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# Sequential Multiple Assignment Randomized Trial (SMART) Designs

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## **Key features**

- Study design developed to build and test adaptive interventions (when and how to modify interventions)
- Multiple randomized treatment assignments performed at key decision points for each participant
- Interventions and decision timing should mimic clinical practice
- Primary tailoring variable (different from primary outcome) used to determine whether changes are needed
- Generally not used when the goal is to determine the single best intervention

## **Settings where SMART trials can be useful**

- Heterogeneous patient outcomes, treatment goals and effectiveness of therapies that change over time
- Need to balance benefits and risks, costs, burden
- Relapse possible, maintaining adherence difficult
- Comorbidities need to be considered in treatment algorithms

## **Advantages of SMART designs**

- Allows comparison of intervention options at different stages of treatment
- Can build tailored, personalized interventions
- Can evaluate interactions between therapies

## **Disadvantages of SMART designs**

- Designs can be challenging and complex, requiring collaboration with statistician
- Pharmaceutical companies may dislike head-to-head comparisons of drugs
- A pilot/feasibility study may be needed to obtain funding

## **Prior to meeting with a statistician**

- Determine pressing clinical questions, hypotheses of primary interest, key decision points and timing, set of feasible treatments at each stage, possible tailoring variables
- Obtain estimates of variability and treatment effects for the primary outcome, estimates of non-response rate



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## References/Resources

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## Notes:



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