Long-Term Weight Loss through Changed Eating and Exercise Behaviour

Itrim is a Swedish franchise company, which provides weight loss and fitness services for adults in the form of long-term, individualised support for weight loss through increased exercise and changed dietary habits. The company was launched in 2003, and at the end of April 2011 had 31 Itrim centres.

Itrim's weight loss program is evidence based (see attachment A) and its content has been devised with practical experience and cost in mind. Changes to improve the program are generated via two main functions: new research findings concerning weight loss through improved diet and exercise, and statistical analysis of Itrim's database (see attachment B).

In addition, discussions are held with Itrim's Scientific Advisory Board and program committee to assess the quality and further development of the program. The Scientific Advisory Board comprises Itrim's Program Director and four clinical researchers and medical doctors (Karolinska Institutet and Uppsala University).

The program committee consists of Itrim's Program Director and Training Director, plus three franchisees who run their own centres.

The Weight Loss Program

Itrim's weight loss program is based on the principle that weight (fat mass) is controlled by the laws of energy, i.e. eating and exercise habits. Because it takes time to change lifestyle, the program lasts two years, which gives each participant long-term and individually tailored help. The aim is that the customer should achieve a meaningful weight loss (at least 5% of their body weight), and keep it off in the long term.

Customers pay a lump sum for the first year of the program, with the option of extending for additional years. Each centre sets its own prices. An average price within the Itrim chain for the weight loss program as of 1 May 2011 was roughly SEK 745/month (Euro 83). Itrim recommends that the costs of the program be paid by the customer him or herself as this increases the likelihood that the customer is sufficiently motivated. Alternatively, an employer may reimburse all or part of the costs once the program has been completed.

Customers attend regular support meetings and weigh-ins with their personal health advisor, where the goals and appropriate behavioural changes are planned and monitored. Before the start of the program there is a 60 minute background interview, including a discussion about current diet and exercise habits, daily routines, family situation, etc. and measurements are taken (waist, weight, body composition).

Follow-up sessions and individual support meetings are held after 10 weeks and then after 6, 12, 18 and 24 months. Customers also have the option of buying extra individual follow-ups during the course of the program.

Once the program has been completed, 24 months from start, there is an option to continue with individual support and follow-up either through Itrim's exercise program (not described in more detail here) or the customer can repeat year two (Stabilisation Phase, see below). This enables customers to decide for themselves how long they require support and monitoring.

The weight loss program comprises three phases: the Weight Loss Phase (first 10 weeks), the Improvement Phase (from week 10 to the end of the first year), and the Stabilisation Phase (year 2 onwards, for as long as the customer wishes).

Throughout the duration of the program customers exercise 30 minutes at the centre 2-3 times each week (combined aerobic and strength training in a circuit), and use step counters to increase their daily exercise.

Weight Loss Phase

As the name suggests, the focus at the start of the program is on weight loss. Because a reduction in calorie intake is a more effective recommendation than increased exercise for achieving weight loss, the content of the program during this phase focuses on reducing caloric intake.

Customers meet in a group of about 15 people for five 60-minute sessions (one each second week). Every group meeting is led by a trained health advisor who gives a fact-based presentation on a relevant subject (e.g. regular mealtimes, fat & sugar, exercise, goals and expectations etc.). This is followed by a general discussion and homework planning for the week, plus review of last week's homework.

There are many health benefits to losing weight, but there are also side effects. Common side effects of rapid weight loss (approx. 1-2 kg weight loss/week) include gallstones, dizziness, feeling cold and hair loss.

The risks of side effects increase in relation to the rate of weight loss. We therefore recommend all customers who wish to undergo a VLCD period (very rapid weight loss) to consult their doctor before starting, and to have a follow-up medical consultation after returning to energy balance. It is the customer's responsibility to make sure that they are in sufficiently good health to undergo the program.

Each customer is offered three options for reducing their calorie intake (note that the results below are average values for people who have undergone the program). The customer decides for him or herself which method to use, in consultation with their allocated health advisor.

- A combination of meal replacement, i.e. powder mixed with water (2 meals a day) and ”regular” food with a limited calorie content (2 meals a day), where the portion sizes are adjusted to each person's required rate of weight loss and target weight. Average rate of weight loss is 0.82 kg/week (1.81 lbs) during the first ten weeks (95% confidence interval: 0.79 to 0.85). After one year, average weight loss is 8.7 kg (95% CI: 8.3 to 9.1), with a 30.2% drop-out rate. 53% of all customers choose this method.

- Meal replacement only, corresponding to 500-800 kcal/day (very low calorie diet, VLCD). VLCD is only suitable for persons with a BMI ≥30 kg/m^2, and can be used for a maximum of 10 weeks. Average rate of weight loss during the first ten weeks is 1.53 kg/week (3.37 lbs) (95% confidence interval: 1.49 to 1.57). One year from start, the average weight loss is 14.3 kg (95% CI: 13.7 to 15.0). The drop-out rate is 20.6% after one year. 31% of all customers choose this method.

- "Regular" food low in sugar and fat. The energy intake is adjusted to each person's desired rate of weight loss and target weight. Average rate of weight loss during the first ten weeks is 0.51 kg/week (1.12 lbs) (95% confidence interval: 0.46 to 0.57). After one year, the average weight loss is 5.8 kg (95% CI: 4.8 to 6.8). The drop-out rate is 25.9% after one year. 17% of all customers choose this method.

Itrim has its own quality-assured range of meal replacement products, approved as VLCD products by the Swedish National Food Administration. Meal replacements can be bought at any centre.

Improvement Phase

After the Weight loss phase comes the Improvement phase, which continues until the end of the first year. Focus on exercise increases, and the customers meet at ten new group meetings to develop a stable diet, exercise habits, and follow up the improvements that began in the weight loss phase. The behaviour changes which the program now focuses on are established predictors for long-term weight loss, based on data from the National Weight Control Registry (se www.nwcr.ws).

NWCR is a survey of individuals from the USA who, using a variety of methods, have succeeded in losing at least 13.6 kg and maintained the weight loss for an average of 5.7 years. The main weight loss strategies were a low-fat diet, daily weighing, a stable breakfast, regular mealtimes, an hour's exercise each day, and limited relapses.

Stabilisation Phase

After the first year, the program continues for at least one more year for those customers who so wish (added cost). The emphasis now shifts towards preventing lapses into old habits, and stabilising new, improved diet and exercise habits. Ten evenly spread-out group meetings and continued individual guidance help customers maintain their new weight. Regular exercise, both at the centre and as part of the daily routine, is a key element of the program.

Annex A. Background to Excess Weight and Weight Loss

The prevalence of overweight (BMI 25-29.9 kg/m^2) and obesity (BMI ≥30 kg/m^2) has increased both in Sweden and internationally. The reason for overweight and obesity is a long-term energy imbalance, which is primarily controlled by food intake and physical activity. Diet and exercise habits are in turn controlled by a number of factors such as genes, environment and stress.

The trend is disturbing, especially bearing in mind the increased prevalence of related illnesses, reduced health-related quality of life, discrimination, bullying, increased healthcare costs, and reduced productivity. Studies indicate that 3-8% of healthcare costs can be attributed to overweight (SBU – The Swedish Council on Technology Assessment in Health Care. Fetma – problem och åtgärder. [Obesity - problems and interventions] Report no. 160, 2002).

There are a variety of methods for losing weight, all of which are based on changed diet and exercise habits. Contrary to what many people believe, it has now been established that the probability of the weight loss being maintained in the long term is greater if the weight loss is rapid (1-2kg/week) than if it is slower (0.5 kg/week), (SBU. Fetma – problem och åtgärder. Report no. 160, 2002).

There are two methods that stand out in terms of delivering rapid weight loss: surgery (not discussed in more detail here) and meal replacement (very-low-calorie diet [VLCD], 500-800 kcal/day for around 6-10 weeks). Pharmaceutical drugs can also lead to a good long-term prognosis provided that they are combined with intensive lifestyle changes.

Meal replacement has been used as a weight loss method for almost a hundred years, and was marketed in the 1970s as ”the last chance diet”. Unfortunately some study participants suffered arrhythmia because of lack of protein and insufficient vitamins and minerals. This led to an adjustment in the content of VLCD products, and these are now approved by the Swedish National Food Administration.

Since the 70s crisis, VLCD has been used as a weight loss method for more than 20 years without serious side effects. The most common side effects are gallstones (10-20%). Common effects (over 10%) include constipation, dizziness, feeling cold, hair loss and bad breath.

Every person who wishes to undergo a VLCD period within Itrim's program is informed of the risk of side-effects, and is expressly advised to seek their own doctor's approval before starting the program. Consultation with a doctor is especially important for customers who are on medication, which often has to be adjusted immediately after the start of the VLCD. Doctors can also play an important role in boosting motivation, for example by testing for risk factors for cardiovascular disease.

Because the VLCD period is not in itself a long-term solution to overweight, the method must always be carried out as part of a long-term support program. This is to improve diet and exercise habits as part of the daily routine, including training on how to prevent relapses, to avoid weight retention.

Good diet habits include regular mealtimes, low-fat, low-sugar foods and a high intake of fruit and vegetables. Increased exercise is central and should be achieved through regular everyday activities (cycling, walking), and varied exercise 2-3 times/week. Weighing oneself regularly, keeping a diary, and basal stress management all further reduce the risk of yo-yo dieting. These are the fundamental principles of Itrim's weight loss program.

Annex B. Itrim's Health Database

Itrim continuously evaluates its results so that fact-based decisions can be taken on appropriate adjustments. This is done primarily through statistical analysis of Itrim's health database which contains a wealth of data. The database and the data are stored on a password-protected server.

The results are primarily analysed in respect of anthropometry, reasons for dropping out, predictors for weight loss, any side effects and harm, and predictors for attendance at group meetings and in the exercise circuit. This is done primarily by means of analysis of variance and regression analysis.

Two methods are used to analyse results: outcomes for those who complete the program (completer analysis), and a more conservative analysis (intention-to-treat), which means that even those who do not complete the program are included in the assessment with a no-change assumption.

The results of Itrim's weight loss program were first presented at the national meeting of the Swedish Society of Medicine (*Svenska Läkaresällskapet*) in Gothenburg in 2006, in the section for obesity research. The abstract is presented in Annex C below. Itrims results have since then continuously been presented at national and international conferences, Annex D through F below.

Annex C. Abstract for the 2006 Annual Meeting of the Swedish Society of Medicine (*Svenska Läkaresällskapet*), Section for Obesity Research.

Weight Loss and Lifestyle Change within the Commercial Sector – a Good Complement to Healthcare?

Erik Hemmingsson, Johan Sundström, Claude Marcus

Background: Only a small proportion of overweight patients currently get state-financed help with weight loss and lifestyle changes. The quality of commercial weight loss programs is still relatively unknown.

Method: 340 participants (BMI 31.9±5.3 kg/m^2; age 47.4±11.8 years, 89.7% female) underwent a commercial 12-month weight loss program (Itrim) comprising 20 one-hour lectures on diet and exercise, 30-45 minutes of aerobic and strength training 2-3 times/week, individual coaching at every weigh-in (at the start, 10, 20 and 52 wks), and homework tasks/diaries. The participants, who all had a BMI >25 kg/m^2, were recruited consecutively between 2004-2005 from six centres in different parts of the country. The participants had all paid for the program themselves (cost approx. SEK 700/month). The participants could choose one of three specific low-calorie diets during the first ten weeks of the program (after which they gradually returned to energy balance): 1) VLCD; 2) 2 meals of normal food + 2 VLCD meals (”2+2”); and 3) normal food with a restricted fat and sugar content (”Normal food”). The intention to-treat principle was used (baseline carried forward). RM ANOVA with baseline weight as a covariate was used for hypothesis testing.

Result: 249 participants completed the 12 months. The dropout rate was 20.6% in the VLCD group (20/97), 30.2% in the 2+2 group (54/189) and 25.9 % in the normal food group. After 12 months the VLCD group had lost 12.3 kg (95% CI 10.4 to 13.7), the 2+2 group 7.6 kg (6.4 to 8.8), and the normal food group 5.7kg (3.5 to 7.9). The VLCD group had significantly better weight loss than both the 2+2 and the normal food groups ($P<0.001$ for both). The 2+2 group achieved significantly better weight loss than the normal food group ($P<0.05$).

Summary: All groups achieved clinically relevant weight loss. The greatest weight loss was achieved when meal replacement was used at the start of the program. Commercial weight loss programs may be an important complement to public healthcare.

Annex D. Abstract for European Congress on Obesity, May 2008.

Efficacy and Consistency of a Franchising Weight Loss Program in the Swedish Commercial sector

Hemmingsson, E[1], Sundström, J[2], Marcus, C[3]

[1] *Karolinska Institutet, Department of Medicine, Stockholm, Sweden*
[2] *Uppsala University, Department of Medical Sciences, Uppsala, Sweden*
[3] *Karolinska Institutet, Division of Pediatrics, Stockholm, Sweden*

Background: Commercial weight loss programs with a scalable structure, operating according to a defined manual including regular quality controls, can partner health professionals when public care is lacking.

Aim: To clarify consistency of weight loss (across years and locations) of a commercial franchise company (Itrim) in Sweden.

Methods: Weight loss at 12 months was analysed for the years 2004-2006, across 11 centres (6 cities), before and after adjustment for baseline body weight, age, gender, and group session attendance. 970 consecutively recruited participants (BMI 31.5 kg/m^2 [sd 5.5], age 47.1 yrs [11.4], 86 % women) were included. The program consisted of 20 one hour group sessions on diet and exercise behaviour change, physical activity (circle training 2-3 times/wk á 30-45 min + pedometers), individual coaching at 0, 10, 26 and 52 weeks, meal replacements, home assignments, and food and exercise diaries. Participants paid their own fee (approx. Euro1000/yr.).

Results: Mean weight loss at 12 months was 10.5 kg (95 % CI: 10.0 to 11.1). In unadjusted analysis, there was a significant weight loss difference between centers ($p=0.03$) but not between years ($p=0.16$). After adjustment for covariates, the difference in weight loss between centers was attenuated ($p=0.10$). Predictors of weight loss were instead baseline body weight (Beta=-0.3 per baseline kg, $p<0.001$), group session attendance (Beta=-0.49 per session, $p<0.001$), gender (Beta=2.4 men>women, $p<0.002$), and age (Beta=0.06 younger>older, $p<0.008$).

Conclusions: Commercial companies, operating according to a defined manual including regular quality controls, can provide consistent weight loss results across time and locations.

Conflict of interest: EH works part time as Itrim's Program Director. JS and CM are members of Itrims Scientific Advisory Board.

Annex E. Abstract for The Obesity Society, October 2008.

Multi-Center Commercial Weight Loss through Caloric Restriction, Behaviour Modification and Exercise: Results Across Time and Location

Hemmingsson, E[1], Neovius, M[1], Sundström, J[2], Marcus, C[3]

[1] *Karolinska Institutet, Department of Medicine, Stockholm, Sweden*
[2] *Uppsala University, Department of Medical Sciences, Uppsala, Sweden*
[3] *Karolinska Institutet, Division of Pediatrics, Stockholm, Sweden*

Background: Commercial weight loss programs based on diet and exercise behaviour change with a scalable structure can partner health professionals in the treatment of obesity and prevention of obesity co-morbidities.

Aim: To clarify consistency of weight and waist loss (across years and locations) of a commercial franchise company (Itrim) in Sweden.

Methods: Weight loss and waist loss at 12 months were analysed for the years 2004, 2005, 2006 and 2007 across 12 commercially operated weight loss centers in 7 cities. 1726 participants who completed one year were included (BMI 31.6 [sd 5.5] kg/m^2, waist 105.0 [12.9] cm, age 47.0 [11.6] yrs, 86 % women). The one-year program consisted of 20 one-hour group sessions on diet and exercise behaviour change, physical activity (circle training 2-3 times/week à 30-45 min, fitness testing and pedometers), individual coaching at 0, 10, 26 and 52 weeks, meal replacements, home assignments, and food and exercise diaries. Participants paid their own fee (approx $1500/year).

Results: Overall weight loss (all mean values are age and sex adjusted) at 12 months was 10.8 kg (95 % CI: 10.4 to 11.4). The mean waist loss was 11.8 (95 % CI: 11.4 to 12.3) cm. Both weight loss and waist loss were stable across years (P=0.43 and P=0.81, respectively) but differed across centers (P<0.001 for both). Mean weight loss across centers ranged from 7.5 (95 % CI: 5.3 to 9.6) to 12.5 (95 % CI: 11.4 to 13.6) kg, with waist loss ranging from 7.1 cm (95 % CI: 3.9 to 10.2) to 16.3 (95 % CI: 14.5 to 18.1).

Conclusions: Commercial weight loss programs can provide stable results across time. Consistency between centers, however, remains a challenge in multi-center commercial weight loss.

Conflict of interest: At the time of submission, EH was employed part time by Itrim International as Program Director. MN, JS and CM are members of Itrim's Scientific Advisory Board.

Annex F. Abstract for the 2009 Annual Meeting of the Swedish Society of Medicine (*Svenska Läkaresällskapet*), Section for Obesity Research.

Evaluation of a franchising weight loss program: 2-year results and drop-out

Erik Hemmingsson [1], Martin Neovius [1], Johan Sundström [2], Claude Marcus [3]

[1] *Karolinska Institutet, Department of Medicine, Stockholm, Sweden*
[2] *Uppsala University, Department of Medical Sciences, Uppsala, Sweden*
[3] *Karolinska Institutet, Division of Pediatrics, Stockholm, Sweden*

Background: Commercial weight loss through lifestyle modification is a growing industry. Results of commercial weight loss programs are seldom published, especially data on long-term weight loss and drop-out.

Method: Data on body weight from 4917 participants (BMI 31.8±5.2 kg/m^2; age 46.7±11.9 y, 86% women) on the Itrim weight loss program in Sweden were available for analysis through a customer database. All participants were enrolled consecutively from 21 centers during 2004-2007. The program consists of group sessions, circle training, fitness testing, individual coaching sessions, home assignments, and diaries. All participants paid their own fee (cost ca €1 000/yr). In September 2006 the company added a 1-year voluntary maintenance program to the existing 1-year weight loss program, thereby also providing 2-year follow-up data.

Results: Of the 4917 starters during 2004-2007, 3390 completed the 1-year follow-up, giving a 31% drop-out rate. In an intention to treat analysis, using baseline carried forward for drop-outs, the average weight loss at 1 year was 7.3 kg (SD 7.9) (10.6 kg in completers only analysis). Sixteen percent (n=248) of the customers enrolling on the weight loss program at or after September 2005 (n=248 of n=1414) started the maintenance program. Eighty-nine percent (n=220) completed the 2-year follow-up (drop-out: 11 %), with an average weight loss of 10.9 kg from baseline (1-year data carried forward for second year drop-outs; -12.3 kg in completers only analysis).

Conclusion: Commercial weight loss programs, where participants pay their own fee, can provide clinically relevant results long-term. A common problem in obesity treatment is drop-out before enrolling on a maintenance program, which is a major challenge for commercial weight loss programs.