



Original Research Article

A comparative analysis of *Vamana* and *Shamana Chikitsa* in prediabetes management: A randomized clinical trialUttamram Yadav ^{a,*}, Santosh Kumar Bhatted ^b^a Department of Panchakarma, Vijayashree Ayurveda Medical College & Hospital Jabalpur, India^b Department of Panchakarma, All India Institute of Ayurveda, New Delhi, India

ARTICLE INFO

Article history:

Received 19 July 2021

Received in revised form

28 June 2023

Accepted 3 July 2023

Available online xxx

Keywords:

Body service

Darvyadi kwatha

Detoxification

Prameha

Prediabetes

Vamana karma

ABSTRACT

Background: Prediabetes is a condition before manifestation of diabetes. It is associated with biochemical change in body due to disturbances in food habits, sleep patterns and sedentary lifestyle. Conventional system of medicine has limitations, however Ayurvedic medicines can be effective for management of this condition.

Objective: To compare the efficacy of *Vamana Karma* (~therapeutic emesis) followed by *Darvyadi Kwatha* (~herbal decoction) with that of oral medication of *Darvyadi Kwatha* with lifestyle modification in reducing HbA1c of the prediabetic participants.

Methodology: After approval of IEC and registration under clinical trial registry of India, 40 patients were registered in two groups suffering from prediabetes in the trial. The primary criteria were HbA1c, FBS & PPBS along with secondary criterias like *Agnibala* (~strength of digestion and metabolism), *Dehabala* (physical strength) and *Satvabala* (mental strength) relief in signs & symptoms of *Prameha* and quality of life (SF-36 Score).

Results: Statistically significant results were observed in both the parameters: (primary & secondary) within the group [VM group (HbA1c (<0.001), FBS (<0.001) & PPBS (<0.001) and SM group (HbA1c (<0.001), FBS (<0.001) & PPBS (<0.001)] and between the group [HbA1c (P < 0.01), FBS (P < 0.01), SF-36 score (P < 0.001) as well.

Conclusion: The present clinical study suggests that there is significant improvement between the groups. On comparison, it was found that treating prediabetic Shodhana was more safe & effective than Shamana.

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1. Introduction

1.1. Background

Prediabetes is a condition of hyperglycemia with HbA1c in the range of 5.7%–6.4%, fasting blood sugar (FBS) levels between 100 and 125 mg/dl and post prandial blood sugar (PPBS) levels between 140 and 200 mg/dl. Prediabetes is a metabolic disorder which can be compared with *Prameha* based on *Prabhutamutrata* (~polyuria) *Avilmutrata* (~turbid urination) *Galatalushosha* (~dryness of mouth & throat [polydipsia]). It has a close resemblance to the disease

Prameha described in Ayurveda [1]. Previous studies have shown an association of increased risk of kidney disease, changes in nephron, dysfunction of cardiac activity, reflected by reduced heart rate variability, decreased parasympathetic modulation of the heart and increased prevalence of male infertility in individuals with prediabetes. Impaired glucose tolerance has shown significantly greater abnormalities detected like increased prevalence of both hyperesthesia, hypoesthesia, and increased heat detection thresholds. There is increasing evidence of idiopathic polyneuropathy, prior to development of diabetes [2].

A clinical condition characterized by excessive turbid urination is broadly termed as *Prameha*, which is further classified into twenty subtypes based on the involvement of *Dosha* and presentation of urine. All the *Prameha* in due course of time converts into *Madhumeha* (~diabetes mellitus) [3]. Management of prediabetes includes oral hypoglycemic drugs. Due to side effects of oral

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Peer review under responsibility of Transdisciplinary University, Bangalore.

hypoglycemic drugs, the condition of patient deteriorates and complications of prediabetes arise [4]. *Prameha* is a disease caused due to *Mandagni* (~low digestive fire and metabolism) [5], *Bahudosh* (~excessive *Dosha*), *Bahudrava Shleshma* (*Kapha* with increase liquidity), and *Abaddhamedha* (~increased bad cholesterol & triglyceride) along with an increase of *Kleda* (~excessive fluidity) in the body, all of which belongs to the group of *Kapha* substance in the body [6]. Hence, *Samshodhana* (*Vamana* and *Virechana*) [7] treatment is one of the best remedies for correcting *Agni* (~digestive fire) [8] and elimination of *Bahudosh*. Further, *Vamana Karma* [9] is the best treatment specifically for the elimination of excessive *Kapha* and related substances like *Kleda* and to reduce *Abaddhamedha* from the body and *Ikshvaku yoga* [10] is indicated in *Prameha* for *Vamana Karma*. *Darvyadi kwatha* also pacifies *Kapha Dosha* and is indicated in *Prameha* patients [11].

We hypothesised that detoxification of body may be highly effective in improving the action of body systems like metabolism along with other systems of the body and organs. Hence *Vamana Karma* followed by oral administration of *Darvyadi Kwatha* and *Darvyadi Kwatha* with lifestyle modification was selected for the treatment of prediabetes.

2. Methodology

2.1. Ethics

After getting approval from the Ethics Committee (AIIA/2018/PG-73), the trial was registered in Clinical Trial Registry of India (CTRI/2019/03/017,952). It was registered as a prospective study. Informed consent forms were obtained from all enrolled individuals in the clinical trial.

2.2. Study design

Open-ended randomized parallel group trial.

2.3. Recruitment of participants and data collection

2.3.1. Plan of study

After screening 75 patients, 20 patients were enrolled (VM group) for a duration of 15 days. Classical *V. karma* with *Ikshvaku yoga* followed by the oral administration of *Darvyadi Kwatha* for 1 month was given. The total duration of the study was 45 days :3 days *Deepana* (~appetizers) and *Pachana* (~digestion promoters) [13], 5 days *Snehapana* (~internal oleation therapy) [14], 2 days *Sarvanga Abhyanga* (~external oleation therapy) [15] & *Vashpa Swedana* (~whole body steam) [16] and their after *Vamana* on second day, 5 days *Samsarjana Krama* (~specific dietetic regimen) [17] and 30 days *Darvyadi Kwatha* respectively. 20 patients were enrolled (SM group) for the oral administration of *D. kwatha* with lifestyle modification for 30 days. Follow-up was done on 46th, 76th, 106th, and 120th day.

2.3.2. Inclusion criteria

Patients of either sex irrespective of their religion, education, occupation, and socio-economic status, participants aged between 30 years and 60 years were included. Obese Patients, HbA1c between 5.7% and 6.4%, fasting blood sugar levels between 100 and 125 mg/dl and postprandial blood sugar levels between 140 and 200 mg/dl along with BMI>25, waist to hip ratio in male>0.95 and female>0.80 were considered to a part of the study (with or without symptoms of *Prameha Prabhutamutrata*, *Avilmutrata*, *Has-tapadataladaha*, *Atipipasa*, *Atikshudha* & *Sandhishoola*).

2.3.3. Exclusion criteria

Patients with type I diabetes mellitus, gestational diabetes, patients on steroids or oral anti-hyperglycemic drugs, suffering from malignant and accelerated hypertension, congestive cardiac failure, pregnant women, lactating mothers, suffering from any serious disease condition, and unfit for *V. karma*, were excluded from the study.

2.3.4. Diagnostic criteria

All patients investigated had HbA1c ranges between 5.7% and 6.4%, fasting plasma glucose 100–125 mg/dl and postprandial blood glucose 140–200 mg/dl [12].

2.4. Trial drugs

The first trial drug was *Ikshvaku Madhuyashti Kashaya yoga* which was used for the *Vamana Karma*. Method of preparation was 6 gm of *Ikshvaku Churna* soaked in 150 ml of *Madhuyashti Kashaya* for the whole night [18]. Post that in the morning 2 gm of *Saindhava* (~salt) & honey qs was added to it. Second trial drug was *Darvyadi Kwatha* and its method of preparation was 10 gm coarse powder of equal quantity of *Darvyadi Kwatha Churna* (equal quantity of *Darvi*, *Suraha*, *Triphala* and *Musta*) boiled with 320 ml of water and reduced to 80 ml, then filtered it and advised to take liquid part before meal twice a day.

2.5. Study intervention

2.5.1. Setting

The study was conducted at OPD and IPD of AIIA, New Delhi.

Vamana (VM) Group: Classical *Vamana Karma* with *Ikshvaku yoga* in schedule for 15 days followed by the oral administration of *Darvyadi Kwatha* in the dose of 80 ml twice a day before meal for 30 days.

Shamana (SM) Group: Oral administration of *Darvyadi Kwatha* in the dose of 80 ml twice a day before meal with life style modification for 30 days.

2.5.2. Study procedure

The *Vamana Karma* was planned for for VM group patients on IPD basis. *Deepana* and *Pachana* were started with *Nagarmotha churna* [19] 3 gm twice a day before meal, and *Panchakola churna* [20] 3 gm twice a day after meal for 3 days. The *Snehapana* was given with *Murchhita ghrita* (~a processed ghee) [21] for 5 days in increasing doses. After that *Sarvanga Abhyanga* and *Vashpa swedana* were done with *Tila taila* (~sesame oil) and *Dashmoola kwatha* (~decoction of ten roots) respectively for 2 days. The *Vamana Karma* was done with classical *Ikshvaku yoga* (*Madhuyashti K. yoga*). On the day of the *Vamana Karma*, the vitals of the patients were measured (only after the digestion of food) and then they were given *Akanthpana* with *Ksheera* (milk). The *Vamaka* drugs were given with *Ikshvaku yoga* and then we waited for one *Muhurta* (48 min). After one *Muhurta Vamana vega* were started, they were continued with *Madhuyashti Phanta* [22] until *Pittanta Darshana* depending on the strength of the patient. After that *Lavnodaka* was given until *Samyaka lakshana* of *Vamana Karma* were observed and vitals were measured frequently [23]. *Samsarjana Krama* was advised for 5 days followed by oral administration of *Darvyadi Kwatha* (80 ml) twice a day before food to the patients for 30 days (see Table 1).

In group – B all patients were given *Darvyadi Kwatha* and a lifestyle modification chart was given to all patients [24–26]:

2.5.3. Diet & lifestyle

Daily schedule chart was given to the patients, details are mentioned in Table 1.

Table 1

Showing proposed timeline of data collections, therapeutic procedures, drugs doses, time schedule and diet & lifestyle modification schedule chart.

Day	Procedure	Investigation		
Day 0	Screening	FBS, PPBS & HbA1c		
Day 1 to Day 15	Classical <i>Vamana karma</i>			
Day 16–Day 45	<i>Darvyadi kwatha</i>			
Day 46	Follow up 1	FBS, PPBS		
Day 76	Follow up 2	FBS,PPBS		
Day 106	Follow up 3	FBS, PPBS		
Day 120	Follow up 4	FBS, PPBS, HbA1c		
Proposed therapeutic procedures, drugs doses and time schedule				
Procedure	Duration	Medicine	Dose	Time
<i>Deepana & Pachana</i>	3 days	<i>Nagarmotha churna</i> <i>Panchakola churna</i>	5 gm 5 gm	TDS
<i>Snehapana</i>	5 days	<i>Murchhita ghrita</i>	Increasing	6am–8am
<i>Abhyanga</i>	2 days	<i>Tila taila</i>	100 ml	After <i>Snehpana</i>
<i>Vashpa swedana</i>	2 days	<i>Dashmoola kwatha</i>	As per requirement	After <i>Abhyanga</i>
<i>Vamana karma</i>	1 day	<i>Ikshvaku yoga</i> (Ikshvaku, madhu, Saindhav and yashtimadhu phant)		After sunrise 6am–8am
<i>Sansarjana Krama</i>	5 days	<i>Peya</i> , <i>Vilepi</i> <i>Akrita yusha</i> <i>Krita yusha</i>	According to Agni bala	Lunch,Dinner
<i>Samshamana medicine</i>	30 days	<i>Darvyadi kwatha</i>	80 ml prepared <i>kwatha</i> twice a days	Before meal
Diet & lifestyle modification schedule chart for pre-diabetic patients				
Daily events	Do's	Don'ts		
Early morning Breakfast	Lukewarm water approximate 250–300 ml before evacuation of stool. Fiber rich whole cereals like Barley, bajra, maize, raagi and its preparations and also can take fruits like papaya, pomegranate and apple.	Tea, coffee and excessive drinking of water. Rissole, fried chapaati, bakery items, packed food, frozen items. Above mention as well.		
Lunch	Same as breakfast, pulses like chickpea, pigeon pea, horse gram, green gram, leafy vegetables like pointed gourd, bitter gourd, drumstick tree and as shallot – carrot and reddish in moderate quantity as per appetite. Use sesame oil and linseed oil.	Curd, milk & milk product, sweat. Above mention as well.		
Dinner	Same as lunch but it should be light and taken between 7pm and 8pm.	Same as lunch		
Vihara (code of conduct)				
Early morning Yoga & exercise	Get up early in the morning 60 min before sunrise (05:30am to 6:30am). Regular pranayama and yoga empty stomach minimum 15 min daily (morning & evening). <i>Naadi shodhan pranayama</i> , <i>Mandukasana</i> , <i>Utthita parsvakonasana</i> , <i>Paschimottanasana</i> , <i>Janu Shirsasana</i> , <i>Makarasana</i> , <i>Dhanurasana</i> , <i>Halasana</i> , <i>Ardhamatsyendrasana</i> , <i>Shashankasana</i> .	Avoid day sleep. Avoid excessive asana & exercise.		

2.6. Study outcomes

The primary outcome was reducing HbA1c levels and the secondary outcome was reducing blood sugar levels-FBS and PPBS

assessed by blood investigation in laboratory AIIA, relief in signs and symptoms of *Prameha*, [28] improvement in *Agni Bala*, *Deha Bala*, and *Chetas Bala* assessed as per Ayurveda assessed by grading score (see Table 2) [29] and overall improvement in Quality of life

Table 2

Assessment criteria of sign & symptoms of *Prameha*, *Agnibala*, *Dehabala* and *Satvabala*.

S.No	Assessment Parameters
1	<i>Prabhutamutrata</i> a) Normal frequency of urine 3–5 times - 0 b) Excessive frequency of urine 6–9 times - 1 c) Excessive frequency of urine 10–12 times - 2 d) Excessive frequency of urine >12 times - 3
2	<i>Avilmutrata</i> A) Clear urine - 0 B) Slight cloudy or smoky (slight turbidity) - 1 C) Turbidity clearly present but news print can be read - 2 D) News print cannot be read (more turbid) - 3
3	<i>Hastapadataladaha</i> A. No burning sensation in hands & feet - 0 B. Mild burning sensation in hands & feet - 1 C. Moderate burning sensation in hands & feet - 2 D. Severe burning sensation in hands & feet - 3
4	<i>Atipipasa</i> A) Normal thirst - 0 B) Upto 2 L of excess intake of fluids - 1 C) Upto 2–3 L of excess intake of fluids - 2 D) More than 3 L of excess intake of fluids - 3
5	<i>Atikshudha</i> a) Food intake normal (2 times a day) - 0 b) Food intake mild increase (3–4 times a day) - 1 c) Food intake moderate increase (5–6 times a day) - 2 d) Food intake severe increase (>6 times a day) - 3
6	<i>Sandhishoola</i> a. No pain - 0 b. Mild pain - 1 c. Moderate pain without swelling - 2 d. Severe pain with swelling & difficulty in movement - 3
Assessment criteria of <i>Agnibala</i> , <i>Dehabala</i> and <i>Satvabala</i>	
S.No	Assessment Parameters
1	<i>Ruchi (Agnibala)</i> a) Equally willing towards all the Bhojya padartha - 0 b) Willing towards some specific Aahara/Rasavishesha - 1 c) Willing toward only one among Katu/Amla/Madhura food stuffs - 2 d) Willing towards only most liking foods not to the other - 3 e) Unwilling for food but could take the meal - 4 f) Totally unwilling for meal - 5
2	<i>Vaata Mutra Purisha Retasam Mukti (Agnibala)</i> a) Occurs easily in normal routine times - 0 b) Difficulty in defecation but Malapravritti daily with discomfort in abdomen - 1 c) Can't pass stool daily & feeling heaviness in abdomen - 2 d) Passes stool after 3–4 days with Grathita, Sakasta Malapravritti - 3 e) Passes stool after 3–4 days with Grathita, Sakasta Malapravritti & having gaseous distention with Udgara-pravritti - 4
3	<i>Balavridhi (Dehabala)</i> a) No weakness - 0 b) Slight weakness - 1 c) Feeling of weakness but ability to work unaffected - 2 d) Ability to work affected - 3 e) Can't do any type of work - 4
4	<i>Nidra Labho Yathakalam (Satvabala)</i> a) Sound sleep - 0 b) Sleep gets disturbed in the early morning - 1 c) Sleeps with disturbed interval & remains unsatisfied with sleep - 2 d) Disturbed sleep in night tries to compensate in day - 3 e) No sleep in night - 4 f) Sleep neither at night nor at night hours - 5
5	<i>Sukhena - Cha - Pratibodhanam (Satvabala)</i> a) Total relief & feeling of wellbeing at physical & mental level - 0 b) Discomfort at mental level - 1 c) Discomfort at physical level - 2 d) Discomfort at both mental & physical level - 3 e) Not feeling well still can pursue work or study - 4 f) Not feeling well & not interested in any activity at all (Avarasatva) - 5

SF36 score assessed with questionnaire. Assessment was conducted for HbA1c, signs and symptoms of *Prameha*, *Agni Bala*, *Deha Bala* and *Chetas Bala* and SF-36 score on the 120th day, and other parameters on 46th, 76th, 106th, and 120th day.

2.7. Sample size

The proposed research project considered was a pilot study and the sample size was 20 participants in each group with the approval of the IRB and IEC committee meetings.

2.8. Randomisation sequence

An unbiased and blind randomization with a block of 4 was adopted using a computer-generated random number.

2.9. Statistical analysis

The obtained data was analyzed for statistical significance using Student's paired & unpaired t-test and a master chart of all the required data was prepared in Microsoft Excel. The results were interpreted as significant ($P < 0.05$), highly significant ($P < 0.01$), and insignificant ($P > 0.05$) (see Fig. 1).

3. Results

3.1. Baseline data

3.2. Socio-demographic details of the participants

A total of 40 patients with prediabetes were registered, out of which 37 completed the course with follow-up, and two patients from VM group and one patient from SM group discontinued the treatment due to emergency conditions at home. Observation of the study showed that majority of the patients belonged to the age group of 40–49 years. 50% of the patients were males and 50% were females. In the present study, the maximum number of patients, i.e. 82.5% were Hindu. While the rest i.e. 17.5% of patients were Muslims. Majority of patients i.e. 90 % were married and 10% were unmarried. Occupation-wise distribution shows that 47.5% of patients were housewife, 20% were employed and 32.5% were unemployed. Socioeconomic status distribution shows that 47.5% of the patients belong to middle class families while 25% to upper middle class families, whereas 15% belong to poor families and 12.5% to lower middle class families. Education status wise distribution shows that 27.5% of patients were post-graduates, 22.5% of patients were illiterate, 20% were graduates, 15% had completed to primary education and 15% had studied till high school school levels. *Agni* wise distribution showed that maximum patients were of *Vishmagni* and *Mandagni* [8]. Majority of patients were of *Pitta-kapha* and *Vata-kapha Prakriti* (~constitution) [30]. In VM group ($n = 19$) therapeutic emesis observed 7, 8 and 4 patients were *Uttama suddhi* (excellent), *Madhyam suddhi* (medium) and *Heena suddhi* (mild) respectively.

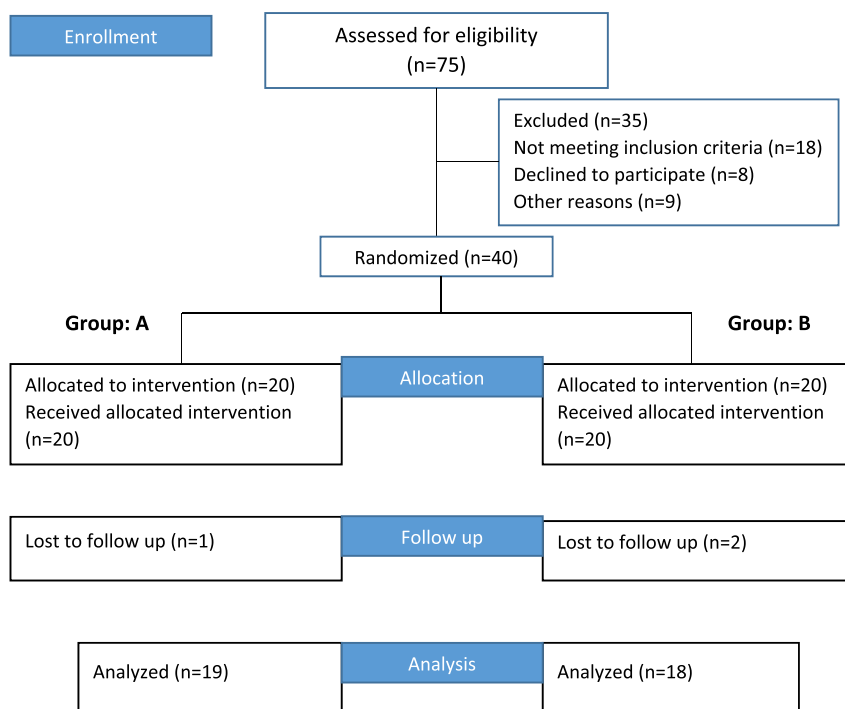


Fig. 1. CONSORT Diagram depicting patient enrollment.

3.3. Treatment outcome

The results of analysis of primary outcome were statistically significant among both the groups. Secondary outcome results also showed significant improvement in primary parameters. Parameters (FBS and PPBS) assessed during different intervals (Days 45, 76, 106, and 120) depicted that gradually sugar levels increased in VM group patients. However it did not exceed more than normal limits and in SM group patients sugar level gradually decreased but VM group was benefitted than SM group. Between the group statistic results showed significant improvement in primary outcome.

3.4. Post-treatment follow-up

The outcome of treatment in terms of sugar level was tested on days 46, 76 and 106, and physical activity, mental strength and quality of life were followed on 120-day.

3.5. Adverse Effects

No adverse effects were noted during the study, but as two patients did not follow the diet and lifestyle in the given chart, they felt discomfort in the abdomen and flatulence for a few days especially during *V. karma* but did not need to any treatment. The symptoms disappeared once they started following the given diet chart.

4. Discussion

Prameha occurs due to changes in food habits, irregular sleep patterns, and mental stress or anxiety leading to an imbalance in biological systems of the body or a disturbed threshold of the digestion capacity in the intestine and further leads to an imbalance in functional capacity of other systems of the body. It gradually leads to imbalance in anatomical structure of the body as well. Metabolic disorder is imbalance in threshold of digestion capacity of the intestine, and prediabetes is also one among the metabolic disorders. *Prameha* develops due to the suppression in activity of beta cells of Islets of Langerhans and disturbed gut-brain- islets axis which leads to an increase in blood sugar levels, this phenomenon is corrected by the correction in the functioning of gut, digestion, metabolism, and elimination of toxic substances. Pathogenesis of *Prameha* starts with *Mandagni* in general and *Medodhatvagni* *Mandya* (~low-fat metabolism) in particular which is not able to convert glucose into glycogen, hence blood sugar levels increase in the blood along with the increase in *Kleda*, *Bahudrava shleshma*, and *Abadha meda* in the body. In course of time also vitiating the *Pitta Dosha* leads to a burning sensation in the feet (Neuropathy) and then vitiating *Vata Dosha* leads to development of Radiculopathy and other complications as well.

4.1. Probable mode of action of therapeutic emesis

Vamana Karma is the best treatment for the elimination of vitiated *Kapha-Pitta Dosha* and related body constituents. It reduces, *Kleda*, *Abaddhameda* which are major culprits in *Prameha*. *Ikshvaku* [*Lagenaria siceraria*—Linn (bottle gourd)] was used for *Vamana Karma*. It is specifically indicated for *Vamana Karma* in *Prameha*. It has been found effective in diabetes, hypertension, asthma, etc. in phytochemical and pharmacological studies [31].

4.2. Probable mode of action of palliative Darvyadi Kwatha

The contents of *D. kwatha* mainly acts on the gastrointestinal tract which increases the *Agni* due to ingredients like *Nagarmotha*

containing *Laghu* (~light), *Ruksha* (~dry) *guna*, and *Tikta rasa*. It helps in cleansing of gut due to ingredients like *Haritaki*, *Bibhitaki*, and *Amalaki* which are laxatives and improves the functioning of gut-brain-Islets axis and reduces *Kleda* in the body due to ingredients such as *Triphala*, *Devadaru*, *Daruharidra* and *Nagarmotha* which have *Ruksha*, *Laghu guna* and *Kashaya*, *T. rasa* [19].

4.3. Probable mode of action of lifestyle modification

Lukewarm water liquefies the fat, reduces weight, helps in digestion and reduces excessive *Kapha* and related substances like *Kleda*. Barley, bajra, maize, ragi and its preparations sock fat, liquidity and related substances due to *Ruksha* (~rough) property. Timely intake of food and sleep helps to maintain healthy biochemical levels in the body. Yoga and exercise acts on the all health dimensions. Yoga has the potential to induce stem cell trafficking from the bone marrow to the peripheral blood, which may lead to tissue regeneration by replacement and recruitment of cells differentiated from the stem cells. Yoga asanas also modulate gene expression and increase muscle activity, strength, endurance, flexibility, and balance, resulting in favorable effects on body weight, adiposity, dyslipidemia, and insulin resistance [27]. Exercise has a positive role in maintaining glycemic levels, increasing the insulin sensitivity, and also improving cardiovascular risk factors.

4.4. Rationale of study drug

The permanent treatment for diabetes is still a challenge in allopathic medicine and the Ayush system of medicine, so we searched Ayurveda literature for a treatment and we found curative treatment advised for all types of diabetes which is *Vamana karma* with *Ikshvaku yoga* for the purpose of bio-purification of the body and *Darvyadi Kwatha* as hypoglycemic palliative medicine (by *Acharya Charaka*). This treatment we was planned for prediabetes patients, but *V. karma* only can be conducted in a certain special environment (IPD basis) specially in diabetic/prediabetic patients and it's difficult to take leave for 15 days from the particular job. So we planned a second group to follow palliative *Darvyadi Kwatha*-with lifestyle modification. Study results showed both groups effective but therapeutic emesis followed by herbal decoction (Gr.1) is only the permanent solution prior to developing diabetes.

4.5. Future research direction

This clinical study may be conducted on multi-centric and large sample size on the same clinical study and also may evaluate the pharmacodynamics and pharmacokinetics action of therapeutic emesis and herbal decoction as well in future.

This clinical study suggests that there were significant differences observed between the groups in terms of HbA1c, FBS, Sandhishoola, Ruchi Agnibala, and SF-36 scores when treated with *Vamana Karma* alongside *Ikshvaku yoga* and *Darvyadi Kwatha*, combined with lifestyle modifications in *Prameha*. No adverse reactions to the treatment were reported. These findings suggest the potential for conducting future multicenter studies with larger sample sizes.

Source of support

Nil.

Author contribution

Uttamram yadav: Conceptualization, Methodology, Data Collection, Data curation, Writing, Original draft preparation. **Santosh Kumar Bhatted:** Review, Analysis, Supervision.

Declaration of competing interest

None.

Acknowledgement

We thank the Director of All India Institute of Ayurveda, New Delhi under the Ministry of Ayush, and the Department of Pan-chakarma, All India Institute of Ayurveda, New Delhi for the given opportunity. Also thanks to Prof. Umesh Shukla for his encouragement in our study, Dr. Galib R. for giving triphla kwatha churna, & Dr. Anil Verma helped us during the analysis of data.

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