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Development and evaluation of a pedagogical tool to improve the understanding of a quality checklist: a randomised controlled trial

Submission date 18/12/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 21/02/2007	**Overall study status** Completed	
Last Edited 09/05/2007	**Condition category** Signs and Symptoms	

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

N/A

Study information

Scientific Title

Acronym
CILS

Study objectives
Assessing the quality of reports of Randomised Controlled Trials (RCTs) is particularly important for clinicians critical appraisal of the healthcare literature and for systematic reviewers. In fact, evidence suggests that inadequate reporting is associated with biased treatment effect estimates. Quality assessment is often achieved by use of checklists or scales. In the field of Non Pharmacological Treatment (NPT), a checklist - the checklist to evaluate a report of a nonpharmacological trial (CLEAR NPT) - was developed to assess the quality of RCTs included in meta-analysis. However, reproducibility issues have been raised because these checklists use items inconsistently defined and not well understood by reviewers such as blinding, dropout and withdrawals or an intention-to-treat analysis. To improve the understanding of the CLEAR NPT, we developed an Internet-based Computer Learning System (ICLS). To evaluate the impact of the ICLS on proper coding with the CLEAR NPT, we carried out an RCT comparing ICLS to no specific training.

The aim of this study was to develop and evaluate a pedagogical tool to enhance the understanding of a checklist that evaluates reports of Non Pharmacological Trials (CLEAR NPT).

Ethics approval required
Old ethics approval format

Ethics approval(s)
No ethical approval required as no patients were tested for this trial.

Study design
Randomised controlled trial comparing two groups of participants

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Improving the understanding of a quality checklist

Interventions
We developed an Internet-based Computer Learning System (ICLS). This pedagogical tool used many examples from published randomised controlled trials to demonstrate the main coding difficulties encountered when using this checklist.

Randomised participants received either a specific web-based training with the ICLS (intervention group) or no specific training.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The primary outcome was the rate of correct answers compared to a criterion standard for coding a report of randomised controlled trials with the CLEAR NPT.

Secondary outcome measures
Secondary outcomes were the rate of correct answers for each item and a qualitative assessment of the ICLS by the survey participants completed after fulfilling the training program.

Overall study start date
01/04/2006

Completion date
01/07/2006

Eligibility

Key inclusion criteria
Members from three different categories of participants were invited by e-mail to participate in the randomised controlled trial:
1. Members of Health Technology Assessment international (HTAi) (n = 430)
2. Directors of Evidence-based Practice Centers (EPC) (n = 13) who develop systematic reviews and technology assessments on topics relevant to clinical, social science/behavioural, economic, and other healthcare organisation and delivery issues
3. Corresponding authors of meta-analyses of NPT published between 1st January 2004, and 3rd March 2006 (n = 100)

Participant type(s)
Patient

Age group
Not Specified

Sex

Not Specified

Target number of participants
78

Key exclusion criteria
Participants not completing inclusion criterias

Date of first enrolment
01/04/2006

Date of final enrolment
01/07/2006

Locations

Countries of recruitment
France

Study participating centre
Département d'Epidémiologie Biostatistique et Recherche Clinique
Paris
France
75018

Sponsor information

Organisation
National Academy of Medicine (Académie Nationale de Médecine) (France)

Sponsor details
16 rue Bonaparte
Paris
France
75272

Sponsor type
Research organisation

Website
http://www.academie-medecine.fr/index.cfm

ROR
https://ror.org/01b266018

Funder(s)

Funder type
Research organisation

Funder Name
This work was supported by a grant from the National Academy of Medicine (Académie Nationale de Médecine) (France).

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results:	04/05/2007		Yes	No