



Appendix 1

International Physical Activity Questionnaire



INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the **last 7 days**. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous** activities that you did in the **last 7 days**. **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

1. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, aerobics, or fast bicycling?

_____ **Days per week**

No vigorous physical activities → **Skip to question 3**

2. How much time did you usually spend doing **vigorous** physical activities on one of those days?

_____ **Hours per day**

_____ **Minutes per day**

Don't know/Not sure

Think about all the **moderate** activities that you did in the **last 7 days**. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.



3. During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

_____ **Days per week**

No moderate physical activities → **Skip to question 5**

4. How much time did you usually spend doing **moderate** physical activities on one of those days?

_____ **hours per day**

_____ **minutes per day**

Don't know/Not sure

Think about the time you spent **walking** in the **last 7 days**. This includes at work and at home, walking to travel from place to place, and any other walking that you might do solely for recreation, sport, exercise, or leisure.

5. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time?

_____ **days per week**

No walking → **Skip to question 7**

6. How much time did you usually spend **walking** on one of those days?

_____ **hours per day**

_____ **minutes per day**

Don't know/Not sure

The last question is about the time you spent **sitting** on weekdays during the **last 7 days**. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.

7. During the **last 7 days**, how much time did you spend **sitting** on a **week day**?

_____ **hours per day**

_____ **minutes per day**

Don't know/Not sure

This is the end of the questionnaire, thank you for participating.



Appendix 2

Diabetes Self Care Activity Questionnaire



Summary Of Diabetes Self Care Activities

Diet

1. How often did you follow your recommended diet over last 7 days?

1	Always	
2	Usually	
3	Sometimes	
4	Rarely	
5	Never	

2. During the past week, what percentage of your meals included high fibre food, such as fruits, fresh vegetables, whole grain bread, dried beans, peas and bran?

1	0% [16]	
2	25% (1/4)	
3	50% (1/2)	
4	75% (3/4)	
5	100% (all)	

3. During the past week, what percentage of your meals included high fat food such as butter, ice-cream, oil, nuts and seeds, mayonnaise, avocado, deep fried food, salad dressing, and bacon, other meat with fat or skin?

1	0% [16]	
2	25% (1/4)	
3	50% (1/2)	
4	75% (3/4)	
5	100% (all)	



4. During the week what percentage of your meals Included sweets and desserts such as pie, cake, jelly, soft drinks (regular not diet drinks), cookies).

1	0% [16]	
2	25% (1/4)	
3	50% (1/2)	
4	75% (3/4)	
5	100% (all)	

Glucose testing

5. On how many of the last 7 days (that you were not sick) did you test your glucose (blood sugar) levels?

1	Everyday	
2	Most days	
3	Some days	
4	None of the days	

6. Over the last 7 days, what percentage of the glucose (blood sugar or urine) test recommended by your doctor did you actually perform?

1	0% [16]	
2	25% (1/4)	
3	50% (1/2)	
4	75% (3/4)	
5	100% (all)	

Diabetes medication

7. How many of your recommended number of pills to control diabetes did you take that you were supposed to?

1	All of them	
2	Most of them	
3	Some of them	
4	None of them	
-8	Don't take pills	

The End

Thank You



Appendix 3

Participation Information Letter



Participation Information Letter

University of Pretoria

Department of Biokinetics, Sport and Leisure Sciences & Department of Clinical Epidemiology

TITLE: Effect of a Community-Based Exercise and Lifestyle Intervention on Health Outcomes in Persons with Type 2 Diabetes Mellitus

INTRODUCTION

You are invited to volunteer for a research study. This information leaflet is to help you to decide if you would like to participate. Before you agree to take part in this study you should fully understand what is involved. If you have any questions, which are not fully explained in this leaflet, do not hesitate to ask the investigator. You should not agree to take part unless you are completely happy about all the procedures involved. In the best interests of your health, it is strongly recommended that you discuss with or inform your personal doctor of your possible participation in this study, wherever possible.

WHAT IS THE PURPOSE OF THIS TRIAL?

You have been diagnosed as suffering from Type 2 diabetes mellitus and the investigator would like you to consider taking part in the research. The study will use male and female type 2 diabetic patients from the Mamelodi outpatient diabetic clinic. The participants are required to be between the ages of 40- 60 years without major complications.

WHAT IS THE DURATION OF THIS TRIAL?

If you decide to take part you will be one of approximately **160** patients. The study will last for up to **5 months**. You will be asked to visit the investigator **2** times per week for 5 months. At each visit you will undergo the following:

Twice weekly for 5 months you will be given an exercise session, the intensities will vary as we progress with the exercise. Twice a month after the exercise session you will receive education on dietary aspects for 1/2 an hour to an hour,

this will be in total 10 lectures for the experimental group and 10 lectures for the control group which will be conducted at different times. Various topics will be discussed on diabetes and diet.

2 tubes of blood (one for HbA1C and the 2nd tube for lipid profile).

Anthropometric tests (weight, height, body girths) will be used to determine weight loss before and after the exercise sessions.

Capillary Glucose test (pre- and post exercise) to observe the acute effects of an exercise session on blood glucose.

It is important that you let the investigator know of any medicines (either prescriptions or over-the-counter medicines), alcohol or other substances that you are currently taking.

HAS THE TRIAL RECEIVED ETHICAL APPROVAL?

This clinical trial Protocol was submitted to the Faculty of Health Sciences Research Ethics Committee, University of Pretoria and written approval has been granted by that committee. The study has been structured in accordance with the Declaration of Helsinki (last update: October 2000), which deals with the recommendations guiding doctors in biomedical research involving human/subjects. A copy of which may be obtained from the investigator should you wish to review it.

WHAT ARE MY RIGHTS AS A PARTICIPANT IN THIS TRIAL?

Your participation in this trial is entirely voluntary and you can refuse to participate or stop at any time without stating any reason. Your withdrawal will not affect your access to other medical care. The investigator retains the right to withdraw you from the study if it is considered to be in your best interest. If it is detected that you did not give an accurate history or did not follow the guidelines of the trial and the regulations of the trial facility, you may be withdrawn from the trial at any time.

IS ALTERNATIVE TREATMENT AVAILABLE?

This study does not aim to replace any treatment for diabetes. It is advised however that people with diabetes do exercise. If you do not want to participate in the exercises you will receive your standard medicines like always.



MAY ANY OF THESE TRIAL PROCEDURES RESULT IN DISCOMFORT OR INCONVENIENCE?

Drawing blood is normally done as part of routine medical care and presents a slight risk of pain/ discomfort. Your protection is that experienced personnel perform the procedures under sterile conditions. A total of 2 tubes of blood will be collected over the course of the entire study. The strenuous exercise sessions will also result in you perspiring, which can cause temporary discomfort.

WHAT ARE THE RISKS INVOLVED IN THIS TRIAL?

The exercises may cause temporary muscle soreness but with continuous exercise the pain will disappear. The risk of low blood sugar may occur; if the situation arises a carbohydrate snack will be available to correct the condition.

ARE THERE ANY WARNINGS OR RESTRICTIONS CONCERNING MY PARTICIPATION IN THIS TRIAL?

During the exercise sessions it is likely for a participant to feel faint, dizzy or weak if this occurs the participant must stop exercising immediately and the investigator has to be alerted so that the participant can be attended to.

DISCONTINUATION OF TRIAL

My participation in this research may be terminated without my consent if the investigators (s) believe that any portion of the study will put me at undue risk. My participation may also be terminated if I do not adhere to the study protocol.

INSURANCE AND FINANCIAL ARRANGEMENTS

University of Pretoria will provide payment for all trial procedures and reasonable medical expenses, which you may incur as a direct result of this trial as determined by the department of Biokinetics, Sport, and Leisure Sciences and the investigator. Neither you nor your medical scheme will be expected to pay for any study medication or trial procedures. You will be given R10 per visit to cover your transport costs.



SOURCE OF ADDITIONAL INFORMATION

For the duration of the trial, you will be under the care of **Yvonne Paul**. If at any time between your visits, you feel that any of your symptoms are causing you any problems, or you have any questions during the trial, please do not hesitate to contact him/her. The telephone number is **0834457111/(012) 3185806/5216 (W)/(012) 3202470 (H)**, through which you can reach him/her or another authorized person.

CONFIDENTIALITY

All information obtained during the course of this trial is strictly confidential. Data that may be reported in scientific journals will not include any information, which identifies you as a patient in this trial. Should you wish, you may also contact the Ethics Committee, University of Pretoria on any issues related to the study.

Any information uncovered regarding your test results or state of health as a result of your participation in this trial will be held in strict confidence. You will be informed of any finding of importance to your health or continued participation in this trial but this information will not be disclosed to any third party in addition to the ones mentioned above without your written permission. The only exception to this rule will be cases in which a law exists compelling us to report individuals infected with communicable diseases. In this case, you will be informed of our intent to disclose such information to the authorized state agency.



INFORMED CONSENT

I hereby confirm that I have been informed by the investigator, **Yvonne Paul** about the nature, conduct, benefits and risks of the clinical trial. I have also received, read and understood the above written information (Patient Information Leaflet and Informed Consent) regarding the clinical trial.

I am aware that the results of the trial, including personal details regarding my sex, age, date of birth, initials and diagnosis will be anonymously processed into a trial report.

I may, at any stage, without prejudice, withdraw my consent and participation in the trial. I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the trial.

Patient's name _____
(Please print)

Patient's signature _____ Date _____

Investigator's name Yvonne Paul
(Please print)

Investigator's signature _____ Date _____

I, Yvonne Paul herewith confirm that the above patient has been informed fully about the nature, conduct and risks of the above trial.

Witness's name* _____ Witness's signature _____ Date _____
(Please print)



VERBAL PATIENT INFORMED CONSENT

I, the undersigned, **Yvonne Paul**, have read and have explained fully to the patient, named And/or his/her relative, the patient information leaflet, which has indicated the nature and purpose of the trial in which I have asked the patient to participate. The explanation I have given has mentioned both the possible risks and benefits of the trial and the alternative treatments available for his/her illness. The patient indicated that he/she understands that he/she will be free to withdraw from the trial at any time for any reason and without jeopardizing his/her subsequent injury attributable to the drug(s) used in the clinical trial, to which he/she agrees.

I hereby certify that the patient has agreed to participate in this trial.

Patient's Name _____

(Please print)

Investigator's Name Yvonne Paul

(Please print)

Investigator's Signature _____ Date _____

Witness's Name _____ Witness's Signature _____ Date _____

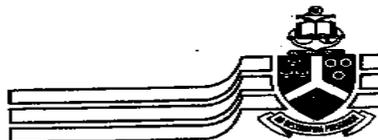


Appendix 4

Ethical Approval and Protocol Number



FWA Nr. 0000 2567
IRB Nr. 0000 2235



University of Pretoria
Faculty of Health Sciences Research Ethics Committee
University of Pretoria
Date: 4/11/2004

Soutpansberg Road
MRC-Building
Room 2 - 19

Private Bag x 385
Pretoria
0001

Number	:	66/2004
New Title	:	The efficacy of a 20 week resistance training program in patients with type 2 diabetes mellitus.
Investigator	:	Y Paul; Department of Biokinetics, sport and leisure sciences; Pretoria Academic Hospital; University of Pretoria.
Sponsor	:	None - Supervisors: HJ van Heerden / P Rheeder

This Protocol and Informed Consent have been considered by the Faculty of Health Sciences Research Ethics Committee, University of Pretoria on 18/08/2004 and found to be acceptable

Prof P Carstens	BLC LLB LLD (Pret) Faculty of Law
Prof S.V. Grey	(female) BSc (Hons); MSc; DSc: Deputy Dean
*Prof V.O.L. Karusseit	MBChB; MFGP (SA); M.Med (Chir); FCS (SA): Surgeon
Dr M E Kenoshi	MB,ChB; DTM & H (Wits); C.E.O. of the Pretoria Academic Hospital
Prof M Kruger	(female) MB.ChB.(Pret); Mmed.Paed.(Pret); PhD. (Leuven)
Dr N K Likibi	MB.BCh.; Med.Adviser (Gauteng Dept.of Health)
Dr F M Mulaudzi	(female) Department of Nursing,
Miss B Mullins	(female) BscHons; Teachers Diploma;
*Snr Sr J. Phatoli	(female) BCur (Et.A) Senior Nursing-Sister
*Prof H.W. Pretorius	MBChB; M.Med (Psych) MD: Psychiatrist
*Reverent P Richards	B.Th. (UNISA), M.Sc. (Applied Biology) (Knights), M.Sc (Med) (Wits), TechRMS, DipRMS
*Dr L Schoeman	(female) Bpharm, BA Hons (Psy), PhD
Dr C F Slabber	BSc (Med) MB BCh, FCP (SA) Acting Head; Dept Medical Oncology
Prof J.R. Snyman	MBChB, M.Pharm.Med: MD: Pharmacologist
*Dr R Sommers	(female) MBChB; M.Med (Int); MPhar.Med;
*Prof TJP Swart	BChD, MSc (Odont), MChD (Oral Path) Senior Specialist; Oral Pathology
Prof C W van Staden	MBChB; Mmed (Psych); MD; FTCL; UPLM; Dept of Psychiatry

DR R SOMMERS; MBChB; M.Med (Int); MPhar.Med.
SECRETARIAT of the Faculty of Health Sciences Research Ethics Committee - University of Pretoria



Appendix 5

Exercise Sheet

Exercises were executed as Follows:

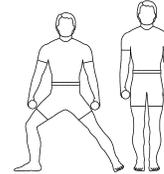
1. 3 sets of 10-12 reps , reps are increased as months progressed
2. Hold exercise for 4 Seconds
3. Rest 30 Seconds between sets
4. Perform 1 repetition every 4 sec

1. Resist Ankle Dorsiflexion Longsit with Elastic



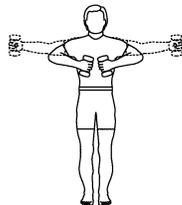
- Sit on floor or couch with leg in front
- Attach elastic to secure object in front of foot
- Attach other end of elastic to forefoot.
- Pull foot backward toward shin.
- Slowly return and repeat

4. Resist Hip Abduction/Knee Flexion



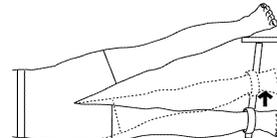
- Stand with weight in hands.
- Loop elastic around thighs, near the knees.
- Keep ankles together, spread knees apart.
- Return to start position and repeat.
- Repeat sets to right side.
- Use Dumbbells

2. Resist Elbow Extension (Arms Abducted) with Weights (DB).



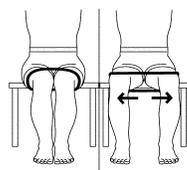
- Hold weights in hands, palms inward as shown.
- Keep elbows out from sides
- Straighten arms.
- Return and repeat.
- Use 2 DB

5. Resist Hip Add Side-lying with Leg Weights



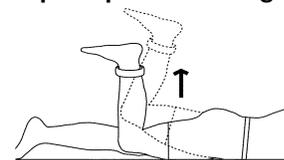
- Lie on involved side.
 - Support uninvolved leg on chair as shown.
 - Keep involved leg straight, weight on ankle.
 - Lift leg upward.
- Return to starting position

3. Resist Hip Abduction Sit with Elastic

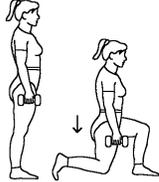
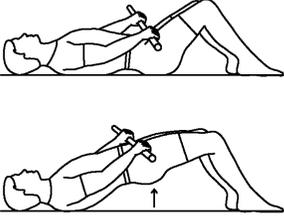


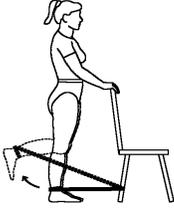
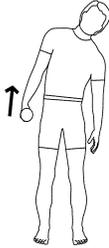
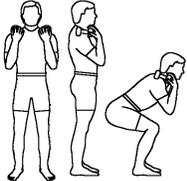
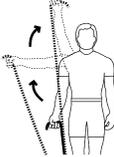
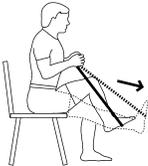
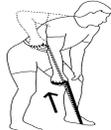
- Sit on chair.
- Loop elastic around thighs, near the knees.
- Keep ankles together, spread knees apart.
- Return to start position and repeat.

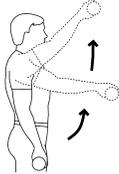
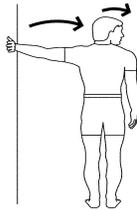
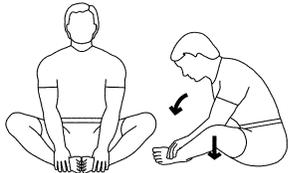
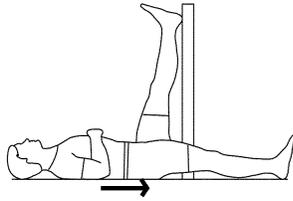
6. Resist hip ext prone with leg weights



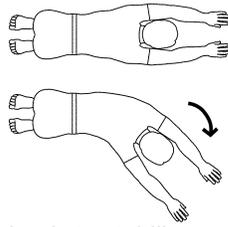
- Lie face down.
- Place weight on ankle.
- Start with leg bent to 90 degrees.
- Lift involved leg up.
- Return to starting position

<p>7. Resist Hip external Rotation Sidelying with Elastic</p>  <ul style="list-style-type: none"> ▪ Lie on right side with knees bent and elastic looped around thighs just above knees ▪ Keep heels together and lift left knee upward. ▪ Lower and repeat. ▪ Repeat series lying on left side and raising right leg. 	<p>10. Resist Hip/Knee Flexion (Forward Full Lunge) with Weight</p>  <ul style="list-style-type: none"> ▪ Hold weights at sides, palms inward. ▪ Step forward, bending knees to 90 degrees as shown. ▪ Rear knee should almost touch the floor. ▪ Push back up to standing. ▪ Repeat.
<p>8. Resist Hip Extension Supine</p>  <ul style="list-style-type: none"> ▪ Lie on back with knees bent as shown. ▪ Place bar across hips. ▪ Lift up buttocks. ▪ Lower and repeat. <p>Special Instructions:</p> <ul style="list-style-type: none"> ▪ You may need to stabilize weight with hands to keep it from slipping. 	<p>11. Resist Hip/Knee Flexion (Lunge)</p>  <ul style="list-style-type: none"> ▪ Stand with one foot on middle of band. ▪ Grasp ends of band and loop around hands at chest level, keeping elbows bent. ▪ Place other leg behind with knee slightly bent. ▪ Keep trunk straight and bend front knee, lowering body downward. ▪ Slowly return to upright <p>Special Instructions:</p> <ul style="list-style-type: none"> ▪ Keep back straight, avoid rounding back.
<p>9. Resist Hip Flexion Sit with Elastic</p>  <ul style="list-style-type: none"> ▪ Sit in chair. ▪ Loop elastic around thigh slightly above knee, stabilize ends of band under opposite foot. ▪ Lift one leg up, slowly return. ▪ Repeat. 	<p>12. Resist Hip/Knee Flexion (Reverse Lunge) with Weight</p>  <ul style="list-style-type: none"> ▪ Stand holding weights at side, palms inward ▪ Step back with one leg until rear knee almost touches floor ▪ Front leg should not extend past toes ▪ Push back up forward to a standing position ▪ Repeat on both legs

<p>13. Resist Knee Flexion with Elastic Standing at Chair</p>  <ul style="list-style-type: none"> ▪ Stand in back of chair, holding chair for support. ▪ Attach elastic to chair leg. ▪ Loop elastic around ankle ▪ Bend knee backward ▪ Lower and repeat 	<p>16. Resist Lumbar Sidebend with Weights</p>  <ul style="list-style-type: none"> ▪ Stand, holding weight in left hand. ▪ Bend to right. ▪ Return to start position and repeat. ▪ Repeat sets with weight in right hand and bending to left.
<p>14. Resist Knee Forward Squat with Weight</p>  <ul style="list-style-type: none"> ▪ Stand with feet about hip distance apart ▪ Toes should be slightly pointed outward and aligned with knees ▪ Hold weights (dumbbells) in hands, resting on shoulders ▪ Squat down until thighs are almost parallel with floor while moving buttocks backward, similar to beginning to sit in a chair ▪ Return to start and repeat <p>Special Instructions Start with a partial squat and increase as you become familiar with the movement</p>	<p>17. Resist Shoulder Abduction (Vertebral Emphasis) Unilateral with Elastic</p>  <ul style="list-style-type: none"> ▪ Stand on elastic ▪ Begin with arm at side, elbow straight, holding elastic, palm forward ▪ Raise arm upward, out to side and over head ▪ Slowly return to starting position
<p>15. Resist Knee Press with Elastic</p>  <ul style="list-style-type: none"> ▪ Sit in chair. ▪ Loop elastic around bottom of foot as shown. ▪ Hold elastic in both hands. ▪ Push leg down straightening at knee <p>Slowly return to start position and repeat.</p>	<p>18. Resist Shoulder Bent Row</p>  <ul style="list-style-type: none"> ▪ Secure elastic under opposite foot. ▪ Hold elastic in involved arm. ▪ Slightly bend hips and knees and support upper body with other arm as shown ▪ Pull up on elastic, raising elbow to shoulder height. ▪ Slowly return to start <p>Special Instructions Contract abdominal muscles and maintain a neutral spine, not allowing trunk to twist.</p>

<p>19. Resist Shoulder Flexion Unilateral with Weights</p>  <ul style="list-style-type: none"> ▪ Begin with arm at side, elbow straight, palm down with weight in hand. ▪ Raise arm in front over head. ▪ Return to starting position. 	<p>22. Stretch Cervical/Thoracic/Arm Neural</p>  <ul style="list-style-type: none"> ▪ Stand with left arm on wall, hand backward as shown. ▪ Slowly turn body outward until as stretch is felt across chest. ▪ Slowly turn neck to right until a stretch is felt down the front of arm. ▪ Hold stretch for 20 seconds and repeat on the alternative side
<p>20. Stretch Cervical Extension Sit</p>  <ul style="list-style-type: none"> ▪ Sit in chair with good back support. ▪ Sit with proper posture. ▪ Slowly bend neck backward stretching the muscles on the front part of neck ▪ Hold stretch for 20 seconds and return to start position. 	<p>23. Stretch Groin Sit</p>  <ul style="list-style-type: none"> ▪ Sit with knees bent, soles of feet together ▪ Slowly let your knees drop to floor. ▪ Grasp ankles with hands and lean forward from the hips <p>Special Instructions</p> <ul style="list-style-type: none"> ▪ Try to keep elbows on inside of knees.
<p>21. Stretch Cervical Sidebend with Pressure Opposite Side</p>  <ul style="list-style-type: none"> ▪ Sit or stand. ▪ Place right hand on top of head ▪ Keep head facing forward and gently pull head sideways to right ▪ Repeat with left arm ▪ Hold stretch for 20 Seconds 	<p>24. Stretch Hamstring Supine Wall</p>  <ul style="list-style-type: none"> ▪ Lie on back, leg elevated and positioned at doorway as shown. ▪ Buttocks should be about 5 inches from wall, low back flat on floor. ▪ Gently slide buttocks toward wall, keeping knee straight, until stretch is felt. ▪ Relax and repeat.

25. Stretch Iliocostalis



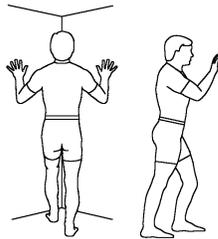
- Kneel on heels to stabilize your hips.
- Lean forward, arms over head, as shown.
- Slowly walk hands to right until stretch is felt.
- Repeat to left

28. Stretch Rhomboids/Trapezius



- Sit in chair.
- Cross arms over abdomen.
- Slowly bend neck down.
- Slowly lean forward, keeping elbows straight and reach to floor.
- Hold and repeat.

26. Stretch Pectoral Standing



- Stand in corner
- Place arms at chest level on wall.
- Gently step forward, keeping back straight.
- Return to start position
- Hold stretch for 20 seconds repeat 5 Times

27. Stretch Piriformis Longsit



- Sit with right knee bent, right ankle to outside of left leg
- Grasp knee and pull thigh across chest toward left shoulder
- Relax and repeat with left leg.
- Hold exercise for 20 Seconds