Chapter 3

3. METHODOLOGY

3.1 Operational Definitions

Exercise is a subset of physical activity and is more formal and exertional in nature. It is planned, structured and repetitive bodily movement performed to improve or maintain one or more components of physical fitness. Exercise is often performed to achieve objectives such as improved fitness, performance and health, and can provide a means of social interaction.

Moderate physical activity is defined as activities with energy expenditure of 3 to 6 METs. People who perform activities of this intensity for 30 minutes per day will meet the recommendations for cardiovascular benefit.

Vigorous physical activity is defined as activities with energy expenditures of greater than 7 METs. It is suggested that people who are already doing moderate-intensity physical activity on most days of the week begin to include these types of activity into the daily routine. Increasing cardio-respiratory fitness has additional benefits.

Cardio-respiratory fitness is defined as the ability of the circulation and respiration to supply oxygen during sustained physical activity.
**Standard care:** Advise people with Type 2 diabetes that lifestyle modification, by changing patterns of eating and physical activity, can be effective in controlling many of the adverse risk factors found in the condition. Provide access to a dietitian (nutritionist) or other health-care professional trained in the principles of nutrition, at or around the time of diagnosis, offering one initial consultation with two or three follow-up sessions, individually or in groups. Provide ongoing counseling and assessment yearly as a routine, or more often as required or requested, and when changes in medication are made. Individualize advice on food/meals to match needs, preferences, and culture. Advise control of foods with high amounts of sugars, fats or alcohol. Integrate drug therapy, where needed, into the individual’s chosen lifestyle. For people choosing to use fixed insulin regimens, advise consistent carbohydrate intake at meals. For these people, as well as those on flexible meal-time and basal insulin regimens, offer education on assessment of carbohydrate content of different types of foods. Provide advice on the use of foods in the prevention and management of hypoglycaemia where appropriate. Introduce physical activity gradually, based on the individual’s willingness and ability, and setting individualized and specific goals. Encourage increased duration and frequency of physical activity (where needed), up to 30-45 minutes on 3-5 days per week, or an accumulation of 150 minutes of physical activity per week. Provide guidelines for adjusting medications (insulin) and/or adding carbohydrate for physical activity.

Both nutrition therapy and physical activity training should be incorporated into more broadly based diabetes self-management training programmes. For weight reduction in people with Type 2 diabetes who are obese, it may sometimes be appropriate to consider weight loss medications as adjunct therapy. (6, 23)


3.2 Study Design

Randomized Controlled trial of parallel design comprising of three groups was conducted involving subjects with Type 2 DM from August 2011 to January 2014.

3.3 Sample Size Calculation

Based on prevalence of Type2 DM in Sikkim and effect size of 0.4 from a pilot study for primary outcome HbA1c, power at 80% and level of significance at .05, standard deviation of 2; sample size of 90 was required in three groups to know which is a better intervention. However, this was a 6 months follow-up study we expected an attrition of 15%; therefore we decided to recruit 115 subjects in each group. We also kept the option of Intention to treat analysis if attrition was beyond 15%.

3.4 Method of Randomization

Permuted Block Randomization was used. Thirty blocks were used with ten allocation chits in each block. Allocation of subjects was blinded and it was monitored by an independent person who was unaware about groups.

Study protocol was approved by Institutional Ethics Committee and then study was registered with Clinical Trials Registry-India- CTRI/2011/08/001954.
3.5 Subjects

Total of 902 subjects were identified out of which 565 were excluded due to several reasons mentioned in Figure 3.1. Interested subjects were invited to an assessment visit, at which the study was explained and informed consent was obtained. Subjects who met inclusion criteria were concealed allocated by another person, who was unaware of study, randomly by block randomization in three groups after which a baseline physical examination was performed and laboratory tests were ordered. There were 112 subjects in yoga group, 110 in music group and 115 in control group at first stage. At the end of 6 months there were 96 subjects in yoga group, 92 in music group and 90 in control group. Reasons and stage of drop out has been shown in Fig.3.1.
Assessed for eligibility (n=902)

Excluded (n= 565)
- Not meeting inclusion criteria (n=127 )
- Declined to participate (n=61 )
- Other reasons (n=40 )

Randomized (n= 337 )

<table>
<thead>
<tr>
<th>YOGA</th>
<th>MUSIC</th>
<th>CONTROL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allocated to intervention (n=112 )</td>
<td>Allocated to intervention (n=110 )</td>
<td>Allocated to intervention (n=115 )</td>
</tr>
<tr>
<td>- Received allocated intervention (n=107)</td>
<td>- Received allocated intervention (n=104)</td>
<td>- Received allocated intervention (n=101)</td>
</tr>
<tr>
<td>- Did not receive allocated intervention (n=5 )</td>
<td>- Did not receive allocated intervention (n=6 )</td>
<td>- Did not receive allocated intervention (n=14 )</td>
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<tr>
<td><strong>Reasons</strong>: 3-refused at end moment and 2 did not turn up for tests</td>
<td><strong>Reasons</strong>: 4 didn’t turn up and 2 refused for tests</td>
<td><strong>Reasons</strong>: 14 did not turn up for baseline tests</td>
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Lost to follow-up (n=6)
- 3 didn’t turn up for tests
- 3 had to start on insulin

Lost to follow-up (n=8)
- 4 didn’t turn up for tests
- 2 had to start on insulin
- 2 communication lost

Lost to follow-up (n=2)
- did not turn up for tests

Analysed (n=96 )
- Excluded from analysis (n=5); Did not turn up for tests

Analysed (n=92 )
- Excluded from analysis(n=4)
- 3 developed complications and 1 did not turn up for tests

Analysed (n=90 )
- Excluded from analysis(n=9)
- 1 died and 8 did not turn up for tests

Figure 3.1: CONSORT Flow diagram of subjects’ allocation, intervention, drop outs, follow-up and analysis.
3.6 Inclusion Criteria
It comprised of Type 2 DM subjects over 20 years of age according to American Diabetes Association (ADA) criteria of diagnosis.(26) HbA1c range from 7%-9%, diagnosis of Type 2 DM for >1 Year, stabilized on Oral hypoglycemic agents(OHA) for atleast 3 weeks, no prior exposure to Yoga therapy and Music therapy as well as no involvement in structured exercise program self reported.

3.7 Exclusion Criteria
It excluded subjects requiring insulin, subjects with A1c >9%, hypertension, unstable or under investigated coronary artery disease, cancer, severe osteoporosis or any other musculoskeletal disorder which may limit administration of yoga therapy, diagnosed cerebrovascular disease, subjects on antipsychotic drug like SSRI, aversion of music, already practicing yoga or music therapy.

3.8 Procedures
Demographic and baseline assessment (Annexure-1-Proforma) was done on first day and intervention was started from the subsequent day. All subjects underwent clinical assessment by supervising physicians. All the subjects received standard care (6) and Exercise prescription was done by a qualified physiotherapist at moderate intensity of physical activity as per American Diabetes Association (ADA) Standards of Care guidelines.(28) Standard care was derived from standard guidelines published by leading bodies in Diabetes care.(6, 23, 28, 32) Subjects in yoga group and music group were trained for two subsequent weeks after which they were asked to practice for 6 months along with their standard care.
prescriptions. Medications were prescribed by supervising physician as per standard guidelines. Subjects in control group were asked to adhere to standard care protocol only. On finishing supervised program all subjects in yoga group were given a ‘Yoga booklet’ with instructions written in English and local language Nepali. Music group subjects were given Audio-CD for Music listening and all subjects of all groups were provided with a ‘general instruction booklet’ which consisted of diet prescription and general information related to disease, standard care and physical activity.

Adherence to program was ensured by asking all the subjects to maintain a ‘daily log’ in a diary to keep a proper record of the activities and lapse. One of the subject attendants was also asked to accompany subject during training and same countersigned once the subject finished practice at home. All the subjects were called over telephone every week in order to know their compliance as well as their difficulty. Subject companion was also contacted at same time to countercheck. Subjects were asked to visit once a month after supervised training while practicing at home. All the groups were tested under similar laboratory conditions.

3.8.1 Yoga group (YG) was taught pranayama and yoga-asana by an instructor daily for initial two weeks and then they were called regularly at an interval of 1 month for supervision and compliance for 6 months. At the end of 3 and 6 months all outcome measures were repeated. The whole yoga intervention consisted of following exercises:
3.8.1.1 Warm ups: (starting from the head, working towards the toes. 10 repetitions of each movement)


3.8.1.2 Asanas

Standing

Surya Namaskar- Starting from 3 turns of each poses being maintained for ten seconds and adding each turns every week

Tad asana- starting from ¼ minute and adding ¼ minute every week

Trikonasana- starting from ¼ minute for each side, adding ¼ minute per week

Sitting

Vajrasana- starting from ¼ minute and adding ¼ minute every week

Padmasana- starting from ¼ minute and adding ¼ minute every week

Ardhamatsyendrasana- starting from ¼ minute for each side, adding ¼ minute per week

Paschimotrasana- starting from ¼ minute for each side, adding ¼ minute per week

Prone

Bhujangasana- Starting from 3 turns to be maintained for ten seconds and adding one turn every week

Dhanurasana- Starting from 3 turns to be maintained for ten seconds and adding one turn every week
Supine

_Halasana_- Starting from 3 turns to be maintained for ten seconds and adding one turn every week

_Naukasana_- Starting from 3 turns to be maintained for ten seconds and adding one turn every week

_Shavasana_- starting from 2 minutes and adding a minute per week

3.8.1.3 Pranayama

_Bhastrika-pranayama_- starting from 3 min/day and adding 1 minute every month

_Kapal-bhati_- 10 min/day

_Anulom-viloma_- starting from 5 min/day and adding 1 minute every month

_Bhramari_- 5 times a day

3.8.2 Music Group

Subjects in this group got an Audio-CD consisting of collection of ten types of non-lyric Indian classical instrumental music. The collection was of 60-80 beats per minute, known to have relaxing effect. Personal preference of music has better effect on subject’s responses to music. The subjects got supervised training for two weeks after which they were asked to practice for 6 months. Subjects were called every month for supervision and compliance. At the end of 3 and 6 months all outcome measures were repeated.
There are certain factors which are important to consider while selecting music as intervention to promote relaxation. These factors are pitch and tempo, preference for music, sensitivity and type of music. In this study all possible factors were taken care of. (47)
Music group subjects listened to their selected music through head phones via a portable audio disc player for approximately 30 minutes in two sessions (morning and afternoon) on each day. Participants were given instructions which was adapted from a previously published literature by the same author.(16)

3.9 Outcome Measures

Primary Outcome measures were Glycated hemoglobin (HbA1c), Fasting Blood glucose level (FBS), Post prandial glucose level (PPBS), Body mass index (BMI), Lipid Profile.

Secondary measures were State trait anxiety inventory (STAI), Beck depression inventory (BDI), Diabetes- Quality of Life (D-QOL),(29) Exercise self efficacy,(53) and Blood Pressure (BP).

3.10 Statistics

Data was analyzed by SPSS (version 22.0; SPSS inc. Chicago, Ill). Data analysis was blinded. First normal distribution of samples was plotted and verified by Smirnov-Kolmogorov test. All samples of variables under test was normally distributed and we decided to use ANOVA with repeated measures followed by post-Hoc analysis with Bonferroni’s test, p<0.05 was considered to be statistically significant. ANOVA was used to analyze the changes in outcome variables from baseline to 3 months and 6 months in a group and between the groups to know that which intervention caused greater change.