CHAPTER 8

8.1 APPRAISAL

Thus, the present study infers that yogic life style could accrue several physical and mental health benefits improving the quality of living of T2DM patients through holistic cleansing. Further, it is also evident that the yoga life style intervention shows highly significant improvement in all clinical as well as psychological indices while comparing with the improvement indicated in the non-yoga control group who are under conventional treatment on anti- hyperglycaemic agents.

8.2 SUMMARY

Based on the findings of the present randomized controlled studies, 16 week yoga based lifestyle modification program brought significant improvements in several metabolic indices of major importance in the management of T2DM including glycaemic control, lipid level, and improvement of anthropometric characteristics, Health Satisfaction and Quality of Life among the mongoloid patients with T2DM.

8.3 CONCLUSION

In conclusion, the findings of the present study suggest that yoga lifestyle along with conventional treatment could bring about significant improvements in glycemic control, lipid profile, body composition, and psychological indices resulting in physical and emotional self satisfaction in subjects with T2DM.

8.4 IMPLICATION OF THE STUDY

Several evidence based studies among the diabetic population showed the effectiveness of yoga in reducing the risks of progression of T2DM state. The present study will be the first randomized controlled trial studies among the Indian mongoloid patients with T2DM that will show the evidence that yoga significantly affect the T2DM patients not only in reducing the hyperglycaemeia state but also improving the health satisfaction and quality of life.

8.5 APPLICATION OF THE STUDY

Apart from significant improvements in anthropometric characteristics and metabolic parameters in yoga intervention group, there were significant difference in Quality of Life

and Health Satisfaction domain score between the control and the yoga group. The Yoga group also demonstrated greater improvement in the psychological measurements domain score than the control.

8.6 STRENGTH OF STUDY

The study was the first of its kind to investigate the role of integrated yoga intervention programme exclusively for the T2DM patients of mongoloid race of Manipur State.

It was a community based randomized controlled study for management of T2DM on metabolic parameters through cost effective life style modification programme of yoga practice.

A comprehensive yoga module was ideally designed after extensive literature review to make a perfect integration of eight limbs of Seer *Patanjali's astanga yoga* (eight-limbs of yoga philosophy) to suit for targeted disease under study. The study embodied the yoga intervention with an emphasis on *asanas, pranayamas, surya namaskar* and cyclic meditation with yoga education program in addition to dietary modification and conservative treatment with anti-hyperglycaemic agents.

The present study emphasised on the long term impact of yogic life style on the current Health Satisfaction and Quality of Life of the patients with T2DM as psychological outcome measures of yoga intervention.

No adverse events among the patients were observed during and after yoga intervention.

Both the experimental yoga group as well as non-yoga control group fully complied with the guidelines framed for the respective group during the period of investigation. Both the experimental and the control groups were under constant supervision of a senior endocrinology doctor of JNIMS, Hospital.

A new approach of combination treatment of yoga and modern medicine has been proposed to check further progression of T2DM which seems to give a new insight into the reversibility of the disease process.

8.7 LIMITATION OF THE STUDY

The exact requirement of duration for yoga sessions for the patients could not be assessed due to limitation of time for five batches of yoga intervention groups.

Data on dietary modification of the patients could not be collected and recorded apart from diabetic dietary lecture.

Medicine score could not be assessed on the basis of Doctor's prescription except the assessment done on the basis of the health satisfaction and quality of life improvement scores.

8.8 SUGGESTIONS FOR FUTURE RESEARCH

Suggest for advanced yoga research for T2DM involving larger sample size for long term study (with follow-up practice at home) integrating a well-stepped yoga module to provide more confirmatory evidence for prevention and control of T2DM.

Dietary modification and medicine score study be substantiated with proper monitoring and reported with scientific evidence.

Need to conduct research at molecular level to explore the mechanism of yoga practice in hormonal homeostasis for reversal of T2DM disease.

In case, the risk of T2DM is based on identified genetic loci, research on Genome sequencing may provide additional insights and possible therapies.

Suggest in depth research in yoga practice to un-fold the mechanism involved in improving the scores of various psychological assessments including health satisfaction and quality of life.

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APPENDIX

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APPENDIX-1

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Document Information

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Sources included in the report

	49) Ibohal Nongthombam-Impact of Yoga based Treatment on Blood Glucose levels and Lipid
SA	Profile write up (1).doc
SM	Document 49) Ihohal Nonothombam-Impact of Yoga based Treatment on Blood Glucose levels

Document 49) Ibohal Nongthombam-Impact of Yoga based Treatment on Blood Glucose levels and Lipid Profile write up (1).doc (D130523455)

SA Chapter IV & V_P.Anuja_12071.doc
Document Chapter IV & V_P.Anuja_12071.doc (D64019152)

SA poonam thesis.pdf
Document poonam thesis.pdf (D127220928)

SA Results and discussion -part -II.docx
Document Results and discussion -part -II.docx (D17249292)

SA Final Thesis by sonal bhardwaj 30-10-2020.pdf
Document Final Thesis by sonal bhardwaj 30-10-2020.pdf (D83402391)



JAWAHARLAL NEHRU INSTITUTE OF MEDICAL SCIENCES, IMPHAL- 795008

No. Ac/02/IEC/JNIMS/2016/R

Dated: Imphal, the 22nd Oct 2016

To,

Nongthombam Ibohal Singh (PI)

Research Scholar

SVYASA University, Bangalore

Dr Ksh Achouba Singh (Co-PI)

Associate Professor (Endocrinology)

Department of Medicine

Jawaharlal Nehru Institute of Medical Sciences, Imphal

Dear Mr Nongthombam Ibohal Singh & Dr Ksh Achouba Singh,

The office of the Institutional Ethics committee, Jawaharlal Nehru Institute of Medical Sciences, Imphal reviewed and discussed on your research Proposal No. 24/16/2016(R) version 02, submitted on 21/10/2016 entitled 'A study on the effect of an integrated Yoga program on self-satisfaction among Type 2 DM patients of Mongoloid origin attending JNIMS hospital, Imphal'.

The following sub-committee members were present at the time of taking the decision.

- 1 Prof L Fimate, Prof & Head, Dept of Forensic Medicine, JNIMS, Member
- 2 Dr.Kh. Lokeshwar Singh, Assoc Prof. Dept. of Medicine, JNIMS, Member
- 3 Dr. A. Kaini Pfoze, Assoc.Prof. Dept. of Anatomy, JNIMS, Member
- 4 Dr N. Somorjit Singh, Assoc. Prof, Dept. of Surgery, JNIMS, Member
- 5 Dr Bishwalata RK, assoc Prof, Dept.of Community Medicine, Member Secretary

In persuasion of the resolution No.3/23/16(R), I am to convey that the opinion of the committee about the protocol as under:

Opinion of the Sub- Committee:-

The sub-committee resolved that the study titled "A study on the effect of an integrated Yoga program on self-satisfaction among Type 2 DM patients of the Mongoloid origin attending JNIMS hospital, Imphal" is Recommended/Approved by the IEC, JNIMS for a period of 6(six) months commencing from 1st October 2016.

Yours' sincerely,

(Dr Bishwalata Rajkumari)

Member Secretary, IEC, JNIMS

Kishvalata

APPENDIX 4mber Secretary Institutional Ethics Committee

JNIMS



J.N. Institute of Medical Sciences

Porompat, Imphal East

No. JIMS/Academic, 3(40)/Ph.D/15

Imphal the 28th December, 2016

To

Dr. Ksh. Achouba Singh Assoc. Prof. Department of Medicine, JNIMS, Imphal.

Subject: - Permission for use of Examination Hall (Old Faculty Block) for Yoga Practice of Diabetic patients.

Sir,

I am to inform you that Shri N. Ibohal Singh, Research Scholar (Yoga) working under your guidance as Research Scholar for Ph.D degree under the Swami Vivekananda Yoga University, Bengaluru can utilise the old Examination Hall for practice of yoga by the Diabetic patients.

However, the Hall will be available only after January, 2017.

The Research Scholar will have the responsibility for proper maintenance of all the furniture and electrical items in the hall.

Yours faithfully,

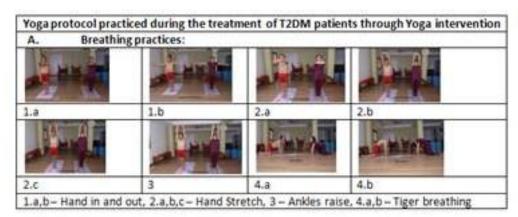
(Prof. W. Gyaneshwar Singh)
Dean (Academic)
JNIMS, Porompat
Imphal the 27th December, 2016

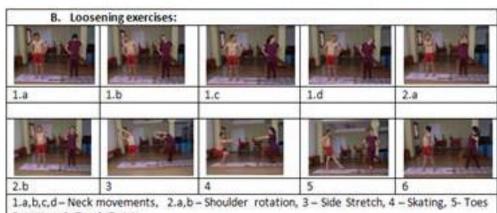
No. JIMS/Academic. 3(40)/Ph.D/15

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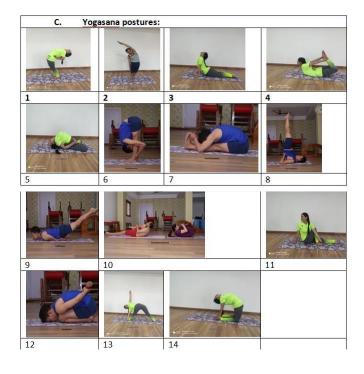
- 1. The Director, JNIMS for information.
- 2. Shri N. Ibohal Singh, Research Scholar (Yoga).
- 3. Office file.

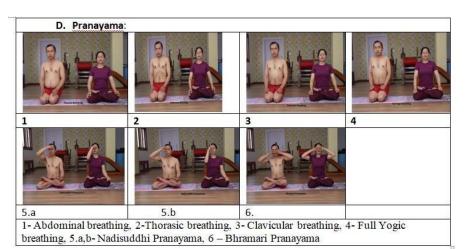
APPENDIX-4

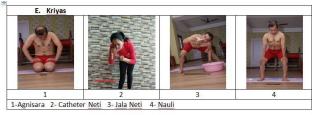




Rotation, 6- Trunk Twist







QOLID Questionnaire

Instruction

The following assessment asks how you feel about the impact of diabetes on your quality of life. Your response will help us find ways for improving diabetes care. If you are unsure about which response to give to a question, please choose the one that appears to be the most appropriate. We would request you to attempt to answer all questions. However the choice or decision to not to answer a particular question is entirely yours. You can always seek the help of the interviewer in case there is any confusion regarding the meaning of some questions or choice.

Role Limitation Due to Physical Health

1. How often do you miss your work because of your diabetes?

Always	Frequently	Often	Sometimes	Never
1	2	3	4	5

2. A person with diabetes has the requirement of adhering to a schedule for eating and taking regular medication. How often does this affect your work?

Always	Frequently	Often	Sometimes	Never
1	2	3	4	5

3. How often does diabetes affect your efficiency at work?

Always	Frequently	Often	Sometimes	Never
1	2	3	4	5

4. How often do you find diabetes limiting your social life?

Always	Frequently	Often	Sometimes	Never
1	2	3	4	5

5. To what extent do you avoid traveling (business tour, holiday, general outings) because of your diabetes?

A lot	Highly	Little	Very little	Not at all
1	2	3	4	5

6. Compared to others of your age are your social activities (visiting friends/partying) limited because of your diabetes?

Always	Frequently	Often	Sometimes	Never
1	2	3	4	5

Physical Endurance

An important part of understanding your general health and well being has to do with your ability to perform various activities.

Thus for the following questions please indicate if your health has limited your activities in following areas in the past three months. Please tick any one option.

1. How often in last three months has your overall health problems limited the kind of vigorous activities you can do like lifting heavy bags/objects, running, skipping, jumping.

Always	Frequently	Often	Sometimes	Never
1	2	3	4	5

2. How often in last three months has your overall health problems limited the kind of moderate activities you can do like moving a table, carrying groceries or utensils.

Always	Frequently	Often	Sometimes	Never
1	2	3	4	5

3. How often in last three months has your overall health problems limited you from walking uphill or climbing 1-2 floors.

Always	Frequently	Often	Sometimes	Never
1	2	3	4	5

4. How often in last three months has your overall health problems limited you from walking 1-2 km at a stretch.

Always	Frequently	Often	Sometimes	Never
1	2	3	4	5

5. How often in last three months has your overall health problems limited you from bending, squatting, or turning.

Always	Frequently	Often	Sometimes	Never
1	2	3	4	5

6. How often in last three months has your overall health problems limited you from eating, dressing, bathing, or using the toilet.

Always	Frequently	Often	Sometimes	Never
1	2	3	4	5

General Health

1. In general would you say your health

Poor	Fair	Good	Very good	Excellent
1	2	3	4	5

2. How well are you able to concentrate in everything like working, driving, reading etc?

Not at all	A little	Moderate	Very much	An extreme amount
1	2	3	4	5

3. How many times in the past three months have you had fatigue/felt very tired?

Always	Frequently	Often	Sometimes	Never
1	2	3	4	5

Treatment Satisfaction

The following set of questions would enable us to know how satisfied are you with your treatment for diabetes. Please tick any one option.

1. How satisfied are you with your current diabetes treatment?

Very dissatisfied	Moderately dissatisfied	Neither satisfied nor dissatisfied	Moderately satisfied	Very satisfied
1	2	3	4	5

2. How satisfied are you with amount of time it takes to manage your diabetes?

Very dissatisfied	Moderately dissatisfied	Neither satisfied nor dissatisfied	Moderately satisfied	Very satisfied
1	2	3	4	5

3. How satisfied are you with the amount of time you spend getting regular checkups (once in 3 months)?

Very dissatisfied	Moderately dissatisfied	Neither satisfied nor dissatisfied	Moderately satisfied	Very satisfied
1	2	3	4	5

4. A person with diabetes needs to exercise for 35-45 min, 4 times a week. Keeping this in mind how satisfied are you with the time you spend exercising?

Very dissatisfied	Moderately dissatisfied	Neither satisfied nor dissatisfied	Moderately satisfied	Very satisfied
1	2	3	4	5

Symptom Botherness

1. How many times in the past three months have you had thirst/dry mouth?

Always	Frequently	Often	Sometimes	Never
1	2	3	4	5

2. How many times in the past three months have you felt excessive hunger?

Always	Frequently	Often	Sometimes	Never
1	2	3	4	5

3. How many times in the past three months have you had frequent urination related to diabetes management?

Always	Frequently	Often	Sometimes	Never
1	2	3	4	5

Financial Worries

The following set of questions will help us know how your diabetes has affected your or your family's finances. Please tick any one option!.

1. What do you think about the cost involved in your management of diabetes?

Very expensive	little expensive	reasonable	not at all expensive
1	2	3	4

2. To what extent has your priority of expenditure shifted towards diabetes management?

A lot	Highly	Little	Very little	Not at all
1	2	3	4	5

3. To what extent has your family budget got affected by the expenses related to the management of diabetes?

A lot	Highly	Little	Very little	Not at all
1	2	3	4	5

4. To what extent has your diabetes limited your expenditure on other aspects of life (Movies, outings, parties etc)?

A lot	Highly	Little	Very little	Not at all
1	2	3	4	5

Emotional/Mental Health

1. How satisfied are you with yourself?

Very dissatisfied	Moderately dissatisfied	Neither satisfied nor dissatisfied	Moderately satisfied	Very satisfied
1	2	3	4	5

2. How satisfied are you with your personal relationships (family, friends, relatives and known tos)

Very dissatisfied	Moderately dissatisfied	Neither satisfied nor dissatisfied	Moderately satisfied	Very satisfied
1	2	3	4	5

3. How satisfied are you with the emotional support you get from your friends and family?

Very dissatisfied	Moderately dissatisfied	Neither satisfied nor dissatisfied	Moderately satisfied	Very satisfied
1	2	3	4	5

4. How often are you discouraged by your health problems?

Always	Frequently	Often	Sometimes	Never
1	2	3	4	5

5. All people want to fulfill certain roles and lead their lives in a purposeful manner. To what extent do you feel that you have been able to lead your life in the same way?

Not at all	A little	Moderate	Very much	An extreme amount
1	2	3	4	5

Diet Satisfaction

Diabetes demands a little modification in diet, thus the following set of questions would help us know how much satisfied you are with modifications in your diet.

(For participants who have been advised some dietary modification/counseling).

1. How often do you feel because of your diabetes a restriction in choosing your food when eating out?

Always	Frequently	Often	Sometimes	Never
1	2	3	4	5

2. As you have diabetes, how much choice do you feel you have in eating your meals or snacks away from home e.g. if you go in a party and there is a buffet where there are also a lot of fried snacks and desserts would you be able to make enough choice?

No choice	Very little	little	enough	A lot
1	2	3	4	5

3. How often do you eat the food items that you shouldn't, in order to hide the fact that you are having diabetes.

Always	Frequently	Often	Sometimes	Never
1	2	3	4	5

Current Health Satisfaction Questionnaire (CHES-Q)

		Strongly disagree	Disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Agree	Strongly agree
1.	I am satisfied with my current body weight.	1	2	3	4	5	6	7
2	I am satisfied with my current level of energy.	1	2	3	4	5	6	7
3.	I am satisfied with my current appetite (my overall desire to eat).	1	2	3	4	5	6	7
4.	I am satisfied with my current ability to sleep through the night.	4	2	3	4	5	6	7
5.	I am satisfied with my current ability to do physical activities such as walk or climb stairs.	1	2	3	4	5	6	7
6.	I am satisfied with my current ability to have social interactions with family and friends.	1	2	3	4	5	6	7
7.	I am satisfied with my current attitude toward diabetes.	1	2	3	4	5	6	7
8.	I am satisfied with my current mood.	1	2	3	4	5	6	7
9.	I know my current blood sugar levels.	1	2	3	4	5	6	7
10.	I am satisfied with my current blood sugar levels.	1	2	3	4	5	6	7
11.	I know my current blood pressure.	1	2	3	4	5	6	7
12	I am satisfied with my current blood pressure.	1	2	3	4	5	6	7
13.	Overall, I am satisfied with my current health.	1	2	3	4	5	6	7
14.	My current level of knowledge about diabetes is	l Not at all	2 Son	newhat	3 Knowledgeable	4 Very		5 Extremely
		knowledgea	ble kno	wledgeable	0.70	knowledgeab		knowledgeable

INFORMED CONSENT

Part- I (Participants Information Sheet)

Participant ID:

Title: A study on the effect of Integrated Yoga Program on Self-satisfaction among the Type2 DM patients of Mongoloid origin attending JNIMS, Imphal.

Principal Investigator: Nongthombam Ibohal Singh

Purpose of the Study:

Holistic approach of Integrated yoga intervention for a period of 4 months along with conventional treatment as usual may improve the glycaemic parameters and self satisfaction among the T2DM patients of mongoloid origin.

Aims:

There is no valid published report of scientific study for management of T2DM illness through intervention of integrated yoga program on self satisfaction among the T2DM patients of Manipuri community. It is essential to research social cognitive factors that impact self- satisfaction in patients with T2DM.

Objectives:

- (i) To study the effect of intervention through integrated yoga programme for management of T2DM patients of Mongoloid community.
- (ii) Considering the importance of health satisfaction as individual strategy for managing T2DM, the Current Health Satisfaction Questionnaire (CHES-Q) and Quality of Life Instrument for Diabetes Questionnaire (QOLID-Q) are considered for pragmatic assessment of many aspects of diabetes related health satisfaction.

Introduction:

Type 2 Diabetes Mellitus(T2DM) is the single most important metabolic disorder and non-communicable disease that affect nearly every organ system in the body. This dreaded disease is projected to increase to 300 million people worldwide by 2025 (Snnemmari, 2005). India is considered as the 'Diabetes Capital of the World' as the number of diabetes subjects steadily increases. In 2006, diabetic population in India was 40.9 million and it is estimated to increase to

69.9 million in 2025 and 80 million in 2030. Even more alarming is shifting age of onset in diabetes patients. Now, younger age people are found to be suffering from diabetes. The prevalence of T2DM in Manipur is to the tune of 20 percent of the total population of the State from the age group

total population of the State from the age group 20 to 60 years (NE State Diabetes Society,2010). A comprehensive report on the result of a National survey conducted on the use of Complementary and Alternative medicine(CAM) among the persons suffering from diabetes mellitus was documented by Yeh et al.(2002) giving about 20% of the respondents benefitted from CAM in treating diabetes. The present study is a holistic health care approach in lieu of the present conventional approach alone for the treatment of T2DM. The intervention of an integrated yoga programme like yoga asanas, pranayamas, kriyas including Transcendental meditation(TM) and Self Management of Excessive Tension(SMET) which include the mind and body interaction will be scientifically carried out considering the relevant parameters like metabolic, anthropometric data, glucose tolerance test(GTT), serum insulin estimation, plasma total cholesterol, serum urea, serum creatinine, serum lipid profile, ECG, exercise tolerance test, etc. among the Type 2 Diabetes Mellitus patients of Manipuri community attending JNIMS Hospital, Manipur so as to assess the response of the integrated yoga programme.

Study design / Procedure:

The diabetic patients will be diagnosed by a Senior endocrinologist on the basis of their clinical test reports, anthropometric data, etc. The sample size will be of 60 patients(age from 30-60 years) or more. A set of age and sex matched control with T2DM will be maintained with traditional treatment. Pre - and Post - treatment/ yoga intervention/health satisfaction questionnaire data on all the parameters studied will be maintained for analysis using Statistical Package for Social Sciences(SPSS).

Eligibility: The patients who have been clinically and medically diagnosed as T2DM by a senior endocrinologist Doctor will be eligible for the study.

Exclusion Criteria: The patient with myocardial infarction or cerebro-vascular illness, major psychiatric disorder, serious retinopathy, renal problems will be excluded.

No bias on class, caste, ethnicity, race for the study. However, so far no scientific study has been done on yoga intervention or complementary and alternative medicine for treatment of T2DM. Hence, the present study will be emphasised on the Manipuri Community.

Risks and benefits: No risk.

Pre and post Glucose level control either fasting plasma glucose(FPG and Post-prandial) and/or glycolated haemoglobin (HbA1c) will be the primary outcome measure in the study. Yoga may offer a promising lifestyle intervention for decreasing weight related type 2 diabetes risk factors and potentially increasing psychological well being.

Compensation for participation: No

Ancillary care:

If any condition or disorder discovered during this study period is not related to it, you will be referred to the proper hospital or concerned doctor for further management .

Confidentiality:

If you wish to hide your identity, all efforts will be made to protect your privacy and confidentiality. The project staff will keep your personal information confidential. Besides this consent form, all other forms and samples will mention only the assigned code number. The forms linking your name and code number will be withheld from others. The information will not be revealed except with your permission. However, collective data without identifiers will be presented and may be published.

Privacy:

Interview will be conducted in a separate room and data will be kept confidential.

Right of withdrawal:

You may decide not to take part or withdraw from the study at any time. However you will continue to receive ongoing routine medical care.

Part - II (Consent form)

Statement to be made by a person willing to participate in the study

I have read this consent form completely/this consent form has been read out to me in my own language. I understand that I can withdraw my participation anytime, if I feel so. I have received and understood the information about my rights and have been promised that my personal information shall be kept confidential if I should desire so. All my doubts have been cleared.

I want to participate in this study myself by my own free will and am willing to (Circle number/s that is accepted):

- 1. Count the study person.
- 2. Answer the questionnaire.
- 3. Recommend any other person who is suffering from T2DM and known to me.
- 4. Permit the publication / presentation of report.
- 5. All (1+2+3+4)

I have been offered a copy of my consent form and I want a copy of my consent form/I do not want a copy of my consent form. I understand that anytime I can contact the investigators in case of doubt. I have been promised to be supplied any new development/ information which has a bearing to this study.

Part - II (Consent form)

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1

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Publication

Sl. No	Publication				
1	Singh N I, Pradhan B, Pandey M, Parajuli N, Singh AK.				
	Influence of Yoga-based program on health satisfaction in the				
	Mongoloid patients diagnosed with type 2 diabetes mellitus.				
	Yoga Mimamsa [serial online] 2021 [cited 2022 May				
	24];53:109-15. Available from: https://www.ym-				
	kdham.in/text.asp?2021/53/2/109/333351				
2	Singh, N. I., Pradhan, B., Pandey, M., Parajuli, N., & Singh,				
	A. K. (2022). Effect of 16-weeks of Yoga Intervention on the				
	Quality of Life of Type-2 Diabetes Mellitus patients of				
	mongoloid community. Turkish Online Journal of Qualitative				
	Inquiry. 13(1), 893-902				
3	Singh, N. I., Pradhan, B., Pandey, M. & Singh, A. K. (2022).				
	Relationship between FBS, PPBS, HbA1c and Urine Glucose				
	in the Type 2 Diabetes Mellitus patients having different				
	levels of Serum Urea. Turkish Online Journal of Qualitative				
	Inquiry. 13(1).1301-1305				