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A randomised controlled trial to evaluate a novel CD-ROM learning package against the standard lecture - training system for research governance in the teaching of new researchers in an NHS Trust

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Registration date 28/09/2007	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 12/10/2017	**Condition category** Other	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0054184076

Study information

Scientific Title
A randomised controlled trial to evaluate a novel CD-ROM learning package against the standard lecture - training system for research governance in the teaching of new researchers in an NHS Trust

Study objectives
Is the use of a CD-ROM teaching package more cost effective than traditional lecture methods of teaching Research Governance to new researchers?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Not Applicable: Education

Interventions
The purpose of this study is to determine whether a CD-ROM can provide education in research governance to new researchers as effectively but more cheaply and conveniently than routine lecture teaching. A CD-ROM teaching package has been produced that is identical to a Power point teaching presentation. Staff at the Cardiothoracic Centre - Liverpool NHS Trust who have research as part of their job description will be invited to attend a half day study day in the lecture theatre of the hospital and provided with an information sheet to decide if they wish to take part in the study or not.

On arrival in the lecture theatre subjects will be asked to consent to the study. Those who do will be randomised by pre numbered envelopes prepared by the clinical governance department.
1. Those subjects randomised to lecture will remain in the lecture theatre and receive 2 hours of the power point presentation with hand outs and web site addresses so that they have identical information to the CD-ROM group.
2. Those randomised to CD-ROM will be provided with a disc containing the PowerPoint presentation, web links and copies of important documents. They will be able to use this at home or with assistance from the librarian in the library.

All participants will be requested not to discuss source documents with other members of the research group. They will also be requested to return in 2 weeks time for a knowledge multichoice questionnaire and a satisfaction survey.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Cost effectiveness will be measured by cost per hour per attendee taking into account only direct costs, with the assumption that the CD-ROM will be used for the same length of time as the lecture. Subjects who do not attend the exam will be considered exam failures and their data will be included in the cost effectiveness. Subjects who attend the exam but obtain less than the 50% pass mark will also be considered exam failures.
2. Satisfaction with the teaching method will be analysed via Lickert scale questions from Price J 2005 and written responses to open ended questions.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/04/2006

Completion date
01/06/2006

Eligibility

Key inclusion criteria
Participants will be identified by obtaining lists of staff on Banding 6 & 7 with research as part of their job description. These staff will then be approached by letter also enclosing a study information sheet. Participants will be recruited and consented on attendance at the lecture theatre for the teaching session.

Subject inclusion criteria:
1. Age > 18 years
2. Able to give informed consent
3. Research active
4. Employee of the Cardiothoracic Centre - Liverpool NHS Trust

The sample size has been calculated to detect a £2.50 difference in cost using a 2 sample t test . at 90% power with a mean population wage of £ 20.46 and a standard deviation of 1.8. This will be calculated by taking the direct costs of subject wages per hour spent learning and the unit cost of the teaching method. This provides a sample size of 24 (12 in each arm of the study). To allow for drop outs and to obtain 24 evaluable questionnaires a total of 30 subjects will be enrolled.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
30

Key exclusion criteria
1. Unable to take ½ day for teaching and follow-up
2. No access to computer
3. Involved in another study within the last 30 days

Date of first enrolment
01/04/2006

Date of final enrolment
01/06/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Clinical Trials Unit
Liverpool
United Kingdom
L14 3PE

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
The Cardiothoracic Centre Liverpool NHS Trust (UK), NHS R&D Support Funding

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration