APPENDIX 2

INFORMED CONSENT

TITLE OF STUDY: Effects of therapeutic exercises on quality of life and selected cardiopulmonary and anthropometric parameters in breast cancer survivors.
INVESTIGATOR: AWETO, Happiness A. (Mrs.)
CONTACT PHONE NUMBER: 08028964385

Purpose of the Study
You are invited to participate in a research study. The purpose of this study is to show the effects of therapeutic exercises on selected cardiopulmonary, anthropometric and quality of life parameters in breast cancer survivors.

Participants
You can participate in the study if you are a survivor of breast cancer (BC) with stage I or II or III BC. You are also eligible if you are a non-smoker have no known pathologies like uncontrolled hypertension, diabetes and no muscle or joint problems of the lower limb.

Procedures
If you volunteer to participate in this study, you will be asked to do some exercises which will increase the rate at which you breathe and at which your heart is beating.

Benefits of Participation
There may/may not be direct benefits to you as a participant in this study. However, we hope to learn more on how exercises help BC survivor to live a healthier life with an improved quality of life. This research may also guide us in the design and prescription of exercises to BC survivors.

Risks of Participation
Your safety is guaranteed during participation in this study as it carries minimal risk. However, you may become tired after walking on a treadmill which is one of the equipments to exercise with in this study. All procedures are normal, not life threatening and should not cause any harm or negative effects to your health.

Cost/Compensation
There will not be any financial cost on you to participate in this study. The study will take 30 to 60 minutes per session, three times in a week between 10a.m to 2p.m from Monday to Friday. It will last for duration of 12 weeks.

Contact Information
If you have any questions or concerns about the study, you may contact the above named investigator on the stated phone number. For questions regarding the rights of research subjects, any complaints or comments regarding the manner in which the study is being conducted you may contact department of Physiotherapy, College of Medicine of the University of Lagos, Ido-Araba, Lagos.
Voluntary Participation
Your participation in this study is voluntary. You may refuse to participate in this study or in any part of this study. You may withdraw at any time without prejudice to your relationship with the hospital. You are encouraged to ask questions about this study at the beginning or any time during the research study.

Confidentiality
All information gathered in this study will be kept completely confidential. No reference will be made in written or oral forms that could link you to this study. All records will be stored in a locked facility at University of Lagos and the teaching hospitals from which you are recruited.

Participant Consent
I have read the above information and agree to participate in this study.
A copy of this form has been given to me.

_________________________________________  ______________________
Signature of Participant                                      Date

_________________________________________
Participant’s Name
Appendix 3

GROUP

Bio Data
Name:
Address:
Age:
Occupation:
Phone No.:

Medical History
BC Stage:
Menopausal Status:
Type of Surgery done:
Hormone Therapy:
Any known pathologies (C-P and others)

Social History
Smoking status:
Structured exercise involvement in the past 6 months:
Exercise Stress Test:

Outcome Measures

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<th>Anthropometric Parameters</th>
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APPENDIX 4

EDUCATIONAL AND COUNSELING SESSIONS’ CONTENT

The problems BC survivors are faced with are as follows:

1) Psychosocial Impact of BC

   a) Self-concept: Most BC survivors’ perception about themselves changes with the disease. They also believe that other people’s perceptions about them have changed.

   b) Body image: They believe they are disfigured and have lost their femininity after surgery.

   c) Intimacy and sexuality: BC survivors experiencing sexual problems following diagnosis and treatment vary from 10% to 88% (Morton, 2008).

2) Physical Issues due to BC

   a) Nausea and vomiting induced by chemotherapy is usually present.

   b) Pain: It may be acute or chronic.

   c) Lymphoedema: This is the accumulation of lymph in soft tissue of the upper limb after surgery. It may also be caused by radiotherapy or the disease.

   d) Female fertility/pregnancy issues: Premenopausal women whose cancer is oestogen/progesterone sensitive are given drugs that inhibit the production or actions of these hormones. This leads to infertility.

   e) Fatigue: Most BC survivors feel tired easily. This is one of the negative effects of treatment and the disease process.

   f) Cognitive difficulties: High doses of chemotherapy are associated with impairment in the speed at which information is processed in the brain.
3) Psychological Distress Caused by the Disease

a) Anxiety: 15% to 23% of people with BC have anxiety.

b) Depression: 20% to 35% of people with BC have depression.

c) Post-traumatic stress disorder: This is present in 3% to 12% of BC survivors.

d) Stress and adjustment reactions: BC survivors who perceive they have poor support are more likely to experience greater psychological distress.

**Anxiety: Symptoms of Anxiety include:**

i) Racing heart: The heart beats so rapidly.

ii) Pain, pressure or tingling in the chest.

iii) Butterflies or churning in the stomach.

iv) Constipation or diarrhea.

v) Tight tense muscles.

vi) Lump in throat.

vii) Dry mouth.

viii) Feeling dizzy, light headedness ‘spaced out.’

ix) Choking smothering sensations.

x) Rubbery or jelly legs.

xi) Trembling or shaking.

**Depression: Symptoms of Depression include:**

i) Feelings of hopelessness/helplessness.

ii) Loss of pleasure/happiness (anhedoria).

iii) Sleep disturbances.
iv) Irritability and/or uncontrolled anger.

v) Feeling worthless.

vi) Guilty.

vii) Feeling like crying but cannot.

The means of Dealing with these Problems include:

1. **The Cognitive-behavioural model** is the psychotherapy technique that is usually used in group therapy to reduce **anxiety** and **depression**. This therapy is based on the fact that a person’s feelings are created by her thoughts which give rise to moods.
   - BC survivors should manage their thinking by being aware of their thoughts.
   - They should keep journals.
   - They should quickly identify any distortions in their thinking and try to correct them.
   - They should use ‘coping self – talk’ such as I can meet this challenge, I don’t like relying on others but it is necessary to have help at the moment. There are still things I can do for myself. I won’t get overwhelmed; I will take one step at a time.

2. **Relaxation Methods**: BC survivors should practice relaxation. 2 relaxation methods available to choose are progressive muscle relaxation and deep breathing.

   Daily relaxation practice has been shown to significantly reduce stress, anxiety and depression (Morton, 2008).

3. **Self-help Tips**: BC survivors should knowledgeable on self-help tips. Examples are the 10 things they should do to reduce stress.
i. They should not be perfect nor even try to be.

ii. They should not be all things to all people.

iii. They should take a break for a while when they are tired in order to regain a sense of control. This means that things should be left undone when they are tired.

iv. They should not spread themselves thin.

v. They should learn to say ‘no’ when they are too tired to perform a task for someone. This helps them to avoid additional pressures.

vi. They should schedule time for themselves and their support groups. If they have children, they may ask a family member or neighbor to look after them in order to get time for them.

vii. They should not work hard at all times to look tidy, elegant and attractive. They may look otherwise.

viii. They should switch off and do nothing regularly.

ix. They should never feel guilty.

x. They should especially be their best friend and never their worst enemy.

- They should loose themselves in an enjoyable non-demanding activity such as reading a book, seeing a movie or gardening.

4. **Diet and Nutrition:** BC survivors should eat lots of vegetables and low fat diets which have been proven to reduce cancer (Quillan, 2008). They should avoid some certain foods which increase nervous tension. They should avoid excessive tea, coffee, chocolate, coca-cola and high sugar feed and take lots of water instead.

5. **A Sense of Community:** They should be part of BC support groups and be consistent at attendance to meetings. The study by Spiegel *et al* (1989) observed that BC survivors who
participated in counseling sessions and were part of a BC support group survived twice as long as normal BC survivor. This notion is that being part of a community could increase survival by 100%. In groups, people meet together to discuss common experiences and give emotional support to each other.