A prototype software to sensitize medical undergraduate students to animal research methodology

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Abstract

In India medical undergraduate students(UGs) are encouraged to do short term research projects. Since the UGs are exposed to research for the very first time, they need to be sensitized, especially when they take up research involving animals. With this in mind, a prototype software has been developed to introduce the UGs to research involving animals and ethics of animal experimentation. Using the software, the UGs can conduct a simulated experiment with a hypothetical new drug to find out its effects on the rabbit eye. They will follow the steps of research such as pilot study, sample size calculation, randomization, blinding, control and filling up forms for necessary permissions. They will collect data by doing the experiment on the screen, tabulate and analyse the data statistically and draw conclusions. Further the software includes information about 3R principles, ethical requirements and the governmental guidelines on animal experiments for self-learning. Using live animals for the sole purpose of teaching research methodology to UGs is not ethically sound, but the software can be used as an alternative. Sensitizing the UGs to research methodology and the ethical principles of animal experimentation will go a long way in refining the methods and reducing the number of animals when they conduct live animals experiments.

Keywords: research methodology, rabbit eye, 3Rs, undergraduate students, software

The problem and the need

Medical undergraduate students (UGs) in India are encouraged to do short term research projects. The Indian Council of Medical Research (ICMR) offers short term fellowships for UGs (Short Term Research Studentship Program) for the past 27 years to carry out a small research project during summer vacation (http://www.icmr.nic.in/shortr.htm). Those who opt for basic research are given projects involving animal experiments. Most of them have very little idea about research as they have not done any research projects before or undergone training in research methodology.

Hence the UGs need to be sensitized about research methodology and ethics of animal usage before they start doing the research project. It is believed that such sensitisation will improve their skills in planning and execution of experiments and ability to analyse results and help them design better and ethically sound research projects.

Solution

Using live animals for the sole purpose of teaching research methodology and ethics to UGs is not ethically sound. If some alternative methods which do not use animals are developed, the ethical dilemma of training the UGs in animal research methodology can be solved. One of the solutions is to develop a simulation software that can be used to sensitize the UGs without involving live animals at all. Hence it was decided to develop a computer software with the following objectives :

The software should

(a) impart animal research methodology to medical undergraduates.

(b) provide an opportunity to conduct a simulated animal research project.

(c) make the user familiar with planning and execution of research, data analyses and report writing.

Methods

To achieve the above objectives, the software was designed to include the following :

1. the background details on experimental design, data analyses and ethical issues concerning animal usage

2. a module to conduct a simulated research project on 'the effects of drugs on the rabbit eye'

3. a provision to plan and execute the above research project, analyse the simulated data and write a report of the project

The software was written in VisualBasic 6.0 and compiled to create a standalone .Exe file. An 'install routine' was incorporated to facilitate installation from CD. A 'help file' which includes 'operating instructions' was created and integrated with the software. The background material was written in 'rich text format' using MS Word and a .RTF file was created for each topic. Coding to display these files during 'runtime' was included in the software.

Software features

The software opens with a 'menu' divided into a few major sections (Fig. 1).

Usage

The user is expected to carry out each option under each menu item sequentially. The software is user-friendly and easy to navigate. Instructions and explanations are available under each step. The pretest and posttest include a set of 20 questions. This can be used to evaluate the effectiveness of the software and for self assessment by the user. The options under Read menu consists of text material for the user to read and understand the concept of research and a few related aspects. The theory behind various steps of research is given when the user is asked to plan the respective step. For example when the user clicks the button 'Hypothesis', the window shows a 'Read' button at the bottom and this will display information about hypothesis – 'What is hypothesis?' and 'How to

The section titles and the contents dealt under each is given below:

Menu	Deals with
Read	*Background material on*
	Introduction to research, Good laboratory practice (GLP), Committee for the Purpose of Control and Supervision of Experimental Animals (CPCSEA), Animal research ethics, 3Rs
Plan	*Various steps of planning include*
	Literature search, Formulating hypothesis, Selection of animal model, Framing objectives, Planning a pilot study, Experimental design, Selection of statistical methods, Calculating sample size, Protocol writing
Execute	*Step by step execution of the project*
	Applying for ethics permission, Carrying out randomization, blinding and allocation concealment, Collecting data (experimentation), Data screening
Analyse	*Data analysis*
	Tabulation of data, Statistical analysis , Drawing conclusions
Finish	Report writing
	The software includes a pretest and a posttest on research methodology and statistics. References for further reading are also included. The menu page shows buttons to display instructions, review the options chosen by the user while conducting the and exit the program.

formulate hypothesis?'. Each step (option) under 'Plan' includes this feature. Further the user can review at any stage of planning the options he/she has chosen
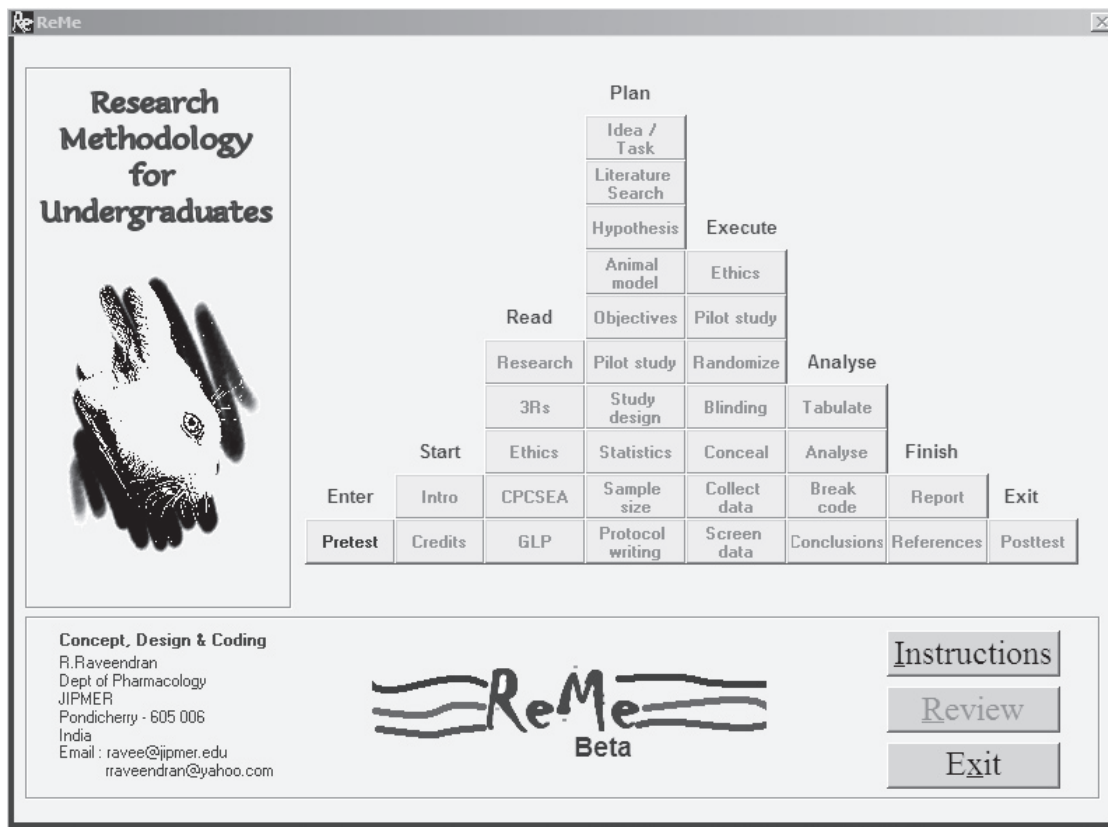

Fig. 1. Screenshot showing the Main Menu of ReMe

by clicking the 'Summary' button. Once the planning is over, the user is expected to write a protocol. A document writing facility is provided for this purpose along with a template to fill in the details. This document can be saved and reviewed later. Similarly the users can fill in the form for the ethics committee approval and save it too.

Having planned the study, the user can execute it too. The data collection (experiment) screen displays rabbit eyes, drugs and tools for testing. The user is expected to measure the pupil size and intraocular tension (IOT) and elicit light and corneal reflexes before drug administration using appropriate tools such as scale, tonometer, torch and cotton swab. The tools are provided on the screen and the user has to click it and carry them to the eye for measurement. Then the drug/vehicle is instilled on the eye (according to the randomization procedure planned) and the parameters are measured once again. The data are entered on the data entry screen which can be activated by user.

The user is expected to tabulate and analyse the data. The code (if blinding is implemented) can be broken after the analysis of data and the drugs used are revealed. The conclusions are drawn by the user who is expected to write the final report.

SWOT analysis

The software has the following 'strengths' and 'weaknesses'. The 'opportunities' provided by the software and the associated 'troubles' are also listed in below :

Concluding remarks

The above software is probably the first one to teach research methodology to UGs. It is expected that the software will enhance the research and analytical skills of UGs leading to reduction in wastage and unnecessary suffering of animals.

The software will be available from www.indphar.org for free download.

Strengths	Weaknesses
1. *In silico* advantages	1. *In silico* disadvantages; simulation is a simulation after all
2. Most steps of research are covered	2. The experiment can provide only predetermined results
3. 'Theory' as well as 'practice' of experimentation, data generation, analysis are included.	3. Only limited information on different aspects of research is available
4. The effectiveness of the module can be tested using the pre & post test.	4. The user is forced to choose an option rather than expressing open ended response; the user's choices are restricted.
5. Available free of cost; no licensing restrictions.	5. Self-learning may be difficult and a tutor's help may be required for students.
Opportunities	**Troubles**
1. UGs involved in research projects can use the software to familiarize themselves with research methodology and ethics.	1. Distribution of the software on the Net may be hampered by its large size. Downloading may be difficult for those who do not have a broadband connection.
2. Teachers guiding research students will find it useful to teach the students.	2. Effective usage depends on the teacher's attitude and acceptance of the software as a teaching aid.
3. Since the software is free, colleges can avail the opportunity to include it as a resource material for training.	3. The software is yet to be validated.