

**CHAPTER - 5**  
**METHODS**

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## 5.0. METHODS:

In principle, the controlled trial was conducted to the highest standards available in Indian systems of medicine today, CONSORT in *Āyurveda*, the *Āyurveda* parallel to the CONSORT program for biomedical controlled trials. (Schulz, K. F., Altman, D. G., & Moher, D. 2010).

### 5.1. STUDY DESIGN

A three-arm Controlled Trial of *early detected T2DM patients not yet taking drugs*.

Group 1: An intervention group with herbal juice, *Rasāhāra*, treatment and Yoga.

Group 2: An intervention group with Yoga only, the same treatment as Group 1

Group 3: No intervention Control Group, kept under physician's observation and wait-listed for full *Rasāhāra* and Yoga as the Group 1.

**5.1.1 Sample size:** G\* power analysis of previous Yoga for Diabetes studies suggested that 30 in each group would be sufficient.

**5.1.2. Inclusion criteria:** male; age 18 to 70 years; early detected T2DM not yet on medication; sugar levels: FBS 100 to 170, PPBS 150 to 220 mg/dl.

**5.1.3. Exclusion criteria:** Inability to practice *Yoga*; very low BMI: < 20, mental disorder; already with diabetes complications (CKD, retinopathy, stroke, MCI etc.)

**5.1.4 Source of participants:** early pre-T2DM patients detected at Bhopal Central Jail. The Jail hospital authorities took keen interest in the study and helped with data collection costs. The Jail Superintendent had agreed to the study, since Jail meal times were already as we recommended.

**5.1.5 Ethical consideration:** Participants signed Informed Consent Forms; SVYASA's Institutional Ethical Committee approved the study design.

### 5.2 ALLOCATION TO GROUPS:

On external advice, participants were assigned to groups based on order in first FBS measurement to try to obtain equal values in this variable; in the event this was not a success.

### 5.3 INTERVENTIONS (Duration: 13 weeks)

**5.3.1** Group 1: Full *Rasāhāra* uniform for the group, and Yoga program.

**5.3.2** Group 2: Yoga program (practiced together with Group 1) Groups 1 and 2 practiced Yoga together throughout the intervention, with no dropouts, a remarkable achievement.

**5.3.3** *Rasāhāra* (Herbal Juices): The following herbs were selected for use in the study.

**5.3.3.1** *Āmalaki* (*Embilica Officinalis*) (50 ml): 8 gm dried powder, soaked for 12 hours.

balances *Vāta*, *Pitta* and *Kapha* in the body, reduces frequent urination and burning sensations, and also polydipsia (Deng, 2012);

**5.3.3.2** *Guḍuci* (*Tinospora Cardifolia*) (50 ml): 15 gms stem: Balances all 3 *dosas*, reduces urination, and strengthens the immune system (Saha & Ghosh, 2012);

**5.3.3.3** *Vāsā* (*Adhatodavasica Nees*) (50 ml): 4 gms leaves (green): Balances *Kapha* & *Pitta*, reduces frequent urination, skin diseases, breathing problems (Changani, 2010);

**5.3.3.4** *Wheatgrass* (50ml): 25 gms. Best anti-oxidant and food supplement to nourish the body (Vaidya & Devasagayam, 2007).

**5.3.4 Selection of herbs** used in the study was guided by *Vaidya P. Y. Vaidya* (*Khaḍivāle*) in Pune, who made the following points:

**5.3.4.1** They grow in the local climate during the season of the study.

**5.3.4.2** They have well established medicinal value according to both *Āyurveda* texts and modern scientific research.

**5.3.4.3** Benefits had also been well verified on patients at the 5 Herbal Juice Clinics.

**5.3.5 Demerits of *Rasāhāra*** (Herbal Juices):

**5.3.5.1** Juices don't contain fibre so patients may suffer slight constipation.

**5.3.5.2** Juices may not taste good.

**5.3.5.3** Growing or finding herbs in big cities may not be easy.

### **5.3.6 Collection of *Rasāhāra* Plant Materials:**

**5.3.6.1 *Āmalaki*:** Fresh fruits were purchased in markets in Bhopal, Madhya Pradesh, and prepared as dried powder according to methods stated by *Pune's Vaidya P.Y. Vaidya*.

**5.3.6.2 *Guḍuci*** plants, originally identified and authenticated by *Vaidya P.Y. Vaidya (Khaḍivāle)* were grown organically in a prepared area at the author's clinics, and harvested fresh each evening for use the following morning.

**5.3.6.3 *Aḍusā*** plants, similarly identified and authenticated by *Vaidya P.Y. Vaidya (Khaḍivāle)*, were grown by organic methods in a specially prepared area at the author's main clinic, and harvested fresh each morning.

**5.3.6.4 *Wheatgrass*:** Freshly grown at the author's second clinic. Planted in a clean, airy place in separate lots specially prepared for growing wheatgrass; grown without chemical fertilizers or pesticides from organic wheat grains.

### **5.3.7 Preparation of the *Rasāhāra* Herbal Juices**

The *Rasāhāra* were prepared in the jail itself by experienced workers from the clinics by blending in purified, filtered water from a standard water purifier provided by the jail. No plastic containers were used at any stage of preparation of the juices.

**5.3.7.1 *Āmalaki*:** The amount of dried powder required for the 38 Group 1 members was soaked overnight in a specified amount of water, and brought to the Jail.

**5.3.7.2 *Guḍuci*:** the correct weight of the plant was blended in measured quantities of similar purified, filtered water from the jail water purifier.

**5.3.7.3 *Aḍusā*:** the correct weight of the plant was blended in the right amount of water.

**5.3.7.4 *Wheatgrass*:** Seven day old plants were cut from their roots, washed clean, and then blended in purified water, and strained to prepare their juice.

Preparation at the jail enabled herbs to be administered within half an hour of blending etc.

## 5.4 Daily Yoga Practice

Yoga classes were conducted seven days per week in the jail itself, in a community hall large enough for 100 participants. Classes were conducted by a trained Yoga Teacher with the assistance of a trained Yoga Trainer together with one of the prisoners, who had previously practiced yoga in the jail by himself. The Yoga Teacher gave all the instructions, while the assistants helped participants to follow instructions.

## 5.5 Yoga Intervention: (see Table 5.1)

The Yoga Intervention consisted of:

**5.5.1** Warming up *Sukṣma Vyāyāma* exercises (about 10 mins): flexion of head and neck, limbs and torso to warm muscles and stimulate lymph flow (Table 5.2);

**5.5.2** 12 part Sun Salutation (*Suryanamaskāra*) (10 rounds, about 15 mins) (Table 5.3);

**5.5.3** Alternating single nostril breathing (*anuloma-viloma*) *pranayama*, (10 rounds)

**5.5.4** *Bhrāmhari prāṇayāma* breathing exercise, (10 rounds, each in 3 parts):

**5.5.4.1-** Inhale for 4 seconds.

**5.5.4.2-** Exhale for 8 seconds with vocalization of ‘Mmm...’ that is *makāra*.

**5.5.4.3-** Observe breath for 8 seconds.

- Vocalization of *makāra* for 8 seconds is stimulation, while
- Observation of breath for 8 seconds is relaxation.

**5.5.5** 2 rounds of *Nādānusandhāna* (separate vocalization of ‘A’, ‘U’ and ‘Mmm...’)



**Figure 5.5.01** Participants practicing Cyclic Meditation



**Figure 5.5.02** Participants practicing *Nāḍī Śuddhī*



**Figure 5.5.03** Participants practicing *Bhrāmari Prāṇāyāma*



**Figure 5.5.04** Participants practicing *Nādānusandhāna*

**TABLE 5.5.1 SUKṢMA VYĀYĀMA (WARMING UP EXERCISES)**

S.No.	Practices	Steps
1	Fingers movement	1
2	Palms movement	1
3	Wrists movement	3
4	Elbows movement	1
5	Shoulder joints movement	2
6	Neck movement	4
7	Waist movement	2
8.	Hip movement	1
9.	Calf muscles movement	1
10.	Toe tightening	1
11.	Ankle movement	2
12.	Knee cap tightening	2
13.	Patella movement	3
14.	Knee stretching and movement	2

**Loosening Exercises: List in Order of Performance**

1. Loosening Exercise Standing
2. Jogging (*sthiti: Tāḍāsana* )
3. *Mukha dhouti* to relax (Inhale from both nostrils and exhale from mouth)
4. Forward & backward bending
5. Sideward bending
6. Spinal twist
7. *Parivrtta trikoṇāsana* swing

Practice	<i>Sukṣma Vyāyāma</i>	Cyclic Meditation	<i>Surya Namaskāra</i>	<i>Prāṇāyāma</i>		
				<i>Nāḍi Shodhana</i>	<i>Bhrāmari</i>	<i>Nādānusadhāna</i>
Amount	One time daily	One time daily	2 rounds daily	10 rounds two times daily	10 rounds two times daily	2 rounds two times daily

**Table 5.5.2 Yoga Practices Given To Participants.**

**Table 5.5.2 Caption:** Table 5.5.2 shows the yoga practices given to participants.

**SURYA NAMASKĀRA (SUN SALUTATIONS):** (2 rounds in 5 minutes) *Sthiti: Tāḍāsana*

हिरण्मयेनपात्रेण सत्यस्यापिहितम मुखं । तत्त्वं पूषण अपावृणु सत्यधर्माय दृष्टये ॥

*Om Hiranmayena pātrena Satyasyāpihitam mukham, Tatvam pushan apāvrunu satya dharmāya dristaye*

Like a lid to a vessel, O sun, your golden orb covers the entrance, to lead me to truth.

Before first two rounds participants recited each *Mantra*:

1-*Om Hram Mitrāya Namah,*

2-*Om Hrim Ravaye Namah*

After two rounds they recite only *mantras*-

3-*Om Hrum Suryāya Namah, 4-Om Hraim Bhānave Namah, 5-Om Hroum Khagāya Namah,*

6-*Om Hrahaḥ Pushne Namah, 7-Om Hrām Hiranyagarbhāya Namah, 8-Om Hrim Maricaye*

*Namah, 9-Om Hrum Adityāya Namah, 10-Om Hraim Savitre Namah, 11-Om Hroum Arkāya*

*Namah, 13-Om Hrahaḥ Bhāskarāya Namah*

1. *Ekam - Hastauttānāsana-* Inhale
2. *Dve - Padahastāsana-* Exhale
3. *Trini - Aḥwasancālanāsana-* Inhale
4. *Catvari - Tulāsana-* Exhale
5. *Panca - Ḥaḥankāsana-* Inhale and Exhale
6. *Ḥata - Sāstānganamaskāra* No inhale exhale
7. *Sapta - Bhujangāsana-* Inhale
8. *Asta - Parvatāsana-* Exhale
9. *Nava - Ḥaḥankāsana-* Inhale and Exhale
10. *Daḥa – Aśwasancālanāsana-* Inhale
11. *Ekadaḥa – Pādahastāsana-* Exhale
12. *Dvādaḥa – Hastauttānāsana and back to sthiti*

**Table 5.5.3: CYCLIC MEDITATION (CM):**

Practice	Relaxation <i>Āsanas</i>					Relaxation		
						IRT (Instant relaxation technique)	QRT (Quick relaxation technique)	DRT (Deep relaxation technique)
Name and Time	<i>Tiryaka Taḍasana</i> (30 second balances both side)	<i>Ardha kati cakrāsana</i> (60 balances second)	<i>Pādahast āsana</i> (60 balances seconds)	<i>Uṣṭrāsana</i> (60 balances second)	<i>Śaśankāsa na</i> (60 balances seconds)	1 minut (Tightening and relaxation)	3 minutes (Abdominal breathing 5 rounds in Supine posture)	7 minutes ( <i>Savāsana</i> in Supine posture)

Table 5.5.3 captions: Table 5.5.3 shows five relaxation *Āsanas* and three *Śavāsanas*.

At the start of Cyclic Meditation practice, participants lie supine in *Śavāsana* keeping eyes closed; they listen to instructions to carry out practices slowly, with awareness and relaxation.

CM Practice then starts with a verse from *Māṇḍukya Upanishad Kārikā 3.44* (0:40 min);

Isometric Contraction of Body Muscles follows, ending with supine rest (1:00 min.);

slowly coming up from the supine position and standing at ease (*Tāḍāsana*), ‘balancing’ the weight on both feet (centring) (2:00 min.);

First Posture, bending to the right (*Ardhakaticakrāsana*, 1:20 min.);

Instructions about relaxation and awareness (*Tāḍāsana* 1:10 min);

bending to the left (*Ardhakaticakrāsana*, 1:20 min.);

*Tāḍāsana* (1:10 min.) as before;

Forward Bending (*Padahastāsana*, 1:20 min.);

*Tāḍāsana* (1:10 min.);

Backward Bending (*ardhacakrāsana*, 1:20 min.);

Slowly coming down to *Supine Rest* (SR) posture with instructions to relax different parts of the body in sequence (10:00 min.).

(Supine rest is practiced as traditional *Śavāsana* (the corpse posture), which means lying flat on the ground with the legs apart, arms away from the sides of the body, palms facing upwards, with eyes closed.)

All postures are practiced slowly, with awareness of all the sensations felt.

Total Duration of Practices: 22:30 min. (Nagendra HR. Nagarathna R. 1986)

## 5.6 ASSESSMENTS: 5 Levels

1. Demographic Assessments
2. Conventional T2DM Markers: HbA1c, FBS, PPBS, Lipid profile
3. Other Blood Parameters
4. Physiology (Heart) Parameters
5. *Āyurveda* Parameters, Measurement of *Doṣa Prakriti /Vikriti* manually.

### Parameters Measured

#### 5.4.1 Demographic assessments (concerning T2DM)

- Gender
- Age
- Height
- Weight (p&p)
  - Hence BMI

#### 5.4.2 Conventional T2DM Markers

- FBS (15 day)
- PPBS (15 day)
- HbA1c (p&p)
- VLDL (p&p)
- LDL (p&p)
- HDL (p&p)
- Triglycerides (p&p)
- Total Cholesterol (p&p)

#### 5.4.3 Other Blood Parameters

- HB (p&p)
- pH (p&p)
- Creatinine (p&p)

#### 5.4.4 Other Physiology (Heart) Parameters

- Pulse Rate (15 day)
- SBP (15 day)
- DBP (15 day)
- BHT (p&p)

#### 5.4.5 *Āyurveda* Parameters Levels of:

- *Vāta Bala* (+ to +++) or (1 to 2,3,4,5,6) degree
- *Pitta Bala* (+ to +++) or (1 to 2,3,4,5, 6) degree
- *Kapha Bala* (+ to +++) or (1 to 2,3,4,5, 6) degree