A Randomized Controlled Trial Enhancing Non-Communicable Diseases Health Literacy of Indian Youth

Rahul M. Jindal (jindalr@msn.com)
Uniformed Services University
https://orcid.org/0000-0002-8731-0671

Research Article

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Abstract

Background

There is a theory-praxis gap related to health literacy interventions focused on non-communicable diseases (NCD) among young people. We designed a NCD curriculum and investigated its’ effect on health literacy in non-medical, non-nursing college students in India. We deliberately selected non-medical and non-nursing college students as we hypothesized they would have minimal baseline knowledge of NCDs.

Methods

We initially carried out a pilot study in 85 students in a four-day long workshop (12 teaching hours) using empirically developed health literacy instrument. We administered the curriculum to 120 randomly selected students in 4 colleges, while 50 students were controls. The curriculum was given over 4 days for a total of 32 hours. Each lecture comprised of didactic lecture followed by discussion and skills testing of measuring BP and blood sugar. Health literacy was measured using a specifically designed tool at baseline and endline. Difference in health literacy scores between the two time-points was analyzed using the t-test. Multiple linear and Poisson regression models were used for covariates.

Results

Study groups were comparable at baseline. The intervention group showed 20.6% higher health literacy score at endline versus control group (p<0.001). Participants scoring 40% or above on the health literacy measure in both groups were comparable at baseline. However, the proportion of participants scoring 40% or above was higher in the intervention group versus control group at endline (p<0.001).

Conclusions

We provide empirical data to support incorporation of NCDs as a credit course in college curricula in low and middle income countries. This is the first study in the Indian context that addressed NCD-related health literacy in a randomized trial.

Introduction

Non-communicable diseases (NCD) are a critical global concern due to the significant mortality and morbidity\(^1\). The significant socio-economic impact associated with NCD threatens sustainable development, necessitating action at global, regional, and national levels\(^2\). An epidemiological transition with escalating burden of NCDs are evident across India. This is complicated by disease onset a decade...
earlier in Indians compared to residents of high-income countries, increasing their risk of adverse medical and socio-economic consequences\(^3\).

NCD risk factors may be higher among youth since it is a transformative time, characterized by experimentation and susceptibility to risk behaviors\(^4\). It has been shown that the youth in India have low levels of awareness about NCDs\(^5\), as well as the requisite skills to make healthy lifestyle choices\(^6\). There is a high prevalence of NCD-related risk behaviors and metabolic risk factors in this age group. It has also been shown that this age group is exposed to a barrage of media messages that influences their health behavior, which makes it imperative to empower youth to make informed lifestyle choices\(^6\).

Health literacy skills empower young people to make informed health decisions throughout their life\(^7\). Moreover, health literacy in youth has the potential to extend well beyond them, young people can spread health-related messages to their families, peers, and others in their social network, thus acting as agents of social change. Health education and health literacy are widely recommended as cost-effective measures to reduce preventable NCD risk factors, specifically, actionable recommendations based on context-specific health literacy interventions are emphasized in order to prevent and control NCDs.

A way to develop health literacy skills in young people is to incorporate them in formal education\(^8\). School- and college-based interventions have been proven to be cost-effective\(^9\). Lifestyle interventions with school and college going youth in India have shown the potential to increase awareness about NCD and related risk factors. However, only a few of these studies have used a randomized controlled design to evaluate their effectiveness. Most of these interventions have primarily targeted health behavior change, with health education as the primary component. Improved health literacy is conceptualized as a primary outcome of health education within the broader context of health promotion.

Research on health education with a health literacy focus is at an early stage in India. Although we found several studies assessing extent of health literacy and its association with health status, especially in areas of dental and mental health, child undernutrition, and NCD self-management\(^10\), we could not find any intervention study that operationalized health literacy in the Indian context.

Current efforts towards addressing health awareness in NCD in India\(^11\), include online resources, and school curricula. These are however, limited by one or more of the following - minimal emphasis on practical application, and lack of emphasis on critical thinking.

Our literature search confirmed that nutrition education curricula taught in secondary schools in India have been critiqued by teachers, parents and participants as being outdated, inadequate in imparting practical skills, and emphasizes rote learning\(^12\). 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. We
deliberately selected non-medical and non-nursing college students as we hypothesized they would have minimal knowledge of NCDs.

**Methods**

We have used the CONSORT guidelines to report our trial\textsuperscript{13}.

**Specific objectives:** To design, deliver, and test the effectiveness of a health literacy curriculum in increasing NCD-related health literacy as measured by a specifically designed questionnaire in college students in Gujarat, India. We planned a randomized controlled trial with intervention and control groups to evaluate the effectiveness of the curriculum.

**Theoretical premise:** The theoretical premise of the curriculum was health literacy within the health promotion paradigm, viewed through a social epidemiological lens. Following the World Health Organization preamble, 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\textsuperscript{14}. We adopted the Health Literacy Skills (HLS) Framework proposed by Squiers et al. with several conceptual modifications (Figure 1) based on the eco-social theory\textsuperscript{15} and Nutbeam’s\textsuperscript{16} tripartite model of health literacy.

We have modified the HLS framework in the following domains:

1. The framework posits that ecological influences moderate components of conceptual framework in several ways. 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.

2. We contend that engaging in a health behavior does not necessarily lead to improved health outcomes for two reasons. First, 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 and may remain unaddressed. Second, 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, which may remain unaltered.
3. We incorporate critical health literacy as a dimension of health literacy skills. As Nutbeam posits, adequately emphasizing critical health literacy has the potential to act laterally to promote social action that impacts social determinants of health.

4. We extend the concept of a dynamic nature of health literacy in the HLS framework and propose that health literacy skills further amplify this through a feedback loop from comprehension of stimuli to knowledge (Figure 1).

Content selection: Curriculum content was informed by the theoretical framework (Figure 1). We primarily focused upon two health conditions i.e. high blood pressure and diabetes mellitus, both have a high prevalence in India\(^\text{17}\); and preventable risk factors, dietary modifications and physical activity.

Development of the curriculum: We consulted several sources such as 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. We reviewed regional variations in food practices across India, as well as social causes of health disparities\(^\text{18}\). We referred to food labelling laws, including their historical context in Indian and global contexts\(^\text{19}\).

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

Developing the evaluation tool: A number of approaches and instruments have emerged for measuring health literacy\(^\text{20}\). However, none were sensitive and specific to objectively assess impact of our intervention. We therefore, developed an entirely new health literacy instrument to assess functional, communicative, and critical dimensions of health literacy. The final measure comprised 22 questions and participants were given 50 minutes to complete the test (Table 2).

Pilot test: We carried out a pilot study in 85 students in a four-day long workshop (total of 12 teaching hours) and carried out baseline and endline data collection using the empirically developed health literacy instrument.
Sample size estimation: We defined our outcome of interest as average difference in percentage scores between endline and baseline in the intervention and control groups. We used formula to determine the sample size as suggested by Smith et al.\textsuperscript{21}.

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

$$n = \frac{\left( (z_1 + z_2)^2 (\sigma_1^2 + \sigma_2^2) \right)}{(\mu_1 - \mu_2)^2}$$

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

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.

Sampling design: We administered the curriculum to 120 randomly selected students in 4 non-medical and non-nursing colleges in the city of Ahmedabad, while 50 students served as controls.

Implementation of the intervention: The modular design of the curriculum given over 4 days for a total of 32 hours. (Table 3) from January 2018 to April 2018. Each lecture comprised of didactic section followed by discussion and skills testing of measuring BP and blood sugar. The first author was accompanied by a research fellow who helped with logistical arrangements and recording observations and feedback.

Data collection: Baseline and endline data in the intervention group were collected after delivering the modules. In the control group, we also collected baseline and endline data but no teaching was given.

Data analysis: Statistical analysis was carried out using STATA data analysis software, version 12.1, owned by StataCorp, Texas, USA, and licensed to the host institute. 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. We carried out
a t-test for comparing mean difference-in-difference scores between the two groups. Multiple linear regression models were fitted accounting for the background characteristics, study site and baseline percentage as covariates.

**Results**

Intervention and control groups were comparable at baseline as shown in Table 1. Mean age of participants in the intervention group was 19.2 years (SD 1.8 years) and 19.6 years (SD 1.4 years) in the control group.

Study groups were comparable in terms of percentage scores on health literacy at baseline. The intervention group showed an average of 20.6% points higher health literacy score at endline versus control group (p<0.001). The endline-baseline difference in health literacy scores were significantly different (p<0.001) between the two groups. The mean endline difference scores were comparable across background characteristics in both groups, with one exception: those with and without the intention to improve fitness in the intervention group (p<0.05) (data not shown). None of the background characteristics showed statistically significant associations with the difference-in-difference scores independent of intervention (data not shown).

Based on the multiple linear regression models, the average difference-in-difference scores (endline-baseline) was 18.49 percentage points higher in the intervention group as compared to the control group, accounting for college setting and percentage score at baseline (p<0.001). The proportion of participants scoring 40% or above on the health literacy measure in both groups were comparable at baseline. However, the proportion of participants scoring 40% or above was higher in the intervention group versus control group at endline (p<0.001).

Based on Poisson models, the incidence risk ratio of participants scoring 40% or above on the health literacy measure at endline was 2.37 times (p<0.05) higher in the intervention group versus control group, after adjusting for baseline health literacy score in percentage points and study sites.

**Discussion**

Our findings suggested that our theory-based, context specific, NCD-related curriculum significantly improved literacy on multiple dimensions among college-going youth in Gujarat, India. The curriculum was effective for students with diverse academic and socio-economic backgrounds. 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 a randomized design. We, therefore, compared our findings with health education intervention studies that aimed at improving NCD awareness among youth. Gavaravarapu et al.\(^22\) carried out an intervention using a communication module to promote food label reading skills of school-going adolescents in Hyderabad, India. They reported 16.5% increase in food label reading skills in the intervention group (n =116), versus 1.85% increase in the comparison group (n = 59) (p<0.001).
Strengthening food label interpretation skills was one of the learning objectives of our intervention. Although we did not separately assess this component, our overall finding of an average increase of 27.52% (SD: 14.65) in the intervention group as compared to an average 8.99% (SD: 4.83) increase in the control group, is consistent with the findings by Gavarvarapu et al.

Classroom-based health and nutrition education intervention among college-going volunteers (n = 351) in Odisha, India, reported a significant improvement of 11.36% in the average score of knowledge on nutrition and health in student volunteers after the intervention. Significant improvement in the percentage of student volunteers answering correctly was observed in most items related to knowledge about nutrition and lifestyle diseases\textsuperscript{10}. Chaudhary et al.\textsuperscript{23} reported an increase in the percentage of school-going adolescents who demonstrated knowledge about major risk factors of NCD ranging between 24 - 47% after a single education session of 45 minutes. Our findings showed a 75% increase in the proportion of students who scored 40% or above in the intervention group as compared to 22% in control group (p < 0.001).

A study by Shah et al.\textsuperscript{24} reported significant improvement ranging from 7 - 19% increase in the percentage of 15 - 18 years old school students who answered key nutrition, physical activity and NCD-related questions correctly after the intervention (n = 448) vs. before intervention (n = 539). Singhal et al.\textsuperscript{25} reported a significant improvement in knowledge scores among 11th grade school students after a multicomponent intervention on nutrition and lifestyle education for behavior modification. Randomly selected intervention group (n = 99) showed improvement in knowledge related items as compared to the control group (n = 102).

Our study has several limitations. We did not measure the long-term impact of intervention on health literacy. It is possible that higher scores immediately after intervention are due to content remaining fresh in students’ memory. Future studies should consider long-term follow-up of the study population with repeated measurements of health literacy scores at different time points. Another weakness is the empirical use of health literacy tool which has not been validated. We hope our work will stimulate other researchers to undertake this task.

This is among very few studies globally, and to the best of our knowledge, first study in the Indian context that addressed NCD-related literacy comprehensively in healthy populations in a college setting in a randomized trial. Our curriculum is also unique in its content and approach on disease prevention and health promotion with skills testing of measuring BP and blood sugar.

Our findings can serve as a basis for the incorporation of health literacy modules in college curricula giving appropriate credits for both theoretical knowledge and skills testing. The findings of our study is potentially a step towards policy change that supports and encourages health literacy in NCD in India and in other low and middle income countries.

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**Abbreviations**

Non-communicable diseases (NCD), Health Literacy Skills (HLS)

**Declarations**

*Conflict of interest:* No financial conflict of interest exists.

*Funding:* None

*IRB:* The Institutional Ethics Committee (Indian Institute of Technology Gandhinagar) approved the study. All the study participants signed the written informed consent form. The study was registered retrospectively on the ISRCTN registry (ISRCTN28814900).

*Authorship:* All authors contributed to conception, design, execution, analysis and interpretation of data. All authors were involved in drafting the article and revising it critically for important intellectual content, have read and approved the final version of the manuscript.

**Tables**

Tables 1-3 are in the supplementary files section.

**Figures**
Figure 1

Health Literacy Skills framework: adapted and modified from Squiers et al. [51] (Note: All the arrows and boxes in grey and text in bold represent our modifications.)

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Tables.docx