

Example of a SMART using Design II

1 Introduction

We consider a trial on adaptive pharmacological and behavioral treatments for children with ADHD (W. Pelham, P.I.).

2 Motivation

A number of efficacious pharmacological and behavioral interventions are available for the treatment of ADHD. However, it is unclear whether the first-stage treatment should be pharmacological or behavioral.

3 Trial Components

There are four treatments under study. They are

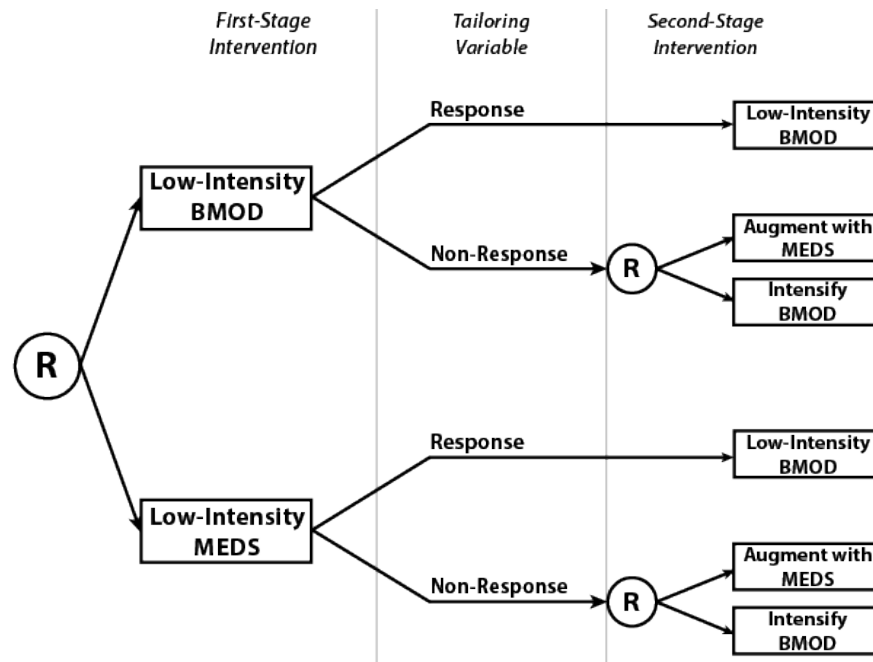
1. Low- and high-dose methylphenidate (a psychostimulant) (MEDS)
2. Low- and high-intensity behavioral modification (BMOD)

The tailoring variable used were scores on the Impairment Rating Scale (IRS) and an individualized test of target behaviors (ITB); both are well-known instruments which assess response to treatment.

4 Embedded Adaptive Interventions

There are four adaptive interventions embedded in this design. They are

1. “Give low-intensity BMOD. If the child responds to treatment, continue providing low-intensity BMOD. Otherwise, if the child does not respond, augment low-intensity BMOD with MEDS.”
2. “Give low-intensity BMOD. If the child responds to treatment, continue providing low-intensity BMOD. Otherwise, if the child does not respond, switch to high-intensity BMOD.” to CBI, MM, and placebo. Otherwise, augment NTX with TDM.”
3. “Give low-dose MEDS. If the child responds to treatment, continue providing low-dose MEDS. Otherwise, if the child does not respond, augment low-dose MEDS with BMOD.”
4. “Give low-dose MEDS. If the child responds to treatment, continue providing low-dose MEDS. Otherwise, if the child does not respond, switch to high-dose MEDS.”



5 Outcome Measures

Outcome measures include time-varying ratings of child behavior (from parents and teachers) as well as final IRS and ITB scores after 8 months.

References

- [1] Lei, H., Nahum-Shani, I., Lynch, K., Oslin, D., and Murphy, S. A. (2012), "A 'SMART' Design for Building Individualized Treatment Sequences," *Annu. Rev. Clin. Psychol.*, 8, 21-48.
- [2] Pelham, W. E., & Fabiano, G.A. (2008), "Evidence-based psychosocial treatment for ADHD: An update", *Journal of Clinical Child and Adolescent Psychology*, 31, 184-214.