Date:15.07.2016

Effectiveness of a home-based, self-administered exercise program for hands in patients with Systemic Sclerosis: a Randomized Controlled, Single-blind, Clinical Trial.

NCT Number:

Informed Consent Form

This informed consent form is for female participants with Systemic sclerosis. We would like to invite you to attend a research study being conducted at rheumatology outpatient clinic in Cukurova University Hospital. The title of our research study 'Effectiveness of a home-based, self-administered exercise program for hands in patients with Systemic Sclerosis: a Randomized Controlled, Single-blind, Clinical Trial'.

Systemic sclerosis, also known as scleroderma, is a chronic disease that can affect skin and internal organs. In general, patients are divided into two subtypes according to the skin involvement. These subtypes include diffuse and limited scleroderma. While skin involvement is seen over to the elbows and knees in diffuse scleroderma, it is generally seen distal to the elbows and knees in limited scleroderma. The skin involvement can be observed as thickening in both subtypes and it can cause hand dysfunction. The other reasons that lead to decrease hand function are puffy hands, digital ulcers, calcinosis, and joint contractures. Decreased hand function can cause the impairment of daily life activities such as eating, dressing. Also, debilitation in doing routine activities can lead to psychological stress. Hand exercises have been proved as an efficient method to improve hand function in the literature.

The reason we are doing this research is to show the impact of self administered, home based hand exercises on hand function of patients with scleroderma. In addition, we are investigating whether general health quality and psychological conditions are ameliorated by these exercises. When patients agree to participate in the study, they will be randomly divided into two groups. Both groups will be assessed by first clinician in terms of hand function, general health, daily life activities, and psychological status. These assessments will be done before treatment, at the end of the first month, and at the end of the second month after treatment. Both groups will be informed about scleroderma and routine care. The first group will be in training for how they will exercise at home. Exercise program will be explained by second clinician who is an expert in physical medicine and rehabilitation. In addition, patients will take booklets which illustrate the exercises they will make and a checklist which provide self-control. Meanwhile, the second group will pay attention to self care. At the end of the study, the patients who will enroll in the second group will also get educated in terms of hand exercises. In case you decide to participate in this study, we will obtain your medical records provided that they will be kept confidential. When you decide to sign the written informed volunteer consent form, you will give us to access your medical records to use them for this research. These records will be kept confidential and we will not reveal them without protecting your identity.

Your participation in this research is entirely voluntary. It will be your choice whether to participate or not. After participation, you may leave from this research at any time even if you agreed earlier, without any penalty or sanction. Whether you choose to participate or not, or to withdraw from this research, all services you receive at this clinic will continue and nothing will change. You do not have to decide today whether or not you

will participate in this research. Before you decide, you can talk to anyone. Whenever you want, you and/or your legal representative will be informed in any time in terms of your results. If you do not understand any statement, please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me or other doctors who charge of this research.

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask any questions about this research. The purpose of this research was clarified by the doctor named below. I consent voluntarily to participate as a participant in this research, without any pressure or coercion.

Date:

Patient	Name-Surname:
	Signature:
Witness	Name-Surname:
	Signature:
Researcher	Name-Surname:
	Signature: