Study Protocol

Study title: Designing and testing a theory based non-communicable disease curriculum to enhance health literacy among youth: A randomized controlled trial in Gujarat, India

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Introduction:

Health literacy skills help people make informed health decisions. However, there is a theory-praxis gap related to health literacy interventions focused on non-communicable diseases (NCD) among young people. We designed a contextually relevant, theory-informed NCD health literacy curriculum and investigated its effect on NCD health literacy among non-medical, non-nursing college students in the state of Gujarat, India.

This study was carried out under aegis of Indian Institute of Technology Gandhinagar (IITGN) as a part of doctoral studies of Ankita Shah. The study was funded by IITGN, Dr. Rahul Jindal, Professor of Surgery and Global Health, Uniformed Services University, Bethesda, Maryland and Dr. Malavika Subramanyam, Assistant Professor, Social Epidemiology, IITGN.

Dr. Malavika Subramanyam is the Principal Investigator (PI) of this study. Ankita Shah is a doctoral student at IITGN and is the co-PI of this study. The concept of this study was developed

during discussion with the team during Dr. Rahul Jindal's Fulbright-Nehru scholarship to India (2016).

Literature review:

Current efforts towards addressing health awareness, education, communication in general and specifically addressing NCD in the Indian context [1-7, 8-12], include online resources, and school curricula. However, they are limited by one or more of the following:

1. *Major emphasis on disseminating information and facts and minimal emphasis on imparting skills for practical application of health information.* For instance several efforts follow an approach where they teach that transfats (an example) should be avoided without imparting the skills to identify the food items that are loaded with transfats, and the skills to identify and replace it in their diet given their context such as college dormitory living.
2. *Limited ability to treat a topic in a contextually relevant, holistic manner.* For instance, food related advice to prevent obesity typically over-emphasize calorific value of food and undermine its nutritive value, food and cooking preferences, food availability, and affordability across cultures and contexts.
3. *Focus on instructional learning and memorization and/or application of disseminated information but limited emphasis on critical thinking to help decision-making when presented with health information from various sources.* For instance, these efforts frequently place a limited emphasis on imparting skills to critically analyze any sort of health related information or advertisements and judge the credibility of the claims made. This is especially relevant to the choice of products frequently labelled as "healthy," such as corn-flakes, sugar substitutes, heart-friendly edible oils and so on. While clear directions on what the participants should or should not do may help in bringing about the recommended behavior change in their current context, it might not be much helpful

in enabling them to make healthier lifestyle choices, in different spatio-temporal contexts and across life-stages, both of which are highly dynamic.

4. *Over-simplistic and incomplete explanations of biological processes underpinning the disease outcomes.* The explanations provided are often insufficient for the participants to appreciate the importance of behavior change and might also mislead them. For instance, approaches that teach that diabetes means increased blood sugar levels, without emphasizing the role of insulin and all three macronutrients in regulating blood sugar sufficiently.This may lead the participants to erroneously link refined sugar (only) as the principal cause of the increase in blood sugar level and may lead them to think that curtailing or replacing refined sugar (only) would be sufficient to prevent or control diabetes. tTeaching that advocates avoiding high fat, salt, and sugar (HFSS) food without emphasizing the role of healthy fats and high fiber food in maintaining good health, may not adequately equip the participants to choose healthier food options.
5. *Inadequate sensitization about structural determinants of health.* For instance, how global markets and advertising drive food production, marketing and consumption of several food items linked with adverse health effects. How several groups with vested interest influence law and policy making processes related to food, resulting in weak laws or policies.
6. *No explicit mention of theoretical underpinnings guiding the curriculum design, and a limited incorporation of health literacy in the purpose and methodology of health education and communication.*

Our literature search confirmed that nutrition education curricula taught in secondary schools in India have been critiqued by teachers, parents, and participants as being contextually irrelevant, outdated, inadequate in imparting practical skills, and emphasizing rote learning [13, 14]. Additionally, health education is more often included as one (and sometimes the only) component of behavior change interventions. One problem with this approach is the intrinsic assumption that

most of those who receive health education are in need of behavior change, in the short foreseeable time-period; and/or health education needs to be targeted to those who are in need of behavior change. Health education is approached in a limited way (as described above) in such interventions. Most such interventions do not explicitly mention the use of any theoretical framework in the design of interventions. And, very few interventions specify drawing from a health literacy approach. Therefore, health knowledge, if measured, is measured as one of the subsidiary outcomes in such interventions and a comprehensive assessment of health literacy is rare. Health education is thus not only narrowly operationalized, but importantly, it is viewed as instrumental to behavior change, highly underestimating its intrinsic value. Comprehensive health literacy skills, once acquired, are an important asset, which one could use whenever required during the entire life course. One could utilize the acquired skills for their family and social network, thus becoming an important resource within their community and social network. As Nutbeam [15] posits, when critical health literacy is adequately emphasized, it could potentially act laterally to promote social action that impacts social determinants of health. He insists on conceptualizing health literacy as a primary outcome of health education efforts, a public health goal worth achieving [15].

This highlights the theory-praxis gap related to health literacy interventions across age groups, especially in NCD-related literacy interventions. We, therefore, investigated the effect of a contextually-relevant, theory-informed, health literacy curriculum on NCD literacy among non-medical and non-nursing college students in the state of Gujarat, India.

Study protocol:

1. Specific objectives: To design, deliver, and test the effectiveness of a health literacy curriculum in increasing NCD-related health literacy in college students in Gujarat, India. The

curriculum was aimed at increasing critical awareness and practical skills related to the prevention of NCDs.

2. The NCD health literacy curriculum:

2.1 Theoretical premise: The theoretical premise of the curriculum was based on health literacy within the health promotion paradigm, viewed through a social epidemiological lens. Following the World Health Organization [16], we conceptualized health literacy as "the personal, cognitive, and social skills which determine the ability of individuals to gain access to, understand, and use information to promote and maintain good health." We considered health literacy as a key determinant of health and health equity [15, 17, 18]. We adopted the Health Literacy Skills (HLS) Framework proposed by Squiers et al. [19] with several conceptual modifications (Figure 1) based on Krieger's ecosocial theory [18] and Nutbeam's [15] tripartite model of health literacy.

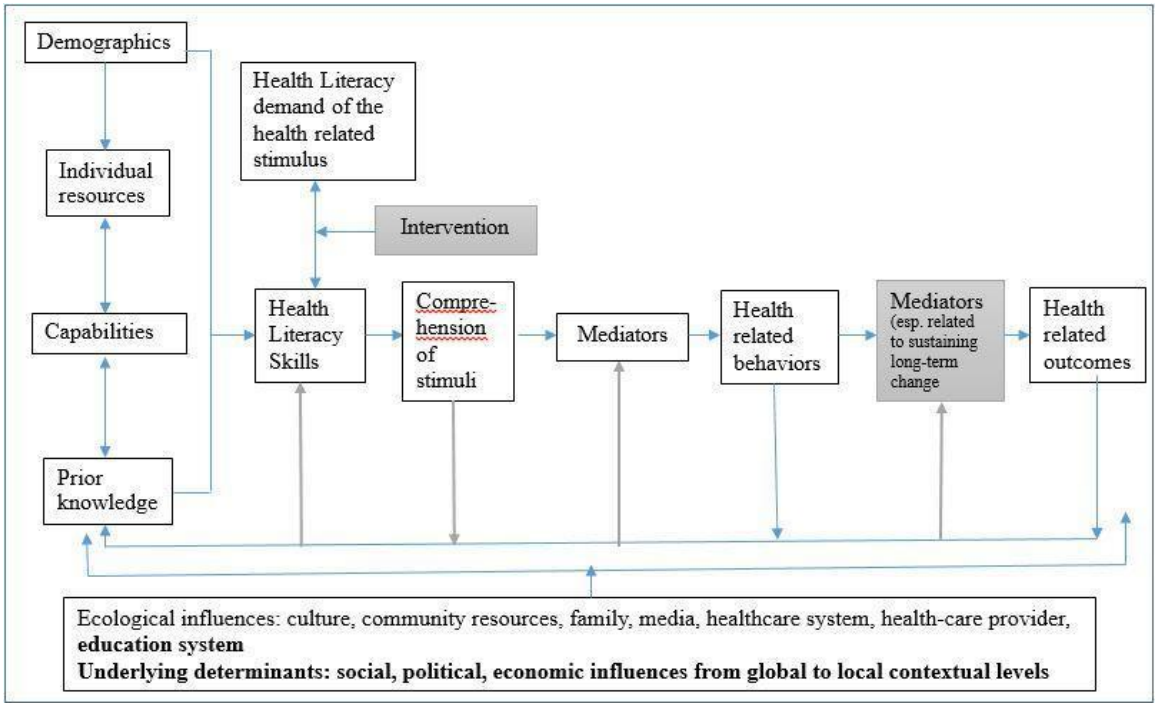

Figure 1: The Health Literacy Skills framework: adapted and modified from Squiers et al. [19]

(Note: All the arrows and boxes in grey and text in **bold** represent our modifications.)

The HLS framework integrates health literacy determinants and associated outcomes into a single causal-conceptual model, conceptualizing health literacy as a dynamic construct, and as a skill that influences the comprehension of health-related stimuli. It assumes complex, multiple levels of ecological influences on health literacy, health behaviors, and health outcomes.

We have modified the HLS framework in the following conceptual domains:

1. The framework posits that ecological influences moderate components of conceptual framework in several ways [19]. We extended this proposition to an upstream level, emphasizing the influence of broader social, political, and economic influences, from global to contextual level in producing and maintaining systematic health differences within and across populations through a range of mechanisms and pathways [18].
2. We contend that engaging in healthy behavior does not necessarily lead to improved health outcomes. The health behavior needs to be performed:
    - Accurately (for instance washing hands with soap with correct hand washing technique);
    - Adequately (a range of interconnected health behaviors simultaneously) (for instance washing hands, covering cooked food, reheating cooked food properly, a range of precautions related to drinking water and related to outside food may collectively affect incidence of diarrheal episodes (health outcome) which may still be insufficient to produce an observable difference in nutritional status of children);
    - For a sufficiently longer duration of time (which is sometimes lifelong);
    - At every recommended instance (for instance all the doses of vaccines); and,
    - In a timely manner (for instance all the vaccines on time), to get the maximum advantage.

    Engaging in a health behavior, therefore, takes time before its observable health outcomes become evident. Thus, health behavior needs to be sustained before health impact becomes visible at the community level. However, the determinants of sustenance of behavior appear to be different from the determinants of initiation of behavior change [8, 20-22] and may remain unaddressed. Additionally, a range of health determinants other than behavior change such as the health system, environment, food policies and other upstream determinants can

affect health outcomes [18], which may remain unaltered. Therefore, we posit that a range of mediators operate between health behavior and health outcomes, and are moderated by upstream determinants.

3. We incorporate critical health literacy as a dimension of health literacy skills. As Nutbeam [15] propounds, adequately emphasizing critical health literacy has the potential to act laterally to promote social action that may impact the social determinants of health.
4. We extend the concept of the dynamic nature of health literacy proposed in the HLS framework [19] and propose that health literacy skills further amplify such skills through a feedback loop from comprehension of stimuli to knowledge (Figure 1). Health literacy is an asset which may or may not result in an immediate health related action, partly because the action might not be required immediately; but it may help build more knowledge and skills, amplifying the health literacy of, and helping others in, the family and the community [15].

2.2 Content selection: Curriculum content was informed by the theoretical framework (Figure 1) and addressed the limitations in the current approach. For this study, we primarily focused upon two health conditions i.e. high blood pressure and diabetes mellitus, both of which have a high prevalence in India [23, 24]; and two preventable risk factors - diet and physical activity. Our curriculum was taught to groups of participants and was used to steer the discussion towards understanding the development of health conditions and the role of modifiable risk factors in primordial, primary, and secondary prevention. Furthermore, our curriculum aimed to impart critical thinking and decision-making skills about practical solutions regarding food and lifestyle choices within contextual constraints.

The following topics were included in the curriculum:

1. Type 2 diabetes mellitus, essential hypertension: Known risk factors, underlying processes, complications, diagnosis, and management.

2. Physiological and anthropometric indices: Their importance in primary and secondary prevention, technical skills to measure them, and the interpretation of obtained values.
3. The essential role of modifiable risk factors in primordial, primary, and secondary prevention of NCDs.
4. Macro and micronutrients in food: The types, roles, and dietary sources.
5. Reading and interpreting food labels.
6. Making healthy food choices in different contexts (for instance in the dining hall of a dormitory or the food court of a shopping mall)
7. Physical activity and exercise: The types and health effects.
8. Incorporating physical activities in daily routine.
9. Critical health literacy skills: Critical evaluation of health related information and dispelling common myths about the etiology, diagnosis, and prevention of NCDs.

2.3 Development of the curriculum: We initiated the curriculum design by specifying learning objectives for each module as per our health literacy model, which then guided content development. We ensured that the content adequately covered functional, interactive, and critical health literacy domains for each of the chosen topics. We included a discussion on health information from a variety of sources (such as gossip, print media, advertisements, the internet, etc.); and in different contexts (such as in day-to-day life, while shopping for food items in supermarkets or grocery stores, while eating out at college cafeterias or restaurants).

We consulted several sources such as renowned textbooks and peer-reviewed literature in clinical medicine, human physiology, health promotion, disease prevention, behavioral risk factors, food and nutrition science, exercise physiology, health behavior change theories, and health education [25-38]. We reviewed regional variations in food practices across India [39], as well as the social causes of health disparities [40-42]. We referred to food labelling laws, including their historical context and current debates around them in Indian and global contexts

[43]. We also consulted public health practitioners and scholars from different regions of the country to understand diverse dietary practices across regions that might have health implications.

The material was developed in English as PowerPoint presentations (Microsoft Office PowerPoint program), accompanied by a written script. We also used several online videos.

We emphasized the logical sequencing of concepts to maintain narrative continuity, minimized use of medical jargon, and explained complex concepts with analogies from everyday life experiences. For instance, the experience of demonetization (sudden change in the currency policy) in India was used while explaining the concept of insulin resistance. We presented ideas using pictorial schema to make them interesting and used animated slides for clarity, avoiding cluttering. We incorporated multiple in-class, hands-on exercises to impart practical skills as well as contextual examples e.g. discussing food items available in college cafeterias. We also showed images of actual (anonymized) food labels from supermarkets, cafeterias, and food outlets, to explain food label reading and giving hands-on-training thus retaining the contextual relevance of the topics discussed. Video content available on social media was used for audio-visual demonstration of several complex concepts (such as the changes inside the body due to diabetes mellitus). Each topic was covered in an interactive manner with the participants being encouraged to engage in hands-on activities, ask questions, and share their views.

We emphasized conceptual clarity, practical skills useful in everyday context, and the application of critical thinking while dealing with any information or situation that may impact health. All content was tailored for use with college youth. We also encouraged the use of these skills to help family members and other members of the participants' social network.

The curriculum was developed in a modular form. This allowed flexibility in delivery of contents as per logistical feasibility and preferences of different study sites. **Table 1** gives an

overview of the content, the number of hands-on activities, and estimated time of delivery for each module.

Table 1: Overview of curriculum modules

No.	Title	Contents	Number of Hands- on activities	Estimated time of delivery
Conceptual foundation				
1	NCD: concept and concerns	Difference between communicable and non-communicable diseases, general characteristics of NCDs, current rates of prevalence of different NCDs globally and in India (disability and deaths), social and economic cost involved with NCDs, role of prevention in reducing this burden.	01	30 minutes
2	Risk factors: concept and importance	What do we mean by risk-factors, how are these associated with NCDs, different types of risk factors, role of risk-factors in NCDs prevention	01	30 minutes
Health conditions				
3	Diabetes mellitus (DM): what, how and why	Role of sugar in blood, role of insulin on blood sugar level and in the body, what occurs to blood sugar in DM, what occurs to insulin in DM, different risk factors involved in occurrence of insulin resistance, important complications of poorly controlled DM, available treatment options, role of controlling modifiable risk factors in reducing risk of getting DM and related complications, and in improving treatment efficacy, dispelling common myths associated with DM	04	
4	DM: measuring capillary blood sugar	Overview of laboratory tests to detect DM, and related complications, role of blood sugar monitoring in effective control of DM, learning to measure capillary blood sugar (and interpret obtained values) using digital blood glucose measuring device	01	
5	Hypertension (HT): what, how and why	What is blood pressure, role of blood pressure in the body, overview of factors involved in creation of blood pressure, physiological fluctuations in blood pressure levels (during exercise, in acute stress), what is HT, factors involved in its occurrence, important complications of poorly controlled HT, available treatment options, role of controlling modifiable risk factors in reducing risk	04	60 minutes

		of developing HT and related complications, and in improving treatment efficacy, dispelling common myths associated with HT		
6	HT: Measuring blood pressure using digital machine	Method of detecting HT, overview of tests to detect HT related complications, role of blood pressure monitoring in its effective control, learning to measure blood pressure (and interpret obtained values) using digital blood pressure measurement device,	01	30 minutes
7	Atherosclerosis and Dyslipidemia: what, how and why	What is atherosclerosis, how does it develop, its involvement with HT, role of cholesterol in blood and in body, normal blood cholesterol levels, what is dyslipidemia, how does it occur, its association with atherosclerosis, obesity and insulin resistance, dispelling common myths associated with dyslipidemia	01	30 minutes
8	Overweight and obesity: what, how and why	What is it, important risk factors associated with its occurrence, from where does the excess fat come and how does it get deposited in the body, role of caloric management in its prevention and control, health implications of having excess weight, health benefits of maintaining optimal weight, dispelling common myths associated with its prevention, control and causation	03	60 minutes
9	Obesity: anthropometry	Measuring body weight, height and waist circumference (WC), calculating body mass index (BMI) and learning to interpret the obtained values of BMI and WC	02	30 minutes
Life-style risk factors				
10	Diet and dietary modifications	Why do we need food? Concept of macro and micronutrients in food. Macronutrients: role in the body, types and sub-type and specific characteristics of each, concept of glycemic index and glycemic load of food items, ro of sugar and different subtypes of fat on blood cholesterol level and in occurrence of atherosclerosi dietary sources of each macronutrient, relative advantages and limitations of each source, identifyi food items that are good sources of each macronutri available to and consumed by the participants in different contexts, critical analysis of relative advantages and limitation of each food item,	10	120 minutes

		identifying healthier food items and alternatives for not-so-healthy food items within different contexts, dispelling common myths associated with diet and food.		
11	Making sense of food labels	Food labeling guidelines in India, meanings of commonly used abbreviations, codes and alternative names indicating similar ingredients, interpreting, ingredients list and nutrition facts on the food label, identifying ingredients with not-so-healthy nutrients on the food label, critically evaluating credibility of nutrition/health claim made for the food item, selecting healthier food item from given option, bas on information available on the food label.	05	90 minutes
12	Physical activity and exercise	health implications of leading a physically inactive life, how do we get health benefits from engaging in physical activity (especially related to health conditions covered here), different types of physical activities (including overview of different types of exercise, and specific benefits from each type) with examples of routine activities and household chores recommended minimum levels of physical activity f all age-groups, ways to incorporate physical activity daily routine, precautions while engaging in physica activities, dispelling common myths associated with physical activity and exercise	03	60 minutes
13	Critical perspectives NCDs and related risk factors	Creating sensitization towards role of various social, economic, political and legal factors at different levels (from global to local); including powerful forces such as market, urbanization and globalization; in creation, sustenance and reinforcement of the unequal distribution of NCDs related risk factors, disease burden and resources including awareness and skills to reduce exposure to the same across population by discussing examples related to food items and nutrition products' marketing, food labeling laws, health care access and affordability, lack of policies related to health education, and so on.	01	60 inutes

Remarks:

1. The estimated time of delivery of each module budgets for the explaining of concepts and demonstration of methods (if any) by the instructor. We have ensured that the time allows for each participant to perform these tasks themselves. It therefore follows that the time needed depends on the total number of participants in one batch.

2. Hands-on training activities designed for each module are largely group based activities involving the demonstration of the understanding the concepts, application of the learnt concepts, identifying scenarios where the concepts could be applied in during day-to-day life for themselves and in the family or social network. These activities could take more time than the estimates shared here if the study participants are greater in number or take more time to open up and participate.

3. Our estimates of the time needed is based on our experience of delivering these modules at different study sites. These should be treated as best estimates. The time taken to deliver a particular module depends on several factors such as participants' characteristics (active interest, interactive ability), number of participants in one batch, the extent of background knowledge about biology and nutrition, the sessions' schedule (the whole day workshop or a few hours on a particular day), sessions' timings (fresh morning hours versus tiring afternoon hours!) and so on.

2.4 Content validity: The content was developed and reviewed by a team of experts which included social epidemiologists and public health practitioners with a background in medicine, as well as expertise in health education, public health nutrition, and health promotion.

3. Developing the evaluation tool: A number of approaches and instruments have emerged for measuring health literacy, resulting in the availability of a variety of measures [44-59]. However, none were sensitive and specific to objectively assess the impact of our intervention. We therefore, developed an entirely new health literacy instrument, based on the health literacy model underpinning this study. It assessed functional, communicative, and critical dimensions of health literacy, and was a context (health promotion in youth) and content (NCD and related risk factors) specific measure. The instrument design was guided by content included in the curriculum modules as well as learning objectives of each module. We revisited the learning objectives of each module and identified two to four essential learning objectives per module. To assess the extent to which each essential learning objective was achieved, we developed more than one question related to that objective. Thus we developed a pool of questions, each treating health literacy as a latent construct [60]. We then categorized these questions based on their difficulty level: questions which required application of the concepts learned in the curriculum were categorized as difficult, while the questions that required demonstration of understanding of

the concepts learned through the curriculum were categorized as easy. The final measure included a mix of easy and difficult questions for each module. The questions tested the understanding and application of the contents delivered through the curriculum rather than memory-based recall of information. The questions were a mix of different types: those requiring the choice of a correct option from the given choices, writing one or two sentence responses to a given situation, identifying healthier food choices based on given information, and critically reviewing health information. Situations and examples relevant for college youth were included. Responses to each question were graded using the answer key developed along with the instrument.

The evaluation measure was pilot tested. Of the total 127 questions developed, the final measure for all the modules comprised 30 questions. The measure used was uniform across the college sites, contingent upon the number of modules covered at that site: at sites where all the modules were not delivered, the measure included questions pertaining to the modules delivered during the pre-test and post-test. Participants were given 50 minutes to answer the whole measure. At the study sites where the full measure was not used, participants were given 30 to 40 minutes, depending upon the number of questions included.

4. Pilot test: We carried out a pilot test at a college of social work in a medium-sized town in Gujarat. We delivered the curriculum as a four-day long workshop and collected baseline and endline data using our health literacy instrument. Eighty-five students attended the workshop, and we delivered 11 out of total 13 modules in 11.5 net teaching hours. As per students' preference, we delivered the curriculum in the local language (Gujarati), retaining the English power-point slides, and translating the data collection tool into Gujarati.

Based on the inputs from the participants and faculty members at the site of the pilot study, we refined the curriculum by removing redundant content, simplifying complex concepts, adding more practical examples, and changing the sequencing of the contents to improve

consistency. Since several other institutes had indicated a preference for Gujarati language, we translated all of the modules into Gujarati to improve clarity and retention of the delivered content.

Our experience from the pilot study indicated that the feasibility of delivering the intervention was challenging in multiple ways. It was highly contingent upon the convenience and logistical support from the colleges acting as potential study sites. We thus made three major changes in our design:

1. We allowed variation in the intervention delivery among different study sites including variation in the workshop duration, total number of modules delivered, time-gap between baseline and endline data collection, and between the study groups. We meticulously recorded these variations and accounted for them during analysis.
2. We decided to impart physiological and anthropometric measurement skills as per the original plan but did not measure these skills during the endline due to time constraints.
3. We changed the sampling design from simple random sampling to random sampling at group (cluster) level, incorporating a design effect in our final sample size.

5. Sample size estimation: We defined our outcome of interest as average difference in percentage scores between endline and baseline percentages in the intervention and control groups. We used formula (1) to determine the sample size as suggested by Smith PG, Morrow RH and Ross DA (Ed.) [61].

Sample size required in each group to detect a specified difference $D = \mu_1 - \mu_2$, with power specified by z_2 and the significance level specified by z_1 is given by

$$n = [(z_1+z_2)^2 (\sigma_1^2 + \sigma_2^2)] / (\mu_1-\mu_2)^2 \qquad (1)$$

where $\sigma_i (i=1,2)$ is the standard deviation of the outcome variable in both the groups.

As we did not have estimates of the average and standard deviation values at population level for the outcome of interest, we estimated values for these parameters as educated guesses using data obtained through our pilot. The average difference in percentage scores between endline and baseline percentage in our pilot intervention group was 31.37 with SD 14.88. We inserted values in formula 1 as an educated guess.

For 90% power, significance level of 95% and estimated value of SD of outcome variable in both the groups at 15, the estimated sample size to detect a difference of 10% between both the groups was calculated to be 47 in each group.

We considered a design effect of 2 for randomization at group level. Therefore, the sample size was 94 in each group. Considering a response rate of 80% the estimated sample size was finalized as 118 in each group.

7. Study sites: We carried out the intervention in colleges within and outside the city of Ahmedabad in Gujarat, India. We approached 27 colleges in Gujarat which did not offer any health-related majors, located within and outside Ahmedabad, with a request to conduct the study. These colleges offered various majors: engineering, commerce, science, arts, social work or architecture. Most colleges were approached by leveraging the contacts of the research team and their colleagues and through snowballing from thereon. Of the 27 colleges approached, 4 denied permission without giving any specific reason. Of the remaining 23 colleges that showed interest, we carried out the project in five colleges with a match between the preferences and logistical arrangements of the institutes and the resources (especially time) available to us. To maintain confidentiality, we refrain from naming these colleges and refer to them as study sites one through four. The background characteristics of these colleges are mentioned in **table 2**.

Appendix: 2 Back-ground characteristics of study sites

Study site	Location of the college	Academic background of the study participants
1	Urban	Engineering
2	Urban	Engineering
3	Semi-urban	Science
4	Urban	Commerce and Arts
5	Urban	Commerce and Arts

7. Sampling design: At study sites one, two, and three, the college leadership clearly ruled out the simple random sampling of students as operationally infeasible. We were instead recommended to randomize at the group level based on pre-formed student groups for their laboratory experiments sessions. These groups were assigned based on student roll numbers at each study site. After ensuring that the distribution of students within these groups was comparable across the groups, we selected our sample by randomizing the groups. Of the total available groups, half were selected by randomly picking slips with the group number written on it and were assigned to the intervention group; the remaining were automatically assigned to the control group.

At study site four, we were given a list of students who had shown initial interest in participation. We randomly selected half of these students by picking slips with their roll numbers written on them and assigned them to the intervention group. The rest of the students were automatically assigned to the control group. Study site five did not have a control group because of logistical constraints. The total number of study participants selected at each study site is tabulated (Table 3).

Table 3: Number of study participants selected and lost to follow up at each study site

Study site	Final sample size n at baseline		Lost to follow up at the endline N (% of total enrolled at baseline)	
	Intervention group	Control group	Intervention group	Control group
1	57	44	02 (03.38)	00 (00.00)[a]
2	12	24	12 (50.00)	00 (00.00)[a]
3	35	39	04 (10.25)	05 (11.36)
4	16	11	09 (36.00)	08 (42.11)
5	34	NA	00 (00.00)	00 (00.00)
Total	**154**	**118**	**27 (14.91)**	**13 (09.92)**

aEndline measurements in the control group not collected

N.B. In the final data analysis we excluded study site 5, as it did not have a comparable control group.

8. Implementation of the intervention: The curriculum was delivered by Ankita Shah at all the study sites from January 2018 to April 2018. Ankita Shah was accompanied by a junior research fellow during the sessions who helped with logistical arrangements, coordinating with the liaison person at each study site, and recording observations and feedback on the sessions. The colleges found it difficult to set aside the 14-16 hours required for the intervention. They were concerned that this may increase the number of students missing mandatory classes. Therefore, we had to customize our intervention based on the logistical constraints at each college. The modular design of the curriculum, as anticipated, helped us to deliver customized curriculum content as per practical feasibility and the college's preference. A summary of the intervention modules delivered at each study site is presented in Table 4.

Table 4: Specifics of the intervention modules delivered at each study- site:

Study Site	Total Modules delivered	Intervention time		Gap between baseline and endline data collection		Remarks
		Teaching time	Total time	Intervention group	Control group	
1	5	4 hours 30 minutes	6 hours	Same day	Not applicable	Baseline data in the control group was collected 12 days after the endline data collection of the intervention group was completed No endline data in the control group
2	5	4 hours 30 minutes	6 hours	Same day	Not applicable	No endline data in the control group
3	11	6 hours 45 minutes	8 hours 45 minutes	7 days	7 days	Data at both the time-points were collected at the same time in both the groups
4	11	8 hours 30 minutes	12 hours 45 minutes	12 days	14 days	Endline data in the control group was collected 2 days after the endline data collection was completed in the intervention group
5	6	5 hours	7 hours 30 minutes	2 days	NA	No control group

9. Data collection: After obtaining written informed consent, we collected baseline background information from each participant in both groups using an information form developed for this study. Following this, we collected baseline health literacy data simultaneously in both groups (except for study site one, please refer to Table 2), using our health literacy assessment tool. In study site one, participants in the control group could only be made available for one hour, 12 days after the intervention was delivered to the intervention group, owing to their busy laboratory schedule.

Endline data in the intervention group were collected after delivering the intervention modules. Endline data in the control group was collected after completing the intervention in the intervention group. However, endline data from the control group was not collected at all the

study sites. As the intervention was delivered in the form of a one-day workshop at study sites one and two, we did not obtain endline data for control groups. The college leadership was hesitant to ask the control group students to stay back for a few hours without allowing them to attend the workshop, only to have them fill out the same instrument for a second time on the same day. At study site three, endline data in the control group were collected at the same time as in the intervention group. However, at study site four, endline data in the control group were collected two days after they were collected from the intervention group. These details are summarized in table: 4. The same health literacy assessment tool was administered to both study groups at the same study site, with the same amount of time to fill it out at the baseline and endline.

10. Data analysis: Statistical analysis was carried out using STATA version 12.1. We calculated the baseline and endline scores using the answer key we had developed along with the evaluation tool. The total score obtained was converted into a percentage using the maximum possible score as the denominator. Baseline and endline scores in percentage were treated as continuous variables.

We calculated the difference in percentage points between endline and baseline scores by subtracting the baseline percentage from the endline percentage for all study participants. Endline scores were missing for control group participants at study sites one and two. In such cases we imputed the average value of 8.98 of difference between endline and baseline percentage scores calculated using data from the rest of the control group (study sites three and four). To make our findings more conservative, we repeated by our analyses by imputing the 75^{th} percentile value of 14 of the difference between endline and baseline percentage scores of the rest of the control group. This difference-in-difference score was one of the two main outcome variables in this study. We carried out a t-test for comparing mean difference-in-difference scores between the two study groups. Multiple linear regression models were fitted accounting

for the background characteristics, study site and baseline percentage as covariates. We retained study site and baseline percentage as covariates in our final model. The average difference-in-difference score across different subcategories of background characteristics was compared using ANOVA in both the groups. The difference in mean scores between the two study groups at each time point was also compared with a t test for each study site (separately), as a sensitivity analysis.

We also used binary outcome indicators created from the continuous baseline and endline percentage scores by setting a 40% score as the cut-off value. Participants scoring 40% or above were grouped together. The binary outcome indicator measures the number of participants who scored 40% or above in both study groups, separately for baseline and for endline. Fixing 40% as the cut off value was inspired by the percentage score cut-off used by the study colleges to declare a student as having passed a course: 35% of total score in the final examination. We initially planned to set 50% as cut-off, but no participants scored above 50% at the baseline; so we fixed the cut-off value at 40%—higher than the passing cut-off value for the subjects taught in all the study sites. We used chi-square tests to compare the proportion of participants scoring 40% or above between the two study groups at each of the time points. We fitted Poisson regression models yielding Incidence Risk Ratios for the binary outcome. We fitted multivariable Poisson models to account for the background characteristics, study site, and baseline percentage as covariates. We retained study site and baseline percentage as covariates in our final model.

10. Ethical considerations: The Institutional Ethics Committee IITGN approved the study. The IEC approval number is IEC/2017-18/3/MS/019. Participants were given a consent form with detailed information about the nature of the study, their role, the voluntary nature of their participation, and their right to withdraw from any session or the entire study without giving any reason. Ankita Shah verbally explained the contents of the consent form to the

participants who were given an opportunity to seek clarifications before signing the form. All the study participants signed the written informed consent form before participating in the study.

Conclusion:

We aim to demonstrate effectiveness of our theory-based, context specific, NCD related health literacy curriculum significantly improved literacy on multiple dimensions among college-going youth in Gujarat, India. To our knowledge, this is the first study in the Indian context to design an intervention using the health literacy framework and evaluate it using an experimental design. Given that India presently has one of the world's largest youth population exposed to substantial risk of NCD, such prevention efforts have great potential to address this challenge. We emphasize the intrinsic value of health education aimed at improving health literacy, beyond its instrumental importance in bringing about behavior change.

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