TrialTree: an interactive randomized trial design application

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Background

The science of research-on-research has highlighted important gaps in the research enterprise, notably the many studies that are poorly designed, executed and not replicable, amounting to research waste. About 50% of research waste in clinical research comes from poorly designed studies.[1] Close to 21% of clinical trialists consider study design to be the biggest challenge they face.[2] To date, there are no electronic tools that streamline the trial design process, allow for collaboration among multiple researchers, or support capacity building in trial design. We sought to develop such a tool.

Methods

Using an iterative design process based on current literature on trial design, and user feedback from students and investigators, we built an algorithm-based, electronic, randomized trial design tool. A preliminary set of key features for trial design such as a clear research question, a knowledge gap, equipoise and a hypothesis were set and built upon. Feedback for inadequate design choices and tips on how to optimise trial design were included. We also included access to additional resources including reporting guidelines, recommended checklists, choice of outcomes, statistical analysis plans and extensive resources on a wide variety of randomized trial designs.

Results

The electronic tool (TrialTree) is now freely available and promotes design consistency, allows for co-design of trials by researchers in different parts of the world, and can generate standardized analytical plans. It includes direct feedback, trial design tips, and a downloadable report. The tool complies with current guidance for trial design and incorporates various consensus-based tools for enhancing trial design (e.g., PRagmatic Explanatory Continuum Indicator Summary [PRECIS-2], Template for Intervention Description and Replication [TIDieR], Standard Protocol Items: Recommendations for Intervention Trials [SPIRIT], Core Outcome Measures in Effectiveness Trials [COMET], and TrialForge). It can be used by both learners and seasoned researchers interested in optimizing the design of their randomized trials.

Modules

- **Basics:** use this module to enter basic information about your trial
- **Design:** use this module to declare the main interest of you trial
- **PICO:** use this module to describe your participants, intervention, comparison, and outcome
- **TIDIER:** use this module to provide further details about your trial
- **SAP:** use this module to create a tabular statistical analysis plan
- **Full SAP:** use this module to create a complete statistical analysis plan
- **SPIRIT:** use this module to complete the SPIRIT checklist
- **Trial resources:** select trial resources from a comprehensive list

Conclusion

TrialTree is an innovative electronic tool that will enhance trial design and capacity building, especially in parts of the world where methodology resources are limited. It can be accessed here: https://bit.ly/3ovDYWI

References

1. Chalmers I, Glasziou P. Avoidable waste in the production and reporting of research evidence. The Lancet.;374(9683):86-9
2. Burrows A. The 8 biggest challenges facing clinical trial professionals (2016): https://bit.ly/3jAkIXV (Accessed 28 June 2021)

Scan the QR code to access TrialTree

Figure 1: Login page

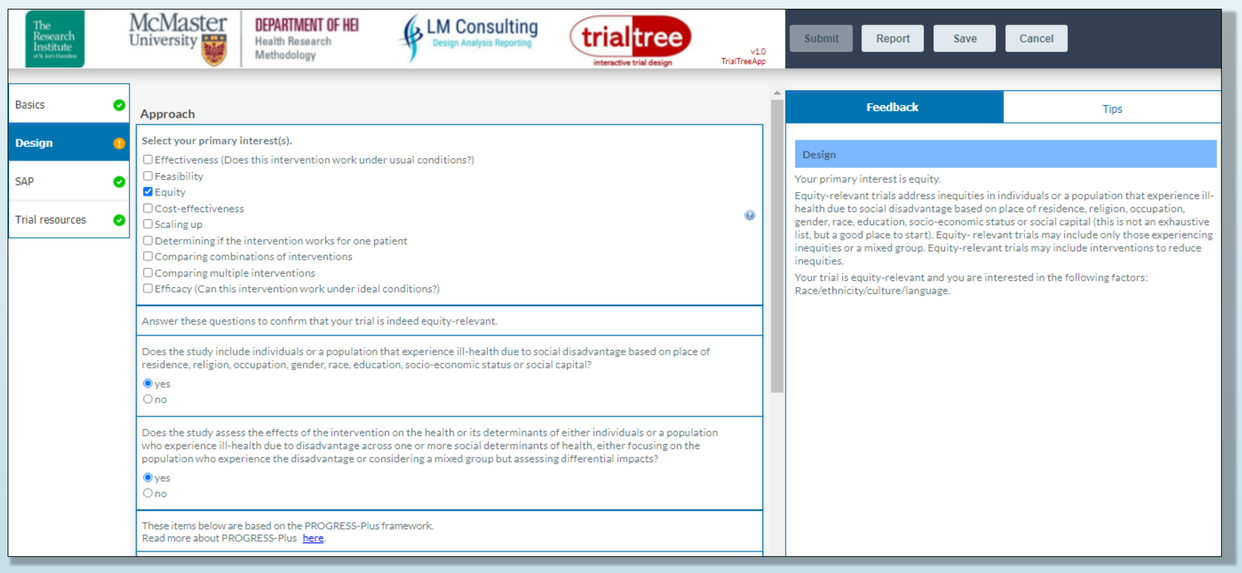

Figure 2: Sample active session showing modules on the left, user selections and feedback on the right

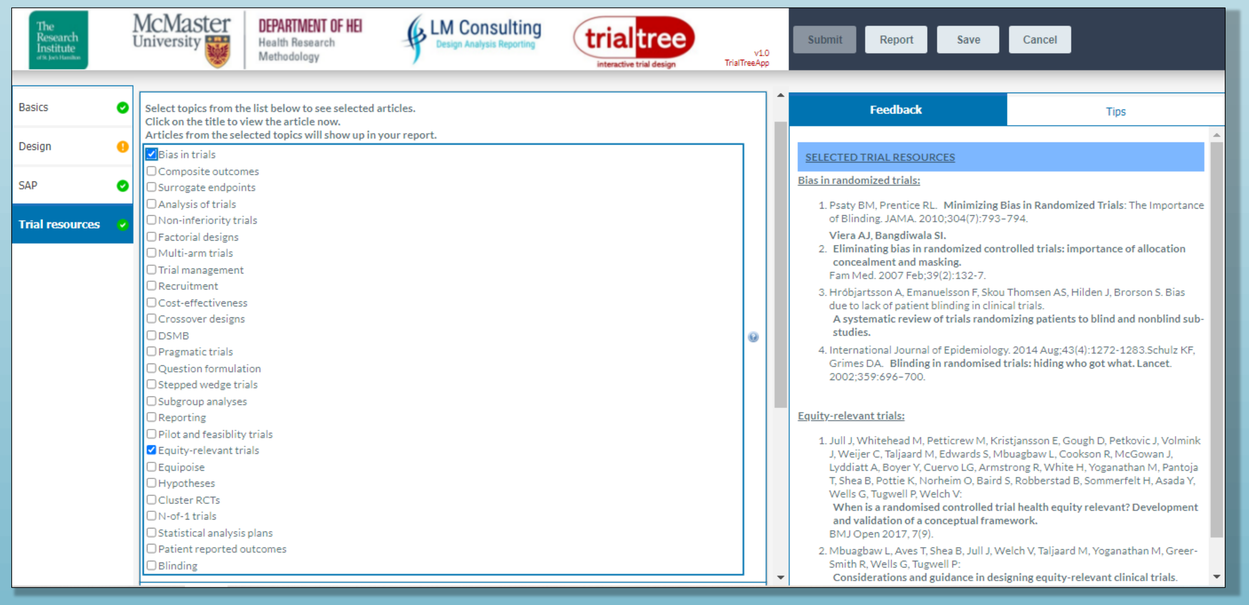

Figure 3: Sample active session showing a variety of trial design resources

Acknowledgements

Daeria Lawson, Stephen Noorduyn, Thuva Vanniyasingam, Lehana Thabane, Robby Nieuwlaat, Zena Samaan, Mike Walsh, Behnam Sadeghirad, Solange Durao