Data Supplement for Luby et al., A Randomized Controlled Trial of Parent-Child Psychotherapy Targeting Emotion Development for Early Childhood Depression. Am J Psychiatry (doi: 10.1176/appi.ajp.2018.18030321)

CONTENTS

Training/Supervision/Fidelity Monitoring: All study therapists were master's level clinicians who were trained to proficiency in standard PCIT. Training on the ED module was conducted by the PI. The study PI, an experienced preschool child psychiatrist, provided weekly clinical supervision to study therapists. A master PCIT trainer/clinician provided ongoing consultation to the study clinicians during on-site visits and regular telephone consults, and one of the study therapists was formally certified to train therapists to administer PCIT. Following established procedures, fidelity monitoring of PCIT-ED was completed by an observing co-therapist at random sessions. Integrity and fidelity checklists were done at each session by the therapist, consistent with PCIT protocol.

Therapy Completion: Of the 114 subjects randomized to PCIT-ED, 6 did not complete any therapy sessions, and 93 completed all 20 therapy sessions. The mean (SD) number of sessions completed was 17.4 (6.0).

Maintaining the Blind: A select group of clinicians remained blind to whether or not participants were randomized to treatment. These blind clinicians had offices in locations where they would not interface with families coming for treatment and had no knowledge of if or when participants received treatment. Blind clinicians were the sole interviewers to complete all post assessments. Non-blind child interviewers reminded parents at the beginning of each post assessment that the parent interviewer was blind to whether or not they had received treatment and when. This allowed parents to ask any necessary questions before interacting with the blind interviewer. All randomization emails, confirmation calls, scheduling requests, and childcare were completed by non-blind interviewers to protect against the potential of the blind being broken. Following each post assessment, blind interviewers rated whether they believe the family had or had not completed treatment and their confidence in that rating. On occasions where a family broke the blind the interviewers then noted

this in the coding section. The blind was broken in N=8 subjects.

Imputation Methods: The MI and MIANALYZE procedures in SAS v9.4 were used to create 25 multiply imputed datasets that were then pooled for analyses comparing post outcomes in PCIT-ED and WL subjects. Variables included in the multiple imputation process were the baseline characteristics corresponding to the outcomes of interest, gender, and the baseline variables age, income-to-needs ratio, externalizing disorder, and internalizing disorder. Several subjects were missing baseline income- to-needs ratio, so these scores were imputed in addition to the outcome measures. Imputations were conducted by randomization group. General linear models for the continuous variables and a logistic regression for MDD diagnosis were then conducted on the multiply imputed datasets, covarying for baseline characteristics, gender, and baseline externalizing disorder.

FIGURE S1. PCIT-ED Study Design

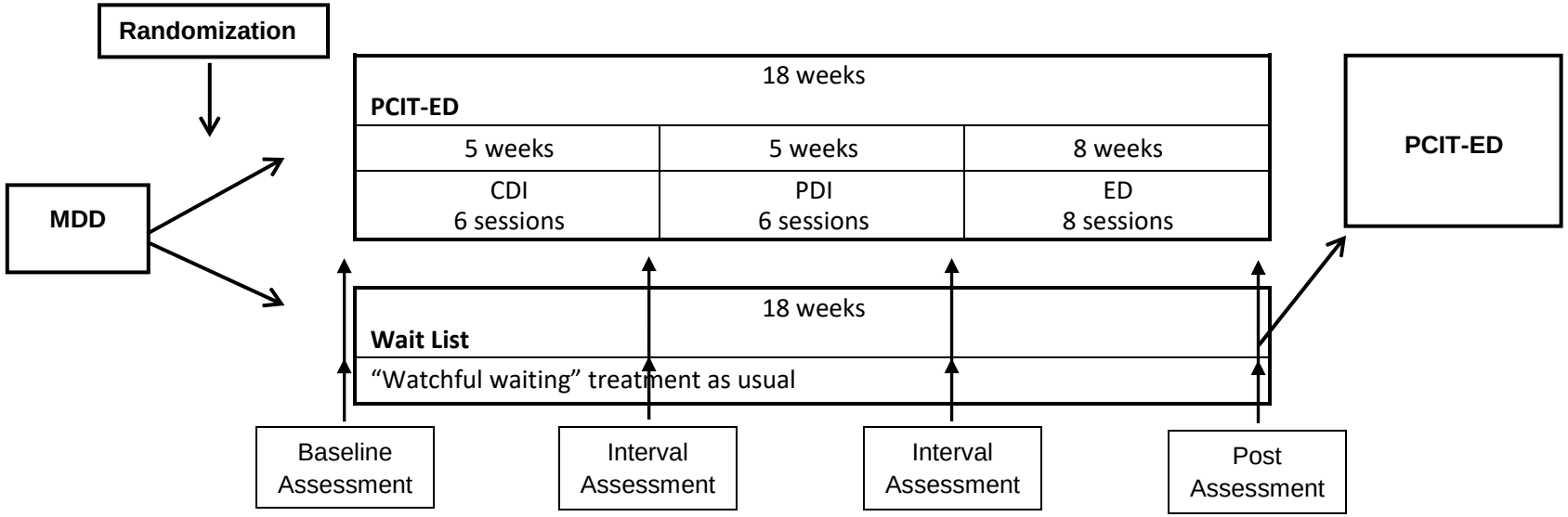
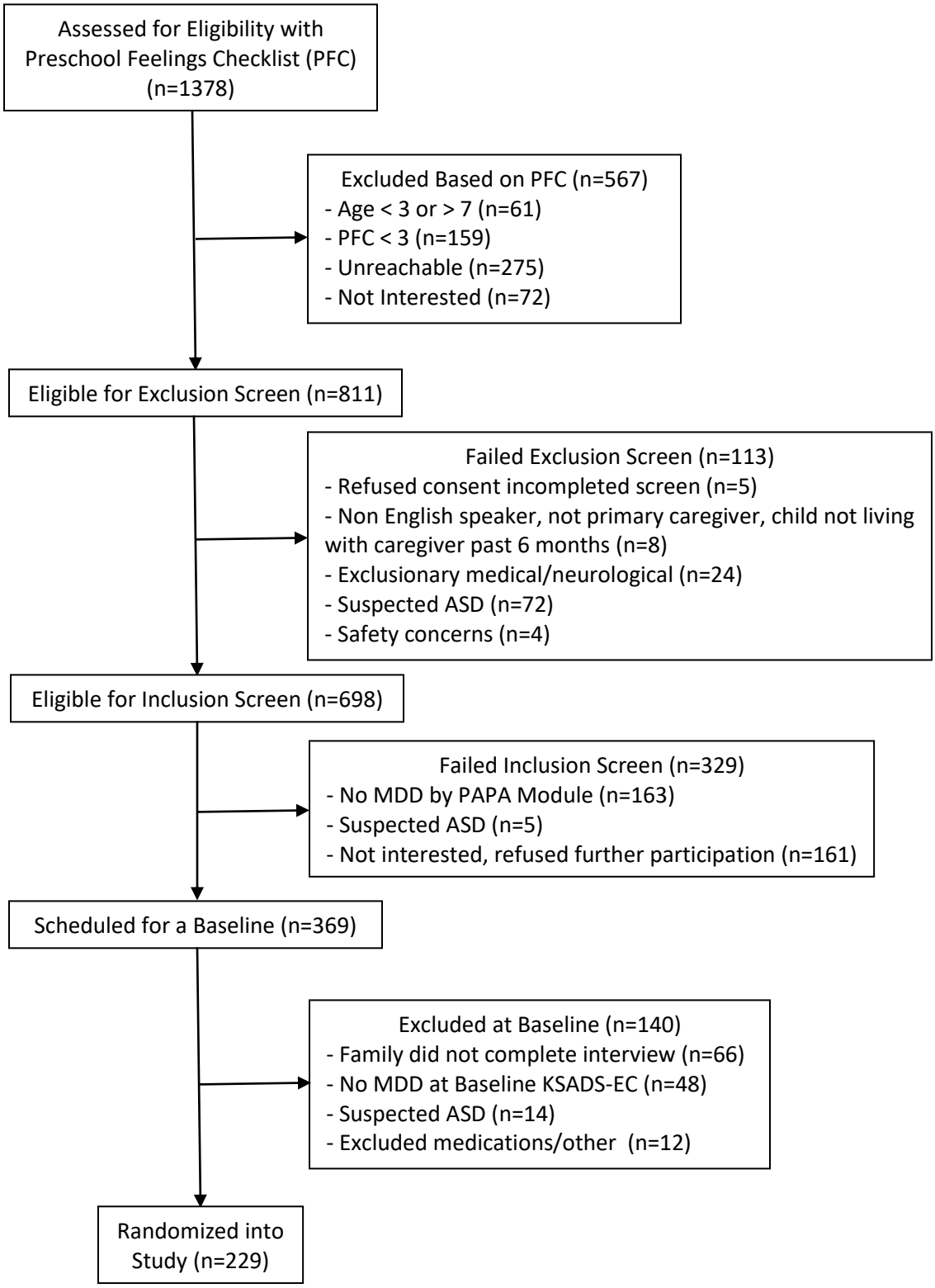
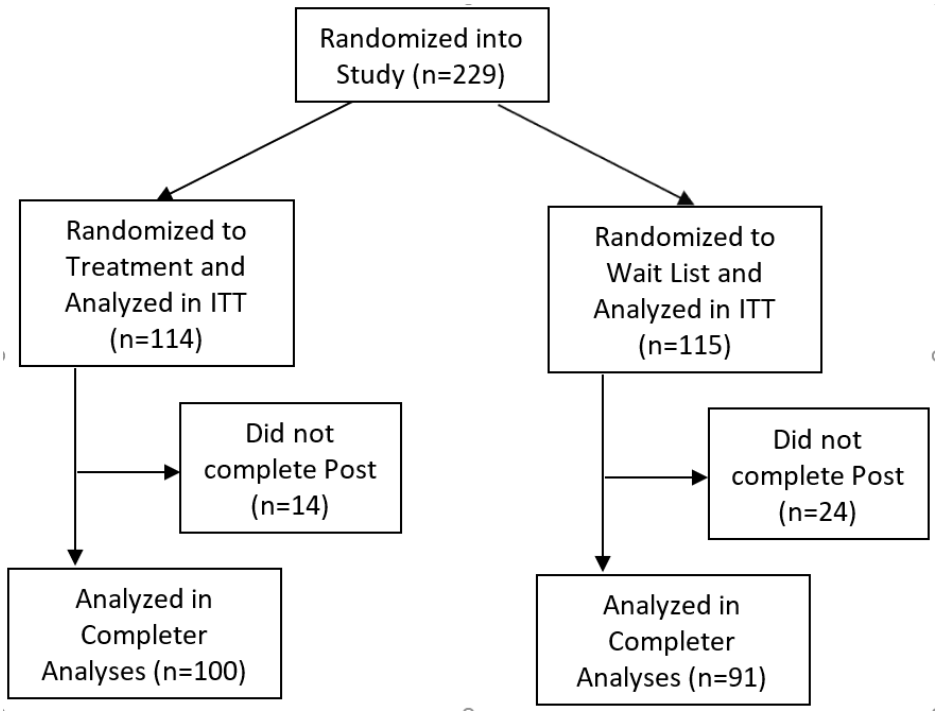


FIGURE S2. CONSORT Diagram of PCIT-ED Study



(Continued)

(Figure S2 continued)



Therapy Compliance: There were 20 therapy sessions over 18 weeks. 93/114 (81.6%) subjects completed all 20 sessions. The mean (SD) of sessions completed was 17.4 (6.0). The following table shows number of subjects by number of sessions completed.

N sessions	N subjects
0	6
3	3
4	3
5	2
8	1
9	1
14	2
15	1
16	1
17	1
20	93

TABLE S1. Post Assessment Demographic Characteristics of PCIT-ED and Wait List Subjects

	Wait List (N=91)		PCIT-ED (N=100)			
Post Demographics	**Mean**	**SD**	**Mean**	**SD**	**t**	**p**
Age	5.66	1.15	5.61	0.97	0.33	0.7431
Income-to-needs ratio	2.94	1.34	3.24	1.21	-1.59	0.1125
	%	**N**	**%**	**N**	χ^2	**p**
Female gender	33.0	30	34.0	34	0.02	0.8799
Hispanic ethnicity	8.8	8	14.0	14	1.27	0.2601
Race						
Caucasian	73.6	67	86.0	86	F.E.	0.0594
African-American	13.2	12	5.0	5		
Asian	0.0	0	1.0	1		
More than 1 race	13.2	12	8.0	8		

F.E. = Fisher's Exact test

TABLE S2. Baseline Emotion, Cognitive, and Executive Characteristics in PCIT-ED and Wait List Subjects

	Wait List (N=115)		PCIT-ED (N=114)		Wait List vs. PCIT-ED	
ERC	**Mean**	**SD**	**Mean**	**SD**	**t**	**p**
Lability/negativity	38.50	7.23	37.75	6.50	0.82	0.4157
Emotion regulation	23.21	3.36	23.22	3.34	-0.02	0.9809
My Child	**Mean**	**SD**	**Mean**	**SD**	**t**	**p**
Guilt reparation	24.42	5.25	24.28	4.98	0.21	0.8361
Guilt feelings	18.44	2.50	17.82	2.61	1.83	0.0687
	Wait List (N=100)		**PCIT-ED (N=98)**		**Wait List vs. PCIT-ED**	
BIS-BAS	**Mean**	**SD**	**Mean**	**SD**	**t**	**p**
BAS Drive	21.65	4.53	20.99	5.28	0.94	0.3459
BAS Reward responsiveness	28.28	4.14	27.67	4.48	0.99	0.3237
BAS Fun seeking	19.50	4.36	19.24	4.35	0.41	0.6807

TABLE S3. Baseline Parenting Stress Index in PCIT-ED and Wait List Subjects

	Wait List (N=113)		PCIT-ED (N=114)		Wait List vs. PCIT-ED	
PSI	**Mean**	**SD**	**Mean**	**SD**	**t**	**p**
Distractibility/hyperactivity	28.98	7.01	27.30	6.66	1.86	0.0648
Adaptability	32.22	5.67	32.07	5.35	0.21	0.8366
Reinforces parent	12.62	4.50	12.61	3.99	0.01	0.9923
Demandingness	29.50	6.59	28.65	6.00	1.01	0.3129
Mood	19.50	3.04	18.84	3.24	1.59	0.1136
Acceptability	15.58	3.59	14.92	3.44	1.40	0.1621
Child domain	138.41	21.03	134.40	18.54	1.52	0.1295
Competence	32.14	7.18	31.05	7.27	1.14	0.2574
Isolation	14.66	5.36	14.24	5.08	0.61	0.5426
Attachment	13.39	4.61	12.92	3.87	0.83	0.4081
Health	12.29	4.23	11.67	4.00	1.15	0.2524
Role restriction	19.45	5.91	19.18	5.50	0.35	0.7247
Depression	22.38	6.69	21.63	6.44	0.85	0.3955
Spouse	19.23	6.85	18.63	6.43	0.67	0.5033
Life stress	9.15	8.29	9.65	9.85	-0.41	0.6818
Parent domain	133.95	30.50	129.32	29.19	1.17	0.2449
Total stress	272.32	43.98	263.71	41.77	1.51	0.1333
Defensive responding	39.09	10.87	38.49	10.36	0.42	0.6726