Study Protocol

Effect of Pulsed Electro-Magnetic Field (PEMF) Therapy and Conventional Physiotherapy on Lipid Profile- A Randomised Control Trial

ABSTRACT

Introduction: The term 'lipid profile' describes the varying levels of lipids in the blood, the most commonly reported ones being low-density lipoprotein (LDL) cholesterol, high-density lipoprotein (HDL) cholesterol and triglycerides. Pulsed Electromagnetic field therapy, using this particular process involves directing powerful pulsed energy waves toward damaged or injured area of patient's body. These waves are painlessly and quickly pass through the cells in the damaged cells in the damaged region, increasing the oxygen pressure activating and regenerating cells.

Methodology: 40 subjects will be included in the study. 20 in group 1 and 20 in Group 2. Group 1 will receive Pulsed electromagnetic field therapy with aerobic and resistance exercises while Group 2 will receive aerobic and resistance training exercises as conventional physiotherapy technique.

Discussion: Pedersen and Saltin citing 13 meta-analyses, reported improvements in the lipid profile following exercise. They described this as Category A evidence that exercise can have a positive effect on the pathogenesis, symptomatology and physical fitness of individuals with dyslipidaemia. While the mechanisms underlying the effect of exercise on the lipid profile are unclear, exercise appears to enhance the ability of skeletal muscles to utilize lipids as opposed to glycogen, thus reducing plasma lipid levels.

Conclusion: Conclusion will be drawn based on the outcome measures of the study and the statistical analysis

Keywords: PEMF, Lipid Profile, Physiotherapy, Rehabilitation

Introduction:

The term 'lipid profile' describes the varying levels of lipids in the blood, the most commonly reported ones being low-density lipoprotein (LDL) cholesterol, high-density lipoprotein (HDL) cholesterol and triglycerides(1). High levels of LDL cholesterol indicate

surplus lipids in the blood, which in turn increase the risk of cardiovascular complications. HDL cholesterol transports lipids back to the liver for recycling and disposal; consequently, high levels of HDL cholesterol are an indicator of a healthy cardiovascular system(2). The most commonly used measure of cholesterol is arguably 'total cholesterol', a measure that includes LDL cholesterol and HDL cholesterol. However, given the different effects of LDL cholesterol and HDL cholesterol on health, total cholesterol can be a misleading metric. More sensitive measures report, for example, the total HDL cholesterol ratio, or non-HDL cholesterol levels (i.e. all cholesterol variables that are positively associated with cardiovascular disease(3).

There is a direct relationship between cholesterol levels and ischemic heart diseases. So, we need to keep the cholesterol levels in normal range to prevent ischemic heart diseases. Studies have proved that exercise have helped in reducing the cholesterol levels.

Pulsed Electromagnetic field therapy, using this particular process involves directing powerful pulsed energy waves toward damaged or injured area of patient's body(4). These waves are painlessly and quickly pass through the cells in the damaged cells in the damaged region, increasing the oxygen pressure activating and regenerating cells. PEMF is a cellular exercise for your body. It works in conjunction with the body's own recovery system. Our skins, bones and organs are composed of tiny cells. The membrane of a healthy cll has both positive and negative charges that are required. When a cell became distressed due to disease, trauma or toxin, they lose their ability to function efficiently. PEMF restores the positive and negatives charges of the cell(5).

It is already proven that exercise helps in maintaining the lipid profile. As cholesterol level is one for the problem faced by 1 of 10^{th} individual, a need exists to see for a better way to manage cholesterol levels. So, this study need to be conducted to see the effect of pulsed electromagnetic field therapy on cholesterol levels and the complete lipid profile.

METHODOLOGY

STUDY SETTING:

Once the Institutional Ethical Committee of Datta Meghe Institute of Medical Science approves the study. Study will be conducted in Out patients department of Ravi Nair Physiotherapy College

STUDY DESIGN AND SAMPLE SIZE

It is a randomised control trail study. The participants number, enrolled in the group A will be 20 and in Group B will be 20(n=40)

PARTICIPANTS

INCLUSION CRITERIA: - Subjects with intermittent level of total cholesterol, low density lipoprotein and triglyceride. In age group of 40-60 years of both genders.

EXCLUSION CRITERIA:-

History of Myocardial Infarction. Any recent abdominal surgery. Pregnant women will be excluded. Subjects with pacemakers or with the history of organ transplant will be excluded. Individuals with high fever will be excluded as well.

RECRUITMENT PROCEDURE:-

Patients who visited Physiotherapy OPD in Acharya Vinoba Bhave Rural Hospital with complain of increases cholesterol levels and who fulfilled the inclusion criteria will be included.

PROCEDURE

PARTICIPANT TIMELINE

Study duration is of 1 year and intervention duration is 3 weeks so participant will be enrolled during first 11 months of study so 3 week intervention will be completed successfully. Assessment will be done on 1st day of visit then in midway (1st week) and end (3rd week) of intervention

IMPLEMENTATION

Research coordinator and principal investigator will supervise randomization. Participants will be asked to manually select from the envelope, sealed group allocation for the recruitment into either group.

BLINDING

Tester(s) will be blinded to assign the subjects to the group. To ensure binding, subjects will be mandated not to reveal any details of their treatment to the tester

STUDY PROCEDURE

Ethical approval will be obtained from the university. Sampling will be started after the ethical approval. Subjects with intermediate lipid profile level who satisfies the inclusion and exclusion criteria will be included in the study.

Subjects will be randomly divided into two Groups Group 1 and Group 2. Group 1 will receive PEMF for 30 minutes along with aerobic and resistance training while Group 2 will receive aerobic and resistance training as conventional physiotherapy intervention.

Group 1:- Subjects will be explained about the pulsed electromagnetic field therapy. Patients will be asked to sit in a comfortable position PEMF therapy device will be kept on the chest region of the subject for 30 minutes and the machine will be turned on. Patient will be monitored while receiving the treatment. Post 30 minutes of PEMF patient will be given aerobic training initially and aerobic plus resistance training post 1 week.

Group 2:- Subjects will be given aerobic exercises and resistance training as a control group. Initially aerobic training will be given for 1st week followed by aerobic training and resistance training in 2nd and 3rd week.

Outcome measures:

Primary outcome measure:

Blood Lipid Profile- Blood lipid profile will be done pre and post intervention and the levels of low density lipoprotein, very low density lipoprotein, triglycerides will be seen.

Secondary outcome measure:

Quality of Life- Quality of life will be assessed using SF 36 scale pre and post intervention

DATA COLLECTION AND MANAGEMENT

Data collection

Information about study given at time of recruitment (elaborating the purpose, nature, procedure, benefits and after effects of the intervention) with all baseline tests and assessment will be repeated on 2 more occasions.

STATISTICAL ANALYSIS:

Data collected will be noted down and then will be placed in a tabular format. It will be analyzed with the help of SPSS latest version. Both statistical analyzes should be conducted with a 95% confidence interval (p-value < 0.05) to assess effect of two measures. Homogeneity of the two study classes will be tested for individual studies using the Student's t test. Mann-Whitney U will be used for comparing Groups at baseline.

DISCUSSION: -

Pedersen and Saltin citing 13 meta-analyses, reported improvements in the lipid profile following exercise. They described this as Category A evidence that exercise can have a positive effect on the pathogenesis, symptomatology and physical fitness of individuals with dyslipidaemia. While the mechanisms underlying the effect of exercise on the lipid profile are unclear, exercise appears to enhance the ability of skeletal muscles to utilize lipids as opposed to glycogen, thus reducing plasma lipid levels. The mechanisms may include increases in lecithin-cholesterol acyltrans (LCAT)—the enzyme responsible for ester transfer to HDL cholesterol, which has been shown to increase following exercise training(6).

In this article we will be checking the effect of PEMF therapy on the lipid profile of the subjects. In terms of mechanism of action, one hypothesis is that PEMF may induce Eddy currents in biological tissue, which could in turn mediate downstream biological effects. Recent evidence suggests that SCS and PEMF can mediate changes in gene expression, including genes implicated in pain pathways such as endogenous opioids and eicosanoid enzyme pathways (7).

ETHICAL APPROVAL AND DISSEMINATION:

The participant individuals of the study and DMIMSU who will fund it will be able to retrieve findings of study. After completion of study and publication of results data will be stored in the DMIMSU data repository

Patient Consent

Principal Investigators will obtain the written informed consent from the participant on a printed form (local language) with signatures and give the proof of confidentiality.

Confidentiality

The study program will be explained to the participant, the principal investigator will take subjective information. The consent form will include the confidentiality statement and signatures of the principal investigator, patient and a witnesses. If required to disclose some information for the study, consent will be taken from the patient with complete assurance of his confidentiality

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