

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

<b>Submission date</b> 26/03/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 25/04/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 05/03/2008	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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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  $\alpha$  error rate at 0.05 (two-sided), and the  $\beta$  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

Milano

Italy

20156

# Sponsor information

## Organisation

Italian Cochrane Centre (Italy)

## Sponsor details

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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