

Original Article · Originalarbeit

Complement Med Res DOI: 10.1159/000475663 Published online: July 4, 2017

© Free Author Copy - for personal use only
ANY DISTRIBUTION OF THIS ARTICLE WITHOUT WRITTEN CONSENT FROM S. KARGER AG, BASEL IS A VIOLATION OF THE COPYRIGHT.
Written permission to distribute the PDF will be granted against payment of a permission fee, which is based on the number of accesses rec
Please contact permission@karger.com

High and Low Responders in a Comprehensive Lifestyle Program for Weight Loss - Secondary Analysis of a **Randomized Controlled Trial**

Dieter Melcharta,b Erich Wührc Wolfgang Weidenhammera

- ^a Competence Center for Complementary Medicine and Naturopathy (CoCoNat), Klinikum rechts der Isar, Technische Universität München, Munich, Germany;
- ^bInstitute for Complementary and Integrative Medicine, University Hospital Zurich and University of Zurich, Zurich, Switzerland;
- ^c Deggendorf Institute of Technology, Faculty of Applied Healthcare Sciences, Deggendorf, Germany

Keywords

Obesity · Lifestyle modification program IHM · Weight maintenance · Self-monitoring · Web-based performance measurement

Background/Objectives: Unhealthy lifestyle is often related to overweight and obesity and thus to chronic diseases. Web-based programs might be an option for a comprehensive approach to improving long-term weight management. Data from a randomized controlled trial (RCT) evaluating the impact of a lifestyle program on weight reduction were used for a secondary analysis. The objectives were (a) to identify potential predictors for marked weight loss, (b) to explore associations of weight reduction with changes in health-related variables, and (c) to evaluate whether self-monitoring of the daily lifestyle is associated with weight loss. Methods: 67 subjects with a body mass index of 28-35 who underwent the 1-year 'Individual Health Management' (IHM) program were included in the analysis (mean age 49.8 years, 79% female). Two subgroups (high response: ≥7.5% weight reduction vs. low response: <7.5%) were compared in terms of sociodemographic data, baseline values, and pre-post changes of various risk and protective factors. A logistic regression was performed to identify potential predictors of weight loss. Results: 70% of the subjects fulfilled the criterion of high response. There were no statistically significant differences between the two subgroups with respect to sociodemographic and baseline data. Regression analysis failed to identify any predictors for the amount of weight reduction. Subjects with high response showed a more distinct improvement in life satisfaction and neurovegetative stability. The findings indicated an association between the level of self-monitoring and weight loss. Conclusions: More research is needed to establish optimal strategies for maximizing the longer-term maintenance of weight loss and prevention effects. For weight reduction, support strategies like feedback learning through self-monitoring, reporting systems, and self-performance measurement with questionnaires might ameliorate high-intensity lifestyle modification programs.

© 2017 S. Karger GmbH, Freiburg

Schlüsselwörter

Adipositas · Lebensstilprogramm IGM · Gewichtserhalt · Selbstbeobachtung · Internetgestützte Performanzmessung

Zusammenfassung

Hintergrund/Ziele: Ein ungesunder Lebensstil geht oft mit Übergewicht, Adipositas und chronischen Erkrankungen einher. Internetgestützte Programme könnten im Rahmen eines umfassenden Ansatzes die langfristige Gewichtskontrolle verbessern. Daten einer randomisiert-kontrollierten Studie (RCT) zur Prüfung eines Lebensstilprogramms zur Gewichtsreduktion wurden für eine Sekundäranalyse herangezogen. Die Ziele waren, a) potenzielle Prädiktoren für einen ausgeprägten Gewichtsverlust zu identifizieren, b) Zusammenhänge zwischen einer Gewichtsabnahme und Veränderungen weiterer gesundheitsbezogener Merkmale zu untersuchen und c) zu prüfen, ob die Selbstbeobachtung des täglich praktizierten Lebensstils mit einer Gewichtsabnahme zusammenhängt. Methoden: In die Analyse wurden 67 Personen (durchschnittliches Alter 49,8 Jahre, 79% weiblich) mit einem Body Mass Index von 28-35 einbezogen, die sich dem 1-Jahres-Programm «Individuelles Gesundheits-Management» (IGM) unterzogen hatten. Zwei Teilgruppen (hohes Ansprechen: ≥7,5% Gewichtsreduktion vs. geringeres Ansprechen: <7,5%) wurden bezüglich soziodemografischer Merkmale, Ausgangswerten sowie Vorher/nachher-Veränderungen verschiedener Risiko- und Schutzfaktoren verglichen. Zur Bestimmung von Prädiktoren wurde eine logistische Regressionsanalyse durchgeführt. Ergebnisse: 70% der Teilnehmer fielen in die Gruppe mit hoher Gewichtsreduktion. Es konnten bezüglich der soziodemografischen Merkmale sowie der Ausgangswerte keine statistisch signifikanten Unterschiede zwischen den beiden Teilgruppen gefunden werden. Die Regressionsanalyse konnte keine Prädiktoren für das Ausmaß der Gewichtsabnahme bestätigen. Teilnehmer mit ausgeprägterem Gewichtsverlust zeigten deutlichere Verbesserungen hinsichtlich Lebenszufriedenheit und neurovegetativer Stabilität. Die Ergebnisse weisen auf eine Beziehung zwischen dem Grad der Selbstbeobachtung und der Gewichtsreduktion hin. Schlussfolgerungen: Um optimale Strategien zum langfristigen Erhalt der Gewichtsabnahme und zur Sicherung präventiver Effekte zu entwickeln, ist noch mehr Forschung nötig. Zur Gewichtsreduktion könnten umfangreiche Lebensstilprogramme durch unterstützende Feedback-Maßnahmen optimiert werden. Dazu gehören Selbstbeobachtung, fragebogengestützte Erhebungen der eigenen Performanz sowie individuelle Berichte.

Kaiserstraße 9, 80801 Munich, Germany ga39fos@mytum.de

Introduction

Overweight is considered an important risk factor for different chronic diseases like cardiovascular diseases (CVDs), cancer, and other chronic conditions [1]. CVDs are the number 1 cause of death globally [2]. According to the World Health Organization (WHO), 'most cardiovascular diseases can be prevented by addressing risk factors such as tobacco use, unhealthy diet and obesity, physical inactivity, high blood pressure, diabetes and raised lipids' [1]. The WHO factsheet reports further: 'People with cardiovascular disease or who are at high cardiovascular risk (due to the presence of one or more risk factors such as hypertension, diabetes, hyperlipidaemia or already established disease) need early detection and management using counselling and medicines, as appropriate' [1]. Obesity has been proposed by the American College of Cardiology/American Heart Association and Task Force on Practice Guidelines as a 'disease' requiring treatment [3, 4]. Also the WHO, the German Federal Court, the European Parliament, and the German Obesity Association regard 'obesity as a chronic disease caused by a complex interaction between genetic factors and environmental or lifestyle factors' which carries increased morbidity and mortality and needs lifelong treatment [4, 5]. Obesity is a heterogeneous disorder and individualized assessment, risk stratification, and treatment are required. It is associated with many comorbid conditions, which has major implications for longevity, quality of life, and health care costs [5]. The impact of weight loss and the need to prevent weight regain are considered in relationship to the prevention or improvements in weight-related complications. It could be shown that a linear association exists between the body mass index (BMI) and the risk of developing type 2 diabetes, hypertension, CVD, and other chronic diseases in both men and women [6]. Lifestyle modifications are the means of choice to reduce weight in persons with a BMI of 28-35 [4, 5, 7].

We developed a comprehensive lifestyle intervention program called 'Individual Health Management' (IHM) to help affected persons increase their physical activity, reduce calorie intake and practice both self- and stress management. Individual care, group support and a tailored Web-based program blend to achieve the desired goals. In this context, the Web-based system VITERIO® offers a tool combining self-monitoring of individual lifestyle risks and health protection factors with tailored advice. The basic goal of IHM is to empower people to be their own health manager in order to attain a longer healthy life and increased life satisfaction. Secondary goals are the reduction of weight, stress, medication intake, and cardiometabolic risk factors and - in the long term - of morbidity and mortality. The central element of IHM is a form of selfmanagement that provides the individual with the ability to take care of and optimize his or her so-called physiological basis functions (exercise, nutrition, vegetative balance, resistance, thermoregulation, sleep, rhythm) and psychosocial and cognitive basic competences (self-competence, social competence) in everyday life, with the objective of sustainably increasing, maintaining or restoring his or her personal quality of life and life satisfaction through a

healthy lifestyle. All participants were offered 3 different diet strategies: (i) fasting (per week 1 regular day, 5 waiver days, 1 food restriction day with < 900 kcal plus fasting during week 7), (ii) 2-day diet (5 regular days, 2 consecutive food restriction days with < 600 kcal), (iii) meal replacement (1 regular day, 5 waiver days, 1 food restriction day with meal replacement < 900 kcal plus meal replacement in week 7) for free choice. The principle of the program lies in the strengthening of the self-perception and selfreflection of maladaptive behavior and inadequate emotional-cognitive assessments and their correction, and the functional optimization of the independent vegetative nervous system. The communicative risk should be supplemented by means of health-oriented communicative resources and achieved through the systematic feedback of one's own progress and consequences from symptoms and results, with the help of reports, graphics, and personal advice. More details of the IHM lifestyle program have been published elsewhere [8].

A randomized controlled study (RCT; named Tailored Lifestyle Intervention Study (TALENT)) examining the efficacy of the IHM on weight control was recently conducted in Bavarian spa regions. This multicenter study included 166 overweight subjects (BMI 28–35) allocated to IHM and a control group (conventional care, receiving only written advice for a healthy lifestyle) by a 2:1 randomization ratio. Based on the intention-to-treat (ITT) analysis of weight reduction as the primary endpoint, the study showed a clear and statistically significant benefit of the IHM group compared to the control group at the end of the 12-month study period. While participants of the lifestyle program lost 8.7 kg, on average, the mean weight reduction in the control group was 4.2 kg [9]. A weight reduction of 7.5% after 1 year was considered a successful and sustainable effect. More details of the study protocol have been published elsewhere [10].

However, many individuals have difficulties adhering to recommendations concerning a healthy lifestyle, and long-term adherence with such lifestyle changes is usually low. Obesity is a lifelong challenge for these people. Not the initial weight loss but continued weight loss and the maintenance of a healthy weight are the true difficulties. Thus, it is important to learn more about people who adhere successfully to lifestyle changes.

Consequently, we used the data of the TALENT study for a secondary analysis to explore what kind of participants of the lifestyle program were highly successful in weight loss and weight maintenance compared to those subjects presenting a smaller weight reduction effect. More specifically, the objectives of the present analysis are

- 1) to identify potential predictors of marked weight loss by comparing two subgroups, 'high' versus 'low' response, in terms of their baseline status before intervention;
- 2) to explore associations of weight reduction with changes in variables from a comprehensive set of health-related variables like blood pressure or life satisfaction;
- 3) to evaluate whether daily self-weighing and daily self-monitoring of the accomplished steps by a pedometer are associated with better weight loss and a decreased risk of weight regain.

Methods

Sample

The present analysis is based on a sample of 67 overweight subjects as part of the above-mentioned TALENT study who were randomly assigned to the intervention group IHM. The sample incorporates only those participants who passed through the study 'per protocol' and provided enough data by questionnaires in order to monitor their lifestyle changes and to get feedback on the effects.

Intervention

The IHM program is based on a blended learning concept comprising a 12-week basic training phase followed by a 9-month maintenance phase [8]. It is defined by the following key features: (1) Web-based and physician-led health screenings; (2) a structured 12-week basic training with a core curriculum providing tuition in self-management strategies for weight loss and stress reduction; (3) weekly supervised group sessions during the core curriculum; (4) tailoring of materials, strategies, and lifestyle goals; (5) continuous self-monitoring and feedback on the achieved progress; (6) regular contact with physicians and specially trained IHM health coaches, based on either face-to-face or distant lifestyle counseling; (7) recurrent 1-day health seminars (refresher day) to ensure the sustainability of the obtained results.

Outcome Measures

For this analysis, 2 different data sets are used: The first data set was captured as data of the TALENT study and comprises sociodemographic data as well as standardized measurements of body weight, size (BMI calculation), waist circumference, and blood pressure, carried out by the study personnel at baseline and at months 3, 6, 9 and 12. The second data set encompasses data from questionnaires filled in only by participants of the IHM TALENT study group in 3-month intervals:

FINDRISK questionnaire [11, 12]: 8 questions (sum of risk points) to assess the risk of developing diabetes type 2 within the next 10 years.

Tedium Measure Scale (TM) [13]: A self-report questionnaire to assess the severity of burnout symptoms by 21 items scored on a 7-point scale.

 $\label{lem:Questions on Life Satisfaction (FLZ) [14]: A short question naire for assessing global subjective quality of life covering 8 areas of life.}$

Sense of Coherence Scale (SOC) [15]: 13-item short form to assess health competence according to Antonovsky's concept of sense of coherence.

Social Support Scale (SSS) [16]: A 19-item questionnaire to assess the grade of social support.

Self-Efficacy, Optimism and Pessimism (SWOP) [17]: A questionnaire to estimate the degree of self-efficacy, optimism, and pessimism in the context of health belief models.

Vegetative stability: A total score for neurovegetative stability is compiled from a list of 42 somatic and mental complaints (4-point scale; from 0 = no to 3 = strong). Additionally, a subscore for sleep disorders is provided.

Food habits: Participants were asked to judge the recent frequency of consumption on a list of 46 different foods/beverages. Vegetables, fruits and fibers are considered healthy food and the corresponding items were summarized to a score ranging from 0 = never to 8 = several times a day, on average. Accordingly, one score for sugar-containing food and carbohydrates and another one for fatty food (each ranging from 0 = never to 4 = repeatedly per day) were calculated.

Physical activity: The amount of daily physical exercise leading to an elevated heart rate was assessed using 3 activity level categories (poor: predominantly sedentary/just going for a walk; moderate: 30–45 min for 1–3 times per week; high: more than 150 min per week or more than 30 min each day).

Intensity of self-monitoring: IHM participants were recommended to use a pedometer for physical activities in daily life as well as to monitor their body weight by daily measurements. The number of accomplished steps and the weight were to be documented in the electronic health portal. The numbers of entries during the 12-month program were used as indicators of the level of self-monitoring of the individual life style.

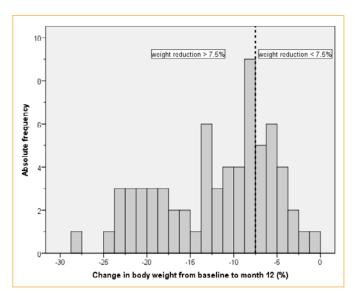


Fig. 1. Distribution (absolute frequencies) of percentage change in body weight between baseline and month 12; the dotted line shows the separation of 'high' and 'low' response.

Statistical Analyses

The core element for the statistical analyses was the degree of weight reduction at month 12 compared with the baseline value. With respect to a cut-off value of 7.5% weight reduction, two subgroups were defined: 'high response' = 7.5% or more and 'low response' = less than 7.5% weight reduction. To identify potential predictor variables, the two subgroups were compared by means of sociodemographic parameters and the baseline values of all outcome parameters. In addition, a logistic regression analysis was performed with the binary dependent variable 'subgroup' and the baseline values as potential predictors. To analyze the association between weight reduction and the changes in concomitant outcome variables, the 2 subgroups were compared in terms of the pre-post change scores.

To test for statistical significance of the differences between both subgroups, χ^2 tests were used for categorical variables, and t-tests, for independent samples for numeric variables. For selected variables (grade of physical activity), a prepost comparison within each group was performed (McNemar's test). Error probabilities for the large number of single tests were not adjusted. The analysis has to be interpreted as an explorative approach.

All statistical analyses were performed by IBM SPSS software, version 22.

Results

High and Low Response

There were 48 subjects (70%) exceeding the defined threshold of at least 7.5% weight loss and 19 subjects (30%) with a weight reduction below this level. No single participant showed an increase in body weight at the end of the 12-month program (fig. 1). The mean reduction was 14.6% and 4.9% in the 'high response' and 'low response' subgroup, respectively. A weight reduction of 20% or more of the initial body weight was observed in 11 subjects (16.4% of the total sample).

Sociodemographic Data of the Subjects

The majority of the study participants were female (79.1%, 53/67) and < 60 years of age (83.5%, 56/67). The 2 response groups

Table 1. Comparison of the 2 subgroups 'high response' versus 'low response' with respect to sociodemographic parameters

	High response (≥7.5% weight reduction; N = 48)	Low response (<7.5% weight reduction; N = 19)	Difference between subgroups
Gender			
Female	37 (77.1%)	16 (84.2%)	ns
Male	11 (22.9%)	3 (15.8%)	
Age, years			
≤45	15 (31.3%)	6 (31.6%)	ns
46-59	28 (58.3%)	7 (36.8%)	
≥60	5 (10.4%)	6 (31.6%)	
M (SD)	49.3 (9.1)	50.8 (11.8)	ns
Education			
Low	12 (25.0%)	6 (31.6%)	ns
Middle	28 (58.3%)	8 (42.1%)	
High	8 (16.7%)	5 (26.3%)	
Occupational situation			
Employed	42 (87.5%)	12 (63.2%)	ns
Retired	4 (8.3%)	5 (26.3%)	
Unemployed	1 (2.1%)	0 (0.0%)	
Unpaid work	1 (2.1%)	2 (10.5%)	
Living alone			
Yes	4 (8.3%)	2 (10.5%)	ns
No	44 (91.7%)	17 (89.5%)	
Smoker			
No	43 (89.6%)	17 (89.5%)	ns
Yes	5 (10.4%)	2 (10.5%)	
Alcohol			
No	24 (50.0%)	10 (52.6%)	ns
Yes	24 (50.0%)	9 (47.4%)	
If yes, <1 glass/day	17	8	
1-2 glasses/day	5	1	
Willing to change lifestyle for better health			
Yes, in parts	3 (6.3%)	2 (10.5%)	ns
Yes, definitely	45 (93.8%)	17 (89.5%)	

SD = Standard deviation; ns = not significant.

do not differ significantly in gender, age, education, occupational status, living alone status, consumption of cigarettes and alcohol as well as motivation for lifestyle change (table 1).

Baseline Values

The baseline values of body weight, blood pressure, burnout symptoms, pre-diabetes (FINDRISK score), neurovegetative status, sleep, sense of coherence, social support, optimism, food habits (including smoking and drinking alcohol), physical activities and self-efficacy (including willingness to change) show no significant differences between the two subgroups (table 2). There is only 1 parameter (lower pessimism score in the 'low risk' group) showing a statistically significant test result. No single variable could be identified as potential predictor in the logistic regression model. All potential baseline variables failed to be included in the regression equation.

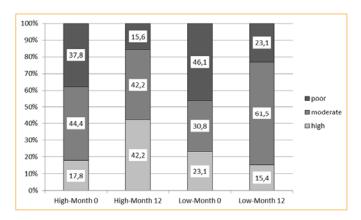


Fig. 2. Change in physical activity (high response: n=45; low response: n=13). Poor: predominantly sedentary/just going for a walk; moderate: 30-45 min for 1-3 times per week; high: more than 150 min per week or more than 30 min each day. Change from month 0 to month 12 within group 'high response': p=0.002, within group 'low response': p=0.392 (McNemar's test).

Table 2. Comparison of the 2 subgroups 'high response' versus 'low response' with respect to the baseline values (before intervention)

	High response (≥7.5% weight reduction)		Low response (<7.5% weight reduction)		Difference between subgroups	
	M (SD)	n	M (SD)	n	#	95% CI
Risk factors						
Body weight, kg						
Total	89.3 (11.7)	48	92.8 (10.2)	19	ns	-9.6 to 2.7
Men	102.5 (11.4)	11	104.8 (1.6)	3	ns	-10.1 to 5.5
Women	85.4 (8.6)	37	90.5 (9.5)	16	ns	-10.5 to 0.2
BMI	31.9 (1.9)	48	32.4 (2.2)	19	ns	-1.50 to 0.63
BP systolic	131.6 (15.2)	48	128.0 (13.0)	19	ns	-4.36 to 11.53
BP diastolic	85.0 (8.4)	48	82.2 (8.6)	19	ns	-1.73 to 7.39
FINDRISK points	13.7 (2.9)	48	14.7 (4.6)	19	ns	-3.41 to 1.27
Burnout, total	3.17 (0.75)	48	3.17 (0.72)	19	ns	-0.41 to 0.40
SWOP pessimism	8.8 (2.1)	47	7.5 (2.7)	18	*	0.06 to 2.56
Protective factors						
FLZ life satisfaction, total	54.6 (31.8)	48	62.5 (29.9)	19	ns	-24.9 to 9.0
Vegetative stability, total	36.5 (16.5)	48	37.2 (20.0)	19	ns	-10.2 to 8.8
Vegetative sleep	4.54 (2.25)	48	4.47 (2.76)	19	ns	-1.23 to 1.37
SOC health competence	64.0 (11.2)	47	62.8 (11.2)	18	ns	-4.99 to 7.39
SWOP optimism	12.1 (2.1)	47	12.3 (1.7)	18	ns	-1.35 to 0.89
SWOP self-efficacy	28.7 (5.1)	47	27.6 (5.7)	18	ns	-1.87 to 4.01
Social support	59.8 (13.8)	47	58.8 (15.3)	18	ns	-6.95 to 8.82
Food habits						
Vege/fruit	3.46 (1.04)	47	3.24 (1.03)	18	ns	-0.36 to 0.79
Sweets/carbs	1.29 (0.44)	47	1.31 (0.46)	18	ns	-0.26 to 0.23
Fatty food	1.07 (0.30)	47	1.08 (0.38)	18	ns	-0.19 to 0.17
Physical activity						
Score $(0 = high, 6 = poor)^a$	3.40 (1.92)	48	3.42 (1.95)	19	ns	-1.07 to 1.02

^aPoor: predominantly sedentary/just going for a walk; moderate: 30–45 min for 1–3 times per week; high: more than 150 min per week or more than 30 min each day.

M = Mean; SD = standard deviation; CI = confidence interval; BMI = body mass index; BP = blood pressure; SWOP = Self-Efficacy, Optimism, and Pessimism; FLZ = Questions on Life Satisfaction; SOC = Sense of Coherence Scale; Vege = vegetables; carbs = carbohydrates.

Change Values between Months 0 and 12

The comparison of the 2 subgroups reveals a statically significant difference with respect to the sum score for neurovegetative stability as well as for the total score of life satisfaction (table 3). Subjects with higher weight reduction showed a more pronounced improvement of life satisfaction and a more distinct decrease in neurovegetative symptoms. The mean changes regarding blood pressure, diabetes risk (FINDRISK points), and physical activity indicate some benefit associated with higher weight loss but failed to show statistical significance. The frequencies of the physical activity categories before (month 0) and after intervention (month 12) present a different pattern of changes when comparing between high and low weight loss (fig. 2). While the intra-group test for pre-post changes showed a statistically significant result in the 'high response' group, the changes in the 'low response' group were not significant.

Course of Mean Body Weight

Figure 3 illustrates the trajectories of the mean body weight during the 1-year IHM program in both subgroups, separately for men

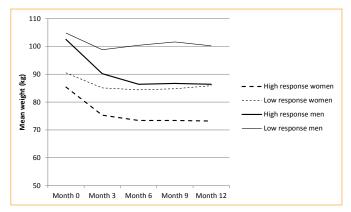


Fig. 3. Course of the mean body weight during the 1-year IHM program in subgroups of high versus low response, split by gender.

and women. High responders lost body weight during the first 6 months and held their mean weight at a plateau in the following course of the program, while low responders showed a regain of average weight after the first 3 months (reduction phase) of the IHM program.

^{*}ns = Not significant; *p < 0.05; **p < 0.01.

Table 3. Comparison of the 2 subgroups 'high response' versus 'low response' with respect to the pre-post changes in risk/protective factors of health

	High response (≥7.5% weight reduction)		Low response (<7.5% weight reduction)			Difference between subgroups	
	M (SD)	n	M (SD)	n	#	95% CI	
Risk factors							
BP systolic	-5.40 (17.97)	48	0.26 (12.70)	19	ns	-14.69 to 3.37	
BP diastolic	-3.12 (9.24)	48	0.42 (8.21)	19	ns	-8.40 to 1.31	
FINDRISK points	-2.50 (3.58)	44	-0.46 (2.90)	13	ns	-4.22 to 0.14	
Burnout, total	-0.84 (0.73)	45	-0.61 (0.73)	13	ns	-0.69 to 0.23	
SWOP pessimism	-2.5 (2.4)	43	-1.6 (2.2)	14	ns	-2.40 to 0.57	
Protective factors							
FLZ life satisfaction total	22.0 (29.3)	45	1.1 (33.2)	13	*	1.8 to 39.8	
Vegetative stability total	-15.6 (13.3)	45	-5.7 (8.0)	14	**	-15.8 to -4.0	
Vegetative stability sleep	-1.38 (1.92)	45	-0.36 (2.34)	14	ns	-2.26 to 0.22	
SOC health competence	8.79 (10.64)	43	6.50 (7.23)	14	ns	-3.84 to 8.42	
SWOP optimism	1.0 (1.8)	43	0.3 (1.8)	14	ns	-0.38 to 1.85	
SWOP self-efficacy	3.4 (3.7)	43	2.6 (4.0)	14	ns	-1.49 to 3.14	
Social support	6.77 (11.06)	43	6.92 (7.02)	13	ns	-6.69 to 6.38	
Food habits							
Vege/fruit	0.26 (1.01)	43	0.33 (0.73)	16	ns	-0.62 to 0.49	
Sweets/carbs	-0.55 (0.46)	43	-0.41 (0.47)	16	ns	-0.41 to 0.13	
Fatty food	-0.37 (0.26)	43	-0.37 (0.38)	16	ns	-0.18 to 0.17	
Physical activity							
Score (0-6) ^a	1.22 (1.83)	45	0.54 (3.26)	13	ns	-2.70 to 1.34	

 $^{^{*}}$ ns = Not significant; * p < 0.05; ** p < 0.01.

M = Mean; SD = standard deviation; CI = confidence interval; BP = blood pressure; SWOP = Self-Efficacy, Optimism, and Pessimism; FLZ = Questions on Life Satisfaction; SOC = Sense of Coherence Scale; Vege = vegetables; carbs = carbohydrates.

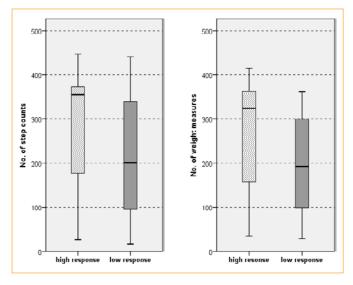


Fig. 4. Level of active documentation in an electronic health portal during the 12-month program: mean number of entries of step counts (left) and weight measurements (right) for both subgroups.

Self-Monitoring as Supplied Support Strategy

A key element of the IHM program is an individual Web-based health portal with certain tools for self-monitoring in order to support program adherence. Participants were taught to continually monitor their weight and the number of accomplished steps during their 1-year program. The 'high response' group showed a greater

frequency of documented self-weighing (257 vs. 200 entries, on average) and step counts (285 vs. 219 entries, on average) compared to the 'low response' group, but failed statistical significance. The distributions of both parameters reveal some extreme outliers. The graphical display of the medians by box-whisker plots indicates a higher degree of self-monitoring in subjects of the 'high response' group (fig. 4).

Discussion

The main findings of our secondary analysis of a randomized clinical trial are: (1) 70% of the subjects with a baseline BMI of 28–35 who underwent a 12-month lifestyle program called IHM complied with the criterion of successful weight reduction (7.5% or more). (2) Based on the available data, the search for predictors of the expected weight loss failed. (3) We could identify different levels of pre-post changes in health-related outcome variables associated with high versus lower weight reduction.

The main issue of a lifestyle program for weight reduction is not to provide the most effective procedure but to offer the best support to overweight adults in their efforts to lose weight and to adhere to lifestyle changes [18, 19]. Provoking people to change and, more importantly, to maintain the modified lifestyle is a critical issue in theory and practice of any comprehensive lifestyle program [20, 21]. Thus, a better understanding of the characteristics of

^aPositive difference = increase in activity.

a successful weight loser as a high responder in comparison to low and non-responders might be helpful for optimizing the process of self-management in such programs.

This present responder analysis provides an additional investigation within the framework of the so-called TALENT study and describes responder groups with regard to weight reduction, with a cutoff point at 7.5% loss of body weight from baseline to month 12. Although sustained weight loss of 3-5% may already lead to clinically meaningful reduction of some cardiovascular risk factors, most medical authorities recommend a weight loss of 5-10% of the baseline weight [4, 5]. When defining the threshold for high response, we referred to the clinically and empirically justified limit of 7.5%. We considered that using the given distribution of weight reduction in our sample, i.e. to split the group by the median value, would be an inappropriate approach. A systematic review on the outcome of weight loss lifestyle modification programs found that, at 1 year, about 30% of the participants had achieved a weight loss of ≥10%, 25% a loss of between 5% and 9.9%, and 40% a loss of ≤4.9% [22, 23]. Our success rates even indicate a slight superiority and at least fulfil these criteria derived from published studies. Differently, subjects of the 'low responder' group already begin to reverse their body weight change after 3 months of program. The usual pattern of weight loss in people undergoing lifestyle interventions is that maximum weight loss is achieved at 3 or 6 months [4, 24]. The following course of body weight normally shows a plateau and a gradual regain over time [4]. The 2013 obesity guidelines of the American Heart Association (AHA) recommend success rates of approximately 8 kg of average weight reduction for high-intensity comprehensive lifestyle interventions [4]. The described responder groups demonstrate a significant difference (p < 0.001) in body weight reduction for both women and men. Thus, both groups might be good representative samples of individuals to assess the characteristics and factors associated with highly successful and less successful weight loss and weight control.

The responder analysis is based on data from the e-health portal VITERIO, which provides performance measurement and assessment tools to improve self-care planning, monitoring and self-care competences by user feedback and a longitudinal outcome service. Self-monitoring and self-assessment - with different tools and questionnaires - should increase risk perception (e.g., for pre-diabetes, pre-burnout) and habit awareness and might induce self-reflection on the monitored behavior and attitudes [25, 26]. The sample description and a comparison of the baseline values indicate in nearly all parameters no statistically significant difference between the two responder groups. One may assume that both groups consist of participants with a similarly high level of motivation to lose weight and that both groups represent subjects who actually lost weight, albeit to a variable extent. Comparison of the change values (month 12 vs. month 0) regarding risk factors – like burnout symptoms and pessimism - do not show any difference either. Weight-related risk factors such as blood pressure and diabetes risk also failed statistical significance. However, subjects with high response present a clear trend towards a positive change of the measured values. It is definitely a limitation of our analysis that the sample size is too small for responder analyses in general.

Apart from the search for predictors of high weight loss, we could show that subjects with high response achieved improved scores in quality of life, with statistically significant differences between the two subgroups. A recent publication of an obesity reduction program supported a positive impact on health-related quality of life (HRQL) in 84.5% of the obese adults [27]. Although the literature asserts that self-efficacy and social support are important characteristics for successful weight loss [28], our own data did not provide different values between high- and low-response groups.

A further finding of the present analysis is a strong improvement of somatic and mental complaints caused by neurovegetative dysfunction. This suggests the assumption that ameliorations in the neurovegetative nervous system might be caused by self-administrated procedures of Kneippism and daily practiced exercise. However, it leaves the question open whether weight reduction by itself is able to induce similar effects.

The IHM program is a 12-month high-intensity comprehensive lifestyle intervention. It contains more than 14 group sessions within the first 3 months of the program and another 3 sessions in the following maintenance phase. Altogether, the 1-year program comprises 70 teaching units with 45 min each. Additionally, there are 6 short distant lifestyle counseling contacts, monthly, by phone, e-mail or Internet, in order to help with a regular brief support by the IHM health coaches. Experience has shown that sustained contact is necessary in order to support people in establishing and maintaining lifestyle changes [29, 30].

Our analysis of self-reported numbers of step counts and weight measures showed that people are reluctant in tracking physiological processes like exercising and eating. Therefore, continuous behavior monitoring by using different presentation techniques (charts, graphics) is necessary to make the subjects keep track of their progress made. We could show that the level of activities with respect to self-reports and performance measurements is associated with weight loss. More activities in self-weighing and step count documentation also go along with a decrease in weight regain. High levels of physical activity (about 1 h per day) and weight self-monitoring proved to be characteristics of individuals who successfully achieve long-term weight loss [20]. Further characteristics are a low-calorie, low-fat diet, taking breakfast regularly, and maintaining a consistent eating pattern across weekdays and weekends [20].

Client and patient participation, engagement, and the ability to perform a healthy lifestyle in everyday life are important components to the success of any training plan and treatment. Nevertheless, health promotion activities typically require the consideration of different partners like physicians, health coaches, and family members, as well as a supporting system in which all this can be delivered [3].

Disclosure Statement

The authors declare that there is no conflict of interests concerning this paper.

References

- 1 World Health Organization (WHO): Cardiovascular diseases (CVDs). Factsheet 317. www.who.int/mediacentre/factsheets/fs317/en/, 2013 (last accessed June 30, 2016)
- 2 Kernan WN, Ovbiagele B, Black HR, et al: Guidelines for the prevention of stroke in patients with stroke and transient ischemic attack: a guideline for healthcare professionals from the American Heart Association/ American Stroke Association. Stroke J Am Heart Assoc 2014:45:2160-2236.
- 3 Peterson ED, Ho PM, Barton M, et al: ACC/AHA/ AACVPR/AAFP/ANA concepts for clinician-patient shared accountability in performance measures: a report of the American College of Cardiology/American Heart Association Task Force on Performance Measures. Circulation 2014;130:1984–1994.
- 4 Jensen MD, Ryan DH, Apovian CM, et al: AHA/ACC/ TOS 2013 guideline for the management of overweight and obesity in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society. Circulation 2014;129(25 suppl 2):S102–S138.
- 5 Wirth A, Wabitsch M, Hauner H: Clinical practice guideline: the prevention and treatment of obesity. Dtsch Arztebl Int 2014;111:705–713.
- 6 Flegal KM, Kit BK, Orpana H, Graubard BI: Association of all-cause mortality with overweight and obesity using standard body mass index categories: a systematic review and meta-analysis. JAMA 2013;309:71–82.
- 7 Fontana L, Hu FB: Optimal body weight for health and longevity: bridging basic, clinical, and population research. Aging Cell 2014;13:391–400.
- 8 Melchart D, Eustachi A, Wellenhofer-Li Y, et al: Individual health management a comprehensive lifestyle counselling programme for health promotion, disease prevention and patient education. Forsch Komplementmed 2016;23:30–35.
- 9 Melchart D, Löw P, Wühr E, et al: Effects of a tailored lifestyle self-management intervention (TALENT) study on weight reduction: a randomized controlled trial. Diabetes Metab Syndr Obes 2017;10:235–245.

- 10 Melchart D, Doerfler W, Eustachi A, et al: The TAL-ENT study: a multicentre randomized controlled trial assessing the impact of a 'tailored lifestyle self-management intervention' (TALENT) on weight reduction. BMC Obesity 2015;2:38.
- 11 Lindström J, Tuomilehto J: The diabetes risk score: a practical tool to predict type 2 diabetes risk. Diabetes Care 2003;26:725–731.
- 12 Bergmann A, Li J, Wang L, et al: A simplified Finnish diabetes risk score to predict type 2 diabetes risk and disease evolution in a German population. Horm Metab Res 2007;39:399–409.
- 13 Pines AM, Aronson E, Kafry D: Burnout: From Tedium to Personal Growth. New York, Free Press, 1981.
- 14 Henrich G, Herschbach P: Questions on Life Satisfaction (FLZM) a short questionnaire for assessing subjective quality of life. Eur J Psychol Assess 2000;16: 150–159.
- 15 Schumacher J, Gunzelmann Th, Brähler E: Deutsche Normierung der Sense of Coherence Scale von Antonovsky. Diagnostica 2000;46:208–213.
- 16 Sherbourne CD, Stewart AL: The MOS social support survey. Soc Sci Med 1991;32:705–714.
- 17 Scholler G, Fliege H, Klapp BF: Fragebogen zu Selbstwirksamkeit, Optimismus und Pessimismus. Psychother Psychosom Med Psychol 1999;49:275–283.
- 18 Sacks FM, Bray GA, Carey VJ, et al: Comparison of weight-loss diets with different compositions of fat, protein, and carbohydrates. N Engl J Med 2009;360: 859–873.
- 19 Atallah R, Filion KB, Wakil SM, et al: Long-term effects of 4 popular diets on weight loss and cardiovascular risk factors: a systematic review of randomized controlled trials. Circ Cardiovasc Qual Outcomes 2014;7:815–827.
- 20 Soleymani T, Daniel S, Garvey WT: Weight maintenance: challenges, tools and strategies for primary care physicians. Obes Rev 2016;17:81–93.
- 21 Thomas JG, Bond DS, Phelan S, et al: Weight-loss maintenance for 10 years in the National Weight Control Registry. Am J Prev Med 2014;46:17–23.

- 22 Christian JG, Tsai AG, Bessesen DH: Interpreting weight losses from lifestyle modification trials: using categorical data. Int J Obes 2010;34:207–209.
- 23 Montesi L, El Ghoch M, Brodosi L, Calugi S: Longterm weight loss maintenance for obesity: a multidisciplinary approach. Diabetes Metab Syndr Obes 2016;9: 37–46.
- 24 Taylor RW, Roy M, Jospe MR, et al: Determining how best to support overweight adults to adhere to lifestyle change: protocol for the SWIFT study. BMC Public Health 2015;15:861.
- 25 Ogden LG, Phelan S, Thomas JG, et al: Dietary habits and weight maintenance success in high versus low exercisers in the National Weight Control Registry. J Phys Act Health 2014;11:1540–1548.
- 26 Hutchesson MJ, Rollo ME, Krukowski R, et al: eHealth interventions for the prevention and treatment of overweight and obesity in adults: a systematic review with meta-analysis. Obes Rev 2015;16:376–392.
- 27 Lemstra ME, Rogers MR: Improving health-related quality of life through an evidence-based obesity reduction program: the Healthy Weights Initiative. J Multidiscip Healthc 2016:9:103–109.
- 28 Verheijden MW, Bakx JC, van Weel C, et al: Role of social support in lifestyle-focused weight management interventions. Eur J Clin Nutr 2005;59(suppl 1):S179– \$186
- 29 Wing RR, Tate DF, Gorin AA, et al: A self-regulation program for maintenance of weight loss. N Engl J Med 2006:355:1563–1571.
- 30 Dunkley AJ, Bodicoat DH, Greaves CJ, et al: Diabetes prevention in the real world: effectiveness of pragmatic lifestyle interventions for the prevention of type 2 diabetes and of the impact of adherence to guideline recommendations. A systematic review and meta-analysis. Diabetes Care 2014;37:922–933.

© Free Author Copy - for personal use only

ANY DISTRIBUTION OF THIS ARTICLE WITHOUT WRITTEN CONSENT FROM S. KARGER AG, BASEL IS A VIOLATION OF THE COPYRIGHT.

Written permission to distribute the PDF will be granted against payment of a permission fee, which is based on the number of accesses required. Please contact permission@karger.com