Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

Supplement to: Weinstein SL, Dolan LA, Wright JG, Dobbs MB. Effects of bracing in adolescents with idiopathic scoliosis. N Engl J Med 2013;369:1512-21. DOI: 10.1056/NEJMoa1307337

Supplementary Appendix

"**Results of the Bracing in Adolescent Idiopathic Scoliosis Trial**"

Weinstein, Dolan, Wright, Dobbs and the BrAIST Study Group

Table of Contents

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The authors would also like to acknowledge the contributions of Drs. Melanie Donnelly, Vani Sabesan, Richard Haynes, Robert Huang, Darrell Hanson, David Feldman, John Grayhack and Nancy Hadley-Miller.

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Additional Details of the Primary Propensity Score Adjusted Analysis

The primary analysis used a propensity score (PS)-adjusted analysis to control for potential selection bias due to nonrandom treatment assignment in the preference arm. The PS derivation model was constructed using multivariable logistic regression, with bracing treatment as the dependent variable. Models included all baseline variables that 1) had no missing values and 2) were unbalanced between the treatment arms ($p<0.05$). The baseline maximum Cobb angle, age, and whether the subject was randomized or not were considered important potential confounding factors to be forced into the PS model. The PS score, then, is the probability that a subject would be braced conditional on these covariates. PS scores were divided into quintiles and overlap between the treatment groups at each quintile was checked. The odds of success (treatment effect) was modeled as a function of treatment received, length of follow-up, and the PS quintile. Achievement of balance in significantly different baseline variables across the quintiles was evaluated via linear regression testing for a quintile*treatment interaction.

The primary analysis population included 242 subjects: 116 subjects (48%) who were randomized to treatment and 126 (52%) who chose their own treatment. We compared characteristics of this population to those who were eligible but declined participation (n=703). There were no significant differences between these two groups in age, sex, predominant race, SRS curve classification, or magnitude of the largest Cobb angle.

Table 1 summarizes the baseline characteristics of this population by treatment assignment method (randomized vs. preference) and by treatment received. The randomized and preference groups significantly differed at baseline on four variables: sex, median interval between diagnosis of scoliosis and trial enrollment, who first noticed the subject's scoliosis and largest degree of apical vertebral rotation. Otherwise, the two groups were equivalent at baseline.

139 subjects were initially assigned to bracing (57%) and 103 to observation. Three subjects decided not to pursue bracing and 10 of the subjects in the observation group opted to receive a brace. Therefore, the as-treated analysis evaluates 146 subjects who were braced

(60%) and 96 subjects who were followed by observation (40%). Eventually, 37 subjects (27%) reported stopping brace wear altogether prior to reaching a study endpoint.

No attempts were made to impute missing values except in the case of standing height. Standing height was found to differ between the two treatment groups in both interim analyses, and in the final primary analysis population. Therefore, the decision was made to impute the missing values (n=2) by using the next available observed height measurement. The braced group was taller than the observation group (156.5 vs. 153.6cm, p=0.03).

PS modeling included the baseline variables height, maximum Cobb angle, age and random vs. preference treatment assignment. PS scores ranged from 0.245 to 0.828; the quintiles included subjects from both treatment groups. There was no statistical difference between the groups in average height at any of the quintiles (all p-values >0.05), therefore, the PS functioned to balance the treatment groups on this variable.

The success rate in the bracing group was 72% compared to 48% in the observation group. Adjustment using the propensity quintile and length of follow-up resulted in an OR of 1.93 (95% CI 1.08, 3.46, p=0.03).

Figure S1. BrAIST Protocol

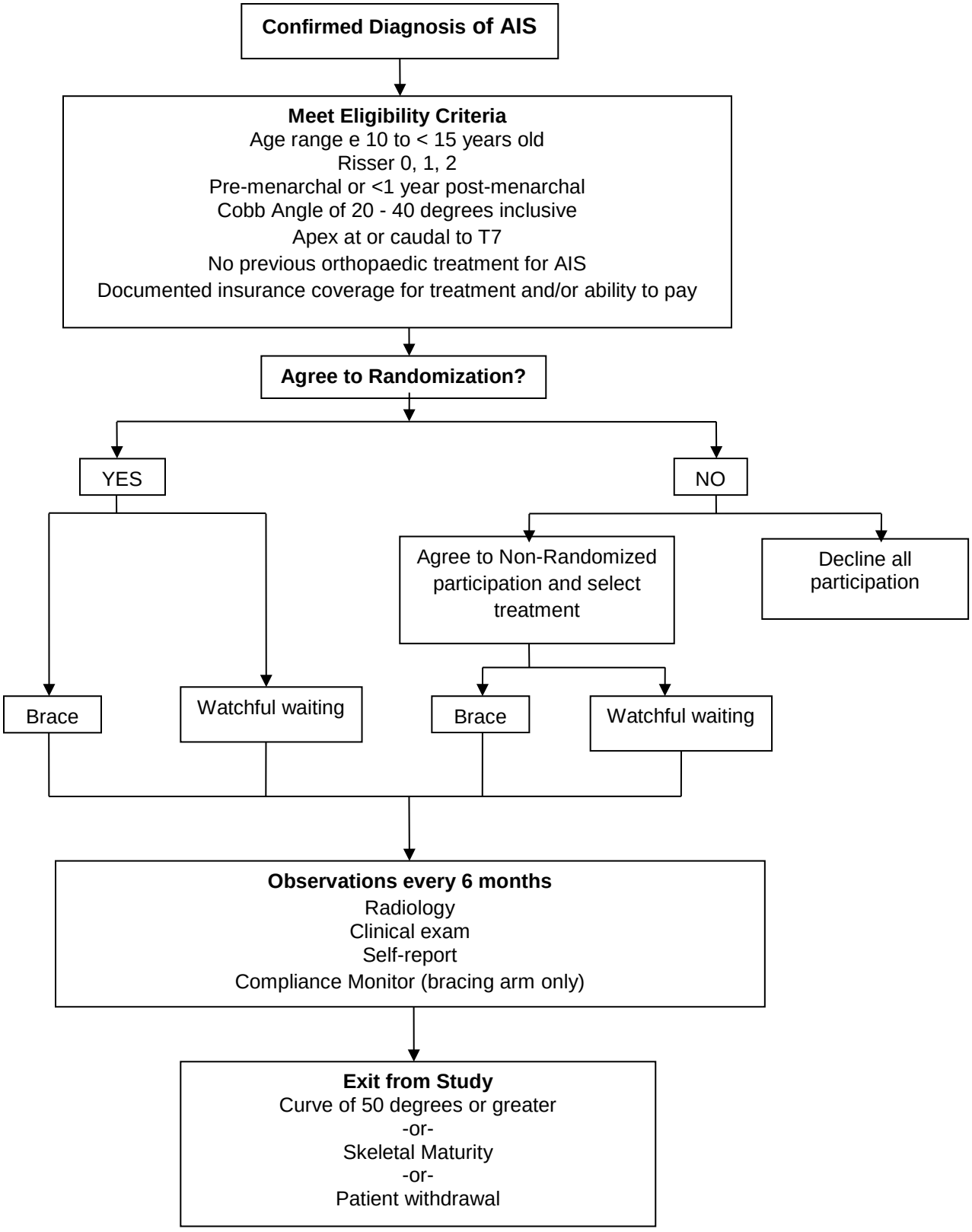

Table SI. Participating Centers by Funding Source

NIH (n=15)	
University of Virginia	University of New Mexico
Washington University in St. Louis	Children's Hospital of Boston
Children's Hospital of Central California	Cincinnati Children's Hospital Medical Center
Rady Children's Hospital	Children's Orthopaedics of Atlanta
Nemours/ duPont Hospital for Children	Seattle Children's Hospital
University of Iowa	Children's Hospital of Philadelphia
Children's Hospital of Pittsburgh	Hospital for Special Surgery
Children's Mercy Hospital, Kansas City*	

Shriner's Hospitals for Crippled Children (n=7)	
Montreal	St. Louis
Salt Lake City	Lexington
Chicago	Sacramento
Twin Cities	

Canadian Institutes of Health Research (n=2)	
Hospital for Sick Children, Toronto	University of British Columbia

Internally-Funded (n=1)
University of Rochester

*Site was original supported by internal funds; currently supported by the NIH

Table S2. Inclusion Criteria

Diagnosis of AIS

Presenting without associated musculoskeletal, neurological or other conditions possibly responsible for the curvature

Maturity

Age between 10 and 15 at consent
Risser 0, 1, or 2
Girls: Pre-menarchal OR post-menarchal by less than 1 year

Curve Magnitude

Largest Cobb angle between 20 and 40 degrees, inclusive
Cobb angle <20 degrees until the age of 10

Treatment

No history of previous surgical or orthotic treatment
Physical and mental ability to adhere to bracing protocol

Insurance or willingness to cover costs of treatment; ability to read and write English, Spanish or French

Table S3. Data Sources and Collection Schedule

	Enrollment	In-Brace film	Q 6 mo	Yearly
Radiographic Data	PA, lateral, bending, hand	PA	PA, hand	PA, lateral, hand
Cobb angle of structural curves	P, R	R	P, R	P, R
Apex and end vertebrae of curves	P, R	R	P, R	P, R
Risser grade	P, R		P, R	P, R
Nash Moe rotation	R		R	R
Percent curve correction	R	R		
Sagittal balance	R			R
Coronal balance	R	R	R	R
Kyphosis				
Lordosis				
Spinal length T_1-L_4	R		R	R
Concave-to-convex vertebral height ratio	R		R	R
Digital maturity stage	R		R	R
Clinical Data				
Weight, sitting and standing height	P		P	P
Ortho/neuro examination	P		P	P
Orthotic Data (brace arm only)				
Dose logger data			P	P
Brace wear diary			S	S
Skin condition under brace			P	P
Orthotist clinical notes	P	P	P	P
Brace Quality Evaluation		BEC		
Self-Report Data				
Child Health Questionnaire[1]	S		S	S
Self-Image Questionnaire for Young Adolescents[2]	S		S	S
PedsQL[3]	S		S	S
Spinal Appearance Questionnaire[4]				
Demographic information	S		S	S
Menarchal status	S		S	S

Key: P=Participating Clinical Centers; R = Radiographic Reading Center; S = Self Report; BEC=Bracing Evaluation Committee

Table S4. Baseline Data – Declined, Consenting, Primary Analysis and ITT Analysis Populations

Variable	Declined (N=703)	Consented (n=383)	p-value	Primary (N=242)	p-value*	ITT (N=116)	p-value**
Age	12.56±1.14	12.45±1.17	0.14	12.67±1.11	0.18	12.64±1.14	0.48
Female Sex	621 (88)	333 (87)	0.50	221 (91)	0.20	101 (87)	0.70
Predominant Race			<0.001		0.08		0.004
American Indian/Alaskan Native/First Nations	4 (1)	3 (1)		3 (1)		1 (1)	
Asian	35 (5)	18 (5)		12 (5)		6 (5)	
Black or African American	38 (5)	41 (11)		22 (9)		15 (13)	
White	553 (79)	305 (80)		189 (78)		88 (76)	
Native Hawaiian or Pacific Islander	3 (1)	2 (1)		2 (1)		2 (2)	
Unknown/Not reported	70 (10)	14 (4)		14 (6)		4 (3)	
SRS Curve Classification			0.05		0.16		0.14
Thoracic	258 (37)	159 (42)		98 (40)		42 (36)	
Thoracolumbar	156 (22)	71 (19)		46 (19)		24 (21)	
Lumbar	78 (11)	28 (7)		17 (7)		9 (8)	
Double Major	105 (15)	68 (18)		46 (19)		26 (22)	
Double Thoracic	21 (3)	14 (4)		10 (4)		6 (5)	
Thoracic/Thoracolumbar	74 (11)	31 (8)		19 (8)		6 (5)	
Triple	11 (2)	12 (3)		6 (2)		3 (3)	
Largest Cobb Angle	29.99±4.89	29.92±4.99	0.80	30.58±4.90	0.11	30.5±6.0	0.15

These data were recorded by the local investigator.

* Compares Declined and Primary analysis populations

** Compares Declined and ITT populations

Table S5. Additional Baseline Data - Primary Analysis Population

	Treatment Assignment Method			As-Treated Group		
Variable	**Randomized Cohort (N=116)**	**Preference Cohort (N=126)**	**P value**	**Observed** (N = 96)	**Brace** (N =146)	**P value**
Weight			0.15			0.31
Mean	45.94±12.65	48.13±10.45		46.12±12.73	47.69±10.79	
Missing	1	3		2	2	
BMI			0.38			0.82
Mean	19.15±4.18	19.58±3.23		19.30±3.82	19.41±3.66	
Missing	1	3		2	2	
Back Pain			0.77			0.32
Yes	40 (35)	45 (37)		30 (32)	55 (38)	
Missing	1	1		2	2	
Asthma			0.89			0.16
Yes	19 (16)	21 (17)		20 (21)	20 (14)	
Missing	1	2			3	
Attention Problems			0.55			0.54
Yes	13 (11)	11 (9)		11 (11)	13 (9)	
Missing					2	
Scoliosis First Noticed			0.02			0.38
Family Doctor/Nurse	53 (46)	76 (62)		47 (49)	82 (58)	
Relative	25 (22)	19 (16)		24 (25)	20 (14)	
School Screening Program	18 (16)	20 (16)		13 (14)	25 (18)	

Other	17 (15)	5 (4)		9 (9)	13 (9)	
Subject	1(1)	1 (1)		1 (1)	1 (1)	
Friend	1(1)	1 (1)		1 (1)	1 (1)	
Missing	1	4		1	4	
Time from Diagnosis to Enrollment (months)			0.03			0.63
Median	3.14	6.38		4.31	5.46	
Missing	20	13		14	19	
Maximum Rotation: Nash Moe			0.003			0.17
0	2 (2)	0		1 (1)	1 (1)	
1	66 (57)	51 (40)		52 (54)	65 (45)	
2	48 (41)	74 (59)		43 (45)	79 (54)	
3	0	1		0	1 (1)	
Sanders Digital Maturity Stage			0.24			0.08
1	2 (2)	0		1 (1)	1 (1)	
2	30 (27)	27 (23)		29 (32)	28 (20)	
3	33 (30)	39 (33)		27 (30)	45 (32)	
4	19 (17)	22 (18)		12 (13)	29 (21)	
5	13 (12)	6 (5)		8 (9)	11 (8)	
6	12 (11)	22 (18)		12 (13)	22 (16)	
7	2 (2)	4 (3)		2 (2)	4 (3)	
Missing	5	6		5	6	

Table S6. Additional Baseline Data – Randomized, Intent-to-Treat Population

Variable	**Observed (N=65)**	**Brace (N=51)**	**P value**
Weight			0.75
Mean	45.92±13.59	46.71±12.19	
Missing	0	1	
BMI			0.96
Mean	19.28±4.41	19.32±4.22	
Missing	0	1	
Back Pain			0.62
Yes	21(33)	19 (37)	
Missing	1	0	
Asthma			0.86
Yes	11 (17)	8 (16)	
Attention Problems			0.87
Yes	7 (11)	6 (12)	
Scoliosis First Noticed			0.08
Family Doctor/Nurse	27 (42)	26 (51)	
Relative	18 (28)	7 (14)	
School Screening Program	6 (9)	12 (24)	
Other	11 (17)	6 (12)	
Subject	1 (2)	0	
Friend	1 (2)	0	

Missing	1	0	
Time from Diagnosis to Enrollment (months)			0.70
Median	3.55	2.75	
Missing	13	7	
Maximum Rotation: Nash Moe			0.53
0	1 (2)	1 (2)	
1	40 (620	28 (55)	
2	24 (37)	22 (43)	
3	0	0	
Sanders Digital Maturity Stage			0.13
1	1 (2)	1 (2)	
2	22 (35)	9 (18)	
3	19 (30)	14 (29)	
4	6 (10)	13 (27)	
5	6 (10)	7 (14)	
6	8 (13)	4 (8)	
7	1 (2)	1 (2)	
Missing	2	2	

Table S7. PedsQL Scores [5] by Treatment (Primary Analysis Population)

	Brace	Observed	P value
Baseline	83.8±14.1 (n=142)	83.3±13.3 (n=94)	0.80
At Endpoint	82.0±17.0 (n=144)	81.9±14.1 (n=92)	0.97

Table S8. PedsQL Scores [5] by Treatment (Intent-to-Treat Population)

	Brace	Observed	P value
Baseline	81.2±15.2 (n=51)	83.0±13.2 (n=65)	0.50
At Endpoint	79.1±15.9 (n=50)	81.2±13.7 (n=61)	0.45

Scores may range from 0 to100; higher scores indicate higher quality of life

Table S9: Adverse Events (Serious and Non-Serious) Primary Analysis Population (As-Treated)

	Brace (N=146)		Observed (N=96)	
	Number of Events = 79		Number of Events = 41	
Adverse Event Description	**Non-Serious (related)***	**Serious** (related)***	**Non-Serious (related)***	**Serious (related)***
Skin bruising/ lacerations (on the trunk)	4 (4)			
Ulcers/ pressure sores (on the trunk)	3 (3)			
Rash (on the trunk)	5 (5)			
Back pain	33 (32)		30 (22)	
Abnormal breast development			1 (1)	
Anxiety	2 (2)			
Depression	1 (1)		1 (0)	
Other - as listed	30 (24)	1 (1)	9 (4)	

***The number in parentheses indicates the number of events related to BrAIST or AIS. Events were considered "related" based on the judgment of the investigator or research coordinator.**

****Events were considered "serious" if the event was *related to the protocol* and resulted in any of the following: intervention required to prevent permanent impairment or damage, hospitalization, persistent disability, life-threatening experience or death.**

"Other" Adverse Events: Brace (n=31)

Serious Adverse Event

Anxiety and depression

Non-Serious Adverse Event

Gastric discomfort/nausea after eating
Asymmetrical patellar reflex.
Right scapular pain.
Self-reported depression, patient no longer participates in usual activities because of his insecurity regarding his back/appearance.
Numbness in left shoulder blade area of back.
Sharp, shooting pain down right arm from shoulder to elbow, numbness in forearm.
Hip pain
Midback pain
Shoulder pain
Knee pain

Neck Pain

Brace causing a lot of hip pain. Rubbing rubs off layer of skin so limits brace wear.

Shoulder and under arm pain after adjustments were made to brace

Pain near the inferior aspect of the right scapula radiating to the axillary region. Area has mild redness. Pt believes the pain is related to brace wear

Right hip goes numb when standing or walking for a long length of time

Asthma flair up

Occasional numbness in arms and legs and occasional spasms in arms only.

Tingling, poking sensation on right rib area where temperature monitor in brace.

Right arm/shoulder pain

Participant is having back pain all the time and is no longer wearing a brace.

Headaches while wearing the brace

Pt. reports having suicidal thoughts

Numbness/ tingling or weakness of arms or legs, limits activity.

Side pain, limits activity

Vasovagal response and fainting during a school field trip

Numbness occasionally in arms and legs

Salter-Harris I fracture distal phalanx of the right great toe

Abdominal pain

Injured ankle - small fracture to growth plate lateral side

Dislocated patella

"Other" Adverse Events: Observed (n=9)

Buttock, hip and thigh pain

Hand & feet numbness

Numbness/tingling in fingers

Shoulder pain

Hip pain from gymnastics

Fracture right great toe

Mild pain in right foot most likely due to clubfeet

Right heel pain due to motor vehicle accident

Uneven shoulders, pain (ache)

 # Events were considered "related" based on the judgment of the investigator or research coordinator.

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