APPENDICES

1.0 INFORMED CONSENT FORM: A SAMPLE COPY

1.1: IFA: INFORMED ASSENT FORM FOR ADOLESCENTS STUDENTS

Informed Assent Form for Children/Minors
Informed Assent Form for students participating in a
Randomized controlled Study
Effect of Integrated Approach of Yoga Therapy on
Adolescent Obesity
(School going children age group from 11 to 17 years)

This Informed Assent form is for the children of

DR KALMADI SHYAMRAVHIGH SCHOOL AND JR COLLEGE

Between the ages of 11 -17 ages who are Obese whom we are inviting to participate in research.

Name of Principal Investigator: Dr.Padmini Tekur
Name of Co-Investigator: Dr. H R Nagendra

Name of Organization: Swami Vivekanand Yoga Anusandhan Samsthana (SVYASA)

Name of Sponsor:
Name of the Private Sponsor:
Shri Ramkumarji Rathi,
Yoga Initiatives,Rathi Foundation

This Informed Assent Form has two parts:

- **Information Sheet (gives you information about the study)**
- **Certificate of Assent (this is where you sign if you agree to participate)**

You will be given a copy of the full Informed Assent Form

Page 1 of 2

Part I: Information Sheet
Introduction

I, Dr Sunanda S.Rathi .Ph.D research Scholar in S-VYASA Yoga University, is doing research on 'Effect of Integrated Approach of Yoga Therapy on Adolescent Obesity' (School going children age group from 11 to 17 years).

I am going to give you information and invite you to be part of a research study. You can choose whether or not you want to participate. We have discussed this research with your parent(s)/guardian and they know that we are also asking you for your agreement. If you are going to participate in the research, your parent(s)/guardian also have to agree. But if you do not wish to take part in the research, you do not have to, even if your parents have agreed.

You may discuss anything in this form with your parents or friends or anyone else you feel comfortable talking to. You can decide whether to participate or not after you have talked it over. You do not have to decide immediately.

There may be some words that you may not understand you may talk to anyone you feel comfortable. You may ask queries talking with about the research please ask us to stop as we go through the information & we will take time to explain. If you have questions later, you can ask them to the Investigator.

Purpose: Why are you doing this research?

Childhood obesity is an issue of serious medical and social concern due to the adoption of a western lifestyle. Consumption of high calorie food, lack of physical activity and increased time on viewing Television are major risk factors for childhood obesity. Obese adolescents are under the risk of medical and psychological complications. Insulin resistance, dyslipidemia, type 2 diabetes mellitus, hypertension, polycystic ovarian syndrome and metabolic syndrome.

Choice of participants: Why are you asking me?

As prevention and treatment of obesity involves lifestyle modification of the entire family. We want to find better ways to prevent obesity it makes children diabetic. Yoga has been found to be an effective tool for the management of obesity. Regular Yoga practice was associated with reducing weight gain, most strongly among individuals who were overweight.

Participation is voluntary: Do I have to do this?

You don't have to be in this research if you don't want to be. It's up to you. If you decide not to be in the research, its okay and nothing changes, everything stays the same as before. Even if you say "yes" now, you can change your mind later and it's still okay.

DR SUNANDA RATHI : I have checked with the child and they understand that participation is voluntary

You will have to come 60 minutes extra before/after school hours, if you decide to take part in the research study.

In this research, we are testing the effect of yoga on psycho-physical functioning of obese students. Other studies of yoga have been shown improvement in psychological and physical functioning in adults and adolescent students. Now we want to evaluate the effectiveness of yoga in obese students.

Yoga is an age old practice, which is being followed in India for hundreds of years. It includes physical exercises called Asanas, breathing exercises called Pranayama and meditation called Dhyana. Along with these, the yoga module used in this research also includes relaxation, lecture sessions and counselling. It is absolutely safe if done according to the instructions given by the therapist (Instructor). You may experience generalized body pain cramps or a catch in the first few days, which is normal and gets all rights by itself

Procedures and Protocol

Once your participation in the study is confirmed, you will be given questionnaires to answer and perform few manual tests, which have to answer before and after 5 weeks intervention. To test effect of yoga we will put students taking part in this research into two groups. The groups are selected by chance, as if by tossing a coin or by any unbiased methods.(www.randmiser.org)

Participants in one group will be given the yoga practice and the other group will continue their normal routine activities. It is important that neither you nor we know which of the two groups you will be included in. The people involved in testing will not know, to which group each one belongs to. This information will be in our files, but will not be disclosed until after the research is finished. We will then compare which of the two has the best results. This is the best way we have for testing without being influenced by what we think or hope might happen.

If there is anything you are concerned about or that is bothering you about the research please talk to the investigator.

I have checked with the child and they understand the procedures

Risks: Is this bad or dangerous for me?

There is no risk.The intervention is safe. It has already been tested on adults and on other children. There has been nothing that has worried us at all. If anything unusual happens to you, you should feel free to call us anytime with your concerns or questions. Another way of us knowing how you are is by having you come to the instructor. If you get sick or have concerns or questions in-between the scheduled visits on Saturday, you should let me or the staffs knows.

Discomforts: Will it hurt?

If there will be any discomforts state these clearly and simply. State that they should tell you and/or their parents if they are sick, experience discomfort or pain. Address what may be some of the child's worries, for example, missing school or extra expense to parents.

While taking blood sample .The injection might hurt for just a second when it goes into your arm. It might get a little bit red and hard around the place where the injection/needle goes in. That should go away in a day.If permission is granted.

I have checked with the child and they understand the risks and discomforts Dr SUNANDA RATHI

Benefits: Is there anything good that happens to me?

The yoga intervention protocol practices may help you or not. But this research might help us to find later that could help other children. There are a couple of good things if you do decide that you want to do this.

I have checked with the child and they understand the benefits DR SUNANDA RATHI

Reimbursements: Do I get anything for being in the research?
No reimbursements. You will be provided free training of Yoga Practices.
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Confidentiality: Is everybody going to know about this?

We will not tell other people that you are in this research and we won't share information about you to anyone who does not work in the research study. After the research is over, you and your parents will be told the results.

Information about you that will be collected from the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except

Compensation: What happens if I get hurt?

We assure nothing will happen to you.If you become sick during the research, we will look after you. Special attendant will be kept. We have given your parents information about what to do if you are hurt or get sick during the research.

Sharing the Findings: Will you tell me the results?

When we are finished the research, I will sit down with you and your parent and I will tell you about what we learnt. I will also give you a paper with the results written down. Afterwards, we will be telling more students, parents, people, scientists and others, about the research and what we found. We will do this by writing and sharing reports and by going to meetings with people who are interested in the work we have done. The research will be shared more broadly, i.e. in a book, journal, conferences, etc.

Right to Refuse or Withdraw: Can I choose not to be in the research? Can I change my mind?

You do not have to be in this research. No one will be disappointed with you if you say no. It's your choice. You can think about it and tell us later if you want. You can say "yes" now and change your mind later and it will still be okay.

Who to Contact: Who can I talk to or ask questions to?

You can ask me questions now or later. You can ask the instructor, co-ordinator or Principal questions if you have any. I have written a number and address where you can reach. You can come and see us. If you want to talk to someone else that you know like your teacher or Yoga Instructor, that's okay too.

If you choose to be part of this research I will also give you a copy of this paper to keep for yourself. You can ask your parents to look after it if you want.

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

PART 2: Certificate of Assent

I understand that the research is about Obesity. Once I confirmed my participation in the study, I will be given questionnaires to answer and perform few manual tests, which have to answer before and after 4 weeks intervention.
I understand that 5 ml blood sample will be taken for physiological test before & after 4 weeks
To test effect of yoga I will be taking part in this research, I understand that there are two groups .The groups are selected by chance, as if by tossing a coin or by any unbiased methods. I may be in one group either the yoga practice group or the other group which will continue their normal routine activities. It is important that neither myself nor anyone knows which of the two groups I will be included in.

If anything is concerned about or that is bothering me about the research I can talk to the investigator or Instructor

I have read this information (or had the information read to me) I have had my questions answered and know that I can ask questions later if I have them.

I agree to take part in the research.

OR

I do not wish to take part in the research and I have <u>not</u> signed the assent below._____(initialled by child/minor)

<u>Only if child assents:</u>

Print name of child _____

Signature of child: _____

Date:_____day month year

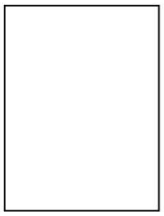
If illiterate: Not applicable as we are doing in school

I have witnessed the accurate reading of the assent form to the child, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness (not a parent)_____ AND Thumb print of participant

Signature of witness _____

Date _____
Day/month/year



Name of the Administrator

Signature of the Administrator **Seal of the School**
Date _____
Day/month/year

I have accurately read or witnessed the accurate reading of the assent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given assent freely.

Print name of researcher :Dr Sunanda Rathi

Signature of researcher_____

Date_____
Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the child understands that the following will be done:

1. Questionnaires to answer and perform few manual tests, which have to answer before and after 4 weeks intervention.
2. 5 ml blood sample will be taken for physiological test before & after 4 weeks. (If permission is grated)
3. 4 weeks yoga intervention if in Yoga Group

I confirm that the child was given an opportunity to ask questions about the study, and all the questions asked by him/her have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this assent form has been provided to the participant.

Print Name of Researcher/person taking the assent Dr Sunanda Rathi

Signature of Researcher /person taking the assent _____

Date _____
Day/month/year

Copy provided to the participant Dr Sunanda Rathi (initialed by researcher/assistant)

Parent/Guardian has signed an informed consent ___Yes ___No _____(Dr SSR initialed by researcher/assistant)

1. 2: ICF: INFORMED CONSENT FORM IS FOR PARENT

Informed Consent Form is for Parents, Local Guardian of adolescent girls & boys of Dr. Kalmadi Shamarao High School and Jr. College -Kaveri Education

Participating in a research titled
A Randomized control Study
Effect of Integrated Approach of Yoga Therapy on Adolescent Obesity
(School going children age group from 11 to 17 years)

Name of Principal Investigator: Dr.Padmini Tekur
Name of Co-Investigator: Dr. H R Nagendra

Name of Organization: Swami Vivekanand Yoga Anusandhan Samsthana

(SVYASA)

Name of Sponsor: Department of Ayush

Name of the Private Sponsor:

Mr.Ramkumar Rathi, Construction House,796/189
Bhandarkar Road ,411004,Pune,Maharashtra

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the study with you)**
- **Certificate of Consent (for signatures if you agree that your child may participate)**

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet

Introduction

I, Dr Sunanda S.Rathi .Ph.D research Scholar in S-VYASA Yoga University is doing research on 'Effect of Integrated Approach of Yoga Therapy on Adolescent Obesity' (School going children age group from 11 to 17 years). My research might help your child to reduce obesity & become healthier. In our research we will take 100 students both girls & boys & as per the inclusion criteria & will ask them some questions. After my study of children, I will talk to you parents and ask your permission. After you have heard more about the study, and if you agree, then the next thing I will do is ask your daughter/son for their agreement as well. Both of you have to agree independently before I can begin.

You do not have to decide today whether or not you agree to have your child participate in this research. Before you decide, you can talk to anyone you feel comfortable with.

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me or of another researcher.

I am going to give you information & invite you to be part of this research .There may be some words that you may not understand you may talk to anyone you feel comfortable. You may ask queries talking with about the research please ask us to stop as we go through the information & we will take time to explain. If you have questions later, you can ask them to the Investigator.

Purpose

We want to find better ways to prevent obesity before it makes serious health problem & make children sick. Obese adolescents are under the risk of medical and psychological complications. Insulin resistance, dyslipidemia, type 2 diabetes mellitus, hypertension, polycystic ovarian syndrome and metabolic syndrome
Childhood obesity is an issue of serious medical and social concern due to the adoption of a western lifestyle. Consumption of high calorie food, lack of physical activity and increased time on viewing Television are major risk factors for childhood obesity.. As prevention and treatment of obesity involves lifestyle modification of the entire family. Yoga has been found to be an effective tool for the management of obesity. Regular Yoga practice was associated with reducing weight gain, most strongly among individuals who were overweight.
In our school curriculum we are not providing yoga practices that are important for teenagers. In this study we will talk to teenage girls and boys about what they know about caring for their bodies in a healthy way including diet habits. We will invite them to share

their knowledge and understanding with us so that we can find ways of meeting their needs.

Type of Research Intervention

This research will consist of doing some blood tests like Lipid Profile, total cholesterol (mmol/l) Triglycerides (mmol/l) HDL/ LDL ratio twice. Before & after 5 weeks.
Anthropometric measurements, Weight, Height, Body Mass Index & other related circumference
Psychological Parameters like answering psychological questionnaires and performing manual tasks. You have to do this before and after 5 weeks of intervention. After school hours your child has to spend 60 minutes. They will be taught yoga in the school campus five days a week for approximately 60 minutes for a total of 5 weeks.

Selection of Participants

We are inviting all obese students from 5th std to 10th std who fit into the inclusion and exclusion criteria by the research associate to participate in this research on yoga. To test effect of yoga we will put students taking part in this research into two groups. The groups are selected by chance, by any unbiased methods. www.randamisor .com

Voluntary Participation

You do not have to agree that your daughter/son can talk to us. You can choose to say no and we know that the decision can be difficult when it involves your children. And it can be especially hard when the research includes sensitive topics like obesity. You can ask as many questions as you like and we take the time to answer them. You don't have to decide today. You can think about it and tell me what you decide later.

If you decide not to allow your child to take part in this research study, do you know what the options for him are?
Your child does not have to take part in this research study, if you do not wish so.
Do you have any questions?

Procedure

Explain what each of the steps or procedures involve. Indicate when the research will take place and where. If there are surveys, indicate where and how the surveys will be collected and distributed.

1) Your daughter/son will take part in a discussion with 100 other teenagers from 11 to 17 year of age group from English medium Dr. Kalmadi Shamarao High School .The girls and boys will be in separate groups. This discussion will be guided by the principal of the school & or by me (Dr Sunanda Rathi).

2) Your daughter/son will participate in an discussion scheduled on Saturday before we start our yoga practices, with the Principal & Dr. Sunanda Rathi ,myself.

3) Questionnaire Surveys
Your daughter/son will fill out a questionnaire which will be provided by Dr Sunanda Rathi and collected by School Authorities .The questionnaire can be read aloud and she/he can give me the answer which she/he wants me to write.
The questions are related to their eating habits, exercises, daily routine & self Esteem.
Theses questionnaires will help us to assess your child's personality.

The group discussion will start with me, along with teachers & Principals & administrator. We will also answer questions about the research that they might have. Then we will ask questions about the health system in this community. We will talk about where they go for information about health, and whether they get the information and services they need and want. We will encourage them to talk about their routine & habits as well as other important health topics such as food and nutrition. These are the types of questions we will ask. We will not ask them to share personal stories or anything that they are not comfortable sharing.

The discussion will take place in in the School Campus, and no one else but the people who take part in the discussion and the guide & I will be present during this discussion.

4) The following applies only to questionnaires and surveys:
If your daughter/son does not wish to answer some of the questions included in the questionnaire, she/he may skip them and move on to the next question. The information written is confidential, and no one else except me, (Dr Sunanda Rathi) will access to the information will have access to her questionnaire. The questionnaires will be destroyed after 12 /15 months or completion of research Procedures and Protocol

Once your participation in the study is confirmed, you will be given questionnaires to answer and perform few manual tests, which have to answer before and after 5 weeks intervention. To test effect of yoga we will put students taking part in this research into two groups. The groups are selected by chance, as if by tossing a coin or by any unbiased methods.

Participants in one group will be given the yoga practice and the other group will continue their normal routine activities. It is important that neither you nor we know which of the two groups your child will be included in. The people involved in testing will not know, to which group child belongs to. This information will be in our files, but will not be disclosed until after the research is finished. We will then compare which of the two has the best results. This is the best way we have for testing without being influenced by what we think or hope might happen.

If there is anything you are concerned about or that is bothering you about the research please talk to the investigator.

B. Description of the Process

- During the first visit, we will give your child ICF (informed consent form) and explain about the study. Only after your & his /her confirmation about participation in the study we will ask few questions about general health and measure BMI of child.

- In the first session a small amount of blood, equal to about 5 ml will be taken from child's arm with a syringe. This blood will be tested for the presence of substances that help to our research findings. At the next visit, which will be 5 weeks later, will again be asked some questions about health & sample of blood test. **If you give us permission**

- One or two days later, child will be allotted one of the groups either that with yoga or that without yoga. As explained before, neither you nor we will know whether you go to yoga group or the non-yoga group.

- If your child gets the yoga group he/she will have to attend yoga session of 60 minutes after school hour in the school campus five times a week for a period of 5 weeks.

- Irrespective of which group you belong to, after 5 weeks, you have to answer all the tests which were previously mentioned. The biological samples obtained during this research procedure will be used only for this research, and will be destroyed when the research is completed. We will take blood from arm using a syringe and needle. Each time we will take about 5ml **if consent is given**

- After 5 week of intervention non-yoga group will be taught yoga for next 5 weeks, same like yoga group if possible.

Duration

We are asking your child to participate in a discussion which will take about 2 hour of her/his time. In the school campus, we can do this after school/work hours. There is also a questionnaire that we will either provide to your child or which we will do together with her/him. This also takes about an hour. Altogether, we are asking for about 2 hours of your child's time. If you decide that your child can take part in the study.
The research takes place over 6 weeks in total. If your child gets a chance to be included in the yoga group, he/she will have to attend yoga sessions five times a week Monday to Friday for 5weeks that would come to around 25 days in total. Each day child will be spending an hour's time in the yoga class conducted in the school campus after school hours. Supervised sessions of yoga practices will be arranged.
We would like to meet you before & three months after intervention. After three months non-yoga group will be given same intervention for three months.

Side Effects

As already mentioned, yoga therapy will have no side effects. It can make your child sometime tired t and it can cause some temporary soreness of the muscles of your body, cramps and muscle catch in the beginning but no reason to worry. However, we will follow closely and keep track of any unwanted effects or any problems. Or we may stop one or more practices.

Risks

There is no risk in practicing Yoga

Benefits

If your child participate in this research, yoga will be provided free of cost. There may not be any immediate & direct benefit but in long run it will help lot if child continues,you're your child's participation is likely to help us to find the answer to the research question. There may not be any benefit to the society at this stage of the research, but future generations are likely to benefit.

Reimbursements

You will not be given any money or gifts to take part in this research. You tell me if you have understood correctly the benefits that your child will have if you allow him/her to take part in the study? Do you know will pay for the biological test & yoga instructor's costs. Do you have any other questions?

Confidentiality

The information that we collect from this research project will be kept confidential. Information about your child that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about your child will have a number on it instead of name. Only the researchers will know what number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except the people involved in the research and the research team
The following applies to focus groups:

We will ask your child and others in the group not to talk to people outside the group about what was said in the group. We will, in other words, ask each participant to keep what was said in the group confidential. You should know, however, that we cannot stop or prevent participants who were in the group from sharing things that should be confidential.

Sharing the Results

The knowledge that we get from doing this research will be shared with you through weekly counselling meetings & sessions scheduled on Saturday before it is made widely available to the public. Confidential information will not be shared. There will be small meetings with parents & teachers which will be scheduled on Saturday. At the end of the study, we will be sharing what we have learnt with the participants and with the community. We will do this by meeting first with the participants and then with the larger community. Nothing that your child will tell us today will be shared with anybody outside the research team, and nothing will be attributed to him/her by name. A written report will also be given to the participants whom they can share with their families. We will also publish the results in order that other interested people may learn from our research.

Right to Refuse or Withdraw

You do not have to take part in this research if you do not wish to do so and refusing to participate will not affect you. You will still have all the normal activities that you would otherwise have in the school. You may stop participating in the research at any time that you wish. You may choose not to have your child participate in this study and your child does not have to take part in this research if she/he does not wish to do so. Choosing to participate or not will not. Your child may stop participating in the discussion/interview at any time that you or she/he wish without either of you losing any of your rights here.

Whom to Contact

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following:

Information about the liable person in case of any injury occurs during the yoga practices.
Principal of the School: Principal – Mrs. Pallavi Naik 9422016011 /020 25456328
Co-ordinator of the project Mrs.Vaishali Shinde 9881877158
Relationship with ICF: She is Principal of the school
Paid Instructor will be appointed to take care.

Dr.Sunanda Rathi:ResearcherMobile:09860100251, Mail ID: sunandarathi@gmail.com

You can Contact Principal of the School of Dr. Kalmadi Shamarao High School and Jr. College English Medium
This proposal has been reviewed and approved by SVYASA yoga university.

IEC is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IEC, contact the technical coordinator,IEC-SVYASA, No 19, 'Eknath Bhavan', Gavipuram circle, Kempegowda Nagar, Bengaluru-560019 Telephone number-08026612669.

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

PART II: Certificate of Consent

Certificate of Consent

I have been asked to give consent for my daughter/son to participate in this research study which will involve her completing one interview discussion and questionnaire for eating habits, daily routine & self-esteem.
Physiological - biological test, Anathematic test

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily for my child to participate as a participant in this study.

Print Name of Parent or Guardian _____

Signature of Parent of Guardian_____

Date _____
Day/month/year

If illiterate

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.

I have witnessed the accurate reading of the consent form to the parent of the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ **AND** **Thumb print of participant**

Signature of witness _____

Date _____
Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the parent of the potential participant, and to the best of my ability made sure that the person understands that the following will be done:

1. Questionnaires to answer and perform few manual tests, which have to answer before and after 5 weeks intervention.

2. 5 ml blood sample will be taken for physiological test before & after 5 weeks if permission is given

3. 5 weeks yoga intervention if in Yoga Group

I confirm that the parent was given an opportunity to ask questions about the study, and all the questions asked by him/her have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the parent or guardian of the participant.

Print Name of Researcher/person taking the consent: Dr Sunanda S Rathi

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1.3: ICF: IN REGIONAL LANGUAGE MARATHI

संशोधनात सहभागी विदयार्थ्यांच्या पालकांसाठी वा स्थानिक पालक यांच्यासाठी माहितीपूर्ण संमती अर्ज

हा माहिती मान्यता अर्ज . कर्नाटक इन्ग्लिश मिडियम औफ कावेरी एजुकेशन

इंग्रजी माध्यम, पुणे ११ ते १७ वर्षगटांतील मुलांमुलीच्या पालकांसाठी वा त्यांच्या स्थानिक पालकांसाठी तयार करण्यात आला असून आम्ही त्यांना यासाठी आमंत्रिम करीत आहोत.

ऐच्छिक प्रतिक्षा यादी नियंत्रित अभ्यास

किशोरवयीन मुलां व मुलींसाठी लठठपणा वर योग थेरपी द्वारा एकात्मिक दष्टिकोन प्रभाव

(शाळेतील ११ ते १७ वर्ष वयोगटातील मुलांमुलींसाठी)

मुख्य संशोधकाचे नाव :- डॉ. पदमिनी टेकूर

सहकारी संशोधकाचे नाव :- डॉ. एच. आर. नागेंद्र

संस्थेचे नाव :- स्वामी विवेकानंद योग अनुसंधान संस्था (एस.व्यासा)

प्रायोजकाचे नाव :- आयुष विभाग

खाजगी प्रायोजकाचे नाव :- रामकुमार राठी, कन्स्ट्रक्शन हाउस, ७९६/१८९ भांडारकर रोड, पुणे ४११००४, महाराष्ट्र

हया माहितीपूर्ण संमति पत्रकाची दोन भागात विभागणी करण्यात आली आहे.

- महिती पत्रक - आपणांशी संशोधनाबाबतची माहितीची देवाणघेवाण करणे
- संमति प्रमाणपत्र - आपला पाल्याला या संशोधन कार्यात भाग घेण्यासाठी आपण सहमत असल्यास आपल्या स्वाक्षरीचे पत्र

आपणांस संपूर्ण माहितीपूर्ण संमति पत्राची एक प्रत देण्यात येईल.

भाग १ : - माहिती पत्रक

परिचय :

मी डॉ. सुनंदा सुरेंद्र राठी एस व्यासा योगा विश्वविदयापीठाची पी.एच डी संशोधक असून किशोरवयीन मुलांमधील लठठपणा व त्यावर योग थेरपी एकात्मिक दष्टिकोन प्रभाव या विषयावर संशोधन करीत आहे

शाळेमध्ये जाणा-या ११ ते १७ वर्ष वयोगटातील मुलांसाठी

माझे हे संशोधनाचा आपल्या मुलाचा लठठपणा कमी होण्यास व त्याचे स्वास्थ नियंत्रित राहण्यास निश्चितच उपयोग होईल. आमच्या संशोधन निकषानूसार या संशोधनात मुले व मुलीं मिळून १०० जणांचा समावेश असेल व त्यांना याबाबत काही प्रश्न विचारण्यात येतील. माझा मुलांसंबधीचा अभ्यास पूर्ण झाल्यानंतर मी आपल्यांशी चर्चा करेन व नंतरच आपणांस आपल्या परवानगीबाबत विचारेल. आपण याचा अधिक अभ्यास करून वा ऐकून व आपणांस मान्य असेल तरच नंतर पुढे जाण्यात येईल व आपल्या पाल्याशी वा मुलांमुलींशी चर्चा करून त्यांच्याकडून संमतिपत्र घेण्यात येईल. मी संशोधन सुरु करण्याआधी आपण व आपला पाल्य दोघांचीही स्वतंत्रपणे संमती आवश्यक असणार आहे.

आपण याबाबत आपल्या पालकांशी वा आपल्या मित्रपरिवरातील आपणांस योग्य वाटणा-या व्यक्तिशी चर्चा करून या संशोधनात भाग घ्यावयाचा का नाही याबाबत सविस्तर चर्चा करू शकता. आपण याबाबत पूर्ण विचार करूनच निर्णय घ्यावा. याबाबत त्वरीत निर्णय घेण्याची आवश्यकता नाही.

मी आपणांस या विषयाची माहीती देवून या संशोधनाचा हिस्सा बनण्यासाठी आमंत्रित करीत आहे. ययामध्ये असे काही शब्द असतील की ते तुम्हाला समजणार नाहीत ते समजण्यासाठी आपण कोणाशीही चर्चा करून समजून घेवू शकता. या संशोधनाबाबतवी माहिती देत असतांना आपणांस काही प्रश्न शंका असतील तर आपण त्या माहिती देत असताना सुध्दा विचारू शकता. आपल्या सर्व शंकाचे निरसन केले जाईल आणि तरी देखील आपल्या मनात काही शंका असल्यास आपण संशोधन प्रमुखाला देखील विचारू शकता.

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संशोधन हेतू :

बालवयातील लठठपणा कमी करणे वा त्यास नियंत्रित करणे जेणे करून पुढे काही मोठा धोका निर्माण होवू नये हा या संशोधनाचा प्रमुख हेतू आहे.

पाश्चिमात्य जीवनशैलीच्या प्रभावामूळे आपणांकडे बाल वयातील लठठपणा ही वैदयकिय व सामजिक चिंतेचा विषय बनली आहे. दूरदर्शन वाढता प्रभाव, अति उच्च कॅलरीजचे अन्न थोडक्यात फास्ट फूड , त्यामूळे येणारी शारिरीक कमतरता हे बालवयातील लठठपणाची प्रमुख कारणे सांगता येतील. हा बाल वयातील लठठपणा तरूणवयात मोठा धोकादायक ठरू शकतो व त्यामूळे वैदयकिय व मानसिक गुंतागुंत वाढू शकते. मधुमेह, इन्शुलिनच्या कमतरतेमूळे रक्त व लघवीमध्ये साखर आढळणे, उच्च रक्तदाब, स्त्री बीजांचा प्रॉब्लेम, व त्यामूळे येणा-या शारीरिक विकती त्यामध्ये विस्मरण, मज्जातंतू दाह, भ्रम, थकवा, शारिरिक लुळेपणा आदि.चा प्रादुर्भाव प्रकर्षाने जाणवतो. या गोष्टींचा प्रतिबंध व लठठपणावर वेळीच उपचार हेतु संपूर्ण परिवाराच्या जीवनशैलीत बदल करणे हे या संशोधनाचा हेतू आहे

यावर योग हे लठठपणा व्यवस्थापन यासाठी एक प्रभावी साधन असल्याचे दिसून आले आहे. नियमित योगा सरावामूळे वजन वाढण्याचे प्रमाण कमी झाल्याचे या संशोधनात आढळून आले आहे.

आपल्या शालेय अभ्यासक्रमात योगा सराव समाविष्ट नाही आणि योगा सराव आजच्या किशोरवयीन मुलांमुर्लीसाठी निश्चितच महत्त्वाचा आहे. आमच्या या संशोधनात किशोरवयीन मुलांमुर्लीसाठी शरीराचा योग्य तो समतोल राखण्यासाठी व त्यास स्वाथ्यपूर्ण ठेवण्यासाठी आरोग्यपूर्ण आहाराचा व त्या अभ्यासाचा देखील समावेश केला आहे. आम्ही त्यांना आमंत्रित करीत आहोत की त्यांनी आपले ज्ञान व समज आमच्याबरोबर शेअर करावे वा वाटावे जेणे करून त्यांच्या गरजा आमच्या लक्षात येतील.

सहभागी हस्तक्षेप प्रकार :

या संशोधनात संपूर्ण क्लोलेस्ट्रॉल(mmol/l) ट्रायग्लिसराइडस (mmol/l) HDL/ LDL, विविध रक्त चाचण्या, एन्थोपामेट्रिक मोजमाप, वजन, माप, उंची, पोटाचा घेर, मानसिक प्रश्नावली व त्यांची उत्तरे, सर्वसामान्य कामे आदिंचा समावेश असेल. व असे दोनदा केले जाईल.आपल्या मानसिक बाबी जाणून झोण्याकरीता आपणांस काही प्रश्न विचारले जातील त्याची उत्तरे आपणांस देणे बंधनकारक असेल. आपणांस वरील सर्व गोष्टी यात भाग घेण्यापूर्वी व पुन्हा ५ आठवडयानंतर करावयाचे आहे.

आपली शाळेची वेळ संपल्यानंतर ६० मिनिटे आपल्याला खर्च करावी लागतील वा थांबावे लागेल. सुरूवातीला ५ आठवडे, आठवडयातून पाच दिवस ६० मिनिटे योग प्रशिक्षण आपल्या शाळेच्या आवारात देण्यात येईल

सहभागी निवड :

या योग संशोधनात आम्ही ५ वी ते १० वी मधील विदयार्थ्यांना आमंत्रित करीत आहोत जे विदयार्थी आमच्या संशोधनातील संशोधनाचे सर्व निकष पूर्ण करतील त्यांनाच या संशोधनात सहभागी करण्यात येईल.या संशोधनाच्या सर्वंकष परिणामाकरिता विदयार्थ्यांचे दोन गट तयार करण्यात येतील. हे दोन गटांची निवड अत्यंत नि:पक्षपातीपणे करण्यात येईल.

स्वयंसेवी सहभाग :

जोपर्यंत तुमची मुले तुमच्याशी या विषयावर चर्चा करीत नाहीत तोपर्यंत आपण संमति देवू नका.या संशोधन कार्यात आपला सहभाग संपूर्णत: ऐच्छिक आहे. यामध्ये सहभागी व्हायचे किंवा नाही हे पूर्ण आपल्यावरच अवलंबून आहे. कारण लठठपणा हा विषय संवेदनशील आहे आणि असे असताना पालकांना जरा कठीणच वाटते.त्यासाठी आपण वेळोवेळी प्रश्न विचारू शकता त्यांचे उत्तरे आपणांस निश्चितच देण्यात येतील. आपण त्वरीत निर्णय करण्यावी गरज नाही. आपण यावर पूर्णपणे सारासार विचार करा आणि नंतरच मला आपला निर्णय कळवा.

आपणांस आपल्या मुलाला या संशोधनात सहभागी करण्याची इच्छा नसेल तर आपण आणखी पर्याय आमच्याकडे उपलब्ध आहेत.

आपल्या मुलाला या संशाधनात भाग घ्यावयाचा नाही परंतु आपली तशी इच्छा नसेल याबाबत आपणांस काही प्रश्न आहेत का ?

प्रक्रिया :

जेव्हा ही संशोधन प्रक्रिया सुरू होईल त्यावेळी यामध्ये कोणत्या पाय-या आहेत वा याची प्रक्रिया कशी आहे हे समजावून घेवू. यामध्ये एक सर्व्हे म्हणजेच निरिक्षण करण्यात येईल व तो केव्हा कुठे एकत्रित करावयाच्या वा कुठे त्याची वाटणी करावयाची हे पाहावे लागेल.

१.आपला मुलगा किंवा मुलीला प्रथम एका चर्चासत्रामध्ये भाग घ्यावा लागेल.त्यामध्ये त्यांच्याबरोबर त्यांच्यास वयाशी साधर्म्य असलेल्या म्हणजेच वय ११ ते १७ वयोगटातील विदयालय मराठी व इंग्रजी माध्यम मुले व मुली असतील. मुला व मुलींचे वेगवेगळे दोन गट तयार करण्यात येतील.या चर्चासत्रास या विदयालयाचे मुख्याध्यापिका किंवा मी डॉ. सुनंदा राठी मार्गदर्शन करतील.

२. आमच्या योग पध्दती सुरू होण्यापूर्वी आपल्या मुख्याध्यापिका व माझे बरोबर दर शनिवारी आयोजित चर्चासत्रामध्ये आपली मुली वा मुली भाग घेवू शकतात.

३. प्रश्नावली सर्वेक्षण वा निरिक्षण

माझे मार्फत आपल्या मुला मुलींना एक छायांकित प्रश्नावली देण्यात येईल आणि ती गोळा करण्याची जबाबदारी शाळेने नियुक्त केलेल्या व्यक्तिची वा अधिका-याची असेल.ही प्रश्नावली जोरात वावून देखील सांगण्यात येईल. त्याची उत्तरे त्यांनी मला लिखित स्वरूपात दयावयाची आहेत.

ही प्रश्नावली त्यांचे दैनंदिन व्यवहार, खाण्यापिण्याच्या सवयी, शारिरीक व्यायाम आणि स्वत:बददलचा आत्मसन्मान वा प्रशंसा याच्याशी निगडीत आहे. ही प्रश्नावाली आम्हांस आपल्या मुलांच्या व्यक्तिमत्त्व समजावून घेण्यास मदत होईल.

प्रथमत: माझी चर्चा शाळेतील शिक्षक, मुख्याध्यापिका, वर्गशिक्षक व प्रशासकासोबत होईल. या चर्चासत्रामध्ये या संशोधनाबददल आम्ही त्यांना देखील प्रश्न विचारणा आहोत.त्यानंतर सामुदायिक आरोग्य प्रणालीबाबत प्रश्न विचारणार आहोत. या चर्चासत्रामध्ये आम्ही त्यांना आरोग्य विषयक माहिती गोळा करण्यासाठी सांगणार आहोत व ही माहिती कोठे व कशी उपलब्ध होईल याविषयी चर्चा करणार आहोत. आम्ही त्यांना आपले दैनंदिन व्यवहार , आहार , पोषण सवयी व इतर आरोग्य विषयक गोष्टी बोलण्यासाठी प्रोत्साहित करणार आहोत व अशा प्रकारचे प्रश्न आम्ही त्यांना विचारणार आहोत.आम्ही त्यांना त्यांच्या व्यक्तिगत आयुष्याबददल व ते आमच्याशी काही विषय शेअर करणार नसतील त्याविषयी काहीही प्रश्न विचारणार नाही.

हे चर्चासत्र हे शाळेच्या आवारातच होईल आणि मी स्वत: व चर्चासत्रात भाग घेतलेले मार्गदर्शक वा प्रशासक यात भाग घेवू शकतील दुसरे कोणीही यामध्ये भाग घेवू शकणार नाहीत.

४.खालील माहिती फक्त प्रश्नावली व निरिक्षण करण्यासाठीच लागू होईल.

या प्रश्नावलीतील समाविष्ट प्रश्नांपैकी एखादया प्रश्नाचे उत्तर देण्याची आपल्या पाल्याची तयारी नसेत तर ते दुस-या प्रश्नावर जावू शकतात त्यांना उत्तर देणे बंधनकारक नाही.ही माहिती अत्यंत गोपनीय असेल व ती फक्त माझेकडे म्हणजेच डॉ. सुनंदा राठी यांचेकडेच असेल. ही प्रश्नावली १२ ते १५ महिन्यांची संशोधन प्रक्रिया व प्रोटोकॉल पूर्ण झाल्यानंतर नष्ट करण्यात येईल.

एकदा का आपण या संशोधन कार्यात वा अभ्यासात सहभाग वा प्रवेश निश्चित केल्यानंतर आपल्या पाल्यास एक प्रश्नावली देण्यात येईल त्याची उत्तरे त्याने लेखी स्वरूपात लिहावयाची असेल.ही प्रश्नावली आधी म्हणजेच संशोधनापूर्वी व ५ आठवडयांचे प्रशिक्षण वा संशोधन पूर्ण केल्यानंतर देखील घेण्यात येईल.या योग प्रभावांचे परिक्षण करण्यासाठी आपणा मुलांचे दोन गट करण्यात येतील. हे दोन गटांची निवड अत्यंत नि:पक्षपातीपणे करण्यात येईल.

हे दोन गट तयार झाल्यानंतर एका गटाला योग सराव प्रशिक्षण दिले जाईल तर दुस-या गट दररोजच्या सामान्य क्रिया सुरू ठेवतील. यात एक महत्त्वाचे असे आहे कि आम्ही ना आपण कोणत्या गटात आहोत हे ओळखू शकत नाही त्याचबरोबर प्रशिक्षणामध्ये समाविष्ट विदयार्थ्यांना हे पण माहित नसेल की आपण कोणत्या गटात आहोत. ही माहिती आमच्याकडे सुरक्षित असेल पण संशोधन पूर्ण होईपर्यंत ती उघड केली जाणार नाही. मग आम्ही या दोन गटात सर्वोत्तम कोण आहे याची तुलना करणार आहोत.आमचा असा विचार किंवा आम्हाला अशी आशा आहे कि हा एक परिक्षणाचा सर्वोत्तम पर्याय आहे.

या प्रशिक्षण संशोधनाबाबत आपण असमाधानी असाल किंवा काही त्रुटी असतील तर आपण मुख्य संशोधकांशी चर्चा वा विचार विनिमय करू शकता.

ब.प्रक्रिया वर्णन:

१. या प्रशिक्षण वा संशोधनाच्या पहिल्या भेटी दरम्यान आम्ही आपल्या पाल्यास माहितीपूर्ण संमति फॉर्म देवू व त्यांना या संशोधनाच्या प्रक्रिसयेबाबतची सर्व माहिती समजावून सांगू वा देवू. आपले व आपल्या पाल्याचे संमति पत्र मिळाल्यानंतरच आम्ही त्यांना त्यांच्या सामान्य आरोग्याविषयी व त्यांच्या वजन , उंची विषयी वा शारिरिक मोजमापाविषयी त्यांना काही प्रश्न विचारण्यात येतील

२. पहिल्या सत्रामध्ये आपले थोडे ५ एम एल रक्त इंजेक्शनद्वारे काढून घेण्यात येईल. हे रक्ताचे योग्य असे परिक्षण केले जाईल कि आपले शरीर हे प्रशिक्षणासाठी तयार आहे किंवा नाही त्याचप्रमाणे आपल्या रक्तामध्ये रोगप्रतिकार शक्ती किती प्रमाणात आहे याचे देखील परिक्षण करण्यात येईल. व आपण या प्रशिक्षणासाठी तयार आहात का नाही याचे मूल्यांकन करण्यात येईल. आमच्या नंतरच्या भेटी दरम्यान म्हणजेच ५ आठवडयांच्या प्रशिक्षणानंतर आपल्याला पुन्हा आपल्या शारिरीक स्वास्थ्य आणि रक्त चाचणीबाबत काही प्रश्न विचारण्यात येतील.आणि थोडे ५ एम एल रक्त इंजेक्शनद्वारे परिक्षणसाठी घेण्यात येईल. **पालकानचि परवानगी मिळाल्यास**

३. एक या दोन दिवसानंतर आपली दोन गटामध्ये विभागणी करण्यात येईल. एक योगा गट व दुसरा विना योगा गट . - सामान्य गट. आधी सांगितल्याप्रमाणे आपण कोणत्या गटात आहोत ते आम्होस वा आपल्या पाल्याला देखील माहीत नसेल.

४. आपला पाल्य जर योगा गटात निवडला गेला असेल तर त्यास शाळेच्या आवारात शाळा सुटल्यानंतर ६० मिनिटे या योगा प्रशिक्षणासाठी आठवडयातून ५ वेळा असे ५ आठवडे संशोधनासाठी थांबाबे लागेल.

आधी सांगितल्याप्रमाणे ५ आठवडयांच्या कालावधी नंतर सुध्दा आपली चाचाणी घेण्यात येईल.हया संशोधना दरम्यान घेतलेले जैविक नमुने अर्थात रक्त वगैरे हे फक्त या संशोधनासाठीच वापरले जातील.संशोधन कार्य संपल्यानंतर ते नष्ट करण्यात येतील. दोन्ही वेळेस आपल्या हातामधून ५ एम एल रक्त सुई व सिरींजद्वारा घेण्यात येईल. **पालकानचि परवानगी मिळाल्यास**

५. ५ आठवडयानंतर सामान्य ग्रुप म्हणजेच नॉन योगा ग्रुप ला जर योगा प्रशिक्षण हवे असल्यास त्यांना सुध्दा देण्यात येईल.

कालावधी :

आपल्या पाल्याच्या वेळेनूसार वा सोयीनूसार चर्चेत सहभागी होण्यासाठी आमंत्रित करू अथवा त्यांना विचारू. ही चर्चा त्यांची शाळा सुटल्यानंतर शाळेच्या आवारातच करण्यात येईल. तेथे एक अजून प्रश्नावली आम्ही आपल्या पाल्यास देवू अथवा आम्ही तेथेच एकत्रित त्याची उत्तरे सोडवू. हे एका तासाचे कार्य आहे परंतु जर आपण आपल्या पाल्याला या प्रशिक्षणामध्ये वा संशोधनामध्ये सहभागी करावयाचे ठरविले तर आम्ही आपल्या पाल्याला दोन तासासाठी देखील विचारू पंरतु तेवढा वेळ त्याच्याकडे असावयास हवा.

हया संशोधनाचा कालावधी अधिकाधिक ५ आठवडयांचा असेल.एकदा का आपणांस योग या गटामध्ये समाविष्ट करण्यात आले तर ५ आठवडे पाच वेळा असे २५ दिवस या प्रशिक्षणाला उपस्थित राहवे लागेल. प्रत्येक दिवशी आपणांस आपल्या परिसरासोबत एक तास आपणांस या योगा प्रशिक्षणासाठी दयावा लागेल.व त्याचप्रमाणे एक अनौपचारिक योग प्रशिक्षण सराव दिवसाचे देखील आयोजन करण्यात येईल. हे प्रशिक्षण आपणांस नक्की आवडेल.

दुष्परिणाम :

आधीच नमूद केल्याप्रमाणे या योग थेरपी केल्यानंतर कुठलेही दुष्परिणाम होत नाहीत. यामूळे आपणांस तात्पुरता शारिरीक थकवा, स्नायुंचे गठन, वेदना आदि तात्पुरते परिणाम होवू शकतात किंवा आपणांस माहित नसलेल्या समस्या देखील उदभवू शकतात.आम्ही याचे बारकाईने निरिक्षण करून त्याचे निराकरण करू अथवा आम्ही आमचे प्रशिक्षणचा सराव बंद करू.

धोका :

योगाचे प्रशिक्षण, अभ्यास वा सराव यांत कोणताही धोका नाही.

फायदे :

आपण या संशोधानात सहभागी असाल तर आपणांस या योगाभ्यासाचे प्रशिक्षण पूर्णपणे मोफत देण्यात येईल. या संशोधनात कदाचित आपला काहीच फायदा होणार नाही पण कदाचित आमच्या संशोधनासाठी याचा नक्कीच उपयोग होईल. असे पण होण्याची शक्यता आहे कि आज या संशोधनाचा फायदा आपणांस होणार नाही पण आम्हांस विश्वास आहे कि पुढच्या पीढीसीठी हे नक्कीच उपयुक्त ठरेल.

शुक्ल वा आदि.

या संशोधनात वा प्रशिक्षणामध्ये भाग घेण्यासाठी आपणांकडून कोणतेही शुल्क वा देणगी आकारण्यात येणार नाही. हे प्रशिक्षण वा संशोधन पुर्णपणे मोफत असेल. आपण मला सांगू शकता की हे प्रशिक्षणाचा वा संशोधनाची प्रक्रिया आपणांस पूर्णपणे अचूक समजली आहे ना. आपणांस हे माहित आहे की जैविक चाचाणी म्हणजेच रक्त तपासणी व योगा प्रशिक्षकाचे शुल्क आम्ही भरणार आहोत. आपले अजून काही प्रश्न आहेत का

गोपनियता :

या संशोधना दरम्यान आम्ही एकत्रित केलेली सर्व माहिती ही गोपनीय ठेवली जाईल.या संशोधनाच्या वेळी एकत्रि केलेली माहीती ही फक्त संशोधनकर्ताच पाहू शकेल.आपल्या माहीतीच्या पुढे आपल्या नावाऐवजी एक नंबर दिला जाईल फक्त संशोधनकर्त्यालाच त्याविषयी माहीती असेल व इतर वेळी ही सर्व माहीती कुलुपबंद असेल. हे एकत्रित केलेले संशोधन, संशोधन कर्ता व सहभागी सोडून कोणालाही दिले जाणार नाही.

आम्ही आपल्या पाल्यास व गटातील प्रत्येकाला हे सांगणार आहोत वा सांगितले आहे की बाहेरील कोणत्याही व्यक्तिला काहीही सांगावयाचे नाही. दुस-या शब्दात सांगावयाचे झाले तर आम्ही प्रत्येकाला याची माहिती दिलेली असणार आहे. आणि आपणांस माहिती आहे कि आपण कोणासही प्रत्येक गोष्टी त्यांच्या गटात वा बाहेर शेअर करण्यासाठी प्रतिबंध करु शकत नाही.

परिणाम व त्याचे सामायिकीकरण :

या संशोधनाद्वारे आम्हांस जे ज्ञान प्राप्त झाले आहे त्याची माहिती देण्यासाठी आपल्या सोयीनूसार आठवडयातून एकदा वा शनिवारी बैठक वा चर्चासत्रांचे आयोजन करण्यात येईल पंरतु गोपनीय माहीती ही सांगण्यात येणार नाही व त्याकरीता पालक व शिक्षकांची शनिवारी बैठक घेण्यात येईल. या

समपुदेशन सत्रानंतर आम्ही आमचे संशोधन अन्य लोंकासाठी प्रकाशित करू. त्यासाठी आम्ही प्रथम सहभागी मुलांमुर्लींची बैठक घेवू आणि नंतर मोठया समुदायाशी चर्चा करू. आम्ही आपणांस अश्वस्थ करू इच्छितो कि सदर माहिती मध्ये आपल्या पाल्याचे नाव कोठेही येणार नाही ते अगदी गोपनीय ठेवले जाईल.या संशोधनाचा लिखित अहवाल यामध्ये सहभागी मुलांमुलीना देण्यात येईल ते तो आपल्या परिवाराशी शेअर करू शकतात. आम्ही हे संशोधन वा निकाल प्रकाशित करणार आहोत जेणेकरून समाजातील अनेक लोक या संशोधनाचा लाभ घेवू शकतील.

मनाई वा मागे घेण्याचा अधिकार :

आपली इच्छा असेल तरच आपण या संशोधनात भाग घेवु शकता अन्यथा आपण हे नाकारू शकता त्यामूळे आपणांवर कोणताही परिणाम होणार नाही.आपण आपल्या शाळेतील रोजचे कार्य प्रकल्प करू शकता. आपण आपल्या इच्छेनुसार केव्हाही हे संशोधन थांबवू शकता वा सोडू शकता. आपण आपल्या पाल्यास सहभागी न करणे हा पर्याय देखील निवडू शकता किंवा आपल्या पाल्यास यामध्ये सहभागी होण्याची इच्छा नसेल तर आपण यामध्ये भाग घेण्याचा विचार करू नका.

संपर्क :

आपणांस काही प्रश्न असतीलतर तुम्ही आम्हांस आता किंवा नंतर कधीही प्रश्न विचारू शकता किंवा प्रशिक्षण सुरु झाल्यानंतरदेखील विचारू शकता. आपल्याला नंतर काही प्रश्न वा शंका विचारवयाच्या असतील तर आपण खाली दिलेल्या व्यक्तिंशी संपर्क करू शकता.

या योगा प्रशिक्षणामध्ये काही इजा वा त्रास झाल्यास खालील जबाबदार व्याक्तिंशी संपर्क साधावा.

शाळेच्या मुख्यध्यपिका -- पल्लवी नाईक -- ०९४२२०१६०११ ०२० २५४५६३२८

आयोजिका --- वैशाली आयोजिका वैशाली शिंदे - ०९८८१८७७१५८

माहीती संमति अर्ज संबंध : त्या शाळेच्या मुख्याध्यापिका आहेत.

काळजी घेण्यासाठी पगारी योगा प्रशिक्षक नियुक्त केला जाईल.

डॉ. सुनंदा राठी , संशोधक - मो. - ९८६०१००२५१, ई मेल : sunandarathi@gmail.com

आपण विदयालय मराठी व इंग्रजी माध्यमच्या मुख्याध्यापिका, संचालिका अथवा नियुक्त प्रशासक यांच्याशी देखील संपर्क करू शकता.

या प्रस्तावाचे पुर्नलोकन आणि समीक्षा एस. व्यासा विश्वविदयालयद्वारा संमत करण्यात आला आहे. हा प्रस्तावातील सर्व माहीती वा सहभागी आयईसी समिति द्वारा संरक्षित आहेत. आपण या आयईसी समितिच्या अधिक माहीतीसाठी तांत्रिक समन्वयकशी संपर्क करू शकता. संपर्कासाठी पत्ता :तांत्रिक समन्वयक, एसव्यासा, नं १९, एकनाथ भवन,गोविपुरम सर्कल, केएमपेगोडा नगर, बंगलौर - ५६००१९, दूरध्वनी : ०८० २६६१२६६९

आपणांस या प्रशिक्षणाबाबत अजून काही प्रश्न असल्यास नि:संकोचपणे विचारू शकता. आपल्या मनात या संशोधनाविषयी अजून काही शंका वा प्रश्न आहेत ?

भाग दुसरा : समंति प्रमाण पत्र

माझे पाल्याने या संशोधन प्रशिक्षणाच्या या चर्चेत वा मुलाखतीमध्ये भाग घेतला होता त्यात त्याने देण्यात आलेल्या प्रश्नावलीची योग्य प्रकारे उत्तरे दिली होती उदा. दैनंदिन सवयी, आहार, शारिरीक आणि जैविक चाचण्या आदि. व त्यानंतरच मला या संशोधतनात माझे पाल्यास या संशोधनात भाग घेण्याच्या परवानगी बाबत विचारण्यात आले.

मी या प्रशिक्षणासंबंधी सर्व मागील माहीती वाचली आहे व मला वाचून दाखविण्यात आली आहे. मला काहीही प्रश्न वा शंका असल्यास ते विचारण्याची संधी देखील संधी देखील देण्यात आली होती व त्यामूळे या संशोधनाविषयी माझे प्रश्नांची मला समाधानकारक उत्तरे मिळाली आहेत. व त्यामूळे मी माझे पाल्याला या संशोधनात वा प्रशिक्षणात सहभागी होण्यासाठी स्वच्छेने समंति देत आहे.

पालकांचे वा स्थानिक पालकांचे नाव :

पालक वा स्थानिक पालक स्वाक्षरी :

दिनांक : / /

तारिख/महिना/वर्ष

पालक वा स्थानिक पालक निरक्षर असल्यास :

त्याकरीता त्यांच्या वतीने साक्षीदाराने स्वाक्षरी करणे आवश्यक आहे. (शक्य असल्यास त्यांनी सहभागी पाल्यांच्या पालकांपैकी कोणाची तरी निवड करावी आणि त्यांनी या संशोधनकर्ता व त्यांच्या सहका-यांशी कायम संपर्कात असणे अनिवार्य आहे.) सहभागी पाल्याचे पालक जर निरक्षर असतील त्यांना त्यांचा अगंठा सही म्हणून मुद्रित करणे आवश्यक आहे.

मी खाली सहभागी पाल्याच्या पालकांच्या वतीने साक्षीदार या नात्याने सही करणार आपणांस नमूद करू इच्छितो की संभाव्य संमति अर्ज मी अचूकपणे वाचला आहे व समजावून घेतला आहे व मला त्याबाबत काहीही प्रश्न वा शंका असल्यास ते विचारण्याची संधी देखील संधी देखील देण्यात आली होती व त्यामूळे या संशोधनाविषयी माझे प्रश्नांची मला समाधानकारक उत्तरे मिळाली आहेत. व त्यामूळे मला विश्वास आहे कि त्यांनी स्वेच्छेने व विश्वासावर हा संमति अर्जावर स्वाक्षरी करीत आहेत.

साक्षीदाराचे नाव :

साक्षीदाराची सही : सहभागी पाल्याच्या पालकांचा अगंठा

दिनांक : / /

तारिख/महिना/वर्ष

संशोधन कर्ता व त्याचे व्यक्तव्य :

मी याचा/याची साक्षीदार आहे कि या प्रशिक्षणाची अचूक माहीती सर्व सहभागी विदयार्थ्यांच्या पालकांना वाचून दाखविली आहे व समजुन सागिंतली आहे आणि मला खात्री आहे की त्यांना खालील बाबींचे स्पष्टीकरण व्यवस्थितरित्या मिळाले आहे.

१. सहभागी पाल्यास एक प्रश्नावली देण्यात येणार आहे व त्यावरून त्यांची एक लेखी परिक्षा घेण्यात येणार आहे व त्याची उत्तरे त्यांनी प्रशिक्षणाच्या सुरूवातीस व १२ आठवडयांचे प्रशिक्षण संपल्यानंतर देखील दयावयाची आहेत.

२. जैविक चाचणी साठी त्यांचे ५ एम एल रक्त प्रशिक्षणाच्या सुरूवातीस व १२ आठवडयांचे प्रशिक्षण पूर्ण झाल्यानंतर चाचाणी साठी घेण्यात येईल.

३. यात त्यांना १२ आठवडे भाग घेणे अनिवार्य आहे.

४. तीन महिन्यांचे आहार वा जेवण सेवनाची माहिती आवश्यक आहे.

मी प्रतिज्ञापूर्वक सांगते की या संशोधनाबाबत प्रश्न वा शंका विचारण्याची संधी मी प्रत्येक पालकांस दिली होती व त्यांच्या सर्व प्रश्नांची माझे अभ्यासाप्रमाणे वा ज्ञानाप्रमाणे त्यांना समजतील अशा शब्दात त्यांना स्पष्टीकरण दिले आहे वा उत्तरे दिली आहेत आणि मला विश्वास आहे की सर्वांनी स्वेच्छेने व पूर्ण संमजसपणे या संशोधनास संमति दिली आहे.

हया संमति अर्जाची छायाप्रत सर्व पालकांना देण्यात येईल.

संशोधकाचे नांव वा ज्याने हा संमति अर्ज घेतला आहे त्याचे नाव : डॉ सुनंदा राठी

संशोधकाची सही :

दिनांक :

दिनांक/महिना/वर्ष

1.4: SCHOOL CONSENT

MALPANI FOUNDATION'S
DHRUV ACADEMY
CBSE affiliated day boarding cum residential school (Affiliation No. 1130187)
Malpani Campus, Dhandharphal, Akole Road, **Sangamner** 422 603, Dist. Ahmednagar (M.S.)
Ph.02425 - 260006, 260015 Fax : 260034. Cell: 8805088005 Email : info@dhruvacademy.com, website : www.dhruvacademy.com

Date: 13 June 2016

To,
Dr. Sunanda S Rathi,
Yoga Researcher,
CEO, Yoga Division,
Rathi Tech Services Pvt. Ltd

Subject: Letter of Consent for **'Effect of Integrated Approach of Yoga Therapy on Adolescent Obesity Programme'**

Dear Madam,

With the reference of subject cited above, I Principal of Dhruv Academy, do hereby give my consent to conduct **Effect of Integrated Approach of Yoga Therapy on Adolescent Obesity Programme** for children age group from 11 to 16 years, to be held at Dhruv Academy Sangamner in the month of July 2016.

Thanking you in anticipation,

Sincerely yours,

Mrs. Archana Ghorpade
Principal

Head Office: Malpani House, I. G. Road, Sangamner- 422605, Dist. Ahmednagar Phone : 02425 - 225011 Fax : 225003

2.0: DEMOGRPHIC DATA FORM

SOCIO-DEMOGRAPHIC DATA-SHEET

(Yoga for Adolescent Obesity Project)

Reg. No…… Date - ……..

Name of Student :- ……..

Age :- …….. STD. …… Sec. …… Roll No……..

Name of Parent :- ……

Age :- …… Gender:- . ……

Education :- 12 yrs (H. S. C.) + …… yrs = …… yrs of Academics.

Undergraduate Graduate Post graduate

Occupation :-

Student Unemployed Self -Employed

Public Sector Professional Private Sector Professional

Family :- Nuclear Extended

Marital Status :-

Single Married Divorced Separated

No. of Children :- ……

Family Income / year :-

- INR 1,00,000 -- INR 5,00,000
- INR 5,00,000 -- INR 10,00,000
- INR 10,00,000 -- INR 15,00,000
- ≥ INR 15,00,000

1

Parent Details

Address :- ……

……..

……..

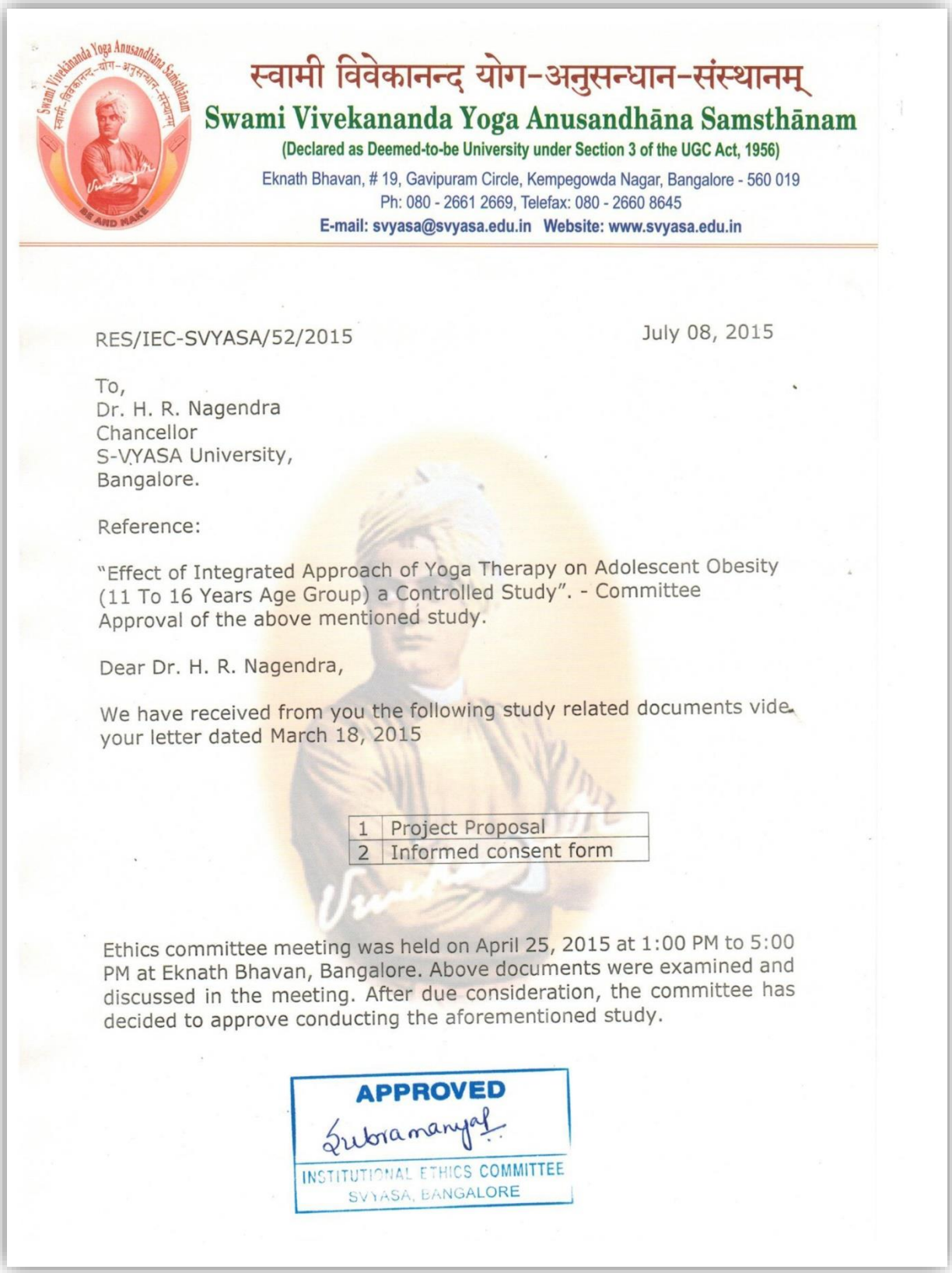
……..

……..

Contact no. :- ……..

Mail ID:-……

3.0 INSTITUTIONAL ETHICAL COMMITTEE APPROVAL



स्वामी विवेकानन्द योग-अनुसन्धान-संस्थानम्
Swami Vivekananda Yoga Anusandhāna Samsthānam
(Declared as Deemed-to-be University under Section 3 of the UGC Act, 1956)
Eknath Bhavan, # 19, Gavipuram Circle, Kempegowda Nagar, Bangalore - 560 019
Ph: 080 - 2661 2669, Telefax: 080 - 2660 8645
E-mail: svyasa@svyasa.edu.in Website: www.svyasa.edu.in

RES/IEC-SVYASA/52/2015 July 08, 2015

To,
Dr. H. R. Nagendra
Chancellor
S-VYASA University,
Bangalore.

Reference:

"Effect of Integrated Approach of Yoga Therapy on Adolescent Obesity (11 To 16 Years Age Group) a Controlled Study". - Committee Approval of the above mentioned study.

Dear Dr. H. R. Nagendra,

We have received from you the following study related documents vide your letter dated March 18, 2015

1	Project Proposal
2	Informed consent form

Ethics committee meeting was held on April 25, 2015 at 1:00 PM to 5:00 PM at Eknath Bhavan, Bangalore. Above documents were examined and discussed in the meeting. After due consideration, the committee has decided to approve conducting the aforementioned study.

APPROVED
Subramanyam
INSTITUTIONAL ETHICS COMMITTEE
SVYASA, BANGALORE

स्वामी विवेकानन्द योग-अनुसन्धान-संस्थानम्
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Ph: 080 - 2661 2669, Telefax: 080 - 2660 8645
E-mail: svyasa@svyasa.edu.in Website: www.svyasa.edu.in

This is to confirm that neither Dr. H. R. Nagendra nor any staff participating in this study were involved in the voting procedures and decision making.

The Institutional Review Board / Independent Ethics Committee (IEC) are expected to be informed about the progress of the study / any changes in the protocol and patient information / informed consent. The investigators are also expected to submit a copy of the final report to IEC for records.

This approval is valid up to the completion of the study at the site.

Please submit to the IEC, the status report of the study as per the SOPs.

The IEC is organized & operates according to the requirements of ICH-GCP, Indian Council of Medical Research Guidelines & Schedule Y.

Best Wishes,

Subramanya P

Dr. Subramanya P,
Member Secretary,
Institutional Ethics Committee,
S-VYASA, Bangalore.

4.0: QUESTIONNAIRES:-SAMPLE COPY

4.1 CHILD EATING BEHAVIOUR: ENGLISH

Child Eating Behaviour Questionnaire (CEBQ)

(Please read the following statements and tick the boxes most appropriate to your child's eating behaviour.)

Reg. No……. Date - ……..

Name of Parent :- ……

Name of Student :- ……..

Age :- …….. ……. Gender :- ……

STD. …… Sec. …….. Roll no. ……

	Never	Rarely	Some -times	Often	Always	
My child loves food	☐	☐	☐	☐	☐	EF
My child eats more when worried	☐	☐	☐	☐	☐	EOE
My child has a big appetite	☐	☐	☐	☐	☐	SR*
My child finishes his/her meal quickly	☐	☐	☐	☐	☐	SE*
My child is interested in food	☐	☐	☐	☐	☐	EF
My child is always asking for a drink	☐	☐	☐	☐	☐	DD
My child refuses new foods at first	☐	☐	☐	☐	☐	FF
My child eats slowly	☐	☐	☐	☐	☐	SE
My child eats less when angry	☐	☐	☐	☐	☐	EUE

Dr. Sunanda Rathi. (M.com, L.L.B., Phd.,YIC,YIDM,Yoga Reserecher)
Contact: Office Mobile: 9673008349,020 - 24330251 ., Mob. 9860100251 .
Mail : info.yicpune@gmail.com,yogainitiatives@gmail.com
Address: 1545/A,Yoga Initiative Centre, 404, Pinnacle Pride, Sadashiv Peth, Tilak Road, Pune – 411030.

1

My child enjoys tasting new foods	☐	☐	☐	☐	☐	FF*
My child eats less when s/he is tired	☐	☐	☐	☐	☐	EUE
My child is always asking for food	☐	☐	☐	☐	☐	FR
My child eats more when annoyed	☐	☐	☐	☐	☐	EOE
If allowed to, my child would eat too much	☐	☐	☐	☐	☐	FR
My child eats more when anxious	☐	☐	☐	☐	☐	EOE
My child enjoys a wide variety of foods	☐	☐	☐	☐	☐	FF*
My child leaves food on his/her plate at the end of a meal	☐	☐	☐	☐	☐	SR
My child takes more than 30 minutes to finish a meal	☐	☐	☐	☐	☐	SE

	Never	Rarely	Some -times	Often	Always	
Given the choice, my child would eat most of the time	☐	☐	☐	☐	☐	FR
My child looks forward to mealtimes	☐	☐	☐	☐	☐	EF
My child gets full before his/her meal is finished	☐	☐	☐	☐	☐	SR
My child enjoys eating	☐	☐	☐	☐	☐	EF
My child eats more when she is happy	☐	☐	☐	☐	☐	EUE
My child is difficult to please with meals	☐	☐	☐	☐	☐	FF

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My child eats less when upset	☐	☐	☐	☐	☐	EUE
My child gets full up easily	☐	☐	☐	☐	☐	SR
My child eats more when s/he has nothing else to do	☐	☐	☐	☐	☐	EOE
Even if my child is full up s/he finds room to eat his/her favourite food	☐	☐	☐	☐	☐	FR
If given the chance, my child would drink continuously throughout the day	☐	☐	☐	☐	☐	DD
My child cannot eat a meal if s/he has had a snack just before	☐	☐	☐	☐	☐	SR
If given the chance, my child would always be having a drink	☐	☐	☐	☐	☐	DD
My child is interested in tasting food s/he hasn't tasted before	☐	☐	☐	☐	☐	FF*
My child decides that s/he doesn't like a food, even without tasting it	☐	☐	☐	☐	☐	FF
If given the chance, my child would always have food in his/her mouth	☐	☐	☐	☐	☐	FR
My child eats more and more slowly during the course of a meal	☐	☐	☐	☐	☐	SE

Total Score :- .....

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4.2 ROSENBERG SELF ESTTEM SCALE

Psychological Assessment tool No. 2

ROSENBERG SELF-ESTEEM SCALE

Reg. No……. Date - ……..

Name of Student :- ……..

Age :- …… Gender :- ……

STD. …… Sec. …….. Roll no. ……

Instructions
Below is a list of statements dealing with your general feelings about yourself. Please indicate how strongly you agree or disagree with each statement.

1 -- Strongly agree
2 -- Agree
3 -- Disagree
4 -- Strongly Disagree

No.	*Questions*	*Scores*
1	On the whole, I am satisfied with myself.	
2	At times I think I am no good at all.	
3	I feel that I have a number of good qualities.	
4	I am able to do things as well as most other people.	
5	I feel I do not have much to be proud of.	
6	I certainly feel useless at times.	
7	I feel that I'm a person of worth, at least on an equal plane with others.	
8	I wish I could have more respect for myself.	

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1

9	All in all, I am inclined to feel that I am a failure.	
10	I take a positive attitude toward myself.	

Signature of Student :- ……

Name of Observer :- …….. …… Signature of Observer :- ……..

Scoring :- Total score :- ……. Negative Score :- ……..

Net score :- …….

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4.3 BODY AWRENESS

Psychological Assessment tool No. 1

Body Awareness Questionnaire

Reg. No…… Date - ……..

Name of Student :- ……..

Age :- …… Gender :- ……

STD. …… Sec. …….. Roll no. ……

Instructions:
Listed below are a number of statements regarding your sensitivity to normal, non emotive body processes. For each statement, select a number from 1 to 7 that best describes how the statement describes you and place the number in the box to the right of the statement.

Not at all True of me ***Very True of me***

1 2 3 4 5 6 7

No.	*Questions*	*Score*
1	I notice differences in the way my body reacts to various foods.	
2	I can always tell when I bump myself whether or not it will become a bruise.	
3	I always know when I've exerted myself to the point where I'll be sore the next day.	
4	I am always aware of changes in my energy level when I eat certain foods.	
5	I know in advance when I'm getting the flu.	
6	I know I'm running a fever without taking my temperature.	
7	I can distinguish between tiredness because of hunger and tiredness because of lack of sleep.	
8	I am aware of a cycle in my activity level throughout the day.	
9	I don't notice seasonal rhythms and cycles in the way my body functions.	

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1

* 10	As soon as I wake up in the morning, I know how much energy I'll have during the day.	
11	I can tell when I go to bed how well I will sleep that night.	
12	I notice distinct body reactions when I am fatigued.	
13	I notice specific body responses to changes in the weather.	
14	I can predict how much sleep I will need at night in order to wake up refreshed.	
15	When my exercise habits change, I can predict very accurately how that will affect my energy level.	
16	There seems to be a "best" time for me to go to sleep at night.	
17	I notice specific bodily reactions to being over hungry.	
18	I can accurately predict what time of day lack of sleep will catch up with me.	

Note: * indicates a reversed scored item.

Signature of Student :- ……

Name of Observer :- ……..

Signature of Observer :- ……

Scoring :-

Total score :- ……..

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4.4 :COGNETIVE ASSESSMENTS :4.4.1 DIGIT LETTER SUBSTITUTION TEST

Cognitive Assessment Tool No. 1

DIGIT LETTER SUBSTITUTION TEST

Reg. No……. Date - ……..

Name of Student :- ……..

Age :- …… Gender :- ……

STD. …… Sec. …….. Roll No……

Instructions:

1. Substitute the digit with corresponding letters as per the given key.
2. Substitute as many possible within the given time .
3. Start & stop only when told.

Substitute Letters :-

1	2	3	4	5	6	7	8	9
E	Y	L	D	J	R	H	T	N

6	2	4	1	5	7	9	3	2	6	8	5

5	4	7	8	1	2	3	4	9	6	3	7

2	4	6	7	8	9	3	1	2	3	7	4

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1

2	9	4	6	8	1	2	5	9	3	4	7

9	7	4	2	3	8	1	5	6	2	9	1

8	6	2	3	9	4	5	7	1	4	3	9

3	5	9	1	2	5	6	2	7	8	9	1

5	4	9	2	7	1	3	2	8	9	5	6

Signature of Student :- ……

Name of Observer :- ……..

Signature of Observer :- ……

Scoring :-

Total Attempted -- ……

Wrongly attempted -- ……

Net Score -- ……..

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4.4.2 SIX LETTERS CANCELLATION TEST

Cognitive Assessment tool No. 2

SIX LETTER CANCELLATION TEST

Reg. No…… Date - ……..

Name of Student :- ……..

Age :- …… Gender :- ……

STD. …… Sec. ……..

Instructions:

1. Search out the target letters given below & cancel them by slash. (/)
2. Cancel as many as possible within given time,
3. Start & stop only when told.

TARGET LETTERS

J T K M U F

J	G	Y	L	S	E	T	B	L	U	V	G	K	H	A	W	U	J	M	K	R	B
X	N	O	D	F	C	K	N	E	H	W	Z	L	J	S	D	Q	L	N	H	U	O
U	K	W	A	I	M	P	G	Q	X	M	F	Y	B	I	R	X	G	F	P	J	K
Z	V	B	H	J	S	Y	D	K	O	S	Q	T	M	P	O	E	I	A	T	L	E
T	L	Y	R	O	Z	L	F	A	U	I	N	Z	G	W	T	J	K	D	R	Y	A
D	S	Q	C	E	T	R	W	Z	J	A	E	H	L	U	Y	V	Z	S	O	N	X
E	W	K	F	H	M	N	C	P	X	R	O	K	I	C	R	F	G	P	I	K	S
G	U	A	P	S	V	I	O	B	D	C	S	F	X	E	H	W	Q	M	L	O	R
H	T	Y	G	D	L	U	Q	G	Y	W	A	B	Z	D	Y	V	U	A	E	Q	P
L	V	O	E	J	Z	F	T	L	E	M	H	Q	J	A	X	R	D	B	Z	N	J
S	W	N	Q	K	H	C	A	Z	N	O	I	S	M	L	E	J	S	H	G	T	F
A	P	F	X	O	R	I	J	B	D	P	K	W	I	J	K	O	R	I	B	Z	A

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1

R	T	Y	B	V	D	X	S	U	F	R	X	O	Q	B	T	B	X	W	D	S	Z
M	I	G	U	W	K	O	C	E	N	V	T	H	Z	M	N	C	U	Y	P	K	E

Signature of Student :- …….

Name of Observer :- …….. Signature of Observer :- ……

Scoring :- Total Attempted -- ……

Wrongly attempted -- …….

Net Score -- ……..

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5 : INTERVENTION MODULE FOR VALIDATION

MODULE DESIGNING
PRACTICES SELECTED FOR INTERVENTION BASED
ON FIVE KOSHAS

PLEASE GO THROUGH THE INTEGRATED YOGA PROGRAMME / MODULE AND CIRCLE / FILE THE APPROPRIATE RESPONSES.

1. Is the programmer content developed in keeping with the aim of study ?			
Not at all	Moderately	Very much	Score
0	1	2	

2. Do you think overall the yoga programmer will achieve its objective of treating obesity In Adolescents (school Children)			
Not at all	Moderately	Very much	Score
0	1	2	

3. SUGGESTIONS FOR ADDING / DELETING ANY CONTENT FROM THE PROGRAMME

4. COMMENTS

5. STGNATURE
DETAILS OF THE VATIDATION EXPERT
Full Name :
Email :
Mobile No. :
Designation :
Address :

MODULE DESIGNING
PRACTICES SELECTED FOR INTERVENTION BASED ON FIVE KOSHAS

Module designed for Adolescent (School Children Age 11 – 17Years)

Sr. no	Practices	Rounds	Minutes	Total Minutes	Score	Remark
1	Yogic Diet	--				FGD
2	Fasting	--				
3	Jalaneti	--				
4	Sutra neti	--				
5	Vamandhouti	--				
6	Laghushankhaprakshalana	--				
7	Trataka	--				
8	Kapalabhati	60	1		2	
9	Jogging with jumping : backward, forward and side with Mukhadhouti	3	2		2	
10	Backward and Forward Bending (PashchaataPurstaatanamana)	10	1		1	
11	Side Bending (ParshvaNamana /ParshvaKarshana)	5	1		1	
12	Back Swing (PrushthaAndolana)	5	1		1	
13	Hip twist (NitambaVyavartana)	5	2		2	
14	Hip Rotation (Nitambachankramana)	10	1		1	
15	Spinal Stretch with folded legs (Baddhapaadamerudandaprasaarana)	5	2		2	
16	Bhunaman	5	2		2	
17	Chakkichalana Stretch	5	1		1	
18	Butterfly	20	1		2	
19	Tiger Stretch (Vyaghraprasaarana)	5	1		2	
20	Dhanurasana and Dhanurasana Swing	5	1		2	
21	Surya Namaskara (5 dynamic and 1 slow)	6	8	8	2	
22	Ardha Kati Chakrasana	1	2		2	
23	Padottanasana	1	2		2	
24	Trikonasana	1	1		2	
25	Parivrittatrikonasana	1	1		1	
26	Vajarasana	1	1		1	
27	Ushtrasana	1	1		1	
28	Sasankasana	1	2		1	
29	Vakrasana	1	1		1	
30	Bhujangasana	1	1		2	

31	Shalabhasana	1	1		1	
32	Naukasanana	1	11		2	
33	QRT (Sheeghrashaithilyatantra)	1	2		2	
34	Hands in and Out Breathing (AntarbaahyaHastachalanaShvasana)	5	1		2	
35	Hands Stretch Breathing (HastaPrasaaranaShvasana)	5	1		2	
36	Ankle Stretch Breathing (Gulf PrasaaranaShvasana)	5	1		1	
37	Alternate Leg Raise Breathing (Vyatyasapaadottanashvasana)	5	1		1	
38	Both Leg Raise Breathing (DwayamPadottanasanashvasana)	10	1		2	
39	Side Leg Raising Breathing (Paarshvapadottanasanashvasana)	20	1		2	
40	Dog Breathing	5	1		2	
41	Rabbit breathing	1	2		1	
42	Nadishuddhi	9	2		2	
43	Bhastrika	3	1		2	
44	Surya AV 27rounds 4 times a day	27	3		2	
45	Bhramari 9 round	3	1		2	
46	Seetali /Seetkari/Sadanta	9	1		2	
47	Nadanushandhan	9	1		1	
48	OM Meditation (OmkarDhyana)		11	2	2	
49	Lecture on Bhakti Yoga	1	--			FGD
50	Bhajan session	1	--			FGD
51	Lecture on Jnana Yoga	1	--			FGD
52	Counselling	1	--			FGD
53	Yogic counseling	1	--			FGD
54	Karma Yoga activity	1	--			FGD

6.0 LIST OF PUBLICATIONS FROM THIS DOCTORAL THESIS

Sr.No	TITLE	JOURNAL	STATUS	AUTHORS
1	Development and Validation of Integrated Yoga Module for Obesity in Adolescents	International Journal of Yoga 11(3), 231–238. doi:10.4103/ijoy.IJOY_38_17	PUBLISHED	Rathi, S. S. Raghuaram, N Tekur, P., Joshi, R. R. Ramarao, N. H
2	Effect of the Yoga on anthropocentric and physical in Adolescent Obesity	Journal of Endocrinology & Metabolic Syndrome 7: 292. doi:10.4172/2161-1017.1000292	PUBLISHED	Rathi, S. S. Raghuaram, N Tekur, P., Joshi, R. R. Ramarao, N. H
3	Feasibility Study of Integrated Yoga Module in Overweight & Obese Adolescent	International Journal of Complementary & Alternate Medicine 10.15406/ijcam.2019.12.00462	PUBLISHED	Rathi, S. S. Raghuaram, N Tekur, P., Joshi, R. R. Ramarao, N. H

6.1 DEVELOPMENT AND VALIDATION OF INTRGRATED YOGA MODULE FOR OBESITY IN ADOLESCENT

International Journal of Yoga:

Official Publication of
Swami Vivekananda Yoga Anusandhana Samsthana University
Volume 11 | Issue 3 | September-December 2018

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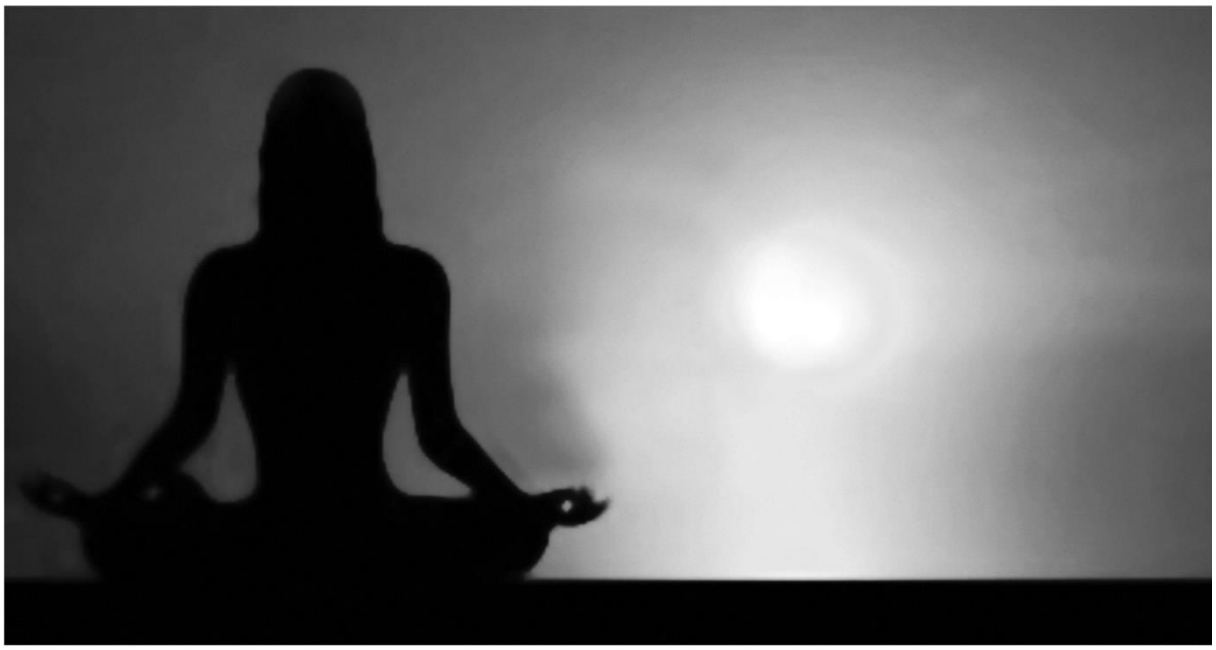

Contents

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Medknow Wolters Kluwer

Original Article

Development and Validation of Integrated Yoga Module for Obesity in Adolescents

Abstract

Background: Obesity is a growing global epidemic and cause of noncommunicable diseases. Yoga is one of the effective ways to reduce stress which is one of the causes of obesity. Nowadays, children in adolescent age are more prone to get obese due to lack of physical activity making them more sedentary.**Aim:** To identify the design and validation of Integrated Approach of Yoga Therapy Module (IAYTM) for obesity in adolescents. **Materials and Methods:** First phase – IAYTM for obesity was designed based on the literature review of classical texts and recently published research articles. Second phase – Designed IAYTM was validated by 16 subject matter (yoga) experts. Content-validity ratio (CVR) was analyzed using Lawshe's formula. **Results:** Yoga practices were designed for Integrated Yoga Module for Obesity in Adolescents. Yoga practices with CVR ≥0.5 and which were validated by 16 yoga experts and approved in faculty group discussion were included in final Integrated Yoga Therapy Module. **Conclusion:** The yoga practices were designed and validated for IAYTM for obesity in adolescents.

Keywords: *Adolescence, integrated approach of yoga therapy, obesity, validation*

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Introduction

Obesity

Obesity (body mass index [BMI] >30 kg/m^2) is more common in women than men. The risk of obesity starts at a BMI of 25 kg/m^2[1] and it is much lower (23 kg/m^2) in southeastern countries that contain genetic predisposition to metabolic disorders. East Asian countries use lower values of BMI.[2] Obesity increases the likelihood of diseases such as heart disease, type 2 diabetes, obstructive sleep apnea, cancer, and osteoarthritis.[3] Researchers consider obesity as one of the most serious public health problems of the 21st century.[4] International organizations such as the WHO, UNICEF, and CARE consider obesity as one of the most neglected public health problems in the society.[5] It is commonly caused by a combination of excessive food intake, lack of physical activity, and genetic susceptibility.[6] Therefore, it can be prevented through a combination of social changes and personal choices.

Adolescent obesity

The prevalence of overweight and obesity in children has dramatically increased over the past two decades.[7] In 2010, 43 million children were obese and this number is expected to reach 60 million by 2020. Of the approximately 45 million, 35 million live in the developing countries. Obese children are likely to remain so in adulthood and are at greater risk of developing noncommunicable diseases such as diabetes, hypertension, cardiovascular diseases, and cancers.[8] Two systematic review articles[9] and one clinical review article[11] suggest that yoga has beneficial effects on mental and physical health in children and adolescents.

Yoga modules to control obesity

Yoga has emerged as one of the evidence-based practices widely used across the globe. Over 10 million Americans practice yoga for health reasons in 2002 and the number has increased to 13 million in 2007.[12,13] Several schools of yoga have come up different modules of yoga practices that have shown a range of positive benefits on BMI in adults and children. A randomized controlled trial on 72 obese adult males resulted in improvement in BMI, hip circumference, waist circumference, and skin-fold thickness. Fourteen weeks of

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integrated yoga-based lifestyle change included yogic diet, asana, pranayama, relaxation techniques, meditation, and yogic counseling.[14] Yoga/meditation users with normal BMI appeared to be more satisfied with their body weight and shape than nonyoga/meditation users.[15] Studies provide strong evidence that the modified Qigong breathing exercise can significantly reduce or even suppress the sense of hunger on an empty stomach. Qigong practice typically involves moving meditation, coordinating slow flowing movement, deep rhythmic breathing, and calm meditative state of mind. Qigong is now practiced throughout China and worldwide for recreation, exercise and relaxation, preventive medicine and self-healing, alternative medicine, and cultivation. Stomach pH was increased by 3 and intestinal pressure was reduced by 12 mmHg in the experimental group and did not change significantly in the control group. The breathing exercise provides comfort in different circumstances, such as lack of regular meals, limited volume or caloric diet, and even during temporary complete absence of food in therapeutic fasting which is useful in obesity.[16]

In a randomized controlled trial on yoga practice for reducing the male obesity and weight-related psychological difficulties, it has been proved that the yoga practice is effective for obesity control for adult male in an urban setting. Improvement in anthropometric and psychological parameters was observed in that study.[17] The 12-week yoga intervention had positive effects on anthropometric and self-reported variables in women with abdominal obesity. Sixty women with abdominal obesity (waist circumference ≥88 cm; BMI ≥25) were randomly allocated in a 2:1 ratio to either yoga intervention (n = 40) or a waiting list (n = 20). Intergroup significant differences in the waist/hip ratio, body weight, BMI, body fat percentage, body muscle mass percentage, mental and physical well-being, self-esteem, subjective stress, body awareness, and trust in bodily sensations were observed.[18]

Mindfulness-based interventions may be both physically and psychologically beneficial for adults who are either overweight or obese. Fifteen studies measuring posttreatment outcomes of mindfulness-based interventions in 560 individuals were identified in an review article.[19] Average weight loss was 4.2 kg. Overall effects were large for improving eating behaviors, medium for depression, anxiety, and eating attitudes, and small for BMI and metacognition outcomes. Therapeutic effects for BMI, anxiety, eating attitudes, and eating behaviors remained significant. Another RCT study of a 12-month computerized mindfulness-based intervention for obese patients with binge eating disorder support that mindfulness work as de-automation element and a moderator of motivation to exercise which can lead to the reduction of impulsive eating and also to an increase in levels of physical activity.[20]

Few studies has been conducted on quality of life for the obese people. A short-term yoga-based lifestyle intervention study, including asana, pranayama, relaxation techniques, lectures, group support, nutrition awareness program, and individualized advice, had positive effect on the overall health the obese people.[21]

These studies have designed and used different yoga modules for obesity. However, there is no validated yoga module for obesity in adolescents. Therefore, this study has been designed to propose a validated yoga module for obesity in adolescent with practices of breathing and loosening, asana, pranayama, and relaxation techniques.

Yoga is a voluntary and mindful technique that has positive impact on obesity at physical and psychological levels. Yoga has effect on serum leptin and serum ghrelin; there two hormones have been recognized to harbor major influence on the energy balance mechanism. Leptin is a mediator of long-term regulation of energy balance, suppressing food intake and thereby inducing weight loss.[22] A study states that voluntary exercise leads to the maintenance of a lower body weight and leaner composition, as well as to improved leptin action, independent of fat mass.[23] Moderated meditation analyses showed that higher levels of mindfulness were associated with better-perceived quality of life through lower body shame.[24] Similar effect on serum leptin by yoga is expected as yoga is a voluntary and mindful technique to get control over mind and body.

Yoga in adolescence

Studies suggest that school-based yoga may provide unique benefits beyond participation in physical practice of yoga under expert supervision was helpful in achieving optimum level of self-adjustment in adolescent students.[25,26] However, to the best of our knowledge, there are no studies on the effect of yoga on obesity in adolescence. Hence, this study was designed to provide Integrated Approach of Yoga Therapy module (IAYTM) for obesity in adolescents.

Validation

Validation using content–validity ratio (CVR) developed by Lawson is a tool to check product, service, or system meets requirements and specifications fulfilling its intended purposes.[27] As there are many different modules of yoga for obesity used by different investigators from different parts of the globe, it was felt that there is a need to have a validated common protocol for obesity which we plan to use in a study on yoga for obesity in adolescents. Hence, the present study for validation was planned and implemented.

Materials and Methods

The designing, validation, and feasibility of Integrated Yoga Therapy Module (IYTM) for obesity [Figure 1] were carried out in the following steps:

Step 1: The need of the adolescents with obesity were enlisted [Table 1].

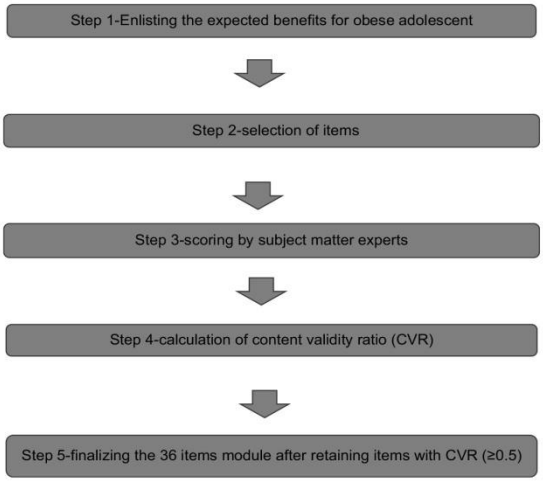

Figure 1: Flowchart of steps in the development for obesity in adolescents

Table 1: Need of adolescents with obesity

	Obese adolescents need
1	Calorie reduction by nutritious yogic diet
2	Increase calorie expenditure
3	Specific practices to reduce fat in different parts of the body, specially around hips, arms, and viscera
4	Deep relaxation to prevent exhaustion after exercises
5	Detoxification to clear constipation and other endotoxins resulting from wrong eating habits and stress
6	Stress management
7	Mind management to adhere to lifestyle
8	Vital energy balance-autonomic balance
9	Mindfulness to achieve mastery over craving for junk food, alcohol consumption if any and enjoy eating healthy food
10	Motivation to allot time for long-term adherence to lifestyle
11	Fun during parities to enjoy adherence

Step 2: The basis of integrated approach to yoga therapy to achieve these goals was understood by studying several yoga texts by the researcher under the guidance of senior yoga masters. This was complemented by the present day scientific understanding that obesity is not only a physical problem but has also deep roots in the mind and emotions. Abdominal obesity has been suggested to be associated with perturbations of the regulation of the hypothalamic-pituitary-adrenal axis. In a study on 51-year-old men (n = 284), salivary cortisol concentrations were determined on repeated occasions over a random working day and perceived stress was reported in parallel which results that perceived stress-dependent cortisol values were strongly related to perturbations of other endocrine axes as well as abdominal obesity.[28] Excessive stress affects biosynthesis of physiological processes and causes an imbalance in cognition and emotions also which results in metabolic disorders such as obesity.[29] During stress corticotrophin-releasing hormone and norepinephrine are released which has impact on hypothalamo–pitutary axis leading to behavioral and peripheral changes. This leads to release of large quantity of glucocorticoids inhibiting action of insulin on skeletal muscles and adipose tissues which is the cause of metabolic disorder such as obesity.[30] This supports that mind and body has strong interaction in pathophysiology of obesity. It proves that along with physical causes, disturbances or problems in mind and emotions are also major contributing factors of obesity pathophysiology.

Attention bias for food could be a cognitive pathway to overeating in obesity. The study results demonstrate that state differences in health versus palatability mind-sets can cause attenuated attention bias for high-calorie food cues in participants with higher eating restraint which can cause bias attention for food.[31]

The concept of how obesity as a mind–body problem occurs was formulated based on the descriptions of five aspects of human existence (*Pancha Kosha Viveka*)[32] and the downward causation of stress-induced diseases (*Adhija Vyadhi*). It states that human being exists at five different layers of existence (*Annamaya* – body, *Pranamaya* – vital energy, *Manomaya* –mind, and *Vijnaanamaya* – intellect, and *Anandamaya Kosha* – soul) which are interconnected and has counterimpact on each other also. Stress at mind disturbs *Prana* and results in abnormalities at body level called disease. Obesity also has root cause as mental stress along with other physical causes. Hence, treatment of obesity includes working on all *Koshas* (body, mind, *Prana*, and intellect). IAYTM for obesity in adolescents also is designed on the basis of *Pancha Kosha* model.

We then went on to compile the corrective techniques described in many texts (Patanjali yoga sutra, Hath Yoga Pradipika, Hatharatnavali, Bhagavad Gita) which offer a reversibility model. Thus, a need-based table of practices for long-term holistic change at all the five aspects of personality[33,34] was prepared. Publications (books and published articles) on yoga for obesity were also reviewed to prepare the list of all practices used in all these studies This yielded forty practice items that are tabulated in Table 2.

Step 3: Validation of the module for obesity: Validation of the 40-item module was carried out by arranging a focused group discussion faculty group discussion (FGD) by inviting sixteen subject matter expert (SMEs), that included five Doctor of Medicine in Yoga, eight Doctorates (PhD) in Yoga with minimum experience of 4–5 years in the field of yoga, and three yoga therapists (MSc in yoga) involved continuously for >7 years in teaching the IAYT techniques to obese participants of all ages. These 16 SMEs marked the content validity on a three (0–2)-point scale, viz., not necessary – 0, useful but not essential – 1, and essential – 2. After validation, data were analyzed using Lawshe's CVR.[35]

Table 2: Basis for development of module

Domains	Yoga practices	Expected benefits
A. *Annamaya Kosha*: Raja yoga	1. Yogic diet	1. Reduce calorie intake with wholesome nutrition
	2. Kriyas (cleansing techniques)	1. Clear constipation
		2. Mastery over hunger pangs
	3. Shithileekarana vyayamas (loosening practices) and Surya Namaskar	1. Exercise effect of yoga to spend calories
		2. Regulation of *Pranic* circulation
	4. Asanas in standing, prone, supine and sitting positions	1. Reduces adiposity in specific parts with emphasis on abdomen, hips, and arms
		2. Trains mind to be stable and calm during stressed condition
	5. Deep relaxation	1. Avoid exhaustion during and after the practice
		2. Improves metabolism
		3. Re-gaining and restarting efficiency of body system
B. *Pranamaya Kosha*	6. Breathing exercises	1. Balances of vital energy
	7. Breathing Kriya (rapid breathing practices)	1. Provides detoxification effect
		2. Breathing in names of animals offers fun for adherence
	8. Pranayama (slow breathing practices)	1. Economizes the expenditure of vital force - to achieve mastery with awareness over *Prana* flows
C1. *Manomaya Kosha*: Raja yoga	9. Practices of *Dharana* followed by *Dhyana*	1. Provides mastery over cravings for junk foods and binge eating habits
		2. Increases mindful eating
	10. Om meditation	1. Reduces stress
C2. *Manomaya Kosha*: Bhakti yoga	11. Yogic counseling using concepts of pure love to the divine	1. Provides catharsis by cognizing the suppressed emotions
		2. Emphasizes the faith in reality
		3. Provide guidance in conflictions in mind
	12. Singing devotional songs	1. Emotion culture through fun and devotion
D. *Vijnanamaya Kosha*	13. Yogic counseling and lectures using concepts of Jnana yoga	1. Gives right knowledge to achieve the required targets
	i. Happiness analysis	2. Enjoy eating healthy food
	ii. Sweet meditation	
E. *Anandamaya Kosha*	14. Yogic counseling and interactive lectures using concepts of Karma yoga - enjoy each moment of life by counting blessings	1. Teaches sense of duty in each act
		2. Maintain awareness under all circumstances
	15. Work in blissful awareness of self-existence	1. Make to face examinations without stress and fear

Statistical analysis

Sixteen SMEs validated all the 40 practices. Lawshe's CVR was calculated for all the 40 items using the formula CVR = $(n_e - N/2)/(N/2)$,[36] wherein n_e = number of SME panelists indicating "essential" and N = total number of SME panelists. As per Lawshe's significance table, the value of CVR for 16 SMEs = 0.5 which means all items with CVR >0.5 are valid and essential for the module.

Results

- Step 1: We presented the list of the needs of adolescents with obesity to FGD; the final comprehensive list of 11 items evolved is tabulated in Table 1
- Step 2: Table 2 shows basis of development of the module with five yogic personality domains and 15 categories of practices; the benefits each component would offer is also tabulated
- Step 3: Table 3 shows the list of 54 items that evolved all groups of practices.

CVR was calculated for physical and breathing practices only. Among them, 33 yoga practices [Table 4] with CVR ≥0.5 were included in designed IYTM. Others practices such as diet, meditation, counseling and lectures on yoga were discussed in faculty group discussion (FGD) meeting and were approved by all participants. Hence, those were also included in IYTM.

Discussion

This study developed a validated module of integrated yoga as a prelude to an RCT for obese adolescents. The content validity was assessed in four steps. After enlisting the needs of obese adolescents at their physical, mental, emotional, spiritual, and behavioral levels, 15 categories of yoga practices under five domains with yogic scriptural basis (*Annamaya* – physical, *Pranamaya* – vital energy, *Manomaya* – mental and emotional, *Vijnanamaya* – intellectual, and *Anandamaya* – spiritual and behavioral) was tabulated. As a next step, 54 items of actual

Table 3: List of 54 items that evolved all groups of practices

Domain	Type of practice	Name of practice	CVR
A. *Annamaya Kosha*: Raja yoga	Diet	Yogic diet	Approved in FGD
		Fasting	
	Kriya	Jala neti	0.34
		Sutra neti	0.26
		Vaman dhauti	0.6
		Laghu Shankhaprakshalana	0.73
		Trataka	0.43
		Kapalabhati	0.875
	Shithileekarana vyayamas (loosening practices) and Surya Namaskar	Jogging with jumping: Backward, forward, and side with Mukha dhauti	0.875
		Backward and forward bending (Pashchaata Purstaata namana)	0.625
		Side bending (Parshva Namana/Parshva Karshana)	0.75
		Backswing (Prushtha Andolana)	0.75
		Hip twist (Nitamba Vyavartana)	−0.75
		Hip rotation (Nitamba Chankramana)	0.5
		Spinal stretch with folded legs (Baddha pada merudanda prasarana)	0.875
		Bhunaman	0.75
		Chakki Chalana stretch	0.5
		Butterfly	0.75
		Tiger stretch (Vyaghra Prasaarana)	0.625
		Dhanurasana and Dhanurasana Swing	1
		Surya Namaskar (5 dynamic and 1 slow)	0.875
	Asanas in standing, prone, supine and sitting positions	Ardha Kati Chakrasana	0.625
		Padottanasana	0.25
		Trikonasana	0.875
		Parivritta Trikonasana	0.5
		Vajarasana	0.75
		Ushtrasana	1
		Sasankasana	0.75
		Vakrasana	0.5
		Bhujangasana	1
		Shalabhasana	0.875
		Naukasana	0.75
	Deep relaxation	QRT (Sheeghra shaithilya tantra)	0.75
B. *Pranamaya kosha*	Breathing exercises	Hands in and out breathing (Antar bahya Hastha chalana Shvasana)	0.375
		Hands stretch breathing (Hasta Prasaarana Shvasana)	0.625
		Ankle stretch breathing (Gulf Prasaarana Shvasana)	0.75
		Alternate leg raise breathing (Vyatyasa paadottana Shvasana)	0.625
		Both leg raise breathing (Dwayam Padottanasana shvasana)	0.625
		Side leg raising breathing (Paarshva Padottanasana shvasana)	0.25
	Breathing Kriya (rapid breathing practices)	Dog breathing	0.40
		Rabbit breathing	0.75
	Pranayama (slow breathing practices)	Nadi shuddhi	0.5
		Bhastrika	0.375
		Surya AV 27rounds 4 times a day	0.75
		Bhramari 9 round	0.375
		Seetali/Seetkari/Sadanta	−0.875
C1. *Manomaya Kosha*: Raja yoga	Practices of *Dharana* followed by *Dhyana*	Nadanu Shandhan	Approved in FGD
	Meditation	OM meditation (Omkar Dhyana)	
C2. *Manomaya Kosha*: Bhakti yoga	Yogic counseling using concepts of pure love to the divine	Lecture on Bhakti yoga	
	Singing devotional songs	Bhajan session	

Contd...

Table 3: Contd...

Domain	Type of practice	Name of practice	CVR
D. *Vijnanamaya Kosha*	Yogic counseling and lectures	Lecture on Jnana yoga Counseling	
E. *Anandamaya Kosha*	14. Yogic counseling and interactive lectures	Yogic counseling	
	15. Work in blissful awareness of self-existence	Karma yoga activity	

FGD=Focused group discussion, CVR=Content-validity ratio, QRT=Quick relaxation technique

Table 4: IYTM practices with content validity ratio ≥0.5 and focused group discussion approved practices

Serial number	Name of practice	CVR
1	Yogic diet	Approved in FGD
2	Fasting	
3	Vaman dhouti	0.6
4	Laghu Shankhaprakshalana	0.73
5	Kapalabhati	0.875
6	Jogging with jumping: Backward, forward and side with Mukha dhauti	0.875
7	Backward and forward bending (Pashchaata Purstaata namana)	0.625
8	Side bending (Parshva Namana/Parshva Karshana)	0.75
9	Backswing (Prushtha Andolana)	0.75
10	Hip rotation (Nitamba Chankramana)	0.5
11	Spinal stretch with folded legs (Baddha paada merudanda prasaarana)	0.875
12	Bhunaman	0.75
13	Chakki Chalana stretch	0.5
14	Butterfly	0.75
15	Tiger stretch (Vyaghra prasarana)	0.625
16	Dhanurasana and Dhanurasana swing	1
17	Surya Namaskar (5 dynamic and 1 slow)	0.875
18	Ardha Kati Chakrasana	0.625
19	Trikonasana	0.875
20	Parivritta Trikonasana	0.5
21	Vajarasana	0.75
22	Ushtrasana	1
23	Sasankasana	0.75
24	Vakrasana	0.5
25	Bhujangasana	1
26	Shalabhasana	0.875
27	Naukasana	0.75
28	QRT (Sheeghra shaithilya tantra)	0.75
29	Hands stretch breathing (Hasta Prasaarana Shvasana)	0.625
30	Ankle stretch breathing (Gulf Prasaarana Shvasana)	0.75
31	Alternate leg raise breathing (Vyatyasa paadottana shvasana)	0.625
32	Both leg raise breathing (Dwayam Padottanasana shvasana)	0.625
33	Rabbit breathing	0.75
34	Nadi shuddhi	0.5
35	Surya AV 27 rounds 4 times a day	0.75
36	Nadanu Shandhan	Approved in FGD
37	OM meditation (Omkar Dhyana)	
38	Lecture on Bhaktiyoga	
39	Bhajan session	
40	Lecture on Jnana yoga	
41	Counseling	
42	Yogic counseling	
43	Karma yoga activity	

FGD=Focused group discussion, CVR=Content-validity ratio, QRT=Quick relaxation technique

yoga practices were selected and subjected to assessment by 16 subject experts in a focussed group discussion meeting. Then, the CVR was calculated to develop the final list by retaining all those items with CVR >0.5.

Advances in technology has resulted in children spending their leisure time in television, mobiles, and ipads resulting in sedentary lifestyle and childhood obesity since last two decades.[37,38] Low levels of physical activity are definitely promoted by an automated and automobile-oriented environment that is conducive to sedentary lifestyle.[39] Hence, weight management by changing sedentary lifestyle of adolescents through yoga practices was the goal of designing IAYT module for obesity in adolescents. Urbanization leads to consumption of huge amount of food items at home and at restaurants, plus consumption of high-calorie food such as high-fat, low-fiber foods, and intake of sweetened beverages that have been shown to promote obesity.[40,41] Urbanization is only the external cause of overeating. The root cause of overeating is a form of stress resulting from demanding situations in the academic and personal lifestyle among adolescents. Regular practice of yoga, especially relaxation techniques, reduces the risk of overeating. Meditation trains the mind to search for happiness form inside instead of searching outwardly. It also make the mind to enjoy eating healthy food. The control over mind decreases the cravings toward junk and fast food resulting in proper intake of high-fiber and less-fat diet.

Yoga practices with CVR <0.5 was removed from IAYTM [Table 5]. The reason for their CVR <0.5 could be these practices are not focused and not having direct impact on adolescent obesity. The principle of selection of yoga practices is physical exercise along with relaxation of mind. However, few texts on Hatha yoga lay more emphasis on improving health through different yogic practices.[42] This module for obesity in adolescents reduces weight as it provides exercise effect to different parts of body, especially arms, abdomen, hip, and thigh region. Muscle work out in body region reduces adipose tissues leading to weight loss. It offers enough work out to burn excessive calories that results in proper balance of calorie intake and energy expenditure. Yoga practices provide deep relaxation to internal body systems which is essential to regain normal functioning of the system. Yoga also strengthens the mind determination to adhere to healthy lifestyle.

Table 5: IYTM practices with content validity ratio <0.5

Yoga practice	CVR
Jala neti	0.34
Sutra neti	0.26
Trataka	0.43
Hip twist (Nitamba Vyavartana)	−0.75
Padottanasana	0.25
Hands in and out breathing (Antar bahya Hasta chalana Shvasana)	0.375
Side leg raising breathing (Paarshva padottanasana shvasana)	0.25
Dog breathing	0.40
Bhastrika	0.375
Bhramari 9 round	0.375
Seetali/Seetkari/Sadanta	−0.875

CVR=Content validity ratio

Practices of *Manomaya Kosha* such as Bhajans (devotional music) and lecture on *Bhaktiyoga* releases stress in mind with relaxation. Practices of *Vijnanamaya Kosha* such as lecture on *Jnana yoga* and counseling help to motivate children in right direction towards success and their goal of life by clearing the intellectual complexes and conflicts. Activity like *Karmayoga* trains their mind to do work with the sense of duty and not as the burden of life which leads to relaxed mind.

These yoga practices makes IAYTM unique from other yoga modules.

Conclusion

- The yoga practices for IAYTM were designed as per yoga texts and the experience of yoga experts
- The designed IAYTM was validated by 16 yoga experts by using Lawshe's content validity formula.

Strength and limitations

This study provides a validated yoga module for obesity in adolescents. We did not conduct other validity and reliability tests for obesity in adolescents. Furthermore, all the panelists of SMEs were from the same school of Yoga (S-VYASA, Bangalore, Karnataka, India). Further study can be planned with reliability test on yoga module for obesity in adolescents.

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Conflicts of interest

There are no conflicts of interest.

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6.2 EFFECT OF YOGA ON ANTHROPOMETRIC AND PHYSICAL ASSESSMENT IN OBESITY

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Effect of the Yoga on Anthropometric and Physical Assessments in Adolescent Obesity

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Abstract

Background: Adolescent Obesity is causing serious public health concern and in many countries threatening the viability of basic health care delivery. Many co-morbid conditions are seen in association with adolescent obesity. Interventions based on Yoga principles are found to have effective solutions for adolescent obesity.

Aim: To evaluate the effect of the Yoga based intervention on anthropometric and physical assessments in Adolescent Obesity.

Methods: RCT (Randomized Controlled Trial) was conducted on 53 obese adolescents for 40 days. Special yoga based training Program was conducted for yoga group. Parameters like weight, Body Mass Index (BMI) parameters, pulse rate, blood pressure, MAC (Mid Upper Arm Circumferences), Ac (Abdominal Circumference), Waist Circumference (WC), HC (Hip Circumference) along with physical tests like sit ups and Flamingo balance tests were assessed before and after intervention for both yoga and control groups. Within and between groups analyses of the variables were analysed.

Result: The study showed significant reduction in weight, body mass index, Hip circumference, and total body fat percentage, subcutaneous fat throughout the body in yoga group and percentage of improvement is more in yoga group than that of control group.

Conclusion: Yoga based intervention is effective to reduced obesity in adolescent children with respect to anthropometric and physical assessments.

Keywords: Obesity; Adolescence; Yoga

Introduction

Adolescent obesity

Overweight and obesity are metabolic conditions in which abnormal or excessive fat accumulation is found to impair health. In 2016, more than 1.9 billion adults aged 18 years and older were overweight. Of these over 650 million adults were obese. The worldwide prevalence of obesity nearly tripled between 1975 and 2016. The prevalence of overweight and obesity among children and adolescents aged 5-19 years has risen dramatically from just 4% in 1975 to just over 18% in 2016. The rise has occurred similarly among both boys and girls: in 2016 18% of girls and 19% of boys were overweight [1]. Obesity leads to adverse impacts on physical as well as psychological functions of the person. Energy-dense overeating, nutrient-poor foods and a sedentary lifestyle have led to an epidemic of obesity all over the world. Apart from physical problems there are issues which affect psychological well-being of an individual [2]. Children in low- and middle-income countries are more prone to inadequate pre-natal, infant and young child nutrition. At the same time, they are exposed to high-fat, high-sugar, high-salt, energy-dense, micronutrient-poor foods. These dietary patterns in conjunction with lower levels of physical activity, result in sharp increases in childhood obesity while under nutrition issues remain unsolved [3].

Assessment of obesity in adolescence

Obesity is a commonly used term with a wide range of meanings with no widely accepted diagnostic definitions or cut-off points are available for children. Mean body fat percentages and percentile curves are available for children 5 to 18 years of age [4]. Several studies have recommended BMI as the preferred measure for evaluating obesity among adolescents 2 to 19 years of age. BMI can be correlated strongly with body fat percentage as it is associated weakly with height, and it identifies the fattest individuals correctly, with acceptable accuracy at the upper end of the distribution like 85th or 95th percentile for age and gender. In 1994, the Expert Committee on Clinical Guidelines for Overweight in Adolescent Preventive Services recommended that children whose BMI exceeds 30 kg/m^2 or is more than 95th percentile for age and gender should be considered obese [5].

BMI is a fairly reliable indicator of body fatness for most people. BMI does not measure boy fat directly, but research has shown that BMI correlates to direct measures of body fat. BMI can be considered an alternative for direct measures of body fat. Additionally, BMI is an inexpensive and easy-to-perform method for screening for weight categories that may lead to health problems. Measuring children's BMI regularly is the first step to maintaining a healthy weight. BMI being an important variable, the full body sensor, composition monitor and scale is used to calculate BMI and other BMI parameters. Full Body Sensing provides a comprehensive understanding of the body composition. The BMI machine calculates the estimated values for body fat percentage, skeletal muscle percentage, resting metabolism and subcutaneous fat in

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different body parts like arms, trunk, and legs using the BI (Bioelectrical Impedance) Method. The monitor also calculates the BMI (Body Mass Index) and body age as well as weight. Resting metabolism is the energy required to maintain vital functions. The total amount of energy used by the body in a typical day contributes resting metabolism (60%-70%), daily activity metabolism (20%-30%) and diet-induced thermogenesis (10%). If less energy is consumed by resting metabolism that can be consumed by daily activity metabolism. Percentage of subcutaneous fat and skeletal muscles are inversely proposal to each other. Skeletal muscle is the type of muscle that can see and feel. Building skeletal muscle can help prevent rebound weight gain. The maintenance and increase of skeletal muscle is closely linked to resting metabolism rate.

Along with BMI, waist circumference in children provides a better estimate of visceral adipose tissue [6,7]. Alternative measures that account for fat distribution include abdominal circumference, hip circumference and mid arm circumference. EUROFIT tests are also one of the assessment tools in adolescent obesity to check physical fines. The measurement of physical fitness for each child helps them to develop positive attitudes towards their bodies and get information about their physical status [8]. Handgrip strength, standing broad jump, flexed arm hang, sit-ups, sit-and-reach and Flamingo balance tests are few EUROFIT tests out of which sit-ups and Flamingo balance tests are significant in adolescent obesity.

Yoga for adolescent obesity

A study consisted of 709 healthy children (with mean age=8.9 ± 1.6 years) suggest that overweight and obesity are limiting factors for fitness performance in adolescence. Interventions promoting children's health should, ideally, begin early in life and involve measures that simultaneously improve fitness and lower fatness [9]. Yoga is widely recognized as an effective tool in maintaining a healthy lifestyle resulting as a vaccine against lifestyle related disorders [10]. According to a study of effect of aerobic & resistance exercise on physical fitness conducted on 60 adolescent obese participants in Karnataka (India), aerobic and resistance exercise in combination reduces fat significantly [11]. But only physical activity has limited scope of correcting the causes of obesity in preadolescence. Other than physical causes like lack of physical exercise, genetic and sedentary lifestyle there are few psychological causes of obesity like low self-esteem, depression, failures to cope up to demanding situations are also not uncommon. The negative experiences in school and at home leads to lower self-esteem found in childhood obesity [12]. Home, child care centre, school, and community environments can influence children's behaviours related to food intake and physical activity also which is a contributing factor of causes of obesity [13]. Along with this, increasing academic stress is also a contributing factor in causes of obesity [14]. Any form of physical activity having limited scope to manage this supportive cause of obesity can manage weight for short duration but fails to provide long termed constant impacts in preadolescence obesity. Whereas Yoga based programs have a wider impact on body, mind, habits, perception and cognition also.

In one month randomized control trial of impact of Yoga on self-esteem in 44 adolescent participants in Hardwar (India), it is noted that the level of self-esteem has significantly increased with experimental group [15]. Yoga lays great significance on strengthening inherent defensive mechanisms of human body and mind. It develops immunity and resistance in human body and helps the body and mind in attaining homeostatic balance. The strengthening of defence mechanism and harmony between mind and body prevents causes of psychosomatic disorders like obesity. The aim of yoga therefore is also the attainment of physical, mental, social and spiritual health [16]. A study conducted on Effect of yoga and physical exercise on physical, cognitive and emotional measures in 98 school children, it is observed that Physical exercise and yoga have different ways of influencing physical fitness, cognitive performance and self-esteem. Both ways showed significant improvements in tests for physical fitness [17]. But, this study has two independent groups without control group and represents geographically north part of India. The findings could be the possible effects of the two interventions, with a degree of uncertainty due to the absence of a control group. There was a need to check generalizability of the findings in a sample drawn from diverse geo-graphical and cultural backgrounds with control group. So, current study was designed to evaluate the effect of validated and feasible yoga based intervention on anthropometric and physical assessments in Adolescent Obesity.

Methods

The complete study has been approved by ethical committee of Swami Vivekananda Yoga Anusandhan Samsthana, Bangalore (Figure 1). 1400 students including both genders were screened from age of 9 year to 14 year (standard 5 to 9) in one of the reputed school in Pune city of Maharashtra state in India. Height, weight and BMI of all the students were recorded and obese participants (Figure 2) having BMI >95th percentile were included who were ready to participate in the study with written consent. Participants having any physical disability, any psychosomatic disorder, consuming any medical drugs and exposed to yoga within last 6 months were excluded from the study. All the participants are randomly divided in two groups. Yoga group (n=30) and control group (n=30). RCT (Randomized Controlled Trial) was conducted on 60 obese adolescents for 40 days. Special yoga based training Program was conducted for yoga group. Yoga intervention was consisting of specially designed and validated yoga protocol of 60 minutes duration which included set of loosening exercises, asanas, pranayamas, suryanamskara, breathing practises and meditation.

This intervention was conducted for 5 days a week for 40 days. 4 sessions of chanting, Karmayoga, Yoga counselling was also provided. Participants of Yoga group were regular in throughout the intervention and maintained 90 percent of attendance. Control group was under observation with normal routine. The diet regulation was only provided for both yoga and control group in order to acquire uniform base with respect to diet. Parameters like weight, pulse rate, blood pressure, MAC (Mid Upper Arm Circumferences), AC (Abdominal Circumference), WC (Waist Circumference), HC (Hip Circumference) along with physical tests like sit ups per minute and Flamingo balance test were assessed before and after intervention for both yoga and control groups. Body Mass Index (BMI) parameters like total body fat percentage, resting metabolism, subcutaneous fat and muscle percentage of whole body, arms, trunk and legs region also calculated using Body composition monitor Model HBF-701 before and after intervention for both yoga and control groups. In yoga group, there were 5 drop outs and from control group 2 children were absent for post parameter collection.

Statistical Analysis

The data was analysed using SPSS software 20 version. Normality test was done using Shapiro Wilk test. The paired sample t test was conducted for pre & post variables which were found normally distributed for both the groups. For not normally distributed variables, Wilcoxon signed ranks test was done. Between groups analysis was done using independent sample t test for the post values of both the groups.

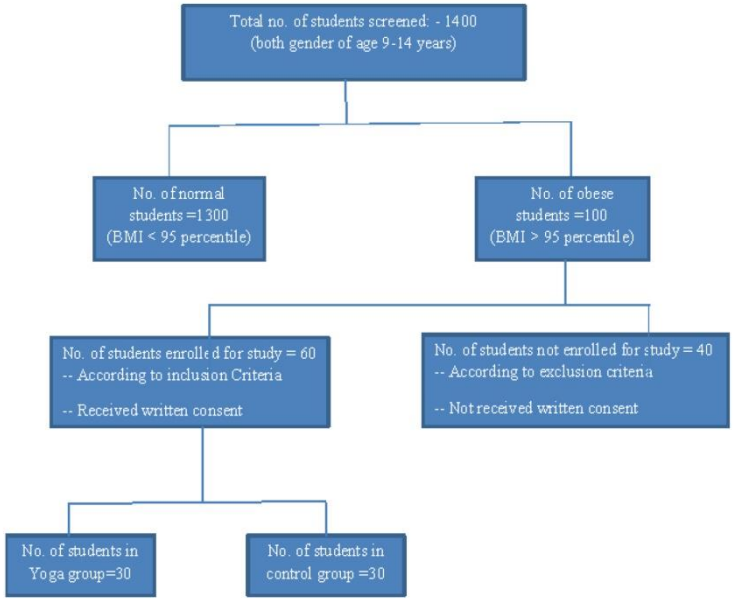

Figure 1: Flow chart of group formation for intervention.

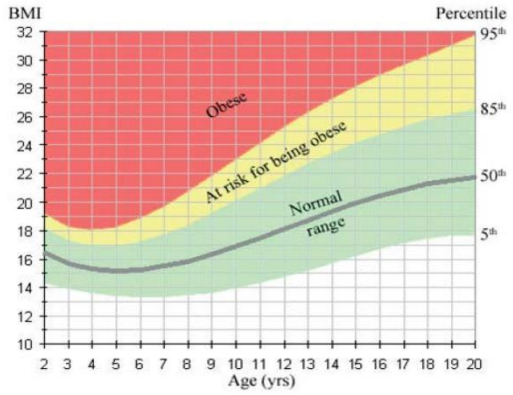

Figure 2: Body Mass Index for age percentile.

Results

The baseline demographic data of age and height of the yoga and control group is described in Table 1. Results of within group analysis of Yoga group are given in Table 2. Parameters like abdominal circumference, waist circumference, hip circumference, total body fat percentage, trunk subcutaneous fat, trunk muscle percentage, legs subcutaneous fat, legs muscle percentage and situps per minute were normally distributed. Hip circumference (p=0.001), total body fat percentage (p=0.001), trunk subcutaneous fat (p=0.005) and legs subcutaneous fat (p=0.03) reduced significantly whereas abdominal circumference (p=0.376) reduced but without significance. Trunk muscle percentage (p=0.021) increased significantly. Waist circumference (p=0.553) increased but without significance. Whole body muscle percentage (p=0.076) and legs muscle percentage (p=0.187) increased but without significance. Number of situps per minute (p=0.566) is decreased but without significance.

NO.	GROUP	YOGA		CONTROL	
1	Gender	Male	Female	Male	Female
		13	17	14	16
2	Average Age (years)	11 ± 1.4		11 ± 1.3	
3	Average Height (cm)	152.91 ± 6.97		152.71 ± 9.18	
4	Average Weight (Kg)	63.86 ± 15.52		62.39 ± 14.21	
5	Average BMI (Kg/m^2)	27.16 ± 5.04		26.43 ± 3.53	

Table 1: The baseline demographic data of age and height of the yoga and control group.

Parameters like weight, BMI, mid arm circumference, pulse rate, systolic blood pressure, diastolic blood pressure, resting metabolism, whole body subcutaneous fat, arm subcutaneous fat, arm muscle percentage and flamingo balance test were not normally distributed. Weight (p=0.018), BMI (p=0.001), whole body subcutaneous fat (p=0.01), arm subcutaneous fat (p=0.021) reduced significantly whereas systolic blood pressure (p=0.30), diastolic blood pressure (p=0.087) and mid arm circumference (p=0.474) reduced but without significance. Muscle percentage of arms (p=0.042) increased significantly whereas pulse rate (p=0.597), Flamingo balance test (p=0.065) increased but without significance.

A result of within group analysis of Control group is given in Table 3. Parameters like abdominal circumference, waist circumference,

No.	Variable	Mean (Pre)	Mean (Post)	t/z value	p value
1	Weight	63.86 ± 15.52	63.14 ± 15.28	2.359[a]	0.018*
2	BMI	27.16 ± 5.04	26.47 ± 4.85	3.344[a]	0.001*
3	Pulse rate	95.5 ± 11.7	97.37 ± 14.48	0.529[a]	0.597
4	Systolic blood pressure	125.16 ± 11.06	122.87 ± 13.42	1.037[a]	0.30
5	Diastolic blood pressure	81 ± 6.83	77.26 ± 17.63	1.712[a]	0.087
6	Mid arm circumference	11.23 ± 1.03	11.07 ± 0.93	0.716[a]	0.474
7	Abdominal circumference	35.89 ± 3.69	35.5 ± 3.77	0.902[b]	0.376
8	Waist circumference	37.65 ± 4.48	37.77 ± 4.81	0.602[b]	0.553
9	Hip circumference	39.49 ± 4.63	38.21 ± 4.71	3.68[b]	0.001*
10	Total body fat percentage	29.83 ± 3.46	27.76 ± 2.72	4.40[b]	0.001*
11	Resting metabolism	1382.83 ± 205.34	1404.33 ± 263.73	1.33[a]	0.183
12	Subcutaneous fat (Whole body)	25.57 ± 5.58	21.96 ± 4.32	2.57[a]	0.01**
13	Muscle percentage (Whole body)	27.13 ± 3.51	28.26 ± 2.89	1.77[b]	0.076
14	Subcutaneous fat (Arms)	39.23 ± 8.58	34.62 ± 6.47	2.315[a]	0.021**
15	Muscle percentage (Arms)	31.01± 6.78	33.98 ± 5.07	2.032[a]	0.042**
16	Subcutaneous fat (Trunk)	22.21 ± 5.35	19.23 ± 3.29	3.085[b]	0.005**
17	Muscle percentage (Trunk)	20.58 ± 2.97	21.55 ± 2.20	2.480[b]	0.021**
18	Subcutaneous fat (Legs)	38.35 ± 8.27	34.27 ± 6.29	2.307[b]	0.03**
19	Muscle percentage (Legs)	41.94 ± 5.21	43.94 ± 4.65	1.359[b]	0.187
20	Sit ups	32.95 ± 7.02	31.5 ± 9.38	0.582[b]	0.566
21	Flamingo Balance test	60.70 ± 37.07	65.75 ± 38.48	1.845 a	0.065

[a]Wilcox test
[b]Paired sample t test
*significant at 0.01
**significant at 0.05

Table 2: Result of within group analysis of Yoga group (n= 25).

No.	Variable	Mean Pre value	Mean Post value	t value	p value
1	Weight	62.39 ± 14.21	62.8 ± 14.73	1.646[a]	0.100
2	BMI	26.43 ± 3.53	26.82 ± 3.58	0.108[a]	0.914
3	Pulse rate	95.07 ± 12.7 7	93.85 ± 11.31	0.781[a]	0.435
4	Systolic blood pressure	125.96 ± 18.54	119.25 ± 13.68	2.596[a]	0.009**
5	Diastolic blood pressure	83.71 ± 9.78	77.5 ± 8.05	2.90[a]	0.004**
6	Mid arm circumference	11.21 ± 1.37	11.35 ± 1.42	1.160[a]	0.246
7	Abdominal circumference	35.51 ± 3.27	35.42 ± 3.28	0.348[b]	0.730
8	Waist circumference	36.50 ± 3.01	36.99 ± 3.67	1.192[b]	0.244
9	Hip circumference	38.84 ± 3.71	38.57 ± 3.93	1.240[b]	0.226
10	Total body fat percentage	29.02 ± 2.65	28.96 ± 2.17	0.157[b]	0.876
11	Resting metabolism	1369.25 ± 218.60	1388.33 ± 238.43	1.287[a]	0.198
12	Subcutaneous fat (Whole body)	24.80 ± 5.11	22.75 ± 4.56	1.150[a]	0.250
13	Muscle percentage (Whole body)	27.20 ± 3.06	28.12 ± 2.93	1.059[a]	0.290
14	Subcutaneous fat (Arms)	38.90 ± 8.16	36.02 ± 7.03	0.997[a]	0.319
15	Muscle percentage (Arms)	30.62 ± 7.27	33.47 ± 6.61	1.261[a]	0.207
16	Subcutaneous fat (Trunk)	21.34 ± 4.32	20.07 ± 3.52	1.359[b]	0.186
17	Muscle percentage (Trunk)	20.87 ± 2.40	21.2 ± 2.08	0.806[b]	0.427
18	Subcutaneous fat (Legs)	38.75 ± 8.81	35.92 ± 7.71	1.439[b]	0.162
19	Muscle percentage (Legs)	42.06 ± 4.94	43.78 ± 4.95	1.128[b]	0.270
20	Sit ups	30.21 ± 8.74	26.78 ± 7.36	2.419[b]	0.023**
21	Flamingo Balance test	72.17 ± 56.41	91.89 ± 58.65	1.173[a]	0.241

[a]Wilcox test
[b]Paired sample t test
**significant at 0.05

Table 3: Result of within group analysis of Control group (n=28).

hip circumference, total body fat percentage, trunk subcutaneous fat, trunk muscle percentage, legs subcutaneous fat, legs muscle percentage and sit ups per minute were normally distributed. Number of sit ups per minute (p=0.023) decreased significantly whereas abdominal circumference (p=0.730), hip circumference (p=0.226), total body fat percentage (p=0.876), trunk subcutaneous fat (p=0.186) and legs subcutaneous fat (p=0.162) reduced but without significance. Waist circumference (p=0.244), trunk muscle percentage (p=0.427) and legs muscle percentage (p=0.270) increased but without significance.

Parameters like weight, BMI, mid arm circumference, pulse rate, systolic blood pressure, diastolic blood pressure, resting metabolism, whole body subcutaneous fat, arm subcutaneous fat, arm muscle percentage and flamingo balance test were not normally distributed.

No.	Variable	Yoga Group (n= 25)		Control Group (n= 28)		t value	p value
		Pre	Post	Pre	Post		
1	Weight	63.86 ± 15.52	63.14 ± 15.28	62.39 ± 14.21	62.8 ± 14.73	0.517[a]	0.60
2	BMI	27.16 ± 5.04	26.47 ± 4.85	26.43 ± 3.53	26.82 ± 3.58	0.053[a]	0.95
3	Pulse rate	95.5 ± 11.7	97.37 ± 14.48	95.07 ± 12.7 7	93.85 ± 11.31	1.052[a]	0.29
4	Systolic blood pressure	125.16 ± 11.06	122.87 ± 13.43	125.96 ± 18.54	119.25 ± 13.68	0.883[a]	0.37
5	Diastolic blood pressure	81 ± 6.83	76.95 ± 8.79	83.71 ± 9.78	77.5 ± 8.05	0.330[a]	0.74
6	Mid arm circumference	11.23 ± 1.03	11.07 ± 0.93	11.21 ± 1.37	11.35 ± 1.42	0.027[a]	0.97
7	Abdominal circumference	35.89 ± 3.69	35.5 ± 3.77	35.51 ± 3.27	35.42 ± 3.28	0.530[b]	0.05[∞]
8	Waist circumference	37.65 ± 4.48	37.77 ± 4.81	36.50 ± 3.01	36.99 ± 3.67	0.593[b]	0.79
9	Hip circumference	39.49 ± 4.63	38.21 ± 4.71	38.84 ± 3.71	38.57 ± 3.93	2.479[b]	0.54
10	Total body fat percentage	29.83 ± 3.46	27.76 ± 2.72	29.02 ± 2.65	28.96 ± 2.17	3.236[b]	0.92
11	Resting metabolism	1382.83 ± 205.34	1404.33 ± 263.33	1369.25 ± 218.60	1388.33 ± 238.43	0.579 [a]	0.56
12	Subcutaneous fat (Whole body)	25.57 ± 5.58	21.96 ± 4.32	24.80 ± 5.11	22.75 ± 4.56	0.606 [a]	0.54
13	Muscle percentage (Whole body)	27.13 ± 3.51	28.26 ± 2.89	27.20 ± 3.06	28.12 ± 2.93	0.036[a]	0.97
14	Subcutaneous fat (Arms)	39.23 ± 8.58	34.62 ± 6.47	38.90 ± 8.16	36.02 ± 7.03	0.383[a]	0.70
15	Muscle percentage (Arms)	31.01± 6.78	33.98 ± 5.07	30.62 ± 7.27	33.47 ± 6.61	0.330[a]	0.74
16	Subcutaneous fat (Trunk)	22.21 ± 5.35	19.23 ± 3.29	21.34 ± 4.32	20.07 ± 3.52	1.241[b]	0.88
17	Muscle percentage (Trunk)	20.58 ± 2.97	21.55 ± 2.20	20.87 ± 2.40	21.2 ± 2.08	-1.637[b]	0.36
18	Subcutaneous fat (Legs)	38.35 ± 8.27	34.27 ± 6.29	38.75 ± 8.81	35.92 ± 7.71	- 0.278[b]	0.77
19	Muscle percentage (Legs)	41.94 ± 5.21	43.94 ± 4.65	42.06 ± 4.94	43.78 ± 4.95	- 0.701[b]	0. 14
20	Sit ups	32.95 ± 7.02	31.5 ± 9.38	30.21 ± 8.74	26.78 ± 7.36	- 0.942[b]	0.09
21	Flamingo Balance test	60.70 ± 37.07	65.75 ± 38.48	72.17 ± 56.41	91.89 ± 58.65	1.568[a]	0.11

aMann-Whitney U test
bIndependent samples t-test
∞significant at 0.05

Table 4: Result of In between group analysis.

Systolic blood pressure (p=0.009), diastolic blood pressure (p=0.004) reduced significantly whereas pulse rate (p=0.435), whole body subcutaneous fat (p=0.250), arm subcutaneous fat (p=0.319) reduced but without significance. Weight (p=0.100), BMI (p=0.914), mid arm circumference (p=0.246), resting metabolism (p=0.198), whole body muscle percentage (p=0.290) and Flamingo balance test (p=0.241) increased but without significance.

Analysis of in between Yoga and control group states that abdominal circumference of Yoga group is decreased significantly than that of Control group (p=0.05). Weight, BMI, mid-arm circumference, hip circumference, total body fat percentage, subcutaneous fat of whole body, arm, trunk and legs has been reduced more in Yoga group than that of Control group but without significance. Number of situps, systolic blood pressure and diastolic blood pressure is decreased in control group more than that of Yoga group but without significance. Pulse rate is found to be increased in Yoga group whereas that of control group is reduced but without significance. Waist circumference is increased more in control group than that of Yoga group but without significance. Resting metabolism, muscle percentage of whole body, arm, trunk and legs are increased more in Yoga group than that of Control group but without significance. Flamingo balance test has been increased more in control group than that of Yoga group but without significance.

Discussion

Obesity especially abdominal is related to academic achievement and cognitive functions in children. Visceral adipose tissues have negative impact on cognitive functions leading to academic decrease among children with obesity because of its dangerous metabolic nature [18].

Excessive adipose tissue also affects the physical inactivity leading to psychological increased sensitivity. These childhoods obesity leaded poorer cognitive function results in decreased measures of intra individual response, even after accounting for intellectual abilities, aerobic fitness [19]. So focus of this study_was to evaluate the yoga based validated intervention on anthropometric and physical variables in adolescent Obesity [20]. Specific anthropometric and physical tests are selected as variables were selected in order to conserve comfort and convenience of the participants with average age of 11 ± 1.4 years. Hip circumference, total body fat percentage, subcutaneous fat of trunk and legs whereas these parameters are reduced in control group but without significance. Subcutaneous fat reduction leads to significant increase of muscle percentage of trunk and leg region. This provides evidence of efficacy of validated yoga based intervention on reduction of adipose tissues in hip, trunk and leg region resulting in reduction of total body fat percentage and overall body weight. Abdominal circumference is reduced significantly in Yoga group and without significance in control group. Yoga group has improved significantly better in this parameter than control group. Yoga intervention practices like dynamic surya namaskara, asana, loosening practices are focused to reduced abdominal adipose tissue. According to one RCT, yoga intervention had moderately strong positive effects on anthropometric variables in women with abdominal obesity. Yoga is safe in women and can be recommended as a technique for combating abdominal obesity in women [21]. Our study provides efficacy of Yoga in same concern in adolescent population. Yoga improves emotional wellbeing in children. The mechanisms underlying these benefits have not been clearly worked out and may involve complex neuro-chemical changes and modified functioning of brain areas within the limbic circuit. Physical activities of control group was not monitored and compared with test group. This is limitation of the study.

Conclusion

Yoga based intervention is effective to reduced obesity in adolescent

children with respect to anthropometric and physical assessments. This study provides evidence to prove efficacy of Yoga to manage increased subcutaneous adiposity in trunk, hip and leg region resulting in weight reduction in adolescent children.

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6.3 FEASIBILITY STUDY OF INTEGRATED YOGA MODULE IN OVERWEIGHT AND OBESITY

International Journal of Complementary and Alternative Medicine

Feasibility Study of Integrated Yoga Module in Overweight & Obese Adolescents

- **Background :-**
  Yoga has been known to have stimulatory or inhibitory effects on the metabolic parameters and to be uncomplicated therapy for obesity. Adolescence are more prone to get obese due to lack of physical activity making them more sedentary.
- **Aim:-**
  To identify feasibility of validated Integrated Approach of yoga Therapy module (IAYTM) for Obesity in adolescents.
- **Method:-**
  RCT (Randomized Controlled Trial) was conducted on overweight & obese adolescents. Special yoga training was conducted for yoga group. Parameters like weight, Body Mass Index (BMI), pulse rate , blood pressure, MAC (Mid Upper Arm Circumferences), Waist Circumference (WC), HC (Hip Circumference), Fasting blood sugar, total cholesterol, High-density lipoproteins, low-density lipoproteins, very low-density lipoprotein & Sr. triglycerides were assessed before and after intervention for both yoga and control groups. Within and between group analysis of the variables were carried out .
- **Result :-**

The study showed significant reduction in weight, body mass index, very low-density lipoprotein & Sr. triglycerides , circumference & Serum cholesterol in yoga group & percentage of improvement is more in yoga group than that of control group.

- **Conclusion:-**
  Integrated Approach of yoga Therapy module (IAYTM) is effective in management of weight , serum triglyceride & very low - density lipoprotein in adolescent obesity.

1

➢ **Keywords :-** Integrated Approach of yoga Therapy module (IAYTM), Obesity, Adolescence, Yoga, Feasibility.

Introduction

Obesity is a medical condition in which excess body fat has accumulated to the extent that it may have a negative effect on health.[1] Energy-dense overeating, nutrient-poor foods and a sedentary lifestyle have led to an epidemic of obesity all over the world.[2] Apart from physical problems there are issues which affect psychological well-being of an individual. Depression is the commonest psychological co-morbidity of obesity. A wide range of treatment options are available for obesity but, balanced nutrition diet and regular physical activity are considered to be the safest and the easiest option.[3] Obesity is most commonly caused by a combination of excessive food intake, lack of physical activity, and genetic susceptibility.[1][4] Authorities view it as one of the most serious public health problems of the 21st century.[5] According to WHO, UNICEF & CARE it is one of the most neglected public health problem in recent years [11].

Adolescence is a transitional stage of physical and psychological human development that occurs between the age of 13 and 19 years [10]. Overweight or obese children are likely to remain so in adulthood and are also at high risk of developing non communicable diseases like diabetes, hypertension, cardiovascular diseases and cancers [15]. The prevalence of overweight and obesity in children has dramatically increased over the past two decades [16]. In 2010, 43 million children were overweight or obese −35 million of whom lived in developing countries- and this number is expected to reach 60 million by 2020 [16]. Two systematic review papers [12,13] and one clinical review paper [14] suggest that yoga has beneficial effects on mental and physical health in children and adolescents.

Yoga has emerged as one of the evidence-based practice in past decade. According to national surveys, yoga practice has increased, with over 10 million Americans practicing yoga for health reasons in 2002 and over 13 million in 2007.[6,7]. Stress-related diseases seems to be an appropriate indication for yoga therapy as large number of literature supports the same.[8]Different schools of yoga have varying proportions of physical, breathing, and mind

activities executed through varied practices. Most of these studies found a varied range of positive benefits on obesity. They have a common objective of voluntary mastery over the modifications of the mind.[9]

In order to provide a yoga for adolescent obesity , we have designed & developed an integrated yoga module for Obesity in adolescents from authentic Yoga texts which was result of group discussion of 16 subject matter experts . The module has been checked for content validity by using Lawshe's content validity ratio. This study is accepted for publication in another publication . Now before going for a proper randomised trial control in larger population ,it need to be checked for feasibility on pilot basis. This study is designed to provide feasibility of Integrated Yoga Module in overweight & obese Adolescents. It also aims to objectively and rationally uncover the strengths and weaknesses of the module. [20] It evaluates the project's potential for success.

Materials and Methods

Two armed perspective RCT (Randomized Controlled Trial) was conducted for 1month on overweight & obese adolescent subjects of a residential school in Sangamner , Pune, Maharashtra , India who did not had any exposure to Yoga previously. Adolescents having any physical disability ,any medical disorder or complication were not included in the study. 100 students were screened & 23 overweight & obese adolescents (15 male and 8 female having BMI above 85 percentile) between 11 & 17 years of age were selected for the study. They were allocated into two groups (Yoga n=14 and control n=9). Signed informed consent was obtained from all participants and their parents or guardians in the prior stage of intervention.

The Integrative Yoga Therapy module for obesity in adolescent consisting of Asanas, Pranayama, Relaxation and Meditation techniques were introduced in a step by step manner. Each session of the intervention was for 60 minutes for five days in a week for 1 month. The control group continued regular activities and no specific physical activity was given . All the participants received same type of meal throughout the month and was continuing their school physical & academic activities like sports or physical education. All the participants were assessed for weight, BMI, pulse, blood pressure, mid-arm circumference waist circumference, hip circumference , fasting blood sugar, serum total cholesterol, high-density lipoprotein , low-density lipoprotein , very low- density lipoprotein , serum triglycerides respectively at baseline

and after 1-month of the intervention. All the 23 adolescents completed the intervention. There were no adverse effects observed during the study period.

Statistical Analysis

The data was analysed using SPSS software 20 version. Normality test was done using Shapiro Wilk's test. The paired sample t test was done for pre & post on all the variables which were found normally distributed for both the groups. Between group analysis was done using independent sample t test for the post values of both the groups. For variables that not normally distributed, Wilcoxon signed ranks test was done.

Results

The baseline demographic data of age and height of the yoga and control group are given in Table 1.

Table 1 : Baseline data of age and height.

Variables	**Yoga Gr. n = 14**	**Control Gr. n = 9**
Age	14.21 ± 1.84	15.22 ± 1.09
Height	1.64 ± 0.09	1.66 ± 0.09

The average age of Yoga group was 14.21 ± 1.84 and that of control group was 15.22 ± 1.09. The average height of Yoga group was 1.64 ± 0.09and that of control group was 1.66 ± 0.09. The minimum age in yoga group was 11 years whereas that in control group was 14 years and the maximum age in both group was 17 years . The minimum height in yoga group was 1.51 meter and that of control group was 1.54 meter . The maximum height in yoga group was 1.85 meter and that of control group was 1.75 meter .

Results of within group analysis of the normally distributed variables of Yoga group are given in Table 2.

Table 2 : Within group analysis results (Parametric test) of yoga Group. (n = 14)

Variables	Pre	Post	T	Sig.
Weight	81.64 ± 13.79	78.99 ± 13.47	7.29	0.000**
Systolic blood pressure	124.57 ± 10.18	121.85 ± 7.87	1.84	0.08
Diastolic blood pressure	81.74 ± 12.28	78.21 ± 8.54	2.71	0.01*
Mid arm circumference	30.20 ± 2.34	31.67 ± 1.68	-2.80	0.01*
Waist circumference	100.5 ± 9.81	99.21 ± 8.57	0.77	0.45
Fasting blood sugar	75.61 ± 7.06	70.49 ± 8.46	2.06	0.05*
HDL	40.25 ± 2.64	40.05 ± 1.89	0.32	0.75
Triglycerides	115.85 ± 30.07	104.54 ± 32.27	4.02	0.001**
VLDL	23.19 ± 6.03	20.90 ± 6,45	4.15	0.001**

*Significance at the level of 0.05

**Significance at the level of 0.001

Weight, blood pressure, mid-arm circumference, waist circumference, fasting blood sugar, , high-density lipoprotein , very low- density lipoprotein , serum triglycerides were normally distributed in Yoga group. There is significant reduction in weight (p = 0.000) , diastolic blood pressure (p = 0.018), fasting blood sugar (p = 0.059), very low- density lipoprotein (p = 0.001) , serum triglycerides (p = 0.001) after intervention. There is significant increase in mid-arm circumference (p = 0.01). There is non-significant reduction in systolic blood pressure (p = 0.08), waist circumference (p = 0.45) & high-density lipoprotein (p = 0.75).

Results of within group analysis of the not normally distributed variables of Yoga group are given in Table 3.

Table 3 : Within group analysis results (Non- Parametric test) of Yoga group (n = 14)

Variables	Pre	Post	Z	Sig.
BMI	30.17 ± 4.37	29.19 ± 4.26	-3.29	0.001**
Pulse rate	77.35 ± 4.60	75.35 ± 4.76	-2.07	0.038*
Hip circumference	109.27 ± 11.98	108.08 ± 12.03	-2.55	0.011*
Sr. cholesterol	107.61 ± 30.54	97.90 ± 20.23	-2.10	0.035*
LDL	44.16 ± 29.29	36.93 ± 20.42	-1.16	0.245

*Significance at the level of 0.05

**Significance at the level of 0.001

BMI, pulse rate, hip circumference , serum total cholesterol, low- density lipoprotein were not normally distributed in Yoga group. There is significant reduction in BMI (p = 0.00), pulse rate (p = 0.03), hip circumference (p = 0.01) , serum total cholesterol (p = 0.03). There is non-significant reduction in low- density lipoprotein (p = 0.24).

Results of within group analysis of the normally distributed variables of control group are given in Table 4.

Table 4 : Within group analysis results (Parametric test) of Control group (n = 9)

Variables	Pre	Post	T	Sig.
Weight	75.11 ± 10.11	75.36 ± 10.46	-0.495	0.634
BMI	26.87 ± 1.71	26.97 ± 1.99	-0.522	0.616
Systolic blood pressure	131.11 ± 10.89	127.44 ± 6.02	1.584	0.152
Diastolic blood pressure	85.33 ± 8.26	82.33 ± 5.61	2.250	0.055
Waist circumference	93.86 ± 5.95	94.47 ± 5.50	-0.514	0.621
Fasting blood sugar	74.55 ± 5.20	74 ± 9.63	0.194	0.851

Sr. cholesterol	94.89 ± 10.06	91.66 ± 8.13	0.260	0.260
HDL	41.80 ± 1.63	42.85 ± 1.86	-3.088	0.015*
Triglycerides	110.98 ± 21.38	94.88 ± 11.68	3.437	0.009*
LDL	30.89 ± 12.07	29.82 ± 9.92	0.331	0.749
VLDL	22.19 ± 4.27	18.97 ± 2.33	3.438	0.009*

*Significance at the level of 0.05

Weight, BMI,blood pressure, waist circumference, fasting blood sugar, Serum cholesterol, shigh-density lipoprotein , low- density lipoprotein, very low- density lipoprotein , serum triglycerides were normally distributed in control group. There is significant reduction in high-density lipoprotein (p = 0.15), serum triglycerides (p = 0.009) & very low- density lipoprotein (p = 0.009). There is reduction in weight (p = 0.634), BMI (p= 0.616), systolic blood pressure (p = 0.152) , diastolic blood pressure (p = 0.055), waist circumference (p = 621),fasting blood sugar (p = 0.851), serum total cholesterol (p = 0.260) & low- density lipoprotein (p = 749) but without significance.

Results of within group analysis of the not normally distributed variables of control group are given in Table 5 .

Table 5 : Within group analysis results (Non - Parametric test) of Control group (n = 9)

Variables	**Pre**	**Post**	**Z**	**Sig.**
Pulse	71.33 ± 4.60	69.88 ± 5.10	-1.219	0.223
Midarm circumference	29.61 ± 2.11	31.89 ± 1.48	-2.433	0.015*
Hip circumference	107.03 ± 3.61	106.92 ± 3.93	-0.105	0.916

*Significance at the level of 0.05

Pulse rate, Mid arm circumference & hip circumference were not normally distributed in control group. There is significant increase in Mid arm circumference (p = 0.015). There is reduction in pulse rate (p = 0.223), & hip circumference (p = 0.916) but without significance.

Between group analysis results are given in Table 6 .

Table 6 : Between group analysis results

Variables	**Yoga Gr. (n = 14)**		**Control Gr. (n = 9)**		**T**	**Sig.**	**Diff. in % of Improvement**
	Post Mean	**% of Improvement**	**Post Mean**	**% of Improvement**			
Weight	78.99 ± 13.47	3.24 %	75.36 ± 10.46	-0.34 %	.684	.501	3.58
BMI	29.19 ± 4.26	3.25 %	26.97 ± 1.99	-0.35 %	1.457	.160	3.61
Pulse	75.35 ± 4.76	2.58 %	69.88 ± 5.10	2.02 %	2.612	.016 *	0.56
Sys. BP	121.85 ± 7.87	2.17 %	127.44 ± 6.02	2.79 %	-1.810	.085	-0.61
Dia. BP	78.21 ± 8.54	4.28 %	82.33 ± 5.61	3.51 %	-1.275	.216	0.76
MAC	31.67 ± 1.68	- 4.86 %	31.81 ± 1.48	-7.42 %	-.203	.841	2.55

WC	99.21 ± 8.57	1.28 %	94.47 ± 5.50	-0.64 %	1.468	.157	1.92
HC	108.08 ± 12.03	1.08 %	106.92 ± 3.93	0.09 %	.277	.785	0.98
FBS	70.49 ± 8.46	6.76 %	74 ± 9.63	0.74 %	-.918	.369	6.02
Sr. Cholesterol	97.90 ± 20.23	9.02 %	91.66 ± 8.13	3.40 %	.875	.391	5.61
HDL	40.05 ± 1.89	0.48 %	42.85 ± 1.86	-2.51 %	-3.487	.002 *	3.00
Sr. Triglycerides	104.54 ± 32.27	9.76 %	94.88 ± 11.68	14.50 %	.856	.401	-4.74
LDL	36.93 ± 20.42	16.36 %	29.82 ± 9.92	3.45 %	.968	.344	12.91
VLDL	20.90 ± 6.45	9.87 %	18.97 ± 2.33	14.51 %	.857	.401	-4.64

*Significance at the level of 0.05

Percentage of improvement (reduction) of weight & serum cholesterol ,waist circumference, hip circumference ,serum cholesterol, low- density lipoprotein , high- density lipoprotein is more in yoga group than that of control group. Percentage of improvement (reduction) of serum triglycerides & very low -density lipoprotein were more in control group than that of yoga group.

Discussion

23 adolescents were intervened by validated IYTM (36 practices), and they were assessed pre- and post-intervention for variables out of which weight ($P < 0.001$), Serum triglyceride & triglycerides ($P < 0.001$) & very low- density lipoprotein ($P < 0.001$) showed statistically significant reduction whereas waist circumference ($P < 0.45$) & high - density lipoprotein ($P < 0.75$) showed statistically non-significant reduction by validated IYTM on obesity in yoga group. This could be due to short duration of study. There was significant reduction in BMI ($p = 0.001$), pulse rate ($p = 0.038$), hip circumference ($p = 0.011$) , serum total cholesterol ($p = 0.035$) in non –parametric test . So these result can not be implicated for the universe.

There is significant increase in mid-arm circumference ($p = 0.01$) in yoga group & ($p = 0.015$) in control group. This could be because that INTEGRATED APPROACH OF YOGA THERAPY MODULE for obesity practises are having more emphasis on below naval part of body especially focused on hips & thighs. Few practises were there like suryanamaskara, chakarsana & Bhujangasana which was having effect on arm muscles but they were not significant. Though intervention period was of 1 month only, results were fascinating may be because of regularity & dedication of participants with research team.

Percentage of improvement (reduction) of serum triglycerides & very low -density lipoprotein were more in control group than that of yoga group. The reason of this could be that all subjects were from same hostel & blinding on the intervention was not possible. Once the intervention started the control groups were aware of the yoga programme though subtle practical details were not known to them. This might have also given them some motivation to do walking

activities. This might have improved their parameters. All 14 adolescents completed the intervention, there were no adverse effects noticed during the study. However, RCT with larger samples are needed to validate its efficacy as a primary intervention.

Strengths & Limitations

This is an exclusive study on adolescent obesity with control group. It is found that INTEGRATED APPROACH OF YOGA THERAPY MODULE is effective for reducing obesity and problems related to avoidance and inflexibility among obese. Further both the groups were having similar age variation as minimization of co factors was done. Blinding on the intervention was not possible since the sample were from same hostel and once the intervention started the control group were aware of the yoga programme though subtle practical details were not known to them. Also the food log format plan was same for both the groups. Current study confirms that the one hour INTEGRATED APPROACH OF YOGA THERAPY MODULE is an effective alternative in adolescent obesity. Small sample size is another limitation of the study. Larger sample study along with psychological parameters is needed to strengthen its efficacy as a primary intervention.

Conclusion

Integrated approach of yoga therapy module having 36 practices for adolescent obesity is effective in management of weight , serum triglyceride & very low - density lipoprotein , hip circumference & serum cholesterol. Yoga group has improved better than control group with INTEGRATED APPROACH OF YOGA THERAPY MODULE. This module has proved efficient in management of adolescent obesity.

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LIST OF TABLES

LIST OF GRAPHS

LIST OF FIGURES

LIST OF PLATES

Plate1

Pilot Project at
Dhruv Academy, Sangmner Maharashtra

IMPORTANCE OF OBESITY PROJECT by
Dr. Sunanda Rathi

CHAIRMAN DHRUV ACEDEMY
Dr. Sanjay Malpani

Plate 2

Pre-Data Collection
Blood Test

Plate 3

Surya Anulom-Vilom (27 TIMES)

4 Times Before Meal

Plate 4

Intervation : Yoga Practices

Plate 5

Demonstration After Intervention

Yoga Group

Plate 6

After Intervention

Participants Feedback

Plate 7

After Intervention

Parents Feedback

Plate 8

Concluding Session

Happy Participants

Plate 9

Councelling By Doctor

Felicitation

PLATE 10

Main Study
Dr. Kalmadi Shamarao High School and Jr. College -Kaveri Education

Consent Session

PLATE 11

Main Study
Dr. Kalmadi Shamarao High School and Jr. College -Kaveri Education

Importance Of Obesity Project

Parents Consent

PLATE 12

Psycological Tools

Brief Of Project

PLATE 13

Parameters

Blood Pressure

Waist Circumferences

PLATE 14

Parameters

Flemingo Balance Test

PLATE 15

Parameters

BMI

PLATE 16

Yoga Practices

PLATE 17

Yoga Practices

PLATE 18

Post Parameters

PLATE 19

Counseling Sessions

PLATE 20

Feedback By Participants

Happy Yoga Group After 5 Weeks

STUDY ONE: PILOT AT DHRUV ACEDEMY SANGAMNER MAHARASHTRA

STUDY TWO: MAIN STUDY
AT DR KALMADI SHYAMRAV HIGH SCHOOL, PUNE MAHARASHTRA