

Oral presentation

## BrAIST: planning and current status of Bracing in Adolescent Idiopathic Scoliosis Trial

LA Dolan\* and SL Weinstein

Address: University of Iowa Healthcare Department of Orthopaedics 200 Hawkins Dr. Iowa City, IA 52242, USA

Email: LA Dolan\* - lori-dolan@uiowa.edu

\* Corresponding author

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The randomized controlled trial has emerged as the gold standard for all clinical research. The combination of randomized assignment to groups, use of strict inclusion and exclusion criteria, standardized protocols and ad hoc power analysis serve to rule out many threats to the internal validity of research results. Thus, it is the most powerful methodology available to researchers investigating the relative effectiveness of treatments.

To date, there have been only 2 randomized studies examining the effectiveness of bracing for adolescent idiopathic scoliosis. The purpose of this presentation is to discuss the planning and the current status of the Bracing in Adolescent Scoliosis Trial (BrAIST). This five-year, > \$5 million project includes 27 healthcare centers, and is funded by the United States National Institutes of Health, the Canadian Institute of Health Research, and the Shriners Hospitals. Additionally, 3 institutions, including the Chinese University of Hong Kong, are participating using internal funding.

The protocol randomizes children with AIS who are at high risk for curve progression to treatment with a thoracolumbosacral orthosis or to clinical monitoring. The study is currently in its second year of recruitment.

BrAIST incorporates several innovations never used in a single study to date:

1) randomization,

- 2) objective brace dose monitoring,
- 3) standardized, objective radiographic measurement,
- 4) comprehensive radiographic, clinical, and psychosocial testing,
- 5) diversity of participating sites and
- 6) ad hoc determination of effect size, based on the risk/benefit considerations of potential patients.

Issues to be discussed include

- Ethics - rationale for the ethics of an observation arm
- Protocol development and implementation - endpoints, measures, quality assurance
- Recruitment and randomization - expectations and actuality
- Bracing quality control - independent review of in-brace films
- Patient/family decision-making - impact of information and being offered a choice
- Brace compliance monitoring - reliability/validity of temperature as proxy for dose