Chapter 3

MATERIALS & METHODS
Study Design: This is a randomized non-experimental cross-sectional study conducted on 1087 Gujarati ethnic school going children and adolescents of age group 5 to 18 years in the Anand district.

Ethical clearance and informed consent:

The study was conducted after the approval of the Human Research Ethical Committee (HREC) of HM Patel Centre for Medical Care and Education and after obtaining the informed consent from the parents/guardians and the principals of the school. (Annexure I)

Permission of the Principals:

The study was conducted by visiting five randomly selected schools in Anand district, three rural and two urban schools. After explaining the objective of the study, a prior permission of the Principals of the schools was taken before starting the study and with each consent form the signatures of the principals were also taken.
Recruitment of the participants:

Inclusion Criteria:

1. Gujarati ethnicity (both parents having Gujarati language as their mother tongue)
2. Age 5-18 years. (Children in first standard were found to be of minimum 5 years of age in the schools chosen. This age group includes children as well as adolescents. Students of more than 18 years of age are rare in schools )
3. All socioeconomic classes

Exclusion Criteria:

The exclusion criterion was presence or a history of any acute or chronic disease state that would affect the study variables.

Age:

The age was calculated on the basis of date of birth mentioned in the school registers in most of the subjects. Some schools had given the photo identity card where the date of birth of the student was printed so the age was calculated on its basis.
History of Illness:

A brief history about any illness of the subject was asked and recorded, if the subject was suffering from illness which might affect the study variables at the time of the investigation, for e.g. acute fever, vomiting, diarrhea, the subject was excluded from the study. Subjects with known renal disorder and valvular heart disease were also excluded from the study.

The subjects were also enquired about any family history of hypertension and related cardiovascular disorders and diabetes mellitus. In personal history, information about smoking or tobacco chewing and or alcohol intake was also sought.

Measurement of Height and Weight:

Height: This was done by marking a centimeter scale on the wall of the room without footwear (height). \(^{(60, 198)}\)

Weight was taken by mechanical weighing machine. BMI was calculated by the formula weight in Kg / (height in meters)\(^2\).
Assessment of physical activity:

Daily minimum 1 hour physical activity by any means (participating in the outdoor games etc.) was taken as “regular” physical activity and less than one hour physical activity per day was taken as “irregular” physical activity. (175)

Diet:

The diet was categorized as vegetarian/mixed/egg-vegetarian.

Socioeconomic Status

On the basis of information provided by the subjects and the class teachers, the socioeconomic status was determined as low, middle and high.

Measurement of Cardiovascular Parameters

All the cardiovascular parameters in the study were recorded in resting condition. The basal pulse rate (PR), systolic arterial blood pressure (SBP) and diastolic arterial blood pressures (DBP) were measured and the pulse pressure (PP) and mean arterial pressure (MAP) were calculated.
Instrument:

The Pulse rate (PR), Systolic blood pressure (SBP) and Diastolic blood pressure (DBP) were measured at the brachial artery from the left arm using the Omron T8 automatic Blood Pressure instrument (Accuracy: BP: ± 4mmHg, PR:± 5) Validated by Association for the Advancement of Medical Instrumentation (AAMI) and British Hypertension Society (BHS).\(^{126}\) Like all other digital blood pressure monitors, this instrument works on the principle of oscillometry. Air is pumped into the cuffs at above average Systolic blood Pressure. Then air is released eventually, which decreases the inside blood pressure in the cuff. The low amplitude oscillations caused by the air pressure of the arm cuff are measured during cuff deflation. While measuring the blood pressure, systolic pressure represents the air pressure at which the oscillations start to occur. MCU (microcontroller unit) is used to detect the point or moment at which oscillations start, and the corresponding pressure in the cuff is measured. During the deflation stage diastolic pressure is recorded at the point when oscillations disappear.

The instrument also has ‘intellisense technology’ which is claimed to be present in OMRON blood pressure monitors only. The IntelliSense Monitor inflates the cuff to the ideal level with each use. No adjustments are required by the user to select an inflation level. This is especially convenient for hypertensive users and for people with certain arrhythmia or heart disorders, because their blood pressure is likely to fluctuate. The advantage is Personalized Inflation for maximum comfort (http://www.omron-healthcare.com.sg/intellisense.htm).
The instrument was validated time to time by counterchecking blood pressures by mercury sphygmomanometer.

Figure 3.1: OMRON T8 Blood Pressure Monitor

Cuff size: A small-sized cuff for small children with a small arm circumference and a medium-sized cuff with a bigger arm circumference for bigger children and adolescents were used.\(^{(45,99,161,182)}\)
Figures 3.2 and 3.3: medium sized and small sized cuff.
The blood pressure measurements were taken during school hours before lunch break, if it was a morning school and one hour after the lunch in an afternoon school. The subjects were given a 10 minutes’ rest and no intake of tea, coffee, food, water in last half an hour was allowed. The blood pressure was measured in sitting posture with a back rest, with cubital fossae at the level of heart.\(^{(78,182)}\)

Pulse rate and Blood pressure were recorded at Intervals of 1 minute in the left arm. The average of the three consecutive readings was used for statistical analysis.\(^{(2,4)}\) The children with exceptionally high blood pressure were asked to take an additional 1 hour rest and then again three consecutive readings were taken and if still blood pressure was found high, it was measured serially during next visits to the school. Blood pressure was measured in both arms in such individuals.
Measurement of body fat and other parameters provided in the fat monitor

Instrument:

OMRON HBF-306 body fat monitor was used to measure the body fat percentage and body fat mass. This instrument also calculates BMI (body mass index) and BMR (basal metabolic rate).

This fat monitor is based on the principle of bioelectrical impedance. Tissues containing much water such as muscles, blood vessels, and bones are highly conductive with electricity, but fat tissues are not.

The fat monitoring was done to get any correlation of blood pressure levels in children and adolescents with the amount of body fat.

Therefore, by using this principle, the ratio of fat tissue compared to other tissues in the body by measuring the electric resistance of the body tissues using extremely weak electric current applications to the body can be determined. As the electric current applied to the human body during the body fat measurement is extremely weak of about 50 KHz to 500μA one will not feel the electric stimulation, and this method is safe for the human body.

The electric resistance is determined by “facilitation of electric conductivity” and the “distance of the electricity conduction”. In order to find “facilitation of electric conductivity” for estimating the ratio of fat, it is necessary to always keep the “distance of the electricity conduction” at the same level.
That is why it is necessary to maintain the correct posture during measurement.

Figure 3.4. OMRON HBF-306 body fat monitor.

Calculations:

Calculation of PP, MBP, FMI (Fat Mass Index), FFMI (Fat Free Mass Index) was done by using formulas:

\[
PP = SBP - DBP
\]

\[
MBP = DBP + \frac{1}{3} PP
\]

\[
FMI = \frac{FM \text{ (Kg)}}{\text{height (meters)}^2}
\]

\[
FFMI = \frac{FFM}{\text{height (meters)}^2}
\]

The Resting Metabolic Rate (RMR; the calorie consumption at rest) was calculated as follows \(^{(108)}\):
Mifflin St Jeor Equation (for RMR1):

Males = 10 x weight in Kg + 6.25 x height in cm - 5 x age in years + 5

Females = 10 x weight in Kg + 6.25 x height in cm - 5 x age in years - 161

Harris Benedict Equation (for RMR2):

Males = 66 + (13.7 x weight in Kg) + (5 x height in cm) - (6.8 x age in years)

Females = 655 + (9.6 x weight in Kg) + (1.8 x height in cm) - (4.7 x age in years)

The body fat analysis could be done only of subjects of 10 years' or more age (the OMRON-306 does not measure fat of children below 10 years).

The RMR calculated by the machine, OMRON HBF-306, was labeled as RMR3.

**Statistical Analysis:** was done by using Microsoft office excel 2007 and SPSS (version 16). A “P” value of .05 or less was considered as statistically significant.