ISRCTN28814900 https://doi.org/10.1186/ISRCTN28814900

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

Registration date
28/08/2020

Overall study status
Completed

Last Edited
10/01/2023

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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?
Dr Ankita Shah
ankita.shah@iitgn.ac.in

Contact information

Type(s)
Scientific

Contact name
Dr Ankita Shah

Contact details
Humanities and Social Sciences
Indian Institute of Technology
Gandhinagar Simkheda
Palaj
Gandhinagar
India
382355
+91 (0)7622022760
ankita.shah@iitgn.ac.in

Type(s)
Public

Contact name
Dr Ankita Shah

Contact details

Humanities and Social Sciences
Indian Institute of Technology
Gandhinagar Simkheda
Palaj
Gandhinagar
India
382355
+91 (0)7622022760
ankita.shah@iitgn.ac.in

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Prevention

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(s)
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

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
30/04/2019

Eligibility

Key inclusion criteria
1. Undergraduate college students
2. Age 18 years or above

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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

India
382355

Sponsor information

Organisation
Indian Institute of Technology Gandhinagar

ROR
https://ror.org/0036p5w23

Funder(s)

Funder type
University/education

Funder Name
Investigator initiated and funded

Funder Name
Indian Institute of Technology Gandhinagar

Results and Publications

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?
Results article		23/02/2022	10/01/2023	Yes	No
Participant information sheet			28/08/2020	No	Yes
Protocol file			28/08/2020	No	No