Improving Outcome Measures in the ISRCTN Clinical Trial Registry

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Trial registration is important

"It is difficult to make informed decisions if publication bias and selective reporting are present"

WHO Statement on trial registration

- **Publically-available record for every clinical trial, before the trial begins, including:**
  - A unique identifying clinical trial number (CTN)
  - The planned research outcomes and methods
- **To prevent unnecessary duplication of research effort**
- **To help patients and the public know what trials are planned/ongoing**
- **To give ethics review boards considering approval of new studies a view of similar work (and data)**

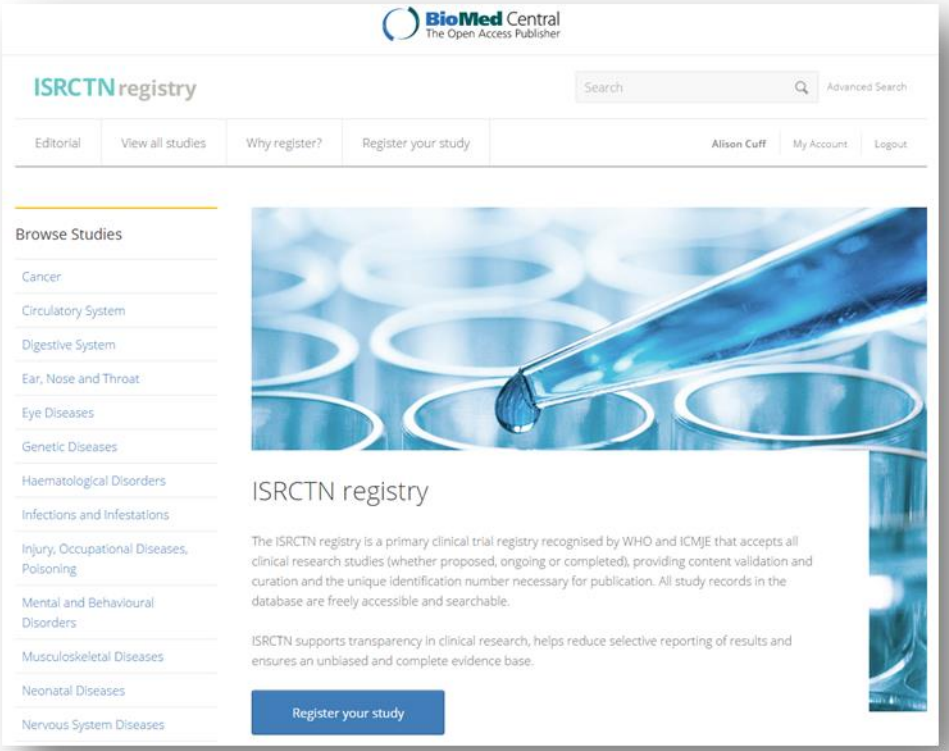
Trial registration is a requirement

- **2004: ICMJE - prospective registration of clinical trials in a WHO primary registry a requirement for publication**
- **2007: FDA Amendment Act made prospective trial registration and summary results reporting within 1 year of trial completion a legal requirement for interventional studies in the US**
- **2008: The Declaration of Helsinki made prospective trial registration a requirement for ethical approval**
- **2016: EU Clinical Trials Regulation making registration and results reporting mandatory for clinical trials in the EU**

Clinical trials should be registered before the first participant is recruited.

The ISRCTN Clinical Trial Registry

- The ISRCTN registry is BioMed Central's clinical trials registry
- One of a number of WHO recognised platforms that allow researchers to publicly register their clinical research studies
- Provides content validation and curation – including for outcome measures
- Outcome measures - one of the 20 items required for trial to be considered fully registered



Observed challenges

- Different studies looking at same condition reporting different outcomes

- Confusion as to what the term *outcome measure* means and how they should be reported

Aims of research

1. To categorise problems with outcome measures as provided by trialists submitting to the ISRCTN registry
2. To test whether a standard instruction helps trialists to provide good outcome measures
3. To test whether directing trialists to the COMET Initiative website (where appropriate) raises awareness of this resource (and therefore outcome measure reporting and core outcome sets)

Data collection

Interventional, health-related studies

31754	Cancer	Prostate cancer	16/02/2016	17/02/2016	pros	Incomplete - no methods	COS for practice	yes	No response	
31765	Circulatory system	Coronary heart disease	17/02/2016	25/02/2016	pros	Incomplete - no methods or timepoints	COS recommended outcome measures	yes	yes	Provided outcome measures in correct format
31774	Oral Health	Pain after canal treatment	20/02/2016		retro	Incomplete - no methods or timepoints	None	yes	No response	
31787	Oral Health	Permanent teeth with advanced caries or dental trauma with pulp exposure	22/02/2016	25/02/2016	retro	Unclear	Overview of literature	yes	yes	They came back thanking me for the link but said it wasn't applicable to them. Did provide "acceptable" outcome measures.
31793	Cancer	Gastrointestinal neoplasia	24/02/2016		retro	Provided results	Definition	yes	No response	

Results

- Collection period: January 2016 to September 2016
- 178 study records evaluated
- 108 identified as having “problematic” outcome measures

Problem	Number	Percentage
Incomplete information	65	60
Results provided	8	7
Provided aims	23	22
Unclear information	6	6
No outcome measures	6	6

Actions taken to improve outcome measures

1. Trialists sent standardised text explaining what an outcome measure is with example
2. If health condition listed in COMET database – refer and track click-throughs
3. Tailored advice sent if more information still needed

Responses to actions

Out of 108 studies analysed, 60 trialists responded to initial query email

How successful was the standardised text?

- **40 out of 60 trialists provided acceptable outcomes**
- **20 required more tailored assistance**

The COMET resource effect

60 out of 108 trialists were not referred to COMET resource

- 45 responded to initial query
- 26 provided acceptable outcome measures in response to standardised text
- 19 needed tailored assistance

48 out of 108 trialists referred to COMET resource

- 15 responded to initial query
- 12 provided acceptable outcome measures in response to standardised text + COMET referral
- 3 needed tailored assistance
- 45 click-throughs to COMET resource

Conclusions & Future Work

What have we learned so far?

1. Qualitative research – but assisting trialists in improving the outcome measures that they provide though both standard and tailored instruction has been successful.
2. Evidence to suggest that a subset of trialists have become aware of the COMET Initiative resource though referral to site

Questions for the future

1. To what extent do ISRCTN outcome measures reflect core outcome sets (COSs)
2. Do trialists want to use COSs ?
3. What role should registries play in promoting COSs?

Thank you for your attention!

I look forward to your questions

ISRCTN registry:

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