

## **CHAPTER 3**

### **METHODS AND PROCEDURES**

#### **3.1 SUBJECTS**

A group of 69 females between the ages of 25 - 40 years (mean age =  $35.26 \pm 6.02$  years), who were recruited through newspaper advertisements, served as subjects. In order to be eligible for inclusion into the study, subjects were required to be physically suitable for a programme of electrical muscle stimulation (EMS) performed on Slimline Slimming Machines in conjunction with, and without, a thermogenic agent (Thermo Lean) and following a specific diet; pre-menopausal; obese (BMI > 30); sedentary (< one 20 minute bout of aerobic or strength training per week over the previous six months); and amenable to being assigned to any of three study groups.

The following specific exclusion criteria were applied:

- a) a history of orthopaedic, cardiovascular, pulmonary or metabolic disease - which could have contra-indicated exercise testing;
- b) a hysterectomy - to avoid changes in oestrogen level;
- c) a prevailing pregnancy;
- d) glandular malfunctions - to avoid the influence of changes in normal hormonal levels;
- e) diabetes - since such subjects could not follow the diet as prescribed;
- f) vegetarianism and the presence of specific food allergies; and
- g) medication usage.

Subjects gave their written informed consent (Appendix A) prior to participating and took cognisance of the compliant requirement of not engaging in any exercise in addition to that required over the duration of the study. During the course of the investigation seven subjects withdrew - three because of medical and four due to personal reasons.

### 3.2 STUDY DESIGN

To recapitulate, the primary aim of the study was to evaluate the effect of an eight-week program of electrical muscle stimulation (EMS) performed on the Slimline Slimming Machines in conjunction with, and without, a thermogenic agent (Thermo Lean) and following a specific diet. In order to achieve this goal a pretest-post test placebo-controlled experimental groups design, with three levels of the independent variable, was adopted for the study (Appendix F). Subjects were randomly assigned to one of the following three groups:

- Group TS (N = 23) - Thermogenic Stimulation and following a standardized diet.
- Group EST (N = 23) - Electrical Muscle Stimulation and Thermogenic Stimulation combined and following the standardized diet.
- Group ESP (N = 23) - Electrical Muscle Stimulation and a Thermogenic placebo combine and following the standardized diet.

In order to enhance compliance and to minimise the dropout rate, personal follow-up phone calls were made randomly and a weighing and motivation session was conducted on every second Wednesday evening over the duration of the study.

**Table 3.1: Subject Characteristics**

GROUPS		TS (N = 23)		EST (N = 23)		ESP (N = 23)	
VARIABLE	UNITS	PRE (Mean)	Std. Dev.	PRE (Mean)	Std. Dev.	PRE (Mean)	Std. Dev.
Age	years	33.50	± 6.65	37.80	± 3.49	34.55	± 6.69
Stature	cm	166.57	± 6.40	166.01	± 6.71	164.87	± 6.52
Body Mass	kg	98.53	± 22.13	99.99	± 17.00	100.12	± 24.08
Body Mass Index	kg/m <sup>2</sup>	35.49	± 7.51	32.53	± 5.13	36.32	± 7.02
Lean Body Mass	kg	51.35	± 6.48	48.86	± 6.88	51.27	± 8.19
Body Surface Area	m <sup>2</sup>	2.06	± 0.19	1.92	± 0.18	2.04	± 0.21
Body Fat	%	46.91	± 4.82	45.26	± 2.77	48.05	± 4.43
Waist-to-Hip Ratio		0.78	± 0.06	0.79	± 0.06	0.79	± 0.06

TS = Thermogenic Stimulation and following a standardized diet.

EST = Electrical Muscle Stimulation and Thermogenic Stimulation following a standardized diet.

ESP = Electrical Muscle Stimulation and following a specific standardized diet (Placebo controlled).

Table I summarises the subject characteristics of the respective experimental groups at the onset of the study. No significant differences ( $p > 0,05$ ) were found between the specific variables of each group, thus reflecting the homogenous nature of each group, compiled by random assignment.

### 3.3 DEPENDENT VARIABLES (MEASUREMENTS)

The following categories of dependent variables were measured during the pre- and post-tests:

- Anthropometry
- Morphology
- Ultrasound Sonography
- Respiratory Quotient (RQ)
- Pulmonary Function

- Haematology
- Cardiovascular Responses
- Musculoskeletal Function

### 3.3.1 Anthropometry

All variables, unless stated otherwise, were measured according to the procedures of the Anthropometric Standardization Reference Manual of Lohman et al. (1988).

#### 3.3.1.1 Stature

Stature is a major indicator of general body size and of bone length. It is an important variable in screening for disease or malnutrition and in the interpretation of body weight (Lohman et al., 1988).

The stature was measured with a calibrated stadiometer. The subject stood barefoot, feet together and heels, buttocks and upper part of the back touching the gauge with head placed in the Frankfort plane, not necessarily touching the gauge. The Frankfort plane was considered as the orbital (lower edge of the eye socket) being in the same horizontal plane as the tragion (notch superior to the tragus of the ear). When so aligned the vertex was the highest point on the skull. The measurement was taken to the nearest 0,1 cm at the end of a deep inhalation.

#### 3.3.1.2 Body Mass

Body mass was measured with a Detecto beam balance scale to the nearest 0,1 kg, with the subject clothed only in a swimming costume, and taking care that the:

- scale was reading zero;
- subject stood on the centre of the scale without support;
- subject's weight distribution was even on both feet; and
- subject's head was held up and the eyes looked directly ahead.

### 3.3.1.3 Skeletal Widths

Skeletal width measurements are used for several research and clinical purposes, such as in the determination of body types according to the Health-Carter somatotyping technique (Lohman et al., 1988; Carter & Heath, 1990). A steel spreading calliper was used to measure the bi-epicondyle breadth of the humerus and the bi-condyle breadth of the femur in cm to the nearest mm.

To measure elbow width (condyle breadth of the humerus) the subject raised the right arm to the horizontal and the elbow was flexed to 90°. The dorsum of the subject's hand faced the measurer. The measurer stood in front of the subject and palpated the lateral and medial epicondyles of the humerus. The calliper blades were then placed on these points.

To measure knee width (condyle breadth of the femur) the subject's knee was flexed to 90° while sitting. The measurer stood facing the subject. The most lateral aspect of the lateral femoral condyle was palpated with the index or middle finger of the left hand while the corresponding fingers of the right hand palpated the most lateral aspect of the medial epicondyle. The calliper blades were then placed on these points.

### 3.3.1.4 Saggital Height

Saggital height or abdominal depth is the vertical distance from the small of the back to the front of the abdomen when the subject is lying supine and is used as an indication of visceral fat (Sjöstrom, 1991). Apparently an increased amount of visceral fat would maintain the depth of the abdomen in a saggital direction, while subcutaneous abdominal fat would have an apposite effect due to the force of gravity (Van der Kooy & Seidell, 1993). Although saggital height was mostly derived from computed tomography or magnetic resonance images in the past, it was measured anthropometrically in this study. A small scale anthropometer which measures to the closest 0.1 mm, was used to determined saggital height. Two measurements were made:

- 1) Saggital  $\frac{1}{2}$  umbi:  
for the first measurement the spirit level of the anthropometer was placed on the abdomen halfway, between the xyphoid process and the umbilicus;

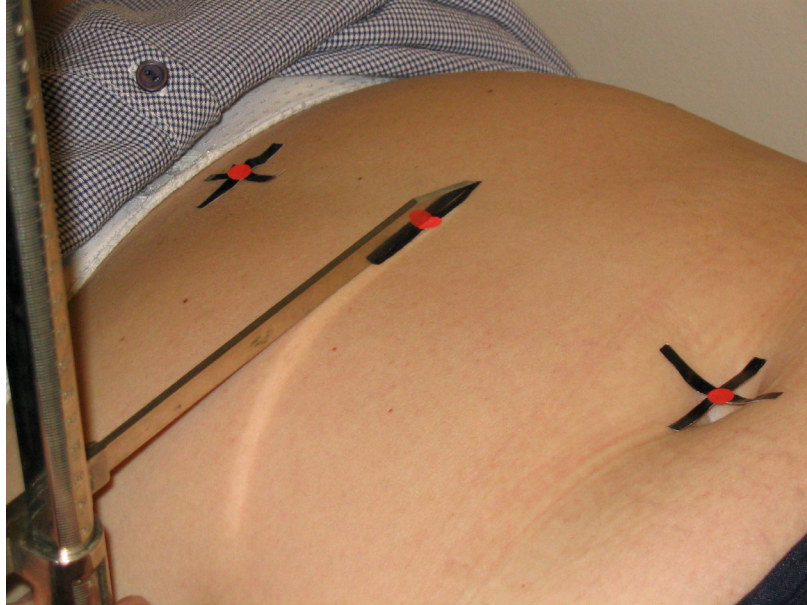


FIGURE 3.2: SAGGITAL HEIGHT  $\frac{1}{2}$  UMBI

- 2) Saggittal umbi:  
and for the second, the spirit level of the anthropometer was placed on the umbilicus (Zamboni et al., 1998).

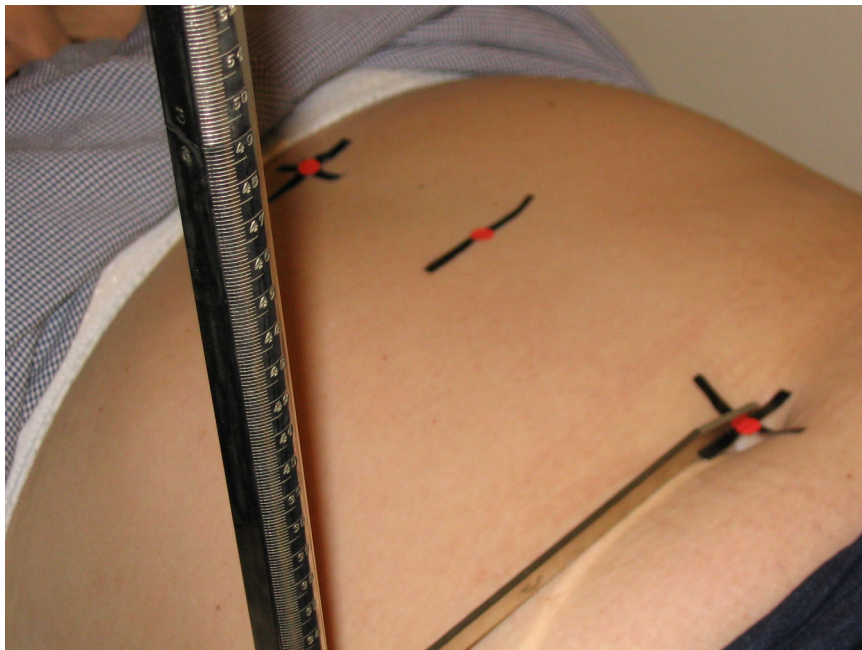


FIGURE 3.2: SAGGITAL HEIGHT UMBI

Measurements were made at the end of normal expiration with subjects lying on their backs on the plinth with knees bent up and the small of the back pushed down on the plinth to counteract the effect of large buttocks.

### 3.3.1.5 Skinfolds

Skinfolds were taken using a John Bull skinfold calliper exerting a uniform pressure of 10 g per mm<sup>2</sup> irrespective of the calliper opening. The following skinfolds were taken (all skinfolds were measured on the right of the body): triceps, sub-scapula, supra-iliac, biceps, medial-calf, abdominal, and mid-thigh.

The skinfold sites were carefully located using the following anatomical landmarks:

**Biceps:** The anterior surface of the biceps midway between the anterior auxiliary fold and the antecubital fossa.

**Triceps:** A vertical fold on the posterior midline of the upper arm, over the triceps muscle, halfway between the acromion process and olecranon process. The elbow was extended and the arm relaxed.

**Sub-scapula:** The skinfold was taken 2 cm along a line running laterally and obliquely downwards from the inferior angle of the scapula at an angle (approximately 45°) as determined by the natural cleavage line of the skin.

**Supra-iliac:** A diagonal fold was taken above the crest of the ilium at the spot where an imaginary line would descend from the anterior auxiliary line (just above and 2-3 cm anterior of the iliac crest).

**Medial-calf:** The subjects were seated (knees at 90°) and with the calf relaxed a vertical fold was raised on the medial aspect of the calf at the level of maximal circumference.

**Abdominal:** Skinfold was taken 3 cm lateral and 1 cm inferior to the centre of the umbilicus.

Mid-thigh: Skinfold was taken on the anterior aspect of the thigh midway between the inguinal crease and the proximal border of the patella.

Two measurements were taken two seconds after the full pressure of the callipers had been applied, and recorded to the nearest 0,5 mm. If the difference was greater than 1 mm, then a third measure was taken and the mean of the closest two recorded.

#### 3.3.1.6 Girth Measures

A Rabone-Chesterman calibrated steel tape and the cross hand technique was used for measuring all 10 girths. The reading was taken in cm to the nearest 0,1 mm from the tape where, for easier viewing, the zero was located more lateral than medial on the subject.

Constant tension on the tape was maintained but ensuring that there was no indentation of the skin while the tape was held at the designated landmark. When reading the tape the measurer's eyes remained at the same level as the tape to avoid any error of parallax. Care was taken to ensure that the tape remained horizontal to the floor during measurement. The ten sites measured were:

1. Calf - at the point of maximum circumference.
2. Mid-thigh - midway between the distance from the superior margin of the patella to the anterior superior iliac spine.
3. Relaxed upper-arm - midway between the distance from the olecranon to the posterior aspect of the acromion, with the elbow extended and palm facing medially.
4. Contracted upper-arm - at the point of maximum circumference.
5. Forearm - at the point of maximum circumference.
6. Hip – at maximum posterior extension of buttocks.

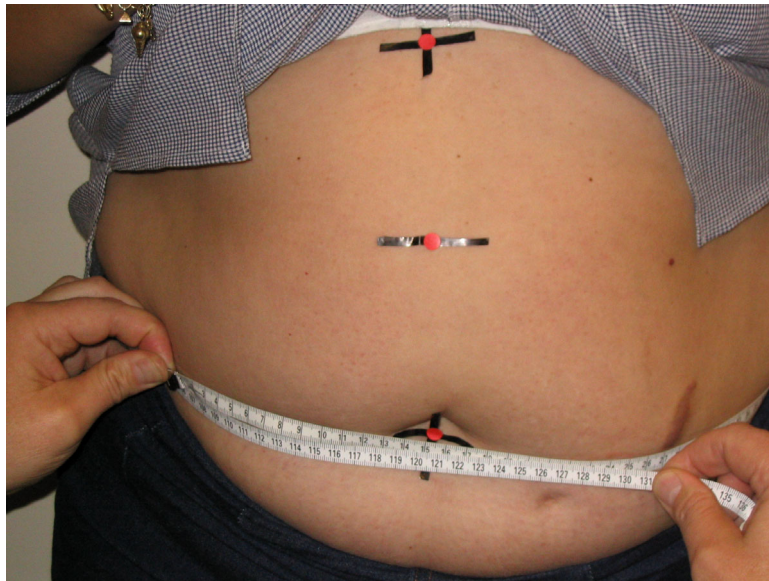


7. Chest - at the level of fourth costo-sternal joints. Laterally, this corresponds to the level of the sixth rib. Measurements were made at the end of a normal expiration.
8. Abdominal - the tape was placed around the subject at the level of the greatest anterior distension of the abdomen in a horizontal plane, not necessarily corresponding with the level of the umbilicus. The measurement was made at the end of a normal expiration.
9. Abdominal ( $AB^1$ ) – abdominal circumference anteriorly midway between the xyphoid process of the sternum and the umbilicus and laterally between the lower end of the rib cage and iliac crests.



**FIGURE 3.3: ABDOMINAL GIRTH  $AB^1$**

10. Abdominal ( $AB^2$ ) – abdominal circumference at the umbilicus level



**FIGURE 3.4: ABDOMINAL GIRTH  $AB^2$**

### 3.3.2 Morphology

#### 3.3.2.1 Percentage Body Fat (BF)

Weltman's obesity-specific anthropometric equations for women aged 20 - 60 years using circumference measures rather than skinfolds, was employed to estimate percentage body fat (% BF). The advantage of using this method was that circumferenced could easily be measured, regardless of the subject's level of body fatness.

The equation is:

$\% BF = 0.11077 (ABC) - 0.17666 (HT) + 0.14354 (BW) + 51.03301$ , where  
 $BW$  = body weight (kg);  $ABC$  (cm): average abdominal circumference =  $[(AB_1 + AB_2)/2]$ , where  $AB_1$  (cm) = abdominal circumference anteriorly midway between the xyphoid process of the sternum and the umbilicus and laterally between the lower end of the rib cage and iliac crest, and,  $AB_2$  (cm) = abdominal circumference at the umbilicus level (Weltman et al., 1988).

### 3.3.2.2 Lean Body Mass (LBM)

Lean body mass (LBM) as a derived anthropometric variable of body composition was calculated as follows:

$$\mathbf{LBM = BM - ABF \quad \text{and} \quad ABF = \frac{RBF \times BM}{100}}$$

where: LBM = lean body mass (kg)  
 BM = measured body mass (kg)  
 ABF = predicted absolute body fat (kg)  
 RBF = predicted body fat (%)

### 3.3.2.3 Body Mass Index

Body mass index (BMI) was used as an additional practical measure of obesity defined as BMI > 30 (Bouchard & Blair, 1999). The BMI was obtained by dividing the subject's mass in kilograms by stature measured in metres, squared:

$$\mathbf{BMI = \frac{Mass (kg)}{Stature (m)^2}}$$

### 3.3.2.4 Body Surface Area

As originally developed by Du Bois & Du Bois (1916) the nomogram for calculating body surface area (BSA) in square meters (m<sup>2</sup>) from height measured in centimetres (cm) and for calculating body weight, measured in kilograms is given in appendix G. The nomogram was used by placing one end of a ruler on the body weight and the other end on the body height. Where the ruler intersects the middle scale is the body surface area (Fox et al., 1993).

### 3.3.2.5 Waist-to-Hip Ratio

Waist-to-hip ratio (WHR) is strongly associated with visceral fat (Ashwell et al., 1985; Seidell et al., 1987) and appears to be an acceptable index of intra-abdominal fat (Jakicic, 1993).

The Anthropometric Standardization Reference Manual (Callaway et al., 1988) recommends measuring the waist circumference at the narrowest part of the torso and hip circumference at the level of the maximum extension of the buttocks. The WHR was established using the standardized measurement procedures described in the Anthropometric Standardization Reference Manual.

The WHR was simply calculated by dividing waist circumference (measured in cm) by hip circumference (measured in cm) (Heyward & Stolarczyk, 1996).

### 3.3.2.6 Somatotype

Heath and Carter have contributed extensively to the field of somatotyping for both men and women (Heath-Carter Anthropometric Somatotype) (Carter & Heath, 1990).

Ten variables were measured to calculate the anthropometric somatotype rating:

- Stature
- Body Mass
  
- Skinfolds
  - Triceps
  - Subscapular
  - Suprailiac
  - Medial Mid-Calf
  
- Bone Widths
  - Biepicondylar Humerus
  - Bicondylar Femur

- Limb Girths
  - Flexed Upper Arm
  - Calf (Carter & Heath, 1990).

Somatotyping describes the body type or physical classification of the human body using endomorphy, mesomorphy, and ectomorphy ratings, respectively.

#### Endomorphy

The first somatotype component is endomorphy and is characterized by roundness and softness of the body. In essence, endomorphy is the “fatness” component of the body. There is a smoothness of contours with no muscle relief.

#### Mesomorphy

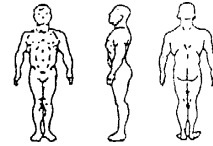
The second component is mesomorphy and is characterized by a square body with hard, rugged and prominent musculature. In essence, mesomorphy is the “muscle” component of the body.

#### Ectomorphy

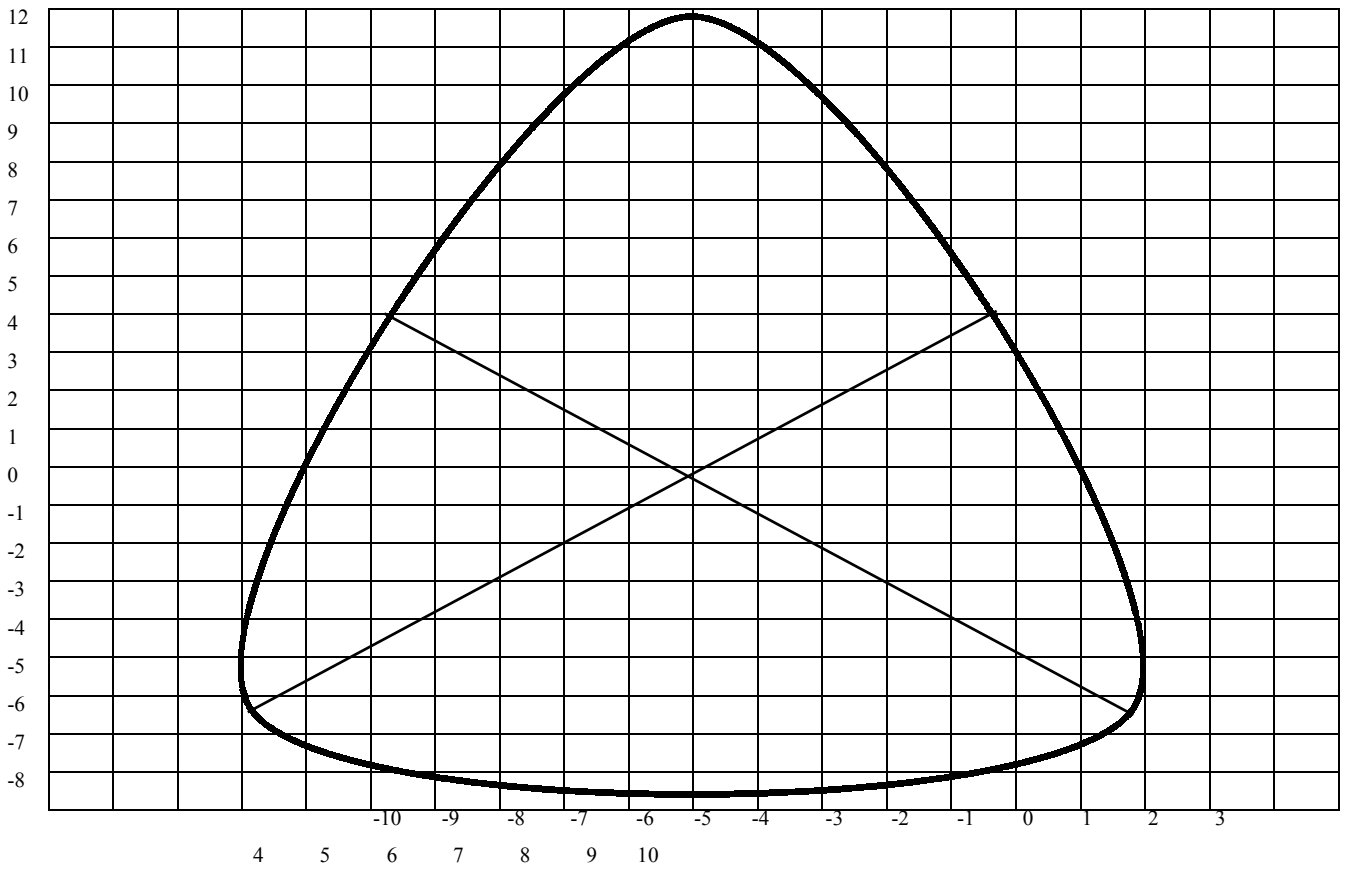
The third component, ectomorphy, includes as predominant characteristics linearity, fragility, and delicacy of body. This is the “leanness” component. The bones are small and the muscles thin. The limbs are relatively long and the trunk short; however, this does not necessarily mean that the individual is tall.

#### 3.3.2.7 Somatogram

A somatogram is an anthropometric profile that graphically depicts subjects pattern of muscle and fat distribution (Carter, 1992). Somatograms may be especially useful for charting changes (pre-and post-test profiles) and monitoring progress of subject's involved in weight management (diet and exercise) programs (Heyward & Stolarczyk, 1996).



MESOMORPHY



ENDOMORPHY

ECTOMORPHY

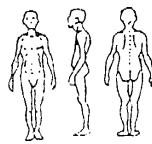
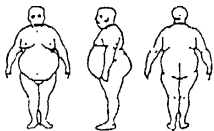


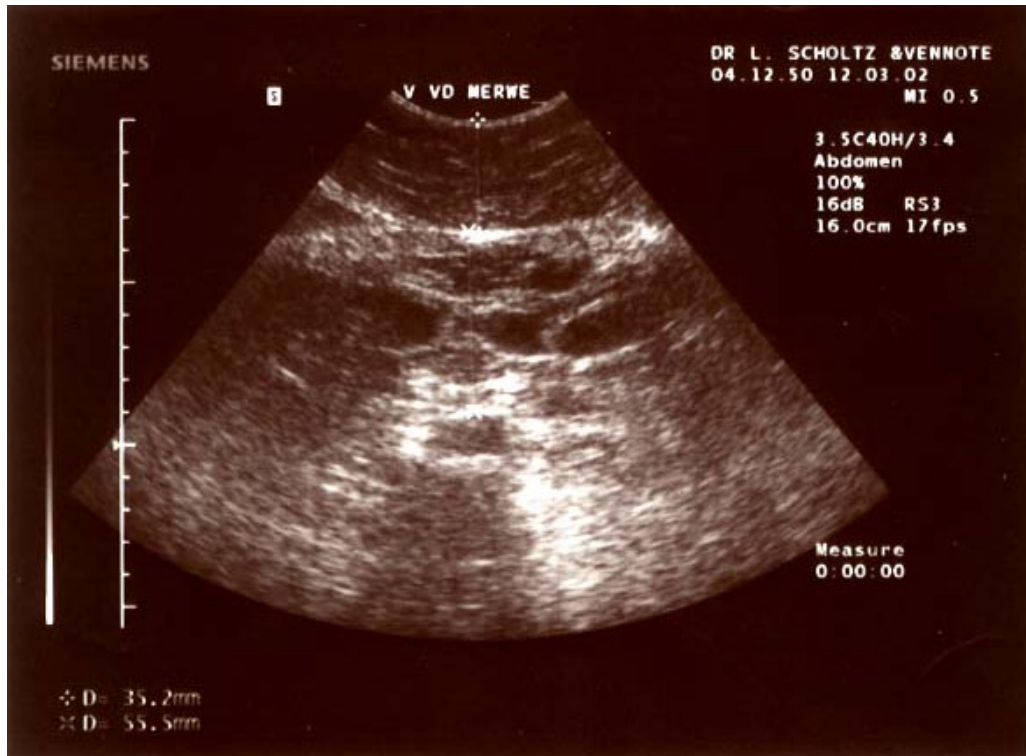
FIGURE 3.5: SOMATOGRAM

### 3.3.3 Ultrasound Sonography



**FIGURE 3.6: SIEMENS (SONOLINE ELLEGRA) SONOGRAPH**

The sonographic measurements were conducted by a practicing specialist at the Jakaranda Hospital, Pretoria using a 3.5 MHz Siemens (Sonoline Ellegra) sonograph. Sonars were taken at a level 10 cm inferior to the xipho sternum on the xipho-umbilical line while the subjects were in a supine position with heels, buttocks and shoulders in contact with the examination table. The transducer was placed on the skin with minimal pressure and measurements were taken after normal expiration. Thicknesses were measured by using electronic callipers placed from leading edge to leading edge. The subcutaneous fat layer was measured from the skin to the M. rectus abdominus and the visceral fat layer (intra-abdominal fat) from the M. rectus abdominus to the anterior wall of the aorta.



**FIGURE 3.7: SONOGRAPHIC MEASUREMENT OF SUBCUTANEOUS AND INTRA-ABDOMINAL FAT**

### 3.3.4 Respiratory Quotient (RQ)

Respiratory quotient was determined by an ambulatory metabolic measurement system (Aerosport KB1-C) with cognisance of the following variables: ambient temperature, barometric pressure, the subject's age, stature, body mass and gender. Subjects lay supine on plinth with the facemask covering nose and mouth. Subjects were asked to breathe in a normal relaxed manner. Respiratory quotient was measured after four minutes while subject was in a steady-state.

As respiratory gas was exhaled through the pneumotach (flow head) a micro sample, proportional to the expired flow, was drawn off through the centre (sample) line of the pneumotach into the base unit. A fixed rate of this proportional sample (known as a pulse) was drawn into a mixing system. For each pulse drawn in, a pulse of identical volume from the mixing system was emitted to the oxygen and carbon dioxide detectors. Over a fixed time period, electronic variable sampling (EVS), allows the



pulse trains to be reduced to a constant volume, resulting in similar equilibration times at varying expired flow rates. Following gas analysis and flow integration, the gas was exported out of the exhaust of the system to ambient air. The whole system was under microprocessor control. RQ was calculated according to standard procedures.

$$RQ = \frac{VCO_2}{VO_2} \quad (\text{Cooper \& Storer, 2001})$$

An important distinction must be made between the respiratory exchange ratio (R) which is a non-steady-state measure derived from instantaneous values of  $VCO_2$  and  $VO_2$  and respiratory quotient (RQ), which is normally derived from steady-state measures of  $VCO_2$  and  $VO_2$ . If the metabolic substrate is purely carbohydrate, then the RQ value is 1.0. When the metabolic substrate is predominantly fat, the RQ approaches 0.7. Whole-body RQ represents the summation of many different organ system RQ values. Since  $VCO_2$  and  $VO_2$  both have units of liters per minute RQ has no units (Cooper & Storer, 2001).

### 3.3.5 Pulmonary Function

Lung volume and lung function was determined by a Schiller CS-200 Ergo-spirometer with cognisance of the following variables: environmental temperature, the subject's age, stature, body mass and gender.

The procedure was replicated for each subject: The nose was closed off by a noseclamp and the subject's bit onto a mouthpiece. Subjects were asked to inhale as deeply as possible, and then exhale explosively and as deeply, quickly and forcefully as possible until the lungs were empty, followed by a second inhalation. Two trials were taken and the best result was recorded.

The following parameters were used:

FVC - Forced vital capacity indicating lung volume expressed in litres.

FEV<sub>1</sub> - Forced expiratory volume during the 1<sup>st</sup> second of FVC.

- FEV<sub>1</sub> % - FEV<sub>1</sub>/FVC \* 100 % - indicating breathing efficiency.
- PEF - Peak expiratory flow - evaluating the effectiveness of the respiratory and abdominal muscles.
- MEF 50% - Maximum expiratory flow when 50% remained to be expired - indicating the bronchial flow.
- MEF 25% - Maximum expiratory flow when 25% remained to be expired - indicating the flow in the bronchial tubes.

### 3.3.6 Haematology

A professional pathology laboratory (Dr's Du Buisson and Partners) performed the blood analysis. All chemistry analyses were done using the Beckman Synchron CX system. Cholesterol reagent was used to measure lipid concentration by a timed-endpoint method (Tietz, 1994).

The following reference ranges were utilized:

Cholesterol	:	3.0 - 5.2 mmol/ℓ
High-density lipoprotein	:	0.9 - 1.6 mmol/ℓ
Low-density lipoprotein	:	2.0 - 3.4 mmol/ℓ
Glucose	:	3.5 - 6.0 mmol/ℓ
Triglycerides	:	0.8 – 1.5 mmol/ℓ

(Tietz, 1994).

### 3.3.7 Cardiovascular Responses

#### 3.3.7.1 Heart Rate

Heart Rate was measured with a Polar Accurex Plus coded transmitter and wrist receiver. The elastic strip was adjusted to fit the subject comfortably. The strap was secured around the subject's chest, with the transmitter on the xyphoid sternum. It

was checked that the moist electrode area was secured firmly against the subject's skin and the Polar logo on the transmitter was in a central upright position. After subjects had been lying in a supine position for five minutes on a plinth in a quiet room, heart rate readings were taken from the wrist receiver.

### 3.3.7.2 Blood Pressure

Blood pressure was measured after the subjects had been lying in a supine position, on a plinth, for five minutes in a quiet room. Measurements were taken with a Tyco sphygmomanometer and Littmann lightweight stethoscope. Blood pressure was taken at the brachial artery by the auscultatory method. Great care was taken that there was no tension in the arm muscles and the forearm was supported with the cubital fossa at heart level. Subjects used a normal adult cuff size. The sphygmomanometer was inflated until its pressure exceeded the systolic pressure within the artery. Blood flow was occluded and a brachial pulse (at the elbow fossa) could not be felt (palpated) or heard (auscultated). The pressure within the cuff was reduced by small increments and the examiner listened until korotkoff sounds were audible. The systolic pressure was the pressure exerted on the walls of the artery when the first soft tic sounds occurred. Diastolic pressure was referred to as the pressure in the artery when the korotkoff sounds were greatly muffled or had disappeared.

## 3.3.8 **Musculoskeletal Function**

### 3.3.8.1 Hip Flexion

The sit-and-reach test (Marrow et al., 1995) was used to determine hip flexion (flexibility of the hamstrings and lower back). The subjects were asked to remove their shoes, and sit at the test apparatus with knees fully extended. The heels were placed shoulder width apart, flat against the box. Arms were then extended forward, with the subject leaning forward and extending the fingertips along the ruler as far as possible. Two trials were taken and the best result was recorded. Measurements were taken in centimetres (cm).

### 3.3.8.2 Abdominal Muscle Endurance

Abdominal muscle endurance was evaluated with sit-ups performed with knees bent and feet fixed. The hands were required to touch the ears and elbows to touch the knees at the end of the curl up. The subject was expected to descend in a controlled manner. The tester's hand was placed palm-side up on the bench such that the wrist made contact with the spine in line with the inferior border of the scapulae.

If the hands were removed off the ears, the elbows did not touch the knees or the back did not touch the testers hand, the sit-up was not counted. The maximum number performed in one minute was recorded. Subjects were permitted to rest within the one-minute period and then restart.

## 3.4 INDEPENDENT VARIABLES (INTERVENTION PROGRAMME)

### 3.3.1 Electrical Muscle Stimulation



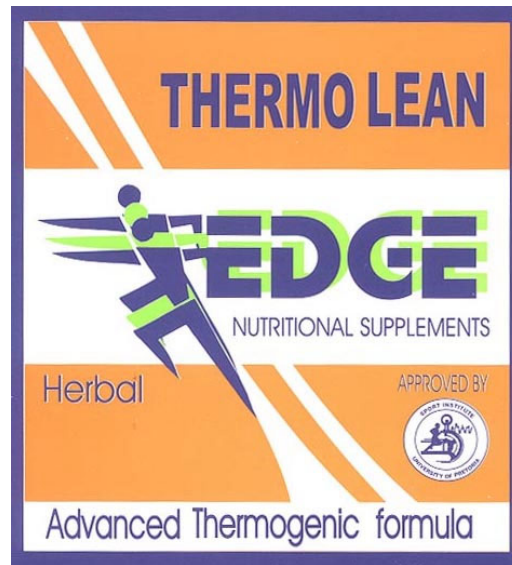
**FIGURE 3.8: SLIMLINE ELECTRICAL MUSCLE STIMULATION (EMS) MACHINE**

Electrical muscle stimulation (EMS) was performed using a Slimline EMS machine. According to the suppliers, Slimline is a unique type of electro-medical apparatus, which ensures that, a perfectly balanced exchange of electrons are constantly flowing between each set of electro pads during treatment. A “Set of pads” consists of one (+) pad and one (-) pad both of which are plugged into one of the eight channels of the Slimline machine, thus providing a total of 16 pads. A greater sensation of contraction is experienced in the region of the (+) pad or positive electrode. This is considered normal and, necessary if treatment is to be effective (Slimline Promotional Literature, 2001).

Slimline slimming machines have three different electrokinetic modulations which perform their functions at varying exercise levels and muscle depths, working in gradual stages, from the deepest or basal muscles to the middle layers and finally to the surface muscle layers. The entire treatment session is controlled by Slimline’s computer, which varies all the modulations, depth of therapy and exercise levels automatically. Pad placements are done according to pad placement charts, provided by the manufacturer. The complete pad placement chart is included in Appendix D.

Each subject used the machine for eight weeks, twice per week for a duration of 45 minutes per session. The training frequency was selected according to the manufacturer’s recommendation of at least two training sessions per week for maximum results.

### 3.4.2 Thermogenic Stimulation



**FIGURE 3.9: THERMO LEAN LABEL**

Thermo Lean is an advanced thermogenic formula which was specifically prepared and capsulated for the study by a pharmaceutical laboratory (Biomox Pharmaceuticals Pty Ltd). It is a unique formulation of special extracts and herbs to nutritionally support the natural release and burning of stored body fat. Thermo Lean aids in a temporary, natural increase in body temperature (thermogenesis). Thermogenesis, when not simply needed for routine food digestion and metabolism, is both a source of heat and, when stimulated through appropriate dietary supplementation, a mechanism to increase metabolic rate. Thermo Lean (2001) is purported to accelerate caloric burning, enhance fat fuel utilization and increase metabolic rate.

Subjects received 200 light brown, odourless, tasteless capsules in a sealed white securitainer. Subjects ingested Thermo Lean capsules for 5 days of the 7 days per week with an initial dosage of four Thermo Lean capsules per day. The dosage was increased to six capsules per day in the 5<sup>th</sup> week of the study. A total of 200 Thermo Lean capsules were consumed by each subject over 8 weeks with no contraindications resulting. Subjects were instructed to maintain an adequate state of hydration while taking Thermo Lean capsules and not to take Thermo Lean capsules after 16:00 to counteract potential insomnia. Instructions, dosage and frequency of use were the same for the placebo capsules.

Composition per serving			
Thermo Lean		Placebo	
Carcinia Cambogia Extract	2000 mg	Cellulose	3415 mg
Gaurana Extract (Paullinia Cupana 22%)	910 mg	Collour Agent	250 mg
White Willow Bark	200 mg		
Yohambine 3% Extract	160 mg		
Citrus Aurantium (Citrus 6% Extract)	125 mg		
Acetyl L-Carnitine	100 mg		
L-Tyrosine	80 mg		
Ginger Root (Zingiber Officinale)	50 mg		
Calcium D Pantothenate	40 mg		
Chromium Polynicotinate	200 mcg		
<b>Total</b>	<b>3665.2 mg</b>		<b>3665 mg</b>

FIGURE 3.10: COMPOSITION OF THERMOGENIC AGENT AND PLACEBO

### 3.4.3 Standardized Diet Program

The standardized dietary intervention program, labelled as the Metabolism Diet, emphasised the maintenance of a normal diet, including appropriate amounts of carbohydrates, protein and fat, viz.:

- Carbohydrates      55 percent
- Protein              15 percent
- Fats                  30 percent

The complete daily Metabolism Diet is included in Appendix E.

In general the subjects consumed normal everyday food, eating different amounts of food (calories) in three phases.

- Low calorie phase

At 1000 calories per day, this phase was designed for maximum weight-loss, while subjects consumed a nutritionally balanced diet. This menu was followed for two weeks.

- Booster phase

After two weeks on the low calorie phase the subjects were required to switch to the booster menu plan with 300 more calories. This phase was designed to boost the metabolic rate. The added calories during the booster phase were made up by carbohydrates.

Subjects alternated between the low calorie (two weeks) and the booster phase (one-week). This was done in order to prevent potential plateaus in the subject's diet (slowing the metabolic rate).

- Re-entry phase

When subjects got to within 2 to 3 kg from their target goal-weight, they switched to the re-entry phase. Subjects thus gradually increased their caloric consumption to reduce the risk of gaining weight. This pre-maintenance period served to get the subject's metabolism ready for normal eating.

In all phases, subjects ate four meals per day viz.: breakfast, lunch, dinner and a metabo-meal which was similar to a late-night supper. By taking more frequent meals, the subjects were able to avoid the feeling of hunger and fatigue often associated with a diet.

### **Basic rules of the Metabolism Diet**

Subjects were required to:

- a) eat everything exactly as it was prescribed;
- b) not eat anything more than indicated;
- c) never skip a meal;



- d) drink plenty of fluids - water (minimum of 2 - 3 glasses per day), diet beverages, and iced tea.
- e) avoid fruit juices (calorie drinks) or liquids high in sodium (e.g. tomato juice);
- f) not add table salt to food, so as to prevent potential water retention, but to obtain their salt intake naturally from foods;
- g) remove all visible fat from meat or skin from chicken, before eating;
- h) avoid all alcoholic beverages;
- i) only consume fresh fruit and fresh or frozen vegetables. Canned products were not permitted to be eaten.

### 3.5 STATISTICAL ANALYSIS

An independent statistician was consulted and utilized for all statistical analyses. Standard descriptive statistics for central tendency (mean) and spread (standard deviation) were applied to all variables measured. Differences between pre- and post-test scores within the three experimental groups were determined by the Wilcoxon signed rank test. The Kruskal-Wallis test for three or more independent groups was adopted as the appropriate statistical technique for the between group inferential analysis of the data. This test is a non-parametric equivalent to a one-way analysis of variance (ANOVA) (Howel, 1992).

In all analyses the 95% level of confidence ( $p \leq 0,05$ ) was applied as the minimum to interpret significant differences among sets of data. Where the null hypothesis of the Kruskal-Wallis test was rejected ( $p \leq 0,05$ ), multiple comparisons were used to detect differences between two groups (TS vs. EST, EST vs. ESP etc.) using Scheffe and LSD (least sign difference) methods (Smit, 2002). All computations were performed using the Statistical Package for Social Science (SPSS), Microsoft Windows release 9.0 (1999).