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# ISPRM/ESPRM guidelines on physical and rehabilitation Medicine professional practice for adults with obesity and related comorbidities

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# European Journal of Physical and Rehabilitation Medicine EDIZIONI MINERVA MEDICA

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**EDIZIONI MINERVA MEDICA** 

ISPRM/ESPRM Guidelines on Physical and Rehabilitation Medicine (PRM) professional practice for adults with obesity and related comorbidities

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### ABSTRACT

**Background:** The World Health Organization (WHO) has declared obesity as the largest global chronic health problem in adults. In the last years, attention has been drawn to the rehabilitative interventions for patients with obesity.

**Aim:** The aim of this manuscript is to provide Physical and Rehabilitation Medicine physicians with evidence-based recommendations for the rehabilitation of patients with obesity and related comorbidities.

Design: Evidence-based guidelines.

Population: Adults with overweight or obesity.

**Methods**: Guidelines were based on GRADE and WHO recommendations. A comprehensive search of the available evidence about rehabilitation treatments for obesity was performed, and 17 separate systematic literature reviews were conducted. For each outcome, estimates of the effects of rehabilitation treatments were computed and employed along with an assessment of quality of evidence, desirable and undesirable effects, values and preferences to formulate the recommendations. Recommendations were reviewed by a consensus expert panel using a modified Delphi process.

**Results**: We strongly recommend providing comprehensive multiprofessional and multidisciplinary interventions including exercise, diet and behavioral or cognitive-behavioral therapy. The nutritional component of these treatments should include diets with either a high-protein or a low-fat content. It is strongly recommended to prescribe frequent moderate aerobic exercise. We strongly recommend providing cognitive-behavioral interventions as the behavioral component of rehabilitation programs.

**Conclusion**: PRM physicians should lead multidisciplinary teams providing comprehensive and individualized rehabilitation programs for patients with overweight or obesity. These guidelines were endorsed by the

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International Society of Physical and Rehabilitation Medicine (ISPRM) and by the European Society of Physical and Rehabilitation Medicine (ESPRM).

*Key words*: Obesity, Overweight, Rehabilitation, Lifestyle, Physical and Rehabilitation Medicine, Guidelines

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# ISPRM/ESPRM Guidelines on Physical and Rehabilitation Medicine professional practice for adults with obesity and related comorbidities

### INTRODUCTION

Insert Table 1 here

### **Definitions and epidemiology**

Overweight and obesity are abnormal or excessive fat accumulation that may impair health (1). Diagnosis of such conditions is based on examination of the person's Body Mass Index (BMI), calculated as weight in kg/height in m<sup>2</sup>. Cutoff values for BMI are reported in Table 2.

Insert Table 2 here

Overweight and obesity are epidemic diseases affecting over 600 million adults worldwide and have been declared by the World Health Organization (WHO) as the leading global chronic health issues (2). It is estimated that the overall overweight and obesity rate in Europe is 53.1%, with 15.9% of adults being obese, with no differences between males and females, and that overweight and obese persons double the number of persons with normal weight in the USA (3,4). Importantly, trends are steadily increasing in both prevalence and overall mean BMI across the whole globe (4,5). Consequences of the spread of this epidemics are manifold and span a broad range of economic and public health effects (4,6). These consequences are mainly due to the fact that overweight and obese patients are at high risk to develop many comorbidities.

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### Comorbidities associated with overweight and obesity

Overweight and obesity are gateway to ill health. Both conditions are associated to various types of adipose tissue disfunction, including impairment in adipocyte storage and release of fatty acids, abnormal production of cytokines, hormonal derangement and mechanical effects of excess adiposity (7). Consequently, overweight and obese adults have a higher risk of developing medical conditions such as type 2 diabetes, all cardiovascular diseases, chronic back pain, obstructive sleep apnoea syndrome, obesity hypoventilation syndrome, gallbladder disease, liver diseases, gout, and several common forms of cancer (7–9). In addition, overweight and obese patients are at risk for mental health issues such as depression and anxiety disorders, in particular when Binge Eating Disorder co-occurs (10). Due to the high rate of comorbidities, overweight and obesity are associated with disability, reduced quality of life and higher mortality.

### Overweight, obesity and disability

Both direct and indirect links exist between overweight and obesity and disability. Excess of adipose tissue mass impacts in postural control and reduces functional mobility, since it has a detrimental effect on stability and walking speed. Due to the load on weight bearing joints, pain can be present. Furthermore, overweight and obesity are associated with impairment of cognitive functions, cause limitation in physical activities and restrict participation (11–13). In 2015, overweight and obesity found to contribute to 120 million disability-adjusted life-years, which represents 4.9% of the totality of the disability-adjusted life-years among adults (2). The management of these conditions, their comorbidities and the associated disability poses a significant challenge for Physical and Rehabilitation Medicine (PRM) physicians.

### The role of Physical and Rehabilitation Medicine physicians

The development of rehabilitation programs is mandatory to address the clinical needs of overweight and obese patients, to reduce the impact of the ensuing disability and, ultimately, the costs for the health system. Obesity is a chronic progressive disease requiring proper treatment based on the severity of disability and on the clinical status of the patient in post-acute and rehabilitation settings, as well as in the long term. PRM physicians are therefore called to provide specialized treatment, but are at present mostly unprepared to treat patients with overweight and obesity (14,15). Existing clinical guidelines for the treatment and management of these conditions (e.g. 16–19) are not specifically focused on rehabilitation interventions and, in addition, their recommendations are not always based on meta-analyses and on the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach, which is the most rigorous and transparent norm for assessing the strength of the evidence. Providing PMR physicians with up-to-date and rigorous recommendations could help to enhance the standard of care to meet the needs of overweight and obese patients.

### **Context of these guidelines**

The European Union of Medical Specialists - PRM Section has published in 2017 an evidence-based position paper (15), developed according to the Methodology defined by its Professional Practice Committee (20), which defined the professional role of PRM physicians and provided clinical recommendations regarding the treatment of patients with overweight and obesity. Clinical recommendations regarded treatment of comorbidities, provision of leadership to multidisciplinary rehabilitation teams, use of a distinctive holistic perspective to the patient care process, development of rehabilitation protocols tailored according the characteristics of the patient's condition. Following that position paper, a Guideline Development Group (GDG) was established to create clinical guidelines for the treatment of patients with obesity specifically focusing on rehabilitation interventions.

### METHODS

The guideline creation process followed the WHO guidelines development process and the GRADE methodology (21–23). Its main steps were creating the GDG, planning the review process, formulating the questions in PICO format (Population, Intervention, Comparison, Outcome), performing a comprehensive search of the available evidence on rehabilitation interventions for overweight and obesity, conducting a systematic review for each question, performing a meta-analysis for each outcome, and formulating

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recommendations based on the quality of the available evidence. The GDG was a panel of PRM physicians, endocrinologists, dietitians and clinical psychologists with experience in the field of rehabilitation of patients with obesity or in the methodology for the development of guidelines. Patients or representative from customer organizations were not involved. None of the participants to the GDG had any financial or intellectual conflict of interest during the study. Currently, updates or revisions of the guidelines have not been planned.

### Systematic literature review

Systematic reviews were based on a unique comprehensive search, which was performed in PubMed, EMBASE, Scopus and Cochrane Database of Systematic Reviews in May 2018. Studies were then screened for inclusion to each of the research questions. No language or publication date restrictions were used. Only data from randomized controlled trials and non-randomized controlled trials was considered. The target population of the guidelines were adult patients with overweight or obesity, with or without comorbidities. Accordingly, inclusion criteria were:

- Adult population;
- Included patients with BMI  $\geq 25$ ;
- Assessed the effect of lifestyle, nutritional, physical or psychological\behavioral treatments;
- Reported data about at least one of the critical or important outcomes.
- Had a follow-up period of at least 3 months.

Exclusion criteria were:

- Studies which included women in pregnancy;
- Pharmacologically induced obesity;
- Non-interventional studies
- Pharmacological treatment with anti-obesity medications
- Bariatric surgery approach

Research questions in PICO format and details about keywords employed during the electronic search are reported in Supplementary Digital Material I.

Decision about the critical, important and less important outcomes to be used during the guideline development process was based on discussion between the members of the GDG. Reduction of weight and BMI was considered critical since it is a fundamental requirement for health improvement, as it is associated with reduction of cardiovascular and cardiometabolic risk factors (24,25) and with clinical improvement in comorbidities (26) and it motivates adherence to treatment and further weight reduction (25). Since the treatment effect on weight and BMI could be confounded by increase in lean mass when rehabilitation treatments include exercise programs or suggest increased physical activity, the GDG decided to consider waist circumference alongside weight and BMI as a critical outcome. as it predicts visceral fat and is an index of central obesity. Waist circumference is associated with cardiovascular risk factors and comorbidities independently from BMI (27), and its reduction is associated with benefits in these domains (28).

Accordingly, critical outcomes were:

- weight,
- BMI,
- waist circumference;

important outcomes were:

- quality of life,
- body fat percentage,
- total cholesterol,
- Low-Density Lipoprotein (LDL),
- High-Density Lipoprotein (HDL),
- systolic and diastolic blood pressure;

and less important outcomes were:

• hip circumference,

- triglycerides,
- fasting glucose,
- fasting insulin,
- Glycated Hemoglobin (HbA1c),
- Homeostatic Model Assessment of Insulin Resistance (HOMA-IR),
- High-sensitivity C-reactive Protein (hs-CRP).

For studies assessing the effects of physical exercise, maximum rate of oxygen consumption (VO<sub>2</sub> max) was considered as an additional important outcome. For studies assessing the efficacy of psychological treatments, additional important outcomes were anxiety, depression and binge eating days. For studies assessing the efficacy of psychological treatments for binge eating disorder, binge eating days was a critical outcome.

### Data extraction and management

Titles, abstracts and, if needed, full texts of articles written in languages other than English, Italian and French were translated using Google translate. Retrieved records were first exported to the QCRI Rayyan software (29) and scanned according their titles and abstract. Reference lists of systematic reviews and guidelines found in this process were scanned to retrieve additional studies to be considered for inclusion. Screened records were then exported to the Colandr software (30), which was used to screen the full text of the remaining records and to perform data extraction. Extracted data were: diagnosis (overweight, obesity, or both), comorbidities (none, metabolic syndrome, diabetes, eating disorders, osteoarthritis, heart disease, or other), treatment description, patients' sex, patients' age, study design (randomized controlled trial, controlled trial, or non-controlled trial), number of patients included, number of patients allocated to each treatment arm, treatment duration, each of the outcomes listed above.

### Assessment of risk of bias

The methodological quality of the included studies was evaluated according the Cochrane Risk of Bias tool (31), which assesses random sequence generation, allocation concealment procedures, study participants or personnel blinding, blinding of the assessors, attrition, reporting bias and other biases. Ratings of the methodological quality of the studies were employed to rate the quality of the evidence for each outcome in the recommendations creation phase.

### **Meta-analysis**

For each research question and for each outcome, when possible, random-effects model meta-analyses were employed to synthetize the results of the included studies. When available, 12-months outcomes were analyzed, otherwise the nearest follow-up longer than 12 months was used. In case neither were present, 6-months follow-up were used. Standardized Mean Differences between the compared treatments were computed based on change scores and their associated standard deviations or, if they were not available, follow-up scores and their associated standard deviations. In case standard errors were reported, standard deviations were computed (32). A Restricted Maximum Likelihood estimator was employed. Heterogeneity was assessed using the  $I^2$  index and presence of publication bias was ascertained using funnel plots. This analysis was performed using the R (version 3.5.1) package *metafor* (33).

### **Creation of the recommendations**

The process of formulation of the guidelines was performed using the GRADEPro software (34). For each outcome, quality of evidence was assessed evaluating seriousness of risk of bias (35), inconsistency (36), indirectness (37), imprecision (38) and presence of publication bias (39). Evidence based on randomized controlled trials was initially rated as of high quality, whereas evidence based on non-randomized trials was initially rated as of low quality. In both cases, quality of evidence was then downgraded by one point for each serious flaw, and by two points for each very serious flaw. The overall quality of evidence was equal to the lowest quality of evidence of critical outcomes (22). Possible ratings were high, moderate, low and very low.

### Formulation of the recommendations

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The formulation of each recommendation was based on an overall assessment of quality of evidence, desirable and undesirable effects, benefits and harms of the treatment, values and preferences, acceptability for clinicians and patients and feasibility and resource use. Patients' values and preferences and acceptability for patients were investigated based on unstructured literature reviews. This information was mainly employed to assess potential patient burdens associated with the treatment under study or, when comparing active treatments, to evaluate which one was more likely to be favorably met by patients. Strong recommendations were formulated when high quality evidence suggested clear benefits of the intervention under scrutiny. Instead, conditional recommendations were preferred when low quality evidence was available or when desirable effects did not strongly outweigh undesirable effects. Following the GRADE and WHO methodology, wording of the recommendations reflected their strength, with wording such as "We strongly recommend..." for strong recommendations and "We conditionally recommend..." or "Consider using..." for conditional recommendations (40). Creation of each recommendation was based on discussion by the GDG. The resulting document was then evaluated by two external reviewers, which were not included in the GDG, to improve the reporting of the guidelines. After this phase, the guidelines were modified accordingly.

### **Modified Delphi process**

A two-round modified Delphi process was finally undertaken to review and refine the individual recommendations (41,42). Both rounds were conducted by e-mail. Participants were four international experts in the field of rehabilitation of patients with obesity. During the first round, participants were asked to rate the quality of each recommendation using a set of 7-point Likert scales assessing four domains adapted from the AGREE instrument, namely scope and purpose, rigor of development, clarity of presentation and applicability (43). In addition, they could provide comments and propose modifications to the recommendations' formulation, content and/or strength. Recommendations which received ratings < 6 in any domain were revised and all recommendations were modified integrating the comments of all the participants. In round 2, the revised recommendations were presented to the participants, as well as

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explanations about the changes that were made. For each revised recommendation, participants were asked to decide whether to accept it, to provide additional modifications or to reject it. The GDG incorporated the modifications proposed in round 2. In both rounds, participants' ratings and responses were anonymous.

### RESULTS

Overall, 7847 studies were screened for titles and abstract and 836 full texts were analyzed. Meta-analyses were performed on 133 studies. Overall, only 14 studies included in meta-analyses reported data about quality of life and, since this outcome was operationalized and measured in a heterogenous way, only a narrative evaluation was performed. Summary of the recommendations, their strength and confidence in their evidence is reported in Table 2. For each recommendation, description of the studies included in the correspondent review, their methodological quality, the evidence tables including the estimates of the effects of each treatment and the evidence-todecision tables are reported in Supplementary Digital Material II. Below are reported the recommendations and a brief comment with information about the treatment which was evaluated, balance of benefits and harms, subgroup and implementation considerations.

Insert Table 3 here

### **Final recommendations**

 We strongly recommend that all obese patients are treated with comprehensive lifestyle interventions including exercise, diet and behavioral or cognitivebehavioral therapy to reduce weight, body mass index, waist circumference, blood pressure and fasting insulin levels. (Strength of the recommendation: strong; confidence of the recommendation: moderate)

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Explanations: Comprehensive and multidisciplinary programs aiming at weight reduction through long-term lifestyle modifications are required for a successful rehabilitation of patients with overweight or obesity. These programs are associated with small-to-moderate improvement in weight, body composition, lipid profile and cardiovascular risk factors after 12 months and studies investigating long-term outcomes show that these results are maintained and that these programs reduce comorbidities rates (44,45). These effects were deemed as substantial and provide strong evidence for the implementation of these treatments. Efforts should be made to motivate the patients to maintain the maximum compliance to each intervention component as well as to ensure long-term adherence to lifestyle changes. Therefore, patients should be informed that such changes should be maintained lifelong. These programs should be administered by a multidisciplinary team and should include tailored diet and exercise goals and individual or group sessions with the aim to facilitate behavior change. They can be provided in outpatients settings. Specific recommendations regarding the content of these programs are discussed in the next sections. The main drawback of lifestyle interventions is in their cost, which is higher than that of less intensive treatments, and in the need of specialized multidisciplinary teams. From the patients' point of view, lifestyle treatments require strong efforts in terms of time and indirect costs. However, even if the costs in terms of time and resources are higher compared to less complex treatments, the benefits of these programs far outweigh the costs associated with them (46,47).

 Consider using internet-based lifestyle interventions to improve weight and BMI in case patients' barriers, such as distance or resource constraints, prevent the attendance to face-to-face lifestyle interventions. (Strength of the recommendation: conditional; confidence of the recommendation: low)

Explanations: Internet-based lifestyle interventions can be considered as a viable and cost-effective way to deliver lifestyle interventions, since they can considerably reduce the costs of the interventions and provide tools that can be used to improve the long-term adherence and compliance to treatment prescriptions, potentially resulting in better longer-term outcomes. These treatments include online information materials, tools for goal setting and self-monitoring, automated feedback and suggestions, chats with clinicians or other patients. Compared to control conditions, these treatments have

shown to be associated with small changes in weight, body composition, blood pressure and glucose levels. However, these treatments are less effective than face-to-face lifestyle interventions in terms of weight loss, and they are not associated with changes in outcomes such as waist circumference and lipid profile. These factors are particularly important because they are related to risk of comorbidities. In addition, creation of new internet-based treatments requires initial investment that might not be available to most of the health providers. Therefore, these treatments should be considered only if face-toface interventions cannot be administered due to patient barriers such as difficulty to schedule treatment sessions, need to travel long distances, or resource constraints. Addition of internet-based treatment components to face-to-face lifestyle treatments has shown to add little value (47,48).

3) We recommend against the use of mobile application-based lifestyle interventions instead of face-to-face lifestyle interventions in the rehabilitation of overweight and obese patients. (Strength of the recommendation: conditional; confidence of the recommendation: low)

Explanations: Mobile application-based lifestyle interventions are considered as an enhancement of internet-based treatments, since they have similar treatment components but are more interactive, can be delivered anytime and allow to extend the patient-clinician relationship over time (49). Although mobile applications can be a viable solution to deliver personalized feedback (see Recommendation 5), the GDG decided to currently recommend against mobile-based lifestyle treatments since the available evidence on their effects is still scarce and these treatments are not associated with better outcomes when compared to health education or other control conditions. Overall, certainty of evidence was low. Further high-quality research is required to support the use of these treatments for the rehabilitation of obese patients.

4) We recommend providing feedback about weight loss and physical activity levels to all overweight and obese patients during lifestyle interventions. (Strength of the recommendation: conditional; confidence of the recommendation: low)
Explanations: Along with self-monitoring, feedback about weight loss and physical activity has been recognized as a key skill for weight loss and weight loss maintenance, since it creates opportunity for positive reinforcement, improves self-efficacy and

enables both patient and clinician to manage progress over time (50,51). Providing feedback is associated with moderate reduction in weight and waist circumference compared to not providing feedback. No undesirable effects were found. We recommend providing feedback about physical activity at least weekly, and feedback about weight loss at least monthly. The main drawback of providing feedback is the need for patients to record their data about physical activity and for care providers to monitor patients over time, which can be time-consuming. However, feedback could be delivered not only with face-to face consultation, but also with phone calls, mobile-based applications or wearable technologies.

5) We strongly recommend extending the care after the weight loss phase of lifestyle interventions by providing individual or group counselling to foster maintenance of lifestyle changes. (Strength of the recommendation: strong; confidence of the recommendation: high)

Explanations: Since a high number of patients regain weight after the weight loss phase, identifying methods to enhance the long-term outcomes of lifestyle interventions is crucial. Lifestyle treatments should include a weight loss phase of 1 to 3 months with frequent contact with the multidisciplinary team with the aim to achieve a weight reduction of approximately 10% (52). After this period, the contacts with the multidisciplinary team should be maintained for at least 1 year. Extending the care is expected to produce a small but significant effect on weight and BMI at 12 months, whereas evidence regarding longer-term outcomes seem to be more scarce and need to be documented (53,54). The frequency of contact with the multidisciplinary team can be reduced (e.g. once per month) compared to the weight loss phase. Methods to extend the rehabilitation include scheduling face-to-face visits, phone calls or organizing group sessions.

6) During the weight loss phase, consider prescribing a high protein diet (~30% of total caloric intake) as the nutritional component of the lifestyle program to overweight or obese patients without history or symptoms of kidney disease. When treating patients with dyslipidemia or kidney disease, consider prescribing a low-fat diet. (Strength of the recommendation: conditional; confidence of the recommendation: low)

Explanations: High protein-low carbohydrate diets (<30% proteins) have been proposed as alternative diets to low fat - high carbohydrate diets since they are claimed to be associated with more pronounced changes in body composition through loss in body fat and with positive effects on cholesterol levels, fasting glucose and insulin sensitivity. High protein diets have shown to be more effective than high-carbohydrates or standard protein diets in terms of weight loss, waist circumference, body fat percentage and triglycerides, even if they are associated with a less marked reduction of systolic blood pressure. Overall, confidence in these results is low. Confidence is higher for the estimates of the effects of these diets on weight and triglycerides (high confidence) and on body fat percentage (moderate confidence). These treatments should be applied with caution since claims about potential adverse effects have been reported. In particular, high protein intake is associated with detrimental effects in patients with existing kidney disfunction and might be related to increased chronic kidney disfunctions in previously healthy individuals (55,56). We therefore recommend screening for chronic kidney disease before suggesting a high protein diet and not to prescribe it long term. Low fat diets are to be preferred in the cases in which high protein diets are contraindicated.

7) When treating non-dyslipidemic overweight or obese patients or patients without kidney disease, consider prescribing a very-low carbohydrate intake (< 20% of total caloric intake) during the weight loss period in order to achieve a more pronounced weight loss. (Strength of the recommendation: conditional; confidence of the recommendation: moderate)

Explanations: Very low carbohydrate diets are considered as an alternative to low fat or isocaloric diets since they are claimed to produce a more pronounced weight loss and to have positive metabolic effects, especially in patients with type 2 diabetes. Very low carbohydrate diets are associated with greater changes in weight, BMI, waist circumference, triglycerides and diastolic blood pressure when compared to low fat diets. However, they are also associated with a less favorable lipidic profile. Overall, certainty of evidence is high. Since low-fat diets and high protein diets are associated with similar results, the former can therefore be considered as an alternative approach to the latter when treating patients with dyslipidemia. Very low carbohydrate diets can be less acceptable by patients compared to isocaloric diets and, since the difference with other diets are small and are associated with worse total cholesterol and LDL levels.

Therefore, choice between these diets should be performed considering patients' preference.

8) We conditionally recommend against prescribing calorie restriction below the patient's total energy expenditure during the weight loss phase of the lifestyle intervention. (Strength of the recommendation: conditional; confidence of the recommendation: low)

Explanations: Prescription of calorie intake below what is needed for weight maintenance is a cornerstone of most of the diets for weight loss in overweight or obese patients. However, unrestricted diets, i.e. diets whose beneficial effect is due to restriction of either carbohydrates, proteins or fats, are associated with more marked effect with regards to weight, BMI and triglycerides levels when compared to restricted diets. The effect size of these difference is small and, overall, certainty of evidence was low. Therefore, we recommend that daily intake of calories during the weight loss phase should be calculated considering the patient's total energy expenditure and that it should be individualized based on nutritional and physical activity habits, presence of comorbidities and previous dieting attempts.

9) We recommend against prescribing low-glycemic load diets rather than low-fat or high-protein diets. (Strength of the recommendation: conditional; confidence of the recommendation: very low)

Explanations: Although low-glycemic load diets are considered as promising dietary approaches for the rehabilitation of obesity (57), when medium-to-long term outcomes are considered these diets did not show larger effects than conventional low-fat or high-protein diets. Overall, the quality of evidence was very low. Even if long-term adherence is similar to other diets (58), it is possible that the restriction of food types of low-glycemic load diets makes it more difficult for patients to also reduce the caloric intake (59). More studies are needed to assess the efficacy of these diets and to identify techniques or modifications that might enhance adherence to the dietary advice.

 We conditionally recommend prescribing aerobic training programs rather than strength training programs, in particular when reduction of blood pressure is a rehabilitation target; whereas strength training should be preferred when reduction

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of insulin is a treatment aim. Choice between strength and aerobic training programs should be made also considering patient's preferences. (Strength of the recommendation: conditional; confidence of the recommendation: very low) Explanations: Aerobic training is the optimal mode of exercise, as it helps reducing weight and fat mass while being less time- and resource-consuming for the patients, since it can be done in non-expensive ways, such as brisk walking or cycling. Compared to strength training, it showed to be associated with stronger changes in systolic blood pressure (moderate effects) and is therefore indicated when reduction of this risk factor is a treatment target. Overall, confidence in these estimates is very low. Aerobic training is considered safe and, in particular during the maintenance phase, can be executed without supervision. Strength training is associated with more marked improvement in fasting insulin. Since there are no differences between strength and aerobic training in critical outcomes, patient's preference should be considered in the choice between these two treatments.

11) We strongly recommend prescribing at least 150 minutes/week of moderateintensity exercise during lifestyle programs. (Strength of the recommendation: strong; confidence of the recommendation: high)

Explanations: The GDG decided to provide a strong recommendation regarding the total duration of exercise since increasing the amount of exercise to 150 minutes/week is associated with more marked reduction in weight and BMI compared to exercise programs with lower frequency. Exercise can be diluted in 3 to 5 days per week. Increasing exercise frequency was considered safe and was not associated with treatment non-adherence. We recommend suggesting patients to maintain these physical activity levels in the long term. Overall, quality of evidence was moderate. In addition, the GDG recommends against high intensity exercise since it is not required to achieve weight loss, it is not associated with improvement in risk of incurring in cardiovascular diseases and could be burdensome for patients. In addition, there is evidence that unaccustomed high-intensity exercise can be associated with cardiac events and, as a consequence, medical evaluation prior to prescription is needed (60,61). Therefore, we recommend moderate-intensity exercise such as brisk walking, cycling, swimming or use of treadmills at an intensity inferior than 70% of the age-predicted maximal heart rate.

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12) We recommend against combining aerobic and strength training when planning the exercise component of lifestyle interventions. (Strength of the recommendation: conditional; confidence of the recommendation: very low)

Explanations: Physical activity combining aerobic and strength exercises was hypothesized to be more effective than aerobic or strength training alone, since it could provide the benefits of both in terms of anthropometric and functional outcomes (62,63). Nonetheless, the combination of these two exercise modalities did not result in better outcomes compared to aerobic training alone. Since it might be burdensome for most patients in terms of time and resource use, requires supervision and provides no additional benefit, combination of aerobic and strength training was not recommended for the rehabilitation of obesity. Overall, certainty of evidence was very low.

13) We strongly recommend providing Cognitive Behavioral Therapy (CBT)-based treatments as the behavioral component of lifestyle interventions to reduce weight and depression symptoms. (Strength of the recommendation: strong; confidence of the recommendation: moderate)

Explanations: CBT is a form of psychotherapy aimed at facilitating behavioral change through cognitive restructuring and skill training. In the context of obesity rehabilitation, this approach aims at helping the development of coping strategies and problem-solving skills, enhancing self-efficacy, improving stimulus control and fostering social activation. In addition, since obesity and depression have a bidirectional association (64), CBT-based treatments also address the cognitions that might sustain both conditions and enhances processes, such as the development of self-efficacy, that are crucial to trigger a positive response by the patient. Compared to standard behavioral treatments, CBT-based treatments were associated with more marked reduction of weight and depression levels (small effect size). Certainty of evidence of the effects on weight and depression was moderate. Certainty of evidence of the lack of effects on BMI was very low. CBT-based treatments might not be indicated for patients with lack of motivation to undergo a psychological treatment.

14) We strongly recommend providing cognitive-behavioral therapy for patients with obesity and comorbid binge eating disorder to reduce binge eating days and depression symptoms. (Strength of the recommendation: strong; confidence of the recommendation: moderate)

Explanations: Binge eating disorder is a condition characterized by uncontrollable episodes of ingestion of a very large quantity of food in a very limited period of time accompanied by a deep sensation of loss of control (65). Such condition should be diagnosed as early as possible since it might impede weight loss, is associated with a worse metabolic and inflammatory profile and, along with obesity, is intertwined with depression (66,67). CBT-based treatments were developed to address obesity and comorbid binge eating disorder by changing dysfunctional cognitions regarding shape, weight and dieting and their relationships with the underlying self-schemas. CBT-based treatments should be preferred over standard behavioral treatments since they reduce binge eating days and depression levels. Overall, certainty of evidence was high. No differences were detected comparing cognitive-behavioral treatments administer individually or in group sessions (68).

### DISCUSSION

As a recent scoping review pointed out, the best practices regarding the rehabilitation of patients with overweight and obesity were still to be defined (69). Given the increasing prevalence of these conditions worldwide and the conceptual shift of considering and treating them as chronic diseases instead of reversible acute conditions (70), specific rehabilitation-focused and evidence-based recommendations were needed. This manuscript presents the first guidelines developed for this purpose. Their relevance lies in the fact that they have been specifically developed for rehabilitative settings and following a rigorous and transparent methodology.

These guidelines strongly encourage to implement the three main interventions, namely diet, physical activity and cognitive behavioral interventions, within comprehensive multidisciplinary and individualized rehabilitation programs. Even if such comprehensive programs have been long advocated, efforts are still needed to further improve their availability (14,71,72). Furthermore, a cultural and organizational shift is

still needed in different rehabilitation settings where patients might also be obese, in order to recognize obesity as a disease, to follow the best practices to treat this condition, and to screen for mental health issues potentially hindering adaptive lifestyle changes (14,73).

Special consideration should be given to overweight or obese patients undergoing rehabilitation after acute events. In these settings, the rehabilitation programs outlined by these guidelines should be carefully adapted based on the clinical conditions of the patient and on treatment priorities. Familiarizing physicians with the multidisciplinary clinical aspects of overweight and obesity might contribute to improve quality and effectiveness of their rehabilitative approaches.

The overall aim of rehabilitation programs for overweight and obesity should be to improve the patients' quality of life (15). Surprisingly, only few studies included in the reviews which were used to formulate the above recommendations reported data about this outcome. Although it is established that patients with obesity suffer from reduced quality of life (74,75), mainly from the impact of comorbidities, lack of randomized controlled trials assessing it might suggest that few treatments are specifically developed to address this outcome. Due to the chronic nature of obesity, it is warranted that future rehabilitation programs and research studies fill this gap.

These guidelines were endorsed by the International Society of Physical and Rehabilitation Medicine (ISPRM) and by the European Society of Physical and Rehabilitation Medicine (ESPRM). They will be spread by the ISPRM with summary documents for clinicians. The following step will be their implementation and evaluation in clinical practice, which will involve the evaluation of the costeffectiveness of the proposed rehabilitation treatments and the monitoring of the implementation of each recommendation, with an assessment of the barriers for its application. This could enable to plan education for professional development focused on patient-centered rehabilitation through comprehensive multidisciplinary programs that should be promoted within the field of PRM specialty.

### CONCLUSIONS

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We recommend providing comprehensive multidisciplinary and multiprofessional lifestyle interventions tailored according to the characteristics of the patient. These interventions should be extended to support the patient in the long term. The nutritional component of these treatments should include diets with either a high-protein or a low-fat content. We recommend suggesting frequent moderate aerobic exercise, which should be maintained as a part of the patient lifestyle. Finally, we recommend providing individual or group cognitive-behavioral interventions to help achieve a more pronounced weight loss and to address comorbidities such as depression and binge eating disorder.

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### NOTES

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BMI	Body Mass Index
CBT	Cognitive Behavioral Therapy
ESPRM	European Society of Physical and Rehabilitation Medicine
GDG	Guideline Development Group
HbA1c	Glycated Hemoglobin
HOMA-IR	Homeostatic Model Assessment of Insulin Resistance
hs-CRP	High-sensitivity C-reactive Protein
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HDL	High-Density Lipoprotein
ISPRM	International Society of Physical and Rehabilitation Medicine
LDL	Low-Density Lipoprotein
PICO	Population, Intervention, Comparison, Outcome
PRM	Physical and Rehabilitation Medicine
VO <sub>2</sub> max	Maximum rate of oxygen consumption
WHO	World Health Organization

### Table 1. List of abbreviations

0

18.5 to < 25	Normal range
25 to < 30	Overweight range
30 to < 35	Obese range (class I)
35 to < 40	Obese range (class II)
$\geq$ 40	Obese range (class III)

**Table 2.** BMI cutoff values for identification of overweight,obesity and obesity classes in adults

1

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	Intervention	Comparator	Favors	Certainty	Favors	Certainty	Strength of the	Confidence
			Intervention		comparator		recommendation	l
1	Lifestyle	Control conditions,	Weight	High	None		Strongly in favour	r Moderate
	interventions	usual care	BMI	High				
	including diet,		WC	Moderate				
	exercise and		Body fat	Low				
	behavioral treatment		percentage					
			Total cholesterol	Moderate				
			HDL	High				
			Triglycerides	High				
			SBP	High				
			DBP	High				
			Glucose	High				
			Insulin	Moderate				
2-	Web-based lifestyle	Face-to-face lifestyle	Body fat	Very low	Weight	Moderate	Conditionally	Moderate
3	interventions	interventions	percentage				against	
			Weight	Moderate	None		Conditionally in	Moderate
							favour	

Table 3. Summary of the ISPRM/ESPRM recommendations for the management of obesity

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	Usual care, no	BMI	Moderate			
	treatment or	Body fat	Low			
	information only	percentage				
		SBP	Moderate			
		DBP	Moderate			
		Glucose	Moderate			
4 Mobile applications-	Control conditions,	Total cholesterol	Low	None	 Conditionally	Low
based lifestyle	usual care, no				against	
interventions	treatment					
5 Providing feedback	Not providing	Weight	Low	None	Conditionally in	Low
about weight loss and	feedback	WC	Moderate		favour	
physical activity						
during a lifestyle						
intervention						
6 Extending care after	Not extending care	Weight	High	None	Strongly in favour	Moderate
weight loss phase	after weight loss	BMI	High			
providing individual						
or group counselling						
and monitoring						

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7-	High protein diets	High carbohydrates	WC	Low			Conditionally in	
8	(~30% of total caloric	diets	Body fat	Moderate			favour	
	intake)		percentage					
			Tryglicerides	High				
		Low fat diets	None		None		_	
9	Very low	Low fat diets	Weight	High	Total	High	Conditionally in	High
	carbohydrates diets				cholesterol		favour	
	(~10% of total caloric		BMI	High	LDL	High		
	intake)		WC	High				
			HDL	High				
			Tryglicerides	High				
			DBP	Moderate				
10	Unrestricted diet	Calorie-restricted	None		Weight	Low	Conditionally	Low
	regimens	diets			BMI	Low	against	
					Tryglicerides	Low		
11	Low glycemic load	Low fat or high	None		None		Conditionally	Very low
	diets	protein diets					against	
12	Aerobic training	Strength training	SBP	Very low	Insulin	Very low	Conditionally in	Very low
							favour	

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13	Aerobic and strength training	Aerobic training only	None		None	Conditionally against	Very low
14	High-intensity exercise	Moderate-intensity exercise	VO <sub>2</sub> peak	High	None	Conditionally against	Very low
15	Exercise at higher	Exercise at lower	Weight	Moderate	None	Strongly in favour	Moderate
	frequency	frequency	BMI	Moderate			
16	Cognitive behavioral	Standard behavioral	Weight	Moderate	None	Strongly in favour	Moderate
	therapy	therapy	Depression	Moderate			
17	Cognitive behavioral	Standard behavioral	Binge-eating days	High	None	Strongly in favour	Moderate
	therapy for binge-	therapy	Depression	High			
	eaters		Anxiety	Very low			

Note. Abbreviations: BMI: Body Mass Index; WC: Waist Circumference; SBP: Systolic Blood Pressure; DBP: Diastolic Blood Pressure

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