MATERIALS & METHODS

SUBJECTS

A group of 200 patients of established osteoarthritis of knee ranging in age from 40-65 years were included in the study. Patients with a history of conditions known to preclude exercise were excluded from the study. Such conditions include coronary heart disease, myocardial infarction, unstable angina, chronic bronchitis, emphysema, peripheral vascular disease, thrombophlebitis, embolism, kidney failure and uncontrolled hypertension etc. The patients were explained the study protocol and written consent was taken from them before the start of study programme (Annexure 1).

Patients were randomly divided into two groups: Group A (Experimental Control Group) and Group B (Experimental Patient Group).

Group A: Experimental Control Group (ECG)

100 patients (Males n= 30, Females n= 70) were included in group A, who were applied conventional physiotherapy programme for two months. The frequency of application was 5 days in a week.

Group B: Experimental Patient Group (EPG)

100 patients (Males n= 32, Females n= 68) were included in group B, who were applied exercise rehabilitation programme along with conventional physiotherapy programme for two months. The frequency of application was 5 days in a week.
In order to make the groups more homogeneous, they were further subdivided into males and females.

**DATA COLLECTION**

Data collection was based on thorough evaluation of the subjects and the findings were recorded in the periodic case sheet of the subjects. The findings were recorded three times during the course of study.

I Before the start of the study: A thorough evaluation of the patients physical characteristics, measurement of clinical health status, measurement of health related fitness, measurement of physiological and biochemical parameters were done before the start of study programme.

II After one month of treatment programme: Again thorough evaluation of the patients physical characteristics, measurement of clinical health status, measurement of health related fitness, measurement of physiological and biochemical parameters were done after one month of treatment programme.

III After two months of treatment programme: Again thorough evaluation of the patients physical characteristics, measurement of clinical health status, measurement of health
related fitness, measurement of physiological and biochemical parameters were done after completion of two months of treatment programme.

It was not possible to control dietary habits of the patients who were at their own will to eat anything. It was the limitation of the study.

Every care was taken to control the factors like drugs. The medical history of the patients was recorded. Few patients were on oral hypoglycaemic drugs and they did not changed the drugs throughout the course of the study. Some patients were on lipid lowering drugs like statins and fibrates and they also continued the same drugs throughout the course of the study.

The various parameters that were included in the study programme were as follows:

1. **The physical characteristics:**
   1. Age
   2. Sex
   3. Height
   4. Weight
   5. Body mass index (BMI)
2. **The clinical health status:**
   1. Pulse rate
   2. Heart rate (HR)
   3. Blood pressure (BP) systolic
   4. Blood pressure (BP) diastolic

3. **The health related fitness:**
   1. Level of Pain
   2. Range of motion of knee joint (ROM)
   3. Strength of muscles
   4. Cardiovascular fitness
   5. Functional status

4. **The physiological parameters:**
   1. Haemoglobin (Hb)
   2. Erythrocyte sedimentation rate (ESR)

5. **The biochemical parameters:**
   1. Fasting blood glucose
   2. Serum cholesterol
   3. Serum triglycerides
   4. High density lipoproteins-cholesterol (HDL-c)
   5. Serum uric acid
EQUIPMENTS

The different equipments used in the present study are largely grouped as follows:

1. Equipments used for the measurements of physical characteristics.
2. Equipments used for the measurements of clinical health status.
3. Equipments used for the measurements of health related fitness.
4. Equipments used for the measurements of physiological parameters.
5. Equipments used for the measurements of biochemical parameters.
6. Equipments used for administration of treatment programme.
7. Equipments used for the statistical analysis of the data.
1. **Equipments used for the measurements of physical characteristics:**
   a) **Stadiometer:** It was used for the measurement of height of the subjects. It had three parts:
      (i) Foot stand
      (ii) Horizontal movable arm
      (iii) Anthropometric rod

      The anthropometric rod had two parts. The lower part was attached with the foot stand and was without scale whereas the upper part of the rod bore the scale from 92 to 203 cms (i.e., 36” to 80”). By joining these two parts a long continuous steel rod of 2 meters length was made. The steel rod 112 divisions of 1 cm each, which is further subdivided into 10 smaller divisions of 1mm each. This instrument being capable of measuring height up to 2 meters could also measure it up to fraction of 1 mm.

   b) **Weighing Machine (Portable):** The spring type portable weighing machine which was calibrated before use and was used to measure body weight. The accuracy of the balance was checked at intervals with standard weight. It could measure weight upto 120 kgs.

2. **Equipments used for the measurements of clinical health status:**
   a) **Pulse rate:** Pulse rate was measured manually by using a wrist watch.
b) **Heart rate:** Heart rate was measured by using POLAR Heart rate monitor. It consists the following parts:

(i) **Chest piece or transmitter:** It consists of transmitter and elastic straps.

(ii) **Wrist watch:** It consists of wrist unit, which displays heart rate, exercise time, exercise zone, duration of exercise and time of day.

c) **Blood pressure:** Blood pressure was measured by using a standard sphygmomanometer and a stethoscope. The sphygmomanometer had the following parts:

(i) **Mercury manometer:** It contains a mercury reservoir and a graduated tube. Its top was connected with an inflatable rubber bag through a rubber tube.

(ii) **Air pump:** It contains a rubber bulb attached with a one way valve at its free end. It also contains a knurled screw and a leak valve at the other end where the rubber tube leading to the cuff was attached.

(iii) **Stethoscope:** A Littman stethoscope was used along with the sphygmomanometer to measure the blood pressure. It contains a bell, a diaphragm and two ear pieces.

d) **Body mass index:** Body mass index of the patient was calculated by the following formula:

\[
\text{BODY MASS INDEX} = \frac{\text{BODY WEIGHT (Kilograms)}}{\text{HEIGHT (Meters)}^2}
\]
3. **Equipments used for the measurements of health related fitness:**

a) **Pain:** Pain was assessed by using Visual Analogue Scale (VAS) from 0 to 10, 0 being no pain and 10 being worst pain.

b) **Range of motion (ROM):** Range of motion of knee joint was assessed by using a Universal goniometer. It consists of a circular body and two arms.

(i) **Stationary arm:** It stays with the body and cannot be moved independently.

(ii) **Movable arm:** It was attached to the fulcrum in the centre of the body of the goniometer by a screw like device that permits the arm to move freely on the body.

(iii) **Fulcrum:** It lies with the joint axis. It is the point from where movable arm moves on the body of the goniometer.

c) **Strength of muscles:** Back-leg-chest dynamometer was used to measure the isometric force provided by the muscles of the back, leg, chest and shoulders. The range of measurement on the dial of the dynamometer was from 0 to 660 lbs. The measurement of the muscular force was read from the dial to the nearest 5.0 lbs.
The Back-leg-chest dynamometer consisted of the following:

(i) Body
(ii) Extended Foot stand
(iii) Hand grip
(iv) Chain
(v) Dial and
(vi) Pointer

Weight cuffs were used to measure the isotonic strength of the leg muscles. Each weight cuff was filled with sand and pebbles, double sewn and had long wrap around to hold weight cuff securely in place. The set included weight cuffs of varying weights i.e. ½ kg, 1kg, 2kgs, 3kgs, 4kgs & 5kgs.

d) **Cardiovascular fitness**: Cardiovascular fitness was measured by using Crompton test (Joshi and Kotwal, 2000). Pulse rate is measured after 3 minutes of rest in supine. Pulse rate is re-recorded immediately on standing. The difference indicates overall simple heart performance.

Grade 1: Good cardiovascular fitness (Difference = 4 beats)
Grade 2: Fair cardiovascular fitness (Difference = > 4 & < 20 beats)
Grade 3: Poor cardiovascular fitness (Difference > 20 beats)

e) **Functional status**: Functional status was measured by using Western Ontario and McMaster Universities (WOMAC) Index of Osteoarthritis. A total of 24 parameters were used under the
following subheadings: Pain, Stiffness & Physical function which contains 5, 2 & 17 parameters respectively. The parameters are:

Pain:

(1) walking
(2) stair climbing
(3) nocturnal
(4) rest
(5) weight bearing

Stiffness:

(1) morning stiffness
(2) stiffness occurring later in the day

Physical function:

(1) descending stairs
(2) ascending stairs
(3) rising from sitting
(4) standing
(5) bending to floor
(6) walking on flat surface
(7) getting in or out of car
(8) going shopping
(9) putting on socks
(10) rising from bed
(11) taking off socks
(12) lying in bed
(13) sitting with support
(14) sitting without support
(15) getting on or off toilet
(16) heavy domestic duties
(17) light domestic duties

Scoring and interpretation of WOMAC scale is as under:

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</tr>
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<td>2</td>
</tr>
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<td>Severe</td>
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</tr>
<tr>
<td>Extreme</td>
<td>4</td>
</tr>
</tbody>
</table>

Interpretation of WOMAC scale is as under:

- Minimum total score: 0
- Maximum total score: 96
- Minimum pain subscore: 0
- Maximum pain subscore: 20
- Minimum stiffness subscore: 0
- Maximum stiffness subscore: 8
- Minimum physical function subscore: 0
- Maximum physical function subscore: 68
4. **Equipments used for the measurements of physiological parameters:**

(a) **Estimation of Haemoglobin (Hb):** Estimation of Haemoglobin was done by Sahli’s method by using Sahli’s haemoglobinometer. It consists of following components:

(i) **Comparator:** It consists of a rectangular plastic box with a slot, which could accommodate the calibrated haemoglobin tube. Non-fading standard brown glass filters were provided on either side of the slot whereas an opaque white glass was fitted behind the slot to provide uniform illumination during colour matching.

(ii) **Haemoglobin tube:** It bears graduation in g% (2-24) on one side and percentage (20-140) on the other side (originally taking 17 g per 100ml blood as 100%).

(iii) **Haemoglobin pipette:** This pipette has only one mark of 20 mm. Unlike RBC and WBC pipette, this pipette does not have any bulb.

(iv) **Pasteur pipette:** This is used for dilution of acid hematin with the haemoglobin tube.

(v) **Stirrer:** A thin glass rod (sometimes blunt at one end) is used for mixing the solution at the time of dilution of acid hematin with distilled water.
In addition to haemoglobinometer, decinormal (N/10) hydrochloric acid, distilled water, spirit, cotton and lancet were required.

(b) **Estimation of Erythrocyte Sedimentation Rate (ESR):**

Estimation of erythrocyte sedimentation rate was done by Westergren method.

(i) **Westergren tube:** This is a 30 cm long glass tube with both sides open. The bore of the tube is of 2.5 mm diameter. The tube is calibrated in mm from 0 to 200 from above to downwards. The graduated volume of the pipette is about 1 ml.

(ii) **Westergren tube stand:** It is a metallic stand with the 6 tubes accommodative capacity at a time. For each tube holder, there is a screw cap that covers the top of the Westergren tube. At the bottom of the tube holder, there is a rubber cushion. When the tube is fitted with the tube, the bottom end of the tube is sealed by this rubber cushion with pressure.

(iii) Sterile solution of 3.8% sodium citrate.

(iv) Disposable syringe and needle.

(v) Sterile swab moist with alcohol.
5. **Equipments used for the measurements of biochemical parameters:**

(a) **Estimation of Fasting blood glucose:** Estimation of fasting blood glucose was done by ERBA Chem 7 (Trans Asia) Semi Automatic analyzer and Autopak kits from Bayer Diagnostics India Ltd.

Reagent 1 (buffer/enzymes/chromogen):

- Phosphate buffer: 95 mmol/L
- 4-aminoantipyrine: 0.2 mmol/L
- p-hydroxy benzoic acid: 5.9 mmol/L
- Glucose oxidase: ≥ 5000 U/L
- Peroxidase: ≥ 5000 U/L

Standard (Glucose 100 mg/dL):

- Glucose: 1 g/L

(b) **Estimation of Serum Cholesterol:** Estimation of Serum Cholesterol was done by ERBA Chem 7 (Trans Asia) Semi Automatic analyzer and Autopak kits from Bayer Diagnostics India Ltd.

Reagent 1 (enzymes/chromogen):

- Cholesterol esterase: ≥ 200 U/L
- Cholesterol oxidase: ≥ 250 U/L
- Peroxidase: ≥ 1000 U/L
- 4-aminoantipyrine: 0.5 mmol/L
Reagent 1A (buffer):

Pipes buffer, pH 6.90 50 mmol/L
Phenol 24 mmol/L
Sodium cholate 0.5 mmol/L

Standard (Cholesterol 200 mg/dL):

Cholesterol 2 g/L

(c) **Estimation of Serum Triglycerides:** Estimation of Serum Triglycerides was done by ERBA Chem 7 (Trans Asia) Semi Automatic analyzer and Autopak kits from Bayer Diagnostics India Ltd.

Reagent 1 (enzymes/chromogen):

Lipoprotein lipase ≥ 1100 U/L
Glycerol kinase ≥ 800 U/L
Glycerol-3-phosphate oxidase ≥ 5000 U/L
Peroxidase ≥ 350 U/L
4-aminoantipyrine 0.7 mmol/L
ATP 0.3 mmol/L

Reagent 1A (buffer):

Pipes buffer pH 7.50 50 mmol/L
ADPS 1 mmol/L
Magnesium salt 0.3 mmol/L

Standard (Triglyceride of 200 mg/dL)

Glycerol (Triglyceride equivalent) 2 g/L
(d) **Estimation of Serum High Density Lipoprotein-cholesterol (HDL-c):** Estimation of High Density Lipoprotein-cholesterol was done by ERBA Chem 7 (Trans Asia) Semi Automatic analyzer and Autopak kits from Bayer Diagnostics India Ltd.

Reagent 1 (Enzymes/ chromogen):

- Cholesterol esterase $\geq 200$ U/L
- Cholesterol oxidase $\geq 250$ U/L
- Peroxidase $\geq 1000$ U/L
- 4-aminoantipyrine $0.5$ mmol/L

Reagent 1A (buffer):

- Buffer phenol pH 6.90 $50$ mmol/L
- Sodium cholate $0.5$ mmol/L

Reagent 2 (precipitating reagent):

- Phosphotungstic acid $2.4$ mmol/L
- Magnesium chloride $39$ mmol/L

Standard (HDL-cholesterol of 50 mg/dL):

- Cholesterol $0.5$ g/L

(e) **Estimation of Serum Uric Acid:** Estimation of serum uric acid was done by ERBA Chem 7 (Trans Asia) Semi Automatic analyzer and Autopak kits from Bayer Diagnostics India Ltd.

Reagent 1 (Enzymes/Chromogen)
Uricase \( \geq 60 \text{ U/L} \)
Peroxidase \( \geq 660 \text{ U/L} \)
4-aminoantipyrine \( 0.23 \text{ mmol/L} \)
Reagent 1A (Buffer)
Phosphate buffer, pH 7.5 \( 50 \text{ mmol/L} \)
DHBS \( 2\text{mmol/L} \)
Standard (Uric acid 6 mg/dL)
Uric Acid \( 0.06 \text{ g/L} \)

Other materials required:

(i) **Centrifuge:** Motor driven centrifuge was used to make a clear supernatant from the whole blood while estimating blood glucose. The centrifuge speed was expressed as 1-5 meaning 1000 to 5000 rpm (Revolutions per minute). Centrifuge tubes were made up of strong glass and are short in size. They were kept in opposite directions i.e. diagonally to each other in order to maintain the proper balance.

(ii) **Incubator:** Electrically operated incubator was used for keeping the test tubes at 37°C as per requirements during procedures of various tests.

(iii) **Autopipette/micropipette:** These were used for dispensing controlled quantities of liquids during tests.

(iv) **Test tubes:** Test tubes were used for different testing procedures as well as for centrifugation. Chemical reactions were performed in it.
(v) **Test tube stand:** It was used to keep the test tubes in an upright position.

(vi) **Disposable syringes with needle:** It was used for taking the blood specimen from the patient.

(vii) **Sterile swabs:** Moist sterile swabs with 70% alcohol were used for cleaning the skin before and after the sample being taken.

(viii) **Standard glucose solution:** It was a solution with known concentration of glucose i.e. 100 mg/dl.

(ix) **0.1 N HCL Solution:** (1/10) of 1N HCL = 0.1N HCL (N=Normality).

(x) **Distilled water:** Distilled water was used for various testing procedures.

6. **Equipments used for administration of treatment programme:**

a) **Treatment couch:** It was cushioned table top upholstered with rexene and cotton bed sheet. The total size of treatment table was length: 72”, breadth 24” and height 32”. It was having a adjustable backrest of 18” length which could be adjusted in height for the desired position.

b) **Hydrocollator Therapy Unit with packs:** It was made of a heavy gauge stainless steel sheet, double walled and well
insulated in between. Overall size was 58 cms x 40 cms x 76 cms, fitted with 2000 watts immersion heater, pilot lamp and a thermostat for heat control. It contained 12 packs of various sizes. The hydrocollator packs contains silica and gel which can absorb heat for a longer duration of time.

c) **Bath towels:** Various size bath towels were used for the application of hydrocollator packs.

d) **Weight cuffs:** Various weight cuffs of varying weights i.e. ½ kg, 1kg, 2kgs, 3kgs, 4kgs & 5kgs were used.

e) **Static cycle:** Adjustable height and varying resistance wheel was pre-equipped in the static cycle. It was also fitted with one hard tyred wheel, standard chain and socket for cycle drive.

7. **Equipments used for the statistical analysis of the data:**

The raw data of the study was fed in a SONY VAIO Laptop with Intel Pentium Dual-Core Processor, 1.73 GHz, 1 GB RAM, 80 GB Hard disk with Intel PRO/Wireless Technology and Windows XP operating systems. The results were analysed by using Statistical Package for Social Sciences (SPSS version 17.0).
METHODS

The methods employed for the study of various parameters are described as follows:

1. Methods for recording of physical characteristics.
6. The treatment programme.
7. Exercise protocol for conventional physiotherapy programme.
8. Exercise protocol for exercise rehabilitation programme.
9. Methods used for the statistical analysis of the data.
1. **Methods for recording of physical characteristics:**
   
a) **Height:** The height of the subjects was measured by stadiometer. It was calculated by measuring the vertical distance between vertex to the stool on which the patient stood. The subject is asked to stand erect on foot stand of stadiometer with both heels touching each other and toes apart by around 30°. The anthropometric rod of the stadiometer was held vertically behind the subject in the mid sagittal plane. The subject’s head was kept in Frankfort Horizontal plane (F-H plane) and asked to stretch the body upwards. The horizontal movable arm of the anthropometer was brought down to the point vertex and the height was recorded up to a resolution of 1mm.

b) **Weight:** Weight of the patient was measured by a weighing machine (spring type). Zero error of the scale was checked before measuring weight. The patient was asked to stand erect with minimal cloths in the centre of the platform of the weighing scale. The weight was recorded in kilograms with a resolution of 0.10 kgs.

c) **Body mass index:** Body mass index of the patient was calculated by the following formula:

\[
\text{BODY MASS INDEX} = \frac{\text{BODY WEIGHT (Kilograms)}}{\text{HEIGHT (Meters)}^2}
\]
2. **Methods for recording of clinical health status:**

(a) **Pulse rate:** Pulse rate was measured by manual method, by using three fingers. Radial pulse was measured. The pulse beats are counted for 15 seconds and then multiplying by 4.

(b) **Heart rate:** Heart rate was measured by using POLAR Heart rate monitor.

Placement of chest piece or transmitter: The electrodes were moistened at the back of transmitter with the help of gel. The chest piece was placed with the help of straps, just below the nipples.

Wrist Unit: Illuminate the wrist unit by pressing the button. It displayed the following things heart rate, exercise time, exercise zone, duration of exercise and time of day.

(c) **Blood pressure:** The subject was asked to lie down in supine position with complete physical and mental relaxation. The arm was laid bare up to the shoulder. The lid of the sphygmomanometer was opened and the lock on the mercury reservoir was released. It was ensured that mercury was at the zero level. The armlet was wrapped around the upper arm keeping the lower edge about 3 cm above the elbow. The cloth was wrapped around the arm so as to cover the cuff completely and to prevent its bulging out from under the wrapping on inflation. The cuff was neither very tight nor very loose. The bifurcation of the brachial artery was located...
in the cubital space, just medial to the tendon of the biceps muscle, and the point was marked with a felt-tip pen. The diaphragm of the stethoscope was placed on this point and was kept in the same position with fingers and thumb. The cuff was inflated slowly until the sounds disappeared. This reading was noted and the pressure was raised 30-40 mm Hg higher. The leak-valve was opened and controlled so that the pressure gradually falls in steps of 2-4 mm. The reading was noted when the first phase of Kortkoff sounds was heard. This indicated the systolic pressure. As the cuff pressure was further released slowly, the character of the sounds changed; they first became murmurish (Phase II), then clear and banging (Phase III), until they suddenly became muffled (Phase IV) and disappeared. This reading was noted which indicated the diastolic pressure, after which the cuff was deflated quickly. The result was expressed as: Systolic/Diastolic mm Hg.

3. Methods for recording of health related fitness:

(a) Level of Pain: Pain was calculated by using Visual Analog Scale (VAS) from 0 to 10. 0 being no pain and 10 being worst pain.
A 10 cm long horizontal line was drawn on paper. Patient was asked to touch the horizontal line, depending upon the severity of pain perceived.

(b) **Range of motion of knee joint:** A Universal goniometer was used to measure flexion-extension of the knee joint which occurs in the sagittal plane around a medial-lateral axis. The subject was placed in the prone position with the hip in 0 degrees of flexion, extension, abduction, adduction and rotation. The foot of the patient was kept over the edge of the examination couch. The proximal joint segment, i.e. femur was stabilized in order to prevent flexion, extension, abduction, adduction and rotation at the hip.

The end feel was determined by doing the passive movement of the knee joint. The soft end feel for both flexion and extension was considered as normal. The firm end feel during the movement of the knee joint flexion and extension indicated tension in the rectus femoris muscle and posterior joint structures respectively. The fulcrum of the goniometer was centered ½ inch below the lateral epicondyle of the femur. The proximal arm was aligned with the lateral midline of the femur, using the greater trochanter for the reference. The scale of the goniometer was read and recorded as the starting position.
The subject was asked to do the movement. The reading was again taken at the end of the movement, which was considered as the end position. The range of motion was recorded as: the number of degrees at the staring position to the number of degrees at the end position. The range of knee flexion was measured from extension to flexion whereas range of knee extension was measured from flexion to extension.

(c) **Strength measurements:**

**Isometric strength:** Isometric strength was measured by using Back-leg-chest dynamometer. Back-leg-chest dynamometer works on the principle of compression. The method used to find isometric strength by using Back-leg-chest dynamometer is as follows:

a) The subject was asked to stand with both feet together on the extended foot stand.

b) The length of the chain was adjusted for the leg lift.

c) The subject was asked to hold the grip in a comfortable, relaxed manner. The knees were not allowed to bend.

d) The subject was asked to exert a maximal effort by pulling upward gradually and not abruptly. The pointer on the dial on the face of the dynamometer indicated the muscular force thus generated.
e) Three trials were recommended at each lift setting. The pointer was reset between trials by gently moving the pointer back to the zero position on the dial. Care was taken not to move the pointer while the trial was in progress.

f) The isometric muscle strength was taken as the average of these three readings.

**Isotonic strength:** Isotonic strength was recorded by using Delorme and Watkins method (1951). 10 Repetition Maximum (RM) were taken as a baseline. It was determined by asking the patient to lift the greatest amount of weight through the range exactly 10 times, maintaining good form and without tricking.

**Cardiovascular fitness:** Cardiovascular fitness was measured by using Crompton test (Joshi and Kotwal, 2000). Pulse rate was measured after 3 minutes of rest in supine. Pulse rate was re-recorded immediately on standing. The difference indicates overall simple heart performance.

- Grade 1: Good cardiovascular fitness (Difference = 4 beats)
- Grade 2: Fair cardiovascular fitness (Difference = > 4 & < 20 beats)
- Grade 3: Poor cardiovascular fitness (Difference > 20 beats)

**Functional status:** Functional status was measured by using Western Ontario and McMaster Universities (WOMAC) Index of Osteoarthritis. A total of 24 parameters were used under the following subheadings: Pain, Stiffness & Physical function which contains 5, 2 & 17 parameters respectively.
The parameters are:

Pain:

(1) walking
(2) stair climbing
(3) nocturnal
(4) rest
(5) weight bearing

Stiffness:

(1) morning stiffness
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Physical function:

(1) descending stairs
(2) ascending stairs
(3) rising from sitting
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(5) bending to floor
(6) walking on flat surface
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Interpretation of WOMAC scale is as under:

Minimum total score: 0
Maximum total score: 96
Minimum pain subscore: 0
Maximum pain subscore: 20
Minimum stiffness subscore: 0
Maximum stiffness subscore: 8
Minimum physical function subscore: 0
Maximum physical function subscore: 68
4. **Methods for recording of physiological parameters:**

(a) **Method for estimation of Haemoglobin (Hb):**

(i) Freshly prepared N/10 hydrochloric acid was taken in the haemoglobin tube upto the mark of 2g%.

(ii) Fairly deep finger prick was made and the first drop was wiped off.

(iii) When the second drop was collected, blood was drawn into the haemoglobin pipette exactly upto the mark (0.02mL of blood).

(iv) The blood was transferred in the pipette into the haemoglobin tube containing hydrochloric acid.

(v) The solution was mixed thoroughly and the tube was left aside for at least 10 minutes to allow the haemoglobin in the solution to be converted into acid hematin. A brown colour developed. By 10 minutes, about 95% of the haemoglobin was converted into acid hematin.

(vi) Distilled water was added drop by drop, stirring thoroughly with the stirrer after every addition of each drop of distilled water until the colour of acid hematin solution matches the colour of the standard (i.e., brown glass in the comparator).
(vii) The colour of the solution was compared with that of the colour of the standard against the natural source of light.

(viii) The value was recorded in g/100 ml or g%.

(ix) This test was repeated for two more times to reduce the error.

(x) Results were taken as the average of three values

\[ \text{Haemoglobin concentration} = \frac{R1 + R2 + R3}{3} \]

(b) Method for estimation of Erythrocyte Sedimentation Rate (ESR):

(i) 2 ml of blood was collected by venipuncture and the blood was mixed with anticoagulant (sodium citrate solution) thoroughly by inversion or swirling. The ratio of blood to the anticoagulant was 4:1. It can also be done by taking 0.4 ml of sodium citrate solution in the 2 ml syringe and drawing blood directly into the solution so that the final volume is 2.0 ml (this should be done very carefully).

(ii) Westergren tube was filled with the citrated blood (upto 0 mark) making sure that no air bubble was trapped within the blood column. The filling can be carried out by suctioning by a rubber bulb. One needs to practice to
keep the upper level at the 0 mark. The best way, to do it, was sucking blood slightly above the 0 level and then bringing the blood level to exactly 0 mark by placing the tip of index finger on the top end of the Westergren tube.

(iii) Westergren tube was placed in the rubber cushion and it was fixed vertically by the metal clips provided with the tube stand.

(iv) The time was noted.

(v) The rack was allowed to stand vertically undisturbed for 1 hour.

(vi) The reading of the clear plasma height at the end of 1st hour was taken.

(vii) The results were recorded in: ..........mm/Hr (Westergren).

5. **Methods for recording of biochemical parameters:**

(a) **Method for estimation of Fasting blood glucose:**

Estimation of blood glucose was done by Glucose oxidase/peroxidase (GOD/POD) method (Trinder, 1969) using Autopak kit from Bayer’s Diagnostics Ltd. The kit consisted of:

(i) Reagent 1 (buffer/enzymes/chromogen) which contained phosphate buffer, p-hydroxy benzoic acid, glucose oxidase, peroxidase and 4-aminoantipyrine; and

(ii) Glucose standard of 100 mg/dl.
**Principle of the Glucose oxidase/peroxidase method:**
Glucose is oxidized by glucose oxidase (GOD) into gluconic acid and hydrogen peroxide. Hydrogen peroxide in presence of peroxidase (POD) oxidizes the chromogen 4-aminoantipyrine to a red coloured compound; the intensity of the red coloured compound is proportional to the glucose concentration and is measured at 505 nm (490 - 530nm).

**Procedure:** Three test tubes Blank, Standard and Test were taken. 1 ml of reagent was added to the three test tubes. 10μl standard was added to the standard test tube and 10μl sample in the test. All were incubated at 37ºC for 15 min and reading was taken.

**Method for estimation of Serum Cholesterol:**
Serum cholesterol was estimated by enzymatic method (Allain et al., 1974; Richmond, 1973) using Autopak kit from Bayer’s Diagnostics Ltd. The kit consisted of:

(i)  Reagent 1 (enzymes/chromogen) containing cholesterol esterase, cholesterol oxidase, peroxidase and 4-aminoantipyrine,

(ii) Reagent 1A (buffer) containing buffer, phenol and sodium cholate;

(iii) Cholesterol standard of 200 mg/dl.
**Principle:** Cholesterol ester and water reacts to form cholesterol and fatty acids in the presence of cholesterol esterase. The cholesterol formed reacts with oxygen to form cholestenone and hydrogen peroxide in the presence of enzyme cholesterol oxidase. This hydrogen peroxide which is formed reacts with phenol and 4-amino-antipyrine to form red quinone and water. The concentration of cholesterol in the sample is directly proportional to the intensity of the red complex (red quinone) which is measured at 500 nm.

**Procedure:** Three test tubes Blank, Standard and Test were taken. 1 ml of reconstituted reagent (i.e. mixture of contents of reagent 1 and 1A) was added to the three test tubes. 10μl standard was be added to the standard test tube and 10μl sample in the test. All were incubated at 37°C for 5 min and reading was taken.

**(c) Method for estimation of Serum Triglycerides:**

Serum triglycerides were estimated by enzymatic colorimetric method (Annoni et al., 1982; Jacobs, 1960). The kit consisted of:

(i) Reagent 1 (enzymes/chromogen) containing lipoprotein lipase, glycerol kinase, glycerol-3-phosphate oxidase, peroxidase, 4-aminoantipyrine and ATP;

(ii) Reagent 1A (buffer) contained buffer and magnesium salt;

(iii) Triglyceride standard of 200 mg/dl.
**Principle:** Triglycerides react with water to form glycerol and fatty acid in the presence of lipoprotein lipase. The glycerol formed reacts with ATP in the presence of glycerol kinase to form glycerol-3-P and ADP. The glycerol-3-P reacts with oxygen to form dihydroxyacetone phosphate and hydrogen peroxide in the presence of glycerol-3-P oxidase. Hydrogen peroxide reacts with 4-aminoantipyrine to form red quinone and water in the presence of enzyme peroxidase. The intensity of purple coloured complex formed during the reaction is directly proportional to the triglyceride concentration in the sample and is measured at 546 nm.

**Procedure:** Three test tubes Blank, Standard and Test were taken. 1 ml of reconstituted reagent (i.e. mixture of contents of reagent 1 and 1A) was added to the three test tubes. 10μl standard was added to the standard test tube and 10μl sample in the test. All were incubated at 37ºC for 5 min. and reading was taken.

(d) **Method for estimation of Serum High Density Lipoprotein–cholesterol (HDL-c):**

Estimation of serum HDL-cholesterol was done by phosphotungstate method (Izzo et al., 1981). The kit consisted of:

(i) Reagent 1 (Enzymes/ chromogen) containing cholesterol esterase, cholesterol oxidase, peroxidase and 4-aminoantipyrine;
(ii) Reagent 1A (buffer) containing buffer phenol and sodium cholate;
(iii) Reagent 2 (precipitating reagent) containing phosphotungstic acid and magnesium chloride;
(iv) HDL-c standard of 50 mg/dL.

**Principle:** Chylomicrons, VLDL and LDL fractions in serum or plasma are separated with phosphotungstic acid and magnesium chloride. After centrifugation, the cholesterol in the HDL fraction, which remains in the supernatant is assayed with enzymatic cholesterol method, using cholesterol esterase, cholesterol oxidase, peroxidase and the chromogen 4-aminoantipyrine/phenol.

**Procedure:** Three test tubes Blank, Standard and Test were taken. 1 ml of reagent was added to the three test tubes. 20μl standard was added to the standard test tube and 20μl supernatant was added to the test. All were incubated at 37ºC for 5 min. and readings were taken.

**(e) Method for estimation of Serum Uric Acid:**

Serum uric acid was estimated by uricase method (Ito, 2000).

The kit consisted of:

(i) Reagent 1 (enzymes/chromogen) containing uricase, peroxidase and 4-aminoantipyrine;
(ii) Reagent 1A (Buffer) containing phosphate buffer
(iii) Standard uric acid (6 mg%)
**Principle:** Uric acid is converted by uricase into allantoin and hydrogen peroxide which in presence of peroxidase (POD) oxidizes the chromogen to a red coloured compound which is read at 500 nm (490 - 550 nm).

**Procedure:** Three test tubes Blank, Standard and Test were taken. 1 ml of reconstituted reagent (i.e. mixture of contents of reagent 1 and 1A) was added to the three test tubes. 25 μl standard was added to the standard test tube and 25μl sample in the test. All were incubated at 37ºC for 5 min. and reading was taken.

6. **The treatment programme:**

Both the groups were treated for two months. Patients of experimental control group were treated with conventional physiotherapy programme and patients of experimental patient group were treated both with conventional physiotherapy programme and exercise rehabilitation programme based on guidelines given by Arthritis Foundation (Gordon, 1993).

7. **Exercise protocol for conventional physiotherapy programme:**

Conventional physiotherapy programme included application of hot packs, isometric exercises, range of motion, stretching exercises, joint mobilization exercises and progressive resisted exercises (American Physical Therapy Association, 2001).
(a) **Isometric exercises for quadriceps and hamstrings:**
Position of the patient was supine lying. A roll of towel was placed once below the knee and then below the heel of the foot. Patient was asked to press the roll of towel down. A cycle of five seconds hold and five seconds rest was given with twenty repetitions in each set.

(b) **Isotonic range of motion exercises:** First, the position of the patient was supine lying. Patient was asked to drag his right heel towards his right thigh as far as possible. A cycle of five seconds hold was given with twenty repetitions in each set, alternatively for each side. Patient was asked to lie prone. Patient was asked to pull his right heel towards his posterior thigh as far as possible. A cycle of five seconds hold was given with twenty repetitions in each set, alternatively for each side. Patient was asked to come in high sitting position. He was asked to swing his leg alternatively for 10-15 mins.

(c) **Stretching exercises:** Quadriceps stretch was applied in prone lying position. The patient was asked to lie prone and bend the knee touching the buttocks. Stretch was applied by flexing the knee further. Patient was asked to hold this position for 5-10 counts. For hamstring stretching, position of
the patient was long sitting. The patient was asked to touch the toes by keeping the knees straight. The patient was asked to hold the stretch for 5-10 counts and then relax.

(d) **Mobilization exercises to knee joint:** Patellar glides (medial-lateral and superior-inferior) were given before starting mobilization. Long axis traction was given to the knee joint. Anterior and posterior glides to the knee joint were given in lying and sitting position.

(e) **Progressive resisted exercises:** Patients were given progressive resisted exercises by using deLorme’s Technique at the Quadriceps table. First of all one repetition maximum (RM) was calculated and then ten repetition maximums. 1 repetition maximum is the maximum weight that can be lifted by the patient once through its complete range of motion.

The patient was asked to perform:

(i) Ten repetitions of one half of 10 RM
(ii) Ten repetitions of three forth of 10 RM
(iii) Ten repetitions of full 10 RM
(iv) 30 lifts 4 times weekly
(v) Progression 10 RM once weekly

8. **Exercise protocol for exercise rehabilitation programme:**

For exercise rehabilitation programme along with conventional physiotherapy programme, mild intensity and long duration aerobic
conditioning exercises (at 60% of MHR) were applied to the whole body (including upper limbs). Treatment programme started with the application of hot packs to the knee joints.

**Aerobic conditioning exercises:** Aerobic warm up was given for 5-10 minutes. It included swinging of arms and legs (upwards, sideways, backwards and laterally). Walking was given for 5-10 minutes and cycling was given for 15-20 minutes (at 60% of MHR), 5 times a week. Aerobic exercises were followed by cool down exercises for 5-10 mins (Brosseau et al., 2006).

9. **Methods used for the statistical analysis of the data:**

Statistical methods play very significant role in the interpretation of the numerical data obtained from the individuals by giving numerical expressions to the relationship and the variations with respect to different aspects. Keeping in view the aims of the study, following statistical tools have been used for the interpretation of data:

(a) **Mean ($\bar{x}$):** It is calculated to measure the central tendency of particular parameters, which is typical value in the tendency of particular parameter. All the individual values of
the variable are then added and then the sum is divided by
the total number of individuals.
\[
\bar{X} = \frac{Sx}{n}
\]

(b) **Standard Deviation**: It is the measure of the variation and is
universally used to show the scatter of the individual
measurements in a given distribution. By definition, it is the
square root of the average of the measurements from the
mean.

S.D. is calculated as follows:

(i) Calculated the mean of all the values.

(ii) Find the difference of each value from the mean.

(iii) Square each of the difference.

(iv) Add up these squares and divided the sum by the
number of observations.

(v) Now take the square root of the whole value, thus:-

\[
SD = \sqrt{\frac{(x - \bar{x})^2}{n-1}} \text{ or } \sqrt{\frac{Ed^2}{n-1}}
\]

Where \(x\) = Observed value

\(n\) = Number of individuals

(c) **Standard Error of Mean (S.E.M.)**: Standard Error of mean
indicate the magnitude of sampling error. Therefore, it is
useful in estimating the average dispersion of arithmetic
around the true mean. It is the ratio of the standard deviation to the square root of the number of observations.

\[
S.E.M. = \frac{SD}{\sqrt{n}}
\]

S.D. = Standard Deviation
\(n\) = Number of Observations

(d) **Test of Significance (t-Test):** This test is applied to determine whether the observed differences between the two sample means \(X_1\) and \(X_2\) are indicative of a real difference of it is due to the random sampling errors.

\[
t = \frac{\bar{X}_1 - \bar{X}_2}{\sqrt{\left(\frac{(SEM_1)^2}{n_1} + \frac{(SEM_2)^2}{n_2}\right)}}
\]

Where,

\(X_1\) = Mean of first group
\(X_2\) = Mean of second group
\(S.E.M._1\) = Standard error of mean of first group
\(S.E.M._2\) = Standard error of mean of second group.

The value of ‘t’ obtained was compared with tabulated values at the appropriate degree of freedom (DF = \(n_1 + n_2 - 2\)) and corresponding ‘p’ values were read from the table.

(e) **p value:** The difference between treated and control groups which would have arisen by chance is ‘p’ value. If it is more than 5% (p value > 0.05), it is considered as insignificant ‘p’ value and if it is less than 5% (p < 0.05), it is considered as significant.