# PILOTING A SCHOOL BASED PROGRAM TO REDUCE CHILDHOOD OBESITY IN TAMIL NADU, INDIA

Master of Public Health Integrating Experience Project

Community Service Grant Proposal

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### **Abbrevations**

AUA: American University Of Armenia

BID: Body Image Dissatisfaction

BMI: Body Mass Index

CDC: Centres For Disease Control And Prevention

DXA: Dual Energy X-Ray Absorptiometry

EE<sub>PA</sub>: Energy Expended Through Physical Activity

GNKQ: General Nutritional Knowledge Questionnaire

IOTF: International Obesity Task Force

IRB: Institutional Review Board

LMIC: Low Middle Income Countries

NCD: Non-Communicable Diseases

NFHS: National Family Health Survey

NHLBI: The National Heart, Lung, And Blood Institute

NSW: New South Wales

RMR: Resting Metabolic Rate

TEF: Thermic Effect Of Food

**TOT**: Trainings Of Trainers

WHO: World Health Organisation

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#### **Executive Summary**

According to World Health Organisation (WHO) "overweight or obesity is defined as accumulation of excess fat in the body that may impair health". Body Mass Index (BMI) is considered as an alternative for body fat measurements. When a child's BMI is between one to two standard deviations above the mean the child is classified as overweight and when it is above two standard deviations the child is classified as obese. Although overweight or obesity is a multifactorial disease, it ultimately results from chronic imbalance in calorie intake and expenditure. Overweight or obesity affects both physical and psychological health. Children who are in the top tenth centile of BMI during their early adolescents are five to nine times more likely to develop into obese adults.

Rapid socio-economic growth, modernisation, urbanisation and adaptation of western lifestyle led to nutritional transition in many low middle-income countries (LMIC) including India. A systematic analysis published in 2016, included a pooled prevalence from 52 studies in different states of India. The study showed a 19.3% prevalence of childhood overweight and obesity. The aim of the proposal is to implement and evaluate a school-based multicomponent program to reduce overweight and obesity among sixth and seventh grade students in Chennai, Tamil Nadu. The program has the following objectives:

1) By the end of 10 months after the implementation of the school-based program, the prevalence of overweight/obese students in intervention group will be 6% lower as compared to the control group after adjusting for baseline prevalence.

- 2) By the end of five months after the implementation of the school-based program, average nutrition knowledge score will be 15% higher in the intervention group as compared to the control group after adjusting for baseline.
- 3) By the end of five months after the implementation of the school-based program, the percentage of students performing physical activity according to the guidelines of WHO which recommends 60 minutes of moderate to vigorous intensity workout every day, will be 30% higher in the intervention group as compared to the control group after adjusting for baseline.

The pilot program will include five randomly selected privately run matriculation schools in Chennai. At the first stage of the program four sixth and seventh grade class teachers and physical education teachers will be educated and trained to educate students on a variety of issues related to obesity. At the second stage of the program the trained class teachers will conduct two lectures every month, throughout the duration of the program (10 months). Every month an educational booklet will be given to the students and the content will be explained by the teachers. Physical education teachers will provide training on cardio workouts and strength training.

The evaluation will be done with a panel group using quasi-experimental, non-equivalent control design. A total of 10 schools will be selected and 260 participants from each school will be surveyed. Simple random sampling will be used to select participants for the evaluation.

The proposal is reviewed and approved by the Institutional Review Board (IRB) of the American University of Armenia (AUA).

It is important to control obesity in childhood to help prevent the development of serious health issues in adulthood. The proposed school-based multicomponent program will help to reduce overweight and obesity among sixth and seventh grade students studying in Chennai, Tamil Nadu.

#### Introduction

# Global burden of obesity

According to World Health Organisation (WHO) "overweight or obesity is defined as accumulation of excess fat in the body that may impair health". It is an important modifiable risk factor of many of the chronic conditions or illnesses like metabolic syndrome, insulin resistant diabetes, hypertension, arthrosclerosis, high blood cholesterol, high blood pressure, respiratory diseases, musculoskeletal disorders, and certain types of cancer. 2,3,4

The amount of fat in an individual can be measured using dual-energy X-ray absorptiometry (DXA), Bioelectrical Impedance Analysis, Densitometry.<sup>5</sup> These methods are highly capable and reliable for measuring total body fat.<sup>5</sup> But these methods are not cost and time efficient, so it is not widely used in epidemiological work.<sup>5</sup> Body Mass Index (BMI) is considered as an alternative for body fat measurements. It is a simple non-invasive method used to calculate the degree of body fat using the height and weight of a person. A persons BMI is acquired when "weight in kilograms is divided by the square of height in meters".<sup>6</sup> The BMI categorises the weight status as "underweight (<18.5 kg/m²), normal (18.5 to 25.0 kg/m²), overweight (25 to 30 kg/m²) and obese (>30 kg/m²)". Considering that children are growing, WHO uses the BMI growth curve to define body weight status as BMI-for -age, for children aged between 5-19.<sup>7,8</sup> According to this classification when a child's BMI is from one to two standard deviations above the mean the child is categorised as overweight and when it is above two standard deviations the child is categorised as obese.<sup>8</sup>

Globally thirty nine percent of the adult population aged 18 and above are overweight and thirteen percent are obese. Based on the incidence rates in 2014 it was calculated that at this rate of projection half of the global population would become overweight/obese by 2030. 10

Overweight or obesity affects both physical and psychological health. In addition to being highly associated with chronic morbidities like type 2 diabetes, hypertension and hypercholesterolemia, 11 both overweight and obesity are related with mortality caused by diabetes and kidney disease and obesity is associated with mortality caused by cardiovascular diseases and obesity-related cancers. 12

In 2014, about 2.0 trillion dollars which constituted 2.8% of the global gross domestic product was spent on obesity. <sup>10</sup>

Non-communicable diseases (NCD) are the cause of 70% of all deaths worldwide.<sup>13</sup> In 2012, 117 million people which is about half of the global adult population had one or more chronic disease.<sup>14</sup> Major reduction in the incidence and prevalence of chronic diseases can be attained by targeting overweight/ obesity. <sup>15</sup>

# **Key determinants**

Obesity results from behavioural, environmental and genetic factors. <sup>16</sup> Behavioural factors include physical activity and diet patterns. Environmental factors influence a person's behavioural decision (like the availability of a place and time for physical activity and the cost of healthy food products). The presence of specific gene pattern is responsible for body weight regulation and influences the body's response to environmental changes. <sup>16,17</sup> Although

overweight or obesity is a multifactorial disease, it ultimately results from chronic imbalance in calorie intake and expenditure. <sup>18</sup>

# **Childhood obesity**

Increase in health care spending in the past few decades is due to increase in childhood and adulthood obesity.<sup>19</sup> Between 1980-2003 childhood overweight and obesity has increased by 47.1%.<sup>20</sup> According to WHO estimates 340 million of the population aged 5-19 were overweight/obese in 2016.<sup>21</sup> In 2000, International Obesity Task Force (IOTF) showed that 10% of the 155 million people between 5-17 years were obese.<sup>22</sup>

Body fat accumulation occurs when energy intake is higher than energy expenditure. <sup>18</sup> Increased energy intake and decreased expenditure results in positive energy balance which causes increased fat deposition. <sup>23</sup> For effective reduction in body weight it is necessary to target both energy intake and expenditure.

National Institute of Health categorises calorie intake based on age, gender and level of physical activity (not active, somewhat active, very active).<sup>24</sup> The amount of calorie requirement increases with increasing physical activity, decreases with increasing age and is higher in male than in female.<sup>24</sup> An average somewhat active 9-13-year-old male requires 1,800 to 2,200 calories each day, for female this range is 1,600 to 2,000 calories per day.<sup>24</sup> Increase in calorie intake is associated with increased consumption of soft drinks, intake of energy-dense fast foods and increased portion size.<sup>25</sup>

Energy expenditure is done through "resting metabolic rate (RMR), thermic effect of food (TEF) and energy expended through physical activity (EE<sub>PA</sub>)". <sup>23</sup> RMR is the energy

required at rest and TEF is the energy required for digesting food. Energy expenditure through physical activity is the most varying and necessary for effective weight reduction.<sup>23</sup> Low level of physical activity is attributed to the increase in sedentary activities like watching television, spending time on the internet and computer games.<sup>26</sup> Lack of time and space are an important environmental barrier to being physical activity. Parents not engaging in activities with children, insufficient recess which is often withheld as punishment, unsafe neighbourhood and lack of recreational structures are some of the factors perceived by children as barriers to physical activity.<sup>27</sup>

The literature shows that overweight/obese children are more prone to adulthood obesity. A systemic review showed that about 42% to 63% of the children who were obese during school-age grew up to be obese adults. Children who are in the top tenth centile of BMI during their early adolescents are five to nine times more likely to develop into obese adults.

Overweight or obesity in childhood has severe devastating effects on physical health. Excess fat causes "dyslipidaemia, hypertension, coagulopathy, chronic inflammation, endothelial dysfunction, sleep apnoea, asthma exercise intolerance, gallstones, steatohepatitis, glomerulosclerosis, slipped capital femoral epiphysis, Blount's disease, forearm fracture, flat feet, type 2 diabetes, precocious puberty, polycystic ovary syndrome (girls) and hypogonadism (boys)".<sup>31</sup> These diseases affect different organ systems like cardiovascular, pulmonary, gastrointestinal, renal, musculoskeletal and endocrine system.<sup>31</sup>

Overweight or obesity may affect the psychological health of children causing depression, anxiety, body image dissatisfaction (BID) and eating disorders.<sup>32,33</sup> Depression and

anxiety can be considered as both cause and consequence of obesity.<sup>32</sup> Studies have showed that increase in body mass is also associated with decrease in self-esteem.<sup>34</sup>

#### **Situation in India**

Rapid socio-economic growth, modernisation, urbanisation and adaptation of western lifestyle led to nutritional transition in many low middle income countries (LMIC) including India .<sup>35</sup> While undernutrition is a major prevailing threat in LMIC's, the "dual burden" of undernourishment and obesity is becoming an important issue in LMIC.<sup>36</sup> According to National Family Health Survey (NFHS-4) of 2015-2016 the number of obese population in India has been doubled over the past 10 years.<sup>37</sup> The survey showed that more than 30% of the population in four Indian states were obese.<sup>37</sup> The proportion of overweight or obese women aged 15-49 has increased from 12.6 % in 2005-06 to 20.7% in 2015-16.<sup>38</sup> There was an increase from 9.3% to 18.9% among men 15-49 years old over the same period.<sup>38</sup>

Prevalence of childhood obesity in India varies across the country. Various studies conducted in Punjab, Maharashtra, Delhi and South India showed that the prevalence ranged from 3%-29%. According to the NFHS-4, 2% of children under the age of five are overweight. Among the urban population living in the southern part of India 21.4% of the boys and 18.5% of the girls between the age range of 13 to 18 are overweight or obese. A systematic analysis published in 2016, included a pooled prevalence from 52 studies in different states of India. The study showed a 19.3% prevalence of childhood overweight and obesity.

#### **Specific Aims/ Objectives:**

The aim of the proposal is to implement and evaluate a school-based multicomponent program to reduce overweight and obesity among sixth and seventh grade students in Chennai, Tamil Nadu.

The program has three main objectives:

- 1) By the end of 10 months after the implementation of the school-based program, the prevalence of overweight/obese students in intervention group will be 6% lower as compared to the control group after adjusting for baseline prevalence.
- 2) By the end of five months after the implementation of the school-based program, average nutrition knowledge score will be 15% higher in the intervention group as compared to the control group after adjusting for baseline.
- 3) By the end of five months after the implementation of the school-based program, the percentage of students performing physical activity according to the guidelines of WHO which recommends 60 minutes of moderate to vigorous intensity workout every day, will be 30% higher in the intervention group as compared to the control group after adjusting for baseline.

The program is targeted towards sixth and seventh grade students (aged 10 to 13) living in Chennai, Tamil Nadu.

#### Rationale for the proposal

It is important to control obesity in childhood to help prevent the development of serious health issues in adulthood. The proposed school-based multicomponent program will help to

reduce overweight and obesity among sixth and seventh grade students studying in Chennai, Tamil Nadu.

The program is targeted towards sixth and seventh grade students, whose age range is from 10 to 13. This age group is of interest because this is the period of early adolescence where they undergo certain developmental changes and attain the body proportion of an adult.<sup>43</sup> This is also the period where their reasoning and decision making ability develops.<sup>44</sup>

Since children spend a great deal of their time at schools, school-based interventions will be more effective than family-based or community-based interventions in imparting knowledge on obesity. Moreover, similar school-based interventions have proven to be effective. For example, a meta-analysis conducted in 2014 with five clinical trials which focused on school-based interventions suggested a 42% drop in the prevalence of obesity. In 2016, a school-based multicomponent intervention among obese children at Karnataka, South India showed that the intervention group's mean BMI was reduced by 2.1% whereas the control group's mean BMI increased by 1%.

The program is to be conducted in Tamil Nadu which is regarded as the state with highest level of urbanisation in 2001.<sup>47</sup> Unlike the United States were the prevalence of obesity is higher in rural than in urbanised areas, India follows a different regional pattern.<sup>48,49</sup>

# **Appraisal of strategies**

According to Cohen and Swift's Spectrum of strategies for obesity prevention intervention, the best way to produce effective obesity programs is to target the organisational setting of the population of interest.<sup>50</sup> This program targets students in early adolescence and

focusing on schools is a sensible way to reach out to that population. Studies have suggested that there is a necessity for school-based prevention programs.<sup>51,52</sup> Besides many studies have proven that school-based interventions are useful in decreasing the prevalence of obesity<sup>45,52–54</sup> Health education and physical education are two most important components influencing on child's health.<sup>55</sup>

A school-based non-randomised control trial conducted for 12 weeks among 7-15 years old in 2013-2014, China, aimed at reducing the BMI by including components of physical activity and health education. <sup>56</sup> By the end of 12 weeks the intervention group had a 2.3% decrease in prevalence of overweight/obesity whereas the control group had a 1.7% increase in the prevalence. <sup>56</sup> Extrapolating the results of this study, to match the duration (10 months or 43 weeks) and comparability of the program, our objective expects a 6% decrease in the prevalence of overweight/obesity.

Higher nutritional knowledge is associated with healthier dietary intake.<sup>57,58</sup> Studies among different populations have shown that nutritional education can improve nutritional knowledge.<sup>59</sup> A pilot study conducted among 13 to 18 year old students improved the knowledge score from 63.4% (pre-test) to 78.8% (post-test).<sup>60</sup> Based on this, our study expects a 15% increase in the average knowledge score among the intervention group.

A study among Chinese students in 2016 showed that only 4.4% of the participants knew about the physical activity recommendations.<sup>61</sup> Since knowledge of physical activity recommendations has been accompanied with higher level of physical activity <sup>61</sup>, educating the students on physical activity recommendations will encourage them to be more active.<sup>61</sup> Moreover, studies have demonstrated the effectiveness of school-based physical education

interventions in improving physical activity.<sup>62–64</sup> In 2014, a program aimed to increase active learning time conducted in UK among school children aged 7 to 9 years, increased the proportion of children performing moderate to vigorous physical activity from 42.51% to 72.59%.<sup>65</sup> Based on this study a 30% increase in physical activity is expected from the intervention group as compared to the control group.

#### Methodology

### **Implementation plan**

The pilot program will include five randomly selected privately run matriculation schools in Chennai. Previous studies from low-middle income countries including India showed a higher rate of overweight/obesity in private schools as compared to public schools. <sup>66–68</sup> These schools will be randomly selected from the Chennai Corporations list of public and private schools. <sup>69</sup> To avoid creating a stigma towards obese students all sixth and seventh grade students will be included in the program.

At the first stage of the program four sixth and seventh grade class teachers who are responsible for the particular class and section (for e.g. VI A, VI B, VI C) from each selected school will be educated and trained to educate students on a variety of issues related to obesity. In addition, the physical education teachers will also be trained to provide training on specific moderate to vigorous intensity activity and strength trainings recommended for early adolescent children. This will be different from the usual classes in which teachers provide a small warm up session followed by optional participation in sports. These physical education teachers will also provide information on the World Health Organisation guidelines for moderate and high intensity workouts recommended for children aged between 5 and 17. These trainings of

trainers (TOT) will be conducted by the experts in the respective fields. The duration of TOT is three weeks which will be conducted throughout the period of three months (one week every month) from April 2019 till the end of June 2019.

At the second stage of the program the trained class teachers will conduct two lectures every month, throughout the duration of the program (10 months). The lectures will be conducted during an entire period which lasts for 30-45 minutes each, covering the causes and consequences of obesity, importance of physical activity, healthy dietary choices and dietary balance. Participation in these lectures will be required and incorporated in their regular schedule on Saturdays. Every month an educational booklet will be given to the students and the content will be explained by the teachers. Physical education teachers who participated in TOT will provide training on cardio workouts and strength training. Differences between these workouts, their advantages and WHO's Global recommendations on physical activity for health will be explained. These training will be conducted once every week for 20-25 minutes after classes. These classes will be conducted in addition to their scheduled physical education classes. The participation in these classes will be required.

Since our participants are in the age range of 10-13, most of their nutritional decisions are controlled by their parents. Therefore, including the parents might improve the effectiveness of the program.<sup>72</sup> Parents of the students will receive a handout for home-based intervention and cook book containing recipes of healthy alternatives for junk foods.

#### **Program content**

#### **Educational materials**

Students will receive an approximately 20-page handout at the beginning of every month for 10 months from July 2019 to April 2020. These handouts will be adapted from different educational sources like KidsHealth, We Can and Nutrition.gov.<sup>73–75</sup> These sources contain credible information designed for children on nutrition. Different sources will be used to adapt the handouts to local food variety.<sup>76,77</sup> The handouts will contain information on:

- Causes and burden of overweight/obesity
- Co-morbidities associated with overweight/obesity
- Importance of physical activity
- Energy balance
- Weight management
- Essential nutrition and Nutritional Myths
- Types of food groups (healthy and unhealthy)

## Handbook for parents

The parents will receive a handbook of approximately 32 pages. This handbook will be adapted from The National Heart, Lung, and Blood Institute's (NHLBI) "Families Finding the Balance" parental handbook. The content of the handbook includes information on energy balance, food choice, portion sizes, physical activity and screening time. They will also receive a cook book which contains around 20 healthy recipes with grains. This cook book will be a collection of different recipes from different cook books.

Overall, the program provides access to

- 20 lectures which lasts for 30-40 minutes
- 43 sessions of physical education training which lasts for 20-25 minutes
- Ten (one for each month of the program duration), 20-page handouts
- 32-page parental handbook
- Cook book with 20 healthy recipes

#### **Evaluation plan**

Evaluation of the program will be done using multi-stage cluster sampling. Ten randomly selected privately run matriculation schools from the Chennai Corporation list of public and private schools.<sup>69</sup> Five schools will be randomly assigned as intervention group where the education program will be implemented and the other five as control group. Sixth and seventh grade attendance registry will be used as a sampling frame. Simple random sampling will be used to choose participants for the evaluation.

### The questions addressed by the evaluation study are:

- 1) Will the prevalence of obesity reduce by 6% in ten months after the implementation of the program when compared to the control group?
- 2) After the implementation of program will the average nutritional knowledge increase by 15% in the intervention group as compared to the baseline?
- 3) After the implementation of the program will the proportion of students performing physical activity according to the guidelines of the World Health Organisation increase by 30% in the intervention group as compared to the baseline and the control group?

The evaluation will be done using quasi-experimental, non-equivalent control design with a panel group.

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# Rationale for the design:

This design allows us to compare and assess the effectiveness of our program by measuring both baseline and follow up indicators in both groups. It is more time and cost efficient than other experimental designs.<sup>79</sup> Since we are using a panel group there will be no difference in characteristics of people compared at baseline and follow-up.

# Sample size

Our first and third objective has a dichotomous outcome, so the sample size is calculated using the formula comparing two proportions

$$n = \left(Z_{\alpha/2} + Z_{\beta}\right)^2 * \left(p_1(1 - p_1) + p_2(1 - p_2)\right) / \left(p_1 - p_2\right)^2$$

 $Z_{\alpha/2} = 1.96$ 

 $Z_{\beta} = 0.84$ 

 $p_1 = 0.193$ 

 $p_2 = 0.133$ 

The calculated sample size is 590.

The obtained sample size is for one group, after calculating for both groups the total sample size is 1,180. Since the schools are clusters the sample size is adjusted for a design effect of 2.

Based on similar studies, the rate of attrition is expected to be 10%.<sup>52</sup> After adjusting for design effect and attrition rate the total sample size will be 2,596. The evaluation involves a total of 10 schools (5 intervention and 5 control), so 260 participants will be selected from each school.

#### **Study Instruments**

Weight will be measured using a digital weighing machine after checking for accuracy and consistency and will be "calculated to the nearest 0.1kg". Height will be measured with a calibrated wall mount measuring tape and will be "calculated to the nearest 0.5cm". The measurements will be taken while in their school uniforms, barefoot. The measurements will be taken by the project coordinator or a staff trained by the project coordinator. BMI will be calculated, and BMI-for-age will be estimated.

The parental questionnaire contains questions about parental education, socioeconomic status, information on child's physical and psychological illness, hours of sleep, current medication and parental exposure level to the program (for example reading the parental handbook and trying out recipes from the cook book). Totally the parents questionnaire has 7 questions in the pre-test and 10 questions in the post-test. It would take around 5-10 minutes to complete the questionnaire.

The children questionnaire will consist of two sessions in the pre-test and three sections in the post-test. Pre-test will assess the nutritional knowledge score and physical activity status; the post test will have an additional section asking about their exposure to the program.

Nutritional knowledge will be assessed using the revised version of Parmenter and Wardle 1999 General Nutritional Knowledge Questionnaire (GNKQ). This questionnaire was initially

developed in United Kingdom, so the questionnaire will be adapted to suit the local cultural differences. It will also be adapted for the adolescent population. Physical activity status will be assessed with the New South Wales (NSW) child health survey questionnaire. Totally the children's questionnaire has 41 questions in the pre-test and 44 questions in the post-test. It would take around 30-45 minutes to complete the questionnaire.

The questionnaires will be in English using simple age-appropriate language so that the questions are easily understandable. While English is the primary medium of instruction in all private schools, and Tamil and other Indian languages are considered as second languages which are optional, it is not possible to guarantee the students' ability to read or write in the local language. Moreover, there may be students with different mother tongue, so using English will be more feasible than using the local languages.

Information on socio-demographic factors will be collected. In addition, participation in other sports activities will be obtained. The questionnaire in the post test will also include an additional part to assess the level of exposure to the program.

#### **Variables**

The independent variable is the presence of the school-based multicomponent program. Minimal exposure rate for a student to be considered exposed is as follows: The student should have attended at least 50% of the lectures (10 lectures) and at least 50% of the physical educational classes (22 classes). The dependent variables are the obesity status, nutrition knowledge and physical activity status. The intervening variables are presence of other diseases or intake of medications influencing the body weight, socioeconomic status, maternal education,

stress, depression, sleep deprivation, participation in other extracurricular activities like sports, dancing and yoga.

#### Threats to internal validity

History can be a threat to internal validity but having a control group from schools in the same location, Chennai, minimises the threat. Any other interventions like advertising campaigns would have a similar effect in both the groups. Presence of control group also minimises maturation as a threat to internal validity. Testing will be a threat because we are collecting data on height, weight, nutritional knowledge and physical activity status at baseline resulting in concerns among students which can lead to changes in the way they respond to the intervention: however, the threat is minimized because of the presence of control group. Instrumentation threat will be limited because we will be using the same instruments to collect data from the students at both baseline and follow up. In addition data will also be collected by the same person at both times. Selection-bias and its associated interactions are a threat because randomization is not done. If the students are randomised the students from the same school might be assigned into intervention and control groups. This might cause chaos among students resulting in compensatory rivalry. Instead, selection bias will be minimized by using panel group, sensitive analysis will also be done to control it. As we are using a panel group design, attrition is a major threat to the study. The threat will be controlled by comparing the population characteristic of the drop outs to those who continued in the study. Compensatory rivalry will not be a threat to internal validity because the students will not be aware that they are compared to the control group. Since our target population does not involve groups with outlying characters, threat of regression to the mean will be absent.

#### Threats to external validity

Testing/intervention interaction will be a threat, collecting data on student's height and weight at baseline could possibly alter their attitude towards the program. Selection/intervention interaction will be a threat, in case of generalisation different populations with different characteristics would participate thus altering the outcome of the same intervention. Hawthorne effect will be a threat because the students will be aware of the evaluation, this could have an impact on how they respond to the evaluation. Multiple treatment interference will be a threat, as the intervention has multiple components and it is impossible to isolate their effects. During generalisation, if a single component is implemented separately the outcome would be different from our outcome.

#### **Data collection**

The parent/guardian of the students who were randomly selected will be invited to the school and their consent for their child's participation will be obtained. In their presence the evaluation process will be explained to the child in simple language and their assent will be obtained.

Height and weight of both the intervention and control group will be collected by the program coordinator or a staff trained by the project coordinator. The baseline measurements will be done in the schools throughout June 2019. During the same period the questionnaires will be distributed and data on initial nutritional knowledge and physical activity status will be obtained. The allotted time for initial data collection is one month.

The same data collection methods will be applied during the follow up measurements.

The initial and final data will be obtained during morning class hours after obtaining permission from the respected teacher, principle or headmaster.

#### **Data Entry**

The obtained BMI and the data collected from the survey questionnaires will be entered in SPSS software and the data will be analysed using STATA.

## **Data Analysis**

Prevalence of obesity and physical activity status will be described using percentages. Nutritional knowledge score will be described in mean, median and mode. To compare the mean nutritional knowledge score and physical activity status between the intervention and control group two-sided t-test will be used. Multiple linear regression will be done to explain the effect of the program and nutritional knowledge score. Logistic regression will be used for obesity and physical activity status. To assess the influence of the level of exposure on the outcome ANOVA test will be used.

#### **Ethical consideration**

The proposal is reviewed and approved by the Institutional Review Board (IRB) of the American University of Armenia (AUA). The aims and objectives of the program will be properly explained to the respective schools selected for evaluation. Each participant will be asked to fill out an assent form. Since the target population are children, parents or guardian of the children will be asked to sign their consent forms. Participation in the evaluation will be voluntary and their rights to drop out from the study will be explained. The students will be informed that their participation in the evaluation will not affect their grades in any way.

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# **Appendix 1: Timeline**

	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun
Sampling and setting	X	X	X													
Identifying experts and developing materials	X	X														
Training of trainers		X	X	X												
Training of data collection staff			X													
Data collection				X										X	X	
Intervention					X	X	X	X	X	X	X	X	X	X		
Data entry and analysis					X	X									X	X
Completing final report															X	X

# **Appendix 2: Budget**

## A. Personnel and specific costs for the program

Item	Appointment	Units	Amount	Total
	type		(INR)	(INR),
				(Dollars)
Teachers	Fixed per	Teachers: 4	Per session:	Total:
	session	Lectures: 20	1,500	600,000
		Schools: 5	Per teacher:	(\$8,955)
			30,000	
Physical education	Fixed per	Teachers: 2	Per session:	Total:
teachers	session	Sessions: 43	1,500	645,000
		Schools: 5	Per teacher:	(\$9,627)
			64,000	
Training experts	Fixed per	Trainers: 2	Per month:	Total:
	month	Months: 3	15,000	90,000
			Per trainer:	(\$1,343)
			45,000	
Paper and printing cost	Fixed per unit	Pages: 20	Per page for	Total:
for educational materials		per month	colour	2,520,000
		Months: 10	printing: 7	(\$37,612)
		Handouts:	Per handout:	

		1,800	140	
			Total	
			handouts:	
			16,200	
Paper and printing costs	Fixed per unit	Pages: 30	Per page for	Total:
for parental handouts		Handout:	colour	378,000
		1,800	printing: 7	(\$5,642)
			Per handout:	
			210	
Paper and printing costs	Fixed per unit	Pages: 25	Per page:	Total:
for cook books		Books: 1,800	1.50	67,500
			Per book:	(\$728)
			37.50	
Rent for coordinating	Fixed per	Months: 16	Per month:	Total:
office (including	month		20,000	320,000
electricity charges)				(\$4,776)
Communication charges	Fixed per call	People: 32	Per minute:	Total: 3,840
		Minutes per	1.00	(\$57)
		person: 120		

Miscellaneous (Travel		Total:
charges)		50,000
		(\$746)

Total in Indian Rupees (INR): 4,674,340

Total in dollars (\$): 69,766

## B. Personnel and specific costs for evaluation

Item	Appointment	Units	Amount	Total
	type		(INR)	(INR),
				(Dollars)
Project coordinator	Fixed monthly	Coordinator: 1	Per month:	Total:
		Months: 16	30,000	480,000
				(\$7,164)
Data collection staff	Fixed monthly	Staff: 4	Per month:	Total:
		Months: 2	10,000	80,000
				(\$1,194)
Data entry staff	Fixed per	Questionnaires:	Per	Total:
	questionnaire	5,200	questionnaire:	780,000
			150	(\$11,642)
Rent for data entry	Fixed per	Month: 4	Per month:	Total:
office and tools	month		10,000	40,000
				(\$597)

Instruments for BMI	Fixed per	Digital weighing	Per machine:	Total:
measurement	instrument	machine: 10	3,500	50,000
		Wall mount	Per measuring	(\$746)
		measuring tape: 10	tape: 1,500	
Paper and printing	Fixed per unit	Pages: 15	Per page: 1.50	Total:
cost of questionnaire		Questionnaire:	Per	117,000
		5,200 (Pre-test and	questionnaire:	(\$1,746)
		post intervention)	22.50	
Miscellaneous				Total:
charges (travel,				300,000
communication				(\$4,478)
charges)				

Total in Indian Rupees (INR): 1,847,000

Total in dollars (\$): 27,567

#### **Appendix 3: Parental Consent Form**

#### **American University of Armenia**

#### Gerald and Patricia Turpanjian School of Public Health

#### **Institutional Review Board#1**

#### **Parental Consent Form**

Evaluation of pilot school-based program to reduce childhood obesity in Tamil Nadu, India

Principle investigator: Tsovinar Harutyunyan, MPH, PhD

Co-investigator: Aida Giloyan, MPH

Student investigator: Abinaya Monica Bakthavatchalam, MPH candidate

Hello! I am \_\_\_\_\_\_. The School of Public Health at the American University of Armenia is evaluating a pilot school-based program to reduce childhood obesity in Tamil Nadu, India. This form is to inform you about the evaluation process and obtain your consent for your child's participation in the evaluation.

The aim of our evaluation is to check the effectiveness of school-based educational lectures and exercise trainings in reducing obesity. The evaluation includes 2,600 students from 10 different schools across Chennai. Of these 1,300 students (5 schools) will be participating in an intervention and the other 1,300 students (5 schools) will be considered as the control group.

Your child has been approached to participate in the intervention program as you belong to the school which was randomly assigned into intervention group. (for intervention group)

Your child has been approached to be a control participant as you belong to the school which was randomly assigned into control group. (for control group)

He/she has been randomly chosen from the list because he/she belongs to the sixth or seventh grade from the selected school. The participation of your child is voluntary. He/she has the rights to drop out from the study at any point of time. Agreeing or disagreeing to participate will not affect your child's grade in anyway.

The evaluation process will require the height and weight of your child. You will be asked to fill a questionnaire that will ask about sociodemographic factors, child health status before and after the study, and parental level of exposure only after the study. In addition, he/she will also be asked to complete a self-administered questionnaire which will take around 30-45 minutes. The questionnaire will include questions to assess his/her nutritional knowledge and physical activity status. After 10 months your child will be contacted, and the same information will be collected. No identifiable information including name will be obtained from your child. The collected information will be confidential and used only for this research. The information will be assessable only by the research team. The final report of the study will contain a summary of the data collected from all 830 of the study participants.

Your child does not have any direct benefit from participating in the program. The collected data will be helpful to understand the effectiveness of such programs and it will lead to future interventions to control obesity and its harmful consequences.

If you have any doubts regarding the evaluation process contact our principle investigator of the project Tsovinar Harutyunyan, MPH, PhD (<u>tsovinar@aua.am</u>). If you feel like your child has been mistreated or harmed by participating in the evaluation, you can contact our Human Participants Protection Administrator, Varduhi Hayrumyan, MS, MPH (<u>auairb@aua.am</u>)

If you agree to let your child participate in the evaluation, please read below and sign this form.

"This project has been explained to my child in my presence, in language he/she can understand. He/she has been encouraged to ask questions both now, and in the future, about the research study".

•		
Name of Parent or guardian:		
Signature:		

Date:

#### **Appendix 4: Children Assent Form**

#### **American University of Armenia**

#### Gerald and Patricia Turpanjian School of Public Health

#### **Institutional Review Board#1**

#### Children Assent Form

Evaluation of pilot school-based program to reduce childhood obesity in Tamil Nadu, India

Principle investigator: Tsovinar Harutyunyan, MPH, PhD

Co-investigator: Aida Giloyan, MPH

Student investigator: Abinaya Monica Bakthavatchalam, MPH candidate

Hello! I am \_\_\_\_\_\_. The School of Public Health at the American University of Armenia is conducting a small-scale school-based study to reduce childhood obesity in Tamil Nadu, India. The aim of our study is to check the successfulness of school-based education and exercise trainings in reducing obesity.

The study is conducted among sixth and seventh grade students. You have been asked to participate in the study as you belong to sixth or seventh grade from the school that was selected.

The study will measure your height and weight. In addition, you will also be asked to finish a questionnaire on nutrition and physical activity which will take around 30-45 minutes. After 10 months you will be contacted, and the same information will be collected. You can skip any question if you are not willing to answer. Participation in this study poses minimal risk. The information you provide will help to reduce overweight and obesity among students in Chennai, Tamil Nadu.

Your name will not be collected. Your answers will not be shared with anyone including your parents/guardian, teachers or peers, it will be used only for the study.

Your participation in the study is voluntary. Agreeing or disagreeing to participate will not affect your grade in anyway. You have the rights to drop out from the study at any point of time.

Do you agree to participate? If yes, shall we continue?

### **Appendix 5: Questionnaire**

# Part A: Parental Questionnaire PILOTING A SCHOOL BASED PROGRAM TO REDUCE CHILDHOOD OBESITY IN TAMIL NADU, INDIA

### Gerald and Patricia Turpanjian School of Public Health

### **American University of Armenia**

#### **Parental Questionnaire**

The questionnaire consists of several parts:

- I. Sociodemographic and socioeconomic factors
- II. Child's Health status
- III. Level of Exposure (only in the post-test of intervention group)

Please read the questions carefully and circle or tick the options that is most appropriate to you. You can skip any question you are not sure or if you do not want to answer.

ID number:
Date of interview (dd/mm/yyyy)://
Starting time of interview (hh/mm): /

#### I. Sociodemographic and socioeconomic factors

- 1) Mothers education:
  - 1. Pre-primary
  - 2. Primary
  - 3. Secondary
  - 4. High school
  - 5. Bachelor's degree
  - 6. Master's degree
  - 7. Doctorate degree
- 2) Fathers education:
  - 1. Pre-primary
  - 2. Primary
  - 3. Secondary
  - 4. High school

	6.	Master's degree
	7.	Doctorate degree
3)	Is y	our family monthly income?
	1.	INR 30,000 and above
	2.	INR 20,000 to INR 29,999
	3.	INR 10,000 to INR 19,999
	4.	INR 5,000 to INR 9,999
	5.	Less than INR 5000
II.	Ch	aild's Health status
4)	Is y	our child suffering from any chronic physical illness? (circle or tick all applicable
	ans	wers)
	1.	Developmental problems
	2.	Diabetes
	3.	Heart disease
	4.	Lung disease (including asthma)
	5.	Stomach/intestine disease
	6.	Cancer
	7.	Eye/vision problems
	8.	Kidney problems
	9.	Problems with joints/bones
	10.	Other problems (describe)
	11.	No chronic health problems
5)	Is y	our child suffering from any phycological illness? (circle or tick all applicable
	ans	wers)
	1)	Depression
	2)	Anxiety
	3)	Stress
	4)	Panic attacks
	5)	Eating problems
	6)	Other problems (describe)
6)	Is y	our child under any prescribed medication?
	1.	Yes
	2.	No
		41

5. Bachelor's degree

If yes, please indicate the medication:
7) How many hours of sleep does your child get per night?
1. More than eight hours
2. Seven to eight hours
3. Six to seven hours
4. Five to six hours
5. Less than five hours
III. Level of Exposure to the program: (only in the post-test of intervention group
8) Did you read the provided parental handbook?
1. Yes
2. No (skip to question 9)
9) If yes, did you implement any of the measures provided in the handbook?
1. All of them
2. Most of them
3. None of them
10) Did you try any recipes from the provided cook book?
1. All of them
2. Most of them
3. None of them
Ending time of interview (hh/mm):/
Thank You for your Participation!!!

# Part B: Children Questionnaire PILOTING A SCHOOL BASED PROGRAM TO REDUCE CHILDHOOD OBESITY IN TAMIL NADU, INDIA

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#### **Children Questionnaire**

The o	questionr	naire	consists	of	several	parts:
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- I. Sociodemographic Factors
- II. General nutritional questions
- III. Physical activity questions

ID number:

IV. Level of exposure (only in the post-intervention)

Please read the questions carefully and circle or tick the options that is most appropriate to you. If you do not find an option that is not appropriate to you, choose the closest answer from the provided options. You can skip any question that you do not want to answer.

School Grade:
Date of interview (dd/mm/yyyy):/
Starting time of interview (hh/mm):/
I. Sociodemographic Factors
1) Gender:
1. Male
2. Female
2) Date of birth ( <i>dd/mm/yyyy</i> )://

## **II.** General Nutrition Knowledge Questions

3) Do health experts recommend that people should be eating more, the same amount, or less of the following foods? (*tick one box per food*)

	More	Same	Less	Not Sure
1. Fruit	1 🗆	2 🗆	3 🗆	4 🗆
2. Food and drinks with added sugar	1 🗆	2 🗆	3 🗆	4 🗆

3. Vegetables	1 🗆	2 🗆	3 🗆	4 🗆
4. Fatty foods	1 🗆	2 🗆	3 🗆	4 🗆
5. Processed red meat	1 🗆	2 🗆	3 🗆	4 🗆
6. Wholegrains	1 🗆	2 🗆	3 🗆	4 🗆
7. Salty foods	1 🗆	2 🗆	3 🗆	4 🗆
8. Water	1 🗆	2 🗆	3 🗆	4 🗆

- 4) How many servings of fruit and vegetables per day do experts are advice people to eat as a minimum? (One serving could be, for example, an apple or a handful of chopped carrots) (tick one)
  - 1. Two
  - 2. Three
  - 3. Four
  - 4. Five or more
- 5) Which of these types of fats do experts recommend that people should eat less of? *(tick one box per food)*

	Eat less	Not eat less	Not sure
1. Unsaturated fats	1 🗆	2 🗆	3 🗆
2. Trans fats	1 🗆	2 🗆	3 🗆
3. Saturated fats	1 🗆	2 🗆	3 🗆

- 6) Which types of dairy foods do experts say people should drink? (tick one)
  - 1. Full fat (e.g. full fat milk)
  - 2. Reduced fat (e.g. skimmed and semi-skimmed milk)
  - 3. Mixture of full fat and reduced fat
  - 4. Neither, dairy foods should be avoided
  - 5. Not sure
- 7) How many times per week do experts recommend that people eat oily fish? (tick one)
  - 1. 1-2 times per week
  - 2. 3-4 times per week
  - 3. Everyday
  - 4. Not sure

8) How many tim	) How many times per week do experts recommend that people eat breakfast? (tick				
one)					
1. 3 times per	week				
2. 4 times per	week				
3. Everyday					
4. Not sure					
9) If a person has	two glasses of fruit j	uice in a day, how ma	any of their daily fruit and		
vegetable servi	ings would this count	t as? (tick one)			
1. None					
2. One servin	g				
3. Two servir	ngs				
4. Three serv	ings				
5. Not sure					
10) According to the	he 'eatwell plate' (a g	guideline showing the	proportions of food		
types people sl	nould eat to have a ba	alanced and healthy di	iet), how much of		
people's diet sl	hould be made up of	starchy foods? (tick o	ne)		
1. ½ plate					
2. <sup>1</sup> / <sub>3</sub> plate					
3. ½ plate					
4. Not sure					
11) Do you think t	hese foods and drink	s are typically high or	low in added sugar? (tick		
one box per fo	od)				
	High in added	Low in added	Not sure		
1 D' / 1	sugar	sugar			
<ol> <li>Diet cola drinks</li> </ol>	1 🗆	2 □	3 🗆		
2. Natural	1 🗆	2 🗆	3 🗆		
yoghurt  3. Ice cream	1 🗆	2 🗆	3 🗆		
4. Tomato					
ketchup	1 🗆	2 🗆	3 🗆		
5. Melon	1 🗆	2 🗆	3 🗆		

12) Do you think these foods are typically high or low in salt? (tick one box per food)

	High in salt	Low in salt	Not sure
Breakfast cereals	4 🗆	5 🗆	6 🗆
2. Frozen vegetables	4 🗆	5 🗆	6 🗆
3. Bread	4 🗆	5 🗆	6 🗆
4. Baked beans	4 🗆	5 🗆	6 🗆
5. Red meat	4 🗆	5 🗆	6 🗆
6. Canned soup	1 🗆	2 🗆	3 🗆

13) Do you think these foods are typically high or low in fibre? (tick one box per food)

	High in	Low in	
	Fibre	Fibre	Not Sure
1. Oats	1 🗆	2 🗆	3 🗆
2. Bananas	1 🗆	2 🗆	3 🗆
3. White rice	1 🗆	2 🗆	3 🗆
4. Eggs	1 🗆	2 🗆	3 🗆
5. Potatoes with skin	1 🗆	2 🗆	3 🗆
6. Pasta	1 🗆	2 🗆	3 🗆

14) Do you think these foods are a good source of protein? (tick one box per food)

		Not a good source of	
	Protein	Protein	Not sure
1. Poultry	1 🗆	2 🗆	3 🗆
2. Cheese	1 🗆	2 🗆	3 🗆
3. Fruit	1 🗆	2 🗆	3 🗆
4. Baked beans	1 🗆	2 🗆	3 🗆
5. Butter	1 🗆	2 🗆	3 🗆
6. Nuts	1 🗆	2 🗆	3 🗆

15) Which of the following foods do experts count as starchy foods? (tick one box per

*food)* 

		Not a starchy	
	Food	food	Not sure
1. Cheese	1 🗆	2 🗆	3 🗆
2. Pasta	1 🗆	2 🗆	3 🗆
3. Potatoes	1 🗆	2 🗆	3 🗆
4. Nuts	1 🗆	2 🗆	3 🗆
5. Plantains	1 🗆	2 🗆	3 🗆

16) Which is the main type of fat present in each of these foods? (tick one box per food)

	Polyunsaturate				
	d	Monounsat-			
	Fat	urated fat	Saturated fat	Cholesterol	Not sure
1. Olive oil	1 🗆	2 🗆	3 🗆	4 🗆	5 🗆
2. Butter	1 🗆	2 🗆	3 🗆	4 🗆	5 🗆
3. Sunflower oil	1 🗆	2 🗆	3 🗆	4 🗆	5 🗆
4. Eggs	1 🗆	2 🗆	3 🗆	4 🗆	5 🗆

- 17) Which of these foods has the most trans-fat? (tick one)
  - 1. Biscuits, cakes and pastries
  - 2. Fish
  - 3. Rapeseed oil
  - 4. Eggs
  - 5. Not sure
- 18) The amount of calcium in a glass of whole milk compared to a glass of skimmed milk is: (tick one)
  - 1. About the same
  - 2. Much higher
  - 3. Much lower

- 4. Not sure
- 19) Which one of the following nutrients has the most calories for the same weight of food? (*tick one*)
  - 1. Sugar
  - 2. Starchy
  - 2. Fibre/roughage
  - 3. Fat
  - 4. Not sure
- 20) Compared to minimally processed foods, processed foods are: (tick one)
  - 1. Higher in calories
  - 2. Higher in fibre
  - 3. Lower in salt
  - 4. Not sure
- 21) Which of the diseases is related to a low intake of fibre? (tick one)
  - 1. Bowel disorders
  - 2. Anaemia
  - 3. Tooth decay
  - 4. Not sure
- 22) Which of these diseases is related to how much sugar people eat? (tick one)
  - 1. High blood pressure
  - 2. Tooth decay
  - 3. Anaemia
  - 4. Not sure
- 23) Which of the diseases is related to how much salt (or sodium) people eat? (tick one)
  - 1. Hypothyroidism
  - 2. Diabetes
  - 3. High blood pressure
  - 4. Not sure
- 24) Which of these options do experts recommend to reduce the chances of getting cancer? (*tick one*)
  - 1. Drinking alcohol regularly
  - 2. Eating less red meat
  - 3. Avoiding additives in food

- 4. Not sure
- 25) Which of these options do experts recommend to prevent heart disease? (tick one)
  - 1. Taking nutritional supplements
  - 2. Eating less oily fish
  - 3. Eating less trans-fats
  - 4. Not sure
- 26) Which of these options do experts recommend to prevent diabetes? (tick one)
  - 1. Eating less refined foods
  - 2. Drinking more fruit juice
  - 3. Eating more processed meat
  - 4. Not sure
- 27) Which one of these foods is more likely to raise people's blood cholesterol? (*tick one*)
  - 1. Eggs
  - 2. Vegetable oils
  - 3. Animal fat
  - 4. Not sure
- 28) Which one of these foods is classified as having a high Glycaemic Index (Glycaemic Index is a measure of the impact of a food on blood sugar levels, thus a high Glycaemic Index means a greater rise in blood sugar after eating)? (tick one)
  - 1. Wholegrain
  - 2. White bread
  - 3. Fruits and vegetables
  - 4. Not sure
- 29) To maintain a healthy weight people should cut fat out completely. (tick one)
  - 1. Agree
  - 2. Disagree
  - 3. Not sure
- 30) To maintain a healthy weight people should eat a high protein diet. (tick one)
  - 1. Agree
  - 2. Disagree
  - 3. Not sure
- 31) Eating bread always causes weight gain. (tick one)

- 1. Agree
- 2. Disagree
- 3. Not sure
- 32) Fibre can decrease the chances of gaining weight. (tick one)
  - 1. Agree
  - 2. Disagree
  - 3. Not sure
- 33) What of these options can help people to maintain a healthy weight? (answer each one)

			Not
	Yes	No	sure
1. Not eating while watching TV	1 🗆	2 🗆	3 🗆
2. Reading food labels	1 🗆	2 🗆	3 🗆
3. Taking nutritional supplements	1 🗆	2 🗆	3 🗆
4. Monitoring their eating	1 🗆	2 🗆	3 🗆
5. Monitoring their weight	1 🗆	2 🗆	3 🗆
6. Grazing throughout the day	1 🗆	2 🗆	3 🗆

- 34) If someone has a Body Mass Index (BMI) of 23kg/m<sup>2</sup>, what would their weight status be? (*tick one*)
  - 1. Underweight
  - 2. Normal weight
  - 3. Overweight
  - 4. Obese
  - 5. Not sure
- 35) If someone has a Body Mass Index (BMI) of 31kg/m<sup>2</sup>, what would their weight status be? (tick one)
  - 1. Underweight
  - 2. Normal weight
  - 3. Overweight
  - 4. Obese
  - 5. Not sure

Look at the body shape below:



- 36) Which of these body shapes increases the risk of cardiovascular disease (Cardiovascular disease is a general term that describes a disease of the heart of blood vessels, for example, angina, heart attack, heart failure, congenital heart disease and stroke)? (tick one)
  - 1. Apple shape
  - 2. Pear shape

8. Football

3. Not sure

## **III.** Physical Activity Questions

I Hysicai A	cuvity Questions
37) On abou	nt how many days during the school week does child usually do physical
activity	outside of school hours?
Number	of days
38) On thos	e days, about how many hours does child usually do physical activity?
Hours, 1	minutes,
39) On abou	nt how many weekend days does child usually do physical activity?
Number	of days
40) On a ty	pical weekend day, about how many hours does child usually do physical
activity'	?
Number	of hours
41) In the la	st 12 months, what types of sports and outdoor activities did child play?
1.	Basketball
2.	Cricket
3.	Cycling or bike riding
4.	Dancing or ballet
5.	Jogging or athletics or running
6.	Martial arts
7.	Skateboarding or rollerblading

9	. Swimming
1	0. Other (specify)
1	1. Did not play any sport
IV. Level of E	xposure to The Program: (only in the post-test of intervention group)
42) Out of	the 20 lectures conducted on nutritional education, how many of them did
you no	at attend?
1.	One to three
2.	Four to Six
3.	Six to Ten
4.	More than ten
43) Of the	43 additional physical educational classes, how many of them did you not
attend	?
1.	One to five
2.	Six to Ten
3.	Eleven to Fifteen
4.	Fifteen to twenty
5.	More than twenty
44) Of the	10 handouts provided to you, how many of them did you read?
1.	All of them
2.	Most of them
3.	None of them
	Ending time of interview (hh/mm):/
Thank You for yo	our Participation