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Clinical evidence continuous medical education: randomised educational trial of an e-learning program for transferring evidence based information in primary and secondary care

Submission date 26/03/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 25/04/2007	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 05/03/2008	**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
43-06 SO

Study information

Scientific Title

Acronym
ICEKUBE (Italian Clinical Evidence Knowledge Utilisation Behaviour Evaluation)

Study objectives
This trial is designed to test the effectiveness of ECCE (the Italian acronym for Continuing Education Clinical Evidence) e-learning program for transferring evidence based information to medical doctors after three months of ECCE usage and the retention of the transferred information after six months.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was approved by the local research ethics committee (Research Ethics Board Azienda Sanitaria Locale Città di Milano, Milano) on the 15th December 2007 (ref: 43-06 SO).

Study design
A before and after pragmatic educational randomised controlled trial utilising a two by two incomplete block design.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Knowledge of the best available evidence for effective healthcare.

Interventions
Please note that as of 20/07/2007 the anticipated end date has been extended to 31/09/2007 due to a low recruitment rate. The previous end date of this trial was 31/07/2007. On 18/12

/2007 the anticipated end date was extended again to 01/04/2008 due to a continued low recruitment rate. On the 05/03/2008 the anticipated end date was again amended to show the end date as the 29/02/2008 - this is the date this trial was closed to enrolment.

Sample size/power calculation:
Based on a preliminary examination, we determined that the minimal important difference for this intervention to be considered useful was a 20% absolute improvement.

Based on a preliminary test of 300 doctors, we determined that the mean improvement due to the intervention, was a 28% absolute improvement. Therefore we calculated our sample size to detect a 0.7 standardised difference in the primary outcome, set the α error rate at 0.05 (two-sided), and the β error at 0.10 (power 90%) this yielded a sample size of 45 practitioners per study arm. If the accrual period is two months and the maximum follow-up period is six months with a loss during follow-up of 20% at the end of the study, the total number of practitioners to be randomised has been adjusted upwards to 162 (54 per intervention group).

Intervention:
ECCE is an e-learning tool that uses interactive clinical vignettes based on chapters in Clinical Evidence and a predefined sequence of questions. ECCE has four components:
1. The Clinical Evidence chapter (e.g. headache, chronic tension-type), a clinical vignette derived from the Clinical Evidence chapter gives a plausible medical scenario (e.g. Margaret says to her family doctor: This time I didnt come for me, but to talk about Rachel, my 25-year-old daughter)
2. The lead-in for the clinical vignette and related questions that gives the doctors instructions on what to do (e.g. "more than one answer may be correct)
3. The questions addressing the recall of Clinical Evidence facts or the application of Clinical Evidence facts to the medical scenario, based on which the doctor is to select the correct answer
4. And finally the potential answers (e.g. a list of potential efficacy descriptors for a therapeutic regimen relevant to the theme)

Group one access to ECCE for Clinical Evidence chapters and vignettes lot A and provides control data for Clinical Evidence chapters and vignettes lot B.
Group two access to ECCE for lot B and provides control data for lot A.

To determine the possible Hawthorne effect of this trial, we added to the two-block design arms a third control arm (classical design), in which a minimal intervention was defined. The minimal intervention consisted of one of the elements of the complete intervention, namely the concise printed version of Clinical Evidence and access to the on-line full-text version.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The primary outcome is the basic knowledge of Clinical Evidence contents assessed through the scoring of clinical vignettes selected from ECCE. The test will consist of fixed and multiple choice questions of the selected valid and reliable vignettes and will be administered before (pre-test), immediately after (12 weeks post-test one), and six months after the intervention (post-test two).

Secondary outcome measures
Satisfaction with the information source and its perceived value for the medical education and clinical practice.

Overall study start date
05/04/2007

Completion date
29/02/2008

Eligibility

Key inclusion criteria
All Italian doctors naïve to ECCE who voluntarily adhere to participate. New users to ECCE who connect to ECCE are automatically invited to participate.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
A sample size of 54 practitioners per study arm

Key exclusion criteria
There are no exclusion criteria.

Date of first enrolment
05/04/2007

Date of final enrolment
29/02/2008

Locations

Countries of recruitment
Italy

Study participating centre
Italian Cochrane Centre
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Sponsor information

Organisation
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Sponsor type
Research organisation

Website
http://www.icc.cochrane.org

ROR
https://ror.org/02d4c4y02

Funder(s)

Funder type
Research organisation

Funder Name
Italian Drug Agency (AIFA) (Italy)

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