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Study Of Medicinal Plant-Based Anti-Stress Herbal Tea On Prediabetic Women: Randomized Controlled Trial

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ABSTRACT:

The focus of this study is on the effects of herbal tea made with Ashwagandha (*Withania somnifera*), Ginger (*Zingiber officinale*), Lemongrass (*Cymbopogon citratus*), Tulsi (*Ocimum tenuiflorum*), Stevia (*Stevia rebaudiana*), Thankuni (*Centella asiatica*), and Bay leaves (*Laurus nobilis*) on prediabetic women. In a "single centre randomised controlled trial," participants' blood pressure, serum cortisol, blood sugar levels, and scores on common stress-assessment questionnaires were measured in order to determine the impact of this herbal tea on stress reduction. A total of 62 female participants between age of 18-60 years were considered to be prediabetes out of 100 female participants. The intervention group (Group A) received the herbal tea (150 ml twice a day) daily for 8 weeks, whereas the control group (group B) received similar amount of normal tea on a daily basis. At baseline and 8 weeks later, measurements of "serum cortisol level," "blood sugar level, "blood pressure," and "stress-assessment questionnaires" were made. After adjusting for confounding factors, it was observed that group of participants receiving the herbal tea, experienced a larger decrease in blood sugar level from the baseline. After 8 weeks, a reduction of 26.2% from baseline was observed in the intervention group. In contrast, a reduction of 7.8% was observed in the control group. In Group A, after 8 weeks there was a significant reduction in scores corresponding to all of the item-subsets: 51.5% for the "Depression" item-subset, 73.5% for the "Anxiety" item-subset, 60.7% for the "Stress" item-subset. In contrast, in group B, the corresponding reductions in scores were much smaller: 6.8%, 13.01% and 8.2%, respectively. In case of blood pressure, a reduction of 10.4 % for Group A from baseline compared to Group B which is 2.0% for systolic pressure has been noticed. For diastolic pressure also Group A has larger reduction rate (8.48%) than Group B (0.67%).

Keywords: Prediabetes, Anti-Stress, Herbal tea, Randomized controlled trial

INTRODUCTION:

The term "prediabetes" refers to a situation where the blood glucose levels are higher than normal, but not high enough to warrant a diagnosis of diabetes. Prediabetes consists of two entities viz. impaired fasting glucose (IFG) and impaired glucose tolerance (IGT).Excessive stress can induce a prediabetic state. Stress is a condition arising from external physical or mental overload. It can make a person feel embattled, nervous, anxious or otherwise less capable of full and normal response to environmental demands. Prolonged exposure to stress can unbalance the mental and physiological state of a person, thereby leading to Prediabetic condition. Without lifestyle modifications, both adults and children with prediabetes face elevated susceptibility to progressing to type 2 diabetes. In Indian society, women encounter amplified stressors, navigating complex roles and societal expectations. They contend with pressures stemming from traditional gender norms, family responsibilities, and career aspirations, often facing a delicate balancing act. This heightened stress can manifest in various forms, impacting mental and emotional well-being. Despite these challenges, many Indian women demonstrate resilience and determination, striving to overcome barriers and achieve their goals amidst the demanding landscape of social and cultural expectations. This stress often results in a prediabetic condition, which is

prevalent among many women in India. Diabetes poses severe risks including kidney failure, heart disease, nerve injury, eye damage, foot damage, and more. Implementing lifestyle changes is imperative to mitigate these dangers and maintain overall well-being**[1],[2],[3],[4],[5]**.Diabetic women can still give birth to disabled children, raising serious concerns for our future society**[6].**

More than 80% of individuals with prediabetes remain unaware due to infrequent testing for the condition. The average lifetime expenses for diabetes management drugs per patient are substantial. Moreover, the average total monthly expenditure per patient, delineating medical and non-medical costs, is notably high. This causes financial burden in our society**[7]**. India bore a substantial burden of diabetes treatment costs annually in 2003, with projections indicating a substantial escalation by 2025. This anticipated increase poses significant challenges, reflecting the growing prevalence and impact of diabetes on the nation's healthcare system and economy.

Adaptogens, herbs known for improving an individual's ability to cope with stress, regulate the body's functions during heightened stress, promoting physiological balance, and facilitating adaptation to changing circumstances.A recent definition of an adaptogen is,"a class of metabolic regulators which increase the ability of an organism to adapt to environmental factors and avoid damage from such factors." Our aim is to treat prediabetic condition of women and send them to main stream with ayurvedic intervention using medicinal plant basedanti-stress herbal tea. This hypothesis suggests managing stress levels in prediabetic patients by employing Ashwagandha (*Withania somnifera*), Tulsi (*Ocimum tenuiflorum*), Lemongrass (*Cymbopogon citratus*), Stevia (*Stevia rebaudiana*),Thankuni (*Centella Asiatica*), Bay leaves (*Laurus nobilis*) and Ginger (*Zingiber officinale*). These medicinal plants have demonstrated stress-relieving properties, aiding in stress management **[8],[9],[10],[11],[12],[13],[14]**.

STUDY DESIGN

The research included the use of analysis technique for "the single center randomized controlled trial," that was performed in the *Department of Biotechnology of Bengal Institute of Technology, Kolkata, West Bengal, Baranagar Bagha Jatin Social Welfare Organization, Kolkata and Speech and Hearing Institute and Research Centre, Kolkata*. The period of the research was between 3rd April to 3rd June 2023. The design of this study was further approved by the Central Licensing Authority hereby registers and permits Institutional Ethics Committee, Ruby Hospital Kasba, Golpark, E.M. Bypass Kolkata, West-Bengal to perform duties of ethics committee as specified in the New Drugs and Clinical Trials Rules, 2019.

MATERIALS AND METHODS:

A total of 62 female subjects between age group of 18years-60years with a history of Prediabetes were enrolled into the study after performing relevant clinical examinations and laboratory tests. In the randomized controlled trial, 62 subjects were sequentially allocated in a 1:1 ratio to either the experimental or control group. This allocation helps mitigate selection bias and ensures that both groups are comparable for valid statistical comparisons. These included IDRS test, WHO-5 Wellness index, measurement of blood sugar level, blood pressure, serum cortisol, and assessing their scores on standard stress-assessment questionnaires. They were randomized to the study nutraceutical treatment group, and were asked to take 150 mL herbal tea twice a day for a period of 60 days. Herbal tea drink was prepared by adding 1% (w/v) dry herbal tea mixture in boiling water followed by keeping for 2 minutes, straining and consuming the liquor 5 minutes before lunch and dinner. Dry herbal tea contains Ashwagandha leaf 35% (w/v), Thankuni leaf 10% (w/v), Tulsi leaf 35% (w/v), Lemongrass 10% (w/v), Ginger 2% (w/v), Bay leaf 5% (w/v) and Stevia 3% (w/v). During the treatment period (after2 week, 4 week, 6 week), a follow-up telephone call was made to all subjects to check for treatment compliance and to note any adverse reactions. Final safety and efficacy assessments were done after 8th week.

Table-1: WHO-5 wellness Index [15]:

WHO-5 Well-being Index

Please respond to each item by marking one box per row, regarding how you felt in the last two weeks.		All of the time	Most of the time	More than half the time	Less than half the time	Some of the time	At no time
WHO 1	I have felt cheerful in good spirits.	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1	☐ 0
WHO 2	I have felt calm and relaxed.	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1	☐ 0
WHO 3	I have felt active and vigorous.	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1	☐ 0
WHO 4	I woke up feeling fresh and rested.	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1	☐ 0
WHO 5	My daily life has been filled with things that interest me.	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1	☐ 0

Scoring:
The raw score is calculated by totalling the figures of the five answers. The raw score ranges from 0 to 25, 0 representing worst possible and 25 representing best possible quality of life. To obtain a percentage score ranging from 0 to 100, the raw score is multiplied by 4. A percentage score of 0 represents worst possible, whereas a score of 100 represents best possible quality of life.

Table-2: Indian Diabetes Risk Score (IDRS)[16]

Categorized risk factors	Score
Age (in years)	
<35	0
35–49	20
≥50	30
Abdominal obesity	
Waist circumference female <80 cm, Male <90 cm (Reference)	0
Female 80–89 cm, Male 90–99 cm	10
Female ≥90 cm, Male≥100 cm	20
Physical activity	
Vigorous exercise or strenuous at work	0
Moderate exercise at work/home	10
Mild exercise at work/home	20
No exercise and sedentary at work/home	30
Family history	
Two non-diabetic parents	0
Either parent diabetic	10
Both parents' diabetic	20
Total	100

IF THE SCORE IS...
- ≥ 60: Prediabetes. Very HIGH RISK of having diabetes: Oral Glucose Tolerance Test (OGTT) is recommended to rule out diabetes. If this is not possible, at least a random blood sugar or a fasting blood sugar should be done
- 30 – 50: The risk of having diabetes is MODERATE: It is still recommended to have the above check up.
- < 30: Risk of having diabetes is probably LOW

Subjects were enrolled into the study if they met the following inclusion criteria: (1) women of age between 18 and 60 years, (2) IDRS value > 60 (3) free of psychiatric conditions other than stress (4) have a score less than 15 on the World Health Organization-five (WHO-5) **[17]** well-being index and a score of at least 14 on the Perceived Stress Scale (PSS) **[18]** and (5) could read and write English. On the WHO-5 well-being index, lower scores correspond to higher levels of stress.

Subjects were excluded if they met any one of the following exclusion criteria: (1) they were suffering from any chronic physical, hormonal or psychiatric illness, (2) they were using certain hormonal birth-control measures, (3) they were currently on any medication on a regular basis, (4) they were currently taking any other herbal preparations or formulations (4) they were pregnant or lactating, (5) they had substance dependence (6) they had abnormal laboratory or ECG findings.

Blood sugar Test:
Plasma glucose was measured with glucometer / glucose analyzer for Fasting Glucose level every 2 weeks. Fasting plasma lipid profiles and hemoglobin A1c (HbA1c) levels was measured in a contracted clinical laboratory.Diagnosis of diabetes is made by Oral Glucose Tolerance Test (GTT) using venous blood of the patient. WHO defines prediabetes withimpaired fasting glucose (IFG) with fasting plasma glucose (FPG) of 110 to 125 mg/dL and impaired glucose tolerance (IGT) of 140-200 mg/dL.
- Normal range of fasting glucose level is 72-108 mg/dL or 4 to 6 mmol/L.
- If the range of impaired fasting glucose is 100–125 mg/dL, or 5.7–6.4 mmol/L, it is likely to be prediabetic stage.
- If the range of fasting blood glucose is ≥126 mg/dL or above 7 mmol/, it indicates diabetes.

Blood Pressure measurement:
Sphygmomanometric measurements are considerably simpler, safer, and sufficiently precise in the majority of clinical settings.

- optimal blood pressure ranges from <120mm of Hg (Systolic) and <80mm of Hg(diastolic)
- Normal blood pressure ranges from 120-129 mm of Hg (systolic) and 80-84mm of Hg(diastolic)
- High normal blood pressure ranges from 130-139 mm of Hg (systolic) and 85-89mm of Hg(diastolic)
- High blood pressure ranges from >140 mm of Hg (systolic) and >90 mm of Hg(diastolic). [**19**]

Serum Cortisol Level Test:
Concentrations of serum cortisol and ACTH at 8:00 A.M.,2:00 P.M., and 8:00P.M. were determined every 2 weeks using chemiluminescent enzyme immunoassay. Normal ranges were as follows: cortisol (8:00 am) 170-440 nmol/L, cortisol (2:00 pm) 60-250 nmol/L, cortisol (8:00 pm) 55-138 nmol/Land ACTH (8:00am) 0-10.21 pmol/L. Disturbed circadian rhythm of cortisol was defined if the level of cortisol at 8:00 am was lower than the one at 2:00pm and another at 8:00 pm.

Standard Stress-assessment questionnaires:
The Depression Anxiety Stress Scale (DASS)-21 is a validated tool that is widely used to measure the emotional states of depression, anxiety, and stress: It comprises seven items each, divided into subscales with similar content. As DASS-21 is a shortened version of the original DASS-42, the scales on each subscale are multiplied by 2 for the final score. The 4-point severity scale ranges from 0 (does not apply to me) to 3 (applies to me most of the time). The scores are categorized into normal (0–14), mild-moderate **[20]** and severe (>25). The DASS-21 has a high degree of reliability and validity and can be used across different age groups, cultures, and ethnic groups. The stress scale in the DASS-21 scale has an excellent internal consistency within the range of 0.88–0.95**[21].**

Statistical analysis:
Descriptive statistics such as mean and standard deviation was utilized to condense the collected data.Independent sample t-test was used to compare the difference in mean of between Group A and B.If $P < 0.05$, it was considered statistically significant.

RESULT:

Background and Demographic data:
Out of 100 women, 62 women (subjects) were selected after assessing, testing and studying the subjects. All the women had an age range between 18 and 60 years and had a history of Stress and prediabetes, who were prone to diabetes. Subjects who had chronic physical, hormonal, or psychiatric illness (except stress); were using specific hormonal birth control methods; had regular medication; used herbal supplements; were pregnant or lactating mothers; had abnormal lab or ECG reports, were excluded. The 62 subjects were randomly distributed into two groups in a 1:1 ratio i.e. 31 subjects in each group (n=31). The first Group A was the experimental group, who received150 mL of the formulated herbal tea twice a day. The second group B was the Control group who received regular tea. Both groups were kept under observation for 8 weeks.

Table-3: Demography and baseline of subjects:

Parameters	**Group A (n=31)**		**Group B (n=31)**	
	Mean	**SD**	**Mean**	**SD**
Age (yrs.)	41.8	12.6	38.0	12
Weight (kgs)	59	6.7	62.3	7.4
Height (m)	1.62	0.05	1.66	0.07
WHO-5 wellbeing index	12.4	2.8	10.4	3.9
Pulse rate (/min)	71.8	3.8	73.4	4.2
Systolic Blood pressure (mm of Hg)	135.8	4.2	132.2	6.1
Diastolic Blood pressure (mm of Hg)	87.2	2.9	88.5	3.3

IDRS test:
A method designed especially for the Indian people to determine their risk of type 2 diabetes is the Indian Diabetes Risk Score (IDRS). It considers factors like age, waist circumference, diabetes in the family history, and degree of physical activity. Each factor consists of scores. The summation of all the factors score helps in determining the prediabetic and risk of type 2 diabetes among Indian citizens. IDRS is a quick and easy way to determine if someone is at risk of diabetes without requiring blood work. It supports early identification and preventive actions, like modifying one's lifestyle, to lower the risk of diabetes.
The test was given to the subjects before the start of the clinical trial and again on last day of week 8 i.e. on the last observation day.
The comparative outcomes i.e. the IDR scores of the subjects are given below in the table.

Table 4: IDRS test outcomes:

Parameters	Group A (n=31)		Group B(n=31)	
	Mean	SD	Mean	SD
Baseline	70.40	1.9	72.7	2.3
After 8 weeks	43.7	3.7	70.4	2.6
Change from baseline	-26.7	4.2	-1.6	5.8
% change from baseline	-38	-	-2.2	-

Blood sugar level:

When blood sugar levels are above average but not high enough to be classified as type 2 diabetes, the condition is known as prediabetes. Prediabetes is extremely common in India, affecting a large percentage of the population, especially women in the 18–60 age range. High blood sugar levels over an extended period can cause type 2 diabetes, a dangerous disease that impairs the body's capacity to utilise insulin.

Indian women have particular difficulties controlling their blood sugar and stress levels. Stress levels can be influenced by societal norms, familial obligations, and socioeconomic circumstances. In addition, a tendency toward insulin resistance and specific dietary habits may raise the incidence of prediabetes in this group [**22**].

Table-5: Blood glucose test:

Parameters	Group A (n=31)		Group B(n=31)	
	Mean	SD	Mean	SD
Baseline (mg/dL)	119.65	5.3	120.43	4.7
After 8 weeks (mg/dL)	88.29	3.1	129.8	3.9
Change from baseline	-31.36	6.3	9.37	7.1
% change from baseline	-26.2	-	7.8	-

Blood pressure:

Indian women who are between the ages of 18 and 60 deal with a complicated combination of blood pressure, blood sugar, and stress. Hormones that raise blood sugar levels can be released in response to prolonged stress. Excessive blood pressure complicates the damage to the blood vessels, making it more difficult for the body to properly control blood sugar levels. This raises the chance of developing full-blown diabetes and exacerbates prediabetes. High blood pressure can lead to hypertension and hence increase stress and risk of diabetes. Indian women need to control their blood sugar levels and stress in order to be healthy [**23**].

Table-6: Comparative analysis of Blood pressure in both Group A and B:

Parameters	Group A (n=31)		Group B(n=31)	
	Mean	SD	Mean	SD
Systolic pressure				
Baseline	135.8	4.2	132.2	6.1
After 8 weeks	121.7	2.5	134.9	1.8
Change from baseline	-14.1	5.1	2.7	6.7
% change from baseline	-10.4	-	2.0	-
Diastolic pressure				
Baseline	87.2	2.9	88.5	3.3
After 8 weeks	79.8	2.5	87.9	1.8
Change from baseline	-7.4	5.1	-0.6	6.7
% change from baseline	-8.48	-	-0.67	-

Serum Cortisol Level:

Stress affects Indian women between the ages of 18 and 60 not just mentally but also negatively on their blood sugar levels. The body releases the hormone cortisol in response to stress. Although cortisol helps us feel energized for short periods, it also raises blood sugar levels. Women who already have borderline high blood sugar, or prediabetes, may find this especially difficult. Three times are designated for measuring these levels: 8:00 AM, 2:00 PM, and 8:00 PM for 2 weeks alternatively for 8 weeks.

Expected normal rhythm: Around 8 AM is when a healthy cortisol rhythm peaks and it steadily declines throughoutthe day to reach its lowest position at midnight.Seeking disruption: If the cortisol level at 8 AM is lower than the levels at 2 PM or 8 PM, they regard this as a "disturbed" rhythm. This may indicate that the body isn't generating enough cortisol during the day [**24**], [**25**].

Table-7:Serum Cortisol level outcomes

Parameters	Group A (n=31)		Group B(n=31)	
	Mean	SD	Mean	SD
Baseline (µg/dL)	16.2	3.3	16.3	3.7
After 8 weeks (µg/dL)	12.5	3.1	15.5	3.9
Change from baseline	-3.7	6.3	-0.8	7.1
% change from baseline	-22.8	-	-4.9	-

Standard Stress-Assessment Questionnaires:

Tools containing standardized questions to gauge people's stress levels are typical stress-assessment surveys. They use self-reporting to evaluate several facets of stress, such as psychological and physical symptoms. These surveys offer insightful information about stress reactions and facilitate the long-term identification of stress-related trends. In therapeutic settings, they play a crucial role in screening and directing stress management strategies.[**26**]
Both groups started with similar stress levels. After 8 weeks, the herbal tea group (group A) had significantly lower stress scores compared to the control group (regular tea). The tea group saw reductions in all stress categories (physical symptoms, anxiety, social problems, depression) by up to 67%. The control group saw minimal stress reduction, even showing a slight increase in some categories.

Table-8: Data Evaluation based on GFQ-28 Questionnaires

	Group A (*n*=31)		Group B (*n*=31)	
	Mean	SD	Mean	SD
DASS depression				
Baseline	16.5	9.1	17.6	10.5
After 8 weeks	8.0	5.6	16.4	9.8
Change from baseline	-8.5	11.3	-1.2	8.3
% change from baseline	-51.5	-	-6.8	-
DASS anxiety				
Baseline	17.4	7.6	16.9	6.8
After 8 weeks	4.6	5.7	14.7	10.3
Change from baseline	-12.8	7.9	-2.2	8.5
% change from baseline	-73.5	-	13.01	-
DASS stress				
Baseline	20.4	7.9	21.9	8.7
After 8 weeks	8.0	7.3	20.1	9.0
Change from baseline	-12.4	10.2	-1.8	9.5
% change from baseline	-60.7	-	8.2	-

DISCUSSION:

Overview:
Through a randomized controlled trial, the current investigation sought to determine the effectiveness of a medicinal plant-based anti-stress herbal tea on women with prediabetes. To determine the possible benefits of the intervention, the study carefully chose 62 participants between the ages of 18 and 60 who had a history of stress and prediabetes. To ensure that the experimental and control groups' demographic compositions were equally distributed, these subjects were divided into two groups of 31, each.
A thorough assessment was conducted on the subjects' demographic and baseline characteristics. The baseline characteristics of Group A (experimental) and Group B (control) were comparable in terms of age, weight, height, WHO-5 well-being index, pulse rate, and blood pressure. The comparability of the two groups was guaranteed by these baseline data, which also served as a strong basis for further analysis.

Effects of the Formulated Herbal tea in stress management and prediabetes control:
The Indian Diabetes Risk Score (IDRS) test was a useful tool for determining the individuals' type 2 diabetes risk because it was designed specifically for the Indian population. Both groups had a high risk of diabetes based on their baseline IDRS scores, which were consistent with their prediabetic state. During the 8-week intervention period, the

experimental group showed a significant decrease in IDRS scores when compared to the control group. This substantial drop in IDRS scores points to the potential of herbal tea to reduce type 2 diabetes risk in prediabetic women.
Additionally, the investigation assessed how the intervention affected blood glucose levels, an important factor in the therapy of prediabetes. Better glycemic control was indicated by the experimental group's strikingly lower fasting blood glucose levels when compared to baseline. On the other hand, during the course of the trial, the blood glucose levels of the control group slightly increased. The observed difference in response highlights the advantageous effect of developed herbal tea in controlling blood sugar levels in women who are prediabetic.
Likewise, the investigation evaluated the impact of the intervention on serum cortisol levels and blood pressure, two important markers of metabolic health and stress. The experimental group showed significant drops in serum cortisol and systolic and diastolic blood pressure, which are signs of lowered stress and better cardiovascular health.
Standard stress-assessment questionnaires also showed that, in comparison to the control group, individuals in the experimental group had significantly lower levels of stress, anxiety, and sadness. These results highlight the herbal tea all-encompassing advantages in fostering mental health and stress reduction.

Limitations:
This study has a number of shortcomings despite its encouraging results. The 62-participant sample size is relatively small, which could limit how broadly the results can be applied. The reliability of the results would be improved with a larger and more varied sample.
Furthermore, it's possible that the 8-week intervention period did not adequately capture the long-term effects of herbal tea. Longer-term research is required to evaluate potential negative effects and sustainability. Because the study relies on self-reported metrics, bias may be introduced, which could affect the accuracy of the findings.
Our comprehension of the impact of the herbal tea on stress and prediabetes is restricted due to the absence of research on certain mechanistic pathways. Future studies ought to investigate these mechanisms.
To guarantee that its use doesn't have any negative impacts, long-term safety evaluations are necessary. In summary, although this study offers insightful information, resolving these shortcomings in further studies would improve the quality of the evidence base and effectively guide clinical decisions.

CONCLUSION:

The report outlines the development process of a Medicinal Plant Based Anti-Stress Herbal Tea designed for prediabetic women utilizing ingredients like Ashwagandha, Tulsi, Lemongrass, Stevia, Thankuni, bay leaves, and ginger; this herbal blend aims to significantly reduce stress levels. This method of tea preparation is simple, suitable for home use. Detailed methods for conducting clinical trials are outlined within the report. Statistical analysis of gathered data is provided, followed by a discussion on the overall impact of consuming this herbal tea among the selected participants. This comprehensive examination underscores the potential benefits of incorporating this herbal remedy into the daily routine of prediabetic women, offering a natural approach to stress management. This anti-stress herbal tea has effectively contributed and will be beneficial for society.

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