



A RANDOMIZED, PLACEBO-CONTROLLED, DOUBLE-BLIND, PARALLEL, SUPERIORITY TRIAL WITH HOMEOPATHIC MEDICINE CALCAREA CARBONICA OSTREARUM FOR OBESITY IN ADOLESCENTS

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ABSTRACT

Overweight and obesity in children and adolescents are a major public health issue in India. Whilst many factors (genetic, cultural, socioeconomic and environmental) contribute to develop obesity during childhood, a multidisciplinary intervention (nutritional, behavioural and exercise) is the best approach to improve weight loss. In India, the use of homeopathy for obesity is widespread. Although there are some homeopathic medicines used for obese individuals, there is a lack of well-designed clinical trials to demonstrate its efficacy in weight loss. Calcarea carbonica ostrearum is a homeopathic mineral medicine. It has been demonstrated that Calcarea carbonica has an effect in reducing the percentage of fat in adolescents. Therefore, a randomized, placebo-controlled, double-blind, parallel, superiority trial with a 3 month study duration, will be conducted to prove the efficacy and safety of Calcarea carbonica ostrearum in reducing weight, body mass index (BMI) and fat percentage, as well as, to prove its effect on the lipid profile, fasting serum glucose, glycosylated hemoglobin and insulin.

Keywords: obesity, multidisciplinary intervention, homeopathy, Calcarea carbonica ostrearum

INTRODUCTION

Obesity is a serious health issue that affects a significant proportion of the world's population. It is described as an abnormal accumulation of body fat that increases the risk of contracting a number of illnesses, including type 2 diabetes, cardiovascular disease, and particular malignancies. Traditional treatments for obesity include pharmacological therapies like appetite suppressants and anti-obesity medications, as well as lifestyle changes like diet and exercise. However, some of these therapies may have negative side effects and not all of them may be successful.¹

A variety of health issues, including obesity, have been treated with homoeopathy, a complementary and alternative therapy. Homoeopathy is founded on the idea that "like cures like," meaning that a substance that can generate symptoms in a healthy person can be used to treat a sick person's symptoms with a diluted version of those same symptoms. The goal of homoeopathy is to activate the body's natural ability to heal itself and to advance general health and wellbeing.

It is crucial to investigate homeopathy's efficacy and safety given the potential benefits it may have in the treatment of obesity. This article wants to evaluate studies on homeopathy's usage for obesity and offer insights into how it might be effective as an additional treatment for weight management.

AIMS AND INTERVENTIONS

<p>Aim :- <i>Experimental:</i> Multidisciplinary intervention + homeopathic medication Multidisciplinary intervention (diet, exercise program, motivational support) and Calcareo carb 30c.</p> <p>A single dose of Calcareo carb 30C dissolved in a 30 ml bottle of 30% distilled water. Patients will receive 8 drops PO three times per day.</p>	<p>Intervention/ treatment <i>Drug:</i> Homeopathic Medication A homeopathic mineral medicine, form of impure calcium carbonate, CaCO₃, which can be found in nature in different niches, from limestone to eggshells. <i>Other Name:</i> Calcareo carbonica ostreorum</p> <p><i>Other:</i> Multidisciplinary intervention (Exercise program, diet, motivational support) <i>Exercise program:</i> includes a five-times per week routine: warm-up during 10 to 15 minutes, then 40 minutes of aerobic exercise that will be increased progressively until reaching 60 minutes. Thereafter, muscular strength initiating 5%, and increasing until 10 to 15% of body weight. Then, 10 to 15 minutes of stretching. Finally, 5 min cool-down.</p> <p><i>Diet:</i> Subjects will receive a balance diet calculated based on energetic needs according FAO: 15-20% of proteins, 50-60% of carbohydrate, 20-25% of fat per day.</p> <p><i>Motivational support:</i> 50 min session where empathy and neutral understanding of the perspective and feelings of the adolescent, and his family, are fostered to motivate the change and to state realistic goals in reducing weight.</p> <p><i>Other Name:</i> Combined dietary-behavioural-physical activity intervention</p>
<p><i>Active Comparator:</i> Multidisciplinary intervention + homeopathic placebo Multidisciplinary intervention (diet, exercise program, motivational support) and placebo.</p> <p>Placebo will be prepared with 30% distilled water only, in the same 30 ml bottle. Patients will receive 8 drops PO three times per day.</p>	<p><i>Other:</i> Multidisciplinary intervention (Exercise program, diet, motivational support) <i>Exercise program:</i> includes a five-times per week routine: warm-up during 10 to 15 minutes, then 40 minutes of aerobic exercise that will be increased progressively until reaching 60 minutes. Thereafter, muscular strength initiating 5%, and increasing until 10 to 15% of body weight. Then, 10 to 15 minutes of stretching. Finally, 5 min cool-down.</p> <p><i>Diet:</i> Subjects will receive a balance diet calculated based on energetic needs</p>

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LITERATURE REVIEW

A long-term condition called obesity that can harm one's health is characterised by an excessive build-up of body fat. It is a major global public health issue that is linked to a higher risk of many illnesses, such as type 2 diabetes, cardiovascular disease, and some malignancies.¹

Obesity in adolescents in India is a problem that has to be addressed more urgently. The incidence of overweight and obesity among adolescents aged 10 to 19 years was found to be 19.3%, with 8.9% of adolescents being overweight and 10.4% being obese, according to a national survey carried out by the Indian government in 2016.

The Indian Council of Medical Research (ICMR) published another study in 2019 that found 5.8% of school-age children to be overweight and 13.4% to be obese, representing a prevalence of 19.3% for overweight and obesity.²

Aetiology of Obesity

A complex condition like obesity is brought on by a confluence of hereditary, environmental, and lifestyle variables. The following are some typical aetiologies or causes of obesity:

1. **Genetics:** The genetics of an individual's propensity to obesity are quite important. According to studies, having obese parents considerably raises the likelihood of becoming obese.
2. **Environmental elements** significant environmental variables that contribute to obesity include the availability of bad food options, a lack of physical activity, and sedentary lifestyles.
3. **Unhealthy eating patterns:** Weight gain and obesity can result from a diet that is heavy in calories, saturated fats, Trans fats, and sweets but low in fruits, vegetables, and fibre.
4. **Lack of exercise:** Obesity can result from a sedentary lifestyle that involves little to no exercise. The likelihood of gaining weight and becoming obese is increased in people who spend the most of their time sitting or lying down.
5. **Medical conditions:** Obesity and weight growth can be influenced by a number of medical diseases, including hypothyroidism, Cushing's syndrome, and polycystic ovarian syndrome (PCOS).
6. **Medication:** As a side effect, weight gain has been reported with the use of corticosteroids, antidepressants, and antipsychotics.
7. **Psychological causes:** Stress, anxiety, sadness, and emotional eating are among psychological causes that can result in weight gain and obesity.
8. **Age and gender:** People's metabolisms slow down as they become older, and they tend to become less active, which can lead to weight gain and obesity. Due to hormonal changes that take place throughout adolescence, pregnancy, and menopause, women often acquire weight more quickly than men do.

Effects of Obesity

Numerous detrimental effects of obesity can be seen on a person's social, psychological, and physical health. Obesity has a number of common impacts, including:

1. Obesity raises the chance of contracting a number of chronic conditions, including type 2 diabetes, high blood pressure, heart disease, stroke, and several forms of cancer.
2. Obesity is linked to a reduced life expectancy because it increases the likelihood of developing chronic diseases.
3. Physical restrictions: Obesity can lead to physical restrictions that make it difficult to move, climb stairs, and carry out daily tasks.
4. Joint pain: Carrying around extra weight puts strain on the joints, which can hurt the joints and raise the risk of osteoarthritis.
5. Obesity is a frequent contributing factor to sleep apnoea, a disease in which a person's breathing repeatedly pauses and resumes while they are asleep.
6. Obesity can contribute to mental health issues like depression, anxiety, and low self-esteem.
7. Obese people frequently experience social stigma and prejudice, which impairs their quality of life and causes them to withdraw from society.
8. Obesity raises healthcare expenditures because it increases the chance of developing chronic diseases and necessitates more medical treatment.¹¹

Homoeopathic management of obesity

The use of homoeopathic remedies to assist people lose weight and enhance their general health constitutes homoeopathic therapy of obesity. Based on the patient's symptoms, medical history, and other characteristics, the treatment is individualised.

The following are some conventional homoeopathic treatments for the management of obesity:

1. One of the best drugs for weight loss is called CALCAREA CARB 30. Obesity and weight gain arise from the extra abdominal fat and the metabolism's slow rate of activity. The patient is obese and sluggish. There is a propensity to perspire heavily, particularly on the head. Cold air is intolerable for these patients. The patient has unusual dietary patterns. The eating habits include a penchant for boiled eggs as well as odd foods like lime, chalk, clay, and pencils. The patients are virtually invariably constipated because of a slow metabolic activity. If the extra weight gain is brought on by thyroid issues, this medication might also be taken into consideration. They suffer from polycystic ovary syndrome.²
2. CAPSICUM is suggested when a person has a slow, passive mind. The patient dislikes physical strain and has no interest in engaging in activities that are out of the ordinary. The patient is typically chilly and experiences constant coldness. It is also an effective treatment for alcoholics who frequently crave alcohol and other stimulants. The digestive process is sluggish and slow in Capsicum sufferers.
3. FERRUM METALLICUM 30- One of the finest treatments for anaemia and obesity is ferrum met. Both the mucous membranes and the skin are pallid. Even though you may be anaemic, you might experience facial flushing. The feet and hands are still chilly. The muscles are sluggish and at ease. Due to the patient's extreme weakness, walking and speaking can be challenging. Every action may aggravate heart palpitations that presently exist.⁴
4. ANTIMONIUM CRUDUM 30- it is given to overweight children to aid in weight loss. The youngster who is extremely irritable, has a cross disposition, and dislikes being touched or observed. These kids also clearly dislike taking cold baths. A child's hunger for acidic foods like pickles is a key marker that they should use this medication to reduce weight. Due to a tendency of overeating, the youngster in this situation typically has a heavily white-coated tongue and an abnormal stomach with alternate constipation and diarrhoea.
5. FUCUS VESICULOSIS Q- Fucus is tried when Calcarea carb. Fails. In focus thyroid problem is the main reason for weight gain.
6. NATRUM MURIATICUM 200 is also employed as a successful weight-loss treatment. Natrum mur works best when the body has more excess fat in the thighs and buttocks than in other areas. If a person has put on weight as a result of prolonged stress or despair, this medication works wonders. The patient's body is overheated, and they can't stand the heat of the sun. Patients who need this medication typically have anaemia. The desire for more salt in the diet is another significant symptom reported in people who are candidates for this medication. Patients with natrum mur have a tendency to cry, especially when

- they are by themselves, and this tendency worsens when someone comforts them. They suffer from polycystic ovary syndrome.⁶
7. LYCOPODIUM CLAVATUM 200-Lycopodium is yet another successful weight-loss medicine. This is primarily utilised when the thighs and buttocks have extra fat. Patients who require Lycopodium are those who experience constipation and flatulence on a regular basis. They frequently have a craving for sugary meals. They indulge in hot meals and drinks as well. They have a propensity to eat more than they can handle, which leads to a bloated stomach and weight gain. The individual needing this medication is extremely irritable and easily becomes angry, especially when they are contradicted. Another factor contributing to Lycopodium weight gain is hypothyroidism.
 8. NUX VOMICA 30- Nux Vomica is advised for people who have accumulated too much weight as a result of sedentary lifestyles. Patients who use nux vomica frequently experience the most difficult constipation. Such a person always has the urge to pass faeces, yet they only ever pass a small amount at once. There is also a cold air intolerance. A patient with nux vomica enjoys fatty, spicy, and stimulating foods like coffee or alcoholic beverages. Mentally, the individual is very perceptive of outside influences and is also quite angry.
 9. PHYTOLACCA BERRY Q- Obesity without any possible defect in the system. A general remedy to reduce weight and fat
 10. CALOTROPIS Q- Calotropis is a good medicine for weight loss. Obesity while flesh decreases, muscles become harder and stronger.
 11. IGNATIA 200 - When depression is the root of weight gain, Ignatia is given. People who need Ignatia typically eat a lot out of melancholy, which leads to weight gain. Their emotions are extremely erratic, fluctuating from melancholy to joy and from laughter to sobs.⁵
 12. AMMONIUM CARB 30 – When compared to the tiny legs, the upper torso of Ammonium Carb. is overly obese. Ammonium carb is useful for obese people who are lethargic, constantly feel exhausted, and are feeble. These individuals typically lead sedentary lifestyles. They exhibit great sensitivity to cold air as well.⁷
 13. GRAPHITES 30-Graphites is recommended when women put on too much weight around menopause. The ladies' menses are delayed even at a young age. There may be skin outbreaks on the patient. The skin eruptions exude a thick, gooey liquid. Graphites are most suitable for ladies who are perpetually depressed, cannot stand the cold, and have chronic constipation. There is an increase in cold sensitivity.
 14. PULSATILLA NIG. 30—Pulsatilla is recommended when uterine issues are the cause of obesity. The patient is mild-mannered, kind, and accommodating. The patient dislikes fatty foods and beverages. Another characteristic of this treatment is thirstlessness. The patient enjoys being outside.⁸
 15. SEPIA 30-Sepia can help with weight gain related to menopause. Women that are impatient and uncaring of their family are best represented by sepia. Hot flushes are another issue these ladies could mention. An obvious sign that Sepia has to be treated is a woman's pelvic organs feeling as though they are being pressed downward. They suffer from polycystic ovary syndrome.
 16. THYROIDINUM 3X—Thyroidinum is appropriate when obesity is brought on by subpar thyroid gland function.⁹

METHODOLOGY

- *Study type:* interventional (Clinical Trial)
- *Estimated Enrollment:* 30 participants
- *Allocation:* Randomized
- *Intervention Model:* Parallel Assignment
- *Intervention Model Description:* A randomized, placebo-controlled, double-blind, parallel, superiority trial with 3 month study duration.
- *Masking:* Triple (Participant, Care Provider, Investigator)
- *Masking Description:* Double-blind
- *Primary Purpose:* Treatment
- *Title:* Efficacy of a Multidisciplinary Intervention and Homeopathy for Obesity in adolescence: a Study Protocol for a Randomized Double-blind, Placebo-controlled Trial

- *Actual Study Start Date:* October 10, 2022
- *Estimated Primary Completion Date:* JANUARY 30, 2023
- *Estimated Study Completion Date:* MARCH 13, 2023

Outcome Measures:

Primary Outcome Measures:

- Change from baseline in mean total weight in kilograms (kg) [Time Frame: At baseline and week 4, 8 and 12.]

Weight measured with the participants barefooted and lightly dressed, with a Tanita scale Fitscan BC-545 F segmental body composition monitor. The scale has an eight electrode body composition monitor that displays twenty readings; ten whole body and ten segmental (arms, legs and trunk area).

- Change from baseline in percentage of body fat [Time Frame: At baseline and week 4, 8 and 12.]

Body fat measured with Tanita scale Fitscan BC-545 F segmental body composition monitor. Values greater than 30% for females, and 25% for males, are considered high and of risk

Secondary Outcome Measures:

- Change from baseline in mean total body mass index (BMI). [Time Frame: At baseline and week 4, 8 and 12.]

Weight/height² (kg/m²). Overweight (BMI \geq 85th but $<$ 95th percentile based on the Centers for Disease Control and Prevention growth chart) or obese (BMI \geq 95th percentile).

- Change from baseline in mean total fat mass index [Time Frame: At baseline and week 4, 8 and 12.]

Calculated by dividing fat weight in kilograms by height in meters squared.

Change from baseline in mean total lean body mass (kg). [Time Frame: At baseline and week 4, 8 and 12.]

Calculated by subtracting body fat weight from total body weight: total body weight is lean plus fat

- Change from baseline waist-hip ratio. [Time Frame: At baseline and week 4, 8 and 12.]

Calculated as waist measurement divided by hip measurement.

- Change from baseline in mean total lean muscle mass (kg). [Time Frame: At baseline and week 4, 8 and 12.]

Calculated by total weight of the body minus all the weight due to the fat mass.

- Number and severity of all adverse events [Time Frame: After participants consent and enrolled in the study and 15 days after study completion.]

Adverse event will be defined as any untoward medical occurrence in a subject without regard to the possibility of a causal relationship.

Other Outcome Measures:

- Change from baseline in mean total fasting serum glucose (mg/dl) [Time Frame: At baseline and week 12.]

Blood samples will be collected by venepuncture in the antecubital region of patients after 10-12 hours of overnight fasting and centrifuged within 30-45 min of collection, using an automated chemical analyser. Glucose will be assayed by the glucose-oxidase method.

- Change from baseline in mean total fasting serum triglycerides (mg/dl) [Time Frame: At baseline and week 12.]

Blood samples will be collected by venepuncture in the antecubital region of patients after 10-12 hours of overnight fasting and centrifuged within 30-45 min of collection, using an automated chemical analyser.

- Change from baseline in mean total cholesterol (mg/dl) [Time Frame: At baseline and week 12.]

Blood samples will be collected by venepuncture in the antecubital region of patients after 10-12 hours of overnight fasting and centrifuged within 30-45 min of collection, using an automated chemical analyser.

- Change from baseline in mean total high-density cholesterol (mg/dl) [Time Frame: At baseline and week 12.]

Blood samples will be collected by venepuncture in the antecubital region of patients after 10-12 hours of overnight fasting and centrifuged within 30-45 min of collection, using an automated chemical analyser.

- Change from baseline in mean total low-density cholesterol (mg/dl) [Time Frame: At baseline and week 12.]

Blood samples will be collected by venepuncture in the antecubital region of patients after 10-12 hours of overnight fasting and centrifuged within 30-45 min of collection, using an automated chemical analyser.

- Change from baseline in percentage of glycosylated haemoglobin [Time Frame: At baseline and week 12.]

Blood samples will be collected by venepuncture in the antecubital region of patients after 10-12 hours of overnight fasting and centrifuged within 30-45 min of collection, using an automated chemical analyser.

- Change from baseline in mean total insulin (mU/ml) [Time Frame: At baseline and week 12.]

Blood samples will be collected by venepuncture in the antecubital region of patients after 10-12 hours of overnight fasting and centrifuged within 30-45 min of collection, using a chemiluminescence technique.

- Change from baseline in mean total thyroid-stimulating hormone (mU/L) [Time Frame: At baseline and week 12.]

Blood samples will be collected by venepuncture in the antecubital region of patients after 10-12 hours of overnight fasting and centrifuged within 30-45 min of collection, using a chemiluminescence technique.

- Change from baseline in mean total score of CES-D-R [Time Frame: At baseline and week 12.]

CESDR scale measure symptoms of depression in nine different groups as defined by the American Psychiatric Association Diagnostic and Statistical Manual, fifth edition. The Total CESD-R Score is calculated as a sum of responses to all 20 questions. The range of possible scores is between 0 (for those who say 'not at all or less than one day to all 20 questions' and 60 (for those who say '5-7 days' or 'nearly every day for 2 weeks' for all 20 questions). No clinical significance: a total CESD-R score less than 16 across all 20 questions.

- Change from baseline in mean total score of Screen for Child Anxiety Related Emotional Disorders (SCARED). [Time Frame: At baseline and week 12.]

Appropriate screening tool to aid the diagnosis of anxiety disorders in adolescents attending an outpatient clinic. It consists of 41 items that are rated from 0 to 2, being 0 never, 1 sometimes and 2 always. The cut-off point is 25, that is, there is a probability of at least 70% that the child or adolescent has an anxiety disorder.

Eligibility Criteria

- *Ages Eligible for Study:* 12 Years to 19 Years (Child, Adult)
- *Sexes Eligible for Study:* All
- *Accepts Healthy Volunteers:* No

Criteria

- **Inclusion Criteria:**
 - * 11 to 19 years old.
 - * At least Primary education.
 - * Overweight (BMI \geq 85th but $<$ 95th percentile based on the Centres for Disease Control and Prevention growth chart) or obese (BMI \geq 95th percentile).
 - * Fasting serum glucose $<$ 126 mg/dl.
 - * Glycosylated haemoglobin $<$ 6.5%.
 - * With symptoms that match with *Calcareo carbonica ostryrea*.
 - * Willingness to participate, and verbal and written consent.
- **Exclusion Criteria:**
 - * Pregnancy or breastfeeding.
 - * Cases already undergoing treatment (homeopathic, nutritional or structured physical activity) for obesity within last three months.
 - * Currently use of metformin, orlistat, insulin, other antidiabetic medication, contraceptive pills, medications with effects on lipid metabolism, antiepileptic drugs (carbamazepine, phenytoin, valproic acid, phenobarbital), antipsychotics (clozapine), protease inhibitors (amprenavir, indinavir, nelfinavir, ritonavir, saquinavir), tamoxifen, raloxifene, isotretinoin, acitretin, ciclosporin, azathioprine, sirolimus].
 - * Any condition that prevents physical exercise.
 - * Diabetes, hypertension, thyroid diseases, Down syndrome, mental retardation.

RESULTS

A variety of demographic, lifestyle, and health-related baseline variables of the obesity research group may be pertinent to the study's goals.

1. Age:

Sr. no.	Age group	No. of patient
1	11-13	6
2	14-16	10
3	17-19	14

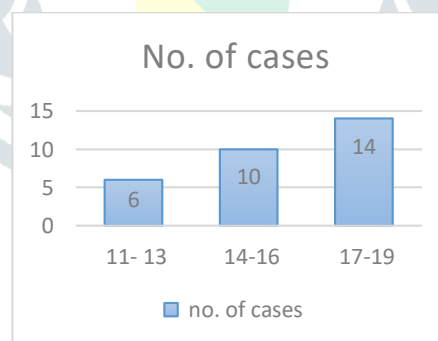


Figure - 01 Age Wise Distribution of Cases

2. Gender:

Sr. no.	Male	Female
1	18	12

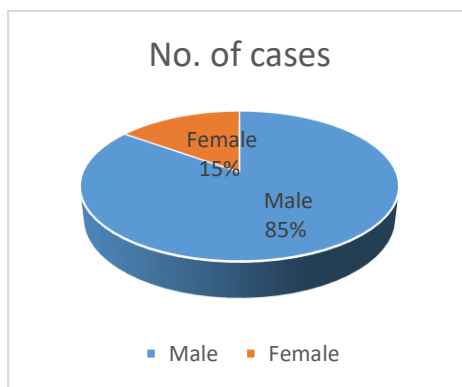


Figure - 02 Gender Wise Distribution of Cases

3. Study Result :

Sr. No.	Group	No. Of cases Allotted	Positive response	No response
1	Receiving Placebo	15	06	09
2	Receiving Calc Carb 30c	15	12	03

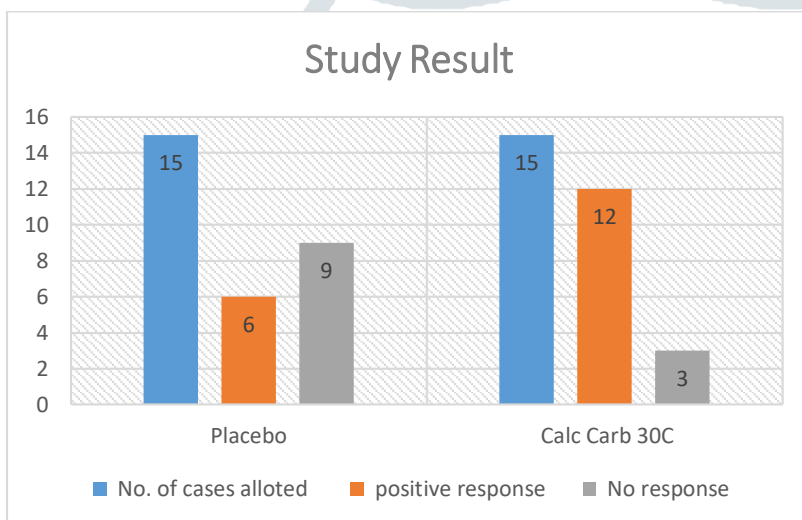


Figure - 03 Study Result

DISCUSSION

Obesity in adolescents maximum cases are noted in between 17-19 years of age in study of 30 participants. Adolescent Male are more prone to obesity in compare to Female. Homoeopathic medicine Calcarea carbonica ostrearium 30C with multidisciplinary approach is proven more effective then placebo control trial with multidisciplinary approach.

CONCLUSION

Although there is not much evidence to support the use of homoeopathic medicines in the treatment of obesity, certain research have indicated that some homoeopathic treatments may be helpful in shedding kilogrammes and enhancing general health. More thorough research is necessary to support these conclusions, though.¹³

It is challenging to reach a conclusive judgement on how homoeopathic therapy affects obesity based on the existing data. While some people may benefit from homoeopathic treatment in terms of weight loss and other health outcomes, others may not respond as well or may need additional interventions.

Homoeopathy should not be used as a stand-alone treatment for obesity; rather, for the best results, it should be combined with other lifestyle changes, such as dietary adjustments and increased physical activity.¹⁴

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