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Homoeopathic management of obesity with capsicum annuum in decimal scale and to determine its safety by phase iv clinical research

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Abstract

Obesity is a chronic metabolic disorder characterized by excessive fat accumulation due to hypertrophy and hyperplasia of adipose cells. According to the World Health Organization (2024), 16% of the global adult population lives with obesity, contributing to increased risk of cardiovascular diseases, diabetes, infertility, and other metabolic complications. This study evaluates the anti-obesity efficacy of *Capsicum annuum* prepared in decimal scale, a homoeopathic remedy known for its active component capsaicinoids, which possess thermogenic and fat-reducing properties. The study aims to assess its impact on body weight, BMI, and lipid profile over a 3-month period in obese patients (BMI 25-40 kg/m²). Plant extracts will be prepared via Soxhlet extraction and analyzed using GC-MS for phytochemical profiling. Fifteen patients will be enrolled following IRB approval under ethical guidelines, and clinical outcomes will be monitored through periodic visits, blood tests, and health assessments. The results are expected to validate the safety and cost-effectiveness of *Capsicum annuum* as a natural anti-obesity agent, promoting evidence-based use of homoeopathy in obesity management.

Keywords: Obesity, *Capsicum annuum*, capsaicinoids, anti-obesity, homoeopathy, Soxhlet extraction, BMI reduction, phytochemical analysis

Introduction

Obesity is defined as an abnormal growth of adipose tissue, due to an enlargement of fat cell size or an increase in fat cell number or combination of both [1]. According to World Health Organization (WHO,2024) of 43% (2.5 billion adults) aged 18 years and above are overweight and 16% (890 million) peoples are living with obesity [2]. As obesity is indeed linked to high cholesterol, Insulin resistance, High blood pressure, Shortness of Breath, Emotional as well as social problems and it does increase the risk of gall stones [3]. Because obesity leads to many complications like Cardio vascular disease, Metabolic disease, Osteoarthritis, Type 2 DM, PCOD and Infertility. Obesity develops from complex factors like environmental changes, lifestyle factors, changes in Neuro- regulation of appetite and energy expenditure [4]. Hence there is a great need of research to reduce fat accumulation and improve human health.

A Dictionary of Practical Materia Medica By John Henry Clarke (volume-1, Pg.no:388) has described Capsicum Annuum corresponds especially to persons of lax fibre and muscles, obesity, fat, persons who dread the open air and affection of Obesity [5-7]. In homeopathy different medicines are mentioned for obesity such as Ammomium Carbonicum, Calotropis Gigantea, Calcarea Carbonica, Thuja Occidentalis, Phytolacca Decandra, Ficcus Indica, Capsicum Annuum etc., One of the best medicine Capsicum Annuum have medicinal value in different parts, especially placenta have Capsaicinoids which is responsible for Antiobesity. However the efficacy of Capsicum Annuum in Decimal scale for anti-obesity with reduction of blood parameter like Lipid profile and reduction in body mass index (BMI) was not yet studied. So this study is to confirm the effectiveness of Capsicum annuum in Decimal scale for patients with obesity to reduce the fat accumulation and Body Mass Index. There are new developments in Pharmacotherapy which aids in obesity prevention and treatment.

Objectives

- To Assess the Anit-obesity activity of Capsicum annuum in patients within a period of 3 Months.
- To determine its effectiveness in reducing body weight and related obesity parameters.

- This research work is proposed to screen the effectiveness of Phyto-drugs against Obesity.
- To Evaluate the safety profile, highlighting its natural origin and no reported side effects.
- To Prove it as a low cost-effective, Accessible and safe supportive measure to control obesity.

Materials and Methods Collection of plant

Collecting from a Herbarium garden provides the advantage of receiving samples that are free of pesticides. Then cleaning the plant manually, by washing, peeling, and stripping leaves from stems to ensure thorough removal of dirt and impurities [8]. Dry plant, material below 300 °C with airflow, protect from sunlight, then powder carefully to improve extraction efficiency without overheating or degrading volatile/heat-sensitive compounds. The dried plant material is ground into a fine powder. The obtained dried extracts are stored at 4°C, then labeled and stored in sterile bottles to make suitable for further analysis [9].

Methods of Solvent Extraction

The extraction of Bioactive Compounds, Particularly Capsaicinods from Capsicum annuum. In Traditional Methods - Soxhelt Extraction, This method is Widely used to extract the Capsaicinods compound from Capsicum annuum [10].

Procedure for Soxhelt Extraction

Using Organic Solvents like methonal or ethanol to hot extract with temperature 65-78°C for 2-6 Hours ^[11]. This Method Allows yields 85-90% But It requires Time, Energy and Solvents volumes ^[10]. A significant Protocal uses 1gm of plant sample + 50ml Methonal for 2 Hours ^[10].

Primary Qualitative Analysis

Qualitative analysis of *Capsicum annuum* involves identification and characterization of various phytochemical Compounds present in plant material⁽¹²⁾. These methods are essential for determining the bio active compounds especially capsaicinods and also responsible for characteristics properties of chilli peppers, and therapeutic effects ^[13].

Quantitative Analysis: GCMS

For qualitative and quantitative analysis of phyto-chemicals can be done by using GCMS Method.

Sample prepartion for GCMS Analysis

Extraction for capsicum annuum of volatile compound using non-polar solvents like ethanol & n-hexane [14]. Before analysis process, Sample are filtered with 0.2 micrometre filtered paper & diluted. In this study Soxhlet extraction will be used because it yields 85-90% [15].

Following GCMS analysis procedure [14]

GC-MS with 5% diphenyl-95% dimethylpolysiloxane column (30 m x 0.25 mm), helium carrier 1.5-1.61 mL/min, Injector 250°C, Oven 50-60°C, EI 70 eV, Spectra 33-450 m/z, Shimadzu GCMS uses as Data Acquisition software [14]

IRB Initial Submission & Approval [16]

Each clinical study must first be approved by a IRB, before being introduced at a study site. An application for Ethics assessment shall be submitted to a applicable IRB Secretary and shall contain the following items:

- a) A submission letter for initial appraisal
- b) A duly accomplished and signed clinical research ethics review application form
- c) An investigator's fight of interest declaration form
- d) Curriculum vitae of the principal investigator
- e) A clinical study classification form
- f) A study protocol
- g) An investigator's brochure
- h) An informed consent form or a subject information sheet in suitable language
- i) Subject recruitment materials (e.g. subject recruitment advertisement or poster)
- i) Documents or materials for use by subjects
- k) A clinical trial insurance certificate

Study Inclusion & exclusion Criteria

a) Inclusion Criteria

- i) Patient age above 18 years old (Male/Female)
- ii) Patient BMI: 25-40 kg/m2.
- iii) Patient Willing to sign the consent form
- iv) Patient who are newly identified & under the treatment for obesity
- v) Non pregnant women.
- vi) Patient who had not taken any vaccination within 6 months.

b) Exclusion Criteria

- i) Patient age below 18 years old. (Male/Female)
- ii) BMI < 25 Kg/m² (Normal or underweight)
- iii) Patient not willing to sign the consent form.
- iv) Pregnant women

Clinical Trial Phase 4 [16]

Phase 4 trials is defined as the trial which is carried out once the drug or device has been approved by FDA during the Post-Market Safety Monitoring.

a) Informed Consent [16]

A process where a subject voluntarily agrees to participate in a trial after being fully informed of all relevant aspects. It is documented through a written, signed, and dated consent form, in accordance with ICH-GCP guidelines.

b) Law & Ethics

Under ICMR Gudieliness [17]:

As per the amended Schedule Y (2005) of the Drugs and Cosmetics Rules, 1945, a clinical trial refers as systematic study of new drugs on human subjects to generate data for discovering and/or verifying the clinical, pharmacological or adverse effect with the objectives determining safety and/or efficacy of a new drug [10].

c) Sample Size

A 15 Sample will be selected based on BMI from Outpatient Department in our College Hospital.

d) Patient Study Visit schedule

	Day	Visit	Visit	Visit	Visit
	1st	2nd	3rd	4th	5th
	± 3	± 3	± 3	± 3	± 3
	days	days	days	days	days
ICF sign	ü	X	X	X	x
Aptitude Questionnaire	ü	ü	ü	ü	ü
Primary Check- up	ü	ü	ü	ü	ü
Medical History	ü	x	x	x	ü
Side effect	X	ü	ü	ü	ü
Blood Investigations	ü	X	X	X	ü

e) Primary Health check-up

This Health check includes Height, Weight, Blood pressure (BP), Pulse rate, Respiratory rate, SPO2, etc.

f) Blood Investigations

Complete blood count + Erythrocyte Sedimentation rate,

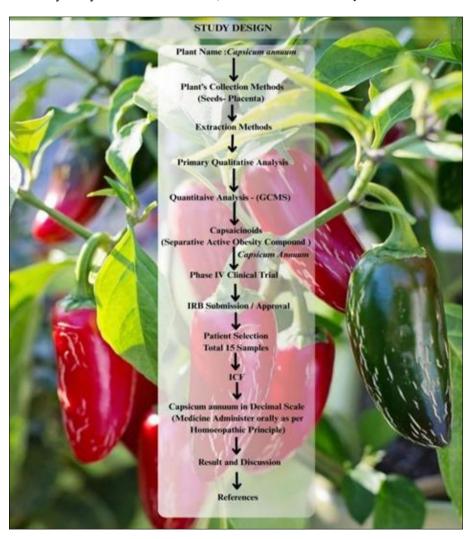
Lipid profile, Renal Function Test, eGFR, Urine Routine.

g) Dosage of Medicine

The patient will receive *Caspicum Annuum* prepared at Decimal Scale, administered orally as per Homoeopathic principles.

Implications

This Research could improve the validity of Homoeopathy through data-driven evidence, perhaps shaping greater acceptance within the medical community. Moreover it can direct subsequent research efforts towards resource efficient health care methods. This research may improve health management by embracing integrated healing approaches. These Findings could elevate treatment quality using patient-centered methods. The successful outcome of this study will provide an effective drug at very low price. Compared with other obesity treatment, Homoeopathic medicine are at very low cost & has no side effects.



Conflict of Interest

Not available.

Financial Support

Not available.

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