

APPENDIX A:

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

R14/49 Naidoo

CLEARANCE CERTIFICATE

PROTOCOL NUMBER M040440

PROJECT

The effect of bed exercises when added to a mobility regimen, on the functional outcome of patients following primary total hip replacement.

INVESTIGATORS

Miss U Naidoo

DEPARTMENT

Physiotherapy

DATE CONSIDERED

04.05.07

DECISION OF THE COMMITTEE*

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 04.09.28

CHAIRPERSON



(Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable

cc: Supervisor : Dr A Stewart

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10005, 10th Floor, Senate House, University.

I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

APPENDIX B:

PATIENT INFORMATION SHEET

Dear patient

My name is Umantha Naidoo and I am a qualified physiotherapist. Currently I am doing my master's degree in physiotherapy at the University of Witwatersrand. I am carrying out a study, to find out whether specific exercises done in bed for example moving a leg to the side and bringing it in again, by patients who have had total hip replacements, help to improve the patient's function, by the day they are discharged from hospital. You are scheduled to have a total hip replacement, I shall be very grateful if you would consider participating in my study.

If you agree to take part in this study, you will be allocated to one of two groups. One group will do the exercises, while the other will not (which is the current policy at the Johannesburg Hospital). Both groups however will be taught how to walk, climb stairs etc in the exact same way. I will be asking you a few questions before you have the operation about your level of function. Also on specific days, after you have had the operation, I will assess your level of function and pain, and range of movement.

Confidentiality will be assured because your name will not be on any of the forms that I use. Participation is voluntary; if you do not wish to take part in this study, or you wish to withdraw from the study at any time, you are free to do so and this will not affect your treatment in any way.

I hope that this study will help us determine a more effective way of treating patients like yourself, who will be having total hip replacement surgery.

Thanking you very much for your time.

Umantha Naidoo
University of Witwatersrand
Student number: 9602675T

APPENDIX C:

CONSENT FORM

I, _____, agree to take part in this study being carried out by Umantha Naidoo. I have read and understood the information sheet given to me. I understand that I can't be identified in any way. I also understand that I can withdraw from the study if I choose to do so, without it affecting my treatment.

Signature of patient:

Date:

Witness signature:

APPENDIX D:

APPENDIX: IOWA LEVEL OF ASSISTANCE SCALE

TASKS

- Supine to sitting on the edge of the bed
- Sitting on the edge of the bed to standing
- Walking 4.57 metres
- Climbing up and down three steps
- Walking speed over 13.4 metres

ORDINAL SCALE AND DEFINITIONS FOR LEVEL OF ASSISTANCE

- | | |
|-----------------|---|
| 0 – independent | No assistance or supervision is necessary to safely perform the activity with or without assistive devices, aids or modifications |
| 1 – standby | Nearby supervision is required for the safe performance of the activity; no contact is necessary |
| 2 – minimal | One point of contact is necessary for the safe performance of the activity including helping with the application of the assistive device (part of ambulation), getting leg(s) on or off the leg rest and stabilising an assistive device |
| 3 – moderate | Two points of contact are necessary (by one or two persons) for the safe performance of the activity |
| 4 – maximal | Significant support is necessary at a total of three or more points of contact (by one or more people) for the safe performance of the activity |
| 5 – failed | Attempted activity, but failed with maximal assistance |
| 6 – not tested | Due to medical reasons or reasons of safety, test was not attempted |
| Contact | Any physical contact between the therapist and the patient or the assistive device (frame, crutches etc) |

ORDINAL SCALE FOR ASSISTIVE DEVICE

- 0 – no assistive device
- 1 – one stick or crutch
- 2 – two sticks
- 3 – two elbow crutches
- 4 – two crutches
- 5 – frame (standard or rollator)

ORDINAL SCALE FOR AMBULATION VELOCITY

Time to walk 13.4 metres

- 0 – ≤ 20 seconds
- 1 – 21–30 seconds
- 2 – 31–40 seconds
- 3 – 41–50 seconds
- 4 – 51–60 seconds
- 5 – 61–70 seconds
- 6 – > 70seconds

RANGE OF SCORES

Minimal score: if the patient was independent in all five tasks (ie level of assistance score = 0) plus did not require an assistive device for the four tasks which involved standing or mobilising (ie assistive device score = 0), the total score = (5×0) for level of assistance score + (4×0) for assistive device score, which = 0.

Maximal score: if the patient was unable to attempt any of the five tasks because of medical reasons or reasons of safety (ie level of assistance score = 6) and the assistive device for the four tasks which involved standing or mobilising would have been a frame (ie assistive device score = 5), the total score = (5×6) for level of assistance score + (4×5) for assistive device score, which = 50.

APPENDIX E:

Pre-operative Patient Data Collection Sheet

1. Subject number:
2. Age:
3. Gender:
4. Pre-existing medical conditions:
5. Musculoskeletal history (Please circle correct answer):
 - 5.1 Main presenting problem with the hip:
Pain / stiffness / decreased function.
 - 5.2 Previous injury to the lower limb that's to be operated on:
Yes / No.
If yes, state the nature of the injury
 - 5.3 General joint problems:
Yes / No.
If yes, state what problems.
 - 5.4 Medication taken for general joint problems:
Yes / No.
6. Pre-admission level of mobility (Please tick appropriate boxes):

Walking aid used	
Assistance needed to get out of bed	
Assistance needed for sit to stand	
Able to climb three steps	
Able to walk 4,57m	
7. Operative approach by orthopaedic surgeon:
Antero-lateral / Posterior.
8. Post operative complications: Yes /No.
If yes, please state complication/s that occurred.

APPENDIX F:

Post-operative patient data sheet

Patient number:

ROM of operated hip:

Flexion	1 st reading	2 nd reading	3 rd reading	Average
Day 3/4				
Day 7/8				
Abduction				
Day 3/4				
Day 7/8				

VAS

Day 3/4 0 _____ 10

Day 7/8 0 _____ 10

ILOA Scale

Day 3/4	Level of assistance	Assistive device
1. Supine to sitting over edge of bed		
2. Sitting on the edge of bed to standing		
3. Walking 4,57m		
4. Climbing up and down 3 steps		
5. Walking speed over 13,4m		
TOTAL		

Day 7/8	Level of assistance	Assistive device
1. Supine to sitting over edge of bed		
2. Sitting on the edge of bed to standing		
3. Walking 4,57m		
4. Climbing up and down 3 steps		
5. Walking speed over 13,4m		
TOTAL		

APPENDIX G:

Patient Exercise Handout

Dear patient:

- Exercises are to be done in bed with you lying on your back.
- These exercises are to be done 2/3 times a day.
- The physiotherapist will help you do these exercises once a day.

Your list of exercises are:

- 1) Bend your ____ knee and hip, keeping your foot supported on the bed. Then straighten your leg fully. Repeat ____ times.
- 2) Take your ____ leg out to the side. Bring back to the center. Repeat ____
- 3) Pump your feet up and down as fast as you can. Repeat ____
- 4) Pull the ____ foot back so that the toes are now pointing toward the ceiling. Push the knee into the bed with some force so that you can feel the front of the thigh tighten. Hold for 5 seconds. Repeat ____
- 5) Place a rolled up towel under your ____ knee. Lift the ____ heel of the bed and straighten your knee. Then lower your heel to the bed. Repeat ____

APPENDIX H:

Handout to Physiotherapists

Research question: Do bed exercises, when added to a mobility regimen, improve the functional outcome of patients following primary total hip arthroplasty?

Procedure:

The researcher, who will be blinded as to which group the patient is in, will collect relevant data from the patients' files pre-operatively. This allows for the patients to be profiled. It also allows one to see if the process of randomisation was successful in achieving homogeneity between the groups. The researcher will record the following details:

- Gender
- Age
- Pre-existing medical conditions (as this can influence rehabilitation outcomes.)
- Operative procedure – whether a lateral/posterior approach was used.
- Major post-operative complications – this can affect the length of stay in hospital. Possible complications are deep vein thrombosis, cardiac events, wound dehiscence etc. Post-operative complications also has influence on how vigorous one may be with the rehabilitation process.

The patient will also be questioned specifically on the following:

- History of previous lower limb pain/injury on the involved side
- Previous general joint problems and whether medication was taken for this.
- Pre-admission level of mobility.

The exercises are performed in supine and comprise of the following:

- Hip and knee flexion
- Hip and knee extension to neutral
- Hip abduction
- Hip adduction to neutral
- Ankle dorsiflexion and plantarflexion
- Static quadriceps contraction
- Inner range quadriceps exercises over a rolled up towel.

Patients were instructed to do each exercise 5 times initially, building up to 10 repetitions.

Patients in the experimental group will be mobilised according to the standard protocol used at the Johannesburg Hospital following total hip arthroplasty (the same protocol used in the Jesudason and Stiller trial, 2002).

The mobility protocol consists of:

Day one post-operatively:

- Sitting over the edge of the bed.
- Attempted standing and walking using appropriate walking aid, with the assistance of one/two physiotherapists as is required.

Day two post-operatively and onwards:

- Progression of mobilisation in regards to distance walked, speed of walking, degree of assistance given by physiotherapist/s, and required mobility aid.
- This will be done according to the individual patients capabilities, and deemed appropriate by the treating physiotherapist. If the patient requires more than one physiotherapist to assist in the mobilisation, a second physiotherapist/physiotherapy assistant will be called in to help.
- The patient will be mobilised once per day by the physiotherapist, but the patient will also mobilise independently or with the assistance of nursing staff, for purposes of toileting, as and when the patient feels confident to do so.