Appendix

Mapping open educational resources on how to justify, design, conduct, analyse, and share randomised clinical trials: a landscape analysis

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Table of content

Supplement 1. Search strategies

MEDLINE ALL Ovid (1946 to 28 February 2024)

1. ('open access' adj3 (education* or web-site* or meducation*)).ti,ab.
2. (((online or video or digital or web-based) adj3 (resource* or material* or program* or education* or training* or course* or learning*)) or e-learning or 'blended learning' or 'micro learning').ti,ab.
3. 1 or 2

Embase Ovid (1974 to 28 February 2024)

1. ('open access' adj3 (education* or web-site* or meducation*)).ti,ab.
2. (((online or video or digital or web-based) adj3 (resource* or material* or program* or education* or training* or course* or learning*)) or e-learning or 'blended learning' or 'micro learning').ti,ab.
3. 1 or 2

CINAHL (Ebsco host; 28 February 2024)

S3 S1 OR S2

S2 TX ((((online or video or digital or web-based) N3 (resource* or material* or program* or education* or training* or course* or learning*)) or e-learning or 'blended learning' or 'micro learning')) OR AB ((((online or video or digital or web-based) N3 (resource* or material* or program* or education* or training* or course* or learning*)) or e-learning or 'blended learning' or 'micro learning'))

S1 TX (('open access' N3 (education* or web-site* or meducation*))) OR AB (('open access' N3 (education* or web-site* or meducation*)))

Science Citation Index Expanded (1900 to 28 February 2024), Social Sciences Citation Index (1956 to 28 February 2024), Conference Proceedings Citation Index – Science (1990 to 28 February 2024), Conference Proceedings Citation Index – Social Science & Humanities (1990 to 28 February 2024) (Web of Science)

#3 #2 OR #1

#2 TI=(((online or video or digital or web-based) N3 (resource* or material* or program* or education* or training* or course* or learning*)) or e-learning or 'blended learning' or 'micro learning') OR AB=(((online or video or digital or web-based) N3 (resource* or material* or program* or education* or training* or course* or learning*)) or e-learning or 'blended learning' or 'micro learning')

#1 TI=('open access' N3 (education* or web-site* or meducation*)) OR AB=('open access' N3 (education* or web-site* or meducation*))

Supplement 2. ASReview training

Training the ASReview algorithm

In our protocol, we contemplated to use all known references on open educational resources from various clinical fields and case studies of implementation of specific online e-learning programs (protocol references 21 to 38). We opted to include four seed references based on the presence of certain keywords like 'evidence-based medicine',[1] 'e-learning course',[2] 'development of an internet platform',[3] and 'open access' and 'education'.[4] We chose five irrelevant references randomly using ASReview's random search button.[5-9]

Furthermore, directly in ASReview, we searched for specific keywords to identify further potential seed references:

"Evidence-based" (10 hits, none relevant).
"Clinical trial" (10 hits, none relevant).
"Randomised clinical trial" (10 hits, none relevant).
"Randomized clinical trial" (10 hits, none relevant).
"Research methods" (10 hits, none relevant).

Supplement 3. Amendments compared to our protocol

1. Searching additional resources

We searched more resources than originally specified in the protocol. See our Data File for the full list of resources (https://doi.org/10.5281/zenodo.15410961).

Clinical trial unit websites

We searched an additional 17 US based clinical trials, in addition to the one listed in the protocol. We also searched the 14 individual ECRIN member websites.

University or learning portals

We searched ClassCentral, and seven more learning portals than specified in the protocol.

Trial registries and national regulatory authorities

These resources were not specified in the protocol. We searched the largest trial registries (ClinicalTrials.gov, the European Union Clinical Trial Register, and ISRCTN). We also searched a range of regulators, including the two largest (US Food and Drug Administration and European Medicines Agency) and a number of national regulators. We furthermore searched the European Network of Research Ethics Committees (EUREC) and the British Health Research Authority's websites.

2. Specification of inclusion criteria for open educational resources

The inclusion criteria were not strictly defined in our protocol due to the exploratory scope of our analysis. We decided to exclude solitary material that was not intended as educational material, e.g. protocol templates, standard operational procedures, and other available documentation, unless this was available along other documents or guidance, in which case we would classify it as 'scattered website material'.

3. Specification of how to categorise included resources

Categorisation of content

In the protocol, we had not prespecified how to categorise the included resources. We decided to do this to better map which content was covered and which content was not covered. We defined five types of OER (e-learning, dedicated trial portals, scattered website material, e-books, and videos), and four formats (guidance, research publications, documentation templates, and tools).

Definition of the five trial stages

In the protocol, we stated to describe the curriculum of each included resource without operationalising this further. We subsequently defined five specific trial stages (justification, design, conduct, analysis, reporting) and categorised the content of each resource according to this staging.

Supplement 4. Full tables of included resources

The 23 key resources from the main article's Panel 2 are highlighted in these five tables.

Note that the resource names are live links to the relevant websites.

Table 1. Dedicated portals (n=22)

Resource	Funder	Synopsis	Content
Australian Clinical Trial Alliance	Public Australian funding	Dedicated platform with learning material on how to conduct clinical trials, including webinars, guidance documents, and extensive toolkits.	1, 2, 3, 4, 5
Clinical Studies Sweden	Swedish Regions	Dedicated portal to the conduct of RCTs with guidance, templates, and a nice roadmap	1, 2, 3, 4, 5
Clinical Trial Information System (CTIS): online training modules	European Union	Dedicated learning portal with 23 modules covering the CTIS reporting system and pertinent topics on trial conduct and reporting.	2, 5
Clinical Trials Kiosk	University of Alabama at Birmingham	Collection of guidance, templates, and tools about conducting clinical trials (focused on local infrastructure).	3
Clinical Trials Transformation Initiative	U.S. FDA and various commercial and non-commercial institutions	Dedicated portal for improving RCT conduct with guidance, research publications, and tools.	2, 3, 5
COMET	EC, MRC, and NIHR	Collection of guidance and research publications about core outcome sets.	2
Design, Analyze, Communicate (DAC)	Bill & Melinda Gates Foundation	Dedicated platform to make trials more informative, including best practice guidance, videos, links to external tools, and embedded e-learning courses.	1, 2, 3, 4, 5
ECRIN Tools	European Clinical Research Infrastructure Network	Dedicated platform with various tools for specific topics, e.g. regulatory aspects or platform trials, with guidance, publications, tools, and templates.	2, 3
ENERI	EU Horizon 2020	Dedicated learning platform on research ethics with 5 e-learning modules (ENERI Classrom), a decision-tree tool, and extensive guidance documents.	2, 3, 5
EUPATI – Open Classroom	EU	Dedicated platform on patient involvement in clinical research with toolbox and multiple e-learning courses.	1, 2, 3, 4, 5
Global Health Network	Various NGOs and the University of Oxford	Learning portal with guidance, collections of links, and e-learning courses on randomised clinical trials, e.g. GCP and data monitoring safety boards.	1, 2, 3, 5
Good Trials	Good Clinical Trials Collaborative (NGO)	Dedicated website with high-level guidance to conduct clinical trials.	2, 3
NHS Health Research Authority	HRA	Dedicated website for investigators on how to plan clinical trials and submit regulatory submissions.	1, 2, 3
NIHR Clinical Trials Toolkit	NIHR	Dedicated platform on trial conduct with a clear roadmap, guidance and templates.	2, 3, 4, 5
NIH Pragmatic Trials Collaboratory	NIH	Dedicated platform for designing, conducting, and sharing clinical trials with guidance, templates, and tools.	2, 3, 4, 5
NorCrin Method's book	Norwegian Regions	Dedicated catalogue of Standard Operating Procedures pertaining to all steps of the trial life cycle.	1, 2, 3
Research Methods Resource	NIH	Dedicated platform on research methods for RCTs focusing on the design of trials with guidance, publications, and tools. Also guidance to NIH specific requirements.	2, 3
SCTO Platforms	Swiss Clinical Trial Organisation	Dedicated platform on clinical trials with guidance, publications, tools, and templates.	2, 3, 4, 5
TrialDesign	Private initiative (MD Anderson faculty)	Dedicated website on how to design oncology trials with guidance and publications.	2, 3, 4
TMRN (Trials Methodology Research Network) Online Training Resource	Health Research Board, Ireland	Dedicated platform for trial methodology with extensive training repository mainly including webinars.	1, 2, 3, 4, 5
Trial Forge	University of Aberdeen	Dedicated portal for improving RCT conduct (focus mainly on recruitment and retention) with guidance and research publications.	2, 3

Training and Resources in Research Ethics Evaluation (TREEE)	Various universities and NGOs	E-learning platform on research ethics and resources on national regulatory ethics frameworks.	1, 2, 3

Table 2. e-learning (n=20)

Resource	Funder	Synopsis	Content
Clinical trials operations specialization	Johns Hopkins University	Coursera course on the conduct of RCTs, divided into four individual topic specific courses.	2, 3, 4, 5
Clinical Trials: Good Clinical Practice Specialization	Novartis	Coursera course focusing on GCP.	3
Comparative Effectiveness and Research training instruction	MD Anderson	EdX course on general RCT concepts, divided into five topic specific courses.	2, 3, 4
Conscious II Program	EU Erasmus Plus Programme	e-learning course in 12 chapters on full RCT conduct.	2, 3, 4, 5
Data management for clinical research	Vanderbilt University	Coursera course on data management in RCTs.	3, 5
Data sciences in pharma - patient centered outcomes research	Genentech	Coursera course on how to develop, measure and validate patient reported outcomes in RCTs.	2
Design and interpretation of clinical trials	Johns Hopkins University	Coursera course and general overview of RCTs.	2, 3, 4, 5
GCP Units	Danish GCP units	e-learning course on GCP (in Danish).	3
ENGAGE	AVAC (Advocacy, Access, Equity) (NGO)	e-learning course on Good Participatory Practice.	3
Faster Together	Vanderbilt University	Coursera course on involving minorities in RCTs.	3
Hands on clinical reporting using R	Genentech	Coursera course on data management and reporting of RCTs.	4, 5
Making data science work for clinical reporting	Genentech	Coursera course on data reporting of RCTs using data science.	5
NIDA training	National Institute on Drug Abuse (NIDA)	e-learning course on GCP.	3
NIH Introduction to the Principles and Practice of Clinical Research	NIH	e-learning course and webinar collection on how to plan, design, conduct, analyse and share randomised clinicals (accessible until 1 August 2025).	1, 2, 3, 4, 5
North Caroline Community Colleges: Introduction to Clinical Research	BioNetwork	e-learning courses on clinical trials.	3
Pragmatic and Group-Randomized Trials in Public Health and Medicine	NIH	e-learning course on pragmatic RCTs.	2, 4
STAT 509: design and analysis of clinical trials	Pennsylvania State University	Course notes about the general concepts of RCTs.	2, 4
The Simplest Guide™ to clinical data analysis with SAS	Packt	Coursera course on RCT documents and how to make clinical study reports.	5
Thinking Critically: Interpreting Randomized Clinical Trials	Stanford University	EdX course on general RCT concepts.	2
Vaccelerate Study Nurse Course	University of Cologne and EU Horizon 2020	e-learning course on GCP for study nurses.	3

Table 3. Scattered websites (n=10)

Resource	Funder	Synopsis	Content
Danish Medicines Agency - Guidance for non-commercial clinical trials	Danish Medicines Agency	Guidance, links to further information (on TrialNation), and templates to protocols and contracts.	2, 3
Duchenne Muscular Disease Hub Toolkit	Duchenne UK*	Collection of guidance, research publications, and documentation templates for conducting DMD trials.	2, 3
EMA scientific guidance	European Medicines Agency	Collection of guidance documents issued by EMA on various topics related to the design, conduct, and analysis of commercial pivotal trials. Also guidance related to design of pivotal disease specific trials.	2, 3, 4
Ethics and Data Protection Decision Tree	EU	GDPR decision tree to identify data protection issues during research projects,	3
FDA Guidance Documents	US Food and Drug Administration	Collection of guidance documents issued by FDA on various topics related to the design, conduct, and analysis of commercial pivotal trials. Also guidance related to design of pivotal disease specific trials.	2, 3, 4
HIV Prevention Trials Network "Manual of procedures"	Various federal US agencies	Collection of instructions and documentation templates for conducting trials in their HIV trial network.	2, 3, 5
MRC Clinical Trials Unit "Methodology"	MRC	Collection of guidance, tools and links within five domains (design, conduct, analysis, meta-analysis, software).	2, 3, 4
University of Oxford "Clinical trials and research governance"	University of Oxford	Overview of trial flow, guidance and templates (related to local infrastructure)	2, 3
Trial Methodology Research Partnership "*Guidance pack*"	MRC	Collection of guidance and publications.	2, 3, 4, 5
UKCRC "*guidance for CTUs*"	UKCRC Registered Clinical Trials Units	Collection of guidance, publications, and templates for trial units, including an e-book on monitoring trials.	2, 3, 4, 5

* Not stated explicitly. Duchenne UK is a non-profit charity, unknown sponsors.

Table 4. Videos (n=9)

Resource	Funder	Synopsis	Content
Best Practices for Integrating Patient Reported Outcomes in Oncology Clinical Trials	National Cancer Institute	Webinar series about the development, use and analysis of patient reported outcomes in oncology trials.	2, 4
Clinical Trials Methodology Course	National Institute of Neurological Disorders and Stroke	Collection of recorded lectures from annual research courses on RCT methods.	2, 3, 4
Crash Course on Clinical Trials	Private blogger (The Brown Feminist, Canada)	Collection of videos on various topics related to clinical trials.	3
Crash Course to Clinical Research	Private blogger (Dan Sfera)	Solitary video explaining the concepts of randomised clinical trials.	2, 3
FDA Clinical Investigator Training course 2024	FDA	Collection of recorded lectures and handouts about the general conduct of RCTs.	2, 3, 4
GCP Mindset	Clinical Research Organisation (GCP Service)	Collection of short videos on various topics, mainly GCP specific.	3, 4
Mind the gap: webinar series	NIH	Collection of webinars on research topics not-exclusively related to RCTs.	2, 4
NIA Clinical Trials Safety Training	National Institute of Aging	Solitary video on adverse event handling in clinical trials	3
Registering and results reporting	NIH	Solitary video on registering and results reporting on ClinicalTrials.gov	5

Table 5. e-books (n=2)

Resource	Funder	Synopsis	Content
Data Safety Monitoring Board Training Manual	Tufts University	e-book on data safety monitoring boards.	3
UK Trial Managers' Network "The Guide to Efficient Trial Management"	University of Oxford	e-book describing all steps in trial conduct, including details on local and national infrastructure	1, 2, 3, 4, 5

EC = European Commission, FDA = US Food and Drug Administration, GCP = Good Clinical Practice, MRC= Medical Research Council, NGO = Non-governmental organisation, NIH = National Institutes of Health, NIHR = National Institute for Health and Care Research, RCT = Randomised clinical trial.

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