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Original Research Article

DOES THE ADDITION OF PULSED ELECTROMAGNETIC FIELD THERAPY TO THERAPEUTIC EXERCISES IN PHYSIOTHERAPY MANAGEMENT IMPROVE BLOOD GLUCOSE LEVELS IN INDIVIDUALS WITH DIABETES MELLITUS TYPE 2? A STUDY PROTOCOL FOR A RANDOMISED CONTROLLED TRIAL

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Abstract

Background: Exercise Therapy is widely used in the physiotherapy management in Diabetes Mellitus Type 2 (DM2) as it helps in normalizing blood glucose levels. Additionally, advanced electrotherapy modalities are also used in the management of DM2 as it helps in normalizing blood glucose levels. Pulsed Electromagnetic Field Therapy (PEMF) is an advanced novel electrotherapy modality used widely by physiotherapists. However, very little is known of the effectiveness of PEMF therapy on blood glucose levels in individuals with DM2 in a Diabetic Rehabilitation protocol. The aim of this trial is to study the effect of PEMF therapy on blood glucose levels in individuals with DM2.

Methods: This protocol describes a double – blinded randomised controlled trial, where 107 participants with DM2 referred for out-patient diabetic rehabilitation will be recruited who are on normal glucose lowering medications. Participants will be randomised using the 'coin toss' method into two groups: Experimental Group – PEMF combined with Therapeutic Exercises and Control Group – Therapeutic Exercises alone. Participants will come to the out-patient Physiotherapy Department daily for 12 weeks except on Sundays for about 72 physiotherapy sessions. The Primary outcome measures are Fasting Blood Glucose (mmol/L), HbA_{1c} (%) and Mean Plasma Glucose (MPG) Estimate levels. The outcome measures will be recorded at baseline (admission to diabetic rehabilitation) and then at 4 weeks, 8 weeks and 12 weeks post admission to diabetic rehabilitation.

Discussion: The findings of this study will determine whether the addition of PEMF therapy to therapeutic exercises will have an effect on blood glucose levels in individuals with DM2. This will then determine whether PEMF therapy should be included as adjunct and / or alternative in the management of DM2 along with therapeutic exercises.

Trial Registration: The trial protocol was registered prospectively with Clinical Trial Registry of India (CTRI/2020/06/025584) on 3rd June, 2020.

Keywords: Diabetes Mellitus Type 2, Pulsed Electromagnetic Field Therapy; Randomised Controlled Trial

MANUSCRIPT

BACKGROUND

Due to dramatic changes in lifestyle, and an increasing aging population, Diabetes Mellitus Type 2 (DM2) has become a leading health problem in the developing countries like India. [1, 2]Approximately, 69 million people in India have DM2. [3] Management of DM2 involves drug and non-drug approaches like diet and exercise. [4, 5]

Exercise therapy, electrotherapy, as well as manual therapy such as kinesiology taping are common physiotherapy techniques are extensively in the management of various conditions. [6-9]Physiotherapy interventions are widely used by physiotherapists in the management of DM2 as it has an effect on blood glucose levels. [10-18]

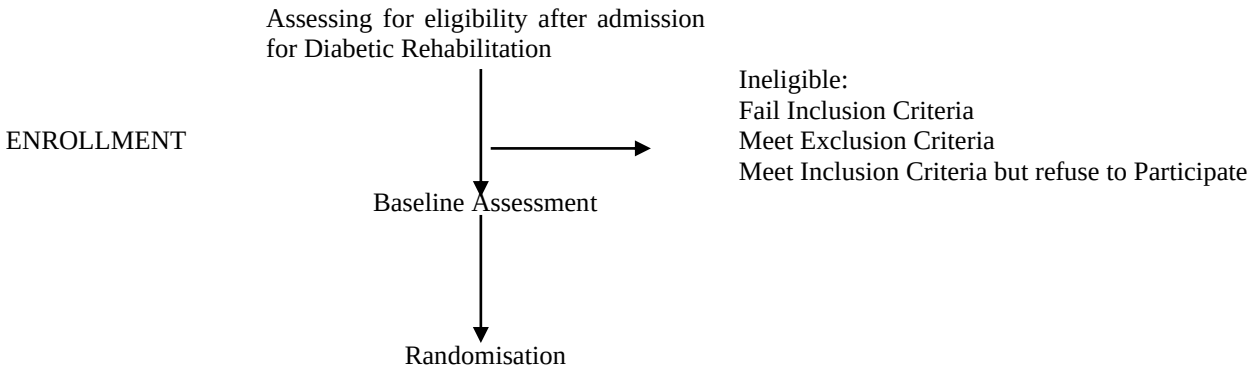
Pulsed electromagnetic field (PEMF) therapy is one of the advanced electrotherapy modalities used currently by physiotherapists worldwide. It is an invisible and non-invasive therapy which is administered by influencing the individual either generally or locally with a magnetic field packed in impulse bundles of frequency ranges between 0.25 and 50 Hz. The electrical energy is used to conduct a series of magnetic impulses through the particular body tissue. This leads to each magnetic impulse inducing tiny electrical signals that stimulate and provide a virtual message for each particular cell. Mitochondrion also known as the powerhouse of the cell absorbs PEMF therapy waves, which activates a series of reactions to increase and store more cellular energy in the form of adenosine triphosphate. Thus, stimulates the biological function of cells, tissues and body systems within the individual resulting in raising the overall vital energy of the individual.

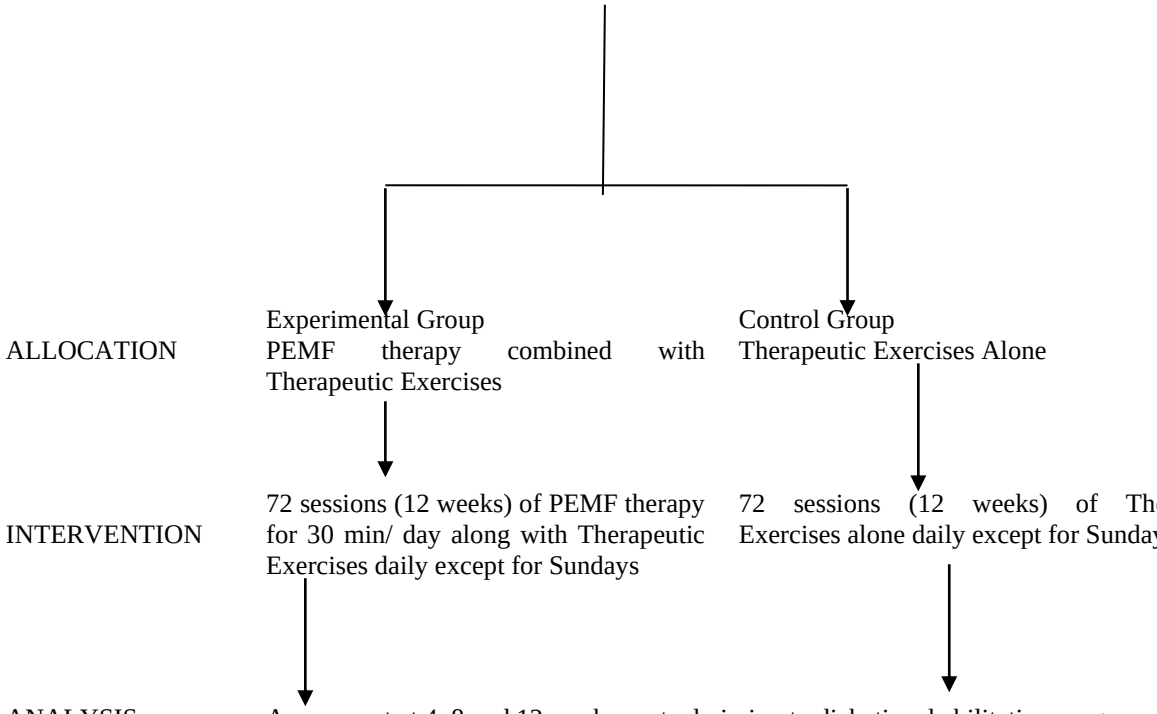
Following are some of the physiological effects of PEMF therapy: a. Enhances capillary formation; b. Accelerates nerve regeneration; c. Enhances synthesis of proteins; d. Increases permeability of cells; e. Increases availability of nitric oxide; f. Increases removal of waste products. [18, 19, 20]
Thus, PEMF therapy can be used in the management of DM2 as it has a potential to have an effect on blood glucose levels in individuals with DM2. [18, 19]

There is a dearth of literature available to date on the effectiveness of PEMF Therapy on blood glucose levels in individuals with DM 2. Thus, we intend to study the effect of PEMF Therapy in individuals with DM 2. As there is a dearth of literature, we intend to do a randomized control trial (RCT), as a RCT is the highest level of evidence in research. The aim of this study is to study the effect of PEMF therapy on blood glucose levels in individuals with DM2.

METHODS

The study design is a double-blinded randomized controlled trial (Flowchart 1) adhering to Standard Protocol Items: Recommendation for Interventional Trials (SPIRIT) guidelines. [21, 22]





Flowchart 1: Flowchart of study protocol

Trial Design

The trial protocol was registered prospectively with Clinical Trial Registry of India (CTRI/2020/06/025584) on 3rd June, 2020. An ethical committee approval was granted by Ethics Committee Dr. D. Y. Patil Vidyapeeth, Pune (Ref. No.DYPV/EC443/2020). Reporting of the RCT will follow the CONSORT guidelines for randomized trials of non-pharmacological treatment and the qualitative assessment would be done based on the PEDro scale for Evidence – Based Practice in Physiotherapy. [22-24]

Sample Size Calculation

According to a study by Anjana R. et al [25] and Iyer S. et al [26] stated that the prevalence of diabetes mellitus type 2 in India is 7.5%.[3,25, 26] Hence, population proportion **(P)** i.e. prevalence is taken as 0.075.

The margin of error is defined as a small amount that is allowed for in case of miscalculation or change of circumstances. We have considered the margin of error **(M)** to be **5%** or 0.05.

S is the sample size to be determined or calculated from an infinite population in India.

Substituting the values of 'Z', 'P' and 'M' in the above formula to determine the sample size for this study

$$\mathbf{S = (1.960)^2 * 0.075\ (1-0.075) / (0.05)^2}$$
$$\mathbf{S = 3.8416 * 0.075\ (0.925) / 0.0025}$$
$$\mathbf{S = 3.8416 * 0.069375 / 0.0025}$$
$$\mathbf{S = 0.266511 / 0.0025}$$
$$\mathbf{S = 106.6044}$$
$$\mathbf{S \approx 107}$$

Therefore, the sample size calculated for this study is **107**.

Participants

A sample of 107 adult male participants of age 35 to 55 years with DM2 will be recruited from 1st July, 2020 to 30th June, 2023 from the Out-Patient department of Dr. D.Y. Patil College of Physiotherapy, Pune – 18.

Participants will be eligible if:-

1. Adult Males

2. Individuals diagnosed with DM2 for more than 6 months (Fasting Plasma Glucose >126 mg/dL < 280mg/dL; HbA_1c> 6.5% < 15.6%)
3. Age between 35 to 55 years
4. Individual on Normal Blood Glucose concentration lowering medications

Participants will be excluded if: - [27]

1. Individuals having a difficulty in attaining sitting position for 30 minutes.
2. Suffering from acute fractures in the spinal region.
3. Individuals with musculoskeletal disorders like strains, sprains, fractures causing an impairment to perform physical activity.
4. Suffering from cardio-vascular disorders.
5. Suffering from neurological disorders.
6. Individuals with DM2 suffering from foot ulcers
7. Individuals undergoing any other form of exercise training
8. Individuals who are hypoglycemic
9. Individuals who are handicapped
10. Females or Trasgenders or Non-adult males
11. Individuals who are suffering from cancer
12. Individuals who are having sensory impairment
13. Individuals suffering from Kidney dysfunction or disorders
14. Individuals with pacemaker
15. Individuals with implants of gel or silicon and / or transplant organs

Randomisation and Allocation Concealment

Eligible participants will be identified by the primary researcher and treating physiotherapist. The primary researcher will inform the participant about the study, give them the patient sheet and provide an explanation about the study in brief. The primary researcher will discuss any questions or queries with the participants and gain an informed consent of willing participants.

Eligible participants will be randomised into two groups via a 'coin toss' method. On 'coin toss' heads occurs the participant will be allocated into 'Experimental Group – PEMF therapy combined with Therapeutic Exercises' and if tails occurs the participant will be allocated into 'Control Group- Therapeutic Exercises alone'. The allocation into groups would be concealed in an envelope. Only the primary researcher would know the group allocation of the participants.

The participants will be informed that there are two different diabetic rehabilitation programs but will not be told that one program includes PEMF therapy. The diabetic rehabilitation will be conducted in a large busy Out- Patient Physiotherapy Department where there are many different patients with different diagnoses treated at the same time by their individual physiotherapists with individual exercise programs dependent on each patients needs. This will reduce the probability of participants from one intervention seeing the other intervention group's exercises.

Procedure

Baseline and all follow –up assessments of Fasting Blood Glucose (mmol/L) and Fasting Blood Glucose (mg/dL) , HbA1c (%) and Mean Plasma Glucose (MPG) Estimate levels will be done by a trained pathologist who is blinded about the type of study being carried out. The Consultant Diabetologist or General Medicine Practioner or Consultant Endocrinologist will diagnose the participant as Diabetes Mellitus Type 2 and refer the participant for Diabetic Rehabilitation to the Out-Patient Physiotherapy Department. All participants will attend daily physiotherapy sessions for 12 weeks except on Sundays for diabetic rehabilitation program.

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Interventions

Therapeutic Exercises[28-50]

Therapeutic Exercises will be provided to both the experimental and the control groups. All participants in this trial will participate in the therapeutic exercises structure of diabetic rehabilitation at the Out-Patient Physiotherapy Department. Under the therapeutic exercises diabetic rehabilitation, the participants attended daily physiotherapy sessions for 12 weeks except on Sundays for the diabetic rehabilitation program.

Therapeutic Exercise Programme: To be followed for 3 days per week on alternate days for 12 weeks

Table 1: Therapeutic Exercise Programme

Day	**Exercise Type**
Monday	Aerobic Exercise
Tuesday	Resisted Exercises
Wednesday	Aerobic Exercise
Thursday	Resisted Exercises
Friday	Aerobic Exercise
Saturday	Resisted Exercises

Warm Up: General range of motion exercises for all peripheral joints.

Aerobic Exercises

Each activity in the sequence will be repeated 8 times and each sequence will be performed for 3 sets.

Week 1 and 2

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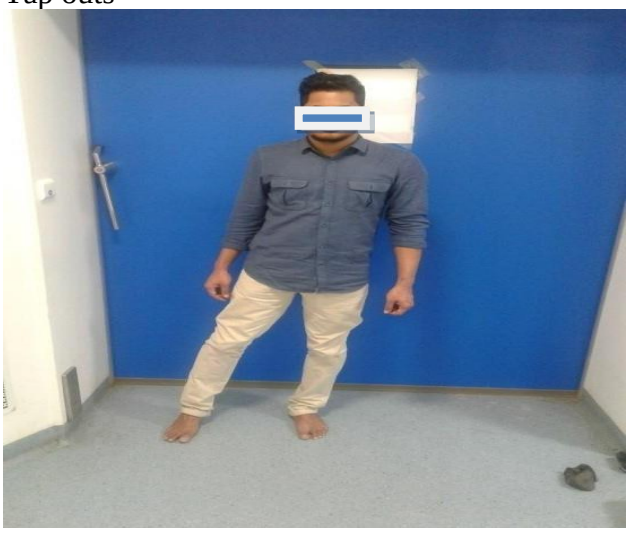
Spot Walking

Tap outs



Spot Walking

Skater - Tap behind foot

Spot Walking
Side Steps

Spot Walking

'V' Walks

Spot Walking High Knees

Spot Walking

Kick Forward

Spot Walking Knee Curls

Spot Walking
Week 3 and 4Spot walking Sidestep

Spot walking Knee Up

Spot walking
Knee Up with hand rotation to same side

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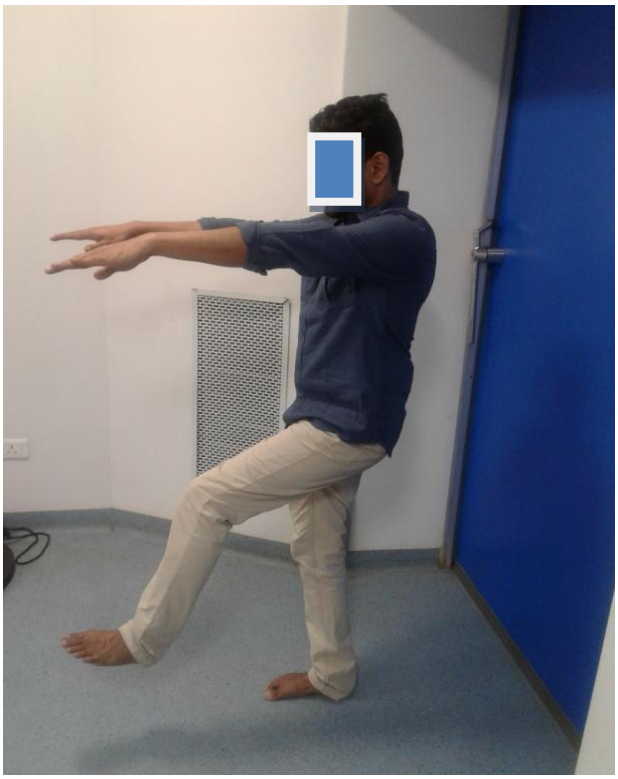
Spot walking Kickforward

Spot walking
Kick forward with arms outstretched



Spot walking
Knee Up with Pull down

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Spot walking
Squat

Spot walking

Week 5 and 6

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Spot Walking
Wide squat throw ball forward

Spot Walking

Wide squat throw ball diagonally upwards

Spot Walking

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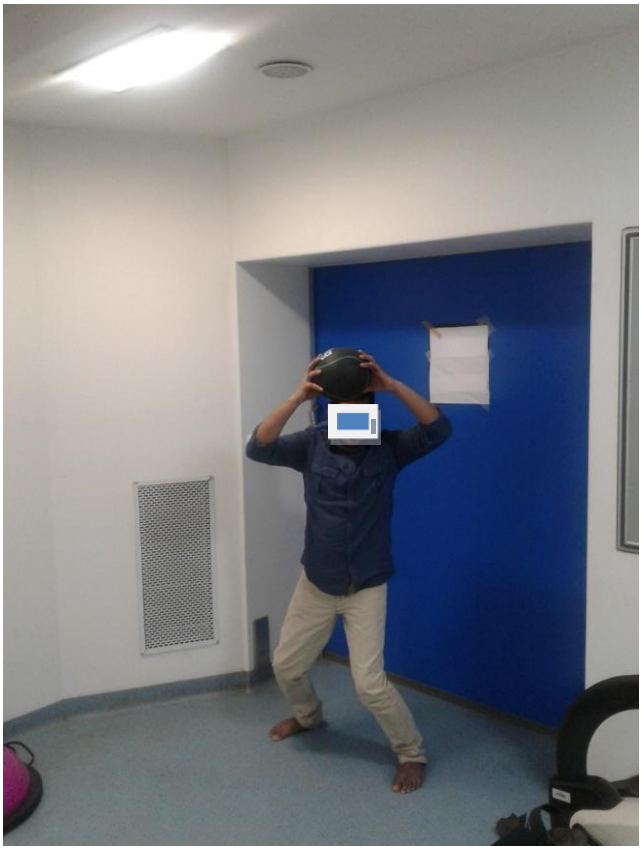
Wide squat throw ball diagonally downwards



Spot walking

Wide squat throw ball upward

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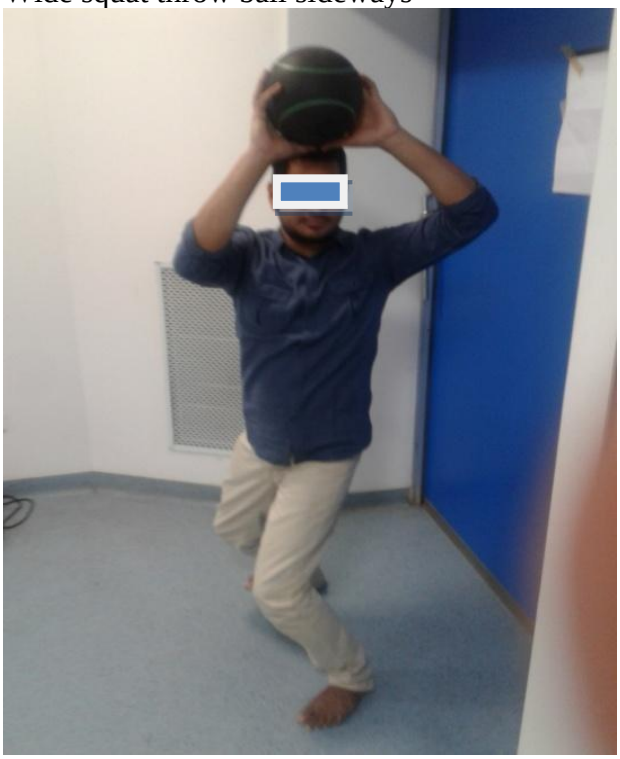
Spot walking
Wide squat throw ball sideways



Spot walking
Wide squat bounce ball on ground

Spot walking

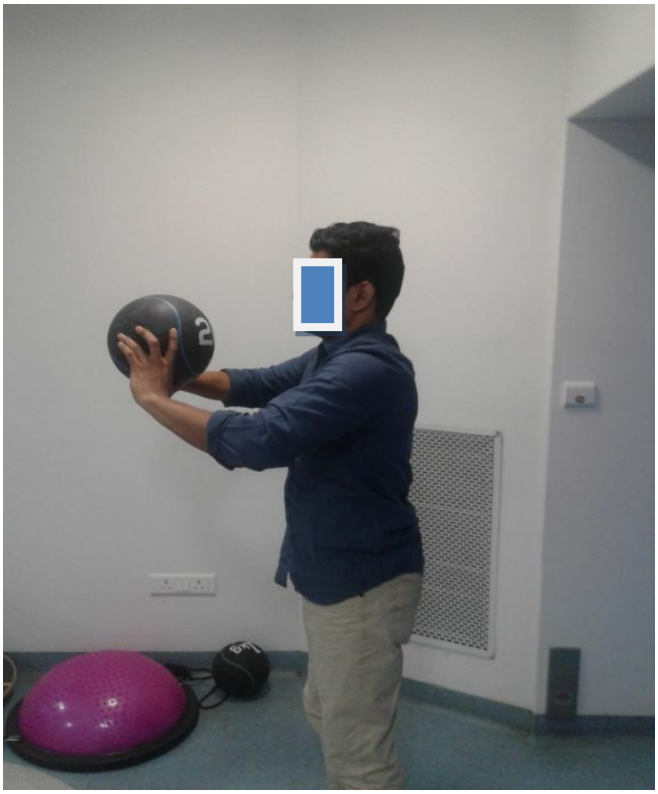
Week 7 and 8
Spot walking
Medicine ball diagonal pattern down to up

Spot Walking

Medicine ball diagonal pattern up to down

Spot Walking

Medicine ball chest throw



Spot walking Oblique"s-Side to Side

Spot walking
Obliques side to side (opposite direction)

Triceps throw

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Spot walking

Biceps throw

Spot Walking
Week 9 and 10
Spot Walking Mini Squat

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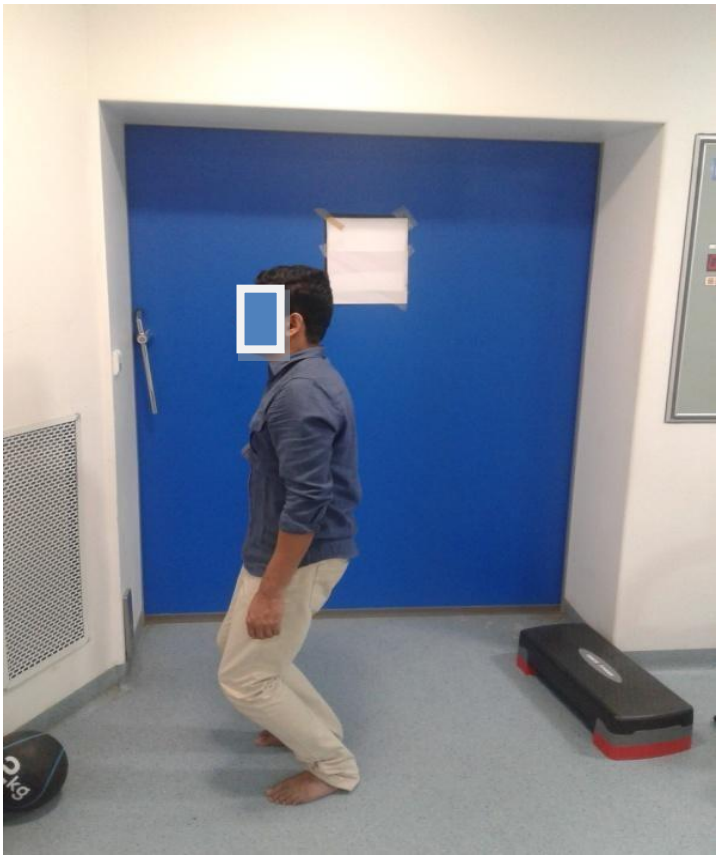
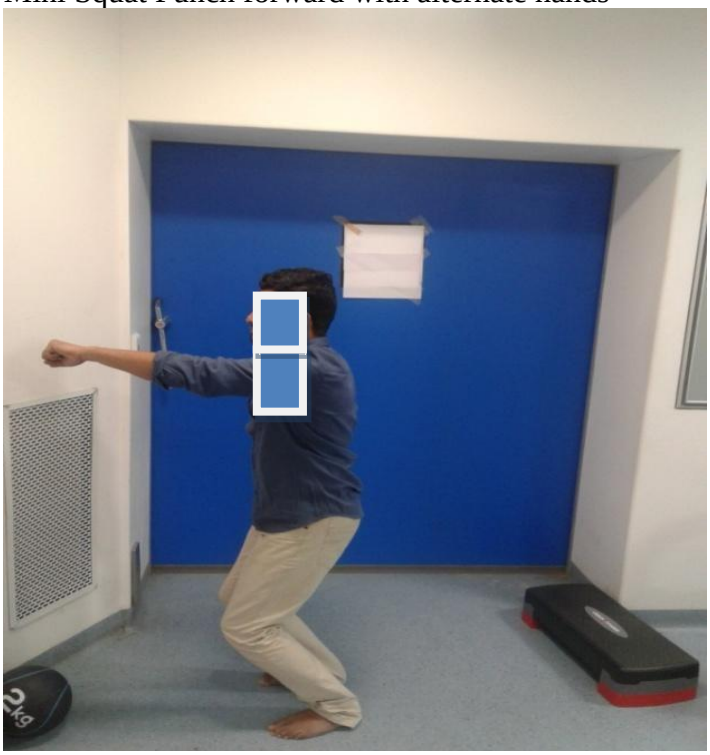


Spot Walking

Mini Squat Punch forward with alternate hands



Spot Walking
Mini Squat Punch Upward with alternate hands

Spot Walking
Punch downward with alternate hands

Spot Walking

Punch Sideways alternately in each direction

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Spot Walking
Punch Sideways Up with alternate hands

Spot Walking

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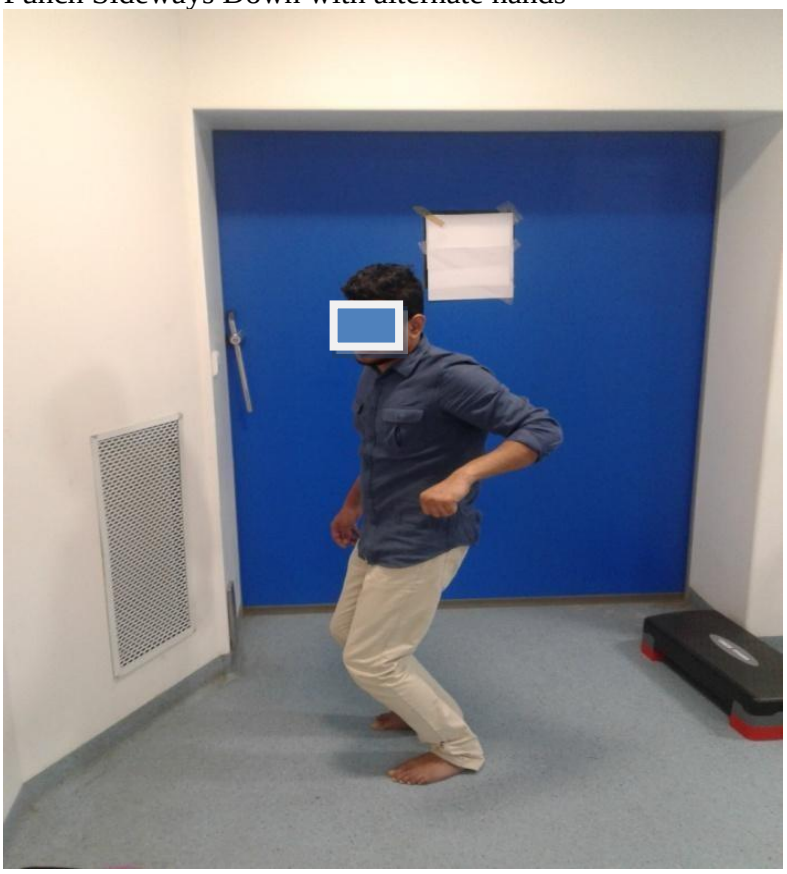
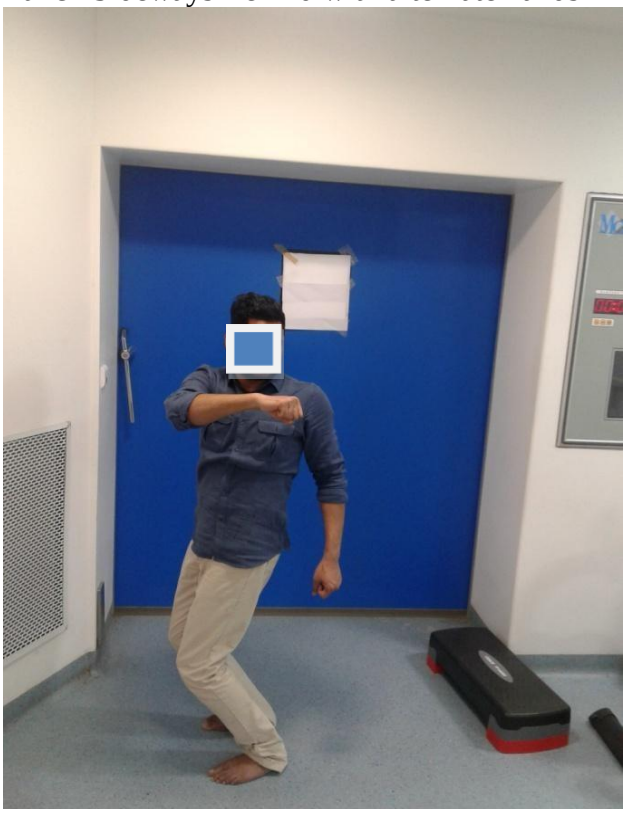
Punch Sideways Down with alternate hands



Spot Walking

Punch Sideways Behind with alternate hands



Spot Walking

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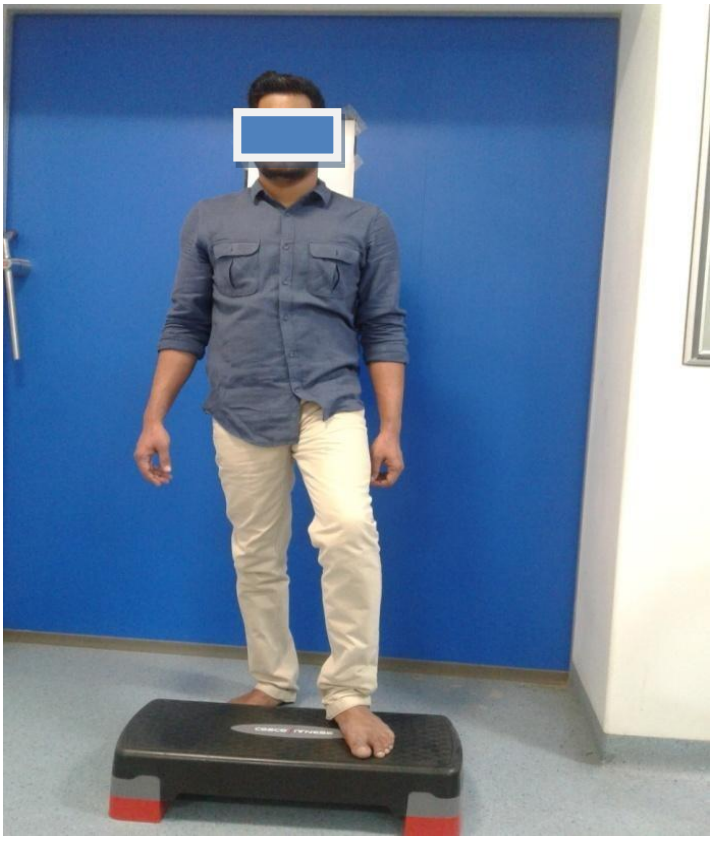
Week 11 and 12
Step Up Up Down Down

a. Step Up

b. Step Up Up



c. Step Up Up Down

d. Step Up Up Down Down

Step Knee down down

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Step Up Up down down
Step Knee down down (other side)
Step Up Up down down
Step Ham Curl down down

Step Up Up down down
Step Ham curl down down (opposite side)

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Step Up Up down down
Step leg back down down

Step Up Up down down
Step Leg back down down (opposite side)
Step Up Up down down
Step kick forward down down

Step Up Up down down
Step kick forward down down (opposite leg)
Step Up Up down down
Step leg sideways down down

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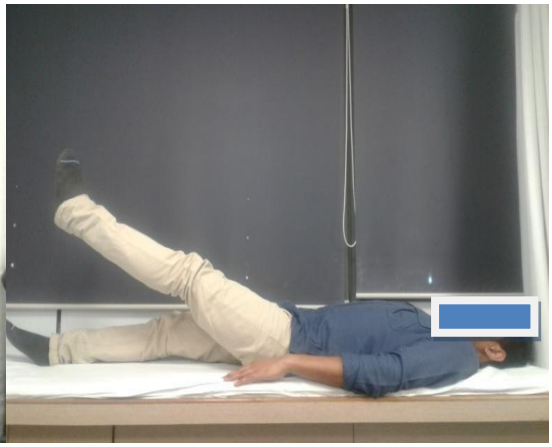
Step Up Up down down
Step leg sideways down down (opposite side)
Step Up Up down down
Resisted Exercises

Table 2: Resisted Exercises for the core muscles to be performed every Tuesday for 12 weeks

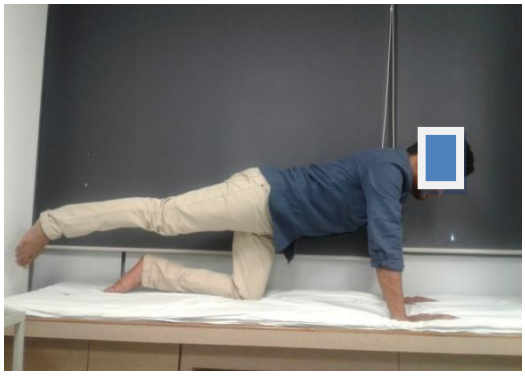
Sr. No.	**Exercise**	**Hold**	**Rest**
1	Pelvic Bridging	8 seconds	3 seconds
2	Supine Straight Leg Raise	8 seconds	3 seconds
3	Quadripod - Raise 1 upper extremity alternatively	8 seconds	3 seconds
4	Quadripod - Raise 1 lower extremity	8 seconds	3 seconds
5	Bird Dog	8 seconds	3 seconds
6	Modified Crunches	8seconds	3 seconds

Pelvic Bridging



Supine Straight Leg Raise

Quadripod - Raise one upper extremity



Quadripod - Raise one lower extremity

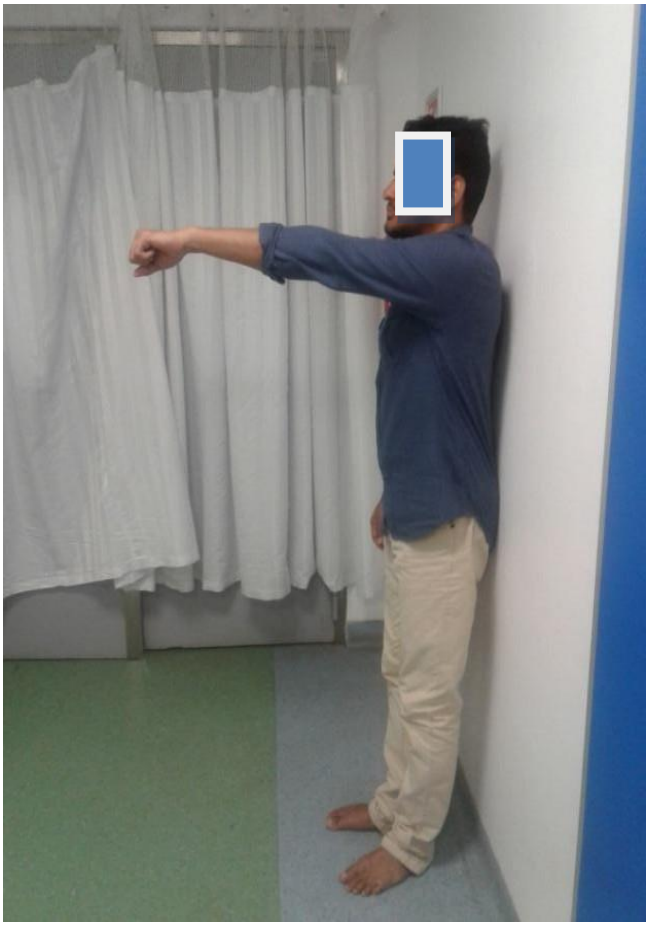
Birddog

Modified Crunches

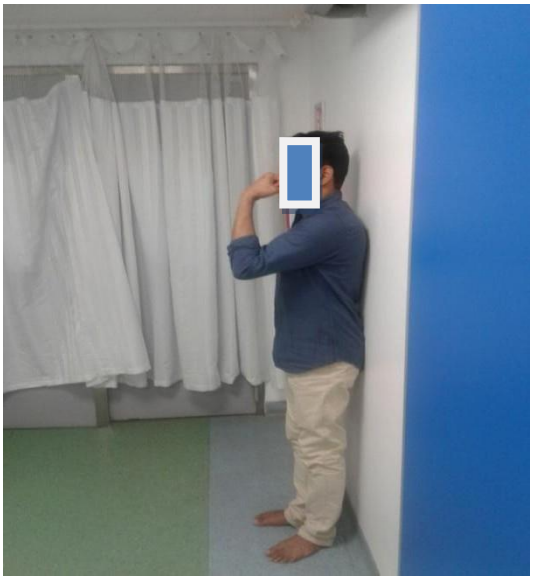
Table 3: Upper extremity resisted exercises to be performed on every Thursday and lower extremity resisted exercises to be performed on every Saturday for 12 weeks.

Sr. No.	**Exercise**	**Hold**	**Rest**
Upper Extremity			
1	Shoulder Flexion to 90 degree	8 seconds	3 seconds
2	Shoulder Abduction to 90 degree	8seconds	3 seconds
3	Bicep Curls	8 seconds	3 seconds
4	Tricep Curls	8 seconds	3 seconds
5	Wrist Curls- Flexion	8 seconds	3 seconds
6	Wrist Curls - Extension	8 seconds	3 seconds
Lower Extremity			
7	Dynamic Quadriceps	8 seconds	3 seconds
8	Hip Flexion above 90 degree in sitting	8 seconds	3 seconds
9	Side Lying Straight Leg Raise	8 seconds	3 seconds
10	Hamstring Curls	8 seconds	3 seconds
11	Heel Raises	8 seconds	3 seconds
12	Toe Raise	8 seconds	3 seconds

Shoulder flexion to 90 degree

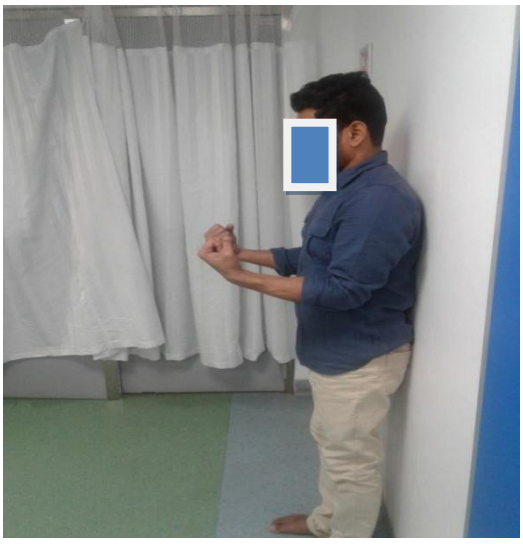


Shoulder Abduction to 90 degree



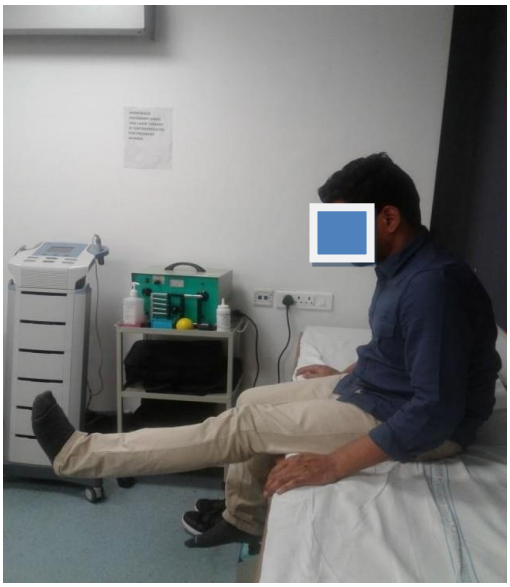
Biceps Curl

Triceps Curl

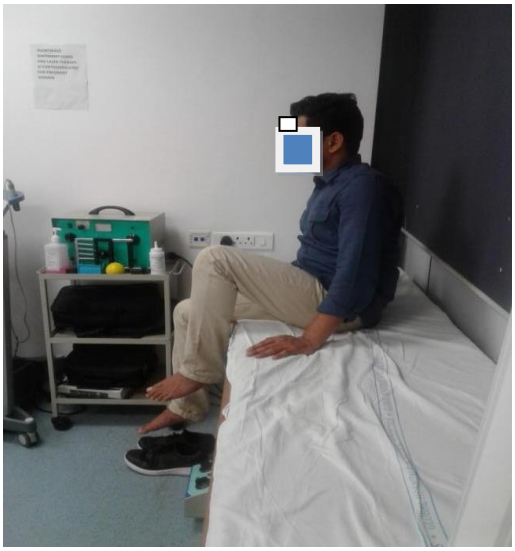


Wrist Curls - Flexion

Wrist Curls - Extension



Dynamic Quadriceps



Hip flexion above 90 degree in sitting

Heel Raises

Toe Raises

Side Lying Straight Leg Raise

Hamstring Curl

Table 4: Progression of Resisted exercises week wise is as follows:-

Week	Repetitions
1 - 3	5
4-6	8
7-9	10
10-12	12

Cool Down: Followed with a cool down period 5 minutes of Savasana.

Cool down - Savasana

If the participant is unable to perform the exercises he will be supported to perform the exercises. All therapeutic exercises will be performed under the supervision of a trained physiotherapist.

Experimental Group[18, 19, 51-57]

Participants in the experimental group will receive the therapeutic exercises program in addition to PEMF therapy for 30 minutes daily for 12 weeks except on Sundays.

Table 5: Intervention Program for Experimental Group

Day		Type of Exercise
Monday	PEMF	Aerobic Exercises
Tuesday	PEMF	Resisted Exercises
Wednesday	PEMF	Aerobic Exercises
Thursday	PEMF	Resisted Exercises
Friday	PEMF	Aerobic Exercises
Saturday	PEMF	Resisted Exercises

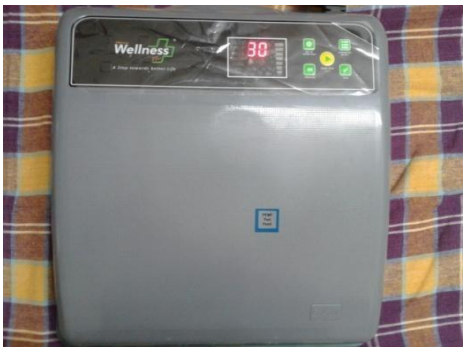
PEMF therapy will be applied with the participant in chair sitting position. The PEMF device will be positioned on the lower back directly perpendicular for the PEMF waves to affect the beta cells of Islets of Langerhans of the head of pancreas.

Position of application of PEMF

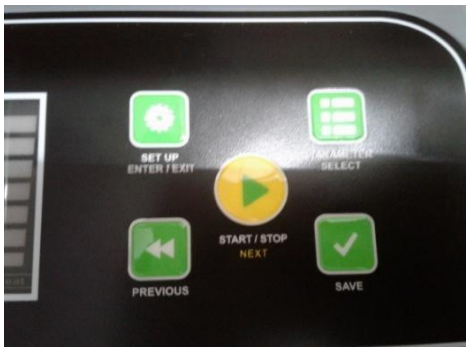
Device Specifications[19]

Device name: Amwaves Wellness - Pulsed Electromagnetic Field Therapy Device

- Pulse range- 0.25 Hz – 44Hz
- Wave form: Square
- Output – quad coil upto 200Gauss
- Duty Cycle -10% – 90% in10%steps
- Quad set (Twin Butterfly) for pulsed output
- Session Duration - 1 to 60minutes
- FIR thermal heat- 35° - 55°C
- HV Micro Currents - Tri level auto-changing
- Electrical Specification- AC 220V-80W
- Weight - 7kg



PEMF Device



Enlarged Image of buttons on PEMF Device

Before any finalized treatment protocol of the PEMF therapy dosage is done, a pilot study would be undertaken with three different treatment dosages.

The best response from among the three would be used finally for the major part of the study.

Table 6: Pilot Study Settings for PEMF therapy before initiating the final study for the experimental group

Settings	**1**	**2**	**3**
Program	12	18	24
Duty %	90	90	90
Duration	30	30	30
Micro C	On	On	On
Heat	45	45	45

After every 24 sessions at week 4, week 8 and week 12 post admission to diabetic rehabilitation program the outcome measures would be reassessed to check for changes in blood glucose parameters. If the participant shows signs of hypoglycemia then the reassessment would be taken earlier. The participants would be recommended to take an opinion of the general physician or endocrinologist or diabetologist to modify the medications dosage as required along with their reports.

If the blood glucose parameters come into normal range before 12 weeks, then PEMF Therapy would be stopped but the exercise regimen would continue.

A session of PEMF will **NOT** be given if:

1. An individual has fever.
2. An individual drinks alcohol within 1 hour before the session

Termination Criteria:

1. Participant feels dizzy
2. Participants feel breathless
3. Patient becomes hypoglycemic

Safety:

1. Participant would be brought to lie down in the supine lying position and made to relax.
2. The participant would be given water to drink.
3. All vital signs would be assessed immediately like blood pressure, heart rate, pulse rate, Oxygen Saturation and respiratory rate.
4. If necessary the participant would be advised to consult a general medical practitioner or any other specialist doctor like Diabetologist.

Precaution:

1. Participant will be advised to drink about 500 ml to 1 L of water between 1 hour prior, during and after treatment with PEMF.
2. Oral rehydrating solution will be kept at handy in the exercise therapy arena.
3. Exercise therapy arena will be well ventilated and light up.
4. Water will be provided to the participant to rehydrate themselves.

The data will be collected and results will be analyzed.

Delivery of the intervention

Due to the physical nature of the intervention, the primary researcher and / or the treating physiotherapist will not be blinded. The primary researcher will himself administer the interventions to the participants in each of the two groups. The therapeutic exercises will be progressed when able to be completed with minimal fatigue and no significant cause of pain due to the therapeutic exercises. Consistency and adherence will also be monitored by the recording of treatment in the participants diabetic rehabilitation record. The diabetic rehabilitation record

includes each exercise performed, the number of repetitions, of each exercise performed, any variations in the exercises performed and reasons for any variations such as adverse events.

Performance Quality

The performance quality will be monitored by the primary researcher. The primary researcher will reassess each participant at the start of each session, and the exercises modified accordingly. If there is any episode of adverse event or pain, the primary researcher will use his/ her clinical reasoning to reduce intensity of particular aggravating exercise or add specific manual physiotherapy treatment as required. To ensure that appropriate muscle adaptation is achieved, the particpant's therapeutic exercises will be progressed according to the American College of Sports Medicine (ACSM) guidelines as soon as the participant is able. [39]

The primary researcher will record the details of each treatment session, and will include the type of exercises and dosage. Any changes to the exercises or adverse responses will be noted.

Outcome Measures

Demographic information to be collected from all participants includes: name, age, duration since onset of disease of DM2, number of sessions, Fasting Blood Glucose (mmol/L), Fasting Blood Glucose (mg/dL), HbA_{1c} (%), Mean Plasma Glucose (MPG) Estimate and Medications Status will be recorded.

The primary outcome measures will be Fasting Blood Glucose (mmol/L), Fasting Blood Glucose (mg/dL), HbA_{1c} (%) and Mean Plasma Glucose (MPG) Estimate levels. The secondary outcome measure will be the Medication Status as prescribed by the Consultant Diabetologist or Endocrinologist or General Medicine Practioner.

Primary Outcome Measures[58 - 62]

1. Fasting Blood Glucose (mmol/L)

A Fasting Blood Glucose (mmol/L) diagnostic cut-off point for the diagnosis of DM2 is 7.0 mmol/L has a very good sensitivity, specificity and reliability.

2. Fasting Blood Glucose (mg/dL)

A Fasting Blood Glucose (mg/dL) diagnostic cut-off point for the diagnosis of DM2 is ≥ 126 mg/dL has a very good sensitivity, specificity and reliability.

3. HbA_{1c} (%)

A HbA_{1c} (%) diagnostic cut-off point of ≥ 6.5% is diagnostic criteria for DM2 and has good reliability, specificity and sensitivity.

4. Mean Plasma Glucose (MPG) Estimate [62]

The Mean Plasma Glucose (MPG) Estimate is derived from Fasting Plasma Glucose and Post Prandiol Glucose correlates strongly with HbA_{1c}. Mean Plasma Glucose (MPG) Estimate are appropriate in diabetes management in the primary care setting, where most management of DM2 occurs.

Secondary Outcome[63-70]

The Medication Status is the secondary outcome which will be used in this study. The Medication Status is based on the assessment, examination and prescription of the Consultant Diabetologist or Consultant Endocrinologist or General medicine Practioner. The two key points to be assessed in medication status are whether a. Tapering of medications have occurred or not and b. Stoppage of medications have occurred or not.

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Adverse Events

Any adverse events or responses will be noted in the participant notes located in the participant's diabetic rehabilitation record file. The primary researcher will check for events of hypoglycaemia, dizziness, fainting, breathlessness or any other adverse event to be noted in the participant's diabetic rehabilitation record file.

Data and Statistical Analysis

Participant characteristics and baseline data in this study will be summarized by descriptive statistics. All data will be analysed with intention to treat principles. Paired 't' tests will be used for intra- group statistical analysis and unpaired 't' tests will be used for inter- group statistical analysis. The Primer of Biostatistics, Version 7, 2011 software will be used for the data analysis for the unpaired 't' test and the paired 't' test.

DISCUSSION

This study describes a protocol for a RCT that will investigate whether the addition of PEMF therapy to therapeutic exercises in individuals with DM2 has an effect on blood glucose levels. This is the first reported study to specifically assess the effect of PEMF therapy on blood glucose levels in individuals with DM2. The trial will provide information to those healthcare professionals working with patients with DM2 to potentially improve outcomes for blood glucose levels in individuals with DM2. This is particularly relevant as the number of individuals with DM2 is rapidly increasing worldwide and especially in India. [71]

Many studies striving to achieve better outcomes for blood glucose levels in individuals with DM2. The main aim in the management of DM2 should be DM2 Remission during the DM2 Reversal journey.[72-77]

Ades P. et al in 2015 in a study in a study investigated the rate of remission of recently diagnosed (< 1 year) type 2 diabetes mellitus in overweight / obese individuals, with a 6 month program of weight loss and exercise. The authors further concluded that individuals with recently diagnosed type 2 diabetes mellitus who are willing to undertake a formal lifestyle program, 80% of study completers and 67% of our total population achieved at least a partial type 2 diabetes mellitus remission at 6 months in their study. [72]

Lemieux I. et al in 2020 in a study stated that lifestyle medicine can be used for reversing diabetes mellitus type 2. The author further stated that a diversity of personalized solutions, which must include a high quality nutritional diet and a physically active lifestyle, along with other important lifestyle determinants such as alcohol consumption, smoking and sleeping habits, should be promoted in order to curb the type 2 diabetes epidemic sweeping the world. [73]

CONCLUSION

There is a need for more knowledge regarding the effect of PEMF therapy on blood glucose levels in individuals with DM2. The findings of this RCT will guide health care professionals involved in the management of patients with DM2 for diabetic rehabilitation.

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ANNEXURE A:-CONSENT FORM

I, Mr./Mrs._____of my own free will of choice, hereby give my consent to include myself in the study " EFFECT OFPULSED ELECTROMAGNETIC FIELD THERAPY IN INDIVIDUALS WITH DIABETES MELLITUS TYPE 2: A RANDOMISED CONTROLLEDTRIAL"

I have been clearly informed to my satisfaction the purpose of the study and thus, I agree to fully cooperate and agree to participate in the study.

I have been informed that no part of information shall be revealed except the data which will be used for the study and adequate secrecy will be maintained.

Also, no part of the information will be used against me.

I am also aware of my right to opt out at any time and prevent the data to be utilized at any phase of the study if I desire.

Signature_____

I, confirm that I have explained the purpose of the study and answered all the questions related to my study.

Investigator" Signature _____

Investigator Certificate

I certify that all the elements including the nature, purpose possible risks and benefits of the above study as described in this consent document have been fully explained to the subject. In my judgment, the participant possesses the legal capacity to give informed consent to participate in this research and is voluntarily and knowingly giving informed consent to participate.

Signature of the Investigator: Dated:____

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Name of the Investigator:_____

ANNEXURE B:- PATIENT INFORMATION SHEET

Diabetes Mellitus type 2 is a condition in which production of insulin is reduced. Thus causes an increase in blood glucose concentration. According to research it is found that nitric oxide concentration is reduced in Diabetes Mellitus. Our treatment programme is aimed at improving the function of beta cells of Islets of Langerhans to improve the secretion of insulin. Thus, aid in the lowering of blood glucose concentration and improving the nitric oxide concentration. The Therapeutic exercises are aimed at utilizing the blood glucose in the muscles.

Thus, it will aid in reducing the blood glucose concentration. Pulsed Electromagnetic Field therapy directly corresponds to an increase in the nitric oxide concentrations thus aiding in the synthesis of insulin.

During the treatment programme you will have to undergo the blood glucose tests like the Plasma Fasting Glucose, HbA_{1c} and Mean Plasma Glucose (MPG) Estimate levels at regular intervals of 24 sessions or earlier if you feel signs and symptoms of hypoglycemia. These tests will tell us the effectiveness of the treatment programme. You will also have to meet your consulting General physician, diabetologist or endocrinologist along with your reports as your medications may need to be tapered down.

Signs and Symptoms of Hypoglycemia:

- Blurry vision
- Rapid heartbeat
- Sudden mood changes
- Sudden nervousness
- Unexplained f atigue
- Pale skin
- Headache
- Hunger
- Shaking
- Dizziness
- Sweating
- Difficulty sleeping
- Skin tingling
- Trouble thinking clearly or concentrating
- Loss of consciousness, seizure, coma

If at all during the treatment session you feel uneasy, you need to report it. The following measures will be taken:

Termination Criteria:

1. Participant feels dizzy
2. Participants feel breathless
3. Patient becomes hypoglycemic

Safety:

Participant would be brought to lie down in the supine lying position and made to relax. The participant would be given water to drink. All vital signs would be assessed immediately like blood pressure, heart rate, pulse rate, Oxygen Saturation and respiratory rate. If necessary the participant would be advised to consult a general medical practitioner or any other specialist doctor like Diabetologist.

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Precaution:

Oral rehydrating solution will be kept at handy in the exercise therapy arena Exercise therapy arena will be well ventilated and light up

You should bring 1 Litre of water along with you for the session. Also water will be provided to you to rehydrate yourselves. You need to rehydrate yourselves in order to help drain out the toxic waste products from your body.

You will have to give information of entire past medical and surgical history, along with your current drug medications that you take.

You will have to provide a copy of your blood glucose test and nitric oxide concentrations tests reports.

A videography of each treatment session will be done to submit it to the Institutional Scrutinizing Committee for the authenticity of the study and it will be monitored regularly.

If at all you have any queries, related to the treatment programme before or during the treatment session, you may ask at any time of the study.

Participant No.:-

ANNEXURE C: -ASSESSMENT FORM

Participant Name:
Age:
Gender:
Date of Assessment:
Diagnosed with Diabetes Mellitus type 2 since:
On medications for Diabetes Mellitus type 2 since:
Checklist for Exclusion Criteria of study :(If any one of the following present then participants is excluded from the study)

1. Individuals having a difficulty in attaining sitting position for 30minutes.
2. Suffering from acute fractures in the spinal region.
3. Individuals with musculoskeletal disorders like strains, sprains, fractures causing an impairment to perform the therapeutic exercises.
4. Suffering from cardio-vascular disorders.
5. Suffering from neurological disorders.
6. Individuals with diabetes mellitus suffering from foot ulcers
7. Individuals undergoing any other form of exercise training
8. Individuals who are hypoglycemic
9. Individuals who are handicapped
10. Non – adult males or females or transgenders
11. Individuals who are suffering from cancer.
12. Individuals who are having sensory impairment
13. Individuals suffering from Kidney dysfunction or disorder.
14. Individuals with Pacemaker.
15. Individuals with implants of gel or silicon and /or transplant organs.

ANNEXURE D: - DATA RECORDING CHART

Name:
Age:
Gender:
Group: A / B
Fulfilling Eligibility Criteria: Yes / No
Date of Pre- Intervention Assessment:
Date of Post Intervention Assessment:

Outcome Measure	**Pre - Intervention**	**After 24 sessions/ 4 weeks**	**After 48 sessions / 8 weeks**	**After 72 sessions / 12 weeks**
Fasting Plasma Blood Glucose (mmol/L)				
Fasting Plasma Blood Glucose (mg/dL)				
HbA_{1c} (%)				
Mean Plasma Glucose (MPG) Estimate				

Medications Status Post Intervention:

Name of Researcher : Signature: