### Aus der

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(Schwerpunkt: Psychosomatische Medizin und Psychotherapie)

# The effects of moderate conservative weight loss treatments on body weight and psychological factors in patients with severe obesity

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### **Table of contents**

Table of abb	reviations	5
1 Introductio	n	8
1.1 De	efinition, diagnosis, and prevalence of obesity	8
1.2 Ae	etiology and comorbidities of obesity	10
1.3 Ol	pesity therapy	12
	1.3.1 Conservative therapy and lifestyle intervention treatment at the University Hospital Tübingen (VIADUK	_
1.4 Re	esearch questions	17
	1.4.1 Realistic weight loss goals	17
	1.4.2 Analysis of the VIADUKT programme	19
2 Results		20
differe	ublication 1: "Conventional weight loss interventions ent BMI obesity classes: A systematic review and arative analysis"	quantitative
	ublication 2: "Attitude Matters! How Attitude Towa ry Influences the Effects of Behavioural Weight Loss Tr	
3 Discussion	1	72
3.1 Ma	ain findings of the two publications	73
	3.1.1 Publication 1: Body weight loss across the classes were similar and the outcomes in Class 3 obcgreatly	esity differed
	3.1.2 Publication 2: In VIADUKT two distinct groups we which differed in baseline characteristic and change in loss, but not in psychological variables	body weight
3.2 lm	plications for practice and further research	81
3.3 Li	mitations	87
3.4 Cd	onclusions	89
4 Summary .		90
5 Zusammen	fassung	93
6 List of refe	rences	96
7 Declaration	n of contribution (of others)	113
8 Acknowled	lgments	115
9 Full list of	publications	116

### Table of abbreviations

A/EB Attrition/ Exclusion Bias

ANCOVA Analysis of Covariance

ANOVA Analysis of Variance

AUS Australia

BA Uncontrolled pre-post intervention without group

comparison

BL Belgium

BMI Body mass index

BWL Body weight loss (Publication 1); Behavioural weight

loss (Publication 2)

C Control group

CAN Canada

CI Confidence interval

Composition

D Day

DB Detection bias

DGEM Deutsche Gesellschaft für Ernährungsmedizin

DM Diabetes mellitus

EOSS Edmonton Obesity Staging System

F Finland

Fig. Figure

GAD-7 General Anxiety Disorder Questionnaire (Score for

general anxiety)

GER Germany

Group 1 Group of RCTs for quantitative analysis

Group 2 Group of RTs and BAs for quantitative pre-post

analysis

I Intervention group

Table of abbreviations 6

Intervention Group No.1

Intervention Group No. 2

IGT Impaired glucose tolerance

IQR Interquartile range

IRA Iran

IRE Ireland

IT Italy

ITT Intention to treat

Kcal Kilocalorie

Kg Kilogram

M Metre

Max. Maximum

MCID Minimal clinically important differences

MD Mean difference

Min(s) Minute(s)

Min. Minimum

Mo Month

MULTI Multicentre worldwide cooperation

N Number

NA Not applicable

N.d. No data

NEG Participants with a negative attitude towards bariatric

surgery

NL Netherland

NR Not reported

NRT Nonrandomized controlled trial

N.s. Not significant

OB Other bias

PB Performance bias

Table of abbreviations 7

PHQ-9 Patient Health Questionnaire (Score for depression)

POR Portugal

POS Participants with a positive attitude towards bariatric

surgery

PP Per protocol

PRISMA Preferred Reporting Items for Systematic Reviews

and Meta-Analyses

RCT Randomized controlled trials

RP Reporting bias

RT Randomized non-controlled trials

SB Selection Bias

Sec. mod. School Secondary modern school

Sec. techn. School Secondary technical school

SD Standard deviation

SE Standard error

SF-12 Short Form 12 Questionnaire (Score for quality of

life)

SP Spain

SW Sweden

T0 Preintervention (of VIADUKT)

T1 Postintervention (of VIADUKT; 6 months later)

TFEQ Three-Factor Eating Questionnaire (Score for eating

behaviour)

UK United Kingdom

UKT Universitätsklinikum Tübingen

US United States

VIADUKT Verhaltensintervention bei Adipositas am UKT

WHO World Health Organization

### 1.1 Definition, diagnosis, and prevalence of obesity

Obesity has become a major public health problem. An individual is classified as obese above a body fat percentage of 20 % (male) or 30 % (female), respectively 125,128

Based on the World Health Organization (WHO), the body mass index (BMI) is the initial assessment tool for the diagnosis of obesity <sup>2,125</sup>. The unit for BMI is kgm<sup>-2</sup>, which is calculated by dividing body weight in kilograms by height in metres squared <sup>2</sup>. BMI is used to define the weight of a person in relation to his or her measurements, without taking age and sex into account. A distinction is made between six different body conditions:

- 1) underweight (< 18.5 kgm<sup>-2</sup>),
- 2) normal weight (18.5 to 24.9 kgm<sup>-2</sup>),
- 3) overweight (25 to 29.9 kgm<sup>-2</sup>),
- 4) Class 1 obesity (30 to 34.9 kgm<sup>-2</sup>),
- 5) Class 2 obesity (35 to 39.9 kgm<sup>-2</sup>), and
- 6) Class 3 obesity (≥ 40 kgm<sup>-2</sup>).

A corresponding risk of morbidity and mortality is assigned to each body condition, and the risk tends to increase with rising BMI <sup>2,279</sup>. On the one side, the BMI convinces due to its simplicity: its measurement requires little time and expense and is non-invasive. Moreover, the BMI has been used for a long time and across all countries. On the other side however, it is only a simplified correlation between BMI and the corresponding morbidity risk. Furthermore, it is not equally valid for all ethnicities e.g., it appears to be higher in Asian ethnicities than in Caucasians <sup>2,76,125</sup>. It is also only an indirect method of measurement and therefore not completely accurate <sup>125,128</sup>. In addition, BMI does not consider the

patient's fat percentage and fat distribution, two important factors that indicate metabolic and cardiovascular health risks. In athletes, for example, BMI increases due to the increased weight of muscle mass, incorrectly suggesting health risks <sup>128</sup>. Subsequently, the waist ratio or waist circumference can be utilized to evaluate abdominal fat distribution; above a certain level, the risk of morbidity is increased <sup>2,279</sup>.

Furthermore, obesity diagnostics should also comprise laboratory blood tests, family medical history, individual nutrition and physical activity patterns, as well as a bulimic eating behaviour or history<sup>128</sup>.

The prevalence of overweight in European adults was 58.7% and the prevalence of obesity (Class 1 to 3) 23.3% in  $2016^{92}$ . In Germany 67% of men and 53% of women had a BMI of  $\geq 25$  kgm<sup>-2</sup>, classifying them as at least overweight (sampling period between 2008 and 2011). Of these, almost one quarter was classified as obese. Furthermore, the data showed that in the period from 1998 to 2008 overall obesity increased, with a particular increase in the younger population. In contrast, the number of adults with overweight remained relatively stable during this period  $^{184}$ .

Obesity is not only a burden for most individuals, but also leads to direct and indirect costs for the health-care system. For example, in Germany the direct costs for diseases related to a BMI  $\geq$  25 kgm<sup>-2</sup> was 8.6 billion euros in 2008 <sup>168</sup>.

### 1.2 Aetiology and comorbidities of obesity

The aetiology of obesity is multifactorial, though not yet fully understood.

According to current knowledge, obesity is caused by a complex interaction of biological, psychosocial, and environmental factors. Obesity is in large part a polygenic disposition, which is based on various additional and largely unknown factors <sup>101</sup>. In contrast, only a minority of obesity can be explained by monogenetic dysfunctions such as changes in the leptin-melanocortin pathway <sup>101,128</sup>.

In medicine a distinction is made between primary and secondary obesity. Primary obesity, the most common form, is due to an imbalance between energy intake and energy expenditure in favour of the former <sup>128</sup>. This can be due to corresponding lifestyle factors, eating behaviour, and psychological factors such as stress, depression, and frustration <sup>111,128</sup>. Secondary obesity is a consequence of endocrinologic diseases such as Cushing's disease and hypothyroidism, but only represents a small percentage of cases. In medical practice it is necessary to exclude or at least consider the secondary forms of obesity, since it is associated with a different therapeutic regime <sup>128</sup>.

Obesity is associated with a variety of comorbidities. Their risk mostly increases with BMI, especially with Class 3 obesity  $^{195,263}$ . In addition, the mortality rate due to obesity increases by up to 50-100 % compared to participants with normal weight (BMI 20 to 24.9 kgm<sup>-2</sup>)  $^{101}$ . Thus, obesity can reduce life expectancy by several years  $^{31,102}$ , especially in individuals with morbid obesity (BMI  $\geq$  40 kgm<sup>-2</sup>)  $^{178}$ .

The comorbidities are numerous and primarily concern internal and orthopaedic diseases such as diabetes mellitus, hypertension, fatty liver, colorectal cancer, other cancerous diseases, knee arthrosis and immobility <sup>101,128,258</sup>.

In addition to the previously described somatic diseases, many psychological comorbidities are associated with obesity. In particular, the risk for affective, somatic, and anxiety disorders is increased in individuals with obesity <sup>36,228,234</sup>.

For example, depression raises the incidence of obesity and, conversely, obesity increases the incidence of depression <sup>181,185</sup>. Additionally, several (psychiatric) medications such as lithium can cause weight gain. In these cases, effects and side effects must be carefully discussed at an individual level <sup>126</sup>.

Other comorbidities that should not be underestimated are binge-eating and night-eating disorder <sup>36,52,212,262</sup>. Binge-eating disorder is characterised by frequent attacks of eating without subsequent vomiting, whereas night-eating disorder refers to eating increased amounts of food at night.

### 1.3 Obesity therapy

There are several approaches for obesity therapy. These include conservative or conventional treatments, pharmacotherapy, as well as bariatric surgery. Conservative or conventional treatments are also internationally known as behavioural weight loss treatments and both terms are used in this thesis. Pharmacotherapy is only used as an adjuvant but can be a helpful support in the initial and possibly the maintenance phase of weight loss <sup>39,77,235</sup>. Bariatric surgery is applied when conservative obesity treatment methods are exhausted.

Based on the German S3 guideline "Prävention und Therapie der Adipositas" the therapy indication depends on the BMI category as well as the fat distribution, comorbidities, risk factors, and the patient's intent In general, indication for therapy is given for BMI  $\geq$  30 kgm<sup>-2</sup> or for BMI  $\geq$  25 kgm<sup>-2</sup> with comorbidities such as hypertension <sup>77</sup>. A weight loss therapy is contraindicated or must be decided on a case-by-case basis in case of pregnancy, lactation period, eating disorder, critical general condition, or psychiatric illness, <sup>77,126</sup>.

In addition to body weight loss, an obesity therapy should achieve a reduction of obesity-associated risk factors and diseases, as well as an increase in quality of life, and reduction of premature mortality <sup>77</sup>.

Since obesity can be considered as a chronic disease, weight loss maintenance is as important as an initial weight loss. However, maintenance of weight loss is a separate and challenging subject and will not be examined in detail here <sup>274</sup>. As outlined by Holzapfel and Hauner, obesity treatment is not a temporally determined process, but represents a years-long if not lifelong behavioural change <sup>134</sup>.

A common initial therapy option for obesity is conservative management, consisting of dietary change, increased physical activity and behavioural changes. This treatment combination is referred to as multimodal, frequently recommended and discussed in more detail in section 1.3.1 <sup>77,126</sup>.

Finally, bariatric surgery is discussed in more detail in the following, as it is another important approach to obesity treatment and is particularly relevant in severe obesity (BMI  $\geq$  40 kgm<sup>-2</sup>).

The indication for bariatric surgery is given in the case of unpromising or exhausted conservative therapy for either Class 3 obesity or Class 2 obesity with one or more comorbidities; comorbidities become more likely as the BMI value increases. The S3 guideline of "Chirurgie der Adipositas und metabolischer Erkrankungen" defines "exhausted" as follows: Either a failure to achieve body weight loss of > 15 % (Class 2 obesity) or > 20 % (Class 3 obesity and above) within 2 years or an increase in body weight of > 10% after a previous decrease in body weight within 1 year <sup>78</sup>. In some exceptional cases, bariatric surgery can be an option as primary therapy. According to the S3 guideline, conservative therapy is not necessary for BMI values above 50 kgm<sup>-2</sup>. Also, in some cases, the severity of the secondary diagnosis may be so great that further postponement of surgery is not appropriate <sup>77,78</sup>. In contrast, patients with ongoing substance abuse, untreated bulimia nervosa and an unstable psychopathological condition, as well as malignant cancers and present or near-term planned pregnancies are an (absolute) contraindication for bariatric surgery <sup>78</sup>.

Several studies describe drastic improvements in diabetes mellitus and great weight losses in participants who underwent bariatric surgery <sup>58,114,280</sup>. But the surgical complications, operative mortality and reoperation rates must be considered. Fortunately, surgical techniques have become much safer over the years <sup>46</sup>. However, further studies, preferably of randomized controlled trial (RCT) quality, are needed to analyse the long-term effects (≥ 10 years) of surgery <sup>198</sup>.

The four most frequently used techniques in bariatric surgery are: (laparoscopic) gastric sleeve, (laparoscopic) adjustable gastric banding, Roux-en-Y gastric bypass and biliopancreatic diversion with and without duodenal switch <sup>144</sup>. In Germany, the gastric sleeve and gastric bypass represent the gold standard and are used most often <sup>245</sup>. The indication for the various surgical techniques depends, among other things, on the BMI and comorbidities <sup>78</sup>.

### 1.3.1 Conservative therapy and lifestyle intervention for obesity treatment at the University Hospital Tübingen (VIADUKT)

As this thesis focuses on the conservative approach in obesity therapy, a detailed overview of conservative therapy is given in the following. As mentioned before, conservative therapy incorporates dietary change, increased physical activity and behavioural changes. As an example, the intervention programme called VIADUKT is presented at the end.

Nutritional therapy should be personalised to the participant. Much more important than the strategy of the diet is the ability of the participant to follow this diet for several months  $^{127}$ . For dietary changes, an energy reduction of 500 kcal per day is recommended, and the participant's health should not be harmed by unbalanced nutrition. With this approach, a weight loss of around 5 to 10 % can be achieved  $^{77,126}$ . The energy deficit can be further increased to 800 to 1200 kcal per day and is often achieved through meal replacements. According to the "Deutsche Gellschaft für Ernährungsmedizin" (DGEM), a diet consisting solely of meal replacement should last no more than 12 weeks but can achieve a greater weight loss of up to 15 to 20 % of initial body weight. This method is therefore often used in cases of severe obesity  $^{77,126}$ , but is also associated with a high dropout rate ( $\geq$  20 %)  $^{32}$ . Regardless of the intensity of the therapy, professional assistance can be helpful to prevent malnutrition and one-sided eating behaviour  $^{77,126}$ 

Patients should be encouraged to increase their physical activity in everyday life. Such a change can not only achieve weight loss but also a reduction in comorbidities and other health issues <sup>126,128,143</sup>. The S3 guidelines recommend > 150 minutes of physical activity per week, with a moderate energy reduction of 1200 to 1800 kcal per week. Endurance training tends to be associated with greater weight loss than strength training. In principle any form of exercise is beneficial, but individual options and restrictions should be considered <sup>77,126</sup>. As the meta-analysis by Franz *et al.* <sup>107</sup> showed, an exercise-only approach is associated with minimal weight reduction and is almost comparable to an advice-only approach. This suggests that conservative therapy is most successful when

it combines diet and exercise <sup>20</sup>. In this manner, nutritional therapy tends to be more crucial in achieving weight loss, whereas exercise therapy seems to be especially supportive for weight stabilisation <sup>138</sup>.

Behavioural therapy has been widely analysed in the context of obesity therapy and provides positive evidence. It should be used in combination with nutritional and exercise treatments and not on its own. Furthermore, it should be personalised, which can be achieved through both group and individual therapy <sup>249</sup>. The following aspects are included in behavioural therapy: Psychoeducation, agreement on therapy goals, self-observation and behavioural analysis, stimulus control, cognitive restructuring, problem-solving strategies, affect regulation techniques, social skills training, and relapse prevention. Psychoeducation is a particularly important element of behavioural therapy. Its primary aim is to provide participants with information about the development of overweight and/or obesity, symptoms, effects, and possible therapy options. Eventually, participants should be able to independently manage crises and/or conflicts ("help for self-help") 126,129,130,148,249. As participants with higher BMI are more likely to suffer from mental disorders, it is therefore often necessary for these patients to receive a more extensive (psycho-) therapeutic approach. This requires an adequate, detailed diagnosis made in advance <sup>126</sup>.

VIADUKT is the acronym for "Verhaltensintervention bei Adipositas am UKT". At the University Hospital of Tübingen (UKT) four interventions with different indications are offered under this name: the conservative weight loss programme (VIADUKT 1), an educational programme for bariatric surgery (VIADUKT 2), a postoperative programme (VIADUKT 3), and the programme for patients with unfortunate bariatric surgery success (VIADUKT 4). In this thesis only the conservative weight loss programme (VIADUKT 1) is analysed and will be referred to as VIADUKT. In the following, the conservative weight loss programme (VIADUKT) is described in more detail:

Mainly adult participants with obesity are included in the programme (age:  $\geq$ 18 years, BMI  $\geq$  30 kgm<sup>-2</sup>).

For six months the patients participate in ten 75-minute group meetings with a nutritionist/psychotherapist. Additionally, twenty 45-minute guided exercise sessions are conducted. The main topics covered in group meetings are nutritional education and behavioural changes with, for example, motivational techniques, stress management, controlled eating behaviour, and body weight relapse prophylaxis.

The health insurance covers 80 % of the programme's costs initially. The costs are fully covered when participants attend at least 80 % of the programme.

Recruitment takes place in two ways: either through the "Plattform Adipositas", a cooperation of psychosomatics, nutritional and sports medicine, endocrinology, and visceral surgery, or through an advertising campaign in which brochures are displayed in general practices around Tübingen or the UKT itself. The "Plattform Adipositas" is the multidisciplinary, primary contact point at UKT for patients, who want to inform themselves about their options on bariatric surgery and/or if an indication for surgery is given <sup>29</sup>.

### 1.4 Research questions

In this thesis, the data from VIADUKT between 2014 and 2019 was examined and statistically analysed. Particular attention was given to the role of participants' attitude towards bariatric surgery, which - from clinical experience - seems to play an important role in body weight loss outcomes. However, in order to classify the results of VIADUKT, which mainly included participants with Class 3 obesity, the question of realistic weight reduction values as a reference value had to be clarified first. To our knowledge, there exists no meta-analysis for this relevant obesity range (BMI  $\geq$  40 kgm<sup>-2</sup>). Therefore, this thesis consists of two contributions: 1) a systematic review and quantitative analysis on body weight loss across all BMI obesity classes in moderate, conservative treatments (1.4.1 and 2.1)<sup>27</sup> and 2) an original contribution reporting the findings of the VIADUKT analysis (1.4.2 and 2.2)<sup>28</sup>.

The following two research questions were examined:

- I) What are realistic weight loss goals across the different BMI classes?
- II) Is it possible to identify distinct patient attitudes towards bariatric surgery, in VIADUKT? If so, do these groups also differ in baseline characteristics, body weight loss outcome, and psychological outcome variables (depression, anxiety, quality of life, and eating behaviour)?

### 1.4.1 Realistic weight loss goals

As discussed above, obesity is a great burden for the individual, but also for society, such that an effective therapy is crucial.

Developing realistic weight loss goals is an important component in the planning and implementation of therapy. It is demonstrated in several studies that participants' expectations of around 25 to 30% body weight reduction are far higher than the results achieved <sup>104,172</sup>. Furthermore, DeJesus *et al.* showed that with a higher BMI value, participants aimed for greater weight loss, while at the same time their perceived ability to achieve this was lower <sup>74</sup>.

In contrast to these expectations, international guidelines recommend a weight loss of 5 to 10 % of the initial body weight within 6 to 12 months 144. The recommendations in the German S3 guideline tend to be higher and further differentiate between individual BMI classes: The suggested body weight loss within 6 to 12 months is > 5 % for overweight and Class 1 obesity and > 10 % for Class 2 and 3 obesity 77. However, these values are based on the lowest level of evidence in the classification of evidence-based medicine; it is stated as "expert consensus with majority approval" 77. The methods of evidence-based medicine are used to develop recommendations for medical interventions that are derived from empirical data. Depending on the available data, a corresponding classification is made from the highest level of evidence, which is based on metaanalyses and/or RCTs, to the lowest level of evidence, which is based "solely" on expert opinion, often due to a lack of empirical data 45. We therefore searched for a meta-analysis, preferably with RCTs, that compare conservative, moderate weight loss treatments in terms of weight reduction for the different BMI classes with a duration of at least six months. To our knowledge, only the systematic review by Barte et al. addresses this issue. However, this publication only includes participants with a BMI of 25 to 40 kgm<sup>-2</sup> (overweight up to and including Class 2 obesity) <sup>24</sup>. The VIADUKT programme on the other hand largely consisted of participants with severe obesity (BMI ≥ 40 kgm<sup>-2</sup>) for which the review by Barte et al. does not specify a realistic weight reduction.

We therefore conducted a systematic review of the percentage and absolute weight reduction in the individual BMI obesity classes. It focused on adult participants with obesity, while exclusively specific patient groups with, e.g., type 2 diabetes or polycystic ovary syndrome, were excluded due to selection bias of specific groups.

The results of the systematic review were published in the article "Conventional weight loss interventions across the different BMI obesity classes: A systematic review and quantitative comparative analysis" by Bauer *et al.* in European Eating Disorders Review in 2020 and are presented in section 2.1 and discussed in more detail in section 3.1.1 of this dissertation <sup>27</sup>.

### 1.4.2 Analysis of the VIADUKT programme

As described in section 1.3.1, VIADUKT is a behavioural weight loss programme at the University Hospital of Tübingen, which started in 2014. After approximately 5 years the programme was evaluated; this evaluation is part of this dissertation.

Changes in body weight in kg (primary outcome) as well as psychological scores in the categories of depression, anxiety disorder, quality of life, and eating behaviour (secondary outcome) were investigated. All data were collected at the beginning and at the end of the VIADUKT programme by means of standardized measurements and questionnaires.

A major aspect of the analysis was also the characterisation of the participants. At the beginning of the programme, demographic information such as age, sex, work status, education, and smoking behaviour were collected with a questionnaire.

As mentioned in section 1.3.1, the therapy decision and obesity counselling at the University Hospital Tübingen takes place within the framework of "Plattform Adipositas". This represents a broad, multidisciplinary approach that includes both conservative and surgical disciplines. Not always, but ideally, such a broad approach is offered. In the VIADUKT programme, a close connection to surgery is given and from our clinical experience participants with a positive attitude towards bariatric surgery appear to have a lower weight loss success rate. Therefore, it was additionally analysed whether and to what extent the attitude towards bariatric surgery affects primary and secondary outcomes. This clinical impression was to be scientifically verified by characterising the different groups, comparing primary and secondary outcomes, and performing a predictor analysis for body weight loss.

The results of the analysis were published in the research article "Attitude Matters! How Attitude Towards Bariatric Surgery Influences the Effects of Behavioural Weight Loss Treatment" by Bauer *et al.* in Obesity Facts in 2021 and are presented in section 2.2 and discussed in detail 3.1.2 of this dissertation <sup>28</sup>.

### 2 Results

**2.1 Publication 1:** "Conventional weight loss interventions across the different BMI obesity classes: A systematic review and quantitative comparative analysis"

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#### REVIEW



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### Conventional weight loss interventions across the different BMI obesity classes: A systematic review and quantitative comparative analysis

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#### **Abstract**

**Objective:** The recommendation for conventional body weight loss (BWL) treatment in obesity is 5–10%. It is not clear whether BWL is similar across the three different body mass index (BMI) obesity classes. The aim was to provide an overview on BWL across these classes in moderate lifestyle/diet intervention programs.

**Method:** A systematic literature search was conducted and the evidence of randomized controlled trials (RCTs) and pre-post design studies synthesized. The outcome was BWL.

**Results:** For RCTs, mean BWL in the intervention group was 3.6 kg (class I) and 5.3 kg (class II), which equates to 4 and 5% BWL, respectively. None of the assessed class III obesity studies met the inclusion criteria. For pre-post design studies, mean BWL was 5.4 kg (class I), 5.5 kg (class II) and 7.9 kg (class III), with high variation within and across studies in the latter. This equates to 6, 5 and, 6% BWL, respectively.

**Conclusions:** BWL of moderate BWL programs are similar across the different obesity classes. For class I obesity, the results differ between RCT and prepost design studies by 2% BWL. The high variation of BWL in class III obesity might reflect different states of motivation such as the attitude towards bariatric surgery.

#### **KEYWORDS**

adults, obesity, review, treatment, weight loss

### 1 | INTRODUCTION

Obesity and its associated comorbidities are a serious public health problem (Bluher, 2019). The underlying

cause of obesity is a chronic imbalance between energy intake and energy expenditure in favour of the former, leading to an accumulation of body weight and in particular body fat mass (Hruby & Hu, 2015).

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The body mass index (BMI) is globally used for classifying body weight (Nuttall, 2015). It is calculated as body weight in kg divided by squared height in meters. A BMI between 18.5 and 24.9 kg/m<sup>2</sup> is categorized as normal weight, a BMI between 25–29.9 kg/m<sup>2</sup> as overweight and a BMI  $\geq$ 30 kg/m<sup>2</sup> as obese. Furthermore, obesity is subdivided into three BMI classes: class I, 30–34.9 kg/m<sup>2</sup>; class II, 35–39.9 kg/m<sup>2</sup>; and class III,  $\geq$ 40 kg/m<sup>2</sup> (Deitel & Greenstein, 2003).

Obesity is associated with a variety of comorbidities such as type 2 diabetes and cardiovascular diseases (Apovian, 2016). Their risks increase continuously with the degree of obesity compared to normal weight, particularly in class III obesity (World Health Organization [WHO], 2000). Besides the individual burden at physiological and psychological levels (Dixon, 2010), obesity leads to high direct and indirect costs for healthcare systems (European Commission, 2006).

The underlying mechanism for obesity treatment is reduced energy intake to promote body weight loss (BWL). This can be mainly achieved through conservative weight-management programs and/or bariatric surgery. Conservative weight-management programs focus on reducing energy intake, improving eating behaviour and increasing physical activity. Ideally, psychological and psychosocial factors are also addressed (Jensen et al., 2014; Yumuk et al., 2015). Pharmacotherapy is another option in obesity management, but is only used as an adjuvant treatment component in certain situations (Lagerros & Rossner, 2013). Bariatric surgery becomes the method of choice in either severe obesity or obesity with comorbidities, when conservative methods have failed (De Luca et al., 2016; Lagerros & Rossner, 2013; WHO, 2000).

There is currently an ongoing debate as to whether or not conservative weight-management programs are still the first treatment option in individuals with a BMI ≥35 kg/m², as surgical procedures have proven to be highly effective and safe, even in lower obesity classes (Feng, Andalib, Brethauer, Schauer, & Aminian, 2019). For conservative weight management programs realistic BWL goals are important to avoid disappointment. In practice, participants often have unrealistic BWL goals, up to one third of his or her initial body weight (Foster, Wadden, Vogt, & Brewer, 1997). In contrast, the common recommended weight reduction goal ranges between 5 and 10% of initial body weight within 6 months (Jensen et al., 2014; WHO, 2000).

Interestingly, it is not clear whether reduction in body weight is similar across the different obesity classes, when conservative BWL programs are used. To our knowledge, only one systematic review has compared BWL data across obesity classes (Barte, Veldwijk,

### **Highlights**

- Body weight loss across the different obesity classes in moderate lifestyle/diet intervention programs is similar.
- For class I obesity, the results differ by 2% total BWL between RCTs and pre-post design studies.
- The variation of BWL within and across studies in class III obesity is high and might reflect different states of motivation.

Teixeira, Sacks, & Bemelmans, 2014). In this review, the inclusion criteria were 1-year weight change after an intervention, consisting of diet and physical activity, in Caucasian adults with a BMI ranging from 25 to 39.9 kg/m² (overweight to class obesity II). In this analysis, comparison of BWL was only based on a pre-post design without control groups, and no randomized controlled trial (RCT) studies were included. The results of the 13 included trials depicted a lower weight change for overweight in contrast to obese participants and no significant weight change differences between class I and class II obesity (Barte et al., 2014).

Therefore, the aim of this systematic review was to compare body weight change by moderate lifestyle and diet intervention programs in patients with obesity separately across the different BMI obesity classes including class III. Initially, we had planned to perform a meta-analysis. However, due to high heterogeneity, which will be discussed later in the manuscript, and no class III obesity RCTs found for analysis, we changed our first intention of doing a meta-analysis. Instead, we decided to do a thorough review on this topic by analysing RCTs in the first step and pre-post trials, which were not necessarily randomized and/or controlled, in the second step.

Our first hypothesis was that BWL depends on the baseline obesity class, with greater BWL expected in individuals with a higher initial BMI category. The rationale for the hypothesis is that resting energy expenditure increases with body weight resulting in larger amounts of energy intake needed to stabilize body weight (Elbelt et al., 2010). Thus, during BWL intervention (diet), the energy deficit might be larger in patients with higher body weight. Our second hypothesis was that BWL in class III obesity shows a large range of variation within and across studies. The rationale for the second hypothesis is that with increasing BMI and comorbidities the wish for a surgical approach might increase in many

patients, leading to less motivation and subsequently less adherence in a conservative treatment setting.

### 2 | METHODS

### 2.1 | Literature information sources and search strategy

The literature search process was divided into two parts. First, a database search was conducted to systematically identify review articles and meta-analyses from the last 5 years which deal with the results of BWL programs according to the search strategy which is recommended for the development of evidence-based guidelines (Ball C; Phillips, 2004). Therefore, a PubMed search was conducted using the following search term: weight loss (title/abstract) AND (review[title] OR meta-analysis [title] AND ["January 1, 2014"][PDAT]:["April 11, 2019"][PDAT]). Additionally, hand-searched reviews were included.

In a second step, original articles were systematically extracted from the review articles and meta-analyses and reported on the basis of the PRISMA statement (Liberati et al., 2009; Moher, Liberati, Tetzlaff, Altman, & PRISMA Group, 2009). Additionally, a hand-search for original articles was performed. The review protocol was registered in the International Prospective Register of Systematic Reviews (PROSPERO; CRD42020132766).

### 2.2 | Eligibility criteria

In the first part of the search, all peer-reviewed review articles and meta-analyses dealing with BWL of conservative programs in overweight and obesity written in German or English and published from January 2014 to April 11th of 2019 were eligible.

Eligibility criteria for the second part of the search were based on the five *PICOS* dimensions, that is, *P*articipants, *I*nterventions, *C*omparators, *O*utcome, and *S*tudy design (da Costa Santos, de Mattos Pimenta, & Nobre, 2007).

Participants: A mixed collective of patients with obesity defined as BMI  $\geq$ 30 kg/m² and aged  $\geq$ 18 years. Studies exclusively conducted in specific patient groups with for example, type 2 diabetes, metabolic syndrome (=central obesity, high blood pressure, high serum triglyceride and low high-density lipoprotein), polycystic ovary syndrome, pregnancy, mobility limitations, mental illness were excluded to avoid selection bias of specific groups. No restrictions were made regarding ethnicity and sex status.

Interventions: BWL programs for patients with obesity consisting of a moderate standard behavioural and nutritional intervention with or without physical activity and a duration of at least 6 months but not longer than 36 months, were included. BWL interventions (a) following extreme dietary approaches such as ketogenic diet, meal replacement, diets with an energy content of less than 1,000 kcal per day or (b) focusing on methodologies such as eHealth programs to increase comparability between intervention methods were excluded.

Comparators: For group 1, a control group from RCTs was necessary. For group 2, studies with control groups were allowed but not necessary since before-and-after comparisons were conducted.

*Outcomes*: The primary outcome was BWL in % or kg, secondary outcomes included change of BMI or other weight-related parameters.

Study design: For group 1, only RCTs were included. For group 2, additionally, randomized non-controlled trials (RTs) and uncontrolled pre-post intervention without group comparison (BA) were included.

### 2.3 | Study selection, data collection and organization

A modified *PICOS*-scheme was applied for study selection and data collection reference (da Costa Santos et al., 2007).

The first and the last author (K.B. and I.M.) independently screened titles and abstracts to identify relevant reviews and meta-analyses after the removal of duplicates. Full-text reviews and meta-analysis were evaluated regarding their eligibility and disagreement concerning eligibility was resolved by discussion. Based on the included reviews RCTs, RTs and BAs studies were extracted and a second search process was performed similarly to the first search. Again, after removing duplicates of the original RCTs, RTs and BAs, the studies were screened by abstract and title. The remaining trials were then tested for eligibility by full-text and were either analysed quantitatively as RCTs (group 1) or pre-post analysis (group 2). The results for both groups were separately presented by BMI obesity classes. Studies were categorized into class I obesity if the mean BMI of participants was between 30 and 34.9 kg/m<sup>2</sup>, into class II obesity if the mean BMI of participants was between 35 and 39.9 kg/m<sup>2</sup> and into class III obesity if the mean BMI of participants was  $\geq$ 40 kgm<sup>2</sup>.

In the case of missing data, the authors of the RCTs, RTs and BAs were contacted by email with a response rate of 35%.

### 2.4 Data items and statistics

The following information was extracted from each included article for groups 1 and 2 and for the different obesity classes: year of publication, sample size, age, sex distribution, intervention design and duration, initial BMI and BWL in kg or body weight after intervention. For group 1, BWL in kg is reported as total BWL (total BWL) and as relative BWL (relative BWL) of the intervention group. The latter was calculated as BWL of the intervention group minus BWL of the corresponding control group. Results across studies are presented by calculating the median [interquartile range], minimum and maximum for: study length, sample size, age and sex for the different obesity classes.

For the quantitative analysis of RCT studies, the sample size, mean and SD are reported separately for the intervention and control group. For both groups the mean difference and 95% CI intervals, as well as the summary of these data across the studies, were calculated using the software package Review Manager 5.3.

Initially, we had planned to perform a meta-analysis. However, the heterogeneity of the studies was too high and not meeting the criteria for a meta-analysis even when applying a random effect model (DerSimonian & Laird, 1986; Normand, 1999). Hence, we performed subgroup analysis for study length (6 months, 7–12 months, 13–36 months) which improved heterogeneity, but still remained high. We did not perform further subgroup analysis to reduce heterogeneity (e.g., according to sex, age etc.) because the majority of studies did not deliver all relevant information needed (DerSimonian & Laird, 1986; Normand, 1999). This would have resulted in the reduction of the studies included leading to a considerable selection bias. Nevertheless, we performed a funnel plot to detect publication bias.

For the quantitative analysis of pre-post studies, the sample size, BWL in kg and the SD were extracted. If BWL was not reported explicitly, the average pre and post body weight data (kg) were used for BWL calculation in Microsoft Excel<sup>TM</sup>. In order to provide a summary of the pre-post data across the studies, BWL of each study was multiplied with the number of participants of the respective study and divided by the total number of participants. Finally, the total mean was calculated as a weighted sum of BWL from the individual studies.

BWL in % was calculated using the fraction mean BWL (kg) divided by mean baseline body weight (kg).

### 2.5 | Risk of bias

A risk of bias score was assessed based on "The Office of Health Assessment and Translation (OHAT) Risk of Bias Rating tool for Human and Animal Studies" (Rooney, Boyles, Wolfe, Bucher, & Thayer, 2014) for studies which were originally thought to be included in a meta-analysis (group 1). The following items were applied: "Was administered dose or exposure level adequately randomized?," "Was allocation to study groups adequately concealed?," "Can we be confident in the exposure characterization?," "Can we be confident in the outcome assessment?," "Were all measured outcomes reported?," "Were statistical methods appropriate?," "Did researchers adhere to the study protocol?" and "Did the study design or analysis account for important confounding and modifying variables in (including unintended co-exposures) in experimental studies?" The rating ranged between: definitely low ("++"), probably low ("+"), probably high ("-" or "NR": not reported), or definitely high risk of bias ("--").

Risk of bias for group 1 was analysed within and across studies and no final scores were calculated, pursuant with the PRISMA statement (Moher et al., 2009). Studies were only excluded in case that all questions were of probably high and/or definitely high risk of bias.

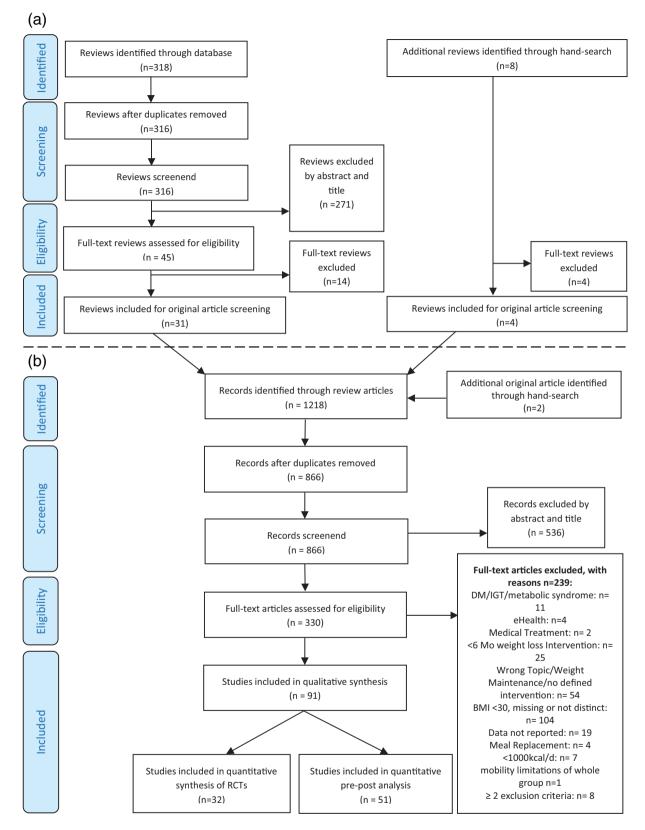
### 3 | RESULTS

### 3.1 | Study selection and categorization

An overview of the dualistic search process is depicted in Figure 1. A total number of 1,218 RCTs, RTs and BAs were extracted from review articles and meta-analyses. For analysis 91 RTs and non-randomized trials were eligible. From these 91 trials, 83 trials were analysed since eight studies utilized the same participants (Appel et al., 2003; Friedman et al., 2012; Heshka et al., 2003; Runhaar et al., 2015; Samaha et al., 2003; Sarwer et al., 2013; Silva et al., 2010; Truby et al., 2006).

For the quantitative analysis of RCTs (group 1) 32 trials were included. Of these trials, 24 were categorized into class I obesity and 8 into class II obesity. No RCT studies were found for class III obesity. Therefore, the primary analysis of RCTs was complemented by quantitative pre-post analysis including RT, BA and RCT studies, which did not fulfil the criteria for the quantitative analysis of RCTs. A detailed description of the studies is given in Table 1 and Data S1.

For the quantitative pre-post analysis (group 2) 51 trials were included. Of these trials, 27 were categorized into class I obesity, 16 into class II obesity and 7 into class III obesity. Of these studies, 12 were RCTs and originally selected for group 1: However, they were included in group 2 for analysis due to missing data. Here, only the intervention group could be investigated. The remaining trials were either RTs or BAs. Eight trials only provided BWL averaged over all interventions rather than for each intervention



**FIGURE 1** Flow diagram of systematic literature search. Legend A systematic search of review articles through database search was conducted (A), followed by a systematic search of original articles through review articles (B). Abbreviations n: Number; DM: Diabetes mellitus; IGT: impaired glucose tolerance; Mo: Month; BMI: Body mass index; kcal Kilocalorie; d: Day [Colour figure can be viewed at wileyonlinelibrary.com]

**TABLE 1** Characterization of RCTs by obesity class

Author, Year	Study length Months	Sample size and characterization N; age (SD); sex (%), BMI (kg/m²) (SD)	Country
Ahern et al., 2017	24	<b>1. C:</b> n = 211; age: 51.9 (14.1); 68% female; BMI: 34.4 (4.6)	UK
		<b>2. I:</b> n = 528; age: 53.3 (14); 68% female; BMI: 34.5 (5.1)	
Blumenthal et al., 2000	6	<b>1. C:</b> n = 24; age: 47.2 (1.8); 46% female; BMI: 32.6 (5.1)	US
		<b>2. I:</b> n = 55; age: 48.5 (1.2); 62% female; BMI: 32.1 (4)	
Cohen, D'Amico, & Merenstein, 1991	12	<b>1. C:</b> n = 15; age: 59.7; 73% female; BMI: 34.2	US
		<b>2. I:</b> n = 15; age: 59.7; 73% female; BMI: 34	
de Vos, Runhaar, & Bierma-	30	<b>1. C:</b> n = 204; age: 55.7 (3.2); 100% female; BMI: 32.5 (4.5)	NL
Zeinstra, 2014		<b>2. I:</b> n = 203; age: 55.7 (3.2); 100% female; BMI: 32.2 (4.1)	
Elmer et al., 2006	18	<b>1. C:</b> n = 241; age: 49.5 (8.8); 63% female; BMI: 32.9 (5.6)	US
		<b>2. I:</b> n=269; age: 50.2 (9.3); 57.2% female; BMI: 33.3 (6.3)	
Greaves et al., 2015	12	<b>1. C:</b> n = 53; age: 63.7 (7.4); 73.6% female; BMI: 32.3 (3)	UK
		<b>2. I:</b> n = 55; age: 66.6 (6.4); 65.5% female; BMI: 33 (3.2)	
Hardcastle, Taylor, Bailey, &	6	<b>1. C:</b> n = 131; age: 50.4 (0.9); 67% female; BMI: 34.3 (0.6)	UK
Castle, 2008		<b>2. I:</b> n = 203; age: 50.1 (0.7); 67% female; BMI: 33.7 (0.4)	
Heshka et al., 2000	24	<b>1. C:</b> n = 212; age: 44 (10); 87% female; BMI: 33.6 (3.7)	US
		<b>2. I:</b> n = 211; age: 45 (10); 82% female; BMI: 33.8 (3.4)	
Jansson, Engfeldt, Magnuson, Pt, &	24	<b>1. C:</b> n = 66; age: 45 (13); 77% female; BMI: 33.6	SW
Liljegren, 2013		<b>2. I:</b> n = 67; age: 49 (13); 67% female BMI: 33.8	
Jebb et al., 2011	12	<b>1. C:</b> n = 395; age: 48.2 (12.2); 86% female; BMI: 31.3 (2.6)	MULTI
		<b>2. I:</b> n = 377; age: 48.2 (12.2); 88% female; BMI: 31.5 (2.6)	
Jenkins et al., 2017	6	<b>1. C:</b> n = 486; age: 44.7; 77%; female; BMI: 32.5 (32 to 33)	CAN
		<b>2. I:</b> n = 145; age: 44.7; 77%; female; BMI: 31.7 (30.8 to 32.7)	
Jones et al., 1999	6	<b>1. C:</b> n = 51; age: 59 (7); 55% female; BMI: 34 (6)	US
		<b>2. I:</b> n = 51; age: 57 6); 55% female; BMI: 34 (6)	
Morgan et al., 2009	6	<b>1. C:</b> n = 61; age: 40.8 (9.6); 75.4% female; BMI: 31.5 (2.9)	UK
		<b>2. I:</b> n = 47; age: 39.9 (10.9); 72.4% female; BMI: 31.2 (2.7)	
Nanchahal et al., 2012	12	<b>1. C:</b> n = 190; age: 49.4 (15.5); 73% female; BMI: 33 (5.4)	UK
		<b>2. I:</b> n = 191; age: 48.2 (14.1); 72% female; BMI: 33.9 (5.6)	
Ockene et al., 2012	12	<b>1. C:</b> n = 150; age: 52.4 (11.6); 77% female; BMI: 34.2 (5.9)	US
		<b>2. I:</b> n = 162; age: 51.4 (10.9); 72% female; BMI: 33.6 (5.1)	
Puhkala et al., 2015	12	<b>1. C:</b> n = 58; age: 46.5 (8.6); male 100%; BMI: 33.1 (4.7)	F
		<b>2. I:</b> n = 55; age: 47.6 (7.9); male 100%; BMI: 32.9 (4.3)	
Rock, Pakiz, Flatt, & Quintana, 2007	6	<b>1. C:</b> n = 35; age: 40 (12); 100% female; BMI: 33.8 (3.4)	US
		<b>2. I:</b> n = 35; age: 42 (11); 100% female; BMI: 34.2 (3.7)	
Rock et al., 2010	24	<b>1. C:</b> n = 111; age: 45 (11); 100% female; BMI: 34 (3.2)	US
		<b>2. I:</b> n = 151; age: 44 (10); 100% female; BMI: 33.8 (3.1)	
Rodriguez-Cristobal et al., 2017	24	<b>1. C</b> : n = 446; age: 55.5 (11.5); 73% female; BMI: 34.1 (4.8)	SP
		<b>2. I:</b> n = 400; age: 57.7 (22.1); 82% female: BMI: 34.1 (4.8)	
Ross et al., 2012	24	<b>1. C:</b> n = 241; age: 52.4 (11.8); 70% female; BMI: 32 (4.2)	US
		<b>2. I:</b> n = 249; age: 51.3 (11); 70% female; BMI: 32.6 (4.1)	

(Continues)

TABLE 1 (Continued)

BMI 1			
Author, Year	Study length Months	Sample size and characterization N; age (SD); sex (%), BMI (kg/m²) (SD)	Country
Shea et al., 2011	8	<b>1. C:</b> n = 294; age: 65.6 (4.5); 57% female; BMI: 31.1 (2.4)	US
		<b>2. I:</b> n = 291; age: 65.6 (4.5); 47% female; BMI: 31.2 (2.2)	
Shuger et al., 2011	9	<b>1. C:</b> n = 50; age: 47.2 (8.9); 84% female; BMI: 33.7 (5.5)	US
		<b>2. I: n</b> = 49; age: 46.8 (12.4); 80% female; BMI: 33.1 (4.8)	
Stevens et al., 2001	36	<b>1. C:</b> n = 596; age: 43.2 (6.1); 68% male; BMI (female): 30.8 (3.5); BMI (male): 31 (2.9)	US
		<b>2. I:</b> n = 595; age: 43.4 (6.1); 78% male; BMI (female): 31 (3.6); BMI (male): 31 (2.9)	
Vissers et al., 2010	6	<b>1. C:</b> n = 21; age: 44.8 (11.4); 75% female; BMI 30.8 (3.4)	BL
		<b>2. I:</b> n = 20; age: 44.7 (13.0); 75% female; BMI: 33.1 (3.4)	
BMI 2			
Anton et al., 2011	6	<b>1. C:</b> n = 17; age: 63.7 (6.7); 100% female; BMI: 35.8 (6.8)	US
		<b>2. I:</b> n = 17; age: 63.7 (4.5); 100% female; BMI: 37.8 (5.5)	
Davis Martin et al., 2006	6	<b>1. C:</b> n = 73; age: 43 (11.4); 100% female; BMI: 39.6 (7.7)	US
		<b>2. I:</b> n = 71; age: 40.7 (12.6); 100% female; BMI: 38.1 (7.5)	
Perri et al., 2008	6	<b>1. C:</b> n = 79; age: 58.6 (6); 100% female; BMI: 36.2 (4.3)	US
		<b>2. I:</b> n = 83; age: 59.2 (6.2); 100% female; BMI: 37.1 (4.5)	
Stolley et al., 2009	6	<b>1. C:</b> n = 106; age: 45.5 (8.4); 100% female; BMI: 39.6 (5.8)	US
		<b>2. I:</b> n = 107; age: 46.4 (8.4); 100% female; BMI: 38.8 (5.5)	
Tsai et al., 2010	6	<b>1. C:</b> n = 26; age: 47.6 (2.5); 88% female; BMI: 37.6 (1.1)	US
		<b>2. I:</b> n = 24; age: 51.3 (2.3); 88% female; BMI 35.4 (1.2)	
Villareal et al., 2006	6	1. <b>C:</b> n = 10; age: 71 (4); 60% female; BMI: 39 (5)	US
		<b>2. I:</b> n = 17; age: 69 (5); 71% female; BMI: 39 (5)	
Villareal et al., 2011	12	<b>1. C:</b> n = 27; age: 69 (4); 67% female; BMI: 37.3 (4.7)	US
		<b>2. I:</b> n = 28; age: 70 (4); 57% female; BMI: 37.2 (5.4)	
Wadden et al., 2011	24	<b>1. C:</b> n = 130; age: 51.7 (12.1); 75% female; BMI 39 (4.8)	US
		<b>2. I:</b> n = 131; age: 52 (12.2); 84% female; BMI: 38.5 (4.6)	

Abbreviations: BL, Belgium; BMI, Body mass index; C, Control Group; CAN, Canada; d, Day; F, Finland; I, Intervention Group; kcal, Kilocalorie; kg, Kilogram; m, Meter; min(s), Minute(s); MULTI, Multicenter worldwide cooperation; N, Number; NL, Netherland.; RCT, Randomized controlled trial; SD, Standard deviation; SP, Spain; SW, Sweden; UK, United Kingdom; US, United States.

individually. In some cases, not all intervention groups of one trial matched our eligibility criteria. If so, only the eligible intervention groups were examined. A detailed description of the single studies is given in Table 2 and Data S1.

### 3.2 | Summary of study characteristics

### 3.2.1 | Quantitative analysis of RCTs (group 1)

Out of the 32 trials, most of the studies (n = 20) were conducted in the US. The rest took place in the UK, Sweden,

Finland, Netherlands, Belgium, Canada, Spain and as a multicentre worldwide cooperation. The original studies were published between 1991 and 2017 (class I obesity from 1991 to 2017; class II obesity from 2006 to 2011).

The eligible number of trials for this quantitative analysis of RCTs included 9,730 participants in total, 8,787 participants for BMI I, and 943 participants for BMI II. In class I obesity the median for age was 49 [44.95–53.85] years and for weight 91.8 [88.4–94.3] kg. In class II obesity the median for age was 55.3 [47.3–65] years and for weight 100.9 [98.8–103.4] kg. The proportion of female sex ranged between 0% to 100% and the mean proportion was 69.6%. A detailed description of the

characteristics for the single RCTs is given in Table 1 and Data S1 and across the RCTs in Data S2.

### 3.2.2 | Quantitative pre-post analysis (group 2)

The trials for the quantitative pre-post analysis were conducted mainly in the US (n = 34). The rest of the studies took place in Spain, Italy, Portugal, Australia, Canada, Ireland, the UK, Finland, Sweden, Germany and Iran; the studies were published between 1992 to 2016 (class I obesity: 1992 to 2016; class II obesity: 2003 to 2014; class III obesity: 1993 to 2016).

For this quantitative pre-post analysis 11,942 participants were analysed, with 4,869 participants representing the class I obesity subgroup, 6,381 the class II obesity subgroup and 692 the class III obesity subgroup. The median weight was 89 [84.1–93.1] kg for class I obesity, 101.6 [99–103.4] kg for class II obesity and, 123.6 [120.2–133.3] kg for class III obesity. A mean of 73.4% of the participants were female and total median age was 47.3 [44.1–53] years. A detailed description of the characteristics is given in Table 2 and Data S1 and across the studies in Data S2.

#### 3.3 | Risk of bias

The risk of bias for the studies included in the quantitative analysis of RCTs was assessed according to the OHAT criteria for each trial individually and is presented in Data S3. The randomization of trials was definitely or probably of low risk of bias. The allocation to the intervention groups were in large parts not reported. If it was reported, the risk of bias was mostly of low or probably low risk of bias. For blinding participants and research personnel, the risk of bias was high in every trial. However, this is a common bias for nutritional studies as blinding is difficult or even impossible to perform. The detection bias was mostly of low or probably low risk of bias, as well as the attrition and reporting bias. Furthermore, the adherence to study protocols was probably of low risk of bias.

The trial dropout rate ranged from 0 to 46% with a median of 13.8% [8–28.5%]. Eight out of the 32 trials had a dropout rate  $\geq$ 30%.

### 3.4 | Summary of study outcome

### 3.4.1 | Quantitative analysis of RCT studies (group 1)

An overview of the quantitative analysis of RCT studies is depicted in Figure 2. In comparison to the control group (relative BWL), the participants of the intervention group of class I obesity lost on average 2.81 kg (CI 95% -3.49 to -2.13) and in class II obesity 4.07 kg (CI 95% -5.90 to -2.25). In total relative BWL was 3.10 kg (CI 95% -3.74 to -2.45). [Corrections made on 30 July 2020, after first online publication: Values in the preceding sentence have been corrected in this version] Thus, on average, the intervention group of class I obesity lost 3% and class II obesity 4% of their body weight.

The total amount of BWL (total BWL) for the intervention group of class I obesity was 3.6 kg and of class II obesity 5.3 kg, which equates to 3.8 and 5.3% total BWL, respectively.

The funnel plot depicted in Data S4 shows an asymmetry with a deficiency in the lower corner on the right and may implicate a reporting bias (Sterne et al., 2011).

Initially, we had planned to perform a meta-analysis. However, the heterogeneity was too high and not meeting the criteria for a meta-analysis even when applying a random effect model (DerSimonian & Laird, 1986; Normand, 1999). We performed a subgroup analysis for the duration of the programs (6, 7–12 and 13–36 months) and the heterogeneity improved but remained high. The results are presented in Data S5. Across the duration of the programs, total BWL in kg decreased over time for class I obesity. For class II obesity the number of studies were too small to draw any conclusions.

We did not perform further subgroup analysis to reduce heterogeneity (e.g., according to sex, age etc.) because most of the studies did not deliver the relevant information needed. This would have resulted in a reduction of studies included leading to a considerable selection bias (DerSimonian & Laird, 1986; Normand, 1999). In addition, no class III obesity RCT studies were found for analysis. However, our intention of this review was to provide an overview of body weight change by moderate lifestyle and diet intervention programs in patients with obesity separately across the different BMI obesity classes including class III. Therefore, we changed our first intention of doing a meta-analysis on this subject and decided to do a thorough review including quantitative analysis and including pre-post studies.

### 3.4.2 | Quantitative analysis of pre-post studies (group 2)

A summary of the pre-post quantitative analysis is presented in Figure 3. Mean BWL for class I obesity was 5.4 kg [range: -0.67 to -13.7], for class II obesity, 5.5 kg [range: 0 to -15] and, for class III obesity 7.9 kg [range of: -3.1 to -18.1]. For class III obesity the analysis is based on less than 700 participants in total and the range of BWL between the studies but also the range within the studies was extremely high. BWL of the three obesity classes equates to 6, 5.3 and 6.3% of baseline weight, respectively. Altogether, the participants achieved a mean BWL of 5.6 kg.

**TABLE 2** Characterization of pre-post trials by obesity class

BMI 1				
Author, Year	Study type	Study length Months	Sample size and characterization N; age (SD); sex (%), BMI (kg/m²) (SD)	Country
Abedi et al., 2010	RCT	6	<b>I</b> : n = 35; age: 51.4 (4.9); 100% female; BMI: 30.1 (6.2)	IRA
Acharya et al., 2009	RT	6	I: n = 151; age: 44.4 (8.6); 87% female; BMI: 34	US
Allen, Stephens, Dennison Himmelfarb, Stewart, & Hauck, 2013	RT	6	<b>I:</b> n = 18; age: 42.5 (12.1); 78% female; BMI: 34.1 (4.1)	US
Arrebola et al., 2011	BA	6	<b>I:</b> n = 60; age: 40 (9); 71% female; BMI: 32.1 (3)	SP
Brinkworth, Noakes, Buckley, Keogh, & Clifton, 2009	RT	12	I1: n = 55; age: 50.3 (8.4), 69% female; BMI: 33.9 (4.3) I2: n = 52; age: 51.0 (7.5); 60% female; BMI: 33.5 (4.1)	AUS
Brochu et al., 2009	RT	6	I1: n = 89; age: 58 (4.7); 100% female; BMI: 32.3 (4.6) I2: n = 48; age: 57.2 (5); 100% female; BMI: 32.6 (4.9)	CAN
Cousins et al., 1992	RCT	6	I1: n = 32; age: 33.6 (6.4); 100% female; BMI: 31.7 (5)  I2: n = 27; age: 32.8 (6.1); 100% female; BMI: 30.3	US
Ello-Martin, Roe, Ledikwe, Beach, & Rolls, 2007	RT	12	(4.5)  I1: n = 49; age: 44.5 (1.3); 100% female; BMI: 33.3 (0.4)  I2: n = 48; age: 45.3 (1.4); 100% female; BMI: 33.4 (0.5)	US
Foster et al., 2012	RT	18	(3.5) <b>I1:</b> n = 61; age: 47.0 (12.02); 89% female; BMI: 33.9 (3.5) <b>I2:</b> n = 62; age: 46.7 (13.0); 94% female; BMI: 34.0 (3.7)	US
Foster-Schubert et al., 2012	RCT	12	I: n = 117; age: 58.0 (4.5); 100% female; BMI: 31.0 (4.3)	US
Griffin et al., 2013	RT	12	I1: n = 36; age: 22.4 (2.4); 100% female; BMI: 34.1 (4.1)  I2: n = 35; age:22.5 (2.3); 100% female; BMI: 33.8 (4.9)	AUS
Hollis et al., 2008	BA	6	I: n = 1,685; age: 54.8 (9.1); 67% female; BMI: 34.3 (4.8)	US
Jakicic et al., 2012	RT	12	I1: n = 165; age: 42.4 (9.2); 82% female; BMI: 33 (3.9) I2: n = 198; age: 42 (8.9); 83% female; BMI: 33 (4.3)	US
Jeffery, Wing, Sherwood, & Tate, 2003	RT	18	I1: n = 109; age: 42.2 (6.4); 58% female; BMI: 31 (2.6) I2: n = 93; age: 42.2 (6.4); 58% female; BMI: 31 (2.6)	US
C. A. Johnston, Rost, Miller-Kovach, Moreno, & Foreyt, 2013	RCT	6	I: n = 147; age: 47.5 (11.7); 89% female; BMI: 33.1 (3.7)	US
Kirby et al., 2011	RCT	12	I: n = 54; age: 47 (10); 81% female; BMI: 34.9 (6.1)	IRL
Koniak-Griffin et al., 2015	RCT	6	<b>I:</b> n = 111; age: 43.3 (7.4); 100% female; BMI: 32.37 (5)	US
Laatikainen et al., 2007	BA	12	<b>I:</b> n = 237; age: Completers 56.7 (8.7); 73% female; BMI: Completers 33.5 (5.9); non-completers 34.7 (6.9)	AUS
McManus, Antinoro, & Sacks, 2001	RT	18	I1: n = 50; age: 44 (10); 88% female; BMI: 34 (5) I2: n = 51; age: 44 (10); 92% female; BMI: 33 (3)	US
Mellberg et al., 2014	RT	24	<b>I1:</b> n = 35; age: 59.5 (5.5); 100% female; BMI: 32.7 (3.6)	SW

### TABLE 2 (Continued)

Author, Year	Study type	Study length Months	Sample size and characterization N; age (SD); sex (%), BMI (kg/m²) (SD)	Country
			<b>12:</b> n = 35; age: 60.3 (5.9); 100% female; BMI: 32.6 (3.3)	
Pellegrini et al., 2012	RT	6	<b>I</b> : n = 17; age: 45.1 (9.4); 100% female; BMI:33.1 (3.8)	US
Rolls, Roe, Beach, & Kris-Etherton, 2005	RT	6	I1: n = 50; age: 44.5 (1.2); 77% female; BMI: 31.4 (0.4)  I2: n = 50; age: 45.1 (1.2); 77% female; BMI: 30.9 (0.5)  I3: n = 50; age: 43.8 (1.2); 77% female; BMI: 30.8 (0.5)  I4: n = 50; age: 45.2 (1.2); 77%; female; BMI: 31.3 (0.4)	US
Ryan, Nicklas, Berman, & Elahi, 2003	RT	6	I1: n = 15; age: 56 (1); 100% female; BMI: 33.6 (1.2)  I2: n = 16; age: 59 (1); 100% female; BMI: 31.1 (1.0)  I3: n = 9; age: 57 (2); 100% female; BMI: 31.4 (1.2)	US
Ryan & Harduarsingh-Permaul, 2014	NRT	6	I1: n = 22; age: 50–76 years; 100% female; BMI: 34 (1) I2: n = 43; age: 50–76 years; 100% female: BMI: 32 (1)	US
Sacks et al., 2009)	RT	24	I1: n = 204; age: 51 (9); 62% female; BMI: 33 (4)  I2: n = 202; age: 50 (10); 67% female; BMI: 33 (4)  I3: n = 204; age: 52 (9); 61% female; BMI: 32 (4)  I4: n = 201; age: 51 (9); 64% female; BMI: 33 (4)  all: Age: 51 (9); 64% female; BMI: 33 (4)	US
Teixeira et al., 2010	RCT	12	I: n = 106; age: 38.1 (7); 100%female; BMI: 31.7(4.2)	POR
Toobert, Glasgow, & Radcliffe, 2000	RCT	24	I: n = 14; age: 64 (10); 100% female; BMI: 32 (4.2)	US
BMI 2				
Carels, Darby, Cacciapaglia, & Douglass, 2004	RT	6	I1: n = 21; age: 54.7 (7.9); 100% female; BMI: 37.8 (5.9)  I2: n = 23; age: 54.7 (7.9); 100% female; BMI: 35.1 (5)	US
Damschroder et al., 2014	RT	12	I1: n = 160; age: 54.9 (9.5); 84% male; BMI: 36.4 (6.4)  I2: n = 159; age: 54.6 (10.5); 88% male; BMI: 36.8  (6.4)	US
Ebbeling, Leidig, Feldman, Lovesky, & Ludwig, 2007	RT	6	<b>I1:</b> n = 37; age: 28.2 (3.8); 81% female; BMI: 37,5 <b>I2:</b> n = 36; age: 26.9 (4.2); 78% female; BMI: 36,6	US
Esposito et al., 2004	RCT	24	<b>I:</b> n = 55; age: 43.5 (4.8); 100% male; BMI: 36.9 (2.5)	IT
Foster et al., 2010	RT	24	I: n = 154; age: 44.9 (10.2); 67% female; BMI: 36.1 (3.5)	US
Frimel, Sinacore, & Villareal, 2008	RT	6	<b>I1:</b> n = 15; age: 70.3 (4.8); 60% female; BMI: 37.5 <b>I2:</b> n = 15; age: 68.7 (4.3); 60% female; BMI: 37.5	US
Gorin et al., 2013	RT	18	<b>I:</b> n = 99; age: 50.4 (9.3); 79% female; BMI: 36.1 (6.2)	US
Kumanyika et al., 2012	RT	12	I1: n = 137; age: 46.8 (11.6); 83% female; BMI: 37.3 (6.4)  I2: n = 124; age: 47.6 (11.9); 86% female; BMI: 37.2 (6.5)	US

(Continues)

TABLE 2 (Continued)

		Study		
Author, Year	Study type	length Months	Sample size and characterization N; age (SD); sex (%), BMI (kg/m²) (SD)	Country
Lagerstrom, Berg, & Haas, 2013	BA	12	<b>I</b> : n = 5,025; age:48.6 (11.3); female: 74.7%; BMI: 35.7 (3)	GER
Latner, Ciao, Wendicke, Murakami, & Durso, 2013	RT	6	I1: n = 52; age: 49.7 (12.3); 64% female; BMI: 35.6 (8.1)	US
			<b>I2</b> : n = 38; age: 49.7 (12.3); 64% female; BMI: 36.1 (7.7)	
Moore et al., 2003	RCT	18	<b>I:</b> n = 415; age: 48.4 (10.9); 75% female; BMI: 37 (5.7)	UK
Nackers et al., 2013	RT	6	I: n = 60; age: 52.5 (9.8); 100% female; BMI: 37.6 (3.8)	US
Perri et al., 2014	RCT	6	I: n = 161; age: 53.2 (12.0); 75% female: BMI: 36.7 (4.0)	US
Pinto, Fava, Hoffmann, & Wing, 2013	RT	12	<b>I1:</b> n = 48; age: 49.2 (9.8); 89.1% female; BMI: 36.4 (5)	US
			<b>I2:</b> n = 49; age: 49 (9.2); 89.8% female; BMI: 35.5 (5.3)	
			<b>I3:</b> n = 47; age: 50.9 (8.8); 91.3% female; BMI: 36.6 (6.1)	
Wadden et al., 2004	RCT	10	<b>I:</b> n = 43; age: 45.6 (9.2); 100% female; BMI: 36.3 (4.9)	US
Yancy Jr. et al., 2010	RT	12	<b>I:</b> n = 72; age: 52.9 (10.2); 28% female; BMI: 39.9 (6.9)	US
Yeh et al., 2003	RT	6	<b>I1:</b> n = 40; age: 48 (9); 100% female; BMI:37.9 (6.7)	US
			<b>I2:</b> n = 40; age: 51 (11); 100% female; BMI: 36.3 (5.4)	
BMI 3				
Dalle Grave, Calugi, Gavasso, El Ghoch, & Marchesini, 2013	RT	12	<b>I1:</b> n = 43; age: 46.7 (10.3); 61% female; BMI: 45.8 (6.5)	IT
			<b>I2:</b> n = 45; age: 46.6 (12.0); 56% female; BMI: 45.4 (7)	
Goodpaster et al., 2010	RT	12	<b>I1:</b> n = 67; age: 46.1 (6.5); 85% female; BMI: 43.5 (4.8)	US
			<b>I2:</b> n = 67; age: 47.5 (6.2); 92% female; BMI: 43.7 (5.9)	
Hakala, Karvetti, & Ronnemaa, 1993	RT	24	<b>I1:</b> n = 30; age: Women: 41 (8), men: 39 (9)	F
			75% female; BMI: Women 43.6 (4.8), men 42.7 (4)	
			<b>I2:</b> n = 30; age: Women: 37 (6),men 40 (10); 75% female; BMI: Women 43.4 (5.4), men 41.7 (3.1)	
Mingrone et al., 2002	RT	12	I: n = 33; age: 30–45; sex: No data; BMI: Women: 48.4 (8.9), men: 47.8 (8.8)	IT
Rudolph, Hellbardt, Baldofski, de Zwaan, & Hilbert, 2016	BA	12	<b>I</b> : n = 190; age: 44.9 (11.4); 90.9% female; BMI: 44.1 (6.2)	GER
Stern et al., 2004	RT	6	<b>I1:</b> n = 64; age: 53 (9); 20% female; BMI: 42.9 (6.6)	US
			<b>I2:</b> n = 68; age: 54 (9); 15% female; BMI:42.9 (7.7)	
Torgerson, Lissner, Lindroos, Kruijer, & Sjostrom, 1997	RT	24	I: n = 55; age: 46.9 (5.8); 70% female; BMI: 40.5 (4.3)	SW

Abbreviations: AUS, Australia; BA, Before-and-after comparison (without control); BMI, Body mass index; C, Control Group; CAN, Canada; d, Day; F, Finland; GER, Germany; I, Intervention Group; IRA, Iran; IRL, Ireland; IT, Italy; kcal, Kilocalorie; kg, Kilogram; m, Meter; min (s), Minute(s); N, Number; NRT, Nonrandomized controlled trial; POR, Portugal; RCT, Randomized controlled trial; RT, Randomized Trial; SD, Standard deviation; SP, Spain; SW, Sweden; UK, United Kingdom; US, United States of America.

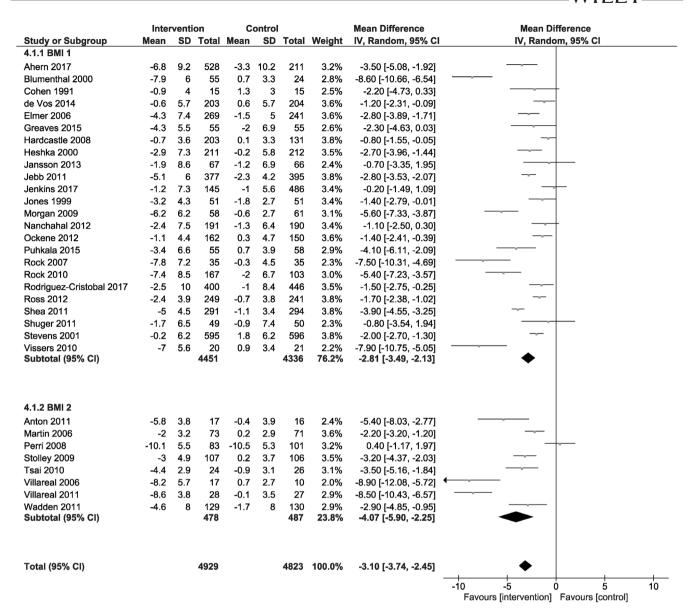


FIGURE 2 Quantitative analysis of randomized controlled trials

### 4 | DISCUSSION

The aim of this systematic review is to compare body weight change by moderate lifestyle and diet intervention programs in patients with obesity separately across the different BMI obesity classes including class III.

# 4.1 | Hypothesis 1 rejected: "BWL is greater in individuals with a higher initial obesity class"

To test hypothesis 1, BWL was presented as a stratified overview across the different obesity classes. For RCTs,

stratification was only possible for class I and class II obesity, showing a relative BWL of the intervention groups (compared to the control groups) by 3 and 4% and absolute BWL by 3.8 and 5.3%, respectively. These results indicate that the recommended 5–10% BWL is frequently not achieved (Jensen et al., 2014; WHO, 2000).

The meta-analysis from Johnston et al. depicted a BWL after a 6-months intervention of 8.73 kg (CI 95% 7.27–10.2) for low-carbohydrate diets and 7.99 kg (95% CI 6.01–9.92) for low-fat diets (B. C. Johnston et al., 2014). In contrast to these trials, the 83 trials described here ranged from 6 to 36 months. This corresponds directly to the LOOK AHEAD study, which described an initial greater BWL for the first year, followed by a decreased amount of BWL in the following years (Look AHEAD

Weight loss (kg) Total Abedi (2010) -0.90 NR Acharya (2009) \_R R1 5.96 151 -0.80 1.40 Allen (2013) 18 Arrebola (2011) -6.73 NR 60 Brinkworth (2009) -13.70 1.80 106 Brochu (2009): I1 -5.10 4 70 89 Brochu (2009): 12 -5.80 4.90 48 Cousins (1992): I2 32 Cousins (1992): I2 -4.50 NR 27 Fllo-Martin (2007): I1 -6 40 6 30 49 Ello-Martin (2007): 12 -7.90 6.24 48 Foster (2012): I1 -3.70 -7.81 Foster (2012): 12 -5 90 -7 87 62 Foster-Schubert (2012) -8.91 NR 117 Griffin (2013): I1 -6.90 36 Griffin (2013): I2 -3.50 NR 35 Hollis (2008) -5.80 4 40 1685 Jakicic (2012 -9.10 NR 165 Jeffery (2003) Johnston (2013) -4.60 NR 147 Kirby (2011) -2 90 NR 54 Koniak-Griffin (2015) NR 111 -0.67 Laatikainen (2007) -2.52 McManus (2001): I1 -4 80 5 60 50 30 -2.90 McManus (2001): 12 8.60 Melberg (2014): I1 35 -8.70 NR Melberg (2014): I2 35 Pellegrini (2012) -3 70 5.70 17 Rolls (2005) -7.60 5.66 200 Ryan (2003) -5.70 NR Ryan (2014) -7.00 -3.31 -7.30 6.95 5.90 Sacks (2009) 811 Teixeira (2010) 106 Toobert (2000) **BMI 1 Total** -5.4 4869 Carels (2004): I1 -7.00 21 Carels (2004): 12 -5.40 NR 23 Damschroder (2014): I1 -2.80 160 Damschroder (2014): I2 -1.40 159 Ebbeling (2007): I1 -5.80 NR 37 Ebbeling (2007): 12 -1 20 NR 36 NR -15.00 55 Esposito (2004) Foster (2010) 154 Frimel (2008) -9.70 4.00 15 Gorin (2013): -7 30 9 95 99 Kumanyika (2012): I1 NR -1.61 124 Kumanyika (2012): 12 -0.62 137 Lagerstrom (2013) NR 4336 -3.80 NR Latner (2013) 90 Moore (2003) 0.00 NR 415 Nackers (2013) -6.23 0.94 Perri (2014) -11.07 NR 161 Pinto (2013): I1 -5.40 0.80 48 Pinto (2013): I2 -6.00 0.80 49 Pinto (2013): I3 -3.60 0.80 47 Wadden (2004) -8.33 8.63 43 72 Yancy (2010) -11.40 NR Yeh (2003) -1.70 3.00 BMI 2 Total -4.3 6381 Dalle Grave (2013): I1 -18.10 14.30 Dalle Grave (2013): I2 -15.90 45 Goodpaster (2010): I1 -12.10 NR 67 NR 67 Goodpaster (2010): 12 -9.90 Hakala (1993): I1 F -15.70 9.00 20 Hakala (1993): I1 M -13.10 8.80 10 Hakala (1993): I2 F -10 40 13 40 20 Hakala (1993): I2 M -15.60 12.00 10 Mingrone (2002): F -7.10 22 Mingrone (2002): M -9.10 NR 11 Rudolph (2016) -4 5 NR 190 -5.10 Stern (2004): I1 8.70 64 Stern (2004): 12 8.440 Torgerson (1997) -6.30 8.70 Abbrevations: BMI: Body mass index; NR: not reported; I1: Weight loss (kg) Intervention group 1; I2: Intervention group 2; kg: Kilogram; CI: Confidence interval

**FIGURE 3** Quantitative pre-post analysis (weight loss [kg] with 95% CI)

Research Group, 2010). In addition, Leblanc et al. analysed RCTs with a mean baseline BMI ranging from 24 to 42 kg/m<sup>2</sup> and over a period of 12–18 months. Out of 67 behaviour modification-based trials, the mean BWL in comparison to the control groups was 2.39 kg (95% CI,

-2.86 to -1.93) (LeBlanc et al., 2018). Therefore, our results are comparable to these outcomes.

The analyses of the RCTs were extended to pre-post comparisons where a stratified overview across all three different obesity classes was possible. BWL was 6% for class I obesity, 5.5% for class II obesity and 6.3% for class III obesity. All obesity classes achieved the recommended BWL of 5-10%.

Thus, for class II obesity the data synthesis of RCTs versus pre-post design studies was similar. For class III obesity this comparison was not possible due to the lack of RCTs. Interestingly, for class I obesity the synthesis of data for the different study types differed by 2% BWL, with the greater BWL achieved in pre-post studies (6% BWL in pre-post, 3.8% BWL in RCTs). This could be attributed to the weight-management programs conducted in the included pre-post studies being more effective for BWL. However, there may be some influencing factors regarding motivation or placebo effect. In the prepost studies, all participants were aware that they received an intervention. This may have resulted in higher expectations and greater motivations for lifestyle change, in comparison with those in RCTs where participants are already aware at study inclusion that they may only receive the less effective intervention status (Enck, Klosterhalfen, Weimer, Horing, & Zipfel, 2011; Sneed et al., 2008; Weimer, Colloca, & Enck, 2015). This principle is also known from drug trials.

Overall, hypothesis 1 was rejected since BWL was rather similar across the three obesity classes for pre-post design studies.

## 4.2 | Hypothesis 2 confirmed: "BWL in class III obesity shows a large range of variation within and across studies"

Interestingly, the conventional treatment program for patients with class III obesity varied extremely. This aspect contributes to the large range of variations in BWL outcome (%) in class III obesity, thus confirming the second hypothesis. Several factors interfere with BWL, both negatively and positively. On the one hand, there was a trend that BWL increased with the intensity. In detail, class III obesity study designs and treatments differed in contrast to class I and II with partly higher intensities and longer durations (Dalle Grave et al., 2013; Hakala et al., 1993) as well as modified designs regarding outpatient interventions with individual meetings (Hakala et al., 1993) or group meetings (Rudolph et al., 2016; Torgerson et al., 1997). Nevertheless, the factors of personal motivation and comorbidities affect BWL and may lead to a great variety within and between studies (Williams, Grow, Freedman, Ryan, & Deci, 1996). Therefore, further insights into motivation for BWL in class III obesity could help to improve conservative BWL treatment. For example, the personal intention against or for bariatric surgery could have great impact on BWL: Intention to bariatric surgery may lower BWL during a conservative BWL program.

### 4.3 | Implications for class III obesity

BWL in people with class III obesity was not higher than in those with class I or II obesity and, the variation of BWL was high within and across class III obesity studies. This emphasizes that for these patients bariatric surgery is a good alternative if not even first choice treatment since greater BWL results can be achieved (Wolfe, Kvach, & Eckel, 2016). Restrictive dietary programs such as total meal replacements are used more frequently in class III obesity. These programs, which are commonly very low caloric, are more effective than food-based or low caloric diets (Ard et al., 2019) but drop-out rates are also often high (>30%) in these programs (Bischoff et al., 2012).

However, not all patients wish to undergo either bariatric surgery or a formula based or other extreme diet. Although anthropometric changes are small in moderate conservative BWL programs, it is extremely important to continue to offer this treatment option for these patients and undecided patients in order to promote the stabilisation and/or improvement of physiological and psychological factors (Fabricatore & Wadden, 2004; Lasikiewicz, Myrissa, Hoyland, & Lawton, 2014). These programs are also important for the prevention of continued weight gain and halting the progression of comorbidities, which are the likely outcomes if untreated (Anderson & Konz, 2001). These programs also instil skills surrounding goal setting, motivation and decision making, which consequently can assist in the stabilisation of physiological and psychological factors (Fabricatore & Wadden, 2004; Lasikiewicz et al., 2014). Therefore, moderate conservative BWL programs as a treatment option for patients with obesity should not be undervalued, and the decision for the specific treatment pathway should be based on the personal situation and desires of the patient.

In order to avoid disappointment and to achieve the best results, it is necessary to treat the patients by a multidisciplinary team as recommended by the current guidelines (Fitzpatrick et al., 2016).

### 4.4 | Strengths and limitations

Overall, this systematic review has its limitations and strengths. A common problem with studies offering diets and behavioural changes is that blinding of the participants and research personnel is impossible. Therefore, the risk of performance bias may be high. Finally, although not scope of this review, we like to mention that this review is not considering the long-term effects of the interventions and therefore no statement about BWL maintenance can be made for the different obesity classes.

Furthermore, as the aim of this analysis was to compare the BWL in moderately intensive BWL programs, the search was not limited to specific standardized treatment programs such as Weight Watchers. This procedure may have contributed to the observed high heterogeneity across the studies (Normand, 1999). Besides, the funnel plot suggests that there might be a publication bias, since studies with small effects or no effects are short-handed. This appears to be a common bias in publications (Dickersin, Min, & Meinert, 1992). In addition, for the statistics of BWL aggregated BMI data were used. Therefore, the accuracy of the data is not as high as possible. Indeed, the analysed group consists in large parts of the described BMI class, but there are almost always other BMI classes represented. This leads to a bias of results. In consequence, out of these results only a trend can be deduced. To minimize this effect, we excluded studies with no distinct participants' characteristics.

To deal with the increasing amount of published studies regarding BWL programs (37,164 hits in PubMed since the last 5 years) we have chosen a search strategy which is common in the development process of evidence-based guidelines. In this case the evidence level is highest in meta-analyses followed by RCTs and non-controlled studies (Ball, Sackett, Phillips, Straus, & Haynes, 2009; Phillips, 2004).

Finally, a limitation of this analysis is that the comparison across all obesity classes based only on RCTs could not be performed due to the lack of studies in class III obesity. A reason could be that the study designs examining conservative treatments often *ab initio* exclude participants with a BMI greater than 39.9 kg/m². A rationale behind this procedure is that these patients may frequently use medications or have mobility limitations, for example, due to knee osteoarthritis.

A special strength of this review is that we aggregated a great amount of RCTs, RTs and BAs, to create a large data basis. In total, 83 original articles (RCTS, RTs and Bas) were included in this analysis, leading to high external validity. Eventually, we were able to provide a stratified overview across the different obesity classes as intended. In addition, we followed a conservative approach and investigated a mixed obesity population.

### 5 | CONCLUSION

When comparing the results across the different obesity classes undergoing a moderate BWL program, there are hardly any differences between the individual classes for BWL in %. To achieve greater BWL than the reached 4–6% from baseline body weight, more intensive program regimes (or bariatric surgery) are probably necessary.

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#### CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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#### SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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Supplement 1.1.: Intervention description of RCTs by obesity class

Author (Year)	Intervention
Author (Tear)	Description
BMI 1	Description
	1. C: booklet by British Heart Foundation of self-help weight-management strategies
(Ahern et al., 2017)	2. I: weekly attendance at local Weight Watchers meetings
·	C: maintain usual dietary and exercise habits; waiting list
(Blumenthal et al., 2000)	2. I: exercised 3 to 4/week; LEARN behavioural weight management program; reduced calories
(Cohen, D'Amico,	1. C: no special instructions or materials; usual care
& Merenstein,	2. I: monthly behavioural session; experimental materials
1991) (de Vos,	2.11 Monthly Scharloural Session, experimental materials
Runhaar, &	
Bierma-Zeinstra,	1. C: no intervention; free to undertake any health-promoting activities
2014)	2. I: lifestyle intervention, consisting of diet and exercise
(Runhaar et al., 2015)*	
(Elmer et al.,	
2006)	1. C: advice only (National High Blood Pressure Education Program lifestyle recommendations)
(Appel et al., 2003)*	2. I: group and individual sessions; DASH diet; moderate-intensity physical activity
(Greaves,	1. C: information about cardiovascular risk and the effects of diet and physical activity
Poltawski,	<b>2. I:</b> dietary changes; minimum of 150 mins/week of moderate activity; waste the waist
Garside, & Briscoe, 2017)	program
(Hardcastle,	1. C: received standard information
Taylor, Bailey, &	2. I: standard exercise and nutrition information; up to five counselling session
Castle, 2008) (Heshka et al.,	2.1. Standard exercise and national information, up to five coansening session
2000)	1. C: two 20-minute sessions with nutrition; printed materials and self-help resources
(Heshka et al.,	2. I: meetings at Weight Watchers
2003) * (Jansson,	
Engfeldt,	1. C: information about dietary; increase of physical activity
Magnuson, Pt, &	2. I: regular appointments with experts; personalized regular exercise; energy restriction
Liljegren, 2013)	4. Consideration are an annual
(Jebb et al.,	1. C: weight loss advice at general practice
2011)	2. I: free access to weekly community-based Weight Watchers meetings  1. C receive Health Canada's food guide; no further advice
(Jenkins et al., 2017)	2. I: dietary advice; no advice for exercise
,	1. C: were told to lose weight, but received no counselling/group support
(Jones et al., 1999)	<b>2.</b> I: dietary advice such as food selection, caloric restriction and preparation; no exercise plan
(Morgan et al.,	
2009)	1. C: maintain their current diet and exercise pattern
(Truby et al., 2006) *	2. I: meetings at Weight Watchers
(Nanchahal et	1. C: usual care in general practice
al., 2012)	2. I: visits by trained advisors in primary care centres
(Ockene et al.,	1. C: received usual care
2012)	2. I: individual and group sessions; increase walking; advice on nutrition (change)
(Puhkala et al.,	1. C: Waiting list
2015)	2. I: monthly lifestyle counselling; advice on diet, physical activity and sleep
(Nanchahal et	1. C: twice consultation with dietitian; print material about dietary and physical activity
al., 2012)	2. I: community-based Jenny Craig program; plus one initial appointment
(Ockene et al.,	1. C: consultation with dietitian; print material about dietary and physical activity
2012)	2. I: received all program material; free-of-charge pre-packaged prepared foods
(Puhkala et al.,	1. C: visits every 3 months; advice on life-style changes, physical exercise, hypo-caloric diet
2015)	2. I: identical treatment as in the control group plus a group motivational intervention
(Ross et al.,	1. C: advice regarding lifestyle
2012)	2. I: intervention with advice on physical activity and balanced diet

(Shea et al.,	1. C: no counselling
2011)	2. I: training and behaviour-based counselling to lose weight
(Shuger et al., 2011)	1. C: self-directed weight loss manual based on "Active Living Every Day" (ALED) and "Healthy Eating Every Day" (HEED) 2. I: Group-based behavioural weight loss program; sessions based on ALED and HEED
(Stevens et al., 2001)	1. C: no intervention 2. I: lifestyle interventions; group meetings and individual counselling focused on dietary change, physical activity, and social support
(Vissers et al., 2010)	1. C: no intervention 2. I: -600 kcal/d; meetings with dietician; aerobic exercise training
BMI 2	
(Anton et al., 2011)	<ul><li>1. C: maintain the usual eating and physical activity patterns</li><li>2. I: weekly group-based weight management session; exercise sessions; deficit of 750kcal/d</li></ul>
(Davis Martin et al., 2006)	1. C: received no special instructions     2. I: monthly active intervention; individually prepared treatment materials
(Perri et al., 2008)	1. C: newsletters, containing advice on weight-loss and recipes for low-calorie meals 2. I: low-calorie eating pattern; increased physical activity; behaviour modification strategies
(Stolley et al., 2009)	1. C: newsletters with advice on general health and safety topics 2. I: Social Cognitive Theory: changes in cognitions, behaviours, and social support
(Tsai et al., 2010)	1. C: quarterly meetings with primary care providers (PCP) 2. I: same visits/ materials as the Control group; brief (15–20 min) individual visits
(Villareal et al., 2006)	1. C: received no therapy 2. I: low-calorie diet; exercise training; behavioural group-based therapy
(Villareal et al., 2011)	1. C: no advice on diet or activity habits; weight-loss or exercise program prohibited 2. I: weight-management instruction; exercise training; deficit of 500-750kcal per day
(Wadden et al., 2011) (Sarwer et al., 2013) *	1. C: quarterly meetings about weight management with primary care provider (PCP) 2. I: PCP visits; sessions with lifestyle coaches; hypocaloric diet; increase of the physical activity
Abbreviations C: Control Group; I	: Intervention Group; min(s): Minute(s); kcal: Kilocalorie; d: Day; * = subpaper, which consists of same study population

## Supplement 1.2.: Intervention description of pre-post trials by obesity class

Author (Year)	Intervention
	Description
BMI 1	
(Abedi et al., 2010)	I: educational booklets and sessions/discussions (reduce cholesterol and saturated fat; increase fruits vegetables, fish and high fibre foods)
(Acharya et al., 2009)	<b>I:</b> standard behavioural treatment program; group sessions; program "Dovepress"; different diet groups
(Allen, Stephens, Dennison Himmelfarb, Stewart, & Hauck, 2013)	I: behavioural interventions based on social cognitive theory; moderate intensity physical activity
(Arrebola et al., 2011)	<b>I:</b> lifestyle modification program; diet; exercise; psychological support in primary healthcare setting
(Brinkworth, Noakes, Buckley, Keogh, & Clifton, 2009)	I1: energy-restricted; very low-carbohydrate diet; behavioural self-management strategies I2: energy-restricted; high-carbohydrate diet; behavioural self-management strategies
(Brochu et al., 2009)	<ul><li>I1: diet and nutrition classes; caloric restriction; no change of physical activity</li><li>I2: diet and nutrition classes; caloric restriction; resistance training</li></ul>

	11: information about diet, exercise plan, behaviour modification strategies; classes with
	dietitians
(Cousins et al.,	12: classes with dietitians; modified information (partner support and parenting skills to
1992)	encourage family changes in eating and exercise behaviours)
(Ello-Martin, Roe,	I1: behaviour change; physical activity; reduced fat intake
Ledikwe, Beach, &	
Rolls, 2007)	12: behaviour change; physical activity; reduced fat intake and increased water-enrich foods
(Foster et al.,	I1: hypocaloric, almond-enriched diet; behavioural treatment
2012)	12: hypocaloric nut-free diet; behavioural treatment
(Foster-Schubert	
et al., 2012)	I: calorie-reduced, low-fat diet; moderate-intensity aerobic exercise program
(Griffin et al.,	<b>I1:</b> High protein diet; physical activity
2013)	12: High carbohydrate diet; physical activity
(Hollis et al.,	I: Meeting with nutrition/behavioural counsellor; moderate calorie reduction; increased
2008)	physical activity
(Jakicic et al.,	<b>I1:</b> diet; physical activity; Standard behavioural treatment
2012)	12: diet; physical activity; STEP program
(Jeffery, Wing,	11: standard behavioural therapy program; reduction of daily energy intake; exercise activity
Sherwood, & Tate, 2003)	12: identical training in diet and behaviour-control skills plus high physical activity
(Johnston, Rost,	The received training in diet and benaviour-control skills plus flight physical activity
Miller-Kovach,	
Moreno, & Foreyt,	
2013)	I: Weight Watchers Membership
(Kirby et al., 2011)	I: dietary intervention; exercise intervention; motivational lectures
(Koniak-Griffin et	It group adjustion plus individual teaching and coaching
al., 2015) (Laatikainen et al.,	I: group education plus individual teaching and coaching
2007)	I: behavioural program with diet and physical activity
(McManus,	
Antinoro, & Sacks,	11: moderate fat (Mediterranean) diet; behavioural modification skills; physical activity
2001)	12: standard low-fat diet; behavioural modification skills; physical activity
(Mellberg et al.,	I1: Palaeolithic diet (information/cooking); behavioural changes
2014) (Pellegrini et al.,	12: Nordic Nutrition Recommendations (information/cooking); behavioural changes
(Pellegrini et al., 2012)	I: behavioural weight-loss intervention (changing eating and activity behaviour)
•	I: energy-restricted low-fat diet; increased physical activity; behaviour modification;
(Rolls, Roe, Beach, & Kris-Etherton,	different diet interventions (I1: two snacks/d; I2: one soup/d; I3: two soups/d; I4:
2005)	comparison diet)
	11: hypocaloric diet; eating behaviour; stress management; modification of binge eating
(Ryan, Nicklas,	12: diet and therapy as I1 plus aerobic exercise (3x per week)
Berman, & Elahi, 2003)	13: diet and therapy as I1 plus resistive training (3x per week)
(Ryan &	
Harduarsingh-	I1: weight loss alone (diet)
Permaul, 2014)	12: aerobic exercise plus weight loss (diet)
	I: Behavioural counselling and physical activity, four different diet interventions (I1: Low fat,
(Sacks et al.,	average protein; I2: Low fat, high protein; I3: High fat average protein; I4: High fat, high
2009)	protein)
(Teixeira et al.,	
2010) (Silva et al., 2010)	
(Silva Et al., 2010)	I: group sessions; physical activity; moderate energy deficit; self-determination theory
(Toobert,	
Glasgow, &	It group physical activity accions Payanal Districtures and a second behavioured
Radcliffe, 2000)	I: group physical activity sessions; Reversal Diet; stress management; behavioural therapy
BMI 2	
(Carels, Darby, Cacciapaglia, &	I1: lifestyle change
Douglass, 2004)	12: lifestyle change with self-control skills intervention (based on LEARN Program)
(Damschroder et	11: in-person Aspiring to Lifelong Health (ASPIRE) weight-loss program
al., 2014)	12: standard weight-loss program (MOVE!)
, , = 1	

(Ebbeling, Leidig,	11. Law glycopmic diet and education, physical activity recommendation
Feldman, Lovesky,	11: Low glycaemic diet and education; physical activity recommendation
& Ludwig, 2007)	12: Low fat diet and education; physical activity recommendation
(Esposito et al.,	I: advice on how to achieve a reduction in total body weight of at least 10%; Behavioural
2004)	and psychological counselling; increased physical activity
(Foster et al.,	It law fat dist combined with a comprehensive lifestyle modification program
2010)	1: low-fat diet, combined with a comprehensive lifestyle modification program
(Frimel, Sinacore,	11: behavioural strategies, balanced diet, prohibition of exercise program
& Villareal, 2008)	12: behavioural therapy plus exercise (progressive resistance training)
(Gorin et al., 2013)	I: standard behavioural weight loss treatment with diet and physical activity
·	
(Kumanyika et al.,	11: behavioural weight loss program; primary care providers meetings
2012)	12: behavioural weight loss program; primary care providers and lifestyle coaches meetings
(Lagerstrom, Berg, & Haas, 2013)	I: change in dietary and exercise behaviour through behavioural interventions
(Latner, Ciao,	in ordinge in dietary and exercise senation through senational interventions
Wendicke,	
Murakami, &	I: group behavioural treatment; behaviour modification; developing
Durso, 2013)	healthy eating behaviours; physical activity
(Moore et al.,	I: nutrition training program; reduction of dietary energy intake; increase of physical activity
2003) (Nackers et al.,	1. Hutilion training program, reduction of dietary energy intake, increase or physical activity
2013)	I: 1500kcal per day diet; standard behavioural lifestyle intervention
(Perri et al., 2014)	I: behavioural weight-loss treatment; low-calorie eating patter; increased physical activity
	I1: group-based behavioural weight loss treatment
(Pinto, Fava,	12: Weight Watchers meetings (free of charge)
Hoffmann, & Wing, 2013)	<b>13:</b> Combination of I1 and I2
	1: 1200–1500 kcal/d balanced deficit diet; LEARN Program; behavioural weight-control
(Wadden et al.,	
2004) (Yancy et al.,	topics; physical activity
2010)	I: small-group meetings with diet; physical activity
,	11: instruction about nutrition, diet, physical activity, and skill-based intervention
(Yeh et al., 2003)	12: instruction about nutrition, diet, physical activity, and standard office-based meetings
BMI 3	
(Dalle Grave,	
Calugi, Gavasso, El	
Ghoch, &	I1: high-protein; cognitive behaviour therapy
Marchesini, 2013)	12: high-carbohydrate diet; cognitive behaviour therapy
(Goodpaster et	I1: initial physical activity and diet
al., 2010)	12: identical dietary intervention; physical activity delayed for 6 months
(Hakala, Karvetti,	
& Ronnemaa,	11: Group counselling; nutritional courses, physical activity, advice for motivation
1993)	12: Individual counselling; nutritional courses, physical activity, advice for motivation
(Mingrone et al.,	I: diet protocol (20 kcal per kg fat-free mass; 55% carbohydrates, 30% fat, and 15%
2002)	proteins); treatment options of obesity
(Rudolph,	
Hellbardt, Baldofski, de	
Zwaan, & Hilbert,	
2016)	I: Change in dietary and exercise behaviour through behavioural interventions
(6)	11: Carbohydrate-restricted diet; no specific exercise program; group-teaching sessions
(Stern et al., 2004)	12: Carbohydrate- and fat-restricted diet; no specific exercise program; group-teaching
(Samaha et al., 2003) *	sessions
(Torgerson,	
Lissner, Lindroos,	
Kruijer, & Sjostrom,	It was the distance and had a distance because
1997)	I: regular dietary and behavioural support
Abbreviations	

#### **Abbreviations**

C: Control Group; I: Intervention Group; min(s): Minute(s); kcal: Kilocalorie; d: Day; RCT: Randomized controlled trial; RT: Randomized Trial; BA: Before-and-after comparison (without control); NRT: Nonrandomized controlled trial; \* = subpaper, which consists of same study population

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**Supplement 2: Characteristics across studies** 

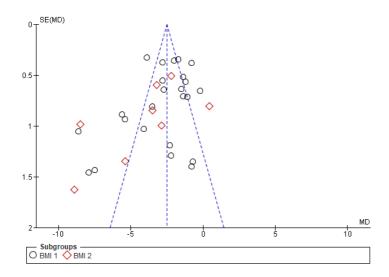
	Median	IQR	Minimum	Maximum
Study length (months)				
All (n=31)	12	[6 - 18]	6	36
RCTs BMI 1 (n=24)	12	[6-24]	6	36
RCTs BMI 2 (n=8)	6	[6 -7.5]	6	24
RCTs/RTs/BAs BMI 1 (n=27)	12	[6-12]	6	24
RCTs/RTs/BAs BMI 2 (n=16)	11	[6-13.5]	6	24
RCTs/RTs/BAs BMI 3 (n=7)	12	[12-18]	6	24
Sample size				
All (n=83)	109.5	[60 - 261]	14	5025
RCTs BMI 1 (n= 24)	323	[106.5 - 528.8]	30	1191
RCTs BMI 2 (n=8)	99,5	[46 - 174.8]	27	261
RCTs/RTs/BAs BMI 1 (n=27)	106	[59.5 - 149]	14	1685
RCTs/RTs/BAs BMI 2 (n=16)	90	[60 - 161]	30	5025
RCTs/RTs/BAs BMI 3 (n=7)	74	[49,5 – 132,5]	33	134
Age of study population (years)				
All (n=83)	48.5	[44.9 - 54.3]	22.4	71
RCTs BMI 1 (n=24)	48.8	[45 – 53.1]	39.9	66.6

All (11–65)	40.5	[44.5 - 54.5]	22.4	<i>/</i> 1
RCTs BMI 1 (n=24)	48.8	[45 - 53.1]	39.9	66.6
RCTs BMI 2 (n=8)	55.3	[47.3 - 60]	40.7	71
RCTs/RTs/BAs BMI 1 (n=27)	46.7	[43.6 - 53.4]	22.4	64
RCTs/RTs/BAs BMI 2 (n=16)	49.5	[47.4 - 53]	26.9	70.3
RCTs/RTs/BAs BMI 3 (n=7)	46.7	[45.2-47.4]	37.8	54
				_
	D - 1			

	Both sexes			
Sex of study population	included	Female only	Male only	NR
All (n=83)	54	24	2	1
RCTs BMI 1 (n=24)	20	3	1	0
RCTs BMI 2 (n=8)	4	4	0	0
RCTs/RTs/BAs BMI 1 (n=27)	14	13	0	0
RCTs/RTs/BAs BMI 2 (n=16)	11	4	1	0
RCTs/RTs/BAs BMI 3 (n=7)	6	0	0	1

## **Abbreviations**

n: Number; RCT: Randomized controlled trial; RT: Randomized trial; BA: Before-and-after comparison (without control); BMI: Body mass index; IQR: Interquartile range; NR: not reported



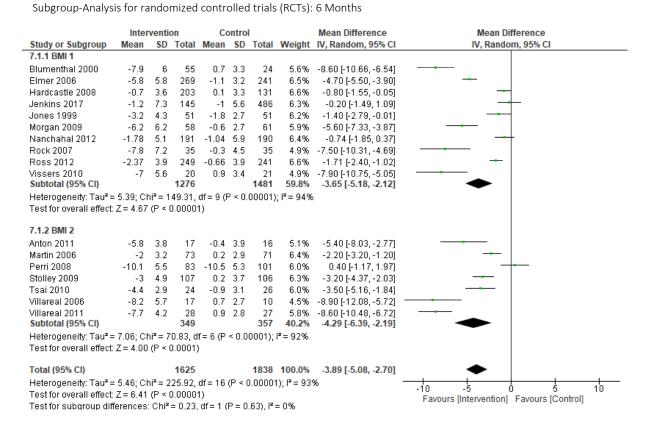
## **Abbreviations**

BMI: Body mass index; SE: Standard Error; MD: Mean difference

	S	В	PB	A/EB	D	В	RP		ОВ		Dropout*
Author (year)	1	2	6	7	8	9	10	11.1	11.2	11.3	
Ahern (2017)	++	+		++	+	+	+	++	+	NA	-
Blumenthal (2000)	+	NR		++	+	+	+	+	+	NA	+
Cohen (1991)	+1	NR		++	+	+	+	-	+	NA	+
de Vos (2014)	++	NR		++	+	+	+	+	+	NA	+
de Vos (2016)	++	NR		++	+	+	+	-	+	NA	+
Elmer (2006)	++	++		++	++	++	+		+	NA	+
Greaves (2015)	++	++		++	++	+	+	+	+	NA	+
Hardcastle (2008)	++	+		++	++	+	+	-	+	NA	-
Heshka (2003)	++	+		++	+	NR	+	-	+	NA	+
Heshka (2000)	++	-		++	+	+	+	+	+	NA	+
Jebb (2011)	++	++		++	+	+	+	++	+	NA	-
Jenkins (2017)	+	++		++	+	+	+	++	+	NA	-
Jones (1999)	+	NR		++	-	+	+	-	+	NA	+
Jansson (2013)	++	++		_	+	+	+	_	+	NA	-
Morgan Truby (2006)	++	NR		++	+	+	+	++	+	NA	+
Morgan Truby (2009)	+	NR		+		+	+		+	NA	+
Nanchahal (2012)	++	NR		++	+	+	+	++	+	NA	_
Ockene (2012)	+	NR		++	++	+	+	-	+	NA	+
Puhkala (2015)	++	++			++	+	+	+	+	NA	+
Rock (2007)	++	NR		++	+	+	+	<u> </u>	+	NA NA	+
Rock (2010)	++	NR		++	+	+	+	++	+	NA NA	+
Rodriguez-Cristobal (2017)	+1	NR		-	+	+	+		+	NA NA	<u> </u>
Ross (2012)	++	+		++	++	+	+	++	+	NA	+
Shea (2011)	+	NR		+	-	+	+	-	+	NA	+
Shuger (2011)	++	NR		++	+	++	+	++	+	NA	<u> </u>
Stevens (2001)		NR					+			NA NA	+
Vissers (2010)	+	NR		+	+	++		+	+		+
Anton (2011)	+			+	+	+	+	+	+	NA NA	+
	++	NR		++	+	++	+	+	+	NA	+
Martin (2006)		NR		++	++	+	+	++	+	NA NA	
Perri (2008)	+	NR		++	++	++	+	++	+	NA	<del>-</del>
Stolley (2009)	+	NR		+	+	+	+		+	NA	+
Tsai (2010)	+	+		+	++	+	+	+	+	NA	+
Villareal (2006)	++	NR		++	+	NR	+	+	+	NA	+
Villareal (2011)	+	NR		++	+	+	+	+	+	NA	+
Wadden (2011)	++	NR		++	++	+	+	++	+	NA	+
+ = definitely low risk of ias = probably low risk of ias /NR = probably high risk f bias - = definitely high risk f bias A = Not applicable	1. Was a concealed Performa 6. Were Attrition/ 7. Were Detection	d? nce bias (P the researd Exclusion b the outcor bias (DB):	B): ch personr vias (A/EB) ne data co	exposure level and hum  implete with	an subject	s blinded to	the study	group durii nalysis?	ng the stud	у?	. ,
<sup>1</sup> = In nested designs, andomization without larification of the andomization method was	Reporting 10. Wer Other bia 11.1. We	g bias (RP): e all measu s (OB):	red outco	mes reporte s appropriat	d?				dy protocol		

experimental studies? \*Dropout < 30%

# Supplement 5.1.



#### Supplement 5.2.

Subgroup-Analysis for randomized controlled trials (RCTs): 7-12 Months

6.76	<b>SD</b> 9.7		Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
	9.7						IV, Nulluolli, 33% CI	IV, Random, 35% CI
	9.7							
_n a		528	-3.26	9.9	211	10.7%	-3.50 [-5.07, -1.93]	
-0.0	4	15	1.3	3	15	7.4%	-2.20 [-4.73, 0.33]	<del></del>
-2.5	6.1	67	-0.8	6.1	66	8.8%	-1.70 [-3.77, 0.37]	<del></del>
-5.1	6	377	-2.3	4.2	395	13.7%	-2.80 [-3.53, -2.07]	
-2.4	7.5	191	-1.3	6.4	190	11.3%	-1.10 [-2.50, 0.30]	<del></del>
-1.1	4.4	162	0.3	4.7	150	12.8%	-1.40 [-2.41, -0.39]	
-3.4	6.6	55	0.7	3.9	58	9.0%	-4.10 [-6.11, -2.09]	<del></del>
-5	4.5	291	-1.1	3.4	294	13.9%	-3.90 [-4.55, -3.25]	+
-1.7	6.5	49	-0.9	7.4	50	6.8%	-0.80 [-3.54, 1.94]	
							-2.51 [-3.30, -1.00]	▼
				= 0.0	002); I²	= 73%		
5.77	(F ~ C	.0000	')					
-8.2	5.7	17	0.7	2.7	10	5.7%	-8.90 [-12.08, -5.72]	
		17			10	5.7%	-8.90 [-12.08, -5.72]	
cable								
5.48	(P < 0	0.0000	I)					
		1752			1439	100.0%	-2.84 [-3.81, -1.88]	•
3: Ch	$j^2 = 40$	3.39. d	f=9 (P	< 0.0	0001):	l² = 79%		<del></del>
				3.0				-10 -5 0 5 10
	•			(P =	0.0001	). I <sup>2</sup> = 93.1	%	Favours [Intervention] Favours [Control]
	-5.1 -2.4 -1.1 -3.4 -5 -1.7 -6; Ch 5.77 -8.2 cable 5.48 63; Ch 5.77	-2.5 6.1 -5.1 6 -2.4 7.5 -1.1 4.4 -3.4 6.6 -5 4.5 -1.7 6.5 06; Chi <sup>2</sup> = 2: 5.77 (P < 0 -8.2 5.7 cable 5.48 (P < 0	-0.9 4 15 -2.5 6.1 67 -5.1 6 377 -2.4 7.5 191 -1.1 4.4 162 -3.4 6.6 55 -5 4.5 291 -1.7 6.5 49 1735 -6; Chi² = 29.75, d' 5.77 (P < 0.0000° -8.2 5.7 17 17 -3able 5.48 (P < 0.0000° -752 -6; Chi² = 43.39, d' 5.77 (P < 0.0000°	-0.9	$ \begin{array}{cccccccccccccccccccccccccccccccccccc$	$ \begin{array}{cccccccccccccccccccccccccccccccccccc$	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	$ \begin{array}{cccccccccccccccccccccccccccccccccccc$

#### Supplement 5.3.

Subgroup-Analysis for randomized controlled trials (RCTs): 13-36 Months

	Inter	venti	on	C	ontrol			Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
7.3.1 BMI 1									
Jansson 2013	-1.9	8.6	67	-1.2	6.9	66	4.3%	-0.70 [-3.35, 1.95]	<del></del>
de Vos 2014	-0.6	5.7	203	0.6	5.7	204	11.5%	-1.20 [-2.31, -0.09]	<del></del>
Rodriguez-Cristobal 2017	-2.5	10	400	-1	8.4	446	10.5%	-1.50 [-2.75, -0.25]	<del></del>
Ross 2012	-2.4	3.9	249	-0.7	3.8	241	14.7%	-1.70 [-2.38, -1.02]	<del></del>
Stevens 2001	-0.2	6.2	595	1.8	6.2	596	14.6%	-2.00 [-2.70, -1.30]	<del></del>
Heshka 2000	-2.9	7.3	211	-0.2	5.8	212	10.5%	-2.70 [-3.96, -1.44]	<del></del>
Elmer 2006	-4.3	7.4	269	-1.5	5	241	11.7%	-2.80 [-3.89, -1.71]	<del></del>
Ahern 2017	-6.8	9.2	528	-3.3	10.2	211	8.4%	-3.50 [-5.08, -1.92]	<del></del>
Rock 2010	-7.4	8.5	167	-2	6.7	103	7.2%	-5.40 [-7.23, -3.57]	<del></del>
Subtotal (95% CI)			2689			2320	93.4%	-2.32 [-2.99, -1.65]	•
Heterogeneity: Tau² = 0.63; 0	Chi <sup>2</sup> = 23	.89, d	lf = 8 (P	P = 0.003	2); I² =	67%			
Test for overall effect: Z = 6.7	77 (P < 0	.0000	1)						
7.3.2 BMI 2									
Wadden 2011	-4.6	8	129	-1.7	8	130	6.6%	-2.90 [-4.85, -0.95]	<del></del>
Subtotal (95% CI)			129			130	6.6%	-2.90 [-4.85, -0.95]	
Heterogeneity: Not applicable	le								
Test for overall effect: Z = 2.9	32 (P = 0	.004)							
Total (95% CI)			2818			2450	100.0%	-2.35 [-2.99, -1.72]	•
Heterogeneity: Tau <sup>2</sup> = 0.59; 0	Chi <sup>2</sup> = 24	.49, d	lf = 9 (F	P = 0.00	4); l² =	63%		-	
Test for overall effect: $Z = 7.2$									-4 -2 0 2 4
Test for subgroup difference	s: Chi²=	0.31	df = 1	(P = 0.5)	8), l²=	0%			Favours [Intervention] Favours [Control]

#### **Abbreviations**

BMI: Body mass index; SD: Standard deviation; CI: Confident Interval;

RCT: Randomized controlled trial; Intervention: group, which received body weight loss program (moderate standard behavioural and nutritional intervention with or without physical activity); Control: group, which received no information/program or to a small(er) extend

2 Results 57

**2.2 Publication 2:** "Attitude Matters! How Attitude Towards Bariatric Surgery Influences the Effects of Behavioural Weight Loss Treatment"

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# Attitude Matters! How Attitude towards Bariatric Surgery Influences the Effects of Behavioural Weight Loss Treatment

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#### Keywords

(Behavioural) weight loss  $\cdot$  Lifestyle  $\cdot$  Motivation  $\cdot$  Morbid obesity

#### **Abstract**

Introduction: Multidisciplinary obesity services at university hospitals usually treat patients with more complex and severe obesity. In addition, patients with Class 3 obesity, in particular, have different attitudes regarding the choices of therapy. *Methods:* This explorative study investigated the effect of patient attitudes towards bariatric surgery on body weight change (primary outcome) and psychological improvement (secondary outcomes: quality of life, depression, anxiety, and eating behaviour) in a 6-month moderate behavioural weight loss (BWL) programme in a university outpatient setting. *Results:* 297 patients with mostly Class 3 obesity participated in the programme. The patients did not yet have any indications for bariatric surgery. Of the participants, 37% had a positive attitude towards bariatric surgery (POS), whereas 38% had a negative attitude (NEG). The drop-

out rate was 8%. NEG participants lost significantly more body weight than the POS participants (intention-to-treat population: 4.5 [SD: 6.3] kg versus 0.4 [SD: 5.8] kg; p < 0.001). In both subgroups, anxiety, depression, the mental score for quality of life, and eating behaviour improved. **Conclusion:** A BWL treatment in a clinical setting identified 2 distinct groups with different attitudes towards bariatric surgery that were associated with different body weight change outcomes. These groups may require differently targeted programmes to achieve the best body weight loss results.

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#### Introduction

Obesity and its associated comorbidities, such as Type 2 diabetes, cardiovascular diseases, and orthopaedic ailments, are becoming a key, rapidly growing public health problem [1]. The risks of comorbidities increase with the degree of obesity compared to normal weight, with severe risks in Class 3 obesity [2]. As for psychological comor-

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bidities, overweight and obesity are associated with a higher prevalence of depression in adults, with subgroup differences observed. For example, the relationship between obesity and depression is higher in women [3–5]. Similarly, people with overweight or obesity are more likely to have anxiety symptoms [6, 7]. Furthermore, obesity is associated with a higher prevalence of binge eating disorder and night eating syndrome [8, 9]. Overall, the level of psychological distress is high in these patients, especially those with Class 3 obesity [10, 11].

The aims of obesity therapy are body weight loss and the reduction of comorbidities. Thus, the therapy options for obesity are behavioural weight loss (BWL) treatments or bariatric surgery [12, 13]. Pharmacotherapy is another option for obesity management, but it is only used as an adjuvant treatment component in certain situations [13]. For BWL treatment, the body weight loss goal commonly recommended is between 5 and 10% of initial body weight within 6 months [2, 14]. However, this is not always achieved [15, 16], and body weight loss maintenance remains a major challenge [17]. In contrast, the percentage body weight loss after bariatric surgery is much higher and often equivalent to 30% or more of initial body weight, even for long-term outcomes [18, 19]. Nevertheless, psychological improvements (especially depressive symptoms) are observed with BWL treatments, irrespective of body weight loss success [10, 20]. Similarly, depression and anxiety improve after bariatric surgery [21, 22]. However, follow-up care is important, especially for patients with significant depression symptoms, to support body weight loss outcomes [23]. BWL treatment usually consists of a combination of nutritional, physical activity, and behavioural interventions. Consequently, a multidisciplinary approach offers the best chance for effectiveness [14].

Overall, BWL treatment programmes mainly focus on patients with Class 1 and 2 obesity [2, 24, 25]. There are no randomized controlled trials for patients with Class 3 obesity analysing the success of moderate BWL treatment programmes. Rather, the literature focuses on trials employing meal replacement strategies or extreme diets of <1,000 kcal/day for this patient population [16]. Pre-post design BWL treatment studies differ in intensity and duration for Class 3 obesity [26, 27], which may explain the high variation in body weight change outcomes across the studies [16].

According to European and American guidelines, metabolic and bariatric surgery is considered if other body weight loss attempts have failed, with a few exceptions in the case of comorbidities [14, 28]. These evidence-based guidelines help with the decision of the ap-

propriate treatment pathway, taking into account body mass index (BMI), body fat distribution, and the patient's comorbidities [29]. Patients undergoing bariatric surgery are generally younger, less well educated, have a higher BMI, and suffer more often from depression in comparison to patients participating in BWL treatments [30–32].

At the University Hospital of Tübingen, Germany, a 6-month lifestyle intervention programme for patients with obesity (VIADUKT) is offered. The programme targets patients with obesity, with the majority of them having Class 3 obesity (mean BMI =  $42.7 \text{ kg/m}^2$ ). The heterogeneity of the patients taking part in VIADUKT is high, and 75% of the patients are directly referred from the multidisciplinary obesity service of the university hospital. Some patients do not fulfil the criteria for bariatric surgery due to the lack of a prior BWL treatment (BMI  $\geq$ 40 kg/m<sup>2</sup> but BMI  $\leq 50 \text{ kg/m}^2$  without comorbidities), whereas others have the indication but do not wish to undergo bariatric surgery and prefer to focus on BWL treatment approaches [33]. Thus, the underlying motivations for participating in VIADUKT are quite different, and the participants have different attitudes towards bariatric surgery. Willingness to change and ambivalence towards change were identified as key variables for successful behavioural change. For example, tailoring successful interventions, identifying stages of motivation, and promoting motivation for change have been recognized as pivotal within the treatment of eating and weight disorders [34, 35].

In this explorative study, we address the issue that clinical outpatient BWL treatment programmes for patients with Class 3 obesity are facing in practice: a heterogeneous patient population with different attitudes towards bariatric surgery. Therefore, the aim of this study was to characterize the VIADUKT programme with regard to change of body weight as the primary outcome and quality of life, psychological factors (depression and anxiety), and eating behaviour as secondary outcomes, as well as to distinguish between patients with different attitudes towards bariatric surgery. Specifically, the focus was on patients with a positive attitude towards bariatric surgery (POS group) in contrast to those patients with a negative attitude (NEG group). We hypothesized that (i) the baseline characteristics of NEG participants, in contrast to POS participants, have lower values on measures of body weight and psychological scores; (ii) body weight loss is lower in POS participants in comparison with NEG participants; (iii) eating behaviour improves, but inferiorly, in POS vs. NEG participants; and (iv) quality of life, anxiety, and depression improve over the course of treatment in all participants.

#### **Materials and Methods**

Study Design and Participants

This is a prospective follow-up study, recruiting participants undergoing the BWL treatment VIADUKT at the University Hospital Tübingen, Germany. The study is approved by the Ethics Committee of the University Hospital Tübingen, Germany with the number 391/2019BO2.

Recruitment was conducted via the multidisciplinary obesity service of the university hospital, consisting of an interdisciplinary team from psychosomatic medicine, endocrinology, nutritional medicine, sports medicine, and visceral surgery. This multidisciplinary obesity service is the initial contact point for bariatric surgery at the university hospital, which is significantly involved in the allocation of the therapy pathway. In addition, leaflets were distributed among general practices in the area of Tübingen and the university hospital itself.

Inclusion criteria were an age of at least 18 years; in addition, a BMI of at least 30 was desired but not required. Participants were excluded in the case of language difficulties. This was determined if communication via telephone was not possible.

Data from May 2014 (programme start) to September 2019 were analysed which corresponded to 297 patients having participated in the programme. Baseline characteristics were collected before intervention and included body weight, body height, and questionnaires for quality of life, anxiety, depression, and eating behaviour. The details for these measurements are described in detail in the section "outcomes."

#### Treatment

"VIADUKT" is an acronym for "Verhaltensintervention bei Adipositas am UKT," which is a BWL treatment for patients with obesity at the University Hospital Tübingen. The intervention consists of ten 75-minute group meetings and twenty 45-min guided exercise sessions delivered by a multidisciplinary team, which consisted of the disciplines psychosomatic medicine, nutritional science, and sports medicine. The group meetings focus on nutritional education and promote lifestyle changes. Specifically, patients are educated on motivational strategies, flexible and controlled eating patterns, basics for regular physical activity, stress management techniques, and strategies for long-lasting weight loss maintenance. This is according to the German clinical practice guidelines for obesity [36].

Demographics were assessed by standard questionnaires ahead of the programme, including nationality as an answering option using a blank field. Body weight was assessed using a calibrated scale at the end of or before the group meetings. Criteria for successful intervention exposure were participation of at least 80% in the group meetings and exercise sessions; otherwise, the participants were defined as non-completers. Prior to the course, the participants contributed to the costs with 20% of the total amount; the rest of the amount was covered by health insurance. In case of an 80% participation in the programme, the personal contribution was refunded by the health insurance, independent of body weight change outcome.

#### Outcomes

Body weight change in kilogram was the primary outcome for this programme and was measured by standard techniques, using the same calibrated scale (Seca 701; Vogel & Halke, Hamburg, Germany) before (T0) and at the end of the intervention (6 months later, T1). For the measurement, participants wore lightweight clothes and no shoes. Height was measured in centimetres using a stadiometer at baseline only.

Secondary outcomes were measured via questionnaires for quality of life, depression, anxiety, and eating behaviour and were also assessed at T0 and T1. The applied questionnaires are described below in detail. The patients were asked once about their attitude towards bariatric surgery using the open question: "What is your attitude towards bariatric surgery?" The answers were categorized into: "Yes, bariatric surgery is an option for me" (POS), "No, bariatric surgery is not an option for me" (NEG), "I am not sure" (Uncertain), and if no information was given, the participants were referred to as "Not Clear". The results for primary and secondary outcomes are presented for the whole group and for the 2 subgroups POS versus NEG.

The Patient Health Questionnaire (PHQ-9) is a screening tool for depression and consists of 9 items. The possible answer options are "not at all," "several days," "more than half of the days," or "nearly every day." Once completed, a score is calculated and categorized into none to minimal (0–4), mild (5–9), moderate (10–14), moderately severe (15–19), or severe (20–27) levels of depression [37].

The Generalized Anxiety Disorder Questionnaire (GAD-7) is used for screening generalized anxiety disorder and consists of 7 items. The possible answer options are "not at all," "several days," "more than half of the days," or "nearly every day." Once completed, a score is calculated and categorized into minimal (0–4), mild (5–9), moderate (10–14), or severe (15–21) anxiety [38].

The Short Form 12 contains 12 items to assess health-related quality of life, consisting of mental and physical component summaries that compare the patient's outcome to the general US population [39]. The average is set at 50, with a standard deviation (SD) of 10 and higher (lower) scores indicate a better (worse) health status.

The German version of the *Three-Factor Eating Questionnaire*, which contains 3 subscales ("Cognitive Restraint," "Disinhibition," and "Feelings of Hunger"), focuses on eating behaviour and largely consists of dichotomous yes/no questions [40].

The above questionnaires have been used and validated in patients with obesity (anxiety and depression [22, 41], quality of life [42, 43], and eating behaviour [22, 44, 45]).

#### Statistical Analysis

The data analysis was performed with SPSS Statistics for Windows, Version 24.0 [46]. For continuous variables, normal distribution was tested with the Kolmogorov-Smirnov test and equality of variances between groups with Levene's test. Data are reported as mean (SD), confidence interval along with the median (interquartile range) due to non-parametric data distribution. Frequencies are given as percentages (%).

Baseline differences between the 2 subgroups POS and NEG were tested with the Mann-Whitney U test for metrical data and with the  $\chi^2$  test or the Fisher's exact test for nominal data when the frequency of cells was too low. Differences between T0 and T1 for the whole study population (body weight and psychometry) were analysed with the Wilcoxon signed-rank test. To analyse group (POS vs. NEG) and time (T0 vs. T1) interactions, the robust  $2 \times 2$  ANOVA was conducted along with the non-parametric van der Waerden test for data confirmation [47]. Since the results did not

deviate between the ANOVA and van der Waerden tests, only the ANOVA data are reported. In case of different baseline levels between the NEG and POS groups, an ANCOVA (dependent variable: differences in scores between T1 and T0, fixed factor: POSNEG group, covariable: score at T0) was performed. Two-tailed tests were applied throughout the manuscript. To account for multiple testing, only p values < 0.001 were considered as statistically significant and p values < 0.05 as a trend. The corresponding effect sizes for the  $\chi^2$  test and Mann-Whitney U test are defined as follows: 0.1 = low effect, 0.3 = medium effect, and 0.5 = high effect.

For the primary outcome, the results for the total group and both subgroups were presented in online suppl. Table 1 (see www. karger.com/doi/10.1159/000517850 for all online suppl. material) separately for the responders (weight reduction achieved) and the non-responders (weight reduction not achieved or weight gain occurred). Response was further differentiated into low (0-4.9%), medium (5-9.9%), and high  $(\ge 10\%)$  percentage body weight loss.

For secondary outcomes, "minimal clinically important differences" (MCIDs) were analysed when possible. For the analysis, MCIDs were set for anxiety and depression at a value of 4 points [37, 48] and for quality of life at 3 points [49]. Additionally, for anxiety and depression, the scores were categorized into subgroups according to the manual guidelines (depression:  $0-4 = \min$  minimal,  $5-9 = \min$ ,  $10-14 = \max$ , 15-21 = severe depression; anxiety: 15-21 = severe anxiety and the percentages of participants who switched subgroups (improved or worsened) or remained stable in their subgroup.

A hypothesis-driven simple linear regression was calculated to predict body weight change (delta body weight in kilogram between T0 and T1) based on the attitude towards bariatric surgery POS or NEG.

#### Missing Data Imputation

Missing data for primary and secondary outcomes were replaced by the predictive mean matching method after data were analysed with Little's test of missing completely at random to detect whether the missing data were random [50].

#### Primary Outcome

For the per-protocol population, participants were only included if body weight (kg) was provided at T0 and T1 of intervention, and if they were not classified as a non-completer ( $\geq$ 80% exposure). The per-protocol population consisted of 267 participants (missing data at T0 and T1: n = 7; non-completer: n = 23).

The intention-to-treat population consisted of 297 participants. The results of the predictive mean matching method did not substantially deviate from the last observation carried forward method, the latter having been methodologically criticized [51] but used by most of the lifestyle intervention studies cited in this article.

#### Secondary Outcome

In case of missing data for quality of life, depression, anxiety, or eating behaviour, either for single items or complete questionnaires at either T0 or T1, a multiple imputation with 5 iterations was performed [48, 49]. Cases with single-item imputations were included in the per-protocol population, and cases with complete questionnaires and/or single-item imputations were included in the full-data population. Participants were excluded if secondary outcome data were missing at both time points, T0 and T1 (n = 19). For the imputations, the predictive mean matching method with the predictors sex and age was used to replace single items and/or complete questionnaires that were missing at T0 or T1 [52]. The percentage of missing data for complete questionnaires ranged between 5 and 21% for quality of life, depression, anxiety, or eating behaviour at T0 or T1 (T0 eating behaviour: 5.5%, T1 eating behaviour: 20.1%, T0 anxiety: 11.9%, T1 anxiety 20.8%, T0 depression 18.3%, T1 depression 20.8%, T0 quality of life 7.2% and T1 quality of life 20.8%).

#### Results

A total of 297 (mean BMI =  $42.7 \text{ kg/m}^2$ ) patients took part in the VIADUKT lifestyle intervention programme at a university hospital setting. Out of these, 23 participated in <80% of the meetings and were classified as noncompleters. Thus, the drop-out rate was 8% for this programme.

From the total sample, 113 (38%) participants declared to not desire bariatric surgery (NEG), whereas 111 (37%) participants wanted to receive bariatric surgery (POS). Thirty participants were undecided (Uncertain), and for 43 participants, no information about their decision was available (Not Clear). In this study, the focus is on the differences between the NEG and POS groups, which represent 75% of the study population.

#### Baseline Characteristics

The POS group scored significantly higher in depression, lower in quality of life (mental and physical scores), and were younger (p < 0.001). In addition, POS participants tended to be less well educated, had higher scores in anxiety and lower scores in feelings of hunger, and were more often foreign (p < 0.05).

In contrast, body weight, sex, personal status, composition of household, and the 2 subscales of eating behaviour "cognitive restraint" and "disinhibition" were similar between the groups. A detailed overview of the baseline characteristics for the total group and the subgroups is presented in Table 1.

#### Characteristics of Non-Completers

The participants who did not complete the programme (n = 23) had a mean age of 42.4 (SD: 12.3) years, a body weight of 127.6 (SD: 23.3) kg and a BMI of 44 (SD: 5.7) kg/m<sup>2</sup>, and 73.9% were women. The drop-outs consisted of 35% NEG, 17% POS, and 48% Not Clear. There were no significant baseline differences between programme completers and non-completers (drop-outs).

Table 1. Baseline characteristics of participants

	Total group	POS group	NEG group	Statistics for POS
	mean (SD) [95% CI]	mean (SD) [95% CI]	mean (SD) [95% CI]	<b>versus</b> NEG Mann-Whitney U test/ $\chi^2$
Age, years	41.5 (12.1) [40.1–42.9]	38.9 (11) [36.9–41.0]	44.8 (12.6) [42.6–47.2]	U = 4595.500, p < 0.001,
BMI	42.7 (5.4) [42.1–43.4]	43.5 (5) [42.6–44.4]	42.4 (6.2) [41.3–43.6]	r = -0.23 U = 5320.00, p = 0.063,
Range: min to max Weight kg	27.6–63.3 123 6 (21 0) [121 2–126 0]	30.8-63.3 125 5 (21.1) [118.8-	27.6–61.4 122 8 (21 8) [121 6–129 4]	$r = -0.12$ $II - 5754 00 \ n - 0.286$
Range: min to max	74–184	126.8] 74–184	77.8–179.5	r = -0.07
	N (%)	N (%)	N(%)	
Sex (female), <i>n</i> (%)	225 (76)	(08) 68	83 (74)	$\chi^2$ (1, $N = 224$ ) = 1.422,
Nationality	229 (86) / 36 (14)	7 (80) / 19 (20)	97 (94) / 6 (6)	$\chi^2 = 0.253, \psi = -0.06$ $\chi^2 = (1, N = 199) = 8.824,$
German/10reigner Smoker	68 (23)	34 (31)	21 (19)	$p = 0.003, \phi = -0.211$ $\chi^2 (1, N = 195) = 3.803,$ $\xi = 0.051, \xi = 0.140$
Personal status				$p = 0.051, \varphi = 0.140$ $\chi^2 (1, N = 193) = 6.349,$
Single	83 (32)	32 (34)	26 (26)	$p = 0.258$ , $\varphi = 0.182$
Married	140 (54)	49 (52)	59 (60)	
Separated	5(2)	2(2) E(E)	1(1)	
Ulvorcea Widowed	21 (8) 4 (2)	3 (3) 1 (1)	10 (10) 2 (2)	
Others	6(2)	5(5)	$\frac{1}{1}(1)$	
Comp. of household				$\chi^2 (1, N = 192) = 9.729,$
Alone	40 (15)	11 (12)	18 (18)	$p = 0.126$ , $\varphi = 0.226$
With partner Alone with Child(ren)	67 (26) 19 (7)	18 (20)	35 (35) 6 (6)	
Partner and Child(ren)	93 (36)	39 (43)	33 (33)	
With parents	27 (10)	10 (11)	(9) 9	
Others	13(5)	7 (8)	3(3)	2 (1 M = 102) = 18 320
Level of education Sec. mod. school	78 (30)	36 (39)	23 (23)	$\chi^{-}(1, 10 = 193) = 16.320,$ $v = 0.002, \omega = 0.314$
Polytechnic	3(1)	3(3)	0(0)	
Sec. techn. school	87 (34)	33 (36)	34 (34)	
High school	39 (15)	12 (13)	15 (15)	
University	43 (17)	8(9)	24 (24)	
Omers	0 (3)	(6) 6	4 (4)	

	Total group		POS group		NEG group		Statistics for POS versus
	Mean (SD) [95% CI]	Median [IQR]	Median [IQR] Mean (SD) [95% CI]	Median [IQR]	Mean (SD) [95% CI]	Median[ IQR]	NEG Mann-Whitney U test
Quality of life (SF-12)							U = 3649.000, p < 0.001,
a. Mental component summary 42.4 (11.4) [41.0–43.7] b. Physical component summary 35.2 (11.2) [33.9–36.5]	42.4 (11.4) [41.0–43.7] 35.2 (11.2) [33.9–36.5]	42.1 [34.9–51.9] 34.3 [26.6–44.6]	42.1 [34.9–51.9] 39.0 (10.9) [36.9–41.1] 34.3 [26.6–44.6] 31.3 (10.5) [29.3–33.3]	39.2 [30.1–46.4] 29.3 [23.6–37.4]	45.8(11.3) [43.6–47.9] 39.0 (10.2) [37.0–40.9]	47.6 [38.2–55.0] $r = -0.29$ 39.2 [30.7–47.8] $U = 3221$ .	47.6 [38.2–55.0] $r = -0.29$ 39.2 [30.7–47.8] $U = 3221.500, p < 0.001,$
							r = -0.36
Anxiety (GAD-7)	7.8 (4.8)	7	8.8 (5.0)	8	7.0 (4.5)	9	U = 4412.500, p = 0.012,
Score	[7.3-8.4]	[5-11]	[7.8-9.7]	[5-12]	[6.1-7.8]	[3-10]	r = -0.17
Depression (PHQ-9)	9.3 (5.2)	6	11.1 (5.4)	11	7.6 (4.5)	7.5	U = 3366.500, p < 0.001,
Score	[8.7–9.9]	[6-12.8]	[10.1-12.1]	[7-15]	[6.8-8.5]	[5-10]	r = -0.34
Eating behaviour (TFEQ)							U = 5482.000, p = 0.945,
1. TFEQ-subscale: cognitive	8.5 (3.9) [8.0–8.9]	8 [6–11]	8.3 (3.7) [7.6–9.0]	8 [6–11]	8.2 (3.9) [7.6–9.1]	8 [6-10.8]	r = 0.00
restraint							U = 5093.000, p = 0.340;
2. TFEQ-subscale: disinhibition	9.9 (3.5) [9.4–10.3]	10 [7-13]	9.6 (3.6) [8.9–10.3]	10 [8-13]	10.0 (3.4) [9.5–10.7]	10 [7-13]	r = -0.07
3. TFEQ-subscale: feelings of	7.9 (3.4) [7.5–8.3]	8 [5–10.8]	7.4 (3.8) [6.7–8.1]	9 [6–11]	8.4 (3.2) [7.9–9.1]	8 [4.3–11]	U = 4605.00, p = 0.039,
hunger							r = -1.4

BMI, body mass index; CI, confidence interval; Comp. of household, composition of household; GAD-7, Generalized Anxiety Disorder Questionnaire; IQR, interquartile range; kg, kilogram; m, metre; n, sample size; PHQ-9, Patient Health Questionnaire; SD, standard deviation; Sec. mod. school, secondary modern school; Sec. techn. school, secondary technical school; SF-12, Short Form 12; POS, participants who had a positive attitude towards bariatric surgery; NEG, participants who had a negative attitude towards bariatric surgery; TFEQ, Three-Factor Eating Questionnaire. Statistics: U = Mann-Whitney U test;  $\chi^2 = \chi^2$  test;  $\varphi =$  effect size (for  $\chi^2$  test); r = effect size (for Mann-Whitney U test); p < 0.001 is considered statistically significant Body Weight Change

A detailed overview of the body weight change data is presented in online suppl. Table 1.

## Per-Protocol Population

The mean percentage reduction of body weight was 2%. This equates to a mean body weight change of -2.4 (SD: 6.1) kg, ranging from -28.2 kg to +15 kg (z = -6.325, p < 0.001, n = 267, r = -0.39). Mean percentage reduction of body weight was 4% in the NEG group and 0.4% in the POS group, equating to a mean body weight change of -4.5 (SD: 6.3) kg and -0.6 (SD: 5.8) kg, respectively (F [1,207] = 22.895, p < 0.001, partial  $\eta^2 = 0.1$ ).

## Intention-to-Treat Population

The mean percentage reduction of body weight for the total group was 2%, which equates to a mean body weight change of -2.4 (SD: 6.1) kg (z=-6.309, p<0.001, n=297, r=-0.37). In comparison, the mean percentage reduction of body weight was 4% for the NEG group (n=113) and 0.3% for the POS group (n=111), equating to a mean body weight change of -4.5 (SD: 6.3) kg and -0.4 (SD: 5.8) kg, respectively (F [1,222] = 26.600, p<0.001, partial  $\eta^2=0.107$ ).

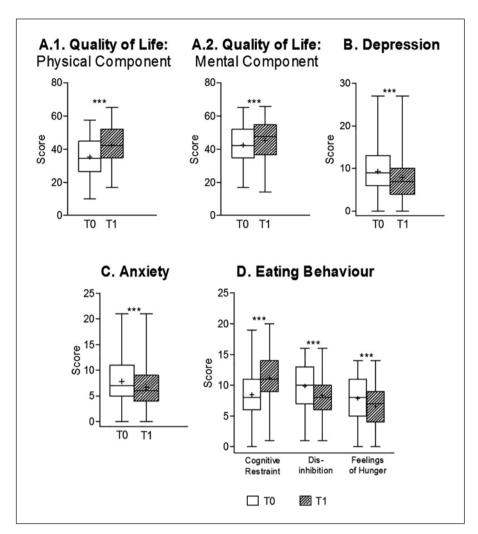
### Questionnaires

The data were analysed for the per-protocol population and for the full-data analysis. Since no differences between the approaches were found, the results of the full-data analysis are presented.

Quality of Life: Short Form 12 Questionnaire (SF12)

Overall, the physical and mental component summaries improved significantly (Fig. 1). Similar patterns were also found within the 2 subgroups POS and NEG with one exception: For the POS group, the physical component summary did not change over the course of time (Fig. 2).

Furthermore, the results were scored based on MC-IDs (online suppl. Table 2). For the mental and physical scores, the value was set at 3 points [49]. In total, the physical score improved in 41%, remained stable in 36%, and worsened in 23% of the patients; the mental score improved in 46%, remained similar in 27%, and worsened in 27% of the patients. In detail, for the POS and NEG groups, half of the participants achieved MCID for the mental scores, as well as 50% of the NEG group for the physical scores. In contrast, only one-third of the POS group reached the MCID for the physical scores. The results are reported in detail in online suppl. Table 2.



**Fig. 1.** Secondary outcomes of the whole study population: quality of life, depression, anxiety, and eating behaviour of the total study population for pre- (T0) and post-intervention (T1): Scores for physical quality of life (A.1), mental quality of life (A.2), depressive symptoms (B), anxiety symptoms (C), and eating behaviour (D) are presented. The data are shown as boxwhiskers (median with upper and lower quartiles), whose difference describes the interquartile range (IQR) and minimum and maximum (=whiskers). Mean is depicted as "+." Increases from T0 to T1 for quality of life and cognitive restraint, as well as decreases from T0 to T1 for anxiety, depression, disinhibition, and feelings of hunger, represent an improvement. \*\*\* Significant differences between T0 and T1 (p < 0.001).

Anxiety and Depression: Generalized Anxiety Disorder Questionnaire (GAD-7) and Patient Health Questionnaire (PHQ-9)

Anxiety and depression symptoms improved (Fig. 1), and both subgroups (POS and NEG) benefited equally when analysed separately (Fig. 2). The values for depression improved in 38%, worsened in 17%, and remained stable in 45% of the patients. For anxiety, the values improved in 33%, worsened in 13%, and remained stable in 54% of the patients.

In addition, the MCID was calculated conservatively, setting the boundary value at 4 points for both scores [37, 48]. For anxiety, MCID improved in 25%, worsened in 8%, and remained similar in 67% of the patients. Likewise, for depression, the MCID improved in 29%, worsened in 6%, and remained stable in 65% of the patients. The results for each subgroup separately are

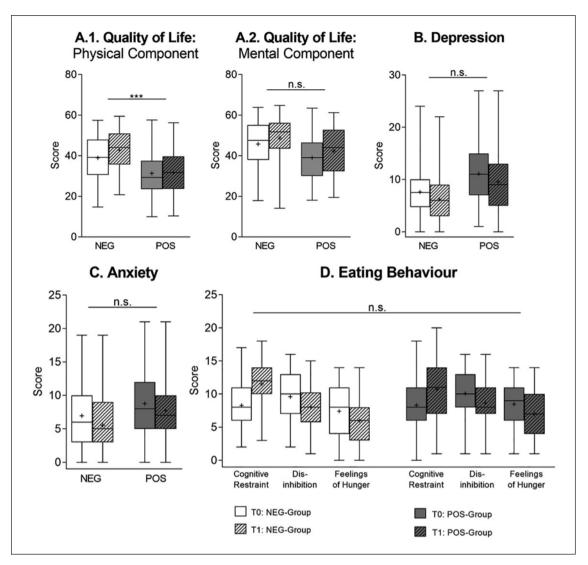
comparable to these findings and are reported in online suppl. Table 2.

Eating Behaviour: Three-Factor Eating Questionnaire (TFEQ)

The subscales "disinhibition" and "feelings of hunger" decreased from pre- to post-treatment. Although "cognitive restraint" increased in the total group (Fig. 1), the patterns were similar between the POS and NEG groups (Fig. 2).

#### Prediction of Body Weight Loss

A hypothesis-driven simple linear regression was considered to predict body weight change (kg) based on the attitude towards bariatric surgery POS or NEG. Attitude towards bariatric surgery was able to significantly predict body weight loss (F [1,222] = 26.6, p < 0.001). The  $R^2$  for



**Fig. 2.** Secondary outcomes of POS versus NEG: quality of life, depression, anxiety, and eating behaviour in patients with POS and NEG for pre- (T0) and post-intervention (T1): Scores for physical quality of life (**A.1**), mental quality of life (**A.2**), depressive symptoms (**B**), anxiety symptoms (**C**), and eating behaviour (**D**) are presented. The data are shown as box-whiskers (median with upper and lower quartiles), whose difference describes the interquartile range (IQR) and minimum and maximum (=whiskers). Mean is

depicted as "+." Increases from T0 to T1 for quality of life and cognitive restraint, as well as decreases from T0 to T1 for anxiety, depression, disinhibition, and feelings of hunger, represent an improvement. Statistics for time × group interactions are indicated: \*\*\*Significant difference (p < 0.001); n.s., not significant. POS, patients with a positive attitude towards bariatric surgery; NEG, patients with a negative attitude towards bariatric surgery.

the overall model was 0.107 (adjusted  $R^2 = 0.103$ ), indicative for a moderate goodness of fit according to Cohen (1988) [53]. An explorative stepwise regression model including further baseline variables (age, sex, quality of life, depression, and anxiety – data that did not ideally fulfil the requirements for this analysis) did not contribute to generating a significantly better model.

#### Discussion

This is the first study assessing exploratively the impact of patient attitudes towards bariatric surgery in the context of a BWL treatment for patients with severe obesity seeking support at a university hospital setting. As hypothesized (i), baseline characteristics indicated differences between participants of the NEG and POS groups.

Overall, the POS group strongly resembled baseline characteristics reported for patients before bariatric surgery [30–32], with POS participants being younger and having a higher depression score with a lower score in quality of life. The POS participants also tended to be less well educated and were more likely to be foreign and have a higher smoking rate. An inverse correlation between the level of education and smoking has been previously identified [54]. Thus, it appears as though socioeconomic status plays a role in the willingness to consider bariatric surgery as an option in this cohort.

As hypothesized (ii), body weight loss in the POS group was lower in comparison to the NEG group. A BWL treatment similar to the presented study here but conducted in an outpatient, non-hospital-associated setting is depicted by Rudolph et al. [55]: 190 participants with a mean BMI of 44.1 (SD: 6.2) kg/m² had a mean body weight change of -4.5 kg in 1 year. Due to the non-hospital-based setting, it can be expected that the ratio of patients with a positive attitude towards bariatric surgery may be low, but this is mere speculation.

Overall, the range of body weight change achieved in BWL treatments in patients with Class 3 obesity is broad across and within studies, and the reasons, especially for the latter, are unclear [16]. None of the studies reported on the attitude towards bariatric surgery, which could be an explaining factor for the high body weight change variability within them, similar to our findings. Since self-motivation is a decisive factor for body weight change [56, 57], this raises the question of whether a relationship exists between not desiring bariatric surgery and self-motivation for behaviour change. However, we are unable to determine this from the results of the study, and further investigations are necessary.

Eating behaviour improved as described in hypothesis (iii), but against our assumptions, no differences were observed between the POS and NEG participants, despite distinct body weight change differences. We assume that participants of the POS group started reflecting on their dietary intake and eating behaviour but lacked implementation. This may have led to an overestimation of their improvements in eating behaviour. Overall, it is well documented that eating behaviour and dietary intake patterns improve during BWL treatments, and that disinhibition and feelings of hunger do not directly correlate with body weight change [58, 59].

In line with hypothesis (iv), the participants benefited with regard to psychological aspects. The MCIDs for anxiety and depression improved for 26–32% of the patients and were unchanged for 62–67%. For quality of

life, the MCID was reached by almost 50% in the mental score. Differences in the physical scores were observed, with 50% MCID in the NEG group and over 30% in the POS group. Thus, despite the blunted weight loss of the POS group, with 44% not achieving body weight change during the VIADUKT programme (non-responders), the intervention affected the physical quality of life of almost one-third of the group. The participants whose quality of life improved achieved a body weight change of -3.5 (SD: 5.3) kg, whereas the others lost 1.5 (SD: 6.2) kg. This trend of the greater the body weight loss, the more likely the change in quality of life was also reported by Lasikiewicz et al. [20] and Kolotkin et al. [60]. However, the change in depression is not as highly associated with body weight change [20] and can be independent of it [10].

Considering that the baseline characteristics of the POS participants are similar to patients who underwent a bariatric surgery, and that the BWL treatment outcomes are rather poor, it could be argued whether this treatment is ideal for this particular subpopulation. It should also be questioned very critically in light of the current ongoing debate as to whether or not conservative weight management programmes should be the first treatment option in individuals with a BMI ≥35 kg/m<sup>2</sup>, since surgical procedures have turned out to be highly effective and safe, even for lower obesity classes [19]. Nevertheless, 6 months of working towards improving lifestyle factors resulted in improved eating behaviour and mental strength. This might have an impact on long-term weight regulation, and patients may also continue to benefit from the new skills after bariatric surgery, but this is speculation as the literature on this issue is contradictory [61, 62]. In addition, group dynamics are known to be an important factor for body weight change in BWL treatments [63]. Having POS and NEG participants in the same group setting appears to be difficult with regard to goals, and peer support can hardly be expected.

Another perspective on the results could include motivational issues. Although the relationship between attitude towards bariatric surgery and motivation to change is not clear, participants might benefit more from the behavioural intervention if their motivational stage was identified. This information could be utilized to better tailor behavioural interventions to the individual and provide an opportunity to work on their motivation and ambivalence towards change, for example, by applying techniques such as motivational interviewing. This technique has been shown to also work well in other serious and chronic conditions [34, 35].

The presented study has several strengths and limitations. First of all, one strength is that we assessed the attitude towards bariatric surgery to allow a stratified analysis for a reasonable sample size at baseline and over the course of the intervention. Various facets of psychological well-being were investigated, which are often neglected in the evaluation of such programmes. In addition, the drop-out rate was very low at 8%, which may have contributed to the fact that the costs of the programme were only fully covered by health insurance in the case of 80% programme participation of the individual participant. A particular strength of this study is that it illustrates the challenges that clinics are facing when offering outpatient weight loss programmes that are directly connected to a multidisciplinary obesity service. However, this is also a limitation, as the results of this study cannot be transferred to the general population of obese patients, as the target group addressed here is highly burdened and has a more complex health condition and medical history. A limitation is the uncontrolled study design of this investigation. As outlined above, we did not find a single randomized controlled trial comparing moderate BWL treatments in patients with Class 3 obesity [16]. All other studies dealing with this topic had a similar pre- and post-design. Furthermore, we did no follow-up to analyse weight loss maintenance. In general, weight loss maintenance is problematic and requires a continuous multidisciplinary approach [17].

Finally, alongside other studies dealing with BWL treatment procedures, we showed that this method has its limitations as discussed in detail elsewhere [16]. Nevertheless, not all patients wish to undergo either bariatric surgery or a meal replacement/extreme energy restriction diet. For these patients or still undecided patients, it is extremely important to offer BWL treatments with moderate caloric restrictions in order to support the stabilization and/or improvement of body weight, reduce severity of comorbidities, and improve quality of life and psychological health. Without intervention, further body weight gain and aggravation of comorbidities are likely. Thus, providing options for moderate BWL treatments for patients with Class 2 or 3 obesity should not be undervalued, as they may provide an important interim step to assist decision making and stabilize physiological and psychological factors. The decision for or against treatment options should be based on the personal situation and desires of the patient.

#### **Conclusions**

In summary, attitude towards bariatric surgery was a predictor for body weight change. However, desirable group dynamics might be hindered if underlying attitudes and goals are too heterogeneous between group members. Therefore, we recommend assessing the attitudes towards bariatric surgery for participants of BWL treatment groups. This information could then ideally be used by group facilitators to tailor sessions and topics covered. Furthermore, education delivery techniques, support, and mitigation of group dynamics as well as leading conversations should be adapted. Special rules could then help to keep the focus on the BWL treatment. For example, while bariatric surgery should not be a topic during the sessions, it could be addressed individually or at a special group meeting with those who wish to have the procedure.

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#### Statement of Ethics

The study is approved by the Ethics Committee of the University Hospital Tübingen, Germany, with the number 391/2019BO2. The participants gave their written informed consent.

#### **Conflict of Interest Statement**

The authors have no conflicts of interest to declare.

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#### **Author Contributions**

I.M., M.T., and H.S. contributed to conceptualization; K.B., I.M., M.T., and K.G.E. contributed to methodology; K.B. and I.M. contributed to software; K.B., H.S., S.S., and P.S. contributed to validation; K.B. and I.M. contributed to formal analysis; S.S., H.S., P.S., and K.B. contributed to investigation; S.Z. and A.N. contrib-

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#### **Data Availability Statement**

All data generated or analysed during this study are included in this article and/or its online suppl. material files. Further enquiries can be directed to the corresponding author.

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12

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Obes Facts Bauer et al. DOI: 10.1159/000517850

Table S1. Body weight change

	Tuble 51. South Worght change					
	Total	Non- Responder: ≤ 0 %Body weight loss	Responder: 0-4.9 %Body weight loss	Responder: 5-9.9 %Body weight loss	≥ 10 %Body	Non- Completer
Total						
N <sub>PP</sub> (%)	267 (100)	93 (35)	115 (43)	42 (16)	16 (6)	23 (-)
ΔBody weight <sub>PP</sub> [kg]	- 2.4	3.3	- 2.8	- 8.5	- 16.7	n.d.
Mean BMI <sub>PP</sub> *	42.7	43.1	42.3	42.3	43.7	44.0
Overweight n (%)	2 (1)	0 (0)	0 (0)	2 (5)	0 (0)	0 (0)
Class I obesity n (%)	12 (4)	5 (5)	5 (4)	1(2)	1 (6)	2 (9)
Class II obesity n (%)	81 (30)	26 (28)	39 (34)	13 (31)	3 (19)	3 (13)
Class III obesity n (%)	171 (64)	62 (67)	71 (62)	26 (62)	12 (75)	18 (78)
			, ,	, ,	, ,	, ,
N <sub>ITT</sub> (%)	297 (100)	110 (37)	124 (42)	45 (15)	18 (6)	23 (-)
ΔBody weight <sub>ITT</sub> [kg]	-2.3	3.1	-2.7	-8.5	-16.3	0.6
NEG group						
N <sub>PP</sub> (%)	100 (100)	21 (21)	49 (49)	19 (19)	11 (11)	8 (-)
ΔBody weight <sub>PP</sub> [kg]	- 4.5	2.7	- 3.3	- 8.8	- 16.6	n.d.
Mean BMI <sub>PP</sub> *	42.2	42.3	42.1	41.4	43.7	42.0
Overweight n (%)	2 (2)	0 (0)	0 (0)	2 (11)	0 (0)	0 (0)
Class I obesity n (%)	6 (6)	1 (5)	4 (8)	0 (0)	1 (9)	1 (13)
Class II obesity n (%)	33 (33)	9 (43)	17 (35)	5 (26)	2 (18)	1 (13)
Class III obesity n (%)	59 (59)	11 (52)	28 (57)	12 (63)	8 (73)	6 (74)
, , ,	,		, ,			
N <sub>ITT</sub> (%)	113 (100)	27 (24)	52 (46)	22 (19)	12 (11)	8 (-)
ΔBody weight <sub>ITT</sub> [kg]	- 4.3	2.3	- 3.1	- 8.7	- 16.4	- 0.1
POS group						
N <sub>PP</sub> (%)	105 (100)	46 (44)	42 (40)	14 (13)	3 (3)	4 (-)
ΔBody weight <sub>PP</sub> [kg]	- 0.6	4.2	- 2.2	- 8.5	- 15.1	n.d.
Mean BMI <sub>PP</sub> *	43.4	44.0	42.4	43.8	43.3	48.1
Class I obesity n (%)	4 (4)	2 (4)	1 (2)	1 (7)	0 (0)	0 (0)
Class II obesity n (%)	28 (27)	8 (17)	15 (36)	4 (29)	1 (33)	0 (0)
Class III obesity n (%)	73 (69)	36 (78)	26 (62)	9 (64)	2 (67)	4 (100)
N <sub>ITT</sub> (%)	111 (100)	51 (46)	43 (39)	14 (13)	3 (3)	4 (-)
ΔBody weight <sub>PP</sub> [kg]	- 0.4	4.2	- 2.1	- 8.5	- 15.1	4.6

Abbreviations: ΔBody weight =change in body weight; BMI=Body Mass Index; Class I obesity = BMI of 30-34.9 kg/m²; Class II obesity = BMI of 35-39.9 kg/m²; Class III obesity = BMI of ≥ 40 kg/m²; ITT= Intention to treat population; N=sample size; NEG group=participants who had a negative attitude towards bariatric surgery; n.d.= no data; Non-Completer=<80% participation in the program; Non-Responder=no body weight loss or body weight gain during intervention; PP=Per Protocol Population; POS group=participants who had a positive attitude towards bariatric surgery; Responder=body weight loss (<0kg) during intervention; Overweight= BMI of 25-29.9 kg/m²;\*data from Per-Protocol-population.

Table S2:	ubgroups		
Variable	NEG group	POS group	Statistics:
n	106	104	
Anxiety [GAD-7]			
Mean <sub>Post</sub> (SD)[95% CI]	5.5 (4.0) [4.8-6.3]	7.7 (4.5) [6.9-8.6]	
$\Delta$ Mean between t0 and t1 (SD)	-1.4 (3.6)	-1.0 (3.9)	F(1)=0.527, $p$ =.469, $\eta_p^2$ =.003
Median <sub>Post</sub> [IQR]	5 [3-8.8]	7[5-10]	Γ(1)=0.327, p=.403, 1μp =.00.
MCID improved (%)	26	26	
MCID did not change (%)	67	64	
MCID worsened (%)	7	10	
Depression [PHQ-9]			
Mean <sub>Post</sub> (SD)[95% CI]	6.2 (4.2) [5.4-7.0]	9.5 (5.8) [8.4-10.6]	
$\Delta$ Mean between t0 and t1 (SD)	-1.4 (3.7)	-1.6 (4.7)	F(1, 207)=3.237, p=.073;
Median <sub>Post</sub> [IQR]	6 [3-8.8]	9 [5-13]	$\eta_{\rm p}^2 = 0.015$
MCID improved (%)	32	26	
MCID did not change (%)	62	67	
MCID worsened (%)	6	7	
Quality of Life [SF-12]			
a) Mental Sum score			
Mean <sub>Post</sub> (SD)[95% CI]	48.7 (10.3) [46.7-50.6]	42.3 (11.5) [40.1-44.5]	
ΔMean between t0 and t1 (SD)	+2.9 (10.8)	+3.3 (10.2)	
Median <sub>Post</sub> [IQR]	51.7 [43.6-56.1]	44.1 [32.5-52.5]	
MCID improved (%)	47	49	F(1, 207)=4.182, p=.042,
MCID did not change (%)	27	26	$\eta_{p}^{2}=.020$
MCID worsened (%)	26	25	
b) Physical Sum score			
Mean <sub>Post</sub> (SD)[95% CI]	42.7 (10.0) [40.8-44.6]	31.6 (11.1) [29.5-33.8]	
$\Delta$ Mean between t0 and t1 (SD)	+3.7 (6.8)	+ 0.3 (7.5)	
Median <sub>Post</sub> [IQR]	44.1 [35.9-50.8]	41.7 [24.0-39.4]	
MCID improved (%)	50	32	F(1, 207)=26.255, <i>p</i> <.001,
MCID did not change (%)	36	37	$\eta_{p}^{2}=.113$
MCID worsened (%)	14	31	
Eating Behaviour [TFEQ]			
a)Cognitive Restraint			
Mean <sub>Post</sub> (SD)[95% CI]	11.5(3.5) [10.9-12.2]	10.7 (4.8) [9.9-11.7]	F(1)=1.579, p=.21
ΔMean between t0 and t1 (SD)	+3.3 (4.2)	+2.5 (4.9)	$\eta_{p}^{2}=.008$
Median <sub>Post</sub> [IQR]	12[10-14]	11 [7-14]	Пр000
b)Disinhibition			
Mean <sub>Post</sub> (SD)[95% CI]	8.1 (3.6) [7.4-8.8]	8.5 (3.4) [8.0-9.3]	F(1)=0.12, p=.912
$\Delta$ Mean between t0 and t1 (SD)	-1.5 (2.8)	-1.4 (3.4)	$\eta_{\rm p}^2 = .000$
Median <sub>Post</sub> [IQR]	8 [6-10]	8 [7-11]	1119000
c) Feelings of Hunger			E(1 207)=1 161 == 202
Mean <sub>Post</sub> (SD)[95% CI]	6.0 (3.6) [5.3-6.7]	6.9 (3.4) [6.3-7.6]	F(1,207)=1.161, $p$ =.283 $\eta_p^2$ =.000
$\Delta$ Mean between t0 and t1 (SD)	-1.4 (3.6)	-1.5 (3.2)	IIp~=.000
Median <sub>Post</sub> [IQR]	6 [3-8]	7 [4-10]	

#### Abbreviations:

 $\Delta$ Mean between t0 and t1=Mean difference from baseline to post intervention; CI=Confidence Interval; GAD-7=generalized anxiety disorder questionnaire; IQR=Interquartile Range; MCID=minimal clinically important difference; n=sample size; PHQ-9=patient health questionnaire; Post=Post intervention/t1; SD=Standard deviation; SF-12=quality of life questionnaire; POS=participants who had a positive attitude towards bariatric surgery; NEG =participants who had a negative attitude towards bariatric surgery; t0=Baseline; TFEQ=Three-factor eating questionnaire; p<.001 is considered as statistically significant

## 3 Discussion

In this thesis, the following two publications are included:

- I. "Conventional weight loss interventions across the different BMI obesity classes: A systematic review and quantitative comparative analysis" (publication 1 by Bauer *et al.* 2020, section 2.1) <sup>27</sup>.
- II. "Attitude Matters! How Attitude Towards Bariatric Surgery Influences the Effects of Behavioural Weight Loss Treatment" (publication 2 by Bauer *et al.* 2021, section 2.2.) <sup>28</sup>.

In this section, the main results of the two publications are summarised and discussed in detail in section 3.1. In addition, the implications of the results on practice and further research are presented in section 3.2. Section 3.3 discusses the main limitations. Finally, a general conclusion is drawn in section 3.4.

#### 3.1 Main findings of the two publications

As detailed in the introduction (section 1.4), the following research questions were examined:

- I) What are realistic weight loss goals across the different BMI classes?
- II) Is it possible to identify distinct patient attitudes towards bariatric surgery, in VIADUKT? If so, do these groups also differ in baseline characteristics, body weight loss outcome, and psychological outcome variables (depression, anxiety, quality of life, and eating behaviour)?

# 3.1.1 Publication 1: Body weight loss across the different BMI classes were similar and the outcomes in Class 3 obesity differed greatly

This systematic review focused on the BMI classification of obesity and presented the associated change in body weight after moderate, conservative body weight loss programmes. As far as we know, this is the first systematic review and comparative analysis, which analysed body weight loss across *all* BMI obesity classes <sup>27</sup>.

#### Overview of the main findings

Overall, a high number of studies were included in the analysis. Due to the lack of Class 3 obesity RCTs, the search was extended to non-controlled trials (RT) and uncontrolled pre-post interventions without comparison (BA) for a quantitative pre-post analysis.

Body weight loss across all BMI classes in the quantitative analysis of RCTs as well as in the quantitative pre-post analysis was similar with 4 to 6 %. Interestingly, the achieved body weight loss was greater in non-randomised study settings, with the biggest difference in Class 1 participants.

Weight loss outcomes within and across the individual studies of Class 3 obesity

– in contrast to the other two classes – differed greatly. Further factors such as

comorbidities or motivational aspects might influence the outcome of body weight loss especially in Class 3 obesity.

# <u>Possible explanations for these findings and comparison with [current data in] the</u> literature

The data from RCTs, RTs, and BAs of this publication provided important information on weight reduction trends during a moderate, conservative treatment programme: Body weight loss in the quantitative analysis of the RCTs was 3.8 % (Class 1) and 5.3 % (Class 2). In the quantitative pre-post analysis this amounted to 6 % (Class 1), 5.5 % (Class 2) and 6.3 % (Class 3). Interestingly, the achieved body weight loss was greater in non-randomised study settings, with the biggest difference in Class 1 participants. It is likely that conservative therapy is more effective for weight loss in pre-post studies, as participants have the certainty of receiving an intervention. This could be associated with higher motivation and expectation for behaviour change. In contrast, when RCTs were conducted, it was possible that participants were only enrolled in the (less effective) control group. Thus, factors such as motivation and placebo effects might influence weight loss outcomes 90,270.

In addition, the results within and across the individual studies of Class 3 obesity differed greatly. For example, average body weight loss ranged from -18.10 kg to -4.5 kg and in some cases, there were high standard deviations of up to 14.3 for the average body weight loss data. The total number of Class 3 participants and studies included in the systematic analysis was also noticeably smaller compared to Class 1 and 2 (trials: n = 7, participants: n = 692). The heterogeneous results of the Class 3 obesity might thus have been caused – among other things - by the lower statistical certainty due to the smaller number of included studies and participants. Nevertheless, the results indicate that even with high BMI values, a conservative weight reduction still has distinct effects on body weight, which is consistent with the findings of Hassan *et al.*  $^{124}$ .

The S3 guideline states that higher weight loss targets can be set for participants with Class 2 or 3 obesity <sup>77</sup>. Such a high target value of more than 10 % might be unrealistic and unattainable in practice. The average weight reduction observed for Class 3 obesity was 6.3 %. However, results varied greatly within and across studies. This heterogeneity of the data indicates that patients with Class 3 obesity may have the potential to achieve high(er) weight reductions but that they are influenced by many factors as we discuss in the following. This in particular might involve motivational aspects. The therapies offered to participants with severe obesity differed more greatly in terms of length and frequencies in contrast to interventions in Class 1 and 2. Additionally, genetic and/or secondary causes for obesity, as well as the corresponding comorbidities and psychological factors, foremost motivational aspects, are more likely to appear in this group which might influence weight reduction. For example, the higher the initial BMI value, the more likely is depression <sup>49</sup>, whilst a high depression score is a negative predictor for body weight loss <sup>44,53,71,95</sup>.

Taking motivation into account, Peacock *et al.* were able to demonstrate that an emotionally charged motivational state led to increased weight loss compared to a pragmatic motivational state <sup>201</sup>. Moreover, Williams *et al.* demonstrated that if the participant feels more independently motivated, weight loss is more likely to be achieved <sup>273</sup>. Applying this to the study situation of obesity therapy, prescription or recommendation of conservative therapy might represent extrinsic motivation and will result in low outcomes if this does not correspond to the individual's motivation.

In the following, the results of this publication are compared to several metaanalyses regarding body weight loss through moderate, conservative therapy for overweight and obesity. As previously stated, publication 1 explicitly includes a differentiation between *all* BMI classes, whereas the comparative analyses do not provide a complete distinction. Therefore, in the comparison of the metaanalyses, only combined data of participants with a BMI of at least 25 kgm<sup>-2</sup> or more are presented. Franz *et al.* provided that within six months body weight loss ranged from 5 to 8.5 % in treatments of diet with or without exercise <sup>107</sup>. In Barte

et al., a review comparing the effects of one-year lifestyle interventions in overweight and obese participants, the body weight loss outcome for the total group was 5 % <sup>24</sup>. Batsis et al. illustrated that in older participants (≥ 65 years) 0.1 to 9 % body weight loss was achieved within 6 to 18 months through behavioural weight loss interventions <sup>26</sup>. Thus, the minimum and maximum results vary between 0.1 to 9 % for a moderate, conservative weight loss treatment lasting 6 to 18 months. The data in this thesis/publication (values) is consistent with these values.

When comparing body weight loss data from publication 1 to the international (5 to 10 % body weight loss within 6 to 12 months for all BMI classes) <sup>144</sup> and national guidelines (> 5 % or > 10 % body weight loss within 6 to 12 months for the Class 1 obesity or Class 2 and 3 obesity, respectively) <sup>77</sup> the following is found: Boundary values are mainly not achieved in the data from quantitative analysis of RCTs. In contrast, the international threshold for all BMI classes and the national threshold for Class 1 obesity are reached in the quantitative pre-post analysis data.

# 3.1.2 Publication 2: In VIADUKT two distinct groups were identified, which differed in baseline characteristic and change in body weight loss, but not in psychological variables

This publication analysed the change of body weight and psychological variables of VIADUKT, a conservative weight reduction programme carried out at University Hospital Tübingen. To our knowledge, this is the first explorative research article, that takes attitude towards bariatrics surgery into account and mainly includes participants with severe obesity (BMI  $\geq$  40 kgm<sup>-2</sup>) in a university-based weight loss programme <sup>28</sup>.

#### Overview of the main findings

In this study, participants were divided into four groups according to their reply to questions regarding "his or her attitude towards bariatric surgery":

1) POS: "Yes, bariatric surgery is an option for me"

2) NEG: "No, bariatric surgery is not an option for me"

3) Uncertain: "I am not sure"

4) Not clear: No information about the attitude was given.

While data from all four groups were included in the study, we mainly focused on two subgroups: POS and NEG, which represented 75 % of participants.

These two groups differed significantly in their baseline characteristics: on average the NEG group were older and had higher scores in quality life as well as lower scores in depression questionnaires.

Body weight loss (primary outcome) for the total group was moderate (2 %). However, the average weight loss significantly varied between groups: While the POS group achieved an average weight loss of only 0.4 %, the NEG group achieved 4 %.

In addition, the total group improved in all investigated psychological aspects (secondary outcome: depression, anxiety, quality of life, and eating behaviour). These improvements were also recorded in the POS and NEG group with one exception: The quality of life (physical component) did not improve for participants in the POS group.

# <u>Primary outcomes: Possible explanations for these findings and comparison with</u> [current data in] the literature

In this publication individual attitudes towards bariatric surgery predicted body weight loss outcomes, which was quantitatively assessed in the hypothesis-driven simple linear regression. With a  $R^2$  of 0.107, a moderate goodness of fit was given. Furthermore, the attitude and motivation of the participants might be associated, but it must be noted that these factors should not be equated, and further research must confirm this assumption. In the literature, an association between motivation and weight reduction is found  $^{80,247}$  and autonomous motivation is a predictor for body weight loss  $^{273}$ . Thus, aspects such as

motivation and psychiatric disorders should be considered in behavioural weight loss treatments <sup>71,208</sup>.

The decision for or against bariatric surgery might influence body weight loss. In Germany, participants are considered for bariatric surgery after evidence for unsuccessful behavioural weight loss treatment is given. Since VIADUKT takes place at the University Hospital the number of participants that aim to undergo bariatric surgery is high. This means that the POS group is generally anxious that too much weight loss ahead of surgery would question the indication for bariatric surgery. However, this presumption of the patients does not align with the German guidelines. Instead, indication for bariatric surgery is given when body weight loss of > 15 % (Class 2 obesity) or > 20 % (Class 3 obesity and above) are not achieved through a six month lasting conservative treatment within two years <sup>78</sup>. Further, preoperative body weight loss has positive impacts on postoperative mortality risk and complications <sup>246</sup>. Complications are even more reduced in higher BMI values 11,30. Moreover, preoperative body weight loss can elevate postoperative body weight loss <sup>150</sup>. In contrast, some analyses indicate contradictory results for body weight loss ahead of surgery. In these cases, postoperative complications such as infections were increased. Unbalanced, drastic weight loss regimes were discussed to be causal for this, as professional help was missing <sup>250,251</sup>.

Another explanation for different body weight loss outcomes in the POS and NEG group is based on the clinical experience of the VIADUKT group leaders regarding group interactions. As the study by Nackers *et al.* illustrated, group dynamics can affect weight loss as well as programme compliance. In cases of group conflict, both factors decreased, whereas a perceived positive group dynamic promoted compliance <sup>193</sup>.

Participants with severe obesity usually have a long medical history with body weight regain and disappointments regarding conservative body weight loss. Thus, bariatric surgery becomes the last option and hope. If health insurers do

not require weight loss up front, as it is common in Germany, participants might endure the programme with no further contribution and attendance.

The different baselines of the POS and NEG group might influence body weight outcomes. In Finkler *et al.*, as in the NEG group, higher age was associated with a higher reduction of body weight <sup>98</sup>. This might be explained by increased participation and adherence among older participants <sup>44,53,95</sup>. Besides, low depression scores are a significant predictor of successful weight loss <sup>44,53,71,95</sup>, which is also consistent with findings in the NEG group.

When comparing the results of VIADUKT to the international recommendations, it became evident that the total group with 2 % body weight loss within six months were far below the expected weight loss of 5 to 10 %. The situation changes when looking at the two groups separately: the NEG group achieved 4 % weight reduction within six months which is still close to the international range of 5 to 10 % within 6 to 12 months <sup>143</sup>. In contrast, the results of the POS group were far from this with only 0.4 % body weight loss. The recommendations in the S3 guideline are set even higher, so that the total group, as well as the POS and NEG groups performed below the threshold values <sup>77</sup>.

At this point, it is necessary to emphasise again that the patients attending VIADUKT are for the most part highly burdened patients (this also applies to NEG patients) seeking help at a university hospital. Thus, they represent a complex patient collective and data from the VIADUKT programme are only comparable up to a certain point to other, outpatient lifestyle or behavioural therapy approaches with mixed patient groups.

Secondary outcomes: Possible explanations for these findings and comparison with [current data in] the literature

First, Lasikiewicz *et al.* systematically analysed that many improvements in psychological well-being are independent of weight reduction <sup>165</sup>. This effect is

found especially in depression <sup>71,95,165</sup>. In contrast, quality of life regarding physical health is dependent on weight loss <sup>155,165</sup>. This was consistent with the findings in this publication.

Second, we had speculated that the POS group would benefit less in terms of eating behaviour. However, the results of the eating behaviour with its three subgroups disinhibition, cognitive restraint, and feelings of hunger, improved equally in the total group, as well as in the POS and NEG group. Our explanation for this was as follows: While all participants received the same information on nutrition (behaviour), thus an awareness of an appropriate eating behaviour had developed, whereas the implementation in everyday life had not (yet) taken place. Besides, Keranen *et al.* reported that cognitive restraint and disinhibition can improve regardless of the body weight loss amount <sup>152</sup>. Furthermore, several studies illustrated that participants often misjudge their eating behaviour. For example, in Lichtman *et al.* participants with low weight loss overestimated the calorie reduction and the amount of exercise significantly <sup>170</sup>. This was confirmed in Abbot *et al.*, where it is further indicated that this was found especially in less educated participants and in participants with unrealistic weight loss values.

Finally, the improvement in (almost) all psychological aspects were independent of the primary outcome and fulfil the success criteria of Hauner *et al.* according to which, apart from weight reduction, an improvement of comorbidities, as well as in psychological aspects such as quality of life should be achieved <sup>121</sup>. This underlines the necessity of moderate, conservative treatments, to improve and stabilise psychological and physiological aspects <sup>1,94,165</sup>.

VIADUKT is therefore a promising and important aspect in the complex therapy regime of obesity. Even though the POS group showed low results in weight reduction, the participants were stabilized at physical and mental variables. After all, obesity therapy is a long-lasting if not lifelong approach and involves more than mere body weight loss.

### 3.2 Implications for practice and further research

#### Publication 1: Implications for practice and further research

The following sections discuss the current (inter-) national guidelines for recommended body weight loss in overweight and obesity and lists possible adjustments based on the results of 3.1.1. But first, it is explained in more detail why the boundary values are set at 5 to 10 %.

Realistic values for body weight loss must be determined with the help of study data, which should have the highest level of evidence as possible. As discussed in more detail in 3.1.1, current data indicate that body weight loss through moderate, conservative treatments ranges between 0.1 to 9 %  $^{24,26,107}$ . These values are in line with the findings of our publications, where we found a body weight loss of 4 to 6 % in publication 1 and 0,4% in POS and 4 % in NEG participants of publication 2. In addition to the sole weight loss outcomes, guidelines also consider the impacts of body weight loss on comorbidities. It is demonstrated that sufficient changes in relation to comorbidities (e.g., hypertension, cholesterol concentration) are achieved despite moderate body weight loss ( $\leq 5$  %)  $^{33,174}$ . For example, clinically significant values for glucose concentrations could already be achieved at these values  $^{144}$ . However, within the recommended weight reduction of 5 to 10 %, the results are more favourable for overall health and especially cardiovascular risks  $^{115,143,144,259,275}$ .

Taken together, the current international boundary values of 5 to 10 % body weight loss seems reasonable and correspond approximately to the data of publication 1. Moreover, it incorporates realistic body weight loss values, which are associated with the most beneficial effects on comorbidities. In contrast, the thresholds in the S3 guideline for Class 2 and 3 are set higher than this data indicates. But this recommendation is based on the lowest level of evidence graduation <sup>77</sup>. Thus, it might be advisable to adapt the German threshold for BMI > 35 kgm<sup>-2</sup> in accordance with the American guideline, since the current outpatient figures show that the recommended value of > 10 % in 6 to 12 months

is very ambitious and does not seem realistic in moderate weight loss treatments <sup>27,107,219</sup>. Furthermore, participants, especially at a younger age, tend to expect even higher weight reductions than stated in the S3 recommendations <sup>172,267</sup>. It has been repeatedly shown that unrealistic assumptions about weight reduction have a negative impact on initial and long-term weight loss, participation in weight loss programmes, and psychological factors <sup>65,267</sup>. Based on this, it seems reasonable that treatment goals should be set realistically <sup>64,77</sup>. Possible adaptations are as follows:

Body weight loss of > 5 % may be recommended, but even body weight loss < 5 % are targetable and clinically helpful <sup>144,174</sup>, as well as relevant for physical and mental health stabilization. Alternatively, the current national recommendation of > 10 % body weight loss for BMI > 35 kgm<sup>-2</sup> might be more specified. Firstly, this recommendation is only possible for some individuals, particularly those with very high initial BMI <sup>98,199</sup>. Secondly, this is achieved foremost through meal replacement approaches and not moderate weight loss regimes <sup>107</sup>. However, from our clinical experience, not all participants wish to undergo meal replacement interventions at first or at all. Furthermore, meal replacements are often associated with a high dropout rate <sup>32</sup>. Accordingly, it might be helpful to list separate boundary values for moderate conservative interventions and meal replacement attempts. As this is still speculative, further studies are needed in the future to confirm these assumptions and/or recommendations.

#### Publication 2: Implications for practice and further research

The attitude towards bariatric surgery should be examined in behavioural weight loss treatments since it has an influence on body weight loss. We conclude that accordingly greater or optimal weight loss results might be achieved. Thus, appropriate adjustments in behavioural weight loss treatments might be beneficial e.g., additional, individual or group appointment for interested participants. For example, participants should get informed on bariatric surgery to understand that it is not a "simple procedure"; it involves lifelong laboratory checks, supplementation, and changes in eating behaviour <sup>78</sup>.

In this context, it is also advisable to ask about expectations on bariatric surgery, as the idea that surgery will lead to a complete change of life can have a negative impact on the postoperative psychological outcome <sup>158</sup>. Reasons for undergoing bariatric surgery vary widely and span the major topics of physiological, emotional, cognitive, as well as interpersonal and environmental aspects <sup>57</sup>.

This corresponds to Daigle *et al.*, who proposed that individual attitudes and expectations towards the obesity treatment should be explored in the context of its desired effectiveness, and that appropriate realistic outcomes should be provided to and discussed with the participant <sup>64</sup>. On the other hand, it must be emphasised that the topic of bariatric surgery should not become a central part in the behavioural therapy setting.

Additionally, based on the different attitudes towards bariatric surgery unfavourable group interactions might be possible, which could have affected VIADUKT results. Thus, in future, it is advisable that group leaders consider and implement the attitude towards bariatrics surgery in the conduction and management of group meetings.

The following should be investigated in further studies: association between attitude and motivation, implementation of the topic's attitude towards bariatric surgery with its possible group effects and participant's expectation on bariatric surgery.

Taken together, adequate approaches are required and can be implemented first and foremost with the help of motivational interviewing <sup>187,247</sup>. It is a common and well-known tool for addressing a patient's motivation. Initially, it was used in substance abuse treatment, but has also resulted in successful outcomes in obesity treatment <sup>23,187,247</sup>. Main topics are encouragement of self-motivation, indicating possible resistances and promoting willingness to change <sup>82</sup>. The S3 guideline also recommends that motivation has to be assessed during the initial examination and indicates it as a crucial component of long-term therapy, especially in the context of behavioural therapy <sup>77</sup>.

# General conclusion derived from the results of publication 1 and 2: Implications and further research for participants with severe obesity

It becomes evident that participants with severe obesity present a heterogeneous, mostly highly burdened group, which might be considered separately in the diagnosis and therapy regime in the future. Within the literature search in publication 1, as well as in the writing of publication 2, we noticed that there are generally fewer studies for Class 3 participants. Due to the reduced number of studies, this group is underrepresented. Thus, clever designed studies targeting participants with severe obesity will be required in the future to achieve the best weight loss and weight loss maintenance results.

First, as demonstrated in publication 1 and 2, weight reduction for participants with severe obesity tend to be moderate. It should be noted that only moderate, conservative interventions without extreme dietary regimes were included in both analyses. Thus, above a certain BMI level, and especially for Class 3, more intensive interventions are needed. For example, apart from the motivational aspects mentioned before, a short-term hypocaloric approach could be helpful to achieve the recommended weight loss goals. However, even this strict calorie regime often seems insufficient and is often accompanied by high drop-out rates. Therefore, especially for Class 2 and 3 obesity, a multidisciplinary approach could be helpful to offer the patient the appropriate combination or sequence of therapies <sup>84</sup>. Consequently, for the future, more multidisciplinary teams and centres for obesity might be needed <sup>100</sup>.

Second, adjustments on BMI values for obesity therapy indication setting might be beneficial. For example, bariatric surgery could be offered sooner to participants with severe obesity. As mentioned before, body weight loss achieved in conservative therapy is moderate with up to 10 % of initial body weight. In contrast, weight reductions achieved by surgery are far greater: Participants undergoing bariatric surgery lost on average 26 kg (CI -31 to -21kg) of their body weight <sup>114</sup>. This correlates to body weight loss of 23 %, 17 %, 16 % and 18 % after 2,10,15, and 20 years respectively <sup>236</sup>.

In this context, the indication for conservative or surgical therapy must be evaluated carefully on a case-by-case basis, in which the advantages and disadvantages of surgery should be considered. For example, the mortality rate of bariatric surgery is very low (for RCTs perioperative 0.08 % and postoperative 0.31 %) <sup>51</sup>. And severity of diabetes improves significantly after bariatric surgery <sup>3,18,43</sup>. But self-harm and suicide attempt rates seem to be higher in participants undergoing bariatric surgery than in a matched control group or general population <sup>50,206,252</sup>. These results underline the necessity of pre- and postoperative psychological diagnostics and follow-up care <sup>171</sup>.

Overall, technical efficacy of bariatric surgery is increasing, and it becomes a safe option of choice, even for participants with Class 1 obesity <sup>97</sup>. Yet, as a sole therapy, it also has its limits.

Thus, the rigid separation of conservative and surgical approaches, with corresponding weaknesses of one, should be replaced by a multidisciplinary, long-lasting process of obesity management for the patient. In this process, conservative therapy can be an important pre- and postcondition for bariatric surgery to achieve physical and psychological improvements. For example, techniques of behavioural weight loss treatments have proven to be useful for the post-bariatric surgery phase and especially for weight stabilisation <sup>225</sup>. After all, bariatric surgery is not an easy or sole solution to obesity and will certainly not lead to a complete transformation of one's life situation, which is sometimes expected from participants <sup>57</sup>. Nevertheless, these recommendations still need to be proven in clinical practice in the future.

Third, further assessment for indication setting for or against a therapy option might be helpful. The Edmonton Obesity Staging System (EOSS), for example, classifies patients into 5 different stages based on obesity-related risk factors, physical and psychological symptoms, and individual functionality. In the following, therapy recommendations are given in relation to the EOSS stage. Sharma and Kushner, who have contributed to the classification, state that EOSS supplements the WHO definition as severity of obesity can be classified more accurately <sup>230</sup>. This was confirmed in studies; EOSS can be used as an

assessment for possible weight developments <sup>47</sup> and as an indication for bariatric surgery <sup>113</sup>. In the future, it might therefore be advisable to include EOSS in the decision-making criteria for bariatric surgery <sup>19,229</sup>. Thus, VIADUKT and "Plattform Adipositas" could benefit from its implementation in screening questionnaires. Currently, these are still speculative assumptions, so that further analyses are necessary.

#### 3.3 Limitations

In publication 1, as is common with dietary and behavioural interventions, blinding was not possible in the RCTs. Furthermore, the number of studies in the literature search was extremely large. Thus, instead of single studies, primarily reviews and meta-analysis were searched. From these, single studies (RCTs, RTs, and BAs) were subsequently added in our analysis if inclusion criteria were met. Moreover, aggregated data are used in the analysis. Thus, participants belonging to a different BMI were included in one BMI class, so the data are not completely accurate. Additionally, in the quantitative pre-post analysis the number of studies and participants in Class 3 were noticeably lower than in Class 1 and 2. This, among other things, might have caused the heterogenous body weight loss outcomes in Class 3. As described in the publication, only tendencies can be identified, which must be confirmed in further studies. Moreover, publication bias was found, which is a frequently occurring aspect in research <sup>81</sup>.

Furthermore, to provide comparability between the different classes and to create reference values for VIADUKT, only moderate, conservative interventions were included. As discussed in 3.2 it becomes evident that Class 3 obesity participants might only be able to achieve the necessary results with the help of more intensive programmes. In addition, to prevent bias on the results, inclusion criteria were such that studies with exclusively patient collectives were not integrated in the analysis. This might have prevented the inclusion of RCTs study of Class 3 obesity.

At last, it must be emphasized that the analysis in publication 1 only compared weight reduction data and no other secondary outcomes. As Hauner *et al.* have described, a successful obesity programme also includes the improvement of comorbidities, as well as psychological aspects such as quality of life <sup>121</sup>. It is a simplified view to make a conclusive statement about the success of the respective studies based solely on the weight reduction values. As mentioned in the introduction, obesity is a complex interaction of somatic and psychological factors that influence each other <sup>36,125</sup>.

In publication 2, the study setting of the programme is on the one hand a strength. It incorporates the difficulties of clinics, which are given when outpatient programmes are integrated in multidisciplinary services. On the other hand, general conclusions can only be drawn to a limited extent due to the special setting of VIADUKT and the particular patient collective. A further limitation is the study design of the VIADUKT without a control group. But to our knowledge no RCT exists that analyses moderate, conservative therapy in Class 3 obesity. Furthermore, in publication 1 and 2 only the short-term change in body weight was considered. However, maintaining the achieved body weight is just as important, but also represents one of the greatest challenge within the therapy 276.

#### 3.4 Conclusions

In summary, body weight loss across the different BMI classes is similar for conservative, moderate body weight reduction treatments. As comorbidities increase with the degree of BMI and higher weight loss amounts are more favourable, conservative therapy may require more intensive interventions, particularly for participants with Class 3 obesity. For example, motivational techniques such as motivational interviewing and brief hypocaloric periods within programmes, as well as open discussion about recommended and realistic levels of body weight loss, might be beneficial. Moreover, the attitude towards bariatric surgery is a predictor for body weight loss. Thus, the attitude towards bariatric surgery and its corresponding possible group interaction should be considered in conservative therapy. From the results of this thesis, it becomes evident that participants in Class 3 obesity present a complex and heterogeneous group. In case of "unsatisfactory" results, especially in higher BMI classes, participation in bariatric surgery might be considered earlier. Overall, conservative, and surgical procedures can be understood as a complement rather than an alternative in the case of "insufficiently successful" therapies, given that obesity requires a longterm or lifelong approach. The increased use of multidisciplinary obesity centres, as well as further assessment tools such as EOSS, could be helpful in decisionmaking on treatment options. In this context, comorbidities, especially diabetes mellitus, but also psychological aspects such as depression and motivation might be considered more strongly.

### 4 Summary

Obesity and its comorbidities such as type II diabetes have become a major public health problem. The direct and indirect costs for the health-care system are enormous and indicate the need for effective therapy.

Body mass index (BMI) is used to classify obesity into three different categories: 1) Class 1 obesity: BMI 30 - 34.9 kgm<sup>-2</sup>; 2) Class 2 obesity: BMI 35 - 39.9 kgm<sup>-2</sup> and 3) Class 3 obesity: BMI ≥ 40 kgm<sup>-2</sup>.

Depending on the BMI value and comorbidities there are two treatment options: a conservative treatment ("behavioural weight loss") and a surgical ("bariatric surgery") treatment. The primary goal of behavioural weight loss treatments is to achieve a body weight reduction of 5 to 10 % within 6 to 12 months, as recommended by international guidelines. In the German S3 guideline "Prävention und Therapie der Adipositas", similiar target ranges are given based on expert opinions: A weight reduction of > 5 % for a BMI of 25 to 35 kgm<sup>-2</sup> and > 10 % for a BMI > 35 kgm<sup>-2</sup> is recommended.

This thesis focuses on behavioural weight loss treatments and the associated change of body weight and psychological variables. First, we conducted a systematic review to examine the extent of weight reduction across all BMI classes. Secondly, we analysed one behavioural weight loss programme regarding body weight loss and psychological variables, namely the six-month lifestyle intervention programme for patients with obesity at the University Hospital Tübingen (VIADUKT).

To the best of our knowledge, only one other systematic review had investigated how the weight reduction in the individual BMI classes differs, but it lacks Class 3 obesity data. As almost two thirds of the VIADUKT participants were categorized as Class 3 obese, the results of this BMI class were of great interest. The publication "Conventional weight loss interventions across the different BMI obesity classes: A systematic review and quantitative comparative analysis" (by Bauer *et al.*, in European Eating Disorder Reviews, 28 (5):492-512, 2020) had

4 Summary 91

been conducted to determine which average weight loss values could be expected across the BMI obesity classes through moderate, conventional weight loss treatments. The results showed that relative weight reduction across the BMI classes was overall very similar, but that the distribution within and across Class 3 was considerably more heterogeneous. We therefore hypothesise that there are further factors that influence the amount of weight reduction in this class.

Subsequently, participant data from VIADUKT were analysed and compared. The inclusion criterion was a BMI of ≥ 30 kgm<sup>-2</sup>, however the mean BMI of the 297 participants was 42.7 kgm<sup>-2</sup>. VIADUKT is a university-based programme with various participants, including participants seeking conservative treatments as well as participants who do not fulfil criteria for bariatric surgery. Based on this heterogeneity of patients and our clinical experience, we examined whether or not weight reduction correlated with the attitude towards bariatric surgery. Two distinct groups were identified: 1) POS – participants who have a positive attitude towards bariatric surgery and 2) NEG – participants who have a negative attitude towards bariatric surgery.

The results were published in the research article "Attitude Matters! How Attitude Towards Bariatric Surgery Influences the Effects of Behavioural Weight Loss Treatment" by Bauer et al., in Obesity Facts, 14:531-542, 2021. It became evident that there were clear differences between the POS and NEG group regarding their baseline characteristics and outcomes in weight loss. POS participants were significantly younger, had a higher depression score, and a lower quality of life score. Notably, we found that a positive attitude towards surgery significantly reduced the extent of weight reduction through behaviour therapy. In contrast, no differences between POS and NEG were found in the change of anxiety, depression, the mental score for quality of life, and eating behaviour; both groups improved equally. Thus, the attitude towards bariatric surgery could provide one of several explanations for the wide variation in body weight loss after behavioural weight loss treatment in patients with Class 3 obesity that we observed in our systematic review. Knowledge of the individual attitude towards bariatric surgery

4 Summary 92

is important for individual goal setting and to work out motivation with targeted interventions.

In conclusion, body weight loss in the different BMI classes through moderate, conventional weight loss treatments is rather similar and outcomes in Class 3 differ greatly across the studies. The attitude towards bariatric surgery is a predictor of body weight loss. Derived from this, participants with BMI ≥ 40kgm<sup>-2</sup> present a heterogeneous and complex group. Consequently, further adaptations such as short hypocaloric approaches and techniques such as motivational interviewing, could help to improve conservative therapy approaches, especially in severe obesity.

5 Zusammenfassung 93

### 5 Zusammenfassung

Adipositas und seine Komorbiditäten wie beispielsweise Typ II Diabetes stellen ein großes Problem für Individuum und Gesellschaft dar. Die damit verbundenen direkten und indirekten Kosten sind enorm, und weisen auf die dringende Notwendigkeit wirksamer Therapien hin.

Mithilfe des Body-Mass-Index (BMI) werden drei verschiedene Adipositas-Klassen unterschieden: 1) Adipositas Klasse 1: BMI 30 - 34,9 kgm<sup>-2</sup>; 2) Adipositas Klasse 2: BMI 35 - 39,9 kgm<sup>-2</sup> und 3) Adipositas Klasse 3: BMI ≥ 40 kgm<sup>-2</sup>.

Ausgehend vom BMI-Wert und den möglichen Begleiterkrankungen ergeben sich primär zwei Behandlungsmöglichkeiten für eine Gewichtsreduktion: eine konservative ("verhaltenstherapeutische") oder eine chirurgische ("bariatrische") Behandlung. Ziel der konservativen Intervention ist nach internationaler Leitlinie eine Gewichtsreduktion von 5 bis 10 % des Körpergewichts innerhalb von sechs bis zwölf Monaten. In der deutschen S3-Leitlinie "Prävention und Therapie der Adipositas" werden basierend Expertenmeinungen auf vergleichbare Zielbereiche angegeben. Für einen BMI von 25 bis 35 kgm<sup>-2</sup> wird eine Gewichtsreduktion von > 5 % und bei einem BMI > 35 kgm<sup>-2</sup> eine Reduktion von > 10 % empfohlen. Zusätzlich soll eine Verbesserung psychischer Faktoren sowie der Lebensqualität erzielt werden.

Diese Dissertation konzentriert sich auf verhaltenstherapeutische Behandlungen zur Gewichtsreduktion und die damit verbundene Entwicklung von Körpergewicht und psychologischen Variablen. Zunächst wurde eine systematische Übersichtsarbeit erstellt, in der das Ausmaß der Gewichtsreduktion in den verschiedenen BMI-Klassen durch moderate, konservative Gewichtsreduktionsprogramme untersucht wurde. Als zweites wurde ein solches Programm zur Gewichtsabnahme analysiert. Es handelt sich hierbei um das sechs-monatige Verhaltensinterventions-Programm für Patienten mit Adipositas am Universitätsklinikum Tübingen (VIADUKT).

5 Zusammenfassung 94

Bisher gab es lediglich eine systematische Übersichtsarbeit, die untersucht hat, wie sich die Gewichtsreduktion in den einzelnen BMI-Klassen unterscheidet. In dieser fehlten jedoch die Daten zur Adipositas Klasse 3. Da fast zwei Drittel der VIADUKT-Teilnehmenden in die Klasse 3 eingestuft wurden, waren gerade die Ergebnisse für diese BMI-Klasse von großem Interesse. Um zu ermitteln, welche durchschnittlichen Gewichtsverlustwerte über alle BMI-Klassen hinweg zu erwarten sind, wurde die Übersichtsarbeit "Conventional weight loss interventions across the different BMI obesity classes: A systematic review and quantitative comparative analysis" (von Bauer et al., in European Eating Disorder Reviews, 28 (5):492-512, 2020) durchgeführt. Dabei wurde festgestellt, dass die mittlere prozentuale Gewichtsreduktion in den verschiedenen BMI-Klassen sehr ähnlich war. Die Ergebnisse in der Adipositas Klasse 3 waren jedoch sehr heterogen. Aufgrund der großen Streuung dieser Daten sind wir daher davon ausgegangen, dass es weitere Faktoren wie beispielsweise motivationsbezogene Aspekte gibt, die das Ausmaß der Gewichtsreduktion in dieser Klasse beeinflusst.

Anschließend wurden die Teilnehmerdaten aus VIADUKT analysiert und verglichen. Einschlusskriterium war ein BMI von ≥ 30 kgm<sup>-2</sup>, während der durchschnittliche BMI der 297 Teilnehmenden jedoch bei 42,7 kgm<sup>-2</sup> lag. VIADUKT ist ein universitär-basiertes Programm, das sowohl Teilnehmende, die eine konservative Behandlung bevorzugen, als auch Teilnehmende, die die Kriterien für eine bariatrische Operation (noch) nicht erfüllen, umfasst. Aufgrund der Heterogenität der Patienten und unserer klinischen Erfahrung wurde deshalb eine mögliche Korrelation zwischen Gewichtsreduktion und Einstellung zur bariatrischen Chirurgie untersucht. Zunächst wurden zwei verschiedene Gruppen identifiziert: 1) POS - Teilnehmende, die eine positive Einstellung zur bariatrischen Chirurgie haben und 2) NEG - Teilnehmende, die eine negative Einstellung zur bariatrischen Chirurgie haben.

Die Ergebnisse wurden im Originalartikel "Attitude Matters! How Attitude Towards Bariatric Surgery Influences the Effects of Behavioural Weight Loss Treatment" von Bauer *et al.*, in Obesity Facts, 14:531-542, 2021 veröffentlicht. Dabei wurde

5 Zusammenfassung 95

deutlich, dass es Unterschiede zwischen den Gruppen hinsichtlich der Ausgangscharakteristik und der Ergebnisse bei der Gewichtsabnahme gab. Die POS-Teilnehmenden waren deutlich jünger, hatten höhere Depressions-Symptomwerte und eine niedrigere Lebensqualität. Insbesondere wurde festgestellt, dass eine positive Einstellung zur Adipositaschirurgie das Ausmaß der Gewichtsreduzierung deutlich verringerte. Abgesehen davon, profitierten die Teilnehmenden beider Untergruppen unabhängig von der Gewichtsentwicklung bezüglich der psychischen Variablen Angst- und Depressionssymptomatik, sowie der mentalen Bewertung der Lebensqualität und beim Essverhalten.

Somit könnte die Einstellung zur bariatrischen Chirurgie eine von mehreren Erklärungen für die großen Unterschiede bei der Gewichtsabnahme nach einer verhaltenstherapeutischen Behandlung bei Patienten mit Adipositas Klasse 3 sein. Dies entspricht auch den Ergebnissen in unserer systematischen Übersichtsarbeit. Daher ist es wichtig, die individuelle Einstellung zur bariatrischen Chirurgie zu kennen, um individuelle Ziele zu definieren und die Motivation durch gezielte Interventionen zu fördern.

Zusammengefasst zeigt sich: Die Körpergewichtsabnahme in den verschiedenen BMI-Klassen durch moderate, konventionelle Gewichtsabnahme-Interventionen ist sehr ähnlich und die Ergebnisse der Adipositas Klasse 3 sind sehr inhomogen. Die Einstellung zur bariatrischen Chirurgie ist ein Prädiktor für die Körpergewichtsabnahme. Personen mit einem BMI ≥ 40kgm⁻² stellen somit eine heterogene und komplexe Gruppe dar. Folglich könnten weitere Anpassungen wie kurze hypokalorische Ansätze und Maßnahmen wie "Motivational Interviewing" zur Verbesserung der konservativen Therapie hilfreich sein.

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# 7 Declaration of contribution (of others)



Medizinische Fakultät

Version August 2020

Herewith I, Kerstin Bauer, declare, that I have contributed to the major part of the following publication:

Conventional weight loss interventions across the different BMI obesity classes: A systematic review and quantitative comparative analysis.

The authors contributed to the publications as indicated in the following table (indicated in %):

#### **Author Contributions**

Contribution	[Kerstin Bauer]	[Teresa Lau]	[Juliane Schwille- Kiuntke]	[Sandra Schild]	[Hans Hauner]	[Andreas Stengel]	[Stephan Zipfel]	[Isabelle Mack]
Conzeptualization	30%		<b> </b>		10%		-	60%
Metholody	70%	-	7,5%	-	7,5%	-	•	15%
Software	70%	-	-			-	•	30%
Validation	70%	20%	-	•	-		-	10%
Formal analysis	80%		-	, ·	-	-	•	20%
writing—original draft preparation	70%	-	-	-	-	-		30%
writing—review and editing	12,5%	12,5%	12,5%	12,5%	12,5%	12,5%	12,5%	12,5%
Visualization	70%	-		-	-	•	-	30%
Supervision	-	-	10%	-		-	10%	80%

Signature of the doctoral candidate (Kerstin Bauer): As supervisor and corresponding author, I (Dr. rer. nat. Isabelle Mack) agree with the declarations by the candidate: Dr. Isa Mack As co-authors, we agree to the declarations above: [Dr. med. Juliane Schwille-Kjuntke] [Dr. rer. nat. Sandra Schild] [Prof. Dr. med. Andreas Stephan Zipfel] [Prof. Dr. med. Hans Hauner] Stengel] Universitätsklinikum Tübingen Validation of an outpatient programme.
Active participation in patient recruitment. Abteilung für Psychosomatische Medizin und Psychotherapio 2

Prol. Dr. S. Zipfel Osinnderstr. 5 72076 Tübingen



#### Medizinische Fakultät

Version August 2020

Herewith I, Kerstin Bauer, declare, that I have contributed to the major part of the following publication:

Attitude Matters! How Attitude Towards Bariatric Surgery Influences the Effects of Behavioural Weight Loss Treatment.

#### **Author Contributions**

The authors contributed to the publications as indicated in the following table (indicated in %):

Contribution	[Korstin Bauer]	[Sandra Schild]	[Heleno Sauer]	[Martin Toufol]	[An- droas Ston- gol]	[Katrin Elisa- beth Glei]	[Philipp Schell- hom]	(Florian Junno)	[Andreas Nieß]	[Ste- phan Zipiel]	[isabelle Mack]
Conzeptualization	30%	•	10%	10%					-		50%
Metholody	70%			7,5%		7,5%					15%
Software	70%			•	•				•		30%
Recruitment of Patients <sup>1</sup>	N.a. <sup>3</sup>	N.a.	N.a.		•		•	140	•	•	-
Data acquisation	80%	10%	10%					-			
Data curation	80%	-		-					-	-	20%
Formal analysis	70%	•			•		•		-	-	30%
writing—original draft preparation	70%	-	•		•				•	•	30%
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Supervision		10%		10%	10%					10%	50%

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As co-authors, we agree to	o the declarations above:	TOU/1
[Dr. rer, nat. Sandra Sphild]	[Dr. rer. nat. Helene Sauer]	[Prof. Dr. med. Martin Teufel]
[Prof. Dr. med. Andreas Stengel]	[Prof. Dr. rer. nak-Katrin Elisabeth Glet]	[Dr. med. Philipp Schellhorn]
[PD Dr. med. Florian Junne]	(Prof. Dr. med Andreas Nieß)	[Prof. Dr. med. Stephan Zidel]
<sup>1</sup> Validation of an outpatient p. <sup>2</sup> Active participation in patien		atische

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## 9 Full list of publications

- a) Bauer K, Lau T, Schwille-Kiuntke J, Schild S, Hauner H, Stengel A, Zipfel S, Mack I. Conventional weight loss interventions across the different BMI obesity classes: A systematic review and quantitative comparative analysis. Eur Eat Disord Rev. 2020 Sep;28(5):492-512. doi: 10.1002/erv.2741. Epub 2020 May 3. PMID: 32363695.
- b) Cook J, Lehne C, Weiland A, Archid R, Ritze Y, <u>Bauer K</u>, Zipfel S, Penders J, Enck P, Mack I. Gut Microbiota, Probiotics and Psychological States and Behaviors after Bariatric Surgery-A Systematic Review of Their Interrelation. Nutrients. 2020 Aug 10;12(8):2396. doi: 10.3390/nu12082396. PMID: 32785153; PMCID: PMC7468806.
- c) <u>Bauer K, Schild S, Sauer H, Teufel M, Stengel A, Giel KE, Schellhorn P, Junne F, Nieß A, Zipfel S, Mack I. Attitude Matters! How Attitude towards Bariatric Surgery Influences the Effects of Behavioural Weight Loss Treatment. Obes Facts. 2021 Sep 14:1-12. doi: 10.1159/000517850. Epub 2021 Sep 14. PMID: 34521092.</u>