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Research Article

Methodology of Tele-rehabilitation Program to Patients with Chronic Inflammatory Demyelinating Polyneuropathy and Guillain-barre Syndrome: Randomised Clinical Trial

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Abstract

Chronic Inflammatory Demyelination Polyneuropathy (CIDP) and Acute Inflammatory Demyelinating Polyneuropathy (Guillen-Barre Syndrome, GBS) are included in the autoimmune polyneuropathy category.

The general clinical characteristics are: weakness, muscle atrophy, sensory disorders with or without pain. It presents peripheral symptoms of symmetric or asymmetric distribution, asymmetric distribution tends to be rarer, with fast or slow progression of the disease and with varying degrees of problem caused to the Autonomous Nerve System [1,2].

GBS is the most common cause of acute, non-traumatic, neuromuscular paralysis in the developed countries, it affects 1-2 people in 100,000 people annually [1-3].

CIDP is an acquired, chronic disorder of the peripheral nerve system which has a strong correlation with the pathological immunological mechanisms [4-6].

The use of telerehabilitation/telehealth has grown a rapidly in the last few years, following an exponential growth due to the rapid development and wide adoption of telecommunication technologies. Telerehabilitation/Tele-physiotherapy, depending on the rehabilitation goals and the special characteristics of the patients, is individually adjusted, meaning that it can utilize special biological functions monitoring equipment, such as an oscilloscope, an oximeter, an electrocardiograph, or a smartphone.

Teleconference is suggested as a general framework because it provides a relative degree of immediacy in the communication between the healer and the patient. It can take place in a one-to-one setting, or in small teams. The aim of this study is the use of telerehabilitation in patients who suffer from CIDP and GBS. The registration ID is TCTR20210622005 on the Thai Clinical Trials Register.

Keywords: Chronic Inflammatory Demyelinating Polyneuropathy; Guillen Barre Syndrome; Acute Inflammatory Demyelinating Polyradiculoneuropathy; Physical Therapy; Exercise; Telerehabilitation

Abbreviations

CIDP: Chronic Inflammatory Demyelinating Polyneuropathy; GBS: Guillen Barre Syndrome; AIDP: Acute Inflammatory Demyelinating Polyneuropathy; RCT: Randomized Controlled Trial; AAN: American Academy of Neurology; NSS Scale: Neuropathy Symptom. Score Scale; NDS Scale: Neurologic Disability Score; INCAT Disability Score: Inflammatory Neuropathy Cause and Treatment Disability

Score; N.R.S: Numeric Rating Scale; IPAQ_GR: International Physical Activity Questionnaire; F.S.S: Fatigue Severity Scale; BDI-I: Beck Depression Inventory-I; SF-36 (MOS): Medical Outcomes Study (MOS) Short-form Health Survey 36 Item

Introduction

Acute Inflammatory Demyelinating Polyneuropathy (AIDP) is the main clinical subtype of GBS syndrome, it is characterized by demyelination, lymphocytic inflammation, varying degrees of loss of axis and endoneural oedema [1-8].

It is considered an autoimmune disorder that affects the membrane of the Schwann cell or the myelin and results in primary inflammatory demyelination as the main pathological finding [9]. When the autoimmune responses stop, the rehabilitation and remyelination start immediately, which is associated with the fast and, in most cases, full recovery from a simple paralysis. Yet, the degree of loss of axes in AIDP is an important factor in the speed of the recovery, the persistent deficits and of the final prognosis [10].

Moreover, as mentioned before, the clinical range of GBS syndrome is heterogeneous and there are axonal variations with the primary immunological attack towards the neuroaxonal [11,12].

CIDP is a chronic variant of AIDP with a similar pathology. It develops in a period of 8 weeks or more. In the international bibliography it is described as a large heterogeneity in the clinical image of CIDP. It tends to be presented as a monophase, hypotropia or a chronic advancing with the symptoms lasting at least 8 weeks. The distribution of sensory and motor findings is usually symmetric, but at the beginning of the illness it can be asymmetrical. There is also observed a generalized annulment of the reflects and often pain is reported.

There are often bursts from the Central Nervous System like tremor of big wavelength and varying frequency, which seems to be the reference point of hypotrophy. There is no mention of predisposition for CIDP, although the data indicate a correlation with autoimmune diseases, diabetes, hypertension, and previous inflammation [13,14].

The sensory and motor deficiencies that are created lead to gait, balance, and functionality disorders of the patient. In the bibliography, it is mentioned the effective role of exercising that brings an important improvement in the muscle strength, gait, and functionality of the patients with CIDP [13-15].

It is well documented the positive effect of exercising in patients with AIDP and GBS in both the motor parameters of the gait circle as well as in the increase of the muscle strength and in the functional rehabilitation of the patients with emphasis on high intensity programs [14-16]. Although CIDP and GBS differ in the progress of the illness the same methods and practices are recommended in the rehabilitation programs [18].

In this study we will implement the exercise protocols depending on the needs of the patients with the help of telerehabilitation. The practice of telerehabilitation/telehealth has been growing rapidly in the last few years, following an exponential growth due to the technological improvement of telecommunications. Especially due to the special conditions created in the past 1.5 year because of the Covid-19 pandemic, the need for distance communication is more important than ever before. In Greece, there has been substantial progress in the acquisition of digital skills by the general population. Telerehabilitation is the provision of health services and rehabilitation from distance using telecommunication technologies and is a part of the general census of the term telehealth [19].

However, the implementation of a theory in real life tends to be slow. Telerehabilitation provides a certain degree of immediacy in the communication between the physiotherapist and the patient either in a one-to-one setting or with the use of small teams. Depending on the needs of the patients, there may be the need for a certain number of visits on the patients' premises for evaluations to take place or guidance to be given in the use of equipment where is needed.

The use and applications of smartphones that are relatively accessible to everyone is mentioned as having positive results in the rehabilitation [20-22]. Smartphone applications will be used for this research.

Telerehabilitation interventions are positively evaluated in areas of preventive care and management of chronic diseases. The patients have reacted positively in the interventions and some of the benefits recorded are reduction of movement, flexibility of exercise time and in some cases, more intensive training compared to that in a healthcare institution [25].

Materials and Methods

- The purpose of this research is to evaluate the effects and the effectiveness of a therapeutical exercise program with telerehabilitation, structured depending on the needs of the patients with CIPD and GBS, against advices given to the patients with CIPD and GBS.
- The protocol of this study was registered on Thai Clinical Trials Register Registration Id (TCTR20210622005)
- This paper has been designed as a RCT with a duration of 3 months (12 weeks) with the goal to evaluate the improvement of functional rehabilitation to patients with CIDP and GBS. It will include experimental measurements of quantitative data from two different teams (Control Group and Intervention Group).

Control group

The patients will be evaluated and they will be given general advice for exercise and physical activity. They will have no further contact with the research team.

Intervention group

- A tailored exercise program will be given to the participants. Twice a week for 12 weeks there will be an online meeting with the research team, to ensure that the exercise plan is implemented correctly and modify the plan depending on the patients' needs.
- The patients will be evaluated by the department of Neuromuscular Diseases of the 1st Neurological clinic of Aegenitio Hospital.
- The exercise program will be done online. The patients will be evaluated 3 times: the 1st time before the intervention, the 2nd time at the end of the intervention and the 3rd time will be 3 months later.
- In this paper, the sample will be selected using purposive sampling following the rules of compatibility and adequacy. The sample will be considered satisfactory using the bibliographical data of other papers as a guidance. The number of patients in every team will be 25-30 people, and in total 50-60 people will participate. The patients will be separated randomly using a lottery in two equal sized teams with quantification in the sex and age ratio.

Eligibility criteria

Inclusion criteria

- They must be 18 years of age or more
- They must have been diagnosed with CIDP or GBS
- They do not follow any other activity plans
- They have a stable medication (that follow for the past 2 months)
- They can consent
- They can communicate

Exclusion criteria

- They are unable to walk or they cannot walk for more than 10 meters on their own
- They have serious vision/auditory issues that hinder their ability to communicate
- They have serious conditions, that do not allow them to participate in exercise programs
- They suffer from cancer.
- They have recently undergone surgery, less than 12 months since surgery date
- They suffer from alcoholism
- They suffer from drug abuse.

Outcome measures

Physical Assessment
Electromyography: The electrophysiological studies comprised determination of motor and sensory nerve conduction velocity, calculation of the amplitude of muscle (check for conduction block) and sensory evoked potential, measurement of the latent time and the amplitude of F-waves for the nerves checked. We used the electrophysiological diagnostic criteria developed by the AAN in 1991.

Digital dynameter
Neuropathy Symptom. Score scale (NSS Scale) The Neurological Symptom Score (NSS) is a 17 question, interview-based assessment of sensory, motor, and autonomic function
Neurologic Disability Score (NDS Scale) The NDS can be used to assess the signs of neuropathy by 35 items for both sides. The evaluation is derived from cranial nerve damage, muscle strength, reflex loss, and loss of sensation (Dyck 1980)
Inflammatory Neuropathy Cause and Treatment Disability Score (INCAT Disability Score): The INCAT comprises two parts, the arm score and the leg score. Based on a patient's level of impairment in their arms and legs, each part is scored between 0 and 5 points, resulting in an INCAT total score between 0 and 10 INCAT Score is related to function, with 0 representing no functional impairment and 10 representing inability to make any purposeful movement with either arms or legs
Numeric Rating Scale (N.R.S): N.R.S evaluates the pain intensity in adult patients. The common form of the arithmetic scale used is a horizontal line from 0 to 10 (scale of 11 points) or from 0 to 100 (scale of 110 points). The respondent is expected to evaluate the pain from 0 to 10, knowing that 0 equals to no pain and 10 or 100 equals to the worst possible pain.
International Physical Activity Questionnaire (IPAQ_GR): The International Activity Questionnaire (IPAQ GR) is a self-report questionnaire that evaluates the physical condition of the respondent. It is designed following the exercise intensity scale, meaning low intensity, medium intensity, and high intensity. It is calculated using MET- Minutes/week. It has been translated and adjusted for the Greek language.
Gait Evaluation
10m Walk Test: The 10m Walk Test is used to estimate the speed of walking in m/sec. The timing is done in the 6 meters in the middle of the walking distance as the first 2 meters are used for acceleration and the last 2 meters for deceleration. In this test, the walking in a normal and fast pace is timed. For each measurement (fast-slow pace) there are two recordings and the average is taken.
Berg Balance scale: The Berg Balance scale is used for the objective measurement of the patient's ability (or inability) to balance themselves safely during a series of preselected exercises. It is a list of 14 items with each of them being comprised by a scale of 5 points that ranges from 0 to 4, 0 being the lowest functionality level and 4 being the highest. The evaluation takes 20 minutes to be completed. It does not evaluate walking. It has been translated and adjusted to Greek.
Evaluation of Fatigue
Fatigue Severity Scale (F.S.S): Fatigue Severity Scale is a self- administered unidimensional 9-item fatigue rating scale. The above scale developed to measure the modality, severity, frequency and impact of fatigue in daily functioning. The answers are scored on a 7-point Likert scale from 1 (complete disagree) to 7 (complete agreement). That means that the higher score indicates worse fatigue and its effects on the patient's activities. It is an easily understood evaluation and it takes on average 8 minutes to be answered. It has been translated and adjusted for the Greek language.
Symptom Rating Scale for Depression and Anxiety: Symptom Rating Scale for Depression and Anxiety is based on Beck Depression Inventory-I (BDI-I). It is an expanded scale and it contains 42 items with subscales from other scales [Beck Depression Scale, Asthenia subscale, Melancholia Inventory, Anxiety Inventory, Mania subscale]. Each question is for a symptom and the respondent will have to answer based on their condition for the past 2 weeks. Each item has a scale 0-3 (0 is the total lack of symptoms and 3 is the existence of symptoms with high intensity). The final grade is the sum of the answers. It has been translated and adjusted for the Greek language.
Quality of life
Medical Outcomes Study (MOS) short-form health survey 36 Item (SF-36): The SF-36 (MOS) questionnaire is comprised by 36 items that are categorized in 8 themed scales (8 different notions of health): physical functioning, physical and emotional limitations, social functioning, bodily pain, general and mental health. The answers in the questions are scored in a scale from 1 to 5 where 1 is the worst quality of life and 5 is the best. The answers help create a diagram that shows the quality of the patient's life.

Ethical and deontological rules

This research will be conducted following the WMA Declaration of Helsinki. During the whole process of the current research there will be confidentiality and the protection of the personal data of the participants during and after the research is conducted. The access to the data will be restricted to the principal investigator.

The results will be used exclusively and only for this research and will only be from this research team. The research data will be kept for 5 years after the research is concluded and then they will be destroyed. The paper records will be destroyed using a physical manner and the digital data will be deleted.

The participants will be informed with clarity about the goal of this research, the confidentiality of the data and the voluntary nature of their participation without a financial incentive and they will be given an information document for the research program. They will participate in a session that explains the details of the research and the participants will have the chance to have a phone call with for more information and clarifications regarding the research. After the conclusion of the research, the participants can, if they wish to, be informed of the research's findings. Furthermore, they will be informed that they can stop participating in the research at any point. All participants will be asked to sign a declaration of participation for the research. In the declaration there will be written that "the participants have the right to not participate or withdraw from the study at any point, without any consequence in terms of their health coverage." With the information document, they will receive a complaint form.

Discussion

Therapeutic exercise is the main tool to help in the rehabilitation of the Peripheral Nerve System. In experimental research there has been observed that the low intensity exercise programs help in the regeneration of nerve axons as well as in the motor and sensory rehabilitation [24-26]. Exercising affects the neurobiological mechanisms that help in the neural regeneration, in the increase of axons that regenerate and in the rate of growth of length of the axons [27-29].

In the clinical practice, it is strongly recommended to use therapeutic exercise due to the positive effect that it has in the recovery of muscle power and in aerobic ability of the patients [14]. The physiological mechanisms that improve the readings of muscle power indicators and of aerobic ability can be caused by the hypertrophy of muscle fibres, increased neural stimulation or due to the anti-inflammatory effect of exercise. The use of a specialized program of therapeutic exercise is necessary due to the vast heterogeny of the patients' population with CIDP and AIDP. Meaning, that the goals that concern the muscle strengthening, balance, walking and physical condition of the patients remain the same, but the exercise parameters are differentiated (repetitions- frequency of exercising) for each patient [13-15]. The differences in muscle strengthening, gait/balance that will arise after intervention will be recorded with the evaluation tools that will be used for Physical assessment and Gait evaluation.

CIDP and GBD are multifactorial models. Apart from the motor sensory disorders there is a mention of pain, fatigue, decreased participation and a fall in the patient's quality of life [30-32].

The feeling of fatigue is mentioned as the main symptom of the CIDP patients. The correlation between fatigue with Central Nervous System is accepted and well documented. The correlation of fatigue with the peripheral nervous system disorders is mentioned but it is not documented if this fatigue relates to the Normal Fatigue which is the muscle weakness or the feeling of fatigue that the person experiences [16]. In this research, the symptoms of fatigue will be evaluated as well as the pain and the quality of life of the patient. Fatigue will be assessed with two questionnaires FSS and Symptom Rating Scale for Depression and Anxiety Scale to evaluate fatigue as a feeling of fatigue and so on Normal Fatigue.

Telerehabilitation interventions has been evaluated positively in the areas of preventative care and management of chronic diseases. The patients have reacted positively to the benefits of telerehabilitation like the decrease of the need to physically travel and in the decrease of the cost, flexibility in the exercise hours and maybe to the intensity of the training compared to a health institution [23,33-35]. Yet, the adoption of technology in the clinical practice remains slow and many obstacles must be overcame [36]. The evaluation of the patient still is a problem, especially in sectors like physiotherapy where a hands-on approach is needed. For example, in the evaluation of muscle strength. Different strategies are advised like the training of the patient's family or of their carer or even training the patient to perform the evaluation themselves [19]. For this research's evaluation a face-to-face approach has been selected.

In this research, the training and having a knowledge about the program's goals by the patients is considered of the most importance. The patients will be trained for the exercise program that they will participate in and they will receive a videocall twice a

week from their physiotherapist. This way, they will achieve two main goals:

- The last few years, emphasis has been given on organizing a rehabilitation program that also trains the patients to participate in the decisions made regarding their health. This way, the patients are more likely to be committed to their rehabilitation exercise program [37,38].

- The participation of the physiotherapist twice a week gives motives and feedbacks towards the rehabilitation of the patient.

Conclusion

This research will study the application of tailored exercises through tele-rehabilitation in patients with CIDP and GBS. There exist strong indications of the positive effect on rehabilitation through the application of tailored exercises. The results of the application/usage of tele-rehabilitation in this group of patients are limited. If the research intervention is effective, it can be applied to a larger population of patients who do not currently have the opportunity of physical presence in the rehabilitation programs and at the same time have direct contact with health professionals. Through telerehabilitation, it is possible to overlook and follow-up in a more coordinated way patients that are located in remote areas with insufficient infrastructure and under other circumstances would be difficult to be approached

Conflict of interest

None declared.

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