## **Executive Summary of Evidence and Consensus-Based Clinical Practice** Guidelines for Management of Obesity and Overweight in Midlife Women: An AIIMS-DST Initiative

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midlife women were finalized with the help of a multidisciplinary team of experts in the guideline development group. Phase I including a systematic and/or narrative review, grading of evidence, and expert opinion was sought to develop clinical practice recommendations for each clinical question. Phase II focused on validation of clinical practice recommendations using the peer-review, Delphi method, and GRADE approach. The guidelines provide clinical practice points to address challenges encountered by midlife women in their attempts to manage obesity via lifestyle modification techniques. The initiation of discussion would help the health-care provider to identify the weight management needs of the women, educate women on different modalities of weight management, and empower them to incorporate corrective lifestyle behaviors. Before initiating the management, a comprehensive assessment of clinical and lifestyle-related parameters should be completed. A personalized behavioral lifestyle modification program addressing the midlife-specific barriers for optimal metabolic, musculoskeletal, and mental health should be planned. A consistent follow-up is required for maintenance of corrective eating and activity habits by addressing midlife-specific barriers for sustenance of healthy weight. These recommendations will be useful in opportunistic screening and management of obesity in midlife women across health-care settings.

Weight gain is an independent risk factor for decline in cardiometabolic and overall

health-related quality of life in midlife women. The AIIMS-DST initiative aims to

develop and validate stepwise recommendations specific for weight management

in midlife women. The key clinical questions specific to weight management in

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## Introduction

Obesity in midlife women is a clinical and public health challenge. Midlife women transitioning from reproductive to nonreproductive phase experience several biological and hormonal changes that lead to weight gain, especially in the abdominal region. [1,2] Further, this menopausal transition affects lifestyle-related behavior such as eating, physical activity, and sleep practices in a way that promotes weight gain. These women find it difficult to manage corrective eating and physical activity behavior in day-to-day life as they prioritize their roles at home and work over their weight and health-related issues. [3]

Weight gain in midlife is also associated with chronic cardiometabolic disorders including diabetes, hypertension, and dyslipidemia, and some obesity-related disorders such as nonalcoholic fatty liver, sleep apnea, and osteoarthritis in later years. Generally, midlife women presenting with weight-related health issues at health-care settings are given generic lifestyle counseling such as "eat healthy foods" and "exercise regularly." [4] Considering the nature of this advice, even highly motivated midlife women find it challenging to maintain corrective lifestyle-related behaviors when they encounter midlife-specific barriers and have poor weight loss outcomes in the long term. [5] Midlife-specific barriers including emotional volatility, body image issues, joint pain, loss of muscle mass, lack of time, competing for household and work-related responsibilities, and lack of social support need to be

## **Box 1: Key Definitions**

Midlife women: Midlife women experience biological, psychological, and social transition due to chronological and ovarian aging. The range for midlife is considered to range from 35-40 years to about 60 - 65 years. This age range includes women in different stages of the reproductive cycle menopausal transition, menopausal stage, and late post-menopausal stage.<sup>[11]</sup>

Menopause: Menopause is the natural physiologic event characterized by cessation of the menstrual cycle or consecutive twelve months without menstrual period reflecting loss of ovarian follicular function.<sup>[1]</sup>

Lifestyle modification: Lifestyle modification can be referred to as the process of gradual adaptation of corrective lifestyle habits such as diet, physical activity, and sleep for the prevention and management of various diseases such as obesity, diabetes, and hypertension. [49,99]

Clinically significant weight loss: Clinically significant weight loss can be defined as at least a 5% reduction of the baseline body weight.<sup>[100]</sup>

Weight Maintenance Phase: The weight maintenance phase is the most important component of the weight loss journey to sustain stable weight loss. According to the Institute of Medicine, weight maintenance can be defined as losing at least 5% of body weight, or reducing body mass index (BMI) by at least 1 unit, and sustaining below this weight for at least 1 year.<sup>[101,102]</sup>

Delphi Method: Delphi method is a relevant research tool for the development of gradual and reliable expert-based consensus where existing literature is uncertain and incomplete. Structured group communication processes are conducted to obtain the best possible consensus of opinion of experts.<sup>[103]</sup>

Recommendations based on Evidence (RBE): The recommendations based on evidence were developed by the experts on the basis of available evidence based literature.

Recommendations based on Opinion (RBO): The recommendations based on opinion were developed by the consensus of experts whenever high-quality evidence based literature was insufficient evidence.

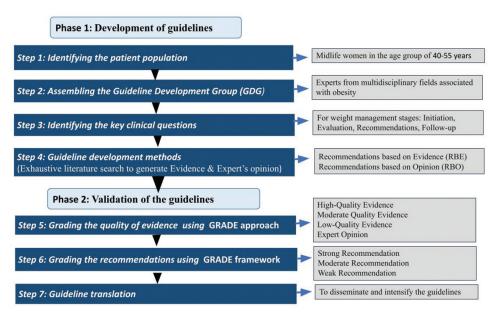


Figure 1: Methodological flow chart to develop and validate evidence and consensus based guidelines

addressed by health-care providers for appropriate weight loss. [6,7]

Health-care providers are obligated to provide opportunistic management to obese and overweight midlife women. This highlights the need to protocolize the management of overweight and obesity in midlife women across different health-care settings using evidence-based clinical practice for ensuring uniform and adequate weight management. The recommendations provide clinical practice points for prescribing lifestyle modification treatment via diet, activity, and behavioral advice to midlife women with obesity. The scope of these recommendations is limited to first-line treatment via lifestyle modification, and it does not include aspects of pharmacological and surgical management.

## **METHODOLOGY**

The guidelines were planned in two phases using standardized methodology as per the National Health and Medical Research Council: (i) development of recommendations and (ii) validation of the developed recommendations. The flowchart for the methodology is outlined in Figure 1. First, an exhaustive list of key clinical questions through literature search, expert opinion, and Delphi method was identified to be addressed by the guideline. In Phase I, a systematic and/or narrative review, grading of evidence, and expert opinion were sought to formulate clinical practice recommendations for each clinical question. In Phase II, the clinical practice recommendations were peer reviewed and validated using the Delphi method and graded using the GRADE approach via

the experts participating in guideline development group (GDG).<sup>[8,9]</sup> Some important definitions are presented in Box 1.

# Phase I: Development of guidelines Step 1: Identifying the patient population

The guideline can help health-care providers to initiate, evaluate, and manage obesity in midlife women undergoing menopausal transition or at the postmenopausal stage. Considering the range of age at menopause as per the Clinical Practice Guidelines on Menopause in Indian women, we define the age range from 40 to 55 years as midlife in the context of the given recommendations.[10] Across literature, the midlife age can extend to 65 years including women in the late postmenopausal phase.[11] The scope of these recommendations is focused only on weight management through lifestyle modification in women transitioning toward menopause and early postmenopausal stage, so women in the late postmenopausal stage were not included in target population.

## Step 2: Assembling the guideline development group

Experts from different multidisciplinary fields management (including associated with weight medicine. endocrinology, gynecology, nutrition, psychology, physical medicine, and rehabilitation) in midlife women were requested to participate in the development and validation of key clinical questions that can be addressed by the clinical practice recommendations for optimum weight management. Further, chairperson and field experts from eminent national organizations such as the

Department of Science and Technology, the Federation of Obstetric and Gynaecological Societies of India, Indian Menopause Society, Association of Physicians of India, Academy of Family Physicians of India, Association of Obstetricians and Gynaecologists of Delhi, Indian Dietetic Association, and the Indian Society of Clinical Nutrition also participated in the GDG. From academia, senior professors across five leading medical colleges of the country participated in the proceedings of GDGs.

## Step 3: Identifying the key clinical questions

A list of pertinent clinical questions was formulated for appropriate management of obesity and was presented to the GDG. In a Delphi exercise by the GDGs, the final key clinical questions were formulated to address the following stages of weight management:

Stage 1: Initiation of discussion for weight management in midlife women

Stage 2: Evaluation for midlife weight management

Stage 3: Clinical Practice Recommendations for midlife weight management

Stage 4: Follow-up for sustainable weight loss in midlife women.

It should be noted that the key clinical questions for pharmacological and surgical management of obesity are not addressed in these guidelines.

## Step 4: Guideline development methods

An exhaustive literature search was conducted independently for each clinical question to generate high-quality evidence. In case of limited and/ or inconclusive evidence, the experts' opinion was warranted. The clinical practice recommendations were categorized into recommendations based on evidence (RBE) and recommendations based on opinion (RBO). The RBE was developed in cases where sufficient evidence was available to form a recommendation by the GDGs. In case of insufficient high-quality evidence, the consensus by experts on required clinical practice led to the formation of RBO.

## Phase II: Validation of the guidelines

All the formulated recommendations were subjected to a two-level peer review before finalization. The quality of gathered evidence and recommendations was assessed using the GRADE approach.

## Step 5: Grading the quality of evidence

The quality of gathered evidence has been sought according to the number and design of the studies as recommended by the GRADE approach [Supplementary Table 1]. [9,12]

## Step 6: Grading the recommendations

The Grade of the recommendation has been determined after considering the GRADE framework. [9] The current recommendations are based on behavioral lifestyle modification (excluding pharmacological and surgical modalities) which are likely to have less potential for harm and/or risk. Thus, the grade of the strength of recommendation should be mainly decided based on feasibility, available resources, and acceptability within the target population in clinical settings. The grades that can be given to the strength of recommendation are presented in Supplementary Table 2.

## Step 7: Guideline translation

The guideline translation program will propagate and intensify the impact of evidence and consensus-based guideline on weight management in midlife women. The guideline translation program aims to:

- Build capacity and improve the competency of health-care providers to disseminate high-quality, evidence-based care to midlife women
- Enhance knowledge of midlife women regarding obesity and its future implications
- Promote evidence-based, high-quality midlife care.

#### RESULTS

# **1. Initiation of discussion for weight management** *Key clinical question 1.1*

When should a health-care provider initiate structured counseling regarding weight management in midlife women?

Recommendation 1.1.1: Opportunistic screening and management of obesity should be provided all through the lifespan of a woman.

Grade: IV A.

Recommendation 1.1.2: In the late thirties, before menopause transition, women should be counseled about the added risk of menopause-related weight gain and body fat redistribution. Opportunistic screening and management of obesity should be continued.

Grade: II A/B.

Recommendation 1.1.3: In the early forties, when women experience menopausal transition, intensive customized weight management counseling should be given. The emphasis should be on corrective lifestyle behavior and handling health issues specific to menopausal transition such as menopausal symptoms, sleep disturbances, psychological distress, bone and joint health, and other comorbidities.

Grade: II A.

#### Note

Generally, women can experience weight gain during puberty, adulthood, and reproductive stages such as pregnancy and lactation due to biological and/or lifestyle-related risk factors.[13,14] In addition, the onset of menopausal transition in women marks an additional risk to gain weight, especially as total body and abdominal fat during midlife.[15] Across the literature, the mean age at menopause is 46 years in Indian women.[10] Further, the mean age of early menopause due to premature ovarian insufficiency was 38 years and late menopause was beyond 54 years.[10] In addition, a concordance was observed in the increase in weight and total body fat, especially around the abdominal region resulting in high cardiometabolic risk in later life.[16,17] Experts believed that health-care providers are obliged to provide weight management advice on encountering women with obesity. The additional risk of weight gain observed during the menopausal transition should be addressed by any health-care provider by empowering midlife women with lifestyle modification advice to manage their weight status.[17] If the midlife woman is overweight or obese, she should be enrolled in a weight management program or referred to a specialist.

## Key clinical question 1.2

What are the components of knowledge, attitude, and practice (KAP) that should be evaluated to plan a personalized weight management intervention in midlife women?

Recommendation 1.2.1: Assessment of KAP related to risk factors and consequences of obesity on the holistic health of women is recommended.

## Grade: III A.

Recommendation 1.2.2: Different modalities for weight management, barriers, and facilitators in their implementation should be evaluated and accounted for in the management plan.

## Grade: III B.

#### Note

The studies indicate that KAP was assessed via cross-sectional surveys on parameters related to weight status in midlife women. Studies reported that an interplay of lifestyle-related, menopausal, and psychological factors is associated with weight gain in midlife women. [1] Midlife women had a limited understanding of correct eating and activity to maintain weight. In addition, they prioritize their roles as homemakers, mothers, and working women over their own health. [18,19]

## Key clinical question 1.3

Who are the health-care providers that can be involved

in the management of overweight and obesity in midlife women?

Recommendation 1.3.1: The protocolized weight management module should be implemented by any health-care provider who encounters a woman in her midlife for routine screening or specific health conditions.

## Grade: IV A.

Recommendation 1.3.2: Wherever feasible, a multidisciplinary team consisting of primary care physicians, clinicians, dietitians, and exercise physiologists/physiotherapists should be involved in weight management of midlife women. Specialists including psychologists/psychiatrists, endocrinologists, orthopedicians, and psychiatrists should be involved, whenever indicated.

#### Grade: I A.

Recommendation 1.3.3: All health-care providers should be empowered with the knowledge and skills for prevention, diagnosis, and treatment of obesity in midlife women.

## Grade: IV B.

#### Note

Studies suggested that a multidisciplinary approach including clinician, nutritionist, psychologist, exercise physiologists/physiotherapists, and a specialist (if indicated) is ideal for appropriate management of obesity in midlife women. [20] Considering the lack of health-care resources in developing countries, experts believe that opportunistic screening and management of obesity should be provided by all health-care providers who encounter midlife women with obesity. They also believed that policy reforms are required to empower health-care professionals at different settings for providing adequate obesity care. [21]

#### Key clinical question 1.4

What could be effective ways of delivering pertinent information to midlife women regarding the management of overweight and obesity?

Recommendation 1.4.1: A combination of face-to-face and technology-supported distance counseling should be planned for the management of weight in midlife women with overweight and obesity.

## Grade: IV A.

Recommendation 1.4.2: Internet and mobile-based applications should be used proactively for improving compliance by enhancing patient education, motivation, self-monitoring, personalized feedback, and managing challenges faced by inappropriate weight management practices.

Grade: II A.

Recommendation 1.4.3: A toolkit consisting of education material apprising midlife women about menopausal transition and its impact on weight status and key management strategies can be developed, distributed, and utilized across various health-care settings.

## Grade: IV B.

#### Note

Several systematic reviews and meta-analyses recommended different counseling strategies weight management.[22,23] In comparison to traditional one-to-one counseling, web-based counseling was minimally effective in managing weight. Some studies found out that web-based physical activity sessions were more effective in managing weight.[24] Experts believe that a toolkit consisting of lifestyle education material can prove beneficial in empowering women in managing their weight. These toolkits should be developed as a public health initiative and distributed across health-care settings to be disseminated to the target population as a part of opportunistic management strategy.

## 2. Screening and risk assessment

## Key clinical question 2.1

What body mass index (BMI) cutoff and other anthropometric parameters should determine the need to initiate weight management intervention in midlife women?

Recommendation 2.1.1: BMI and waist circumference should be used independently for population- and clinic-based cardiometabolic risk stratification and other obesity-related diseases.

## Grade: I A.

Recommendation 2.1.2: For initiating a weight management intervention, the class of generalized obesity should be identified according to the BMI cutoff:

- 18.5–22.9 kg/m<sup>2</sup> Normal weight
- 23.0–24.9 kg/m<sup>2</sup> Overweight
- $\geq 25 \text{ kg/m}^2 \text{Obesity.}$

## Grade: I A.

Recommendation 2.1.3: For initiating weight management intervention, the cutoff reference for waist circumference should be as below:

- Waist circumference less than or equal to 72 cm Normal
- Waist circumference more than 72 cm but less than 80 cm associated with one cardiometabolic risk factor – Initiate weight management advice
- Waist circumference more than 80 cm associated with cardiometabolic comorbidities – Initiate intensive weight management.

#### Grade: I A.

#### Note

Consistent data were found establishing the association of BMI and waist circumference with risk of general and abdominal adiposity, cardiometabolic risk, and obesity-related diseases. Previous National Recommendations on Indian adults suggest that Asian Indians are predisposed to cardiometabolic risk at lower BMI and recategorized the overweight as (23-24.9 kg/m²) and obesity as (≥25 kg/m²).[25] Several studies also identified waist circumference as a responsive indicator of cardiometabolic health.[26-28] In Asian adults, a waist circumference of 80 cm was associated with cardiovascular risk in comparison to 88 cm which was internationally accepted. In addition, a waist circumference of less than equal to 72 cm was considered to be normal.<sup>[25]</sup> In resource-rich settings, dual-energy X-ray absorptiometry scan should be warranted to calculate the total body fat, lean muscle mass, total body water, and visceral fat.[29]

## Key clinical question 2.2

How should dietary practice be evaluated in midlife women?

Recommendation 2.2.1: The detailed dietary evaluation should include an assessment of the usual meal pattern (including the quantity of food items consumed) and dietary habits (including skipping meals, typical frequency of consumption of high fat, salt, and sugar [HFSS] foods, emotional/stress eating).

#### Grade: I A.

Recommendation 2.2.2: Twenty-four-hour dietary recall and food frequency questionnaire for 3 days (2 weekdays and 1 weekend) should be used for dietary evaluation, if feasible. Energy, macronutrient, and fiber intake should subsequently be calculated. Alternatively, a short, validated questionnaire can be used (A short validated questionnaire aims to assess various aspects of dietary habits among midlife women including eating habits and barriers associated with practicing healthy dietary behavior in everyday life).

#### Grade: II B.

Recommendation 2.2.3: Dietary intake of foods rich in protein, iron, and calcium should also be assessed while taking dietary history.

## Grade: IV B.

Recommendation 2.2.4: The barriers faced by midlife women to maintain a healthy diet in their daily lifestyle should be evaluated.

Grade: IV B.

#### Note

Across weight-loss trials, assessment of current caloric intake, dietary habit-related health risks (such sarcopenic obesity, cardiometabolic distress, osteoarthritis), and micronutrient deficiencies is a key step in the dietary management for weight loss in midlife women.[30,31] Ideally, the dietary intake should be assessed using a 24-h dietary recall and food frequency questionnaire. In some studies, the barriers to healthy eating scale were used to assess the challenges faced by adults in maintaining corrective eating behaviors. [32,33] Considering the feasibility of these approaches, the experts suggested an in-depth dietary recall can be used to assess the key points in caloric intake of midlife women.

## Key clinical question 2.3

How should the level of daily physical activity of midlife women be evaluated?

Recommendation 2.3.1: The detailed physical activity evaluation should include an assessment of dedicated physical exercise and domestic, work-related, leisure-related, transport-related, and sedentary activities (screen and sitting time).

## Grade: I B.

Recommendation 2.3.2: Madras Diabetes Research Foundation-Physical Activity Questionnaire (MPAQ) should be used to evaluate the level of physical activity, if feasible. Alternatively, a short validated questionnaire can be used (A short validated questionnaire aims to assess various aspects of physical activity among midlife women including the daily physical activity and barriers associated with inability to follow a physically active routine in everyday life).

#### Grade: II B/C.

Recommendation 2.3.3: The evaluation of the adequacy of physical exercise should be done by assessing type (stretching/strengthening/aerobics/balance), intensity (light/moderate/vigorous), frequency (number of days per week), and duration (number of minutes per day) of exercise.

## Grade: IV B.

Recommendation 2.3.4: Special attention should be given to assess the number of sedentary hours (especially screen time and sitting time) spent during the day.

## Grade: IV A.

Recommendation 2.3.5: Midlife women should be encouraged to discuss the barriers faced by them in maintaining an active lifestyle.

#### Grade: IV A.

## Note

In the current literature, several objective, subjective, and combination tools are available for assessment of physical activity.[34-36] The daily activity levels were calculated as metabolic equivalent values or as categories for activity status ranging from low, moderate, and high status. Most of these tools measured activity status across different domains such as work-related, leisure-related, and sedentary activities.[37-39] For Indians, MPAQ is a developed and validated questionnaire to assess daily physical activity status using a recall method in an interview schedule.<sup>[40]</sup> Considering the feasibility, experts believed that health-care professionals can assess activity status by assessing the frequency of participation in an activity in a week and the nature of the participation. They also recommended that midlife-specific barriers for maintenance of an active lifestyle should also be probed by the health-care provider.

## Key clinical question 2.4

How psychological and behavioral health should be evaluated in midlife women being engaged in the management of overweight and obesity?

Recommendation 2.4.1: Assessment should include inquiry into the presence of a diagnosed psychiatric disorder, especially depression, anxiety, or eating disorder.

## Grade: II A.

Recommendation 2.4.2: If there is clinical suspicion, DASS-21 can be used as an initial screening tool for the assessment of depression, anxiety, and stress.

## Grade: I B.

Recommendation 2.4.3: In case a diagnosed psychiatric disorder is present, the current condition of the psychiatric disorder and use of psychotropic medications should be asked for by the weight management team.

#### Grade: I A.

Recommendation 2.4.4: The referral to a mental health professional should be considered if:

- 1. Dietary history reveals abnormal eating practices to cope with stress
- 2. There is a sudden lack of motivation for weight reduction
- 3. There are persistent interpersonal difficulties with the weight management team
- 4. DASS-21 score indicates the possibility of depression, anxiety, or stress
- 5. There is a history of diagnosed psychiatric disorder
- 6. There is clinical suspicion of a known psychiatric disorder.

## Grade: IV A.

#### Note

A vicious cycle between obesity and decline in mood and cognitive abilities was noted. [41,42] It was observed that obese women were more prone to psychological distress. Further, the increase in distress limited their participation in managing healthy eating and activity behavior, thereby leading to greater risk of obesity. [43] In case of suspicion, DASS-21 should be administered by the health-care provider. [44] The referral to a mental health professional is crucial for maintenance of the corrective eating and activity behaviors, especially in women presenting with disturbed eating patterns, lack of motivation, and history of disorder. [45]

## Key clinical question 2.5

What are the important comorbid conditions (cardiometabolic and other medical conditions) that should be evaluated before initiating management of overweight and obesity?

Recommendation 2.5.1: In midlife women, lifestyle intervention should be initiated if they have any known cardiometabolic risk factors (such as abnormal blood sugar, increased blood pressure, and dyslipidemia) or obesity-related complications (such as nonalcoholic fatty liver and sleep apnea).

#### Grade: I A.

## Note

Across literature, obesity in midlife has a positive correlation with clustering of one or more components of metabolic syndrome (elevated lipid profile, insulin resistance and high blood pressure, and elevated inflammatory markers) and obesity-related disorders with weight gain, total body fat, and central adiposity. [46-48] It has been recommended that biochemical investigations should be undertaken to assess the cardiometabolic risk factors including fasting blood glucose, lipid profile, thyroid-stimulating hormone, glycosylated hemoglobin, fasting insulin, and C-reactive protein as per the indications by the clinicians. [49,50]

## Key clinical question 2.6

How should menopause-related symptoms be evaluated in midlife women being engaged in the management of overweight and obesity?

Recommendation 2.6.1: Menopause rating scale (MRS) may be used for the evaluation of menopausal symptoms, which includes physical, psychological, vasomotor, genitourinary, and sexual domains.

Grade: I B.

Recommendation 2.6.2: The impact of menopausal symptoms severity on weight-related behaviors (diet, physical activity, and sleep) should also be assessed.

## Grade: IV A.

#### Note

A number of tools were identified for the assessment of menopausal symptoms and its severity. [51-55] According to the recommendation on clinical management of menopause in Indian women, MRS was identified as an appropriate assessment scale. [10] In addition, experts also believed that the association between the menopausal symptom severity and lifestyle-related behaviors should be assessed for customizing the weight management strategies.

## 3. Management of overweight and obesity

Key clinical question 3.1

How stepwise weight loss goals should be set in midlife women being engaged in the management of overweight and obesity?

Recommendation 3.1.1: Health-care providers should assess the readiness to engage in weight loss attempts by changing the current diet and physical activity using behavioral modification.

Grade: IV A.

Recommendation 3.1.2: Realistic and sustainable patient-centered weight loss goals should be established after a detailed discussion with the midlife woman.

If feasible, family members should be involved, and similar health goals should be planned for them.

Grade: IV A.

Recommendation 3.1.3: Overweight and obese women should be advised to reduce body weight to a normal BMI (18.5–22.9 kg/m²).

Grade: I A.

Recommendation 3.1.4: A stepwise body-weight loss goal should be set with a target weight loss of 0.5 kg per week attaining a weight loss of 5%–10% of baseline body weight for 6 months (clinically significant weight loss).

## Grade: I A.

#### Note

Several previous recommendations on obesity management and randomized control trials advised a goal of 5%–10% reduction from baseline body weight for 6 months and progressively reaching the ideal BMI.<sup>[56-58]</sup> It was suggested by the experts that the weight loss goals should be mutually set during discussion with the midlife women and their family members (if feasible). These

weight loss goals should be translated into progressive changes in day-to-day lifestyle for improved compliance.

## Key clinical question 3.2

What type of dietary recommendations should be advised for improving weight loss, anthropometric, and metabolic health outcomes?

Recommendation 3.2.1: An individualized diet plan should be recommended considering eating preferences, food habits, and the health status of the participant.

## Grade: I A.

Recommendation 3.2.2: The meal pattern should be spread throughout the day preferably involving three major meals and two snacks.

#### Grade: II A.

Recommendation 3.2.3: The daily dietary calorie intake should be based on the baseline caloric intake and level of physical activity of the midlife woman.

#### Grade: I A.

Recommendation 3.2.4: The diet plan should incorporate an energy deficit of 500 kcal per day to achieve a weight loss of 0.5 kg body weight per week.

## Grade: I A.

Recommendation 3.2.5: Restricted carbohydrate, good-quality fat, and a high protein diet is recommended for midlife women.

## Grade: II A.

Recommendation 3.2.6: Women should be counseled to consume foods rich in protein, calcium, and iron in their daily diet to meet the estimated average requirement.

## Grade: I A.

Recommendation 3.2.7: Dietary fiber intake of 20–30 g per day should be prescribed from whole grains, legumes, nuts, oilseeds, fruits, and vegetables.

#### Grade: I A.

Recommendation 3.2.8: Restricted consumption of food products high in fat, sugar, and salt (HFSS) should be emphasized. Salt intake should be limited to less than 5 g/day.

## Grade: I A.

Recommendation 3.2.9: Dietary intake of foods rich in phytoestrogen from the Indian diet should be encouraged.

#### Grade: III C.

#### Note

Across the literature, weight loss trials recommended individualized hypocaloric plans for weight loss.<sup>[57,59]</sup> Generally, a deficit of 500 kcal was recommended to achieve a weight loss of 0.5 kg body weight in 1 week.[49] Considering this, the average caloric intake prescribed in clinical practice is around 1000-1200 kcal. Across trials, different diets were recommended for achieving a negative caloric balance. The advised diet should be restricted in carbohydrates (40%-50% energy) and include good-quality fats (25%-30% energy), high protein diet (25%-30% energy), and high daily dietary fiber (20-30 g).[59-61] The dietary fiber intake can be incorporated by adding vegetables (4–5 servings per day), legumes (1–2 servings), nuts and oilseeds (1–2 servings), and whole-grain flour in the daily diet.<sup>[61]</sup> Other studies focused on providing corrective dietary habits such as regular meal patterns, incorporation of foods rich in iron, calcium, and Vitamin D, and limiting sugar and salt intake.<sup>[27,62,63]</sup> To manage the menopausal symptoms in midlife women, foods with high phytoestrogen such soybean, flaxseeds, olive oil, almonds, multigrain bread, and blueberry should be incorporated into the diet.<sup>[64]</sup>

## Key clinical question 3.3

What type of physical activity recommendations should be advised for improving weight loss and anthropometric and metabolic health outcomes?

Recommendation 3.3.1: Midlife women should be encouraged to avoid a sedentary lifestyle as far as possible by ensuring participation in dedicated exercise, household-related, work-related, and leisure-related physical activities.

## Grade: II A.

Recommendation 3.3.2: A stepwise progressive and personalized physical exercise regimen based on body weight, presence of cardiometabolic risk factors, and bone, muscle, and joint health should be prescribed.

#### Grade: II A.

Recommendation 3.3.3: The barriers and facilitators for adopting different types of physical exercises should also be considered while prescribing a physical exercise regimen.

#### Grade: IV A.

Recommendation 3.3.4: Women should be encouraged to incorporate up to 300 min/week of moderate-intensity aerobic physical activity or 150 min/week of high-intensity aerobic physical activity or an identical combination of moderate- and high-intensity exercise.

## Grade: I A.

Recommendation 3.3.5: Preferably, daily 60 min of physical activity should be recommended including a combination of moderate-intensity aerobic exercise (30 min), muscle strengthening engaging major muscle groups or balance exercise (15 min), and work-related and/or household-related moderate physical activities (15 min).

#### Grade: I B.

Recommendation 3.3.6: Women can participate in moderate-intensity aerobic activities in short bouts (10–15 min) throughout the day (2–3 times).

#### Grade: II B.

Recommendation 3.3.7: The talk test \* should be used for self-monitoring the intensity of aerobic activities.

#### Grade: I A.

Recommendation 3.3.8: Yogic practice (including physically intensive yoga) can be prescribed for weight management and overall well-being in midlife women.

#### Grade: III A.

#### Note

According to the previous recommendations for physical activity in Indian adults, moderate intensity of activity (150 min/week) is recommended for midlife women.[1,65,66] A combination of different exercises can be planned in a session including aerobic and endurance, strength training, and flexibility exercises. Studies also suggest that focus should also be on maintaining an overall active lifestyle by participating in household- and work-related activities.<sup>[67]</sup> In addition, studies suggested that midlife-specific barriers and challenges should be addressed for recommending progressive individualized activity plans. [68,69] The CDC recommendation on activity recommends a talk-test as a self-monitoring tool to assess intensity of aerobic exercise. The talk-test can be used to assess the intensity of aerobic exercises: comfortable speech denotes light intensity, speech with some difficulty denotes moderate intensity, and speech limited to phrases denotes vigorous intensity.[70] For maintaining overall well-being, studies suggest that women should perform physically intensive yoga.<sup>[71]</sup> However, the results are inconsistent, and more research is required in this area.

## Key clinical question 3.4

What are the behavior modification techniques that should be incorporated in weight management advice?

Recommendation 3.4.1: Behavior modification techniques such as realistic goal setting, motivational interviewing, and self-monitoring strategies should be used.

#### Grade: II B.

Recommendation 3.4.2: Women should be trained regarding problem-solving skills such as defining problems, creating solutions, and opting for the best possible choice.

## Grade: II B/C.

Recommendation 3.4.3: Cognitive restructuring skills such as identifying, challenging, and correcting the negative thoughts and emotions related to weight management should be imparted.

## Grade: II B/C.

Recommendation 3.4.4: Feedback on the accomplishments, achievements, and scope for better progress should be given regularly.

## Grade: II B.

#### Note

Across behavioral lifestyle modification trials for weight management, several behavioral techniques were recommended to improve weight loss outcomes. [72-74] Strategies such as problem-solving, cognitive restructuring, and self-monitoring were more commonly used across trials to improve the compliance of midlife women toward lifestyle modification strategies. [73-76] In addition, feedback from the health-care provider on the weight loss progress empowered women to tackle barriers and challenges faced by them in their weight loss journey.

## Key clinical question 3.5

What is the role of menopausal hormone therapy in a weight management program for midlife women?

Recommendation 3.5.1: Menopausal hormone therapy (MHT) is not indicated solely for weight management in midlife women.

#### Grade: II A.

Recommendation 3.5.2: Weight management by lifestyle interventions may help in improving the overall well-being of midlife women with menopausal symptoms.

## Grade: II A.

#### Note

Across systematic reviews and randomized control trials, MHT was not solely indicated for weight management. However, some trials reported that MHT helped in the management of menopausal symptoms and reduction in weight and total body fat.<sup>[77]</sup> There are inconsistencies reported on the direct significant impact of MHT on weight status.<sup>[78,79]</sup> In addition, a number of cross-sectional surveys report that weight management can help in improvement of overall well-being in women transitioning toward menopause.

## 4. Follow-up for sustainable weight loss

## Key clinical question 4.1

What are the other important parameters in determining the overall improvement in midlife women after undergoing weight management?

Recommendation 4.1.1: In addition to weight management, midlife women with obesity should be appraised and sensitized about the benefits of a healthy lifestyle on bone health, muscle strength, and menopausal symptoms.

#### Grade: II B.

#### Note

Across weight-loss trials, several parameters were used to ascertain the improvement in the overall well-being of midlife women. Parameters including anthropometric variables, cardiometabolic risk factors, bone mass density, menopausal symptoms, psychological distress, and overall quality of life were considered of importance to mark the progress of midlife women after undergoing lifestyle intervention. [35,81,82]

## Key clinical question 4.2

What should be the duration, frequency, and mode of follow-up of midlife women after intervention?

Recommendation 4.2.1: The time schedule for the intervention phase of weight management should be decided based on target weight loss to be achieved in the patient.

## Grade: IV A.

Recommendation 4.2.2: The duration of the intervention phase should be planned such that the patient can lose 5%–10% body weight every 6 months till the target body weight is achieved.

## Grade: I A.

Recommendation 4.2.3: Bimonthly contact should be planned in the initial stages of the intervention phase that can be reduced to monthly contact in the later phase.

## Grade: II A/B.

Recommendation 4.2.4: A combination of physical (face-to-face and/or group counseling) and online meeting modalities/telephonic contacts can be used for the contact.

## Grade: II A.

#### Note

Most weight-loss trials were planned to achieve 5%–10% loss in body weight every 6 months. Some studies had varied frequency of contact ranging from biannual contact to biweekly contact with the participants.<sup>[83]</sup> It was noted

that most studies had a monthly or bimonthly contact to counteract the barriers faced by the midlife women and improve compliance toward the lifestyle modification advice. The most common mode of contact was face-to-face, individualized sessions with a trained interventionist such as a dietitian, physician, or behavior therapist.<sup>[84-86]</sup>

## Key clinical question 4.3

What should be the duration, frequency, and mode of contact during the maintenance phase of the weight management program in a midlife woman?

Recommendation 4.3.1: Weight maintenance phase should be continued throughout life with sequential incorporation of parameters related to holistic well-being.

#### Grade: III A.

Recommendation 4.3.2: Face-to-face contact can be maintained every 3 months coupled with a monthly contact using technological components such as text messages, telephonic calls, and mobile applications.

## Grade: II A.

#### Note

The duration of follow-up in weight maintenance trials ranged from 3 to 48 months.<sup>[87-89]</sup> It was also noted that most studies had monthly follow-up visits along with different forms of contact using various technological modalities such as biweekly transmission of information using individual sessions, newsletters, weekly website logins, and telephonic calls with trained staff.<sup>[90]</sup> To prevent weight regain, maintaining appropriate weight and overall well-being the follow-up should be continued throughout life.

## Key clinical question 4.4

What advice should be given during the follow-up phase for maintenance of weight in midlife women?

Recommendation 4.4.1: At every contact, health-care providers should reinforce healthy eating, physical activity, and sleep habits and address barriers and challenges faced during this phase.

## Grade: II A.

Recommendation 4.4.2: During follow-up visits, self-monitoring through technological devices should be encouraged to maintain weight, dietary, physical activity, and sleep routine records.

#### Grade: II A.

Recommendation 4.4.3: Throughout weight maintenance, special attention should be given to behavioral strategies such as enhancing motivation, social support, self-efficacy, problem-solving, relapse prevention, and addressing individualized barriers.

## Grade: II B.

Recommendation 4.4.4: Clinical and biochemical parameters such as blood glucose, lipid profile, and blood pressure measurements should be done as per the standard guidelines and/or advice by the treating doctor.

## Grade: IV A

Recommendation 4.4.5: Adequate and appropriate care of bone, muscle, joints, and menopausal symptoms should be ensured during follow-up contacts to ensure holistic well-being.

## Grade: IV B.

#### Note

The weight maintenance trial provided advice based on dietary modification, the introduction of physical activity regimen, cognitive behavioral therapy, social support, technological support, and pharmacotherapy. [86,87,91] Across studies, the self-monitoring techniques were used to regulate the dietary, activity, sleep- and weight-related behaviors by providing personal feedback, health promotion education, maintaining contact with interventionist, peer group support, and frequent behavioral prompters. [92-96] Studies also recommended that appropriate holistic care should be provided to ensure metabolic, menopausal, and musculoskeletal health. [1,49]

## **DISCUSSION**

The recommendations provide clinical practice points based on scientific literature and consensus from experts from multidisciplinary fields involved in the management of obesity for midlife women. The recommendations can assist clinicians and other health-care providers to plan evidence-driven opportunistic management of obesity in midlife women. The working module discussing the clinical practice points for management of obesity in midlife women is presented in Box 1.

This makes midlife a critical stage to introduce weight management practice for managing weight and overall health. The recommendations are planned in accordance with the stages of weight management.

Behavioral lifestyle modification is considered the cornerstone for the management of obesity in midlife women. The guideline highlights the appropriate clinical approach to counsel the lifestyle advice in an effective manner that can help in achieving significant weight loss outcomes. The dietary management recommendations can help the nutritionist and other health-care professionals to provide advice related to calorie management, macronutrient manipulation,

meal pattern, emotional eating, consumption of HFSS foods, and healthy dietary habits. Physical activity recommendations help the practitioner to put together a customized exercise regime including aerobics, strength training, and flexibility activities for managing weight, musculoskeletal system, and distress in midlife women. The behavioral modification techniques help to ensure daily compliance of the eating and activity advice and sustenance of the weight loss for the long term.<sup>[97]</sup>

## Suggestions for health-care providers

The recommendations can help the health-care providers in opportunistic screening and management of obesity in midlife women. Health-care providers including primary care often encounter midlife women presenting with various health conditions such as irregular menstruation, joint pain, blood pressure, diabetes, heart disorder, and distress. The health-care providers should aim to appraise the midlife women on the role of obesity in their current medical condition and adopt a well-rounded approach to counsel them. These recommendations can provide appropriate clinical practice points that can be undertaken by the health-care provider to provide optimum obesity care. In resource-constrained settings, the recommendations help the clinician to take up the role of becoming a "single-point contact" for obesity-related management. The implementable action statements can be utilized for capacity building required for advising of appropriate management of obesity at resource-constrained settings including mohalla clinics, Anganwadi clinics, and primary and secondary care units across India. The effective implementation of the guidelines will help to prevent the upward trend of obesity and associated risk of a cardiometabolic disorder that poses a burden to different health-care systems across the country.

## Suggestions for policymakers

A substantial increase in the prevalence of obesity has been projected in India by 2040. [98] It should also be noted that women contribute to a greater proportion of obesity prevalence in comparison to male counterparts. The policymakers should disseminate the clinical practice recommendations in the media, curriculum, public lectures, and policy reforms to prevent the obesity epidemic. The clinicians and allied health-care professionals should be educated on methods to ensure opportunistic screening and management of obesity through lifestyle modification in their daily clinical practice. The government should establish "women wellness clinics" to provide comprehensive healthcare to women. These clinics should empower women with healthy lifestyle habits to maintain their metabolic,

musculoskeletal, and mental health. The dissemination through nutrition education materials such as posters, public lectures, pamphlets, social media websites, television, and mobile applications can help to improve health literacy among women. In addition to improving the overall weight-related behaviors through campaigns, the policymakers should also focus on planning and developing a nonobesogenic environment that would support healthy behaviors to achieve and sustain ideal weight status.

## Strengths and limitations

The strength of the recommendations is that it is comprehensive providing detailed practice points to health-care providers for managing women presenting with obesity in their daily clinical practice. The guidelines also empower the health-care professionals with brief clinical practice points to manage allied obesity-related comorbidities experienced in midlife. The guideline can provide lifestyle modification advice to achieve clinically significant weight loss during both weight loss intervention and weight maintenance phase. The limitations include pharmacological and surgical modalities of weight management were not discussed, and only limited databases were searched for gathering evidence although efforts were made to provide comprehensive evidence for each clinical question.

## **Statement**

This article is being published simultaneously in Diabetes & Metabolic Syndrome: Clinical Research & Reviews (DMSCRR). The full version of the article is being published in Journal of Family Medicine and Primary Care. Considering its potential for widespread public health impact and general interest, the guidelines can be submitted to some more journals for publication. Besides, the guidelines can be published on the Government's website and AIIMS, New Delhi's website.

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#### **Conflicts of interest**

There are no conflicts of interest.

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Supplementary Table 1: Approach to grade the quality of evidence	
<b>Quality of evidence</b>	Description
I	High-quality evidence
	Based on evidence gathered from the literature search, there is substantial certainty that the true effect lies within the estimated effect
	The high-quality evidence will include
	Well designed and executed RCTs consisting of adequate randomization, allocation and blinding, sufficient power and intention-to-treat analysis, and adequate measures for follow up
	Meta-analysis including high-quality RCTs is also included
_	Previously published good quality recommendations/consensus statements and/or position statements given by an organization or working group consisting of experts in that field. The quality of the recommendations should be established on the basis of the appraisal guideline for research and evaluation <sup>[8]</sup>
II	Moderate quality evidence
	Based on evidence gathered from the literature search, it is possible that the true effect may lie close to the estimated effect
	The moderate-quality evidence includes
	Well-designed and executed RCTs with minor methodological limitations impacting the confidence in the estimated effect
	Quasi-randomized trials with good methodological quality
	Systematic and meta-analysis of low-quality RCTs with limited quality
III	Low-quality evidence
	Based on evidence gathered from the literature search, there is limited certainty that the true effect is close to the estimated effect
	The low quality of evidence includes
	Well-designed and executed RCTs with major methodological limitations affecting the confidence in estimated effect
	Well-designed and executed nonrandomized trials including intervention studies, cohort and quasi-experimental studies, case-control studies with minor methodological limitations
	Observational studies with minor methodological limitations
IV	Expert opinion
	Very uncertain that the true effect is close to the estimated effect
	Based on clinical experience, reasoning, and suggestions
	There might be a small net benefit from the suggestion. Based on feasibility, we may incorporate the suggestion for weight management

RCTs: Randomized control trials

Supplementary Table 2: Grades for the strength of recommendation		
Strength of recommendation	Description	
A	Strong recommendation: Quantum of benefit expected >>> resource requirement/logistic needs	
	Certainly, the net benefits, (i.e., the benefits derived from the service/intervention) outweighs the resource requirement for achieving optimal weight loss outcome	
	These recommendations should be universally adopted by the clinicians and allied health-care providers as a standard practice to prevent and manage overweight and obesity in women at an individual, clinical and public health level	
В	Moderate recommendation: Quantum of benefit expected >> resource requirement/logistic needs	
	It is moderately certain that the net benefit from the recommendation is moderate to substantial	
	These recommendations might not be a mandatory part of a standard weight management clinical practice, but their implementation can prove beneficial in attaining significant weight loss outcomes. The implementation of these recommendations should be as per an individual's preference, values, and settings	
C	Weak recommendation: Quantum of benefit expected > = < resource requirement/logistic needs	
	It is at least certain that there might be a small net benefit from the recommendation	
	These recommendations should be incorporated based on resource availability, feasibility, cost-effectiveness, and acceptability in the weight management program	