

Learn from our bumps in the road! Implementing a pragmatic clinical trial.

MCUAAAR SCIENTIST SEMINAR

MAY 18, 2022



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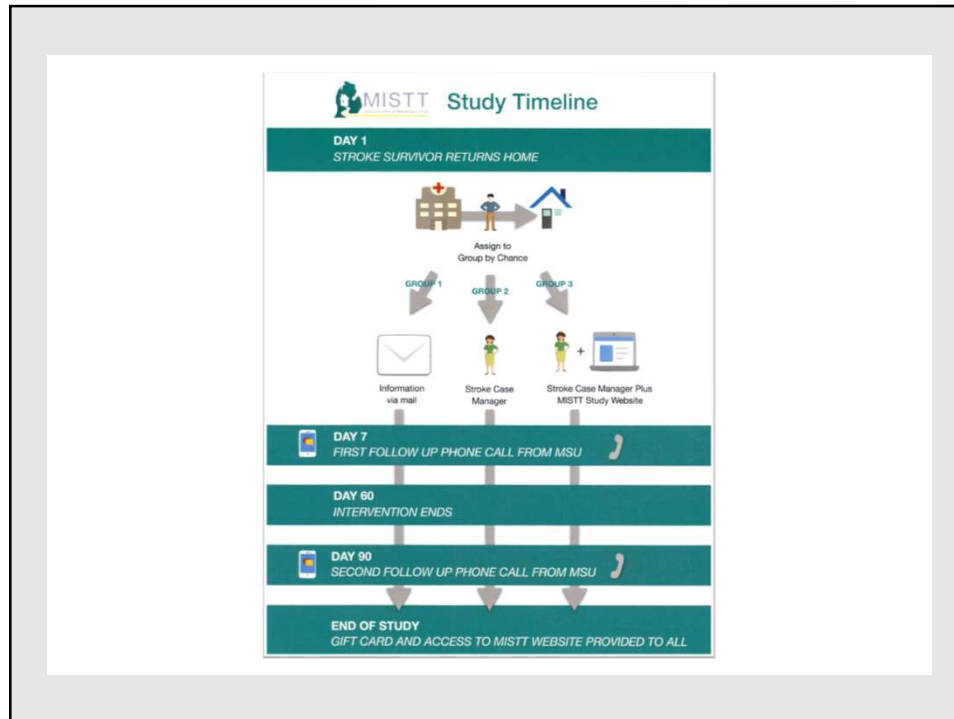
What is a pragmatic trial?

- Real world population
- Real world setting
- Appropriate comparison arm
- Relevant outcomes

Gamerman, V., Cai, T., & Elsässer, A. (2019). Pragmatic randomized clinical trials: best practices and statistical guidance. *Health Services and Outcomes Research Methodology*, 19(1), 23–35.

<https://doi.org/10.1007/s10742-018-0192-5>

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Real world settings

Hospitals
(recruitment)

In-home
(intervention)



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Real world population with real world problems

- Social work case management
- Patient-centered
- Not manualized
- Four main foci
 - Emotional/practical support
 - Improve preparedness
 - Identify/address ongoing unmet needs
 - Education – stroke and stroke prevention

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Relevant outcomes

- Identified through focus groups with patients, caregivers, and health care professionals (and literature/previous research)
- Heavy focus on quality of life, patient activation, caregiver burden (vs 30 day readmission)
- Hard to measure
- Majority did not have far to go on those
- For those with lots of needs were not going to change in 90 days
- Measuring the “right” things?



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Appropriate comparison arm

Usual care – what is that?



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