



# **Specific Naturopathic Modalities Ameliorate Glucose Homeostasis and Other Physiological Parameters in Human Diabetics**

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## **Authors' contributions**

*This work was carried out in collaboration among all authors. Author PGA designed the study, collected the data, performed the statistical analysis, wrote the protocol, and wrote the first draft of the manuscript. Authors KJS, PS and GP conceived and designed the protocol and the analysis, managed literature searches and final presentation of the study. All authors read and approved the final manuscript.*

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## **ABSTRACT**

**Background:** Diabetes Mellitus is now becoming a serious medical and socio-economic issue all over the world. Early initiation of combination therapy has been suggested as a way to achieve glycemic control, postpone the complications and possibly restore  $\beta$ -cell function. Naturopathy and yoga is one of the upcoming medical systems which had showed a promising result for many lifestyle disorders and hence, this study was aimed to evaluate the effect of 10 days Integrated Naturopathy and Yoga (INY) treatment especially Abdomen Massage and Neutral Hip Bath on glycemic control and anthropometric measures.

**Methods:** 100 subjects with diabetes were selected and randomly allocated into Case group

(naturopathy & yoga intervention with Abdomen Massage and Neutral Hip Bath) and Control group (naturopathy & yoga intervention). The subjects were assessed for blood glucose levels and anthropometric measures at baseline and after the intervention of 10 days.

**Results:** The result of this study showed a significant reduction in Fasting Glucose (FG) and Post Prandial Glucose (PPG) after 10 days of intervention where Body Mass Index (BMI) and Waist Hip Ratio (WHR) have not shown significant changes in the groups. The case group has a larger mean difference between pre and post values of FG, PPG, BMI, and WHR as compared to the control group.

**Conclusion:** Abdomen massage with neutral hip bath is relatively better for lowering the FG, PPG along with BMI and WHR, by the activation of adiponectin, Brown Adipose Tissue, Atrial natriuretic peptide and counter-regulatory stress hormones, which control hormonal activity, glucose absorption, metabolism and excretion.

*Keywords: Naturopathy; abdomen massage; neutral hip bath; diabetes mellitus.*

**Trial Registration:** CTRI/2020/02/023590

## ABBREVIATIONS

*IN Y* : *Integrated Naturopathy and Yoga*

*FG* : *Fasting Glucose*

*PPG* : *Post Prandial Glucose*

*BMI* : *Body Mass Index*

*WHR* : *Waist Hip Ratio*

*BAT* : *Brown Adipose Tissue*

*T2DM* : *Type2 Diabetes Mellitus*

*GLUT* : *Glucose Transporter*

*ANP* : *Atrial Natriuretic Peptide*

## 1. INTRODUCTION

Diabetes Mellitus is considered as one of the most predominant and challenging problem of 21<sup>st</sup> century [1]. It is heterogenous metabolic disorder [2] with impairment in carbohydrate, fat and protein metabolism due to inadequate secretion of insulin or reduced tissue sensitivity towards insulin which results in hyperglycemia [3]. According to recent analysis by International Diabetes Federation, the prevalence of diabetes has been increased during past 13yrs by 88% from 246 million in 2006 to 463 million in 2019 [4] and which is projected to reach 629 million by 2045 [5]. It has been increasing in recent decades due to abrupt social and cultural changes, enhancing urbanization, changes in the dietary pattern, physical inactivity and unhealthy behaviour that gives rise to various cardiovascular and life-threatening diseases [6,7]. Type2 Diabetes Mellitus (T2DM) has been viewed as a serious global health crisis which generally manifests insidiously with frequent urination (polyuria), increased thirst (polydipsia), excessive hunger (polyphagia), sudden weight loss, restlessness, blurred vision, fatigue and frequent skin infections [8]. An early detection of

diabetes or prediabetes via screening is essential to recognise the asymptomatic and enables to proceed further with the required treatment [9].

Normalisation of blood glucose levels should be done in order to attain desirable effects in patients with diabetes and to prevent short and long-term complications. The management should be seeded with the knowledge of self-management, nutritional requirements, anti-diabetic agents and lifestyle modification [10]. The cellular resistance to insulin can be reduced by enhancing the blood supply and lymphatic drainage, thus improving the nourishment to the cells and accelerating the self-healing capacity which is required for its normal activities that results in enhancement of inherent power within the body and finally ends up with homeostasis [11]. These functions can be brought to action by INY methodologies like Hydrotherapy, Massage, Acupuncture, Acupressure, Fasting, Yoga, Mud Therapy, Chromotherapy and Magnetotherapy [12]. Massage and Hydrotherapy are most widely used among all modalities where Massage is the practice of systemic rubbing and scientific manipulation of soft tissues with physical (anatomical), functional (physiological) effects [13]. It enhances the parasympathetic activity thereby reducing the serum cortisol levels by influencing the Autonomic Nervous System (ANS) and Hypothalamo Pituitary Adrenal (HPA) axis, thus regulating the glucose metabolism [14]. On the other hand, massage when given particularly to abdominal area, reduces the abdominal fat and waist circumference [46] through which the Brown Adipose Tissue (BAT) gets activated which has gained its attraction as 'antidiabetic tissue' owing to its ability to dissipate energy as heat and forms as a seed for raising

Basal Metabolic Rate (BMR) along with stimulation of incretin released in the body [15]. The recuperative and healing properties of hydrotherapy are based on the body's reaction to hot and cold stimuli due to sensation and pressure exerted by the water. In general, cold temperature stimulates and triggers vital organ functions, heat has a sudorific effect of pain-relieving properties whereas neutral temperature has soothing and relaxing effect [16]. Hence, this study aims at understanding the effect of abdomen massage followed by neutral hip bath on blood glucose levels in individuals with diabetes and there by establishing the extent of its efficacy in the management of T2DM.

## 2. MATERIALS AND METHODS

### 2.1 Study Design

A randomized controlled trial.

The study population was recruited from Shanthivana Yoga and Nature Cure hospital Dharmasthala. Out of 210 subjects screened, 100 subjects were recruited for the study based on the inclusion and the exclusion criteria.

Subjects between 30 to 60 years of age and those who satisfy diagnostic criteria according to International Diabetes Federation were included in this study. Subjects with Diabetes associated systemic complications, with uncontrolled Diabetes, Female subjects during menstruation, and who underwent recent surgery were excluded. Recruited subjects (n=100) who fulfilled the inclusion and exclusion criteria were divided equally into 2 groups by using Computer generated Randomization.

### 2.2 Intervention and Assessment

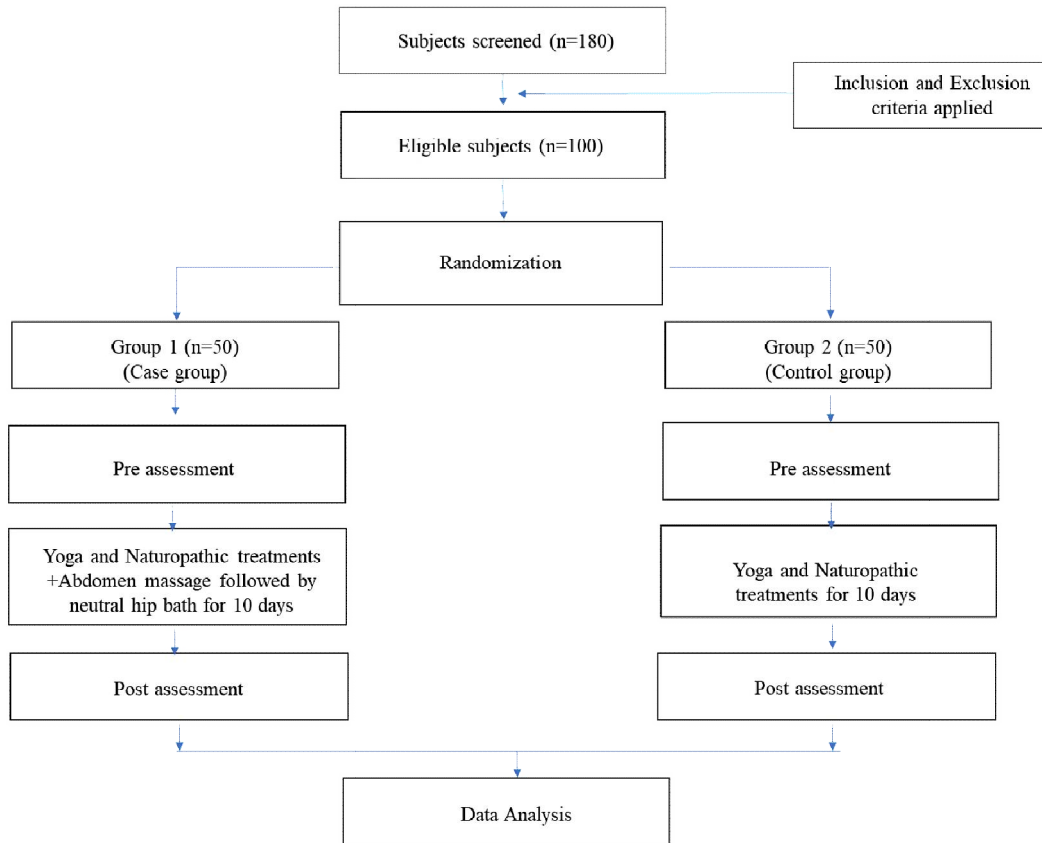
Group 1 (n=50) is the Case group which received Naturopathy and Yoga intervention along with Abdomen massage, given by trained massage therapists, according to the protocol developed by the researcher, for 20 mins followed by Neutral hip bath at 35°C for 15 mins, for 10 days, whereas Group 2 (n=50), the Control group received only Naturopathy and Yoga intervention for 10 days (Fig. 1). The common INY protocol, shown in Table 1 and 2 was implemented with calorie restricted diet.

**Table 1. Naturopathic management protocol**

DAY	Morning (9:30AM TO 11:00 AM)	Afternoon (2:30PM TO 4:00 PM)
1	Cold circular Jet	Cold hip bath
2	Full body massage	Cold abdominal pack
3	Neutral under water massage	Gastro-hepatic pack
4	Sauna bath with cold chest pack	Hot Foot and Arm bath
5	Partial massage to back & legs	Cold spinal spray
6	Alternate immersion bath	Direct mud application to abdomen
7	Sauna bath with cold chest pack	Cold immersion bath
8	Full Mud bath	Cold chest pack
9	Cold Douche to Whole body	Alternate compress to abdomen
10	Steam bath with cold chest pack	Neutral Circular Jet

**Table 2. Yoga management protocol for 90mins**

Kriyas	Jalaneti, Suthra nethi, Vaman dauthi
Loosening exercise and stretching	Neck movements Arm, shoulder, and wrist movements Hip rotation and stretch Spinal twist and stretch Jogging jumping
Standing series	Ardhachakrasana, Padahasthasana, Trikonasana, Parivirtha trikonasana.
Supine series	Uthitta padasana, Sethubandhasana, Pavanamukthasana
Prone series	Bujangasana, Shalabasana, Dhanurasana, Naukasana
Sitting series	Vakrasana, Ardamatsyandrasana, Pachimottasana
Pranayama	Basthrika (50 strokes), Surya anuloma viloma, Nadishodana, Sheetal, Sheetkari, Bhramari
Relaxation technique	Deep Relaxation Technique



**Fig. 1. Illustration of Trial Profile.**

Subjects were assessed for the FG and PPG as a primary outcome and BMI and WHR as a secondary outcome. The assessment carried out on the first day of admission was considered as baseline (pre data) and on the 10th day after intervention as post data.

### 2.3 Statistical Analysis

Statistical analysis was done using Statistical Package for Social Sciences (SPSS) (Version 23.0). Data was checked for normal distribution using Kolmogorov-Smirnov test and Shapiro-Wilk test. Data were not followed normal distribution. Hence, Non-parametric test, Mann Whitney u

test was used to find significant results between groups, whereas Wilcoxon signed rank test was applied for comparison of pre and post-test between groups. p value less than 0.05 was accepted as an indicator for significance.

### 3. RESULTS

The demographic characteristics of the subjects is shown in Table 3. In case group there were 46% (n=23) of males and 54% (n=27) of females with the mean age of 46.89 years and in control group there were 60% (n=30) of males and 40% (n=20) of females with the mean age of 49-56 years.

**Table 3. Anthropometric and demographic data**

Characteristics	Cases group	Control group	p-value
Male	23	30	
Female	27	20	0.161
Age (years)	46.89±7.35	49.56±7.98	0.082
Height (cm)	165.94±8.59	163.86±9.55	0.255
Weight (kg)	79.54±11.05	77.04±15.59	0.121

**Table 4. Comparison of Baseline and post-test outcome measures with and between the groups**

Outcome	Group	Baseline Mean±SD	Post test Mean±SD	Difference Mean±SD	p-value within groups	p-value between groups
FG (mg/dl)	Case	188.4±41.87	151.4±41.63	37.0±18.1	0.001***	0.002**
	Control	203.5±53.16	183.5±52.9	19.9±14.07	0.001***	
PPG (mg/dl)	Case	273.8±63.22	210.6±60.42	63.22±30.88	0.001***	0.02*
	Control	269.6±62.66	237.7±61.7	31.94±27.71	0.001***	
BMI (kg/m <sup>2</sup> )	Case	28.82±3.39	26.69±3.11	2.12±0.86	0.001***	0.24
	Control	28.71±5.68	28.45±5.56	0.25±0.51	0.001**	
WHR	Case	1.003±0.06	0.983±0.05	0.02±0.014	0.001***	0.86
	Control	1.003±0.05	1.0004±0.05	0.002±0.13	0.141	

\*p<0.05 Statistically significant. \*\*p<0.01 and \*\*\*p<0.001 Highly statistically significant  
 FG: Fasting Glucose; PPG: Post Prandial Glucose; BMI: Body Mass Index; WHR: Waist Hip Ratio.

The results of the pre-post comparisons for both the groups are detailed below:

Case group: There was a significant decrease in the FG (p=0.001) with a mean difference of 37.0±18.1mg/dl between pre and post-test. PPG was also significantly reduced (p= 0.001) with mean difference of 63.22±30.88mg/dl, there was a significant decrease in BMI (p=0.001) and WHR (p= 0.001) with mean difference of 2.12±0.86kg/m<sup>2</sup> and 0.02±0.014 respectively.

Control group: There was a significant decrease in the FG (p=0.001) and PPG (p= 0.001) with a mean difference of 19.9±14.07mg/dl and 31.94±27.71mg/dl respectively between pre and post-test. There was a significant decrease in BMI (p= 0.001) with mean difference of 0.25±0.51kg/m<sup>2</sup> and WHR (p=0.141) was not significantly reduced.

Table 4 shows on comparing between both groups, there was a significant reduction in FG (p=0.002) and PPG (p=0.02) after 10 days of intervention where BMI (p=0.240) and WHR (p=0.086) were not significant.

#### 4. DISCUSSION

Naturopathy and Yoga is a holistic approach to treat the whole body, by concentrating on elimination of root cause of disease thereby enhances the body's natural healing abilities. In patients with T2DM, control of blood glucose level is mandatory in order to prevent the complications and to promote the health of the diabetics. The result of this study shows that, after the intervention with INY for 10 days, there is a significant reduction in FG and PPG in what when compared to control group, and proved be

efficient in maintaining glucose metabolism. The previous research on glycemic control with 3 months of INY management resulted in significant changes with improvement in quality of life of the subjects [17]. In this study, the complementary and alternative medicine was used, which is becoming common among healthcare consumers.

Naturopathic medicine's ultimate goal is to enhance the human body's innate power and speed up its self-healing potential [18]. Normally, blood glucose level is controlled by the action of insulin. Abnormality in either secretion, sensitivity or signalling of insulin, results in increased glucose levels in blood. It was found in a study that yoga and naturopathy for 12 weeks has lowered blood sugar levels along with blood pressure. The calorie restricted diet with physical activity was implemented to subjects, which proved beneficial for individuals with diabetes [19]. Another research found that long-term naturopathic treatment for T2DM, made possible changes in risk factors, with significant improvement in blood glucose levels and pressure [20]. A Retrospective Observational study also shows that naturopathy treatment lowers the risk of T2DM and hypertension, with increased glucose regulation and lower blood pressure [21]. A prospective cohort study by Bairy. S in 2016 also shows the role of naturopathy treatments, aiding in reducing the medications and improving the health status of the patients [17]. It is also shown to be effective in maintaining homeostasis by shifting the vitals, favourably like blood pressure, weight, BMI, lipid profile, glycemic status – FG, PPG and HbA1C [22]. On the other hand, massage when given particularly to abdominal area, reduces the abdominal fat and waist circumference [23]

through which the Brown Adipose Tissue (BAT) gets activated which has gained its attraction as 'antidiabetic tissue' owing to its ability to dissipate energy as heat and forms as a seed for raising Basal Metabolic Rate. The BAT activation ensures Glucose homeostasis of the whole body and a positive correlation with insulin sensitivity is also to be noted [15].

In this study, combined effect of abdominal massage and neutral hip bath showed significant reduction in blood glucose levels along with BMI and WHR. The massage for 6 sessions, 1 hour each, resulted with effect in adiponectin, adiponectin-leptin ratio and HOMA IR index, where adiponectin is a fat-derived hormone that appears to play a key role in preventing insulin resistance by controlling the breakdown of glucose and fatty acids [24]. Adiponectin acts as an insulin sensitizer and has anti-diabetic, anti-inflammatory, and anti-atherogenic properties. The activation of two major signal pathways, the 5' Adenosine Monophosphate-activated Protein Kinase (AMPK) and the p38 Mitogen-Activated Protein Kinase, occurs when adiponectin binds to membrane receptors in muscle, such as AdipoR1 and AdipoR2. Activation of these pathways are essential for adiponectin-induced glucose uptake and fatty acid oxidation. Activated AMPK down regulates lipogenic genes and activates fat oxidative pathways and hence adiponectin levels have direct impact on insulin resistance [25].

In a study, when compared to the control group, the abdominal subcutaneous fat and waist circumference decreased dramatically, after massage given 5 days a week, for 6 weeks, in experimental group [23]. The thermogenic effect induced by massage, stimulates the BAT and this active BAT has the potency to lower the FG levels in adults. Changes in active BAT have been related to hormones like Fibroblast growth factor 21 (FGF21), leptin, and adiponectin. FGF21, which is developed primarily by the liver and also by BAT, has been shown to increase GLUT expression and boost insulin sensitivity. Increased thermogenesis and raised glucose and fatty acid usage by metabolically active BAT, result in changes in body composition, including a reduction in body fat [26].

The stress response, which includes an increase in cytokines like tumour necrosis factor- and interleukin-1, as well as the release of counter-regulatory hormones like glucagon, catecholamines, and cortisol, has been linked to the development of insulin resistance [27] The

HPA axis has been shown to be triggered in the presence of acute medical stress [28]. In general, the degree of HPA axis activation correlates with the severity of stress resulting in increased gluconeogenesis and glycogenolysis leading to increased insulin resistance and glucose output. The magnitude of the stress response has been shown to be directly proportional to the degree of hyperglycemia and insulin resistance [27]. Hence, the intense stress-relieving effects of neutral hip bath and massage have increased the possibility that, it could help people with diabetes by inducing the relaxation response, allowing the body to use insulin more efficiently by influencing the counter-regulatory stress hormones [29,30].

Regulating diabetes through hydrotherapy enhances overall muscle capacity to metabolise blood sugar and improves vitality in the body, thereby providing desirable effects in blood circulation [31]. Warm water immersion therapy can increase blood flow volume, which can improve the function of important organs like the brain by promoting the transfer of substances in the blood. Partial immersion was found to be successful in improving the quantity and quality of sleep in elderly people by reducing the serum cortisol levels [32].

Another study shows, Atrial natriuretic peptide (ANP), as well as natriuresis and diuresis, increases after single and serial head-out immersion at thermoneutral temperature, with significant decrease in plasma renin production, aldosterone, and blood pressure [33,34]. ANP are known to increase the serum insulin levels up to 50%, simultaneously inhibiting the glucagon levels, by directly influencing the pancreas [35]. It is also found in a study that, warm water immersion for 10mins, resulted with immediate raise in leptin levels, serum insulin, RBC, WBC and Hb and 30 mins after the treatment leptin levels showed high [36].

Hence it can be suggested that, integrating abdominal massage with a neutral hip bath not only improves insulin sensitivity and signalling, but also reduces abdominal obesity and thereby regulates glucose metabolism. The activation of adiponectin, BAT, ANP, leptin and counter-regulatory stress hormones, which control hormonal activity, glucose absorption and metabolism with excretion, can be attributed to these effects. These might be the mechanisms that justify the beneficial effect of abdomen massage with neutral hip bath for patients with diabetes.

#### 4.1 Strengths of the Study

1. It is a Randomized controlled trail with the clinical application.
2. This is the first study done to evaluate the integrated effect of abdomen massage and neutral hip bath.

#### 4.2 Limitations of the Study

1. Larger sample size would have given more authenticated results.
2. There was no follow up maintained to know further improvement.

#### 4.3 Directions for Future Research

1. The duration of study can be increased, so that the result might show more significance and HbA1C can be assessed, which would aid in understanding the full range of physiological changes.
2. Correlation between glucose levels and WHR can be identified to find out the impact of abdominal obesity on insulin resistance.

### 5. CONCLUSION

The present study suggests that, INY can play a vital role in lowering the raised blood glucose levels, in patients with T2DM. The abdomen massage with neutral hip bath is relatively better for lowering the FG, PPG along with BMI and WHR when compared to other Naturopathic interventions. Hence, it is concluded that, abdomen massage and neutral hip bath along with INY can be employed as an effective mode of treatment for managing of blood glucose levels and preventing further complications in diabetics.

### CONSENT

As per international standard or university standard, Participants' written consent has been collected and preserved by the authors.

### ETHICAL APPROVAL

This research was reviewed and approved by the Institutional Ethical Committee, SDM College of Naturopathy and Yogic Sciences (Registration number: EC-222). Informed consent was obtained from all participants.

### DATA AVAILABILITY

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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### COMPETING INTERESTS

Authors have declared that no competing interests exist.

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