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Anti-Obesity Efficacy of A Novel Herbal Formulation on Diet-Induced Obese Mice: A Pre-Clinical Study

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ABSTRACT

Introduction: Pre-clinical study is to evaluate the efficacy of a novel herbal formulation which provides valuable insights into its potential as a therapeutic intervention for combating various health issues. The purpose of the study was to formulate a novel herbal formulation to treat obesity and test efficacy on Swiss albino mice. **Materials and Methods:** Some plant materials were collected to prepare formulation. For performing the efficacy test of the formulation, there were four groups of Swiss albino mice and each group was composed of five mice. Group-1 was control group which had to have High Fat Diet, Group-2 was another control group which had normal food diet. Group-3 and group-4 were made of obese group of mice where Group-3 and Group-4 had to intake high fat diet with the formulation and marketed anti-obesity drug accordingly. **Results:** After 25 days, it was found that using the formulation and marketed drug twice a day, both the group were shown reduced weight in spite of having high fat diet.**Conclusion:** based on weight loss parameter; it can be stated that the formulation has a potential to be considered as much effective as marketed anti-obesity drug on animal model.

Keywords: Herbal formulation, anti-obesity, pre-clinical study, swiss albino mice

INTRODUCTION

Nowadays, more and more people are interested in using herbal products instead of regular drugs because they appear to be safer and still effective for different health issues (1). Obesity is one of the biggest health problems all around the world right now (2). It happens because many people don't move around enough, eat unhealthy food as well as don't exercise (3). Obesity has advanced as an epidemic in global population at an alarming rate currently (4). Recent studies show that over a billion adults worldwide are overweight, and also to be mentioned that about 300 million of them are clinically obese which means they're extremely overweight (5). Outrageously, being overweight or obese is one of the top reasons for people dying worldwide and the statistics shows with around 2.8 million deaths every year linked to it (6). It is also needed to be noted that being overweight or obese also leads to other serious health problems like diabetes, heart disease as well as certain cancers (7). So, researchers are looking into using dietary supplements with antioxidants and other useful substances to help with obesity and its related issues (8).

Many regular marketed drugs have side effects that can be harmful in many ways. Researchers are trying to find safer options for treating obesity (9). Even though there's a big need for better treatments, there aren't enough good selections available right now (10). That's why people are starting to emphasis more on herbal products. They might be a good alternative because they seem to have fewer side effects as well as cost less (11). While some plants that we can eat have shown promise in helping with weight control, still more research to needs to be sure (12). The endeavor of the study was to formulate a novel herbal formulation by using day to day useable herbal plants for obesity control and examine its efficacy on Swiss albino mice.

MATERIALS AND METHODS

The experiment was conducted inside the labs of the department of pharmacy, North South University, Dhaka, Bangladesh.

Material Collection

first of all, the ingredients of the formulation were collected from local stores maintaining room temperature and humidity. The amounts of the ingredients are given below:

a) Apple Cider Vinegar: collected amount was 500 mL

b) Edible Coconut Oil: collected amount was 20 mL

c) Soy lechithin: collected amount was 1 gm

d) Powdered cinnamon: collected amount was 300 mg

e) Powdered cardamom: collected amount was 300 mg

f) Powdered cumin: collected amount was 300 mg

g) Lemon: collected amount was 25 ml

Extraction of Cinnamon, Cardamom and Cumin

Soxhlet extraction method was used to extract Cinnamon, Cardamom and Cumin separately. First, 100 gm each of cinnamon, cardamom and cumin powder was covered with cotton and kept inside the device. Then approximately 500 mL of ethanol were poured and it was made sure that the cotton pack was fully wet. The extractions of cinnamon, cardamom and cumin with ethanol were taken out and passed through the rotary evaporator. The semi-solid extractions were taken for use.

Extraction of Lemon

Eight (8) lemons were taken and peeled. Juices were taken out. The juice was extracted by using rotary evaporator.

Preparation of Formulation

After literature review and discussion with some nutritionists, following amounts of the ingredients were finalized: 15 mL apple cider vinegar, 5 mL coconut oil, 700 mg lechithin, 3100 mg of cinnamon, 3500 mg of cardamom, 2650 mg of cumin, 1.7 mL of lemon. All them were taken in a beaker. Then were mixed by pipette. 25 mL were taken in test-tube and concentrate water was added to make it 30 mL. After that, the test tube was kept in sonifier and the materials inside the test tube was sonified for 1 hour. Then, test tube was taken out from sonifier when the ingredients were centrifuged. Main products were separated from the water portion by filtration and preserved in a glass bottle for future use.

Animal Model

20 Swiss albino female mice were collected where their age range was 90-100 days and divided into 4 experimental groups where each group contained 5 mice. The mice were kept in the animal house of the Department of Pharmacy, North South University. For daily food, all the mice were given available marketed food which was made for rat and mouse by maintaining the rules and regular of formulary and ethical committee of North South University. Group-1 was considered as control group without High Fat Diet. This group was given only normal food available for the laboratory. Group-2 was considered as control group with High Fat Diet along with normal food. Group-3 was considered as treatment group as they were given High Fat Diet along with the herbal formulation (300 mg/kg, B.W.). Group-4 was also considered as treatment group for comparing with Group-3. Since, they were given High Fat Diet along with Orlistat (200 mg/kg, B.W.) which is a marketed drug for obesity control. All the mice were kept in the animal house where 25 degree Celsius was maintained and proper lighting was maintained such as 12 hours light and 12 hours dark. When they were 3 weeks old and they were given above mentioned food according to group around 6 weeks. Group-1 was considered as negative control and Group-2 was considered as positive control.

Treatment Period

Total treatment period was 25 days. In this period, Group-1 and Group-2 were given as usual diet which was previously provided for each group. Only Group-3 and Group-4 were given the prepared herbal formulation and marketed drug accordingly and they were given High Fat Diet besides.

Daily dose for Group-3: 0.120g of herbal formulation were dissolved in 4 mL of water and mixed well by pipette and given only 300 micro-liters of solution to the mice.

Daily dose for Group-4: 0.045g of Orlistat was dissolved in 4mL of water and mixed well by pipette and given 200 micro-liters of solution to the mice.

The mice were not killed after the experiment.

ETHICAL CLEARANCE

The ethical approval was taken from The Research Ethics Committee of North South University. The ethical approval was issued in 2018.

RESULTS

Weighs of the mice during 1st day of the treatment was collected and given in table-1.

Table-1: Weights during Day-1

Control without High Fat Diet	*Control with High Fat Diet*	*Formulation*	*Drug (Orlistat)*
37.6	35.1	42.9	33.5
31.5	44.0	46.4	42.3
41.8	38.4	55.8	43.0
37.1	35.9	47.4	44.3
34.7	34.9	35.0	47.0

****Weight in gram

After 8 days of continuous providing herbal formulation and drug both twice a day to the Group-3 and Group-4, the weights were measured of the groups and mentioned in table-2.

Table-2: Weights after 8th days

Control without High Fat Diet	*Control with High Fat Diet*	*Formulation*	*Drug (Orlistat)*
39.2	35.8	38.5	35.7
38.1	42.1	44.8	40.0
41.2	40.1	51.6	39.0
38.4	39.3	43.2	43.7
37.5	35.9	31.4	47.7

****Weight in gram

After 12 days of continuous providing herbal formulation and drug both twice a day to the Group-3 and Group-4, the weights were measured of the groups and mentioned in table-3.

Table-3: Weights after 12th days

Control without High Fat Diet	*Control with High Fat Diet*	*Formulation*	*Drug (Orlistat)*
39.2	35.3	38.1	33.1
40.1	46.1	46.2	37.5
42.3	41.2	51.7	41.3
38.5	49.2	40.3	43.7
37.7	35.2	33.1	46.6

****Weight in gram

After 25 days of continuous providing herbal formulation and drug both twice a day to the Group-3 and Group-4, the weights were measured of the groups and mentioned in table-4.

Table-4: Weights after 25th days

Control without High Fat Diet	*Control with High Fat Diet*	*Formulation*	*Drug (Orlistat)*
39.6	39.5	37.1	30.1
42.1	48.4	43.2	37.5
42.3	46.7	48.7	38.3
44.5	53.2	40.3	43.7
39.7	39.2	33.1	41.6

****Weight in gram

In the table-5 and Figure-1, average weight of all groups is given for weight loss comparison according to data collection dates.

Table-5: Average weight of all groups

Days	*Control without High Fat Diet*	*Control with High Fat Diet*	*Formulation*	*Drug (Orlistat)*
1st day	36.54	37.66	45.5	42.02
8th day	38.88	38.64	41.9	41.22
12th day	39.56	41.4	41.88	40.44
25th day	41.64	45.4	40.48	38.24

****Weight in gram

Figure-1: Average weight comparison in gram

In the Figure-2, weight reduction percentage of Group-3 (formulation intake group) and Group-4 (Orlistat intake group) is given.

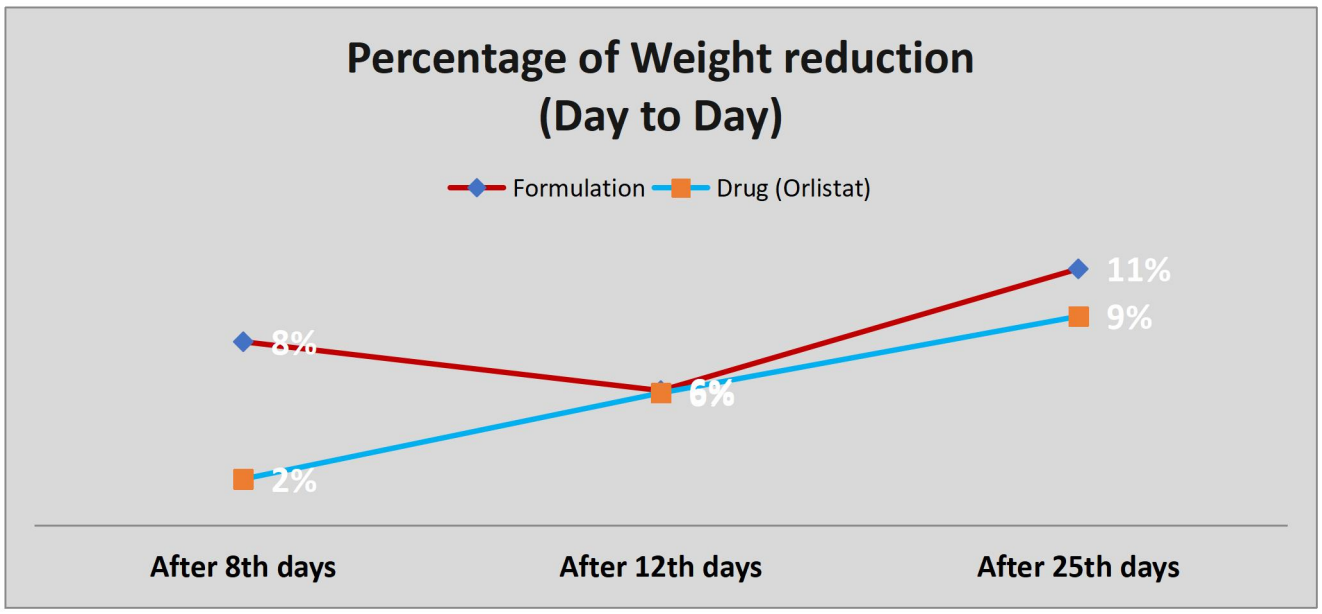

Figure-2: weight reduction percentage

DISCUSSION

It is to state that according to weight loss parameter both formulation and marketed drugs worked. By intaking formulation, mice had 11% weight loss percentage whereas marketed drug intake group had 9% weight loss percentage. In the experiment control group without high fat diet got weight because of age and natural growth. And the high fat diet control group was even getting more weight because of aging, natural growth and high fat diet. On the other hand, despite having high fat diet both experiment group lost weight against time which indicates that both are effective. It was also found that Group-3 and Group-4 had not any physical abnormalities and sudden death or even no abnormal behavior. This highlights the potential of the herbal formulation as a promising therapeutic agent in the management of obesity. The experimental correspondence in weight reduction between the herbal formulation and Orlistat not only recommends comparable effectiveness but also implies this herbal formulation's viability as a potential alternative or supplementary treatment to conventional pharmaceutical methods. This finding can contribute to the diversification of available treatment options addressing the multifaceted nature of obesity with greater efficacy as well as customization. While the present study provides convincing evidence of the herbal formulation's anti-obesity effects, further investigations are necessary to clarify the underlying mechanisms driving its efficacy. Comprehensive investigation of the biochemical pathways as well as physiological interactions involved will not only extend the understanding of the formulation's mode of action but also inform the development of optimized treatment regimens. It is also to mention that long-term safety assessments as well as clinical trials are imperative to ascertain the formulation's sustained effectiveness and tolerability in human subjects. Moreover, the comparative efficacy between this herbal formulation and Orlistat highlights the possibility of mixing natural remedies into mainstream healthcare practices by capitalizing on their perceived safety and accessibility.

CONCLUSION

The experiment showed a very significant outcome on weight loss basis. This can be concluded that this novel formulation has the potential to be considered as good as marketed anti-obesity drugs and can be used as a good alternative of marketed anti-obesity drug with lower cost and easy accessibility.

LIMITATION

There were a few limitations in this study. The number of the animal model was really very low which is a major limitation. The experiment and the conclusion were based on weight loss comparison. So, it cannot be said with proof that this formulation was 100% safe though there was no visual physical problem on mice model.

RECOMMENDATION

The study should be done on a large scale with a large number of different types animal models where dose-response Studies and adverse-effect level (NOAEL) studies should be done. Related biochemical tests such as acute toxicity text, subacute toxicity test, sub-chronic toxicity test, genotoxicity test, reproductive toxicity test, carcinogenicity testing, hematology, serum biochemistry, histopathological examination and urinalysis should be done. If, after that the result is promising; this can be a revolutionary herbal formulation for obesity control.

Declaration by Authors

Ethical Approval: Approved (The ethical approval was taken from The Research Ethics Committee of North South University. The ethical approval was issued in 2018.)

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