetracycline, doxycycline, nalidixic acid, voriconazole, amiodarone, hydrochlorothiazide, naproxen, piroxicam, chlorpromazine), and had a change in their treatment plan in the last 6 weeks were not included in the study.

A total of 132 women were admitted to the clinic at the time of the study. All of them were evaluated as per the conditions of inclusion criteria. Twenty-five women who did not meet the inclusion criteria and another 12 who refused to participate in the study were not included in the study. Therefore, a total of 89 women, 47 in the intervention group and 42 in the control grou*p*, were included in the study through randomization. However, six women from the intervention group and three from the control group were excluded from the study because of various reasons such as rejecting white light administration, familial reasons, and reaching saturation in stratification according to the fatigue level factor. Thus, the study was conducted

with a total of 72 women with 36 in each group (Figure). Patients and at least one of their relatives were informed about the research process and the use of white light in the patient room, along with visual materials. It was ensured that the informed consent form was ready by the patient and, if necessary, a relative. After obtaining written consent and signatures from the patients, the study was initiated.

Randomization and blinding

The study participants were stratified into intervention and control groups using stratified and block randomization methods, respectively. Firstly, patients who met the inclusion criteria and accepted to participate in the study were stratified according to the severity of fatigue (1-3 points, mild; 4-6 points, moderate; 7-10 points, severe fatigue). For block randomization, at least 10 blocks were selected by random drawing among 20 blocks (permutations block 6 and block of size 3 with 1:1) produced by the researchers on SAS 9.4 (SAS Institute Inc., Cary, NC) software package (3-5). Random assignment was continued until there were an equal number of patients (12 patients in each 3 strata) according to their fatigue levels in each group, and the groups consisted of 36 patients (Figure).

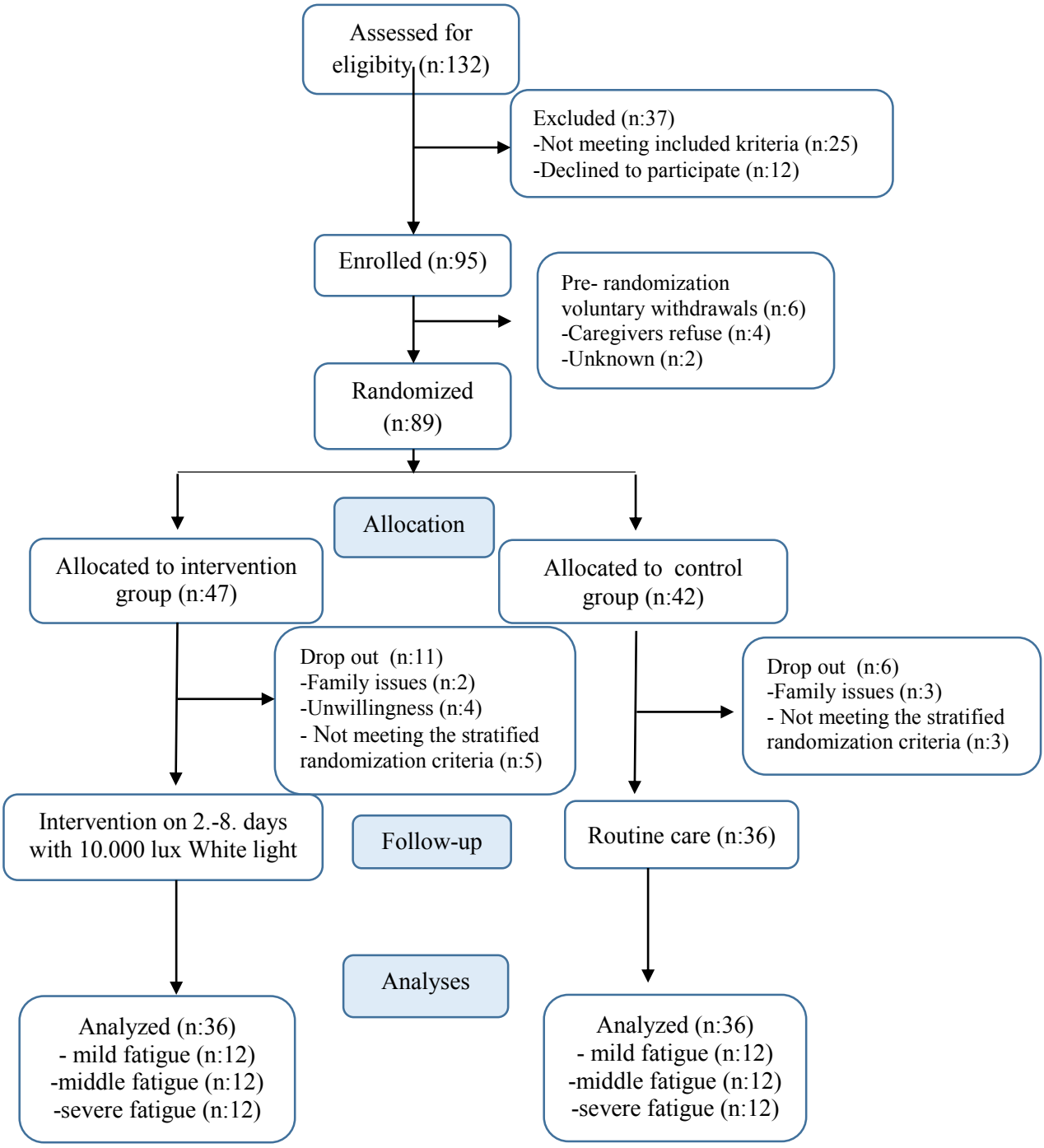

Figure. Diagram of participant flow through study

A researcher among the authors who was not involved in patient care and implementation of interventions evaluated patients for eligibility, enumerated them, collected baseline data, and assigned them to research groups. Moreover, this researcher assigned the research groups at the beginning of the research, the intervention group "A," whereas the control group was coded with the letters "B." Two research assistants (RA) were recruited and trained for this study. Research assistants were two nurses with a bachelor's degree, who were independent of each other and the researchers. The groups to which the patients belonged were reported to the nurses using the appropriate letter code. The first nurse (RA1) who made the interventions to the intervention group. The post-intervention evaluation of the patients in the application and control groups and the entry of the obtained data into the statistics program were made by the other nurse (RA2) who was not informed about the application. Thus, the nurse (RA2) who conducted the evaluations, were blinded. During data entry, coding of the groups was continued. A biostatistician, who was unaware of the purpose of the research, interventions, and groups, performed statistical analysis on the research data. Further, the coding of the groups was terminated by the authors at the end of the analysis. In this manner, double blinding was achieved in the study.

Outcomes and instruments

Observation, interview, and measurement methods were used to collect the data. "Brief Fatigue Inventory (BFI)" and "Descriptive Information Form" were used to evaluate the fatigue level of the patients on the first, ninth, and twenty-first days. The patients' demographic and medical characteristics were obtained from their medical records.

The Descriptive Information Form: This form was used to collect information on the sociodemographic characteristics, diseases, and treatments of the patients.

The Brief Fatigue Inventory (BFI): This inventory was developed by Mendoza et al. (1999) to evaluate the general fatigue level and its effect on activities of daily living in patients with

cancer. The study evaluating its validity and reliability for the Turkish context was carried out by Çınar et al.(2000) Cronbach's alpha internal consistency coefficient of the inventory was found as 0.98. The BFI consists of nine items in total, with three evaluating general fatigue and six evaluating the effect of fatigue on daily life. Individuals rate all items on a scale of "0" (no fatigue) to "10" (the most severe fatigue you can experience), taking into account their status in the last 24 hours. The "general fatigue" level is calculated by taking the average of the first three items of the inventory. The average of the last six items yields a score for the effect of fatigue on the activities of daily living. According to the scores obtained from the BFI, the severity of fatigue of the individual was "0, no fatigue; 1–3, mild; 4–6, moderate; and 7–10, severe fatigue".

Interventions

Descriptive Information Form and the BFI were administered to the patients in both groups on the first day of the application phase, and their baseline assessment was made, which was followed by interventions for energy conservation (organizing the patient's sleep–rest hours, supporting activities of daily living, organizing the living environment, etc.) and energy enhancement (adequate and balanced nutrition). The patients were informed about the study procedure. Between the second and the eighth days of the application phase, the patients in the intervention group were administered a standard white light at 10,000 Lux intensity by an independent nurse (RA1) in their home environment using a Litebook Elite light source (The Litebook Company Ltd., Medicine Hat, AB). The distance between the light source and the patient's face was set at 50 cm, and the intensity of the light for each patient was checked using a Lux Meter. The intervention was applied between 07:00 and 10:00 in the morning for 30 minutes without interruption, and it was continued for seven successive days. The light application procedure was followed based on the previous studies on oncology patients. [16,25] The patient was asked to engage in other activities during the light administration, such as

watching television, reading books, and not to look directly at the light. The second and third evaluations of the fatigue status of both groups of patients were completed on the 9th and 21st days by an independent other nurse (RA2).

Data analysis

The statistical analysis was performed on IBM SPSS v.24 (SPSS, Chicago, IL) software package. To compare the socio-demographic characteristics of groups, independent groups t-test and chi-square analysis were used. Paired samples t-test was used to determine differences between the study groups, and analysis of variance (repeated measurements ANOVA) was employed in repeated measurements. To ensure the balance between the groups and the reliability of the intervention results, the intention-to-treat method was not used in the analyses. Statistical significance level was accepted as p <0 .05.

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