Randomized Controlled Trial of the LEAP Model of Early Intervention for Young Children with Autism Spectrum Disorders

Phillip S. Strain and Edward H Bovey II

The Five Primary Research Questions:

1. Do differential child outcomes occur across study groups after two years of LEAP implementation?
2. What is the relationship between implementation fidelity and child outcomes?
3. Are teachers' characteristics correlated with child outcomes?
4. Does child performance at the beginning of intervention predict ultimate outcomes at two years?
5. How do teachers rate the social validity of their experience implementing LEAP?
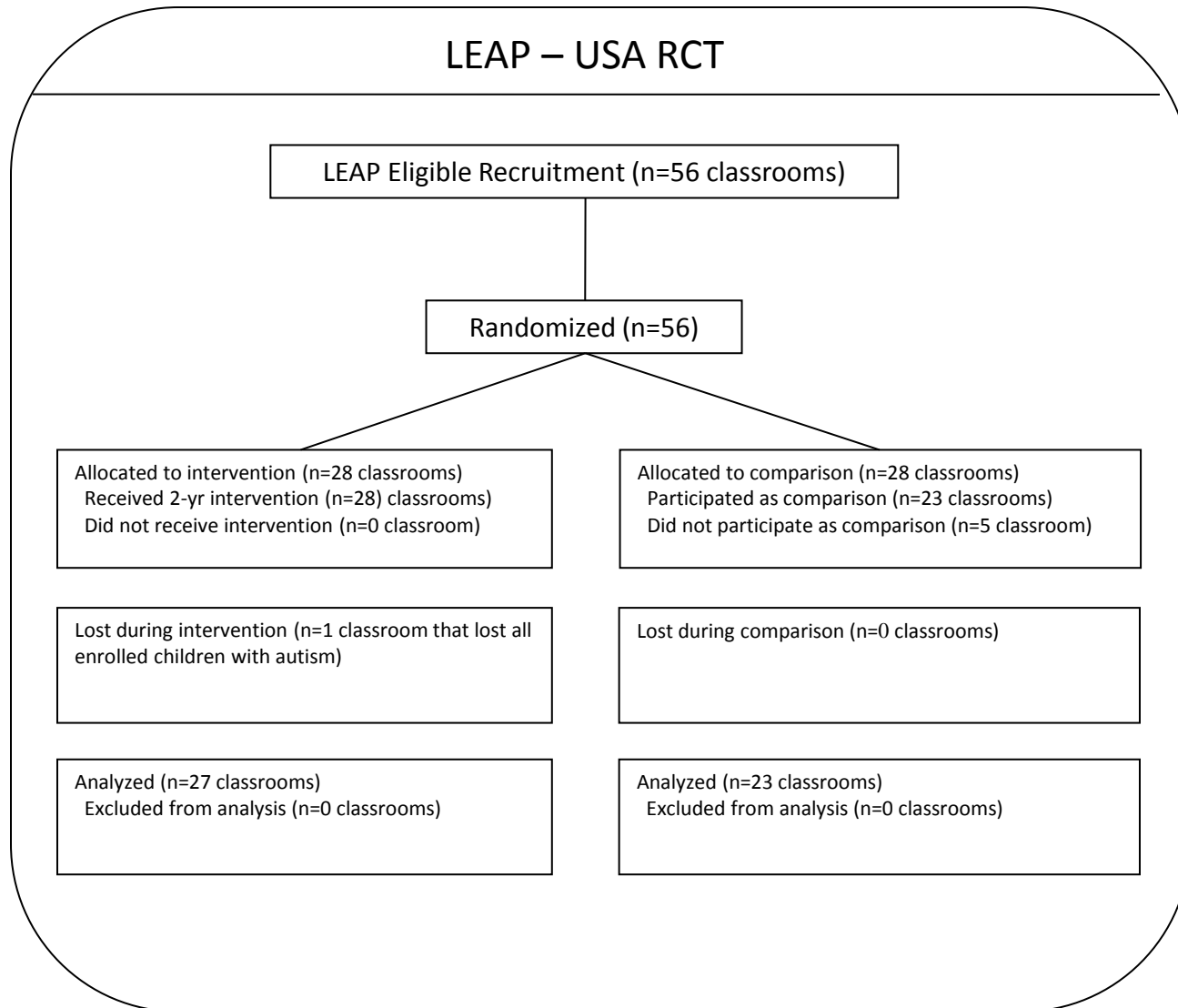
LEAP – USA CONSORT Diagram

LEAP – USA RCT

LEAP Eligible Recruitment (n=56 classrooms)

Randomized (n=56)

Allocated to intervention (n=28 classrooms)
  Received 2-yr intervention (n=28) classrooms)
  Did not receive intervention (n=0 classroom)

Allocated to comparison (n=28 classrooms)
  Participated as comparison (n=23 classrooms)
  Did not participate as comparison (n=5 classroom)

Lost during intervention (n=1 classroom that lost all enrolled children with autism)

Lost during comparison (n=0 classrooms)

Analyzed (n=27 classrooms)
  Excluded from analysis (n=0 classrooms)

Analyzed (n=23 classrooms)
  Excluded from analysis (n=0 classrooms)

Table 1 - Key Input Differences Between LEAP Replication Classes and Manuals Only Classes

LEAP Model Components Contained in the QPI	FULL Replication Training Group	Manuals Only Comparison Group
Classroom Organization and Planning	Written Instruction, Initial Didactic Training, Power Point Presentations, Classroom Coaching & Assistance with Physical Design of Classroom	Written Instruction & Power Point Presentations
Teaching Strategies	Written Instruction, Initial Didactic Training, Power Point Presentations, Classroom Modeling and Coaching , Fidelity Checklists	Written Instruction & Power Point Presentations
Teaching Communication Skills	Written Instruction, Initial Didactic Training, Power Point Presentations, Video Examples, Classroom Modeling and Coaching & Fidelity Checklists	Written Instruction & Power Point Presentations
Promoting Social Interactions	Written Instruction, Initial Didactic Training, Power Point Presentations, Video Examples, Classroom Modeling and Coaching	Written Instruction & Power Point Presentations
Providing Positive Behavioral Guidance	Written Instruction, Initial Didactic Training, Power Point Presentations, Classroom Written Plan, Classroom Modeling and Coaching	Written Instruction & Power Point Presentations
IEP's and Measuring Progress (Data Collection)	Written Instruction, Initial Didactic Training, Power Point Presentations, Workshop Training, Classroom Written Plan, Classroom Modeling and Coaching	Written Instruction & Power Point Presentations
Interactions with Children	Written Instruction & Power Point Presentations Classroom Modeling and Coaching	Written Instruction & Power Point Presentations
Interactions with Families	Written Instruction, DVD Overview, Modeling and Coaching	Written Instruction, DVD Overview

QPI Sample - Promoting Social Interactions

1. Capitalizes on the presence of typically developing peers: 5   4   3   2   1
- utilizes peers as models of desirable social behavior
- encourages peer buddies (i.e., hold hands during transitions, play partner, etc.)
- demonstrates sensitivity to peer preferences and personalities
- shows an understanding of developmental levels of interactions and play skills

2. Utilizes effective environmental arrangements to encourage social interactions: 5   4   3   2   1
- considers peer placement during classroom activities
- effectively selects and arranges *activities* that promote interactions
- effectively selects and arranges *materials* that promote interactions
- plans for consistent social opportunities within classroom routines

3. Uses prompting and reinforcement of interactions effectively: 5   4   3   2   1
- provides sincere, enthusiastic feedback to promote and maintain social interactions
- waits until interactions are finished before reinforcing; does not interrupt interactions
- models phrases children can use to initiate and continue interactions
- gives general reminders to "play with your friends"
- ensures that interactions are mostly child-directed not teacher-directed during free play

4. Provides instruction to aid in the development of social skills: 5   4   3   2   1
- includes social interaction goals on the IEP
- teaches appropriate social skills through group lessons and role-playing opportunities
- incorporates cooperative games, lessons, stories, and activities that promote altruistic behavior into planning

5. Structures activities to encourage and teach: 5   4   3   2   1
- sharing
- turn-taking
- requesting and distributing items
- working cooperatively

6. Utilizes materials that are: 5   4   3   2   1
- high interest
- novel
- high in social value

Table 2 - *Fidelity of Implementation Data*

	Intervention Classes			Comparison Classes		
	Start	End of Yr 1	End of Yr 2	Start	End of Yr 1	End of Yr 2
Mean QPI Scores	2.06	3.12	4.49	1.91	2.22	2.52
QPI Range	1.00-2.84	1.75-3.89	3.08-5.00	1.03-3.25	1.53-3.33	1.09-4.67
Mean Implementation	27%	53%	87%	23%	31%	38%
Implementation range	0%-46%	19%-72%	52%-100%	0%-56%	13%-58%	2%-92%

Table 3 - *Study Participants' Data At Start*

	Full Replication		Manuals Only		
	Mean	SD	Mean	SD	**p scores**
Age at entry (months)	50.1	4.6	50.7	4.2	**>.49**
CARS	39.0	6.2	37.4	5.9	**>.34**
PLS-4 (Total Language Score)[b]	32.8	7.5	34.4	7.2	**>.28**
Mullen ELC[a]	59.6	6.9	63.2	6.6	**>.19**
Visual Reception[b]	32.3	6.6	34.6	7.0	**>.26**
Fine Motor[b]	31.9	6.4	34.8	6.2	**>.22**
Receptive Language[b]	30.8	7.6	33.4	9.0	**>.19**
Expressive Language[b]	28.9	7.4	30.3	8.2	**>.29**
SSRS Positive[c]	13.5	21.5	20.7	20.2	**>.13**
SSRS Negative[c]	63.5	15.2	53.4	16.5	**>.17**

[a] = Standard score
[b] = Age (months developmental) equivalent
[c] = Percentile rank score

Table 4 - *Child Outcomes After 2 Years of Study Participation*

	Full Replication			Manuals Only			
	Mean	SD	Δ	Mean	SD	Δ	**ES**
CARS	32.9	3.9	-6.1	34.6	4.2	-2.8*	**.59**
PLS-4 (Total Language Score)[b]	51.3	8.1	18.5	43.8	7.7	9.4**	**.92**
Mullen ELC[a]	68.5	7.5	8.9	61.4	9.0	-1.8**	**.89**
Visual Reception[b]	52.7	11.5	20.4	46.3	11.6	11.7**	**.80**
Fine Motor[b]	43.3	5.2	11.4	39.8	4.9	5.0*	**.81**
Receptive Language[b]	49.3	7.9	18.5	40.7	7.7	7.3**	**.89**
Expressive Language[b]	38.7	6.4	9.8	35.9	4.4	5.6*	**.60**
SSRS Positive[c]	42.1	12.6	28.6	32.7	11.9	12**	**1.22**
SSRS Negative[c]	56.5	4.2	-7.0	49.1	4.1	-4.3*	**.62**

ES = Effect size difference between Δ for full replication and Δ for manuals only group

*p < .05, **p < .01 comparing Δ for full replication and Δ for manuals only group

Δ = Mean differences between initial assessment and Year 2 data.

[a] = Standard score

[b] = Age (months developmental) equivalent

[c] = Percentile rank score

Table 5 - *Correlation Between QPI Scores At End Of Year 2 And Each Outcome Index Gain Score For Treatment And Comparison Classes*

Outcome Measure	Full Replication r =	Manuals Only r =
CARS	.71	.73
PLS-4 (Total Language Score)	.86	.75
Mullen ELC	.72	.68
Visual Reception	.69	.75
Fine Motor	.80	.77
Receptive Language	.69	.69
Expressive Language	.75	.70
SSRS Positive	.82	.72
SSRS Negative	.67	.72

Table 6 - Social Validity Ratings By Lead Teachers In Intervention Classes

Social Validity Dimension	Mean Rating on 5pt. Scale	Range of Ratings
Applied	4.88	4 – 5
Effective	4.42	3 – 5
Flexible	4.46	2 – 5
Generalizable	4.25	3 – 5
Inexpensive	4.25	2 – 5
Practical	4.00	1 – 5
Simple	4.04	2 – 5
Socially Acceptable	4.83	3 – 5
Sustainable	4.54	3 – 5
Technology	4.71	4 – 5
Promoting Community Inclusion	4.63	2 – 5
Promoting Social Relations	4.50	3 – 5
Promoting General Progress	4.50	3 – 5
Reducing problem Behavior	4.38	2 – 5