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STS 2019
SHORT TERM STUDENTSHIP

This is to certify that Mr. Shardul Vijay Kamale student of MBBS-II of Mahatma Gandhi Missions Medical College, Navi Mumbai has been awarded the Short Term Studentship (STS) for a period of two months during 2019 under the guidance of Dr. Ipseeta Rayme for the project entitled, "Cardio-metabolic risk stratification and life style interventions for risk reduction among overweight and obese children" (Ref. No.2019-04777) and the Report was found to be satisfactory.

Dr. N.C Jain
Scientist G & Head, HRD
ICMR

Prof. (Dr.) Balram Bhargava
Secretary, Department of Health Research &
Director General, ICMR

APPLICATION ATTESTATION FORM (AAF) STS 2019

STS Reference ID: ....2019 – 04777

Name of the Student: ...SHARDUL VIJAY KAMALE

Name of the Guide: ....DR. IPSEETA RAY

Name of Medical/Dental College: ...MGM MEDICAL COLLEGE

Title of the STS Proposal: CARDIO – METABOLIC RISK STRATIFICATION & LIFE STYLE INTERVENTIONS FOR RISK REDUCTION AMONG OVERWEIGHT & OBESE CHILDREN

Certificate to be signed by the Student

I certify that I am an MBBS/BDS student and am here by providing true information in the online application form for STS 2019 best to my knowledge. I am submitting only one application for STS 2019. In the event any information is found to be false, my studentship may be cancelled. I also certify that the research proposal is an original work prepared under the guidance of my Guide. I confirm that I have not committed 'plagiarism' in preparing this proposal. I understand that after evaluation of my proposal, I may or may not be selected and I shall abide by the decision of ICMR.

If selected, I shall follow all instructions provided on ICMR website for carrying out the research, preparation and submission of STS report. I also understand that if I am unable to complete my project & submit the report before the last date, no certificate or stipend will be awarded to me. I have gone through all the Instructions and Terms & Conditions for STS 2019 provided on ICMR website and will abide by them.

Signature of Student: SVKamale   Name of the Student: SHARDUL VIJAY KAMALE

Date: 18 | 11 | 2019

Certificate to be signed by the Guide

I agree to accept the applicant Mr./Ms. Shardul Vijay Kamale studying in MBBS/BDS-I/II/III/IV (tick appropriate). I certify that he/she is not an intern or student of other courses and I will offer him/her all facilities and guidance for carrying out STS research. I also certify that the proposal is an original submission prepared by the student under my guidance. I confirm that neither me and nor my student have committed 'plagiarism' in preparing this proposal. I am forwarding only one STS 2019 student application. If my student is selected, I shall provide required facilities to enable early completion of research work, so that the report is submitted before the last date.

Signature of Guide: _____ Ray 18|1|19

    ~ssor of Pharmacology
    · M. Medical College
    · ...mothe, Navi Mumbai

Name: DR IPSEETA RAY
Designation: PROFESSOR
Department: PHARMACOLOGY

Attested By

Signature of Head of Department

Prof. & H- ...harmacology
M.G.M. Medical College,
Kamothe, Navi Mumbai-410209

Signature of Head of Medical/Dental College

Dean. .
M.G.M. Medical College & Hospital
Kamothe, Navi Mumbai - 410209

(Name in Block letters with seal)   (Name in Block letters with seal)

___

ill form completely & check it before submission.   F

1. **Reference ID:** 2019-04777

2. **Title:** Cardio-metabolic risk stratification and life style interventionsfor risk reduction among overweight and obese children

3. **Introduction :**

The American Diabetes Association (ADA) guidelines indicate that children who are above the 85th percentile for age and gender with additional risk factors should be screened for diabetes[1]. Overweight and obese adolescents are at risk of developing diabetes and heart disease and other diabetes related complications before the age of 35 years[2]. The prevalence of Cardio-metabolic risk factors in many children hasincreased substantially over the last 15 years, anda study conducted in South India has shown that68 % of children have at least one elevatedrisk factor[3]. Clustering of these risk factors will result in enormous personal, societal, and economic costs for many decades. Strategies to address this problem are needed immediately, as prevention of cardio-metabolic disorder is far preferable to treatment[4].

Presence of cardiovascular risk factorsin youth is known to be associatedwith the extent of arterial wall damage and intima-media thickness[5]. Given that many cardio-metabolic risk factors track throughadolescence and into adulthood, it is vital that these risksbe assessed as children progress through puberty and intoearly adulthood[6-7]. Thus, assessment and modulation of Cardiometabolic risk factorsduring childhood is essential. Further, there is a need for effectiveinterventions that target reduction of cardio-metabolic risk factorlevels beginning at an early age.

Hypertension and Obesity in Youth (AHOY) society recently emphasized that besides clinical set up, schools were important stakeholders in population-based health promotion and risk-reduction efforts[8]. Our central hypothesis is that screening and recruitment will be effective in identifying children at high risk for cardiometabolic diseases and successfully enrolling them in a lifestyle modification program.To accomplish this objective, validated non-invasive tools to assess cardiovascular risk (the Healthy Heart Score)[4] and diabetes risk (Indian Diabetes Risk score)[1]scorewill be used in present study to stratify the cardiometabolic risk among the children.The impact of life style intervention on the knowledge regarding preventive strategies for cardiometabolic risk reduction (Diet and Physical Activity, Weight control)will also be delineated.

4. **Objectives**

Primary Objective

1. To stratify the overweight and obese children into various cardiometabolic risk categories (low, medium and high) based on the risk scores
2. To study the impact of life style interventions on preventive strategies regarding cardio-metabolic diseases risk reduction among these children.

Secondary Objective

3. To assess the proportion of overweight and obese children at a risk of developing cardio-metabolic diseases and study their demographic profile and life style patterns.
4. To determine the predominant cardio-metabolic risk factors present among overweight and obese children.

Methodology

Approval from the Institutional Ethics Committee will be obtained before initiating the study.

Study Design: Prospective, Interventional

Study Site: MGM School, Nerul, Navi Mumbai

Study Duration: Four Months (May 2019- August 2019)

Sample size: Approximately 250children will be screened to identify overweight and obese children.Study conducted by Pawar et al. demonstrates the prevalence of overweight and obesity among South Mumbai children as 17.5% and 7.8 % respectively[9].

Assumptions: Educational intervention study prior data indicates that difference in the response of matched pairs is normally distributed with standard deviation 4. If the true difference in the mean response of matched pairs is 2.25, we will need to **study 35 obese and overweight children** to be able to reject the null hypothesis that this response difference is zero with probability (power) 0.9. The Type I error probability associated with this test of this null hypothesis is 0.05.

Study Population: Children who conform to the specified Inclusion and Exclusion Criteria will be enrolled for the study.

Inclusion criteria:

- Age ≥10 years of age
- Obese and overweight children(Age specific BMI cut-off values, Khadilkar, et al, 2002)[10]
- Children and their parents whoagree to sign the informed consent form

Exclusion criteria:

- Age less than 10 years and more than 18 years
- Children and their parents who do not agree to sign the informed consent form

Case Record Form (CRF):

A CRF will be prepared to record the following information of the children

1. **Demographic Profile**
   - Age
   - Gender
   - Anthropometry:BMIand waist Circumference.

2. **Lifestyle**

   - **Physical activity:** refers to the previous 7-days and requires children to recall, activities that they participated in over the previous week[11].

   - **Dietary habits:** The children were required to recall previous 7-days dietary habits.

3. **Cardiovascular fitness:** The test begins with children running 20-m laps at 8.5kmph. Running speed increases by 0.5kmph after each 1-min stage. Children continue running until they can no longer maintain the pace. The test has been shown to be a valid and reliable measure of cardiovascular fitness in children[12].

4. **Blood pressure:**Systolic and diastolic blood pressures will be recordedusing sphygmomanometer.

5. **Healthy Heart Score for Assessment of CVD Risk**

Thus, Healthy Heart Scores could range between 5and 18 with lower scores representing a more favourableCVD risk factor profile.

S. No	Parameters	Score 1 (low)	Score 2 (Moderate)	Score 3 (High)	Score 4 (Highest)
1	BMI				
2	SBP				
3	DBP				
4	Cardiac Fitness				NA
5	Physical Activity				NA
	Total Scores	5	6-10	More than 11	
	Category	Low	Moderate	High	

Scoring: SBP and DBP score 1 $\leq$ 75th percentile, score 2 = 76th-85th percentile, score 3=86th-95th percentile and score 4 $\geq$95th percentile; BMI >95th percentile (score 4) and overweight as BMI between 85th-95th percentile (score 3), 75-85th percentile (score 2) and BMI <75th percentile (score 1). Physical activity: >60min (score 1), 30-60 min (score 2), < 30min (score 3).Cardiac fitness (No of 20m laps completed) above (score 1),within (score 2) or below (score 3) criterion based agedand sex appropriate values.

6. Assessment of Diabetes Risk

S. No	Indian diabetes risk score (IDRS)	Score allocated	Yourscore
1	Age		
	Less than 35	0	
	Between 35-and 49 years	20	
	More than 50 years	30	
2	Abdominal Obesity		
	Waist circumference as per reference standards	0	
	Waist circumference more than 85 % percentile as per reference standards	20	
	Waist circumference more than 95 % percentile as per reference standards	30	
3	Physical Activity		
	Exercise (regular) and strenuous work (reference)	0	
	Exercise (regular) or strenuous work	20	
	No exercise and sedentary work	30	
4	Family history		
	No family history	0	
	Either parent	20	
	Both parents	30	
	Total Score	100	

Scoring: Risk Interpretation as high, moderate and low risk if their IDRS score is $\geq$60, 30-50 and <30 respectively.

Implications

There is accumulating evidence on the increasingprevalence of cardiometabolic risk factors especially amongoverweight and obese children.Furthermore, tracking occurring from childhood to adulthood for many cardiometabolic risk factors which may manifest as overt diabetes and cardiovascular diseases, needs to be checked. Results will provide baseline information on the cardiometabolic risk profile, life style pattern, factors associated with cardiometabolic risk amongoverweight and obese children. The purpose of emphasizing the recommendations elaborated in the standard guidelines(WHOand ADA) through educational intervention is to motivate and assist high-risk children to lower their cardiometabolic risk bymaking healthy food choice, being physically active and reducing body mass indexwherever applicable. Data will provide future guidance on specific preventive actions to initiate at the level of child, parents and School administration for cardiometabolicrisk modification.

References

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3. Ramachandran A, Snehalatha, Yamuna A et al. Insulin Resistance and Clustering of Cardiometabolic Risk Factors in Urban Teenagers in Southern India
4. Kate ER, Darren ER, Heather A et al. Determining cardiovascular disease risk in elementary school children:Developing a healthy heart score. Journal of Sports Science and Medicine (2007) 6, 142-148
5. Raitakari OT, Juonala M, Kahonen M, et al. Cardiovascular risk factors in childhood and carotid artery intima-media thickness in adulthood: the Cardiovascular Risk in Young Finns Study. Journal of the American Medical Association 2003; 290, 2277- 2283.
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7. Claire MN, Ghattu VK, Alicja RR et al. Cardiometabolic Risk Markers in Indian Children: Comparison with UK Indian and White European Children. PLoS One. 2012; 7(4): e36236.
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9. Pawar S , Choksey A , Jain S et al. Prevalence of Overweight and Obesity in 4 Schools of South Mumbai Journal of Clinical and Diagnostic Research. 2016 Mar, Vol-10(3): OC01- OC02
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11. CrockerPR, Bailey DA, Faulkner RA et al. Measuring general levels of physical activity:preliminary evidence for the Physical Activity Questionnairefor Older Children. Medicine and Science in Sports Exercise. 1997; 29, 1344-1349.
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Case Record Form

Title: Cardio-metabolic risk stratification and life style interventions for risk reduction among overweight and obese children

Demographic Profile

Class:		Age:		Gender:	M/F
Height:		Weight:		BMI:	
Waist circumference		SBP		DBP	

Life Style Pattern

Dietary Habits (24 h recall)				Physical Activity(Min/day) *Tick mark*		
Fruits & Veg Intake /day (400-500 g)	Always	Sometimes	Never	More than 60 min	Between 30-60 minutes	Less than 30 minutes
Salt restriction (<5 g/day)				*Cardiac fitness*		
Saturated fat restriction (<30 % of total calories)				(No of 20m laps completed)		

2.Healthy Heart Score for Assessment of CVD Risk

S. No	Parameters	Score 1 (low)	Score 2 (Moderate)	Score 3 (High)	Score 4 (Highest)
1	BMI				
2	SBP				
3	DBP				
4	Cardiac Fitness				
5	Physical Activity				

Total Score: _____   Risk Category:_____

5. Assessment of Diabetes Risk

S. No	Indian diabetes risk score	Score allocated	Your score
1	Age		
	Less than 35	0	
	Between 35-and 49 years	20	
	More than 50 years	30	
2	Abdominal Obesity		
	Waist circumference as per reference standards	0	
	Waist circumference + 1 SD as per reference standards	20	
	Waist circumference + 2 SD as per reference standards	30	
3	Physical Activity		
	Exercise (regular) and strenuous work (reference)	0	
	Exercise (regular) or strenuous work	20	
	No exercise and sedentary work	30	
4	Family history		
	No family history	0	
	Either parent	20	
	Both parents	30	
	Total Score	100	

Total Score: _____   Risk Category: _____

4. **Baseline Knowledge regarding cardio-metabolic risk Modification. Tick Mark the most appropriate choice**

S. No	Risk Factors associated with cardio-metabolic diseases	Extremely likely(5)	Likely (4)	Neutral (3)	Unlikely (2)	Extremely unlikely (1)
		Diet				
1	Are there specific dietary changes that can reduce cardiovascular and diabetes(cardio-metabolic) risk?					
2	Consumption of saturated fats can increase cardio-metabolic risk?					
3	Does increased fruit and vegetables consumption reduce the risk of cardio-metabolic disease?					
4	Is dietary salt associated with high blood pressure?					
		Physical Activity				
5	Does regular physical activity reduce cardio-metabolic risk?					
		Body Weight				
6	Does losing weight reduce the cardio-metabolic risk for those who are overweight or obese?					

5. **Was counselling undertaken on the following Recommendations (Tick Mark appropriate choice)**

S. No	Parameters	Yes	No	Any other Information
		Life Style Changes		
1	Dietary changes			
2	Physical activity			
3	Weight control			

6. **Please rate the information you received during counselling (tick mark appropriate answer):**

S.No	Questions	Very	Somewhat	Neutral	Not very	Not at all
1	Was it useful?					
2	Was it complete?					
3	Was it fair &balanced?					

7. Post Counselling, Knowledge regarding cardiometabolic Risk Modification. Tick Mark the most appropriate choice

S. No	Risk Factors associated with cardio-metabolic diseases	Extremely likely(5)	Likely (4)	Neutral (3)	Unlikely (2)	Extremely unlikely (1)
	Diet					
1	Are there specific dietary changes that can reduce cardiovascular and diabetes(cardio-metabolic) risk?					
2	Consumption of saturated fats can increase cardio-metabolic risk?					
3	Does increased fruit and vegetables consumption reduce the risk of cardio-metabolic disease?					
4	Is dietary salt associated with high blood pressure?					
	Physical Activity					
5	Does regular physical activity reduce cardio-metabolic risk?					
	Body Weight					
6	Does losing weight reduce the cardio-metabolic risk for those who are overweight or obese?					

Participant Information Sheet

Study Title:Cardio-metabolic risk stratification and life style interventions for risk reduction among overweight and obese children

What is the purpose of the present study? Purpose of the study is to assess the cardiometabolic risk profile of obese and overweight children and make appropriate recommendations for lowering cardiometabolic risk based on the standard guidelines for Prevention of Cardiometabolic disease

What is the study procedure?Children attending the MGM Nerul school will be screened and the eligible overweight and obese children will be enrolled in the study after taking informed consent. Child's BP and anthropometric parameters will be recorded. Subsequently the details mentioned on the CRF will be filled up. The non-invasive tools to assess cardiovascular risk (Healthy Heart Score) and diabetes risk (Indian Diabetes risk score) will be used to stratify the children into risk categories (high, medium and low). Appropriate counselling of the children will be undertaken for modification of the cardiometabolic risk.

Who will do the study?The study will be conducted by ShardulKamble, 2nd MBBS student under guidance of Dr.Ipseeta Ray Professor, Dept of Pharmacology

What are the risks discomforts of taking part in the study? The present study involves educational intervention and non-invasive method of cardiometabolic risk assessment. Therefore, there will be no risks involved.

What are the possible benefits of taking part in the study?The cardio-metabolic risk prediction will provide approximate estimates of risk in children who do not have symptoms

of diabetes or coronary heart disease, stroke or other atherosclerotic disease. However, they are useful as tools to help identify those at high cardio-metabolic risk and to motivate children particularly to change their behaviour.

What about confidentiality?Children's identity will be kept confidential during the entire study period. During publication children's information will not be shared with any third party except proper authorities.

Will I be paid for participating in the study? You will not be paid for taking part in this study.

Will I have to pay for any study related investigations/procedures/ treatment? You do not have to pay for related investigations/procedures/ tests.

Whom can I contact for further information? You can contact principal investigator on contact information given below.

  Principle investigator: ShardulKamble/ Dr Ipseeta Ray
  Phone no:9221312216/9819908498
  Email:ipseetamohanty@yahoo.co.in

Informed Consent Form

Study Title: Cardio-metabolic risk stratification and life style interventions for risk reduction among overweight and obese children

Principal Investigator:
Department:
Subject Name:

(Please tick mark the applicable)

1. I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions. ☐

2. I understand that the participation of my child is voluntary and that my child is able to withdraw at any time, without giving reasons, without his/her medical care or legal rights being affected. ☐

3. I understand that the sponsor of the clinical trial, others working on the sponsors' behalf, the Ethics Committee, Legal and the Regulatory authorities will not need my permission to look at the health records of my child both in respect of the current study and further research that may be conducted in relation to it, even if my child withdraws from the trial. I agree to this access. However, I understand that the identity of my child will not be revealed in any information released to third parties or published. ☐

4. I agree not to restrict the use any data or results that arise from this study provided such a use is only for scientific purpose (s) ☐

5. I voluntarily agree to let my child_____take part in the above study ☐

_____
Name & Signature   Date   _____Parents

_____
Signature of Witness (Impartial witness)   Date   _____Name &

_____
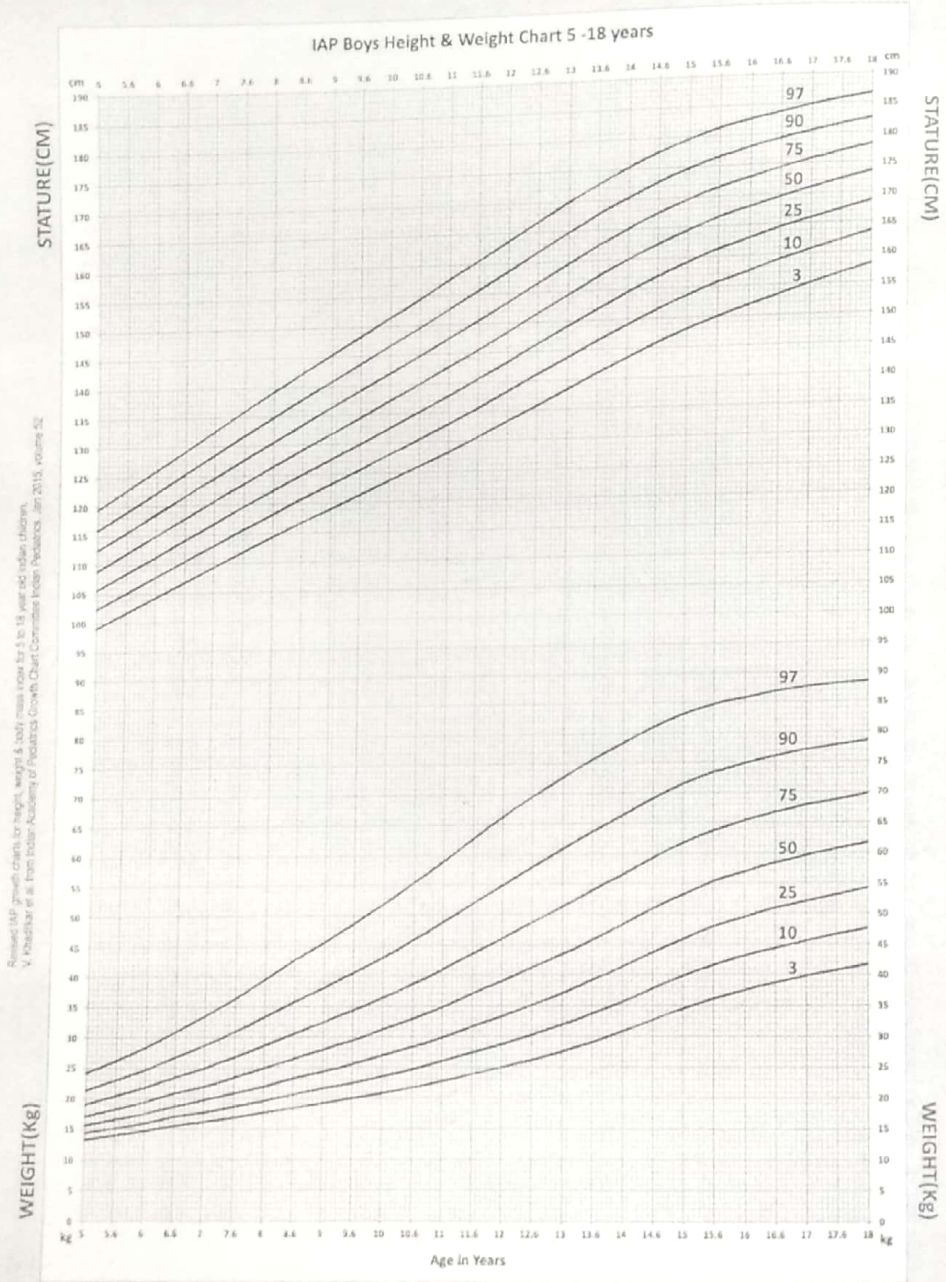Signature of Investigator   Date   _____Name &

5 to 18 Years : IAP Boys Height and Weight Charts

Father's Height _____ , Mother's Height _____ , Target Height _____
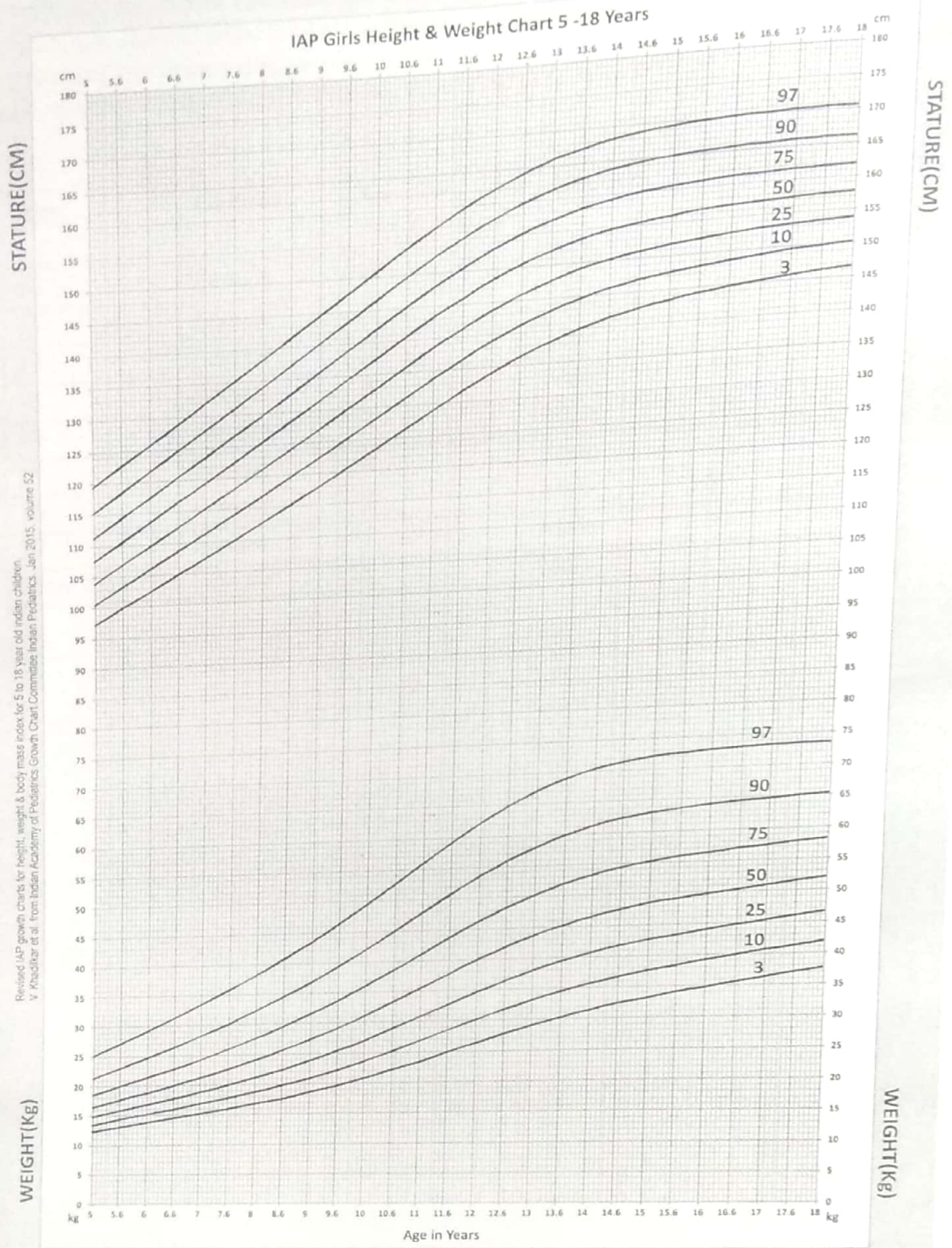

IAP Boys Height & Weight Chart 5 -18 years

5 to 18 Years : IAP Girls Height and Weight Charts

Father's Height _____ , Mother's Height _____ , Target Height _____

IAP Girls Height & Weight Chart 5 -18 Years

STATURE(CM)

WEIGHT(Kg)

Age in Years

Revised IAP growth charts for height, weight & body mass index for 5 to 18 year old Indian children.
V. Khadilkar et al. from Indian Academy of Pediatrics. Growth Chart Committee Indian Pediatrics Jan 2015, volume 52

Progressive Aerobic Cardiovascular Endurance Run (PACER)
Look-Up and Goal Setting Table

Beginning with 2015–16, the PACER, which is one of the three Aerobic Capacity test options available in the FITNESSGRAM[1], is based on student gender, age, and laps only. This table provides the minimum number of 20-meter (20m) laps that males and females need to achieve the Healthy Fitness Zone (HFZ) for the PACER.

S. No	Age	Gender	No of 20m PACER laps	Gender	No of 20m PACER laps
1	10	Female	17	Male	17
2	11	Female	20	Male	20
3	12	Female	23	Male	23
4	13	Female	25	Male	29
5	14	Female	27	Male	36
6	15	Female	30	Male	42
7	16	Female	32	Male	47
8	17	Female	35	Male	50
9	More than 17	Female	38	Male	54

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2019-04540	Ms. sneha bhagirath yadav	Approved
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