



Controlled Clinical Trial of The P.L.A.Y. Project® for Children with ASD

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The P.L.A.Y. Project Model

- Train-the-trainer model
- We train child development therapists and teachers as Home Consultants (HCs)
 - HCs train parents in their home to PLAY
- PLAY is a pragmatic model based on Greenspan's DIR/Floortime framework
- Follows National Academy of Sciences guidelines for intensive intervention
- Addresses core deficits of ASD
- Currently more than 70 agencies trained in 23 states



Research Design



- Controlled small pilot study to prepare for large randomized controlled trial in community setting
- Study sponsored by the National Institute of Mental Health
- Study approved by Institutional Review Board (MSU)
 - Informed Consent procedures followed
- Study team:
 - Richard Solomon Principal Investigator
 - 4 Easter Seals community sites + National office
 - Michigan State University (MSU)
 - » research design and data analysis
- 40 children plus caregivers enrolled
 - 20 received Community Standard intervention (CSI)
 - 20 received The PLAY Project intervention + CSI
- Intervention for 5 to 7 months – short trial for pilot
- Pre- and Post-assessment measures compared



Study Results - Procedures



- Training of sites and therapists accomplished
 - Study procedures, assessment measures, data collection
- Informed Consent procedures followed properly
- 40 children and caregivers enrolled at Easter Seals sites
 - Added attention on enrolling racial / ethnic minorities (15%)
- 38 families completed study
 - 20 families in the PLAY intervention
 - 18 families community standard Control
- ASD diagnosis confirmed by ADOS measure
 - Also provided ASD severity rating
- Assessments pre- and post- for developmental levels, language, social skills, parent stress, parent abilities to interact with child, type and amount of ASD services received, demographics
- Data collection close to 100% successful for all 4 sites
- Michigan State University properly analyzed results
- Established a baseline of developmental study data for both PLAY and Control populations – valuable contribution to field



Study Results - Outcomes



- Outcomes - Trends in right direction
 - Outcomes not statistically significant
 - Small study, short duration
- Overall children in both PLAY and Control made good improvement
- Positive results for PLAY
 - receptive expressive language on Mullen and REEL-3 language measures
 - DQ developmental quotient on Mullen
 - Parent ability to interact increased on FEAS, especially for those with children at low developmental levels
- Neutral or Mixed trends
 - Child developmental levels slightly higher for Controls on FEAS
 - Vineland results mixed between PLAY and Control
 - Parent stress scores remain high on Parenting Stress Index before and after the short intervention period



Conclusion

- Successful pilot study
 - Procedures developed for large trial
 - Preliminary outcomes show positive trends
- Improved measures needed for measuring play and parent-child interactions
- Proposal for next phase submitted to NIMH
 - 6 Easter Seals community sites + National office
 - 192 children and caregivers to be *randomly* assigned
 - » 96 to Control intervention (CSI)
 - » 96 to The PLAY Project intervention + CSI
 - 12 month intervention phase
- Plans to begin next phase in 2009 for 3 years

