

CHAPTER 5

SUMMARY, CONCLUSION AND RECOMMENDATIONS

5.1 GENERAL CONSIDERATIONS REGARDING WEIGHT

5.1.1 Evaluation of a weight-loss program

In the evaluation of a weight-loss program the following criteria should be applied:

- Proportion of weight-loss that is maintained;
- Percentage of participants who experience adverse medical or psychological events and the kind and severity of such adverse events;
- Percentage of participants who complete the program; and
- Percentage of those completing who achieve various degrees of weight-loss.

Whilst weight-loss maintenance was not addressed, when subjecting the weight-loss program used in the current study to the above criteria the following is evident:

- No subjects in any of the experimental groups (TS; EST; ESP) experienced any adverse medical, psychological or psychological events;
- Participants adhered to the program in that only 7 of 69 subjects withdrew from the study in eight weeks; and
- Subjects who were part of the intervention involving dietary restriction, thermogenic stimulation and electrical muscle stimulation, showed greater benefit than those subjects on dietary restriction, electrical muscle stimulation and a placebo instead of a thermogenic agent.

5.1.2 Recommendations for weight-loss programs

- Thermogenic agents, diet, exercise and behaviour modification should be combined.
- Exercise, nutritional, psychological and medical expertise should be consulted.
- The amount and type of counselling should be individualized and/or limited to small groups rather than large audiences/groups.
- The weight maintenance phase is more stable and prolonged when the weight-loss program includes a diet in combination with exercise.
- Individuals with a body mass index (BMI) $> 25 \text{ kg}\cdot\text{m}^{-2}$ should consider engaging in weight-loss efforts to reduce their body weight.
- Individuals undertaking non-medically supervised weight-loss initiatives should reduce their energy intake by 500-1000 kcal·d⁻¹ to elicit a weight-loss of approximately 0.5-0.9 kg·wk⁻¹. It is recommended that dietary fat intake should be reduced to $<30\%$ of total energy intake.
- Individuals seeking weight-loss should include exercise as a key component to their weight-loss program.
- Individuals considering using dietary supplements or weight-loss enhancing agents (thermogenic stimulation) should do so only under the guidance of their personal physician or other trained health care providers (biokineticist).

5.1.3 Pro-active steps for weight-loss

- Health care providers should counsel obese patients (currently a relatively rare event).

- Workplaces should offer healthier food choices in their cafeterias and opportunities for physical activity.
- Schools should offer not only more physical activity, but also the types of activities that help children form the habit of daily lifelong activity.
- Urban planners and residents should motivate for more sidewalks, like paths, and other safe alternatives to cars.
- Parents can encourage their children to get away from screens and monitors and out into yards and parks.

(Koplan, 2000)

5.2 SPECIFIC WEIGHT-LOSS CONSIDERATIONS BASED ON THIS STUDY

The primary aim of this study was to evaluate the effect of an eight-week 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. In order to achieve this goal a pretest-post test experimental groups design, with three levels of the independent variable, was adopted for the study. (See 3.2 – Study Design).

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 following the standardized specific diet.
- Group ESP (N = 23) - Electrical Muscle Stimulation and a thermogenic placebo combined following the standardized diet

After the eight-week intervention programme, and in the light of the results discussed in Chapter 4, the conclusion and recommendations are presented accordingly.

5.2.1 Relative efficacy of the interventions

TABLE 5.1: RELATIVE EFFICACY OF INTERVENTIONS

Composite rating of results after an eight-week intervention programme

- 5 : Greatest effect on specific physiological parameters ($p \leq 0,05$)
 3 : Greatest effect on specific physiological parameters ($p > 0,05$)
 2 : Intermediate effect on specific physiological parameters
 1 : Smallest effect on specific physiological parameters

Variable	TS	EST	ESP	(NVT)
Anthropometry	30	32	13	(12)
Morphology	34	61	34	(19)
Ultrasound sonography	3	10	3	(2)
Respiratory quotient	2	1	3	(1)
Pulmonary function	15	11	10	(6)
Haematology	11	9	10	(5)
Cardiovascular response	7	4	7	(3)
Musculoskeletal function	3	5	4	(2)
Total Score	105	133	84	(50)
Max Score (*)	250	250	250	
Relative Score (%)	42.0	53.2	33.6	

NVT = Number of variables tested

* = 250 is the maximum score attainable for 50 variables tested achieving a rating of 5 (Greatest effect on specific physiological parameters $p \leq 0,05$).

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 standardized diet (Placebo controlled).

Obesity develops when a chronic quantitative imbalance exist between energy intake and energy expenditure. To unbalance the energy equation in the direction of weight-loss, requires decreased food energy intake (diet – Group EST, TS, ESP) increased physical activity (electrical muscle stimulation – Group EST, ESP) increased energy expenditure pharmacologically (thermogenic stimulation – Group EST, TS) or altering all three intervention strategies simultaneously (diet, thermogenic and electrical muscle stimulation – Group EST).

In this study great efforts were made to manipulate the diet in all three experimental groups (metabolism diet) and in two of the experimental groups (EST, TS) efforts were made to increase energy expenditure pharmacologically as a tool to enhance the weight-loss after the eight-week intervention program. There is accumulating evidence to support the hypothesis that a low-energy output phenotype predisposes individuals to weight gain and obesity, whether the low energy output is caused by a low resting metabolic rate (RMR), physical inactivity or both (Plowman & Smith, 1997). Increased energy metabolism is therefore an attractive target because it may allow people to maintain food intake at socially more acceptable levels. There is evidence to support the view that any increase in energy expenditure is not fully counteracted by a similar increase in appetite and energy intake, irrespective of whether the increased energy output was achieved through exercise or pharmacologically (Oomura et al., 1999). Even a slight increase of 2 to 3% in daily energy expenditure through thermogenic stimulation may therefore have clinical relevance, particularly in preventing the decline in resting metabolic rate with weight-loss, but also in decreasing the risk of weight regain following weight-loss. Both groups with a pharmacologic intervention (Groups EST, TS) as part of their intervention program, had the greatest influence on physiological parameters tested thus confirming the above-mentioned hypothesis.

To date, the emphasis in the treatment of obesity has been on restricting the energy intake (dietary) side of the energy balance equation. There are at least two reasons why decreasing energy intake has been favoured over increasing energy expenditure through physical activity. The first is economic. In recent years, the cost of burning extra calories has surged as work has become more sedentary. In the past people were paid to engage in manual labour. Today one pays to exercise, not so much in money, but in foregone leisure time (Postrel, 2001).

Secondly, it has been difficult to demonstrate the efficacy of exercise as a treatment strategy for obesity. Although a considerable number of studies have been done to investigate whether exercise contributes to weight-loss, the results have been mixed (Saris, 1996). McArdle et al. (1996) cite evidence to support the contention that an increased level of regular physical activity may be more effective than dieting for long-term weight control. In a meta-analysis study conducted to assess the effects of exercise on changes in body mass, Ballor and Keeseey (1991) found that increases in physical activity results in body mass reductions. One possible clue to the variability of results in this area (impact of exercise on weight-loss) is offered in a recent review (Saris, 1996), which found that only a few of the studies to-date were well-controlled.

In our study physical exercise was substituted by electrical muscle stimulation (EMS) done on the Slimline Platinum 16 pad machine. In essence, this apparatus was an automatically cycling multiple output, faradic muscle stimulator which produced trains of pulses with variable pulse repetition frequency. The individual pulses were of short duration (0-5 millisecond) and of low energy, but at appropriate gain levels the pulse trains produced rhythmic and powerful muscular contractions when they were fed to the muscle by skin contact electrodes placed over or near the specific motor points. Pre study claims were made that repeated application of such pulse stimulation would produce breakdown of adipose tissue by localized passive exercise of the muscle unit, and so afford a generalized reduction in both size and weight.

As shown in Table 5.1 the most effective overall intervention modality when comparing groups was EST. EST had the greatest effect on anthropometry, morphology, ultrasound sonography and musculoskeletal function. Group TS had the greatest effect on pulmonary function and haematology and ESP had the greatest effect on respiratory quotient and musculoskeletal function. TS and ESP had the same effect on cardiovascular responses. When comparing total scores for number of variables tested both groups with thermogenic interventions (Groups EST and TS) had similar results. Electrical muscle stimulation, following a standardized diet and placebo controlled (Group ESP) also had an impact on physiological parameters but not as significant as group EST and TS. A more critical picture emerged, however, when only those variables showing significant differences in improvements between groups are considered (Table 5.2) to determine the greatest efficacy among the experimental groups.

TABLE 5.2: VARIABLES SHOWING DIFFERENCES* BETWEEN GROUPS

GIRTHS			
- Abdominal	EST = 6.02	>	TS = 4.69 ESP = 4.79
- AB-1 ½ Umbi	EST = 6.42	>	TS = 4.35 ESP = 4.28
SKINFOLDS			
- Triceps	EST = 12.75	>	TS = 9.27 ESP = 6.63
- Subscapular	EST = 9.70	>	TS = 8.64 ESP = 3.93
- Abdominal	EST = 12.14	>	TS = 11.80 ESP = 10.36
INDICES			
- Waist-to-Hip	EST = 2.53	>	TS = 1.27 ESP = 1.27
- Body Surface Area	EST = 3.03	>	ESP = 1.96
SONOGRAPHY			
- Subcutaneous	EST = 21.22	>	TS = 18.04 ESP = 12.11
- Visceral	EST = 27.74	>	TS = 21.87 ESP = 22.82
SAGGITAL HEIGHT			
- Saggital ½ Umbi	EST = 13.50	>	TS = 10.60 ESP = 10.61

* $p \leq 0,05$

Although the magnitude of improvements within groups tended to be greater in the TS group than in the ESP group, neither of these groups showed a statistically greater performance. The use of thermogenic stimulation (Group TS) and a standardized diet was thus as efficacious as the use of electrical muscle stimulation (Group ESP) and a standardized diet without thermogenic stimulation (placebo controlled) and vice-versa.

On the other hand group EST performed better than group TS (9 of 11 variables) and group ESP (10 of 11 variables). The use of electrical muscle stimulation in conjunction with thermogenic stimulation and a standardized diet thus showed greater

efficacy than the use of thermogenic stimulation only in conjunction with a standardized diet or electrical muscle stimulation only in conjunction with a standardized diet. A combination of the two primary modalities thus proved to be the most successful tools for weight-loss among obese woman.

Solving the problem of obesity within the context of this study thus appears to be three fold when considering changes within groups:.

- Energy expenditure through thermogenic stimulation in conjunction with calorie restriction (diet) has clinical and weight-loss relevance for the obese (Group TS).
- Electrical muscle stimulation in conjunction with calorie restriction (diet) has relevance for weight-loss in obese females (Group ESP).
- Electrical muscle stimulation in conjunction with thermogenic stimulation and calorie restriction (diet) has relevance for weight-loss in obese females (Group EST) and has been proven the most effective in this study.

5.2.2 Implication for weight-loss practice

Based on the results of this study obese individuals participating on a program of dietary restriction, thermogenic and electrical muscle stimulation with the aim of achieving weight-loss should note that:

- Diet in combination with electric muscle stimulation (EMS) is effective for weight-loss.
- Diet in combination with thermogenic stimulation, with/or without electrical muscle stimulation (EMS) proved the most effective intervention program after eight weeks.

5.2.3 Limitations of the study

Potentially limiting factors in this study which could be addressed in future studies are:

- Focus on a wider gender, cultural, ethnic and socio-economic diverse population;
- Identification of characteristics in individuals who are successful in weight reduction;
- Identification of appropriate and successful intervention content;
 - Magnitude of weight-loss goals
 - Goals for the rate of weight-loss
- Integration of behavioural methods with thermogenic and electrical muscle stimulation; and
- Extending the duration of the study for long-term observation.

5.3 FUTURE RESEARCH DIRECTIONS

Obesity is a heterogeneous chronic disorder that has many causes, although the fundamental basis is an imbalance between energy intake and energy expenditure. Future research needs to examine the most effective ways to treat and prevent obesity, the causes of obesity and their mechanisms, the influence of fat distribution on health risk, and the development of better methods for assessing energy intake and energy expenditure (NIH, 1998).

5.3.1 Assessment methods

Much of the current research is hampered by the lack of good methods to accurately, objectively, and economically assesses energy intake and expenditure, including physical activity, body composition and fat distribution, and behavioural and

psychological variables. More research is therefore needed to focus on measures to assess intake of fat and other dietary components, levels of physical activity, energy metabolism, and body fat and visceral obesity. In addition, better methods for assessment of psychological, behavioural, and psychosocial variables that may be related to behavioural risk factors for obesity (such as poor diet and inactive lifestyle) are needed, and particularly so for special population segments based on race, ethnicity, and socio-economic status. Methods for assessing culture, social integration, and psychological stress should also be developed (NIH, 1998).

5.3.2 Intervention approaches

Considerable research is needed on intervention approaches to treat and prevent obesity. Increased research on behavioural theory specifically addressing obesity treatment and prevention for all individuals, including children and adolescents, needs to be conducted. More research is needed on behavioural intervention methods conducted in various settings, particularly the primary care setting. Effective programs to treat or prevent obesity in culturally, ethnically, and socioeconomically diverse populations need to be developed and tested. Simple screening tools should be tested for their predictive value in achieving lifestyle modifications that lead to weight-loss or weight control practices. Research is needed on identifying appropriate and successful intervention content; for example, magnitude of weight-loss goals (smaller changes versus larger changes), and goals for the rate of weight-loss 0.5 kg versus 1.0 kg per week; initial weight-loss goal of 5 percent of body weight and, subsequently, an additional 5 percent versus a single initial goal of 10 percent at the outset). Of particular importance is research on the nature and optimal dose of physical activity to promote weight-loss, the maintenance of weight-loss and the prevention of obesity. Also important, are strategies which preserve muscle and bone in the face of weight-loss. More research is needed on identifying the characteristics of individuals who have successfully maintained their weight-loss over the long term. Research on pharmacologic interventions for weight-loss should include evaluating changes in fat distribution, cardiorespiratory fitness, obesity-related comorbidities, and the degree of success of long-term weight-loss maintenance. Better methods for integrating behavioural methods, along with pharmacologic treatment, should also be investigated. Finally, research is needed on environmental and population-based intervention methods, including community- and school-based interventions, to

augment public health approaches toward promoting weight maintenance and preventing obesity in the general population (NIH, 1998).

5.3.3 Causes and mechanisms of overweight and obesity

The regulation of energy balance needs to be explored, including the neuroendocrine factors that control energy intake, energy expenditure, and the differentiation of adipose tissue resulting from excess calories. The genes that are important in human obesity need to be identified. These include those that alter eating and physical activity behaviours, those that effect thermogenesis, and those associated with the comorbidities of obesity. The roles of environmental and behavioural influences on metabolic factors important in obesity, as well as gene-environment interactions, need to be studied. Predictive factors should be examined to identify who is most at risk of developing obesity, and whether there are critical periods of life when these factors are most operative (NIH, 1998).

5.3.4 Abdominal fat, body weight and disease risk

The influence of abdominal fat independent of total body fat on health risk needs to be further defined. More information is needed on the relationship between differential body fat compartments and increased risk, the distribution of body fat compartments among various racial group populations, and the relationship between abdominal fat and disease risk in racial groups. Weight-loss studies should include measurements of abdominal fat, as well as cardiorespiratory fitness, to better assess health improvement. Intentional weight-loss treatments need to be examined in terms of their acute and chronic effect on the development and progression of diabetes, heart disease, and overall mortality. Large prospective studies are needed to examine the relationship of body mass index and body fat distribution to overall mortality (NIH, 1998).