

A study to assess how effective a health education course is at improving awareness about diabetes and heart diseases in youth

Submission date 01/08/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 28/08/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/01/2023	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Several health problems such as high blood pressure, diabetes and heart attacks are becoming increasingly common. Even young people often fall prey to such diseases. The aim of this study is to administer a health awareness curriculum to college youth so that they can become aware of such health problems. This is planned to be delivered as a health literacy workshop among the undergraduate students in non-medical and non-nursing colleges. It requires the students to take up classes that teach a health awareness curriculum. It is administered as a workshop in multiple sessions amounting to be a total of 6 to 14 hours. It delivers information on several health-related issues and enhances skills to make simple changes in the lifestyle to reduce the risk of such diseases. They will also learn how to accurately do a few health tests such as measuring blood pressure and blood sugar, which may help them monitor their own health and the health of those around them. The curriculum combines discussion sessions, demonstrations using simple models, online videos and hands-on training sessions.

Who can participate?

Undergraduate students above the age of 18

What does the study involve?

Participants are randomly allocated to the intervention group or the control group. The curriculum is administered to the intervention group participants. The control group participants do not receive anything. The curriculum is specifically designed keeping in mind the interests and local context of college students. With regards to the evaluation, the questions and the practical demonstration of skills are simple and relate to the contents discussed in the classes. As a part of the study, the participants are required to fill out a questionnaire and to demonstrate their practical skills in performing a few simple health tests, both at the start and the end of the study.

What are the possible benefits and risks of participating?

Potential benefits include gaining knowledge and skills about hypertension and diabetes. The participants will also come to know about their blood pressure and blood sugar levels as well as

body measurements (anthropometric indices). Potential risks are minimal such as a finger prick to measure blood glucose and the pressure from a cuff on their arm to measure blood pressure- both limited to one time, while learning these methods. The discomfort occurring from the finger prick is very much mild and only momentary. This method is generally safe and not known to cause any residual pain or swelling and is commonly used every day even by the general public especially those with diabetes. The participants are cautioned before performing this. All necessary precautionary safety measures and anti-infection measures are thoroughly ensured to minimize the risk of cross-infection or injury. In case any participant is uncomfortable with this, his/her choice is respected. Also, the results of the finger prick sugar test and the blood pressure measurements are not disclosed openly.

Where is the study run from?

Indian Institute of Technology Gandhinagar (India)

When is the study starting and how long is it expected to run for?

August 2016 to April 2019

Who is funding the study?

1. Investigator initiated and funded
2. Indian Institute of Technology Gandhinagar (India)

Who is the main contact?

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Contact information

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CTRI/2020/04/024779

Study information

Scientific Title

Developing and testing a non-communicable diseases related health awareness curriculum among youth

Study objectives

Difference in average scores in percentages on non communicable diseases related health literacy between endline and baseline would be statistically significantly higher among participants in the intervention group in comparison to the participants in the control group ($p < 0.05$).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 26/06/2018, Institutional Ethics Committee (Indian Institute of Technology, Gandhinagar, Palaj Simkheda Gandhinagar; Pin Code: 382355; +91 (0)7923952800; mtrivedi@iiphg.org), ref: IEC/2017-18/3/MS/019

Study design

Interventional randomized controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

See additional files

Health condition(s) or problem(s) studied

Enhancing health literacy regarding non-communicable diseases in undergraduate college students to prevent lifestyle diseases

Interventions

The intervention is developed as a curriculum which aims to build health literacy on a healthy lifestyle to prevent non-communicable (lifestyle) diseases. The curriculum primarily focuses upon diet and physical activity related content aimed at enhancing awareness and skills to prevent diabetes mellitus and cardiovascular diseases. The curriculum is delivered in the form of workshop which includes theoretical sessions, information sharing, concept building and hands-on training on the application of the learnt concepts. The curriculum is administered in the form of an in-class training workshop. The curriculum is developed in a modular form. This allows flexibility in delivery of contents as per logistical feasibility and preferences of different study sites. Depending upon the number of modules to be delivered, the total contact hours in the workshop ranges between 6 to 14 hours.

In order to evaluate the effectiveness of the curriculum in enhancing health literacy, a randomized controlled trial study is designed. The study participants, after obtaining informed consent, are randomly assigned to intervention and control groups. Baseline health literacy score is measured in participants from both the groups, following which, the curriculum is administered to the intervention group participants. The control group participants do not receive anything. The endline health literacy scores are measured in participants from both the study groups after completing the workshop in the intervention group. Health literacy is measured using a specifically designed health literacy measure based on the objectives of the curriculum modules, and it tests health literacy objectively.

The health literacy curriculum is based on strong theoretical underpinnings drawing from theories of social epidemiology, health literacy and health promotion. It is specifically developed targeting college youth, conceptualizing them as potential social change agents.

The random assignment of study participants in the study groups is achieved at group level. The students in colleges have preformed groups for performing laboratory experiments. After ensuring that the distribution of students within these groups was comparable across the groups, the sample is selected by randomizing the groups. Of the total available groups, half are selected by randomly picking slips with the group number written on it and are assigned to intervention group; the remaining are automatically assigned to control group.

Intervention Type

Behavioural

Primary outcome measure

Health literacy measured using health literacy test at timepoints 1 and 2

Timepoint 1: before attending the health literacy workshop at the exact same time in both the study groups.

Timepoint 2:

Intervention group: at any time after attending the health literacy workshop, preferably immediately after the end of the workshop sessions

Control group: at any time after completing the health literacy workshop in the intervention group, preferably at the same time as that of the intervention group

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

01/08/2016

Completion date

30/04/2019

Eligibility**Key inclusion criteria**

1. Undergraduate college students
2. Age 18 years or above

Participant type(s)

Other

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

236

Total final enrolment

397

Key exclusion criteria

The students undertaking medical, paramedical or nursing courses

Date of first enrolment

01/01/2019

Date of final enrolment

31/03/2019

Locations

Countries of recruitment

India

Study participating centre

Indian Institute of Technology, Gandhinagar (IITGN)

Palaj Simkheda

Gandhinagar

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Sponsor information

Organisation

Indian Institute of Technology Gandhinagar

Sponsor details

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Funder(s)

Funder type

University/education

Funder Name

Investigator initiated and funded

Funder Name

Indian Institute of Technology Gandhinagar

Results and Publications

Publication and dissemination plan

Planned publication in a high impact peer-reviewed journal.

Intention to publish date

31/08/2020

Individual participant data (IPD) sharing plan

The researchers have quantitative data, in anonymised form, saved in MS Excel, and could allow access to the data after receiving details on how the requesting party intends to use the data, acknowledges the data source and confirms to adhere to the ethical usage of the data.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			28/08/2020	No	Yes
Protocol file			28/08/2020	No	No
Results article		23/02/2022	10/01/2023	Yes	No