

**Levocetirizine Hydrochloride Tablet Improves
the Nasal Conditions of Patients with Cedar Pollen
Allergy and Maintains their QOL**

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Abstract

Levocetirizine is a drug created by separating only the L-form, which has a high affinity to the histamine receptor, and which is the main active component of the product, from amongst the optical isomers of cetirizine hydrochloride. There have been reports on the usefulness of cetirizine hydrochloride to date; however, we were not able to find any reports on the usefulness of levocetirizine against cedar pollen allergy. Here, we report about the usefulness of levocetirizine against cedar pollen allergy. A significant decrease in runny nose, sneezing and blocked nose was observed after the levocetirizine therapy in terms of subjective symptoms. Furthermore, the levocetirizine therapy is efficacious for cedar pollen allergy in order to maintain patient QOL. These results indicate that the levocetirizine therapy improves the nasal conditions with cedar pollen allergy and maintains their QOL.

Keywords: Levocetirizine, cedar pollen allergy, nasal conditions, QOL

I. Introduction

In Japan, there has been increasing numbers of patients with cedar pollen allergy induced by the scattering of cedar pollen, and this has been becoming a serious social issue in recent years. There is a correlation between the amount of cedar pollen scattered and the incidence rate of cedar pollen allergy, and the number of cases of onset of cedar pollen allergy fluctuates every year. This is because the total amount of pollen scattered depends on the climate conditions of the summer in the previous year and also

because the amount of pollen which patients are exposed to varies depending on the climate conditions in each area. It is important to avoid contact with the antigen in order to inhibit allergic rhinitis; however in the case of cedar pollen, it is difficult to be completely shut off from the pollen in everyday life, and drug therapy as part of symptomatic treatment is the center of treatment for cedar pollen allergy. In drug therapies, it is required to select an appropriate drug depending on the severity and type of disease. There have been reports on the usefulness of cetirizine hydrochloride to date [2-4]; however, we were not able to find any reports on the usefulness of levocetirizine against cedar pollen allergy. Levocetirizine is a drug created by separating only the L-form, which has a high affinity to the histamine receptor, and which is the main active component of the product, from amongst the optical isomers of cetirizine hydrochloride. We recently used levocetirizine which recently started being marketed in Japan, and investigated its usefulness. The following is a report on the results.

II. Testing method

1. Period

Four months from February to May 2012

2. Scope

Thirty two patients aged 15 years old or older who showed a cedar pollen allergy in the form of skin reaction or showed positive on RAST and showed clear symptoms during the period in which cedar pollen is scattered.

3. Methods of administration

Patients who visited the ENT department at Nasu Red Cross Hospital and gave informed consent were requested to fill out a Japan allergic rhinitis standard QOL survey form (JRQLQ no.1) at each consultation (approximately every four weeks). The patients' doctor collected the forms on the day of consultation after checking that there were no fields which were not entered. After consultations, 5mg of levocetirizine was administered to the patients once a day consecutively for four weeks. From the day on which cedar pollen started scattering, the patients were permitted to use a steroid nasal spray depending on their symptoms. In principle, during the study period, the concomitant administration of drugs which may have impacted evaluation decisions in the present study was prohibited. In other words, amongst antihistamine drugs other than the investigation drug, release inhibitors, leukotriene receptor antagonists,

prostaglandin D₂, thromboxane A₂ receptor antagonists and oral steroids and others were prohibited.

4. Methods of evaluation

The adequacy of JRQLQ no.1 has been verified through quantitative and psychological methods, and it is standardized with patients with allergic rhinitis in Japan in scope [5]. Evaluation items consist of: Part 1- subjective symptoms (6 items in total, namely runny nose, sneezing, blocked nose, pruritus in nose, pruritus in eyes, tears in eyes): Part 2 - QOL (17 items in total consisting of the 6 areas of everyday life, outdoor activities, social life, sleep, physical functions and psychological life): Part 3 – the patient's overall condition (1 item). Subjects rated items in Parts 1 and 2 on a scale from 0 (none) to 4 (extremely severe, highly serious) for the 1-2 weeks prior to the investigation day, and they rated the item in part 3 with a face scale from 0 (very happy) to 4 (feel like crying). A t-test was used in statistical analyses and the standard of significance was taken to be 5%. Additionally, in investigating drowsiness, which is the main effect of levocetirizine, the Japanese version of the Epworth sleepiness scale (JESS) was used [7].

III. Results: The questionnaire survey on changes in subjective symptoms

A) Comparison of nose and eye symptoms

A significant decrease in the degree of runny nose, sneezing and blocked nose compared to those prior to treatment was observed after levocetirizine treatment (Diagram 1).

B) Comparison on QOL question items

The results of a survey related to QOL are shown in Diagram 2. The levocetirizine therapy did not create significant differences in the degree of interference with everyday life, interference with outdoor activities, interference with social life, sleep disorders, interference with physical functions nor interference with psychological life compared to prior to the treatment, and QOL was observed to have been maintained.

B) Comparison of comprehensive conditions

The face scale scores are shown in Diagram 3. A decrease in the face scale relative to prior to the treatment was observed, although no significant decrease.

C) Comparison in sleepiness during day time

It was determined that pathologic and extreme sleepiness was a score of 14 or greater on the JESS. 6.5% of all patients complained of extreme sleepiness prior to treatment. 3.1% of all patients complained of extreme sleepiness after levocetirizine therapy, and levocetirizine therapy on the whole did not increase the incidence rate of sleepiness.

IV. Discussion and outlook going forward

Levocetirizine is a drug created by separating out only the L-form of cetirizine hydrochloride. It has high affinity to histamine receptors and is considered to be the main active compound of the drug from amongst the optical isomers of cetirizine hydrochloride [1]. There have been reports on the usefulness of cetirizine hydrochloride to cedar pollen allergy; however we were not able to find any reports on the usefulness of levocetirizine. Therefore, we carried out an investigation into the efficacy of levocetirizine in patients with cedar pollen allergy. In the present study, we investigated the efficacy of the drug in relation to the patients' QOL, not only their subjective symptoms, through evaluations using JRQLQ no. 1. Firstly, a significant decrease in runny nose, sneezing and blocked nose was observed after the levocetirizine therapy in terms of subjective symptoms. In other words, the administration of levocetirizine improved nasal conditions. Since the concomitant administration of the drug and steroid nasal spray was permitted depending on the symptoms of patients after cedar pollen scatter, the results suggested the usefulness of the concomitant therapy of levocetirizine and steroid nasal spray as a post-onset therapy.

In terms of QOL, there were no significant differences in the degree of the following aspects compared to prior to the therapy: interference with everyday life, interference with outdoor activities, interference with social life, sleep disorders, interference with physical functions and interference with psychological life. Therefore it was considered that the levocetirizine therapy is efficacious for cedar pollen allergy in order to maintain patient QOL.

Moreover, the levocetirizine therapy neither increased the incidence of sleepiness nor showed the side effects of excessive sleepiness.

The above results suggest that the use of levocetirizine is safe, improves the nasal conditions of patients with cedar pollen allergy and maintains their QOL. The Japanese

guidelines for allergic rhinitis recommend the oral administration of second-generation antihistamine drugs as the initial treatment in cedar pollen therapy [6]. In this light, we are planning to investigate the potential of the initial therapy with levocetirizine.

Conflict of interest

All authors declare there are no conflicts of interest.

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Diagrams

Diagram 1(A). Runny nose, $p < 0.05$

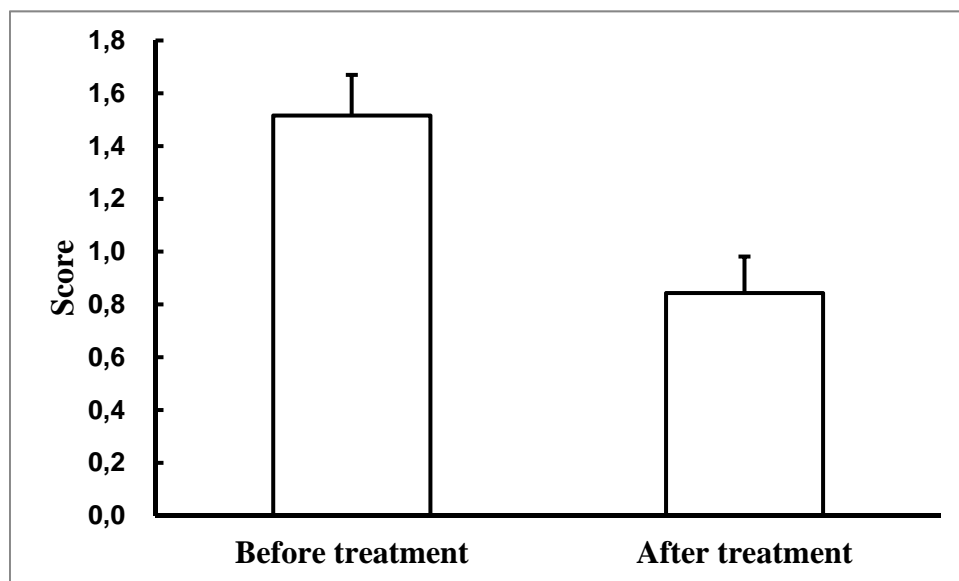


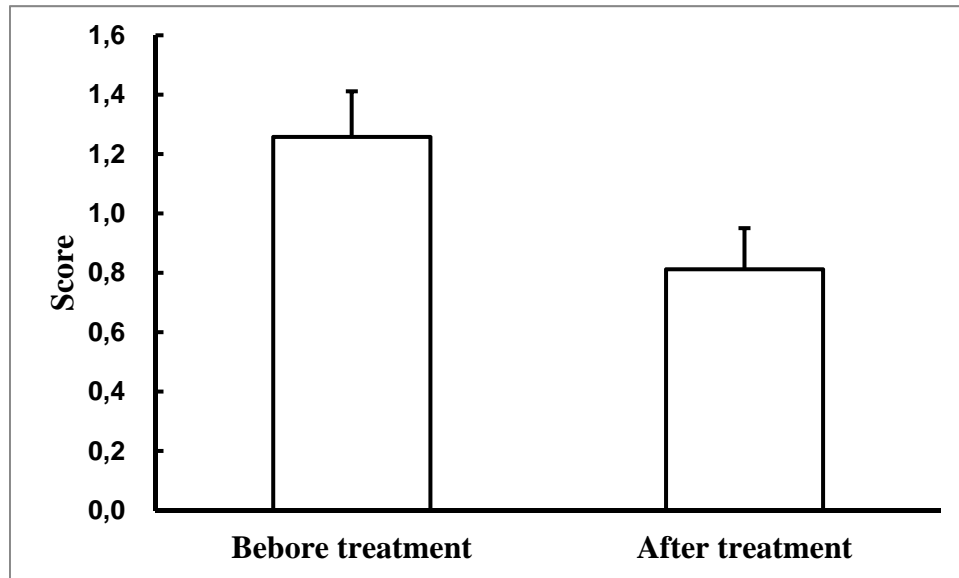
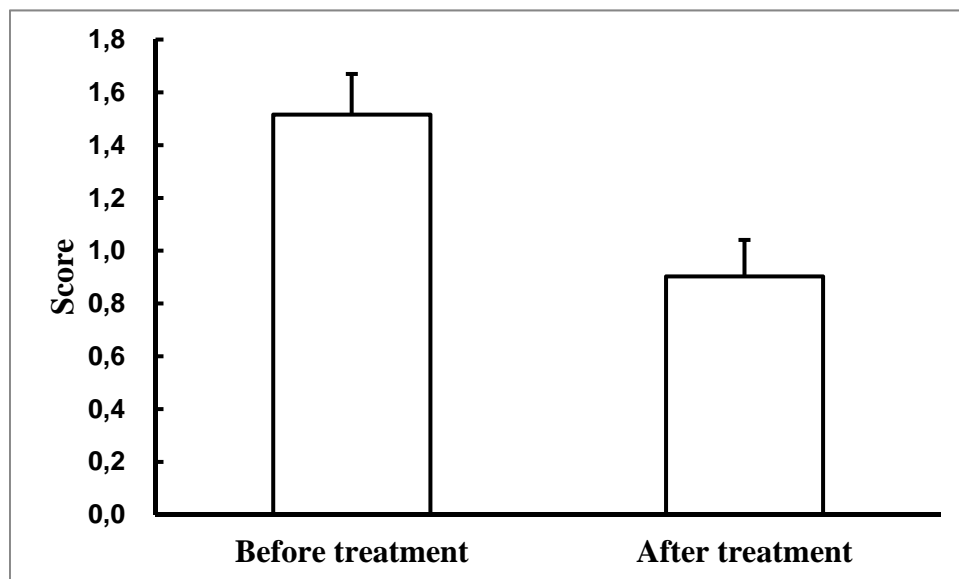
Diagram 1(B). Sneezing, $p < 0.05$ Diagram 1(C). Blocked nose, $p < 0.05$ 

Diagram 1(D). Nasal pruritus, $p>0.05$

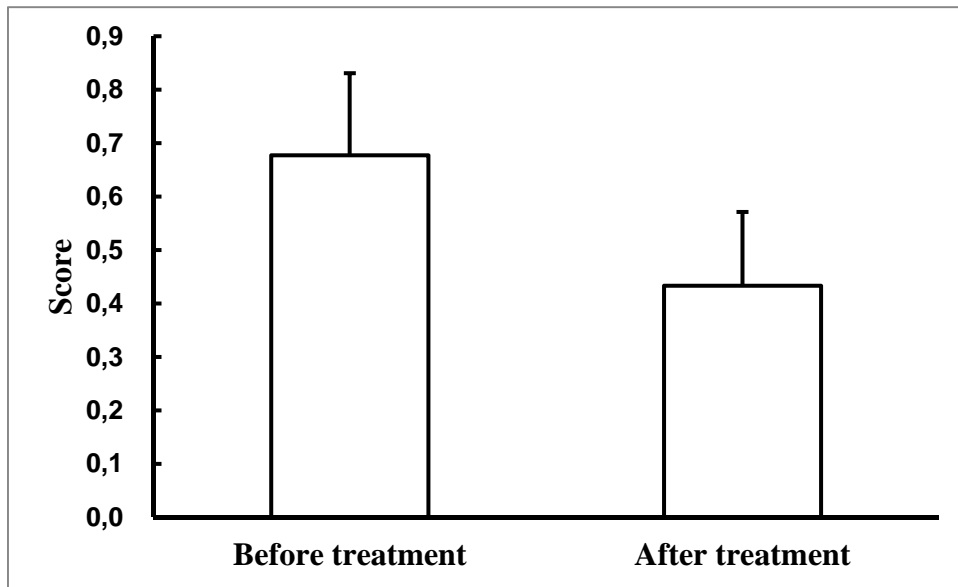


Diagram 1(E). Oculus pruritus, $p>0.05$

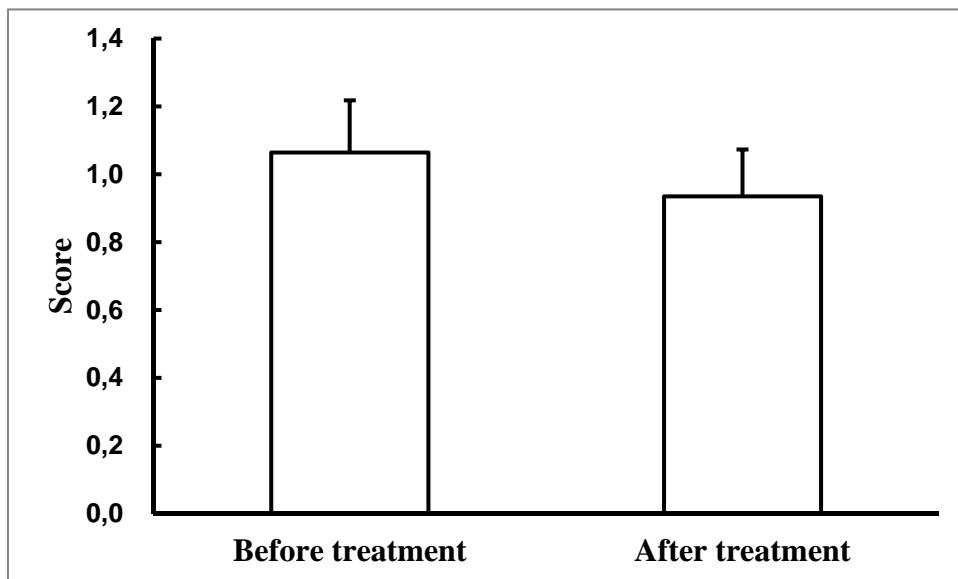


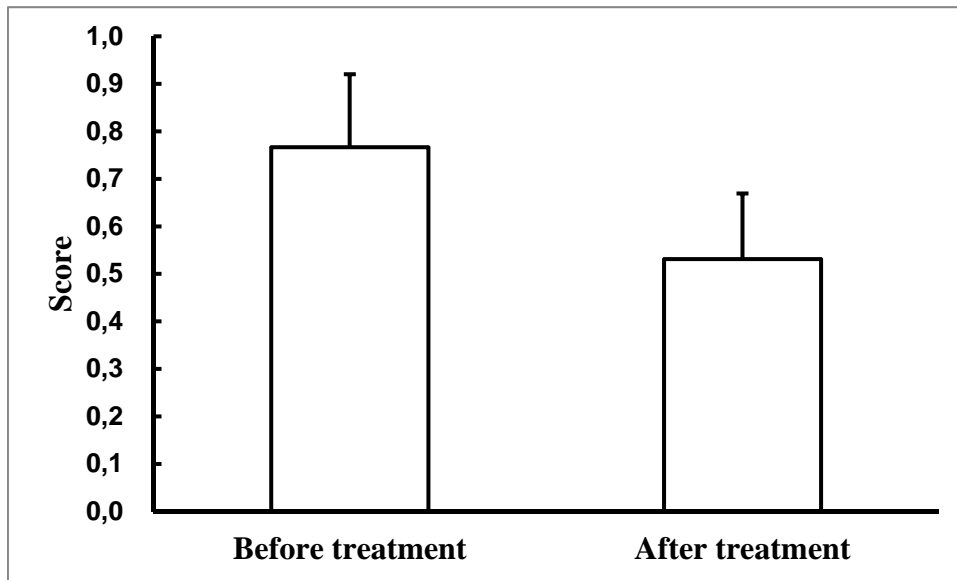
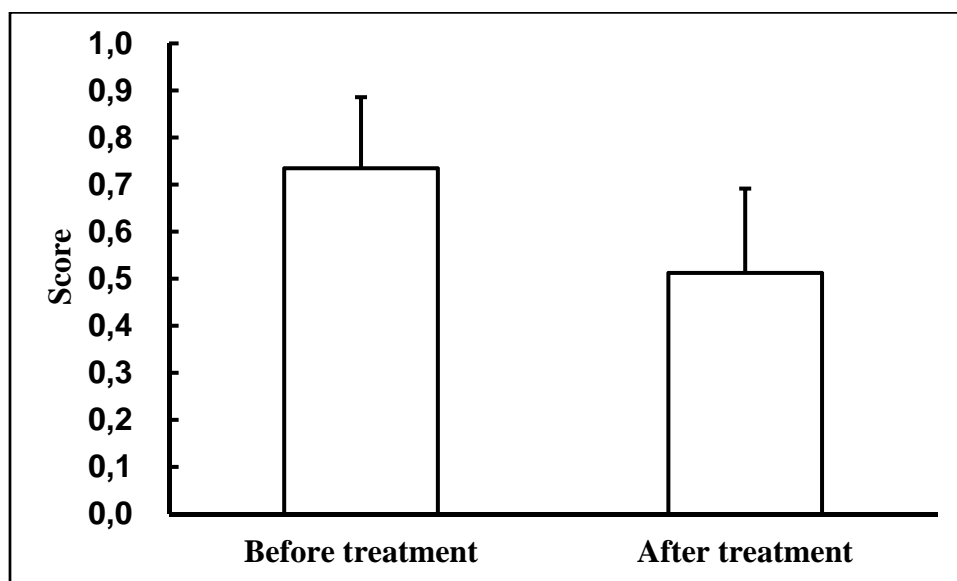
Diagram 1(F). Teary eyes, $p>0.05$ Diagram 2 (A) Everyday life, $p>0.05$ 

Diagram 2 (B) Outdoor activities, $p > 0.05$

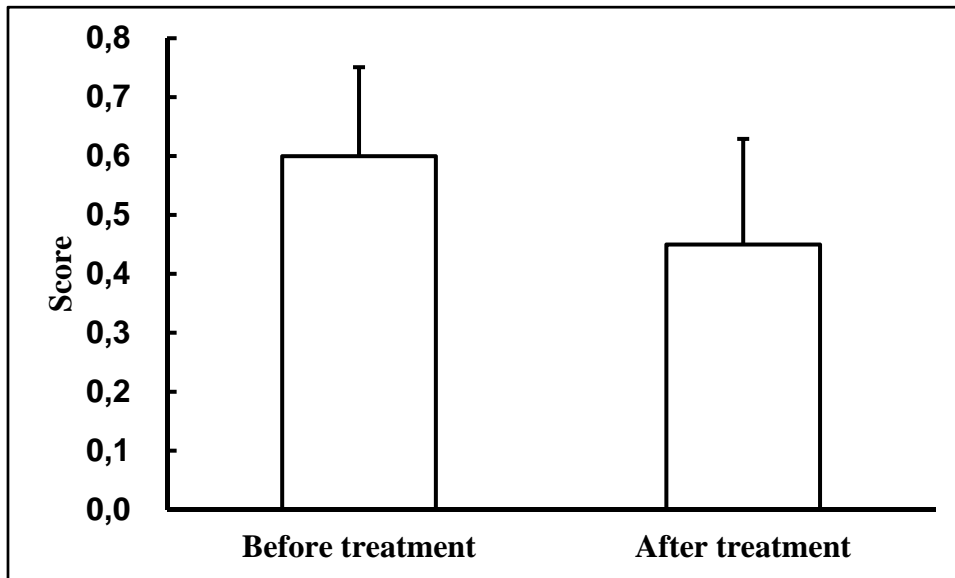


Diagram 2 (C) Social lives, $p > 0.05$

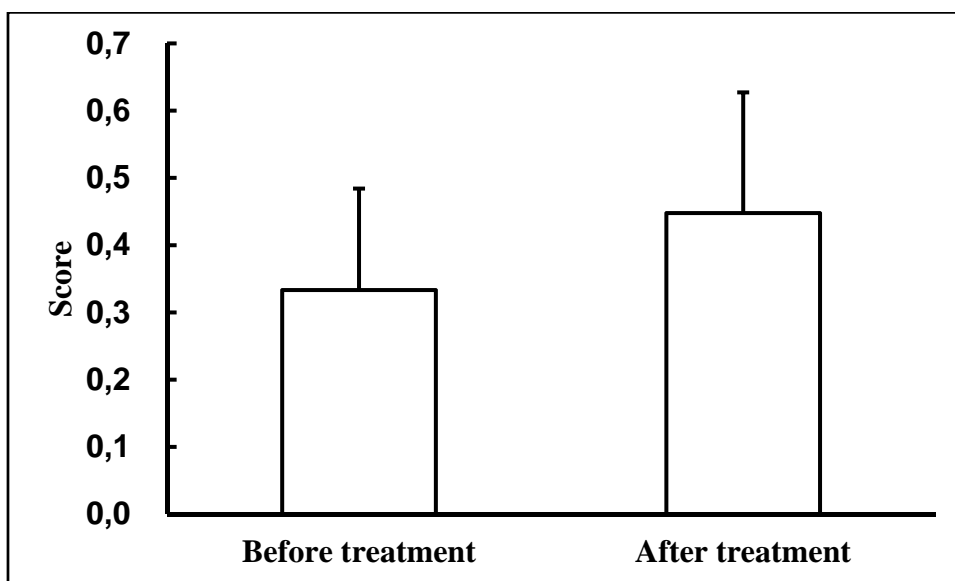


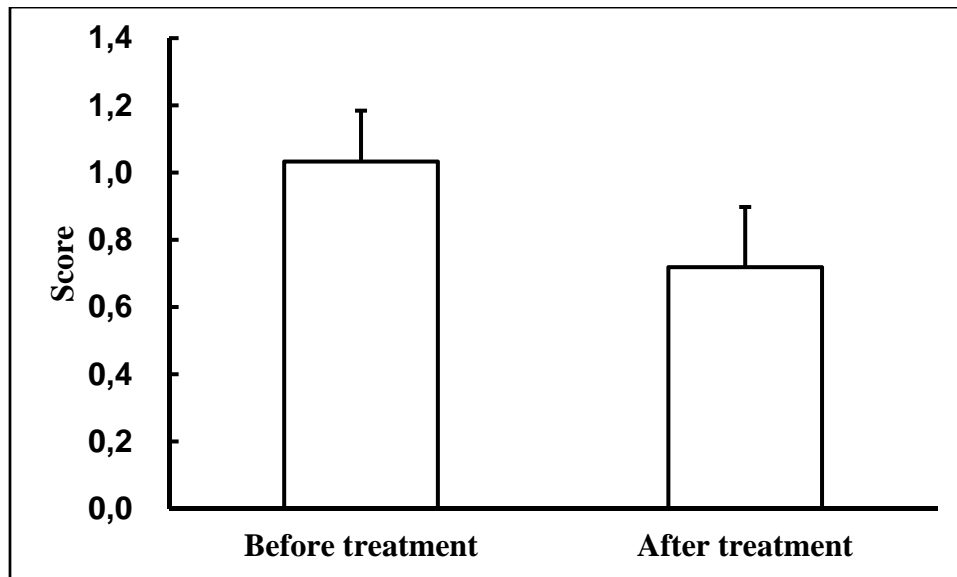
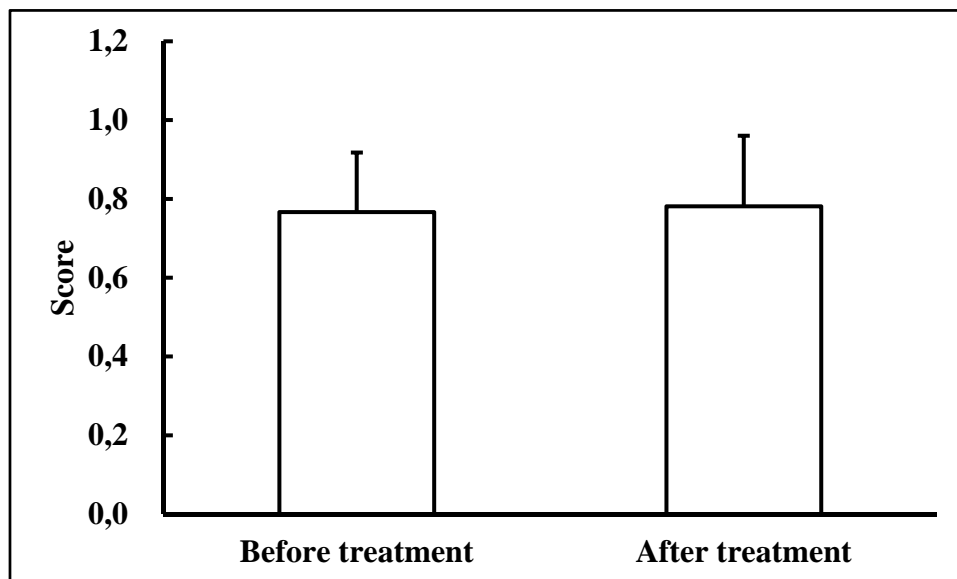
Diagram 2 (D) Sleep, $p>0.05$ Diagram 2 (E) Physical, $p>0.05$ 

Diagram 2 (F) Psychological life, $p>0.05$

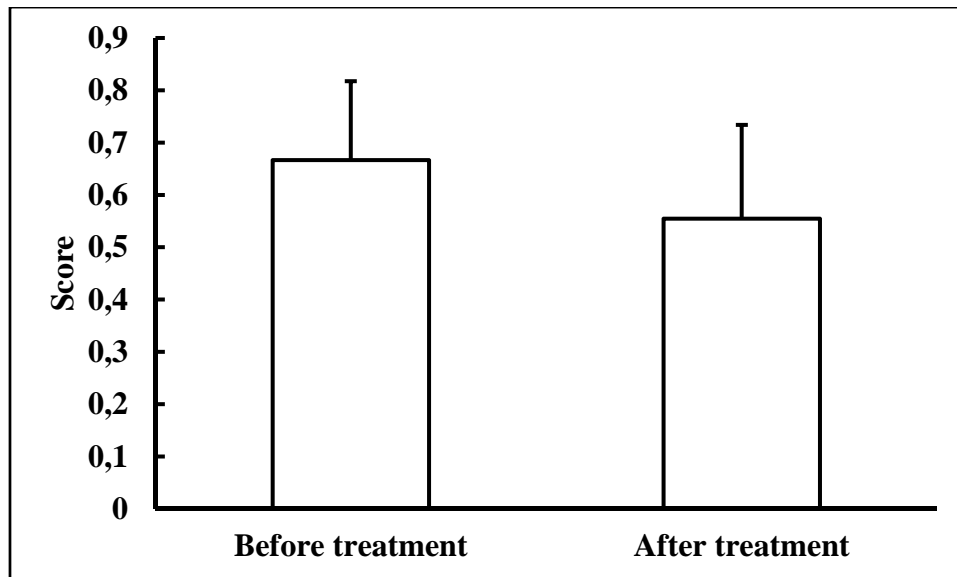


Diagram 3. Comprehensive conditions, $p>0.05$

