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Weight loss in obese patients with type 2 diabetes: Effects of telemonitoring plus a diet combination – The Active Body Control (ABC) Program

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ABSTRACT

Aims: We evaluate the efficacy of the ‘‘Active Body Control (ABC) Program’’ for weight reduction in patients with type 2 diabetes.

Methods: The ABC program combines telemonitoring of the physical activity with a low-calorie diet also preferring carbohydrates with low glycemic indexes. In this 6-month, randomized, clinical trial 35 patients (aged 57 ± 9 years; BMI = 35.3 ± 5.7 kg/m^2) were treated according to the ABC program and 35 control patients (aged 58 ± 7 years; BMI = 34.8 ± 5.9 kg/m^2) received standard therapy.

Results: After 6 months the mean weight loss in the intervention group was 11.8 kg ± 8.0 kg. Glucose and HbA1c were lowered by respectively 1.0 mmol/l and 0.8 percentage points ($p = 0.000$, respectively). The proportion of patients with HbA1c > 7% fell from 57% to 26%. Antidiabetic drugs were discontinued in 13 patients (39%) and reduced in 14 (42%). The reduction of costs on medication per patient was €83 in 6 months. In the control group, there were no relevant changes in body weight, laboratory values or drug treatment.

Conclusions: The ABC program effectively lowers body weight, Hb1Ac and antidiabetic drug use in patients with type 2 diabetes.

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1. Introduction

The combination of overnutrition and insufficient physical activity is the leading cause of type 2 diabetes mellitus in obese individuals, and many efforts have been made to correct these two factors [1,2]. Diets have repeatedly been shown to improve the metabolic situation in these patients [3], in particular when these diets resulted in a loss of weight. An increase in daily exercise has also been reported to lower HbA1c and other measures of carbohydrate metabolism [2,4]. As a result, there is a broad agreement that patients with diabetes type 2 must make a comprehensive change in lifestyle as regards dietary habits and physical activity [5].

Recent advances in telemedicine technology allow continuous monitoring of patients even over large distances. To date this option has been explored in patients with diabetes preferably for monitoring metabolic measures such as glucose or HbA1c [6,7]. Successful monitoring of body weight has been described recently in obese individuals, but not in patients with diabetes mellitus [8,9]. To the best of our knowledge, the usefulness of telemonitoring of physical activity and body

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weight has not been investigated in patients with diabetes mellitus.

In this paper we describe the ABC[1] program and present the results achieved with this program in obese diabetic patients. The ABC program combines three therapeutic elements. The first element is telemonitoring of weight and physical activity with a weekly feedback letter to inform and motivate the patient. The second therapeutic element is a diet combining the traditional avoidance of calorie-rich foods with preference for carbohydrates of low glycemic index (GI) [10]. The third element is cost liability, which improves patient compliance [11]. We have tested these three measures separately in a preliminary study in 142 obese adults. The principal results were that each measure improved weight loss when used alone, and secondly, that the weight losses became almost additive when the three measures were combined [12].

This program therefore combines traditional measures with an innovative use of telemedicine. The latter can act as an additional tool for close and continual care of patients' wishing to reduce elevated body weight. The objective of this study was therefore to test the efficacy of this new ABC-program in diabetic patients.

2. Materials and methods

2.1. Subjects and intervention

The patients were recruited by an advertisement in a regional newspaper, aimed at overweight persons suffering from type 2 diabetes mellitus. The inclusion criteria were a body mass index (BMI) above 25 kg/m^2 and elevated levels of plasma glucose and/or HbA1c and/or regular use of antidiabetic medication. Patients with psychiatric disorders were excluded. Further exclusion criteria were vegetarianism, participation in another weight loss program, and medical treatment for weight reduction. 121 patients replied by telephone and received a letter describing the aims and nature of the study. 85 patients requested further information and were invited to the first of four meetings held at intervals of one week. 70 patients decided to participate and attended the first information meeting, during which they were randomized by lot to either the intervention group ($n = 35$, age 57 ± 9 years, 57% females) or the control group ($n = 35$, age 58 ± 7 years, 46% females). The second meeting served for collection of baseline anthropometric data and blood samples in all patients. The control group continued with the conventional low-fat diet and standard care according to recommendations issued by the Deutschen Diabetes-Gesellschaft [13]. The third and fourth meetings were held only with the intervention group. The third meeting took 2 h and was used to instruct the patients about the energy metabolism of the human body, the energy contents of foodstuffs, energy expenditure by means of exercise, and finally about the importance of the glycemic index in carbohydrates. In total, the patients were advised to lower their calorie intake by 500 kcal/day. The patients were assigned to a low-carbohydrate diet developed by Ludwig [14] as modified by Worm [15]. Emphasis was placed on preference for low-GI carbohydrates, but not on avoidance of carbohydrates as required by the Atkins diet [16]. Concerning nutrition, many practical examples were presented and a leaflet was distributed containing an overview of the aims and background of the study, a table of calorie values, and a table with GI values for various carbohydrates. During the fourth and least meeting the intervention group was trained in the use of the telemonitoring equipment (1 h). Concerning exercise, the patients were advised to increase their usual daily physical activity, like walking or cycling, rather than to engage in particular sports. It was recommended to keep the pulse below 120/min and to perform the exercise slowly enough to be able to talk at the same time [17]. After the initial meetings the patients visited the clinic every 4 weeks for blood sampling and documentation of both actual medication and frequencies of hypoglycaemias for 6 months. The control patients had to attend for their second visit after 6 months. It should be noted that the decisions concerning drug management of the diabetes were not taken by us, but by the patients' own doctors, who received all laboratory results and the most recent body weights every 4 weeks. The study had been approved by the Ethics Committee of the medical faculty and all patients had given written their informed consent.

The telemedical equipment consisted of weighing scales, an accelerometer, and a Homebox which received the data from the scales and the accelerometers via Bluetooth and sent them by a telephone link to a server in Munich (Germany). All instrumentation was from Aipermon GmbH, Munich, Germany. The accelerometers were programmed for each patient with an allowance for age, sex, weight, and individual step lengths for three walking speeds: normal, fast, and jogging. The accelerometers calculate and display on a screen the actual and daily distances at the three walking speeds and the actual and daily exercise related energy expenditure in kilocalorie. These data and the daily weights were then transmitted to a server in Magdeburg University Hospital, where weekly reports were generated by the authors and sent to each patient by mail. Each report gave patient's weight curve from the beginning of the intervention and a graph showing for each day of the past week the duration of physical activity as a percentage of 24 h, with bars in four colours representing four different activity levels from active to jogging, the distance covered in kilometres, and the kilocalorie used up by the exercise. Each letter also contained comments assessing the progress in the past week and aiming to motivate the patient. The total costs to be paid by each patient for the 6 months of the treatment amounted to €150.

2.2. Blood sampling and biochemical measurements

Blood samples were taken from the antecubital vein after a 12-h overnight fast. All laboratory tests were done by commercial enzymatic methods in a random-access analyser (Modular, Roche Diagnostics, Mannheim, Germany) of the hospital's central laboratory, in serum for all the parameters except glucose, which was determined in sodium fluoride plasma. HbA1c was determined in EDTA blood by HPLC (Variant II, Bio-Rad, Munich, Germany).

Blood pressure was determined in a subset of patients in the intervention group ($n = 12$) by means of manual sphyg-

[1] Active Body Control.

momanometers. These measurements were taken by the patients themselves at home. The instruments transmitted their data to us like the accelerometers and the scales via Bluetooth, Homebox, telephone cable, and internet.

2.3. Statistical analysis

We considered weight loss as the primary endpoint, and the metabolic and cardiovascular risk markers and antidiabetic drug usage use as secondary endpoints. It was calculated that 34 participants per group would provide 80% power (at the one-side error level 2.5% level) to detect a difference of 8 kg in body weight. To compensate for expected patient withdrawal, 70 patients were enrolled. The data are presented in the form of mean values and the SEMs. The significance threshold was set at $p < 0.0125$. Statistical analyses of the changes between baseline and the 6-month values were carried out by the Student's *t*-test for within-group differences. The unpaired *t*-test was used to check the differences between the groups. Pearson's correlation was used for the correlation between mean daily energy expenditure and weight loss. All statistical analyses were performed using SPSS software (Version 15, SPSS Inc., Chicago).

3. Results

The study was finished according to the protocol in 100% of the patients in the control group and in 94% of the intervention group. One of the two dropouts was a woman aged 42 who had participated until the end of the study but refused to attend for the final medical check-up. The other dropout was a man of 62, who stopped after 4 months for undisclosed reasons. Up to the time of the dropout these two patients had reduced their weights by respectively 0.6 and 2.6 kg.

The continual transmission of body weight data for each patient allowed us to plot the individual weight courses. These courses over the study period of 6 months are shown in Fig. 1 for all participants, including the dropouts. The bold red line shows the mean weight reduction, which reached 11.8 kg after 172 days ($p = 0.000$). A last observation carried forward (LOCF) evaluation including the two dropouts gave the mean weight loss as 11.3 kg ($p = 0.000$). Fig. 1 also shows that all patients had lost weight and that the greatest weight loss was almost 31 kg. The inset box gives the percentages of patients whose weight loss exceeded 5%, 10%, and 15% of their baseline weight.

All statistically significant changes observed after 6 months in the intervention group and the one change in the controls group are presented in Table 1. In the intervention group there were improvements of between 10% and 16% in the parameters of liver function and of the carbohydrate and lipid metabolism. In the control group there were no changes except for an upward trend of HbA1c by 3% ($p = 0.053$). Blood pressure remained unchanged in both groups.

The continual measurement and regular transmission of data describing the individual physical activity allowed a correlation of this activity with the weight loss achieved. The daily exercise related energy expenditure figures are individual means calculated for the entire 6-month period. Fig. 2 shows the correlation between this daily average energy

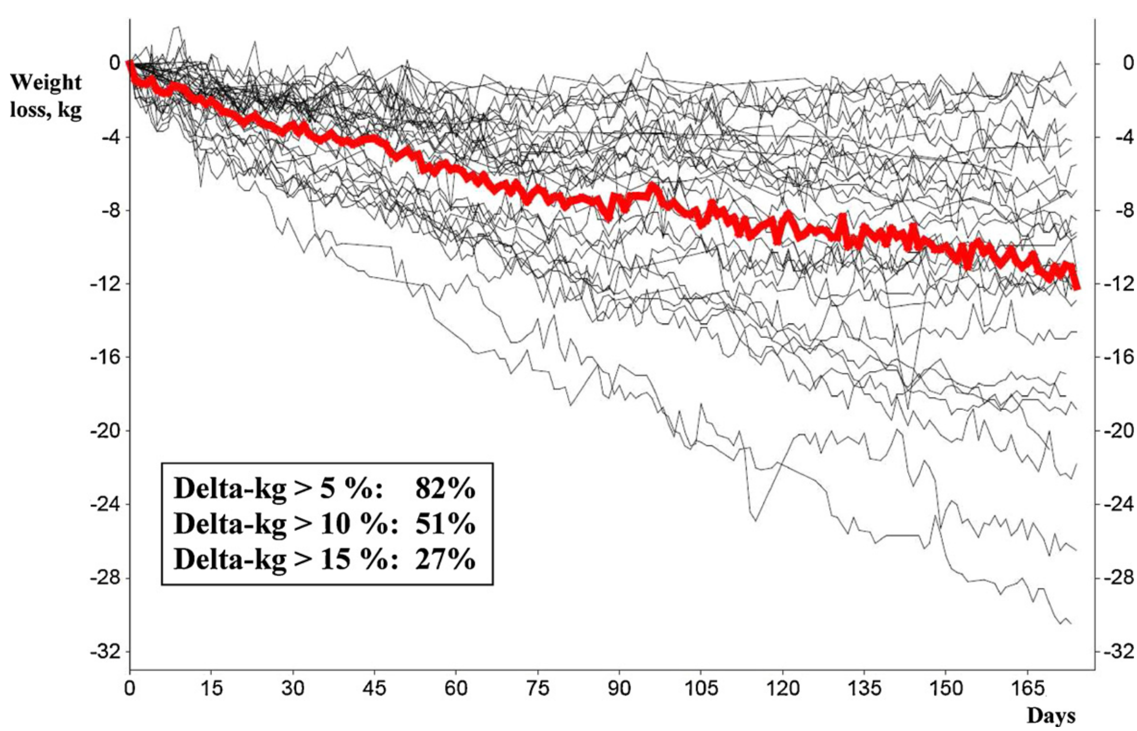

Fig. 1 – Individual weight loss curves in the course of the study. The bold red line marks the mean weight loss averaged over all patients. The inset box gives the percentages of patients whose weight loss exceeded 5%, 10%, and 15% of their baseline weight, respectively. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of the article.)

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Table 1 – Weight-loss after 6 months and associated changes in the intervention group and in the control group. Data are presented as mean values ± SEMs. Statistical analyses of the changes between baseline and the 6-months values were done by the Student's *t*-test for within-group differences. The unpaired *t*-test was used to specify the differences between the groups.

	Intervention group (n = 33)				Control group (n = 35)				Differences between groups at baseline p	Absolute differences after 6 months between groups p	Relative differences after 6 months between groups p
	Baseline	Difference after 6 months (absolute)	Difference after 6 months (relative%)	p	Baseline	Difference after 6 months (absolute)	Difference after 6 months (relative%)	p			
Weight (kg)	102.1 ± 20	−11.8 ± 7.6	−11.3 ± 5.9	0.000	101.4 ± 17	−0.3 ± 2.9	−0.2 ± 2.9	n.s.	0.828	0.000	0.000
Body mass index (kg/m^2)	35.3 ± 5.7	−4.1 ± 2.6	−11.3 ± 5.9	0.000	34.8 ± 5.9	−0.1 ± 1.0	−0.2 ± 2.9	n.s.	0.694	0.000	0.000
HbA1c (%)	7.5 ± 1.1	−0.8 ± 0.8	−10 ± 9.5	0.000	7.6 ± 1.1	0.2 ± 0.2	3.2 ± 10	0.053	0.580	0.000	0.000
Glucose (mmol/l)	7.4 ± 1.4	−1.0 ± 1.4	−12 ± 19	0.001	7.7 ± 2.2	0.2 ± 0.4	3.8 ± 26	n.s.	0.856	0.014	0.007
ALAT (μmol/s l)	0.6 ± 0.4	−1.3 ± 0.3	−13 ± 26	0.003	0.6 ± 0.3	0 ± 0.4	0 ± 0.5	n.s.	0.063	0.143	0.089
Bilirubin	11.3 ± 5	−2.3 ± 3.7	−16 ± 24	0.000	11.4 ± 6.9	−1.9 ± 0.6	−10 ± 6	n.s.	0.445	0.927	0.971
Triglycerides (mmol/l)	2.4 ± 1.8	−0.6 ± 1.7	−16 ± 41	0.02	2.5 ± 1.7	−0.1 ± 0.3	−3 ± 8	n.s.	0.463	0.160	0.115
HDL cholesterol (mmol/l)	1.2 ± 0.4	0.1 ± 0.2	11 ± 25	0.04	1.1 ± 0.3	0 ± 0.3	5.6 ± 3	n.s.	0.593	0.397	0.333

expenditure and the weight loss. The correlation is reasonably good, with $r = -0.58$ ($p = 0.000$).

The improvements in plasma glucose and in serum HbA1c made it necessary to adjust the antidiabetic medication. Table 2 summarizes the changes in drug treatment throughout the study in the two groups. There were few treatment changes in the controls, where discontinuations or dose reductions were balanced by either new prescriptions or increases in the dose. In the intervention group, in contrast, drugs could be discontinued in 13 patients (39%) and reduced in 14 patients (42%). However, dose increases were also more frequent than in the control group: in 18% of the intervention patients vs. 9% in the controls. These increases in the intervention group concerned mostly biguanides, which were dosed higher in those patients who had been receiving combination treatments and in whom the accompanying drug had been either stopped or reduced. No change was noted in the frequency of hypoglycaemias.

Table 3 shows the proportions of patients whose HbA1c values exceeded the treatment limits as proposed by several medical societies. These proportions became worse in the control group, which is in line with the tendency of HbA1c to increase as shown above in Table 1. In the intervention group, in contrast, this proportion was reduced by more than one-half.

4. Discussion

The ABC program combines three elements known to improve weight loss when implemented individually as single measures: a low-calorie diet with a preference for carbohydrates having a low glycemic index, monitoring of physical activity, and patients' motivation and enhancement of compliance by their financial engagement. What is new in the ABC program is bundling of these measures together and the use of telemonitoring of weight and physical activity in parallel with regular feedback and patient motivation?

The efficacy of weight-loss programs depends on care and control [18]. The telemonitoring is probably the most important component of the ABC program. In the first place, the continual recording of physical activity is important for the patients themselves [5]. The patients learn quickly how many calories can be burnt up by certain activities. They get to know their daily achievements and they strive to improve this performance. In the second place, these data enable patient's carer (doctor, specialist nurse, or nutritionist) to provide regular and individualized feedback without the need to visit the surgery, even over long distances. The weekly information and motivation letters were reported to be awaited with eager anticipation and most patients responded sensitively to the information and comments contained in them. This data transfer therefore creates a close patient–carer relationship. Thus, telemonitoring is effective in two different ways: by increasing patient's physical activity and by intensifying his or her guidance.

The fairly close correlation between weight reduction and energy expenditure (Fig. 2) emphasizes the importance of using accelerometers in the ABC program. The energy expenditure of many patients at baseline ranged between 300

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Table 2 – Changes in antidiabetic drug treatment in the intervention group and in the control group. Numbers denote the numbers of patients receiving the respective drug.

	Intervention group ($n = 33$)					Control group ($n = 35$)				
	Medication on entry	Discontinued	Dose reduced	Dose increased	New prescription	Medication on entry	Discontinued	Dose reduced	Dose increased	New prescription
Biguanides	25	1	8	5	2	21	1	1	1	
Acarbose	1									
Glitazones	5	2	1			7	1			1
Sulf. urea anal.	12	8	1			10			1	
Insulin	8	1	4	1		13	1	1	1	
Gliptin	6	1			1	1		1		
Inkretin mim.						1				2
Total		13	14	6	3		3	3	3	3

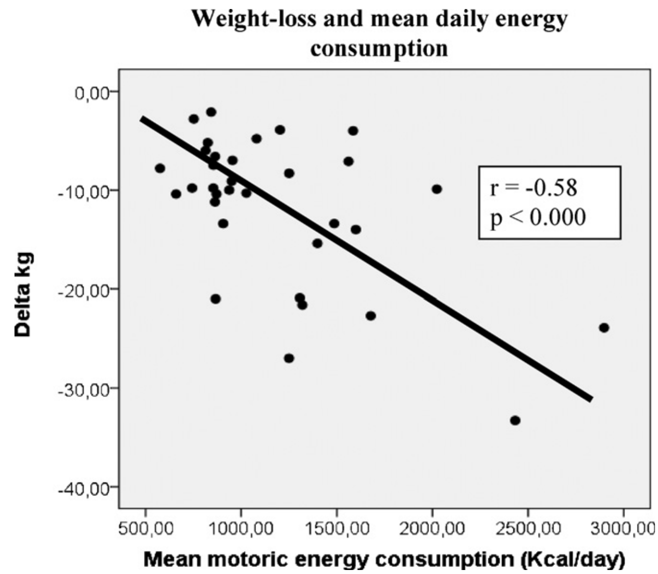

Fig. 2 – Correlation between the individual daily average energy expenditure and weight loss.

and 500 kcal/day. Good weight reductions were achieved when this value had been increased to 1000 kcal/day and beyond. Because this limit is achievable in most patients, we defined it as a recommended daily goal. The mean body weight loss of 11.8 kg in month 6 was more pronounced compared to literature reports about the efficacy of carbohydrate-restricted diets in obese individuals [19,20].

As outlined in Section 1, it could be expected that the combination of weight loss, low GI diet, and increased physical activity would improve the parameters of carbohydrate metabolism, and significant improvements were indeed observed in blood glucose and in HbA1c (Table 1). These biochemical improvements were accompanied by a considerable reduction in the need for antidiabetic medication (Table 2). A drug was withdrawn or its dosage was lowered in 27 out of 33 patients (82%). The dosage of metformin, however, had to be increased in 5 patients on combination treatment (19%), mostly because of a now possible discontinuation or dose lowering of a first drug. Perhaps the most important observation was that the proportion of patients with HbA1c values above 7% decreased from 57% to 26% (Table 3). It is probable that the reduction in sulfonylureas and insulin contributed to the weight loss. The majority of the drug treatment adjustments were necessary during the first months of the ABC program and not, as might be expected, in parallel with the continuing weight loss. This indicates that the changes in diet combined with the increased exercise-related energy consumption lead to an early improvement of carbohydrate metabolism. The relevance of this observation is that carers should monitor their patients at rather shorter intervals when the program begins, such as every 4 weeks, and that after 3 months these intervals could be extended. We have decided, for future studies, to have 4-weekly intervals during the first 3 months and thereafter have check-ups each time an additional 5 kg of body weight has been lost.

Table 3 – Proportions of patients in the intervention group and in the control group whose HbA1c values exceeded treatment goals as defined by medical societies.

HbA1c (%)	Intervention group ($n = 33$)		Control group ($n = 35$)	
	At entry (%)	After 6 months (%)	At entry (%)	After 6 months (%)
≥7.0	57	26	74	80
≥6.5	86	45	89	97

The costs and the time requirements of the ABC programs are moderate. An instrument set (accelerometer, scale, and the data-transmission equipment) costs today €495 and can, of course, be used later for other patients. The data transfer and the stamps cost about €10 per patient per month. The initial instruction on energy balance and nutrition takes 2 h and can be done groupwise. 1.5 h is necessary to instruct a group of 12 patients in operation of the telemonitoring equipment. Writing the report letter takes on average 5 min per patient using our internet platform (www.abc-diaet.com). On the other hand, the savings on antidiabetic drugs added up after 6 months to €83 per patient. Taken together, the costs and the required time are moderate in comparison with conventional programs. One program widely advocated in Germany to improve lifestyle factors in the obese is the "m.o.b.i.l.i.s." program. This required 21 group meetings and 40 training sessions over a period of 12 months under the supervision of medical doctors, physiotherapists, psychologists, and nutritionists and yielded in 391 persons an average weight loss of 6.5 kg [21]. Another recently presented program, aiming to modify lifestyle in obese prediabetic, is the PREDIAS program. In this, small groups received 12 lessons lasting 90 min each over 12 months, at the end of which time the weight loss exceeded that in the control group by 2.4 kg [22]. It appears, therefore, that the cost–benefit ratio of the ABC program is comparatively favorable.

5. Study limitations

Future investigations must look into the question whether the weight loss achieved by the ABC program is sustained. At present we are optimistic that the well-known yo-yo effect of other programs will occur less frequently and will be less pronounced. This assumption is based on the intensive experience of our patients measuring their daily physical activity under our regular guidance. Another open question is whether an even greater weight loss could be achieved by extending of the program beyond 6 months. Fig. 1 shows that the mean weight loss curve flattens out to some degree, but does not become horizontal. On the contrary, many individual weight loss curves continue to fall, in particular the curves of the most successful participants. We have therefore embarked on a follow-up study investigating the long-term effects of the ABC program in diabetic patients.

Summarizing, the ABC program combines innovative telemonitoring with additional sensible measures. In obese diabetic patients it leads not only to a pronounced weight loss but also to relevant metabolic improvements and reductions in antidiabetic drug use. Further studies must be carried out to evaluate the long-term potential of this program.

Conflict of interest

The authors declare that they have no conflict of interest.

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