Empowering clinicians with lifestyle changes for management of diabetes

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ABSTRACT

**Background:** Diabetes self-management education (DSME), the process of teaching people to manage their diabetes, has been considered an important part of the clinical management of diabetes since the 1930s. The goals of DSME are to optimize metabolic control and quality of life and to prevent acute and chronic complications, while keeping costs acceptable. The objective was to assess the effect of neurobics and Sanskar remodelling in diabetic management.

**Methods:** This was an interventional, nonrandomised, pre and post study, conducted in the Department of Physiology, Jawaharlal Nehru Medical College, Wardha, Maharashtra, India. The period of study was 1 year and study participants were diabetic patients, aged between 15-90 years including both sexes. 210 patients were recruited and only 63 were eligible for the study group. The control group of 57 was selected from population. Blood sugar and WHO-QOL was studied in both the groups.

**Results:** There was a statistically significant fall in BMI, FBS, PPBS in between the pre & post-test findings of study group. WHO-QOL-Bref was used to analyze the 4 domains. This study showed that intervention used for the study group caused improvement in all the 4 domains.

**Conclusions:** The study concludes that lifestyle modification programme used in this study like neurobics and sanskar remodelling can be used in the management of diabetes along with routine medications.

**Keywords:** Neurobics, Sanskar remodelling, Diabetes

INTRODUCTION

A recent World Health Organization (WHO) document states that 388 million people globally, will die from noncommunicable diseases (NCDs) diseases like diabetes and heart disease in the next decade. It is also estimated that approximately 246 million people, or 5.9%, in the age group 29-79 have diabetes worldwide in 2007 of which 80% would be living in developing countries.

There were several clinical trials, but they were usually grossly underpowered, had flaws in design and conduct, and most used antidiabetes drugs as the intervention. Luckily, firm positive results from several randomized controlled trials using lifestyle intervention have become available during recent years. A number of large-scale RCTs (i.e., Da Qing DPS, MALMO Feasibility Study, Finnish DPS, United States DPP, Indian DPP, SLIM, and Japanese DPS trials) have been performed in persons who are at risk for T2DM (overweight/obese, IGT and/or IFG) in order to evaluate lifestyle modification of diet and physical activity. The Finnish diabetes prevention study (DPS) was one of the first controlled, randomized studies to show that type 2 diabetes is preventable with lifestyle intervention.
Diabetes self-management education (DSME), the process of teaching people to manage their diabetes, has been considered an important part of the clinical management of diabetes since the 1930s. The goals of DSME are to optimize metabolic control and quality of life and to prevent acute and chronic complications, while keeping costs acceptable. 9,10

The resource intensive interventions used in clinical efficacy trials need to be translated into pragmatic, more affordable, programmes, that can be delivered not only in routine clinical practice but also that retain their effectiveness. 11 Despite advances in Diabetes management, many people with diabetes have less than optimal metabolic control and continue to suffer from preventable complications. The gap between optimal evidence-based medicine and actual practice can be great, dependent not only on the ability of the clinician to make changes in practice patterns but also on the central role of the patient in implementing optimal management plans in daily life. 12 In addition to problems in implementing intensive treatment, questions arose concerning the effects of these regimens on quality of life (QOL) for patients. Intensive regimens also posed new dilemmas for health care practitioners and patients, not the least of which was the dramatic increase in risk for episodes of severe hypoglycemia when patients attempted to lower blood glucose (BG) levels. It quickly became clear that the greatest challenge to contemporary diabetes treatment was overcoming the many psychobehavioral and social–environmental barriers to optimal self-management. 13

An ancient Indian saying is ‘aahar, baivhaar and vichar is the key to healthy living. Relating to this age old dictum, one has to practice healthy eating (their own diet depending upon environment, culture and biodiversity), healthy behaviour which can be achieved by sanskar remodelling and positive thinking which can be practiced by a technique called as neurobics. Neurobics and sanskar remodelling are lifestyle modification programmes (LSMP) and are variants of raja yoga meditation. Our hypothesis was to test whether neurobics and sanskar remodelling can be of additive support in the management of diabetes.

**METHODS**

This was an interventional nonrandomised pre and post study, conducted in the Department of Physiology, Jawaharlal Nehru Medical College, Wardha. The period of study was 1 year and study participants were diabetic patients, aged between 15-90 years including both sexes.

In this study, 210 patients were recruited and only 63 were eligible for the study group. The control group was selected from population, comprising of 57 patients.

Both the group of subjects were oriented to AAD7TM self-care behavior framework, but the subjects in the orientation group were given the intervention. They were taught neurobics through video session by trained facilitators and to sanskar remodeling (SRM) through lecture by experienced raja yoga trainers. They practised neurobics and SRM daily for 10 min in the morning and 10 min in evening. This group was reviewed in the centre every weekend for the first 3 months and after every fortnight for the last 3 months. Patients were called to physiology department for all investigations. Blood sugar estimation was done at the centre.

Compliance was addressed using a log book where signature of subjects were taken for attending all sessions of 20 hours. Compliance to the programme was taken with an adherence more than 90%. Pre-test and post test data’s were taken before the onset and after completion of the study. Patients were referred to their attending physicians if they required medical care during the intervention.

Neurobics in this study was performed as a simple exercise of visualization of cosmic colors and concentrating the cosmic color of yellow, visually on the pancreas. 14 After a brief relaxation, the subject visualizes the soul as a point of white light shining like a diamond in between the eyebrows. Then, he focuses on the supreme soul (who is also a point of white light) and imagines all the color rays of rainbow energy flowing into his body. Next, focus is made on the healing color of yellow coming from the supreme soul, entering the body through the soul and perfusing the pancreas. They were asked to imagine that pancreas are generating more insulin by stimulation of beta cells, which is allowing improved glucose entry into cells, thus decreasing their plasma sugar levels.

The next intervention given was sanskar remodelling for behavior change. The shortcoming of different LSMP diabetic trials was the problem of adherence to the programme in the long run and efficacy check for the less motivated and general population. Unless people are motivated to change or to follow a certain guideline, there cannot be a desired outcome. Rajyoga meditation is a simple procedure which anyone can learn. People of any religion can practice it, as it is the study of one’s own self. Rajyoga meditation basically builds on, one’s energy levels by creating positive thoughts. These generated positive thoughts motivates an individual to adhere to a program. Further these positive thoughts bring about a behaviour change. In this, the person is sitted upright and concentrates on a point of white light. There are 3 stages (1) Initiation: in this stage, thoughts in the mind, come in randomly; (2) Concentration: He now, converts all negative thoughts with positive thoughts of peace, happiness, love, bliss, purity, knowledge and power, (3) Realization: This final stage involves feeling the emotions of these positive thoughts.

This practice of raja yoga meditation is on the lines of Brahmakumaris.
Outcome measures

Data collection period was 3 months. All data were collected by the facilitators.

Blood glucose was measured using a glucometer namely BG03-Dr Morepen, Gluco one blood glucose monitoring system.

Quality of life assessment was done using the WHOQOL - BREF, field trial version, 1996 questionnaire. It has 30 questions which assesses 4 domains namely physical, mental, social and environmental. All the raw scores were converted to 0-100% scale score, using the WHOQOL score chart.

Therefore the key life style outcome measures were blood glucose and WHOQOL domain score. Results were analyzed in the physiology department of JNMC, Wardha. If any information was required patients were contacted.

Program evaluation and statistical analysis

Reliability test of pilot study was calculated using test retest method.

Statistical analysis was done using descriptive and inferential statistics using Wilcoxon. Signed rank test, z-test for difference between two mean and chi square test.

Ethical clearance: Institutional Ethical Committee permission was taken vide reference number DMIMS(DU)/IEC/2013-14/310.

RESULTS

Table 3 compares age, gender, height and weight in both study and control group and shows both group were almost matchable.

Table 4 shows a significant finding between pre-test and post-test findings of fasting blood sugar (FBS) in study group. The findings in control group (Figure 1) is insignificant. Table 5 shows the comparison between 2 groups and the finding is statistically significant (p<0.05).

Figure 1: Comparison of FBS in control group at pre and post-test. Blood Sugar (FBS) in two groups.

| Demographic characteristics | Mean  | SD    | Range  |
|-----------------------------|-------|-------|--------|
| Age (years)                 | 55.52 | 14.92 | 16-82  |
| Gender                      | 48/15 |       |        |
| Height (Meter)              | 1.66  | 0.10  | 1.50-1.80 |
| Weight (Kg)                 | 71.47 | 7.38  | 59-80  |

Table 2: Distribution of patients according to demographic characteristics in control group.

| Demographic characteristics | Mean  | SD    | Range  |
|-----------------------------|-------|-------|--------|
| Age (years)                 | 57.68 | 13.39 | 17-81  |
| Gender                      | 46/11 |       |        |
| Height (meter)              | 1.66  | 0.10  | 1.50-1.80 |
| Weight (Kg)                 | 71.36 | 6.48  | 59-80  |

The finding of post prandial blood sugar in study group (Table 6) is statistically significant and insignificant in control group (Figure 2). Table 7 shows a significant finding between the 2 groups.

Table 3: Comparison of demographic characteristics in two groups.

| Study Group | Control Group | z-value | p-value     |
|-------------|---------------|---------|-------------|
| Age (years) | 55.52±14.92   | 0.83    | 0.40, NS, p>0.05 |
| Gender      | 1.66±0.10     | 0.00    | 1.00, NS, p>0.05 |
| Height      | 71.47±7.38    | 0.08    | 0.93, NS, p>0.05 |

Table 4: Comparison of FBS in study group at pre and post-test (fasting blood sugar).
Table 5: Comparison of mean difference in FBS in two groups.

| Group          | Mean Difference | SD   | z-value | p-value |
|----------------|-----------------|------|---------|---------|
| Study Group    | 16.06           | 14.57| 6.63    | 0.000   |
| Control Group  | 1.40            | 8.54 | S, p<0.05|         |

Table 10 shows the correlation of duration with WHO-QOL domains in study group (post test). The p-value for all the domains was significant at 0.0001 except domain-4. This table shows a positive correlation between duration of disease and quality of life in all the 4 domains with significant correlation in the first 3 domains.

Our observations show that neurobics and sanskar re-modelling (the two interventions) improved FBS, PPBS and quality of life irrespective of the duration of the disease, in diabetic patients of our study.

Table 6: Comparison of PPBS in study group at pre and post-test.

|        | Mean | N  | Std. Deviation | Std. Error | Mean Difference | z-value | p-value |
|--------|------|----|----------------|------------|----------------|---------|---------|
| Pre Test | 372.73 | 63 | 65.51          | 8.25       |                |         |         |
| Post Test | 350.88 | 63 | 67.18          | 8.46       |                |         |         |

Table 7: Comparison of mean difference in PPBS Glucose in two groups.

| Group          | Mean difference | SD   | z-value | p-value |
|----------------|-----------------|------|---------|---------|
| Study group    | 21.84           | 17.88| 7.26    | 0.000   |
| Control group  | 2.56            | 9.50 | S, p<0.05|         |

Table 8: Comparison of WHO-QOL domains in study group at pre and post-test.

| WHO QOL domains | Mean   | N  | Std. deviation | Std. error mean | Difference | z-value | p-value |
|-----------------|--------|----|----------------|-----------------|------------|---------|---------|
| Domain 1 (Physical) Pre test | 53.50 | 63 | 12.23          | 1.54            | 16.68±12.14 | 10.90   | 0.000 S, p<0.05 |
| Post test      | 70.19 | 63 | 10.85          | 1.36            |            |         |         |
| Domain 2 (Mental) Pre test | 42.79 | 63 | 14.82          | 1.86            | 25.12±16.67 | 11.96   | 0.000 S, p<0.05 |
| Post test      | 67.92 | 63 | 15.05          | 1.89            |            |         |         |
| Domain 3 (Social) Pre test | 57.95 | 63 | 19.36          | 2.43            | 12.34±19.54 | 5.01    | 0.000 S, p<0.05 |
| Post test      | 70.30 | 63 | 11.05          | 1.39            |            |         |         |
| Domain 4 (Environmental) Pre test | 35.87 | 63 | 12.12          | 1.52            | 24.76±14.82 | 13.24   | 0.000 S, p<0.05 |
| Post test      | 60.61 | 63 | 12.86          | 1.62            |            |         |         |
DISCUSSION

Observational studies have provided firm evidence that multiple lifestyle intervention decreases the risk of type 2 diabetes.

In this study the average age of subjects in the study group was 55 years and in the control group was 57 years. F. Eriksson & F. Lindgarde in their study selected diabetic Malmo male patients in the age group of 47-49 years. Ramachandran A, Snehalatha C et al too had subject with IGT in the mean age of 45.9±5.7 years. The improvement in sugar level findings in the study group (Lifestyle intervention group) correlates with finding of many researches namely Jaana Lindstrom et al in their study named as ‘finish diabetes prevention study’ (DPS) found that the intensive lifestyle intervention produced long term beneficial changes in biochemical parameters namely plasma glucose and reduced diabetes risk. Mensink M et al found in their study that lifestyle interventions improved glucose tolerance, even in less active population. This result was found after a 2 -hour combined diet and physical activity intervention programme, on glucose tolerance, in Dutch subjects. Yamaoka K et al in their met analysis of RCT’S on efficacy of Lifestyle education to prevent T2DM, concluded that lifestyle education was effective for reducing both 2-n. plasma glucose and RR (relative risk) in high risk individuals and may be a useful tool in preventing diabetes. Yoon U et al reported the result of 7 trials on efficacy of lifestyle intervention in reducing diabetes incidence in patients with impaired glucose tolerance. Considering the heterogeneity in LSM interventions and follow up time, the systematic review concluded that LSM can have a beneficial effect on the incidence of diabetes.

The present study showed statistical improvement in all the 4 domains namely physical, mental, social and environmental in the study group which points to the importance of the interventions given.

Rubin RR et al in their review study found that duration and type of diabetes are not consistently associated with quality of life, and better glycemic control is associated with better quality of life. Hervas A et al conducted a study which aimed to evaluate the impact of diabetes mellitus type 2 on health related quality of life. Their study showed that these patients have a tendency to show results lower than the general population in the health concepts like physical function, bodily pain, general health, social function and role emotional. This study concluded that T2DM is related to a worse perception of QOL related to health, and that impact of certain diseases on the patients should not be measured only through quantification of objective clinical parameters (such as morbidity and mortality). Kalda R et al examined the factors that most strongly influenced the quality of life. They found that patients who were less aware of the disease had a significantly higher quality of life score.

Mechanism of favourable response of meditation

The most impressive evidence in favour of mind-body relationship, which meditation exploits for securing

### Table 9: Comparison of mean difference in WHO-QOL domain in two groups.

| WHO-QOL domains | Group           | Mean difference | SD    | z-value | P-value |
|-----------------|-----------------|-----------------|-------|---------|---------|
| Domain 1        | Study group     | 16.68           | 12.14 | 9.22    | 0.000   |
|                 | Control group   | 1.00            | 5.60  |         | S, p<0.05|
| Domain 2        | Study group     | 25.12           | 16.67 | 10.87   | 0.000   |
|                 | Control group   | 0.33            | 6.70  |         | S, p<0.05|
| Domain 3        | Study group     | 12.34           | 19.54 | 5.23    | 0.000   |
|                 | Control group   | 1.43            | 7.07  |         | S, p<0.05|
| Domain 4        | Study group     | 24.74           | 14.82 | 11.05   | 0.000   |
|                 | Control group   | 1.10            | 7.89  |         | S, p<0.05|

### Table 10: Correlation of duration with WHO-QOL in study group.

| Duration (years) | Domain 1 | Domain 2 | Domain 3 | Domain 4 |
|------------------|----------|----------|----------|----------|
| 0-3 years        | 70.47±11.51 | 67.79±16.01 | 70.50±11.33 | 60.34±13.94 |
| 4-6 years        | 67.55±11.84 | 66.11±15.97 | 68.77±14.71 | 61.55±9.68 |
| 7-9 years        | 68.80±7.75  | 66.40±12.87 | 71.40±5.36  | 56.60±14.31 |
| 10-12 years      | 73.50±5.74  | 73.50±5.74  | 72±6      | 66±6     |
| 13-15 years      | 75±0       | 75±0       | 63±0     | 63±0     |
| Correlation ‘r'  | 0.989      | 0.023      | 0.774    | 0.076    | 0.023 |
| p-value          | 0.0001,S   | 0.0001,S   | 0.0001,S | 0.857, NS |

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The favourable response which we got in terms of blood pressure and blood sugar can be explained in terms of psychophysiological coherence. In physiology coherence means entrainment, resonance and synchronization, all of which causes harmony in different body systems resulting in increased synchronization between the two branches of the autonomic system. An elemental physiological phenomenon called the ‘relaxation response’ (RR) has been shown to produce changes similar to meditation. It is an innate physiological response that is opposite of the stress response. This RR can explain the beneficial effects on FBS and PPBS.

Thus, we understand that reasonable evidence exists for the use of neurobics and sanskar remodelling in the management of T2DM.

Limitations of the study was as follows; HBA1C estimation was not done since it was financially not viable for study participants. Also, HbA1c results can be affected by haemolysis and other conditions with increased red cell turnover (reduced HbA1C) or conditions with reduced cell turnover e.g. iron deficiency (increased HbA1C) or in any other chronic disease states. Moreover, HbA1C results may vary with age and between different ethnic groups.

The confounders like age, height, weight were included in the present study and other confounders like diet and exercise were not included as they were not the focus of our study.

CONCLUSION

With all these findings we finally conclude that lifestyle modification programme used in our study like neurobics and sanskar-Remodelling can empower clinicians in the management of diabetes along with routine medications.

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