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Review Article

Others Section

A Review on Obesity and its Management: Focus on Meal Replacement Therapy

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ABSTRACT

Obesity is one of the major health concerns worldwide. In India, over 135 million subjects are affected by obesity. In the last two decades, the prevalence of obesity has increased rapidly. Several factors such as sedentary lifestyle, increased portion size in diet, environmental factors and genetic predisposition are responsible for the increased prevalence of obesity. Obesity also increases the risk of several disease conditions, which has a negative impact on quality of life, work productivity and healthcare costs, leading to a rise in mortality rates. Asian Indians are at a higher risk of developing obesity-related co-morbidities at lower levels of Body Mass Index (BMI) and waist circumference compared with Caucasians. Weight loss is a logical step in the management of obesity. Even a modest weight loss of 5-10% of total body weight has shown to significantly improve health and well-being. A negative energy balance achieved by lesser calorie consumption than expenditure serves as the basic principle for weight loss. The role of Meal Replacement (MR) in the management of obesity is discussed in this review. Studies have shown that MR is effective for safe weight loss. MR is designed to deliver optimum nutrition with a minimum glycaemic index. Optifast by Nestle Health Sciences is one such MR product, which is effective for weight management in individuals with obesity.

Keywords: Body mass index, Diet therapy, Type II diabetes mellitus, Weight loss

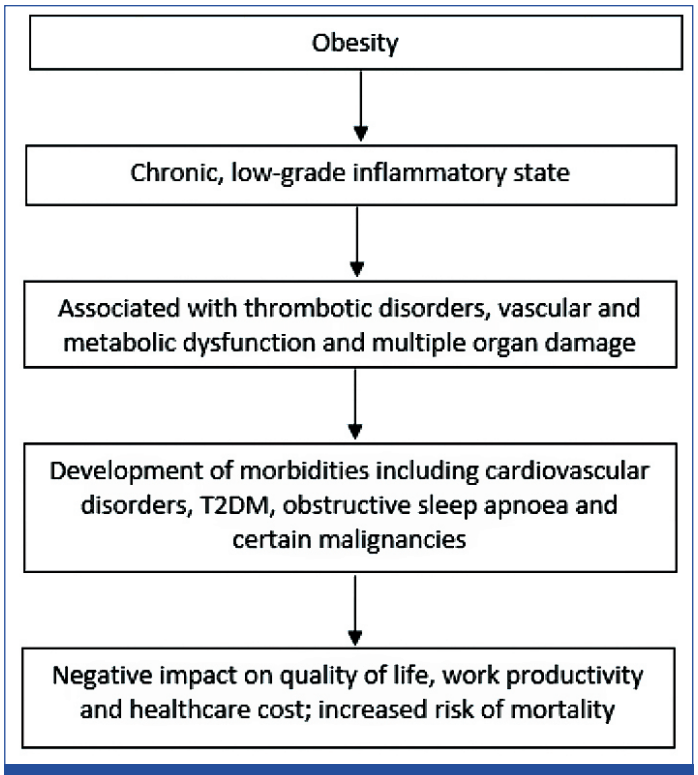
INTRODUCTION

Obesity: The Modern-day Challenge

Obesity is one of the top health concerns across the globe with its worldwide prevalence having nearly tripled since 1975 [1]. According to the World Health Organisation (WHO), more than 1.9 billion adults were overweight in 2016, of whom 650 million were obese [1]. A systematic review in 2019 reported that more than 135 million subjects in India were affected by obesity [2]. Several factors are responsible for the rising prevalence of obesity across the world such as increased portion size in diet, [3] sedentary lifestyle, environmental factors and genetic predisposition [4]. Obesity also increases the risk of several disease conditions such as Type 2 Diabetes Mellitus (T2DM), hypertension, stroke, sleep apnoea, etc., and leads to a rise in mortality rates [Table/Fig-1] [5]. According to a global report, obesity was found to be a driving factor in deaths among patients with Coronavirus Disease-2019 (COVID-19), and the fatality rates due to COVID-19 were 10 times higher in countries with high overweight/obesity rates [6].

Definition of Obesity: One Size Does Not Fit All

WHO defines obesity as a metabolic disorder characterised by abnormal or excessive accumulation of fat which presents a health risk [1]. Positive energy balance (energy intake greater than energy expenditure), leads to the development of obesity [7]. The BMI is used as an indicator of body fatness [1]. Currently, the BMI-based cut-offs as recommended by the WHO are 18.5-24.9 kg/m^2 for normal, 25.0-29.9 kg/m^2 for overweight and ≥30 kg/m^2 for obesity [1,8]. These may not be appropriate for all ethnic groups, including Asian Indians as it is based on data from Caucasian populations [8]. Asian Indians are at a higher risk of developing obesity-related co-morbidities at lower levels of BMI and waist circumference compared with Caucasians. In being cognisant of this fact, a group of over 100 medical experts from all over India developed a consensus document in which the recommended BMI cut-offs for Indians were different from the global cut-offs proposed by the WHO. According to the consensus statement published in 2009, the BMI cut-off for Asian Indians is, normal: 18.0-22.9 kg/m^2, overweight: 23.0-24.9 kg/m^2 and obesity: >25 kg/m^2 [8].



[Table/Fig-1]: Obesity as a driver of various morbidities [5].
T2DM: Type 2 diabetes mellitus

Benefits of Weight Loss in Subjects with Obesity

Even a slightest weight loss of 5-10% of total body weight has shown to significantly improve health and well-being of an individual. Furthermore, weight loss can aid subjects who are obese with prediabetes to prevent developing T2DM and, in the long-term, has a positive impact on cardiovascular mortality. A weight loss of >10% is beneficial in subjects with obstructive sleep apnoea [5]. Weight loss leads to a reduction in the risk of certain malignancies and has a positive impact on asthma, gastro-oesophageal reflux disease, hepatic dysfunction, urinary incontinence, infertility, arthritis and

depression [5]. Further, obesity management plays an important role in the treatment of hyperglycaemia in individuals with T2DM [9].

Management of Obesity

Weight loss is a logical step in the management of obesity. Consuming calories less than the energy expended generates negative energy balance that serves as the basic principle for weight loss. The therapeutic armamentarium for obesity includes a non pharmacological approach constituting physical exercise, diet management and behavioural modifications; pharmacotherapy and surgical procedures [4].

LIFESTYLE MODIFICATIONS

Diet Therapy

Diet therapy is the basic non pharmacological weight loss strategy used widely with or without medical supervision. Various types of diets are followed to lose weight. Although most of the interventions including diet help in initial weight loss, the most challenging task in the long-term is weight maintenance [10]. The dieter initially loses weight but fails to maintain the long-term goal and begins to regain the weight. This phenomenon is called weight cycling or the yo-yo effect, where the dieter seeks to lose the regained weight, and the cycle begins again [11]. Clinical implementation of a diet for a person with obesity can be challenging. The clinical condition, BMI and personal preferences are important factors when designing the diet. Continuous modifications are required depending on the result of the initial diet [10].

The dietary approaches used to reduce energy intake include a Very Low-Calorie Diet (VLCD), Low-Calorie Diet (LCD), low-carbohydrate high-protein diet, low-fat diet [4] and other dietary patterns such as the ketogenic diet, [12] palaeolithic diet [13] and Diet Approaches to Stop Hypertension (DASH) [14]. A LCD is a diet with a reduction of approximately 500 cal/day, whereas, a VLCD diet permits consumption of approximately 800 kcal/day [4]. The low-carbohydrate diet restricts carbohydrate intake to 20 gm/day but is rich in protein and fat. In a low-fat diet, the calories from fat are restricted to 0.7 kcal/day [4]. A ketogenic diet is constituted of very low carbohydrates, moderate protein and high fat advised for a short-term [12]. Palaeolithic diet mostly comprises plant, animal and seafood-based meals [13]. The DASH diet recommends a lower-energy-dense eating pattern with a reduction in intake of less healthy fats (total fat intake <25% of the energy), increased proportion of fruits and vegetables and no reduction in the weight of the food one eats [14].

A high-protein, high-fibre diet provides satiety and favours weight maintenance. However, nutrient requirements must be met [14]. Individuals on diet therapy often regain weight rapidly because of binge-or emotional eating [15]. For adherence to diet, a slow but steady reduction in calories is recommended. Other strategies to control food intake include using portion control tools like smaller plates, cups and serving spoons. Smartphone applications could be used for self-monitoring of daily food intake and portion sizes, which favours sustained weight loss [14]. Using appropriate proportions of food along with MR has also proven to be beneficial in weight loss. Research studies have shown that a substantial weight loss can be obtained by replacing 1 or 2 meals a day with liquid and solid preportioned food {Partial Meal Replacement (PMR)} [14,16]. For weight management over a long-term, PMR is advised with regular food (atleast one meal), and apart from weight loss, it has also shown to decrease the risk factors of diseases that are weight-related. In a meta-analysis, no adverse events were reported to the PMR regime, however, there were drop-outs noted [16]. Achieving significant weight loss can be difficult, time-consuming and tedious for subjects with obesity. For weight loss, tailored diet regimens could help [12].

Exercise and Weight Loss

Irrespective of goals for weight loss, exercise training should be part of obesity management as it aids in an acceptable level of weight loss, helps maintain weight and also has cardiovascular advantages. Many subjects regain the lost weight due to non adherence to the regime. The available data shows that subjects with obesity who have lost weight would need a considerable amount of physical activity to prevent regain of weight [17]. The risk of all-cause mortality decreases with cardiorespiratory fitness of a high level. Physical activity for atleast 200 minutes in a week is suggested to be followed. However, the form and duration of the activity should be designed as per patient requirements [17]. High-Intensity Interval Training (HIIT) comprises of strength training and aerobic exercise. It includes a base fitness level hard intensity training for 20-60 minutes 3-5 times per week, for muscular adaptation, followed by workout alternating with relief periods. HIIT provides benefits in a short span of time. It is preferred to obtain medical fitness prior to starting HIIT [18].

Behavioural Modifications

Changes in physical activity and diet require considerable self-determination that can be achieved through behavioural modifications. The first step is to set realistic, practically achievable goals. Design an appropriate self-monitored weight loss plan (diet+physical activity). Further, identifying and addressing barriers to weight loss including misconceptions is important. Drastic changes in body weight and shape may not be achievable [4]. Counselling, continuous motivation and encouragement during follow-up by the medical personnel enhances adherence and allow necessary modifications [4]. As per the recommendations by the Obesity Society, maintenance of weight loss at approximately 3-5% of the initial weight produces clinically significant benefits with improvements in control of blood pressure, triglycerides, high-density lipoprotein cholesterol, glycosylated haemoglobin (HbA1c) and lowers the risk of developing T2DM [19,20].

Pharmacotherapy

Subjects who fail to achieve weight loss with lifestyle modifications, those with a BMI of ≥30 kg/m^2 and without concomitant co-morbidity or subjects with a BMI of ≥27 kg/m^2 and having atleast two concomitant co-morbidities may be prescribed conjunctive/additional pharmacotherapeutic agents [4].

Orlistat (lipase inhibitor), lorcaserin (serotonin, dopamine and norepinephrine reuptake inhibitor), phentermine/topiramate extended-release (sympathomimetic amine anorectic/antiepileptic combination), naltrexone/bupropion extended-release (opioid antagonist/antidepressant combination) and liraglutide (glucagon-like peptide 1 receptor agonist) are the drugs approved by the US Food and Drug Administration (FDA) for the long-term treatment of obesity [21-23]. Antiobesity drugs approved in India include lorcaserin and orlistat [24].

Liraglutide, approved by the FDA for chronic weight management among children with obesity aged ≥12 years and adults, is to be used as adjunct therapy with a reduced-calorie diet and physical activity [25]. Liraglutide in the dose of 3 mg/day has been approved for the treatment of obesity [26].

The new category of antidiabetic drugs such as glucagon-like peptide 1 receptor (GLP-1R) agonists and dipeptidyl-peptidase IV (DPP-IV) inhibitors are being assessed for the outcome of obesity and metabolic traits [27]. Novel molecules that act on the melanocortin system of the brain or hunger and satiety peptidergic signalling of the gut-hypothalamus axis have been identified by genetic studies [27]. Various potential new targets are currently being evaluated, including vaccines (ghrelin, somatostatin) for weight loss [28].

Once prescribed, the patient should be cautioned and observed for side-effects. A detailed discussion on the pharmacotherapy of obesity is beyond the scope of this review.

Bariatric Surgery

Surgical interventions are recommended for subjects in whom diet and pharmacotherapy failed and have a BMI of ≥40 kg/m^2 or those having a BMI of ≥35 kg/m^2 along with concomitant co-morbidities [4]. Different procedures include vertical Sleeve Gastrectomy (SG), Roux-en-Y Gastric Bypass (RYGB), biliopancreatic diversion with duodenal switch and Adjustable Gastric Banding (AGB) [21,29]. RYGB has shown metabolic benefits that are convincing, while SG produces hormonal changes leading to a better diabetes state [29]. AGB done laparoscopically is the least invasive, however, regain of weight is commonly observed [22]. Over years, the rate of serious complications following bariatric surgery has reduced, with recent data indicating 5% and 0.3%, perioperative morbidity and mortality rate, respectively [22]. Postsurgery weight maintenance is essential to sustain the results. The use of MR could be beneficial in this regard.

MEAL REPLACEMENT THERAPY FOR OBESITY MANAGEMENT

The main focus of this review would be on the role of MR therapy in the management of obesity. MRs are calorie-and portion-controlled meals, with the benefit of retained food environment of the subject, which favours long-term weight loss and helps maintain weight [30]. MR is effective for safe weight loss. These are designed with optimum nutrition, high fibre and a lower Glycaemic Index (GI). MR products are formulations available as a bar or a powder mix [31]. Recently, the effectiveness of MR formulations has been studied widely.

Doctor Referral of Overweight People to Low Energy total diet replacement Treatment (DROPLET) study is a multicentre trial conducted in the United Kingdom (UK) for the safety and effectiveness assessment of Total Diet Replacement (TDR). It is a 12-month programme with behavioural support and TDR with MR products (providing 810 kcal/day) for eight weeks following which food was reintroduced. TDR was well tolerated and led to substantial weight loss and a reduction in the risk of cardiovascular and metabolic disease compared with those on regular support for weight loss [32].

A multidisciplinary, clinical, weight management programme with MR demonstrated a high retention rate (90% at three months and 83% at six months) and excellent outcomes including weight loss of 15±12 kg and a decrease in BMI by 5.1±4.0 kg/m^2 in subjects completing two years in the programme [33]. MR programmes have also been demonstrated to be effective as adjuncts to bariatric surgery. A review and meta-analysis assessed the effectiveness and safety profile of bridging interventions prior to bariatric surgery in subjects with a BMI of ≥50 kg/m^2. A decrease in BMI by 9.8 kg/m^2 (95% confidence interval [CI]: 9.82-15.4, p=0.0006) was observed with a preoperative liquid LCD programme. Thus, MR can be safely used prior to surgical intervention in individuals who are obese [34].

In a randomised trial among elderly subjects with obesity and osteoarthritis, for three months, either one or two meals were replaced with an artificial nutritional preparation. This strategy resulted in effective weight loss with improvement in lipid profile, blood glucose and blood pressure [35].

A retrospective cohort study in adults with severe obesity analysed the effects of a milk-based MR strategy. The results of 24 weeks study showed a significant reduction in body weight and BMI by Week 24 compared with baseline (mean weight loss: 15.9±6.0%, BMI decreased from 50.6±8.0 to 42.6±7.6 kg/m^2, both p<0.001). A significant reduction in HbA1c (from 66.3±13.0 to 48.3±13.5 mmol/mol, p<0.001) and improvement in lipid profiles were observed [36].

Viscous soluble fibre with MR is safe for weight loss. A study included 52 overweight or obese participants (average age 47.1 years, mean BMI 33.8±6.4 kg/m^2). For 12 weeks, participants consumed 57 grams of proprietary PolyGlycopleX (PGX®) MR product at breakfast and lunch each. In addition to MR, they also consumed 5 gm/day of PGX® fibre in granular, powder or capsule form with 250 mL water. Participants were recommended to consume a total of 1200 kcal/day (low-fat, low-GI foods to be included for snacks and dinner). By 12 weeks, a significant reduction in weight (-4.69±3.73 kg), waist (-7.11±6.35 cm), and hip circumference (-5.59±3.58 cm) was observed in all participants (p<0.0001). The BMI scores (n=51) decreased by 1.6±1.4 kg/m^2. The study exhibited short-term weight loss with PGX®MR and PGX® fibre used with a controlled dietary calorie intake [37].

A randomised controlled trial included 90 overweight/obese subjects (weight 90.6±11.3 kg, age 47±7.5 years, and BMI 31.5±2.3 kg/m^2). One group was the MR diet group (MRD-G) and another was the fat-restricted LCD group (LCD-G). Both received similar lifestyle education. For individuals in MRD-G, two daily meals were replaced with a drink that provides low-calorie and high-soy protein. The MRD-G group showed a significant decrease in weight (6.4 *vs.* 3.1 kg), waist circumference (6.1 *vs.* 1.8 cm), triglycerides (-19.6 *vs*.+12.5 mg/dL), leptin (18.2 *vs.* 6.97 ng/mL) and insulin (4.92. 0.58 µU/mL) levels compared with the LCD-G (all p<0.01) [38].

A review of the duration of MR therapy in the randomised trials indicates it to range from a few weeks to a few years. [30-33,35-38] Management of obesity with MR for >1 year has shown to result in a 7-8% reduction in total body weight and only non serious effects have been noted [31]. This data indicate that the duration of MR therapy is mainly based on the expected weight loss for the individual, co-morbidities, and ultimately is as per the advice of the treating healthcare personnel.

Optifast [39]: A Clinically-proven MR Product for the Management of Obesity and Beyond

A new MR product-Optifast (Nestlé Health Sciences) is used to manage obesity. It provides high-quality protein, fewer calories with a low GI, contains 25 vitamins and minerals, and partially hydrolysed guar gum fibre that enhances satiety [39].

A prospective pilot study was conducted among 20 participants with BMI >30 kg/m^2, consulting for weight loss prior to elective surgery (non bariatric). Their meals were replaced with Optifast (800 cal/day). A linear significant decrease in BMI and body fat was observed. Further, a reduction in the level of mean blood pressure, HbA1c and triglycerides were also observed [40].

The Optiwin study revealed that total MR using Optifast+behavioural therapy was highly effective in bringing about significant weight loss compared with the food-based behavioural approach, at weeks 26 and 52 [41]. A recent publication states that a weight loss programme comprising MR therapy with Optifast, physical activity, social support and regular medical monitoring is an effective obesity management strategy in community-based gastroenterology practice [42].

In contrast to the widely held belief that the weight that is lost rapidly is also regained quickly, Purcell K et al., demonstrated that weight regain is similar after both gradual and rapid weight loss. In subjects on the rapid weight loss programme, three meals/day (for 12 weeks), and in those on gradual weight loss programmes, one to two meals/day (for 36 weeks) were replaced with Optifast. The amount of weight regained was not related to the rate of weight loss [43]. A retrospective observational study was conducted among 10,693 participants (with a BMI of ≥30 kg/m^2 or a BMI of ≥28 kg/m^2 with ≥2 co-morbid conditions) in behaviour-based, non surgical, non pharmacological, medically supervised weight management programme. This was an 82-week programme comprising three phases: (i) complete MR for 16 weeks, (ii) transition phase from 17 to 29 weeks and (iii) lifestyle maintenance phase from 30 to 82 weeks. Optifast shakes or soups were the predominantly used MR

products; in addition, Robard bars were used. From the baseline weight, a maximum of 15.3% weight was lost by month 4. By the end of the 5-year follow-up period, the average change in weight was -5.8% from baseline and almost 50% achieved a clinically significant weight loss of ≥5% [44].

Optifast-based VLCD programmes have also demonstrated beneficial effects in subjects who are obese with T2DM. Lim EL et al., demonstrated that normalisation of both beta-cell function and hepatic insulin sensitivity in subjects with T2DM can be achieved with an Optifast-based VLCD programme, showing that this programme can aid in reversing diabetes [45]. This was confirmed in another study by Steven S et al., where an Optifast-based VLCD programme (liquid diet) was accepted and helped achieve continued remission of diabetes for a minimum of six months in 40% of participants who showed response to VLCD [46].

The findings of a multicentre, prospective study among subjects with obesity on a 52-week Optifast programme indicate this to be a highly effective method for weight loss. The authors also stated that for obesity management, the Optifast programme was as effective as invasive interventions such as banding or vertical gastroplasty, as reported in the Swedish Obese Subjects study on individuals with similar initial BMI [47]. A randomised controlled trial, comparing VLCD and LCD with Optifast for 21 days preoperatively in subjects undergoing bariatric surgery demonstrated that with both types of diet, there was a significant reduction in liver volume and body weight [48]. In another study, a preoperative weight loss of ≥8% was achieved with an Optifast-based LCD for four weeks. This was associated with a significant increase in the additional weight loss postoperatively for 12 months, shorter operative duration and length of hospital stay [49]. Some minimal calorie-free food such as non starchy vegetables is allowed to be consumed during the Optifast programme [45]. This ensures adequate satiety and long-term adherence to the programme. For LCD, allowances of quantities of each food in the meals and other nutrients are made. By following the exact protocol, all requirements of macronutrients and micronutrients are met.

The authors of this review met and using their expertise proposed two protocols that would act as guidance for Indian subjects requiring weight loss: (1) Subjects with obesity opting for bariatric surgical intervention, [50] and (2) those not opting for bariatric surgery. Subjects with a BMI of ≥30 kg/m^2 are offered a VLCD regime and those with a BMI of ≥27 kg/m^2 are offered an LCD regime. An overview of the protocols is given in [Table/Fig-2,3]. The Optifast MR protocols are advised to be followed under the supervision of healthcare personnel. These protocols have been designed to ensure the individual's daily nutritional requirements are met (sufficient quantity of protein, essential fatty acids, carbohydrates, vitamins, minerals, and trace elements) and to ensure the weight loss is effective and safe. The recommended number of servings of Optifast MR product ensures that the daily total energy intake is maintained in the range of 800 cal during the intensive phase for quick weight loss in the initial 12-week period (exclusive consumption of MR product). This is followed by gradual weight loss during the next 4 to 8 weeks with consumption of up to 1200 cal/day with a mix of Optifast MR product and 1-2 low-calorie meals. Then the individual moves into the maintenance phase where the calorie consumption is restricted to <1500 cal/day and MR product can be eliminated during this phase. The duration of this phase depends on the treating physician based on the patient's health needs to focus on maintaining weight over the long-term. Optifast MR products are recommended to be used along with cognitive and behavioural counselling [50].

Intensive			
BMI (kg/m^2)	Calories/day	Duration	Optifast servings
≥27 (Overweight)	800-1000	8-12 weeks	2-3
≥30 (Obese)	600-800	6-12 weeks	2-3
Transition			
BMI (kg/m^2)	Calories/day	Duration	Optifast servings
≥27 (Overweight)	1000-1200	4-8 weeks	2
≥30 (Obese)	800-1000	4-8 weeks	2
Maintenance			
BMI (kg/m^2)	Calories/day	Duration	Optifast servings
≥27 (Overweight)	1200-1500	As per the physician's advice	1-2
≥30 (Obese)	Maintenance phase:M1		
	1000-1200	6 months	1-2
	Maintenance phase:M2		
	1200-1500	Continued indefinitely	1-2

[Table/Fig-2]: MR protocol with Optifast for individuals with obesity [39].

Preoperative			
BMI (kg/m^2)	Calories/day	Duration	Optifast servings
≥40: Desirable ≥50: Recommended	600-800	2-4 weeks	2-3
Postoperative			
Phases	Calories/day	Duration	Optifast servings
Intensive	800-1000	8-12 weeks	2-3
Transition	1000-1200	4-8 weeks	2
Maintenance	1200-1500	As per the physician's advice	1-2

[Table/Fig-3]: MR protocol with Optifast for individuals with obesity undergoing bariatric surgery [39,50].

CONCLUSION(S)

Managing obesity can be challenging, but is achievable through restricted diet, rigorous physical activity, lifestyle modifications, pharmacotherapy and sometimes surgical interventions. MR products support these modifications and give a boost to meet the challenging and tedious journey of weight loss, without compromising on the nutritional requirements. Optifast, a new player, has also demonstrated beneficial effects in subjects who are obese with or without T2DM.

Conflicts of interest: All authors have served on Scientific Advisory boards for Nestle Health Science, India. The meeting for authors to prepare the Optifast MR protocol was arranged by Nestle Health Science. However, no honorarium was paid for participating in the meeting or drafting the manuscript. No other potential conflicts of interest relevant to this article were reported.

Contribution by authors: Conceptualisation and design: PC, MN; Literature search: PC, RK, ND; Short listing and review of articles: PC, JT, MN; Manuscript writing: PC, MN; Manuscript editing and finalisation: PC, MN, RK, ND, JT.

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