

Study for evaluation of the metabolic balance® programme

Summary of study results

The main emphasis regarding the contents of the “*Study for evaluation of the metabolic balance® programme*” was the measuring of short-, middle- and long-term treatment results obtained during participation in the programme. Essentially the focus was on the outcome-parameters weight loss, improvement of lipid values and improvement of health-related quality of life.

Analysis of response and drop-outs

A total of N=970 clients started to participate in the programme during the admission period. Thereof N=851 clients were included in the study, so that a drop-out rate of 14,0% resulted at the beginning of the study. In the analyses regarding individual catamnesis times those clients were included of which complete data sets were available, while the cases described as "complete data sets t_0 - t_1 " are those of which a client questionnaire t_0 as well as a client questionnaire t_1 and/or a doctor/attendant questionnaire were available for example. At the time of the survey t_1 (four weeks after commencement) the response quote had a high standard of 85,2% at t_2 (three months after commencement), the response quote was approximately ten percent less (74,4%). At the time of measurement t_3 (six months after commencement) the response dropped to 64,4% and at t_4 (one year after commencement) finally to 55,5%.

Since the response to the catamnesis after a year was not satisfactory, a subsequent survey was done after the actual study. The aim was to supplement the missing indications of weight and was able to increase the response of the last time of measurement to 61,6%. Furthermore all the doctors/attendants and clients participating in the study were requested to mention all possible side-effects or complications that they ascribed to the participation in the programme.

Description of the sample

The analyses of the long-term treatment results are based on the data of N=472 clients in respect of whom a client questionnaire t_0 as well as a client questionnaire t_4 and/or a doctor/attendant questionnaire t_4 were available. With reference to these samples the average age of the clients was 50 years (SD=12,0), while the youngest client was 19 and the oldest 81 years old. 84,1% of the sample was made up of women. With 38,3%, clients with a secondary school-leaving certificate were represented most, 26,5% of the clients had completed secondary modern school and 32,8% had an advanced technical certificate or Abitur¹. While 43,0% of the clients were employed, 18,2% were self-employed. 12,5% worked as housewives or househusbands solely, a further 12,3% were on pension. Nearly two thirds (65,5%) of the test persons were married.

¹ German university entrance qualification

The average body weight at the beginning of the programme was a BMI of 30,3 with a standard deviation $SD=5,6$. Nearly half of the clients (48,3%) had a BMI-value of > 30 , while 18,5% at a BMI of > 35 were within the range of distinct obesity. The waist measurement which is a relevant criterion for the diagnosis of the metabolic syndrome as well as a risk factor for cardiovascular diseases, was an average of 98,8 cm at the beginning and at 79,1% i. r. o. the women and 73,2% i. r. o. the men it was within a range which has to be interpreted as a "severely increased health risk. With regard to the cardiologically related metabolism parameters the total cholesterol presented values that were too high ($> 240\text{mg/dl}$) in 31% of the cases, and the LDL-cholesterol showed values of 160 mg/dl in 23,8% of the cases; at 14,7% the triglycerides were in the marginal range (150-199 mg/dl) and at 13,8% in a high or very high range ($> 200\text{mg/dl}$).

A self-assessment of the health-related quality of life was surveyed by means of the IRES-24 questionnaire, which captures the areas "somatic condition", "pain", "everyday life efficiency" and "mental condition". The participants of the study proved to have values with a high percentage in all four areas and especially in the area "mental condition" which – in comparison with the standard sample of the IRES-24 - have to be evaluated as "noticeable" or even "serious".

Long-term effects

Bodyweight

The following statements regarding changes in the bodyweight from t_0 to t_4 are based on the $N=420$ clients who indicated at the beginning of their participation in the programme that weight loss was an important goal for them personally, and from whom an indication of their weight at both measuring times was available. 46,2% of the clients lost so much body weight while participating in the programme that they could be allocated to a lower BMI-group than at the beginning of their participation at the measuring time t_4 . The weight loss between the two survey times was highly significant statistically. The average weight loss was 7,2 kg ($SD=7,0$). While 29 clients (6,9%) gained weight slightly and no weight change could be ascertained in the case of 13 clients (3,1%), a total of 90,0% of the participants lost weight. Nearly two thirds (64,3%) lost more than five percent of their starting weight: 32,6% were able to reduce their body weight by ten or more percent of their starting weight on the long term.

Metabolism parameters

The analyses with regard to relevant metabolism parameters and the diagnosis of the metabolic syndrome confirmed the health changes in a positive direction. All the investigated metabolism parameters improved during participation in the programme, except the CK (NAC) total value which hardly changed. The percentage of clients with an increased γ -GT value was halved from 18,2% at t_0 to 8,2% at t_4 . Similarly the number of clients with an LDL-cholesterol value at t_0 (23,8%) that was too high was reduced at t_4 (17,4%). The values in the range of the total cholesterol that were too high at t_0 in the case of nearly a third of the clients (31,0%) improved in so far as the value was too high in only 25,7% of the examined clients. The quotient of the total- and HDL-cholesterol was within the optimum range ($\leq 3,5$) at t_0 in the case of 45,7% of the sample; at t_4 this percentage was 59,9%. Similarly the improvement from t_0 to t_4 with regard to the parameter triglyceride in the serum was distinct: whereas the triglyceride-values were too high in 13,8% of the clients in the total group at the beginning, only 7,9% of the clients still had high or very high values after having participated for one year. While 10,0% of the clients still had symptoms of a metabolic syndrome at the time of the survey t_0 , this percentage was reduced to 2,2% one year after beginning to participate.

Health-related quality of life

With regard to the four dimensions as well as the summary total score of the questionnaire IRES-24, highly significant improvements were evident at all measuring times ($p < .001$ in each case). The effects concerning the dimension "mental condition" were most significant during the first four to six week of participation in the programme (intensity of effect $SRM=1,12$). Although the effects decreased with every measuring time, they were still within the range of "strong" effects at the time of the catamnesis after a year ($SRM=0,79$). With a view to the dimensions "somatic health", "everyday life efficiency" and "pain" the most significant effects appeared at the catamnesis after three months; the effects had also decreased at the catamnesis after a year, but remained at least within the range of "middle" intensity of effects.

"Programme adherence" and effects

Particularly insightful effects become apparent if the effect in the abovementioned outcome-dimensions are compared to the so-called "programme adherence", that is the extent to which the clients adhered to the general rules of the programme according to their own estimation (e.g. 'three meals per day'; 'adhere to 5 hours breaks between meals'; 'start each meal with a protein portion' etc.). The relevant evaluation showed a nearly linear highly significant positive connection to such an extent, that better programme adherence was associated with higher effects.

Remarks regarding terminus "effects":

Strictly speaking, the changes of the results parameters cannot be ascribed to participation in the investigated nutritional programme causally and conclusively from a scientific point of view, because an observation study (without control group) can in principle only prove the temporal connection between intervention and outcomes, but not a causal influence of the intervention on the outcomes. However, in the present case a causal interpretation is supported by the fact that a nearly linear connection between programme adherence and outcomes could be proved, and this makes the conclusion plausible that it was the adherence to the programme guidelines that led to better results. In this respect it appears to be just to interpret changes of the outcome parameters as effects of the programme.

Drop-out analyses and representativeness of the sample

The question whether the participants in the study are still representative for the starting sample at the last catamnesis or whether test persons who had worse effects may have dropped out systematically during the course of the study, so that the remaining sample presents a positive selection, is of significant meaning for all effectiveness studies, especially in the evaluation of nutritional programmes. In the present study detailed drop-out analyses therefore investigated each time of the survey, whether systematic differences between the drop-outs and the responders resulted at the previous time of the survey with a view to demographic properties, motivation at the beginning of participation, starting weight, programme adherence and weight changes.

At the time of the catamnesis after 3 months the differences were not significant. However, at the catamnesis after 6 and after 12 months there were marked differences between the two groups of study clients and the drop-out clients with regard to their age and the degree of individual achievement of their goals: With 45,1 years ($SD=12,5$) the drop-out clients were significantly younger ($p < 0.001$) than the clients remaining in the study ($M=49,0$ years; $SD=12,0$) and during the first half year of their participation they had achieved their personal goals to a significantly lower degree ($M=4,8$; $SD=2,6$) than the study clients ($M=6,6$; $SD=2,6$; $p < 0.001$). Furthermore, it became apparent below the level of significance that was determined for the interpretation ($p=0.016$), that the BMI of the drop-out clients at the beginning of participation at $M=30,9$ ($SD=6,9$) was slightly higher than the BMI of the clients who had still remained in the study at t_4 ($M=29,8$; $SD=5,7$). When comparing the responders, significantly more of the younger clients and clients who were unsatisfied with their individual achievement of their

goals dropped out in the middle and long term. Even if the absolute differences are not very large, one can therefore not assume unreservedly that the middle- and long-term treatment results (half a year and one year after the beginning of the study) can be transferred to the total population of all clients who were originally involved in the study. To investigate in how far the sample of the study clients are representative for the total of all clients taking part in the metabolic balance® programme, the investigated sample was finally compared with the total of all clients who were newly admitted to the programme in Germany during the second semester of 2007. The data on hand for both samples were those that are surveyed routinely by metabolic balance® for each client within the scope of drawing up the diet plans (i.e. age, gender, BMI, health risk according to waist measurement, goal of participation in the programme). As a result of the comparison it became apparent that there were only significant differences between the two samples at the starting-BMI and the waist measurement: Within the study population significantly more obese clients were represented ($p < 0.001$) and significantly more clients with a severely increased health risk ($p < 0.001$) than in the total sample. However, in interpreting these results it has to be taken into consideration that the significance level is easy to achieve in the context of the high number of cases of the total sample ($N = 30.634$). With a view to the representativeness of the study clients it can be recorded that the sample is a good representation of the total of clients newly admitted to the programme during the second semester 2007 - apart from the study clients' slightly higher starting burden due to their overweight. Regarding the long-term ascertainment of effects, the overall conclusion may be drawn that participation in the metabolic balance® programme led to verifiable improvements in the health-related quality of life and the health status of study clients and - with a view to those clients whose professed that their goal was weight loss - was accompanied by a distinct reduction of body weight. These improvements were all the more distinct, the better the clients adhered to the general guidelines of the programme.

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