

Principles to Help Guide Next Generation Interventions: Some Examples from Randomized Controlled Trials Concerning School Readiness

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Presentation at conference on “Intervening Early: Progress and Opportunities
in Child Service Settings”

Sponsored by NIDA, ACF, NICHD, NIMH, OBSSR & SAMHSA

Washington, DC

September 18-29, 2007

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Scientific Foundation for Early Intervention

- Research on neuroplasticity (animal models)
- Studies of extreme deprivation (orphanages, maternal deprivation, isolation)
- Demonstration projects
- Naturalistic and longitudinal studies
- Randomized controlled trials (RCTs) to test the efficacy of a planned intervention to alter the life course

PRINCIPLES OF EFFECTIVE EARLY INTERVENTION

1. **Timing (onset, duration, offset)**
2. **Intensity (per day/wk/mth/yr(s))**
3. **Direct learning experiences**
4. **Breadth of services/supports**
5. **Individual differences**
6. **Environmental maintenance**

Ramey & Ramey (1998), American Psychologist

Randomized Controlled Trials (RCTs) we have conducted include:

- Basic Studies of Early Learning
- The Abecedarian Project (ABC)
- Project CARE
- Infant Health and Development Program (8 sites)
- Romanian Orphanage Studies
- Intensive Pediatric CI Therapy (cerebral palsy)
- National Head Start-Public School Transition Demonstration Study (31 sites)
- Pre-K Curriculum Comparison Study
- Child Care Coaching Studies

Ramey & Ramey

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Examples illustrating these principles from some of our longitudinal RCTs

- Interventions for children from highly impoverished, often chaotic environments (Abecedarian Project and Project CARE; Romanian Orphanage studies)
- Targeted interventions for
 - Low birthweight, premature infants (IHDP)
 - Children with moderate to severe neuromotor impairments (Project ACQUIRE)

Principle of Timing

- When the intervention begins and ends can significantly influence the impact on development
- Magnitude of this effect depends, in part, on the outcome measured, its developmental course, and the nature of the intervention
- Principle is highly similar to that in teratology

Two-Phase Design of Abecedarian Project



Campbell & Ramey, *American Educational Research Journal*, 1995

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Abecedarian Preschool Program

Treatment Group

- Adequate nutrition
- Supportive social services
- Free primary health care
- Preschool treatment:
Intensive (full day, 5 days/week,
50 weeks/year, 5 years)
“Learninggames” Curriculum
Cognitive / Fine Motor
Social / Self
Motor
Language
Individualized pace

Control Group

- Adequate nutrition
- Supportive social services
- Low-cost or free primary health care

Campbell & Ramey, 1995
American Educational Research Journal

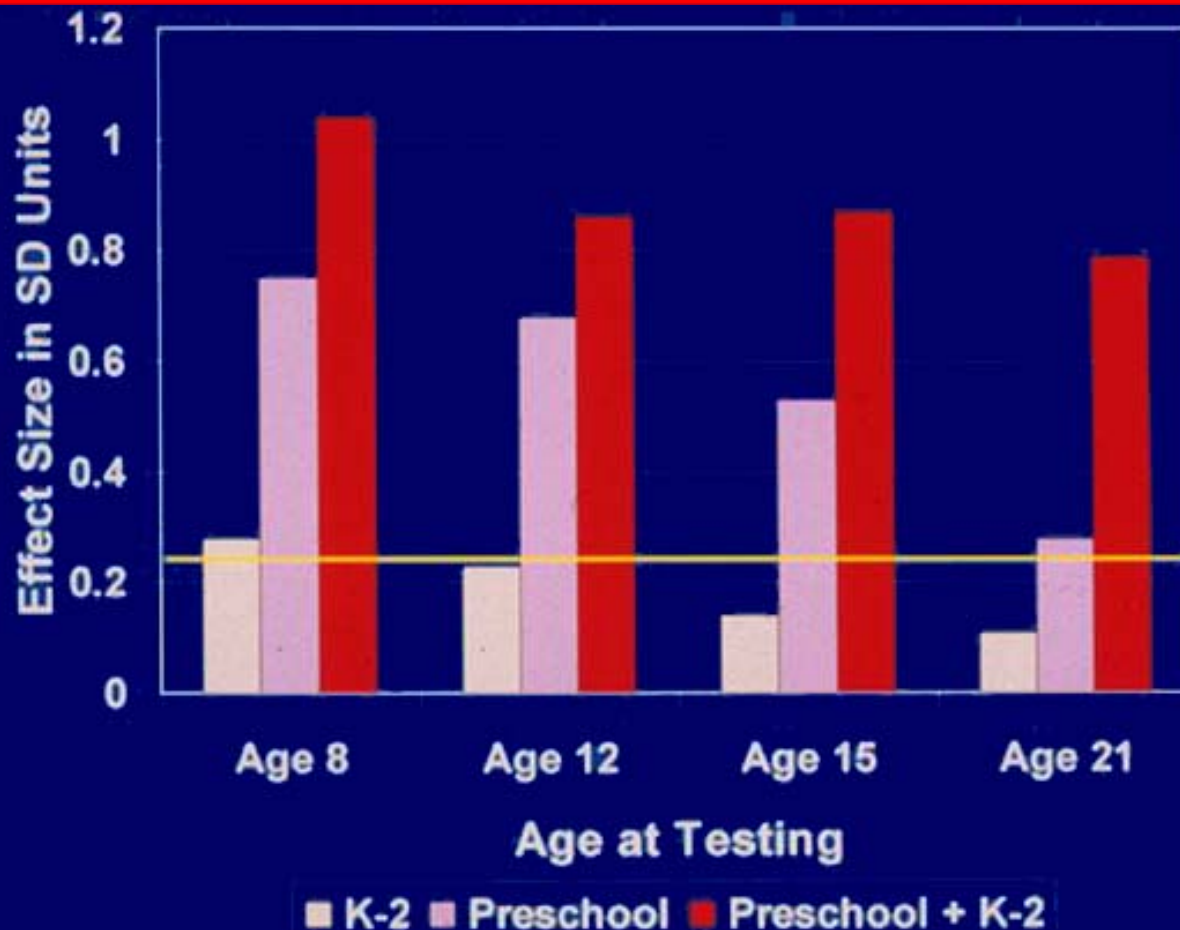
Brief Summary of Abecedarian K-2 Transition Program

- Individualized focus on academic and learning activities in school and at home
- Emphasis on reading, mathematics, and writing
- Master Home/School Resource Teachers (12 children and families per teacher)
- Development of an individualized and documented supplemental curriculum for each child
- Explicit attention and action relevant to family circumstances, as needed
- Summer camps with academically relevant experiences

Ramey & Ramey, 1999

The Abecedarian (ABC) Project

Longitudinal Effect Sizes for Reading by Treatment Group

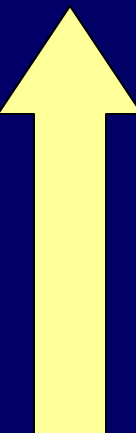


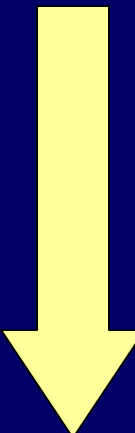
Campbell, Ramey,
Pugello, Sparling, &
Miller-Johnson (2001)
Applied
Developmental
Science

Key Findings from Abecedarian Project

(“Abecedarian” ...one who learns the basics such as the alphabet)

18 Months to 21 Years Old

- 
- Intelligence (IQ)
 - Reading and math skills
 - Academic locus-of-control
 - Social Competence
 - Years in school, including college
 - Full-time employment

- 
- Grade Repetition
 - Special Education placement
 - Teen Pregnancies
 - Smoking and drug use

Plus benefits to mothers of these children (education, employment)

Ramey et al, 2000

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Principle of Dosage

- Interventions which are more intensive (as indexed by hours per day, days per week, etc.) produce larger changes
- Exact specification of “optimal doses” has been very difficult, largely due to cost and pragmatic issues
- Some evidence consistent with “threshold hypothesis” (mostly at lower limit)
- Highly similar to dose-response curve principle in teratology
- Support comes mainly from cross-study comparisons

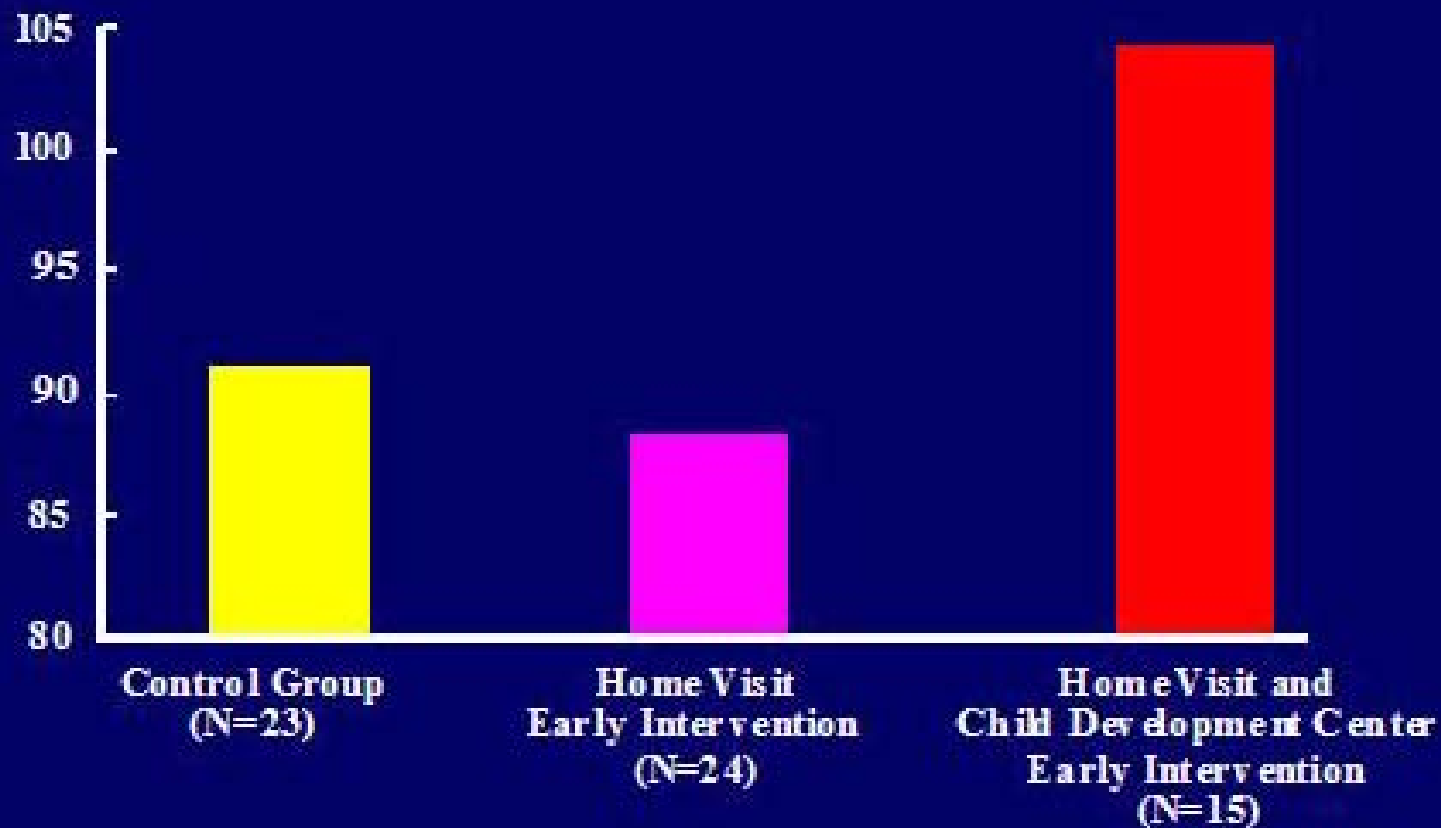
Principle of Direct Learning Experiences

- Interventions that directly alter the child's experiences (i.e., transactions with others and environment) have significantly greater effects than do those that indirectly change the child's life (e.g., parenting programs, coordination of service delivery supports)
- Note: majority of early interventions have focused on indirect effects based on idea that these would lead to sustainable environmental supports (to date, this hypothesis has not been confirmed)

Project CARE

- * RCT designed to replicate Abecedarian Project (ABC)
- * Added a new treatment group to test the efficacy of an intensive 5-year home visiting program using the ABC intervention (to test indirect vs direct effects)
- * Affirmed same findings in early childhood through to young adulthood from educational intervention, but no benefits of home visiting on child outcomes

Mean Stanford - Binet IQ Scores at 3 years of age for 2 Early Intervention Groups and a Control Group of Children from Project CARE



Adapted from Wasik, Ramey, Bryant, & Sparling. Child Development, 1990

Principle of Breadth of Services/Supports

- Early interventions that are multi-component and address child needs in health, cognition, social-emotional development generally produce larger and longer lasting effects

Limitations:

- Research evidence has many confounds, since broader programs also tend to be more intensive and include direct learning experiences
- most intervention programs tested in RCTs focused on children with multiple needs and risk conditions (due to natural co-occurrence)

Principle of Individual Differences

- Some children benefit more (or less) than do other children
- This principle has been affirmed primarily by:
 - Findings that children with greater needs for environmental supports benefit more
 - Findings that children with more substantial CNS insult may not benefit as much from generic (i.e., not spectrum-specific intervention) intervention
- Similar to teratology principle of differential genetic susceptibility or Gene X Environment Interaction Effect

The Infant Health and Development Program (IHDP)

- Intervention replicated Abecedarian Project
- New target group = premature, low birthweight children gestation and < 2500 gm at birth
- Conducted at 8 sites (N=985 children & families)
- Intervention modified for specific biological risk factors
- Educational intervention lasted only until 3 yrs old (CA)
- Follow-up reported through age 18 yrs

IHDP, JAMA, 1990

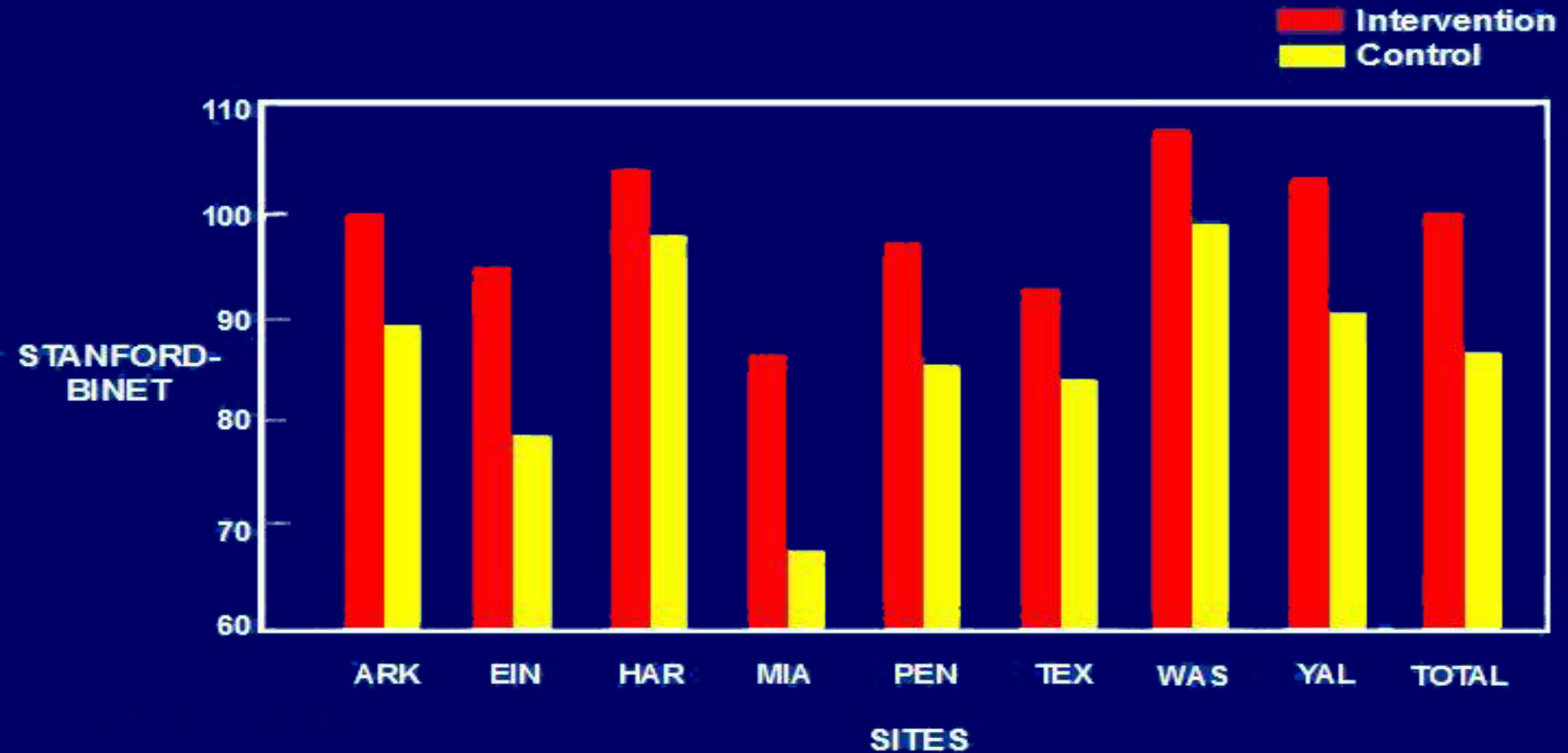
Examples of findings affirming Principle of Individual Differences

- In ABC, children with lowest IQ mothers (<70) showed markedly larger benefits than those whose mothers had IQs >90
- In IHDP, intervention more efficacious in preventing mental retardation (IQ<70) for premature, low birthweight children with less educated mothers or lower IQ mothers
- In IHDP, very low birthweight infants did not benefit as much

Stanford-Binet IQ Scores at 36 Months

Heavier LBW Group (2001-2500gm)

Infant Health and Development, JAMA, 1990 Ramey, AAAS, 1996

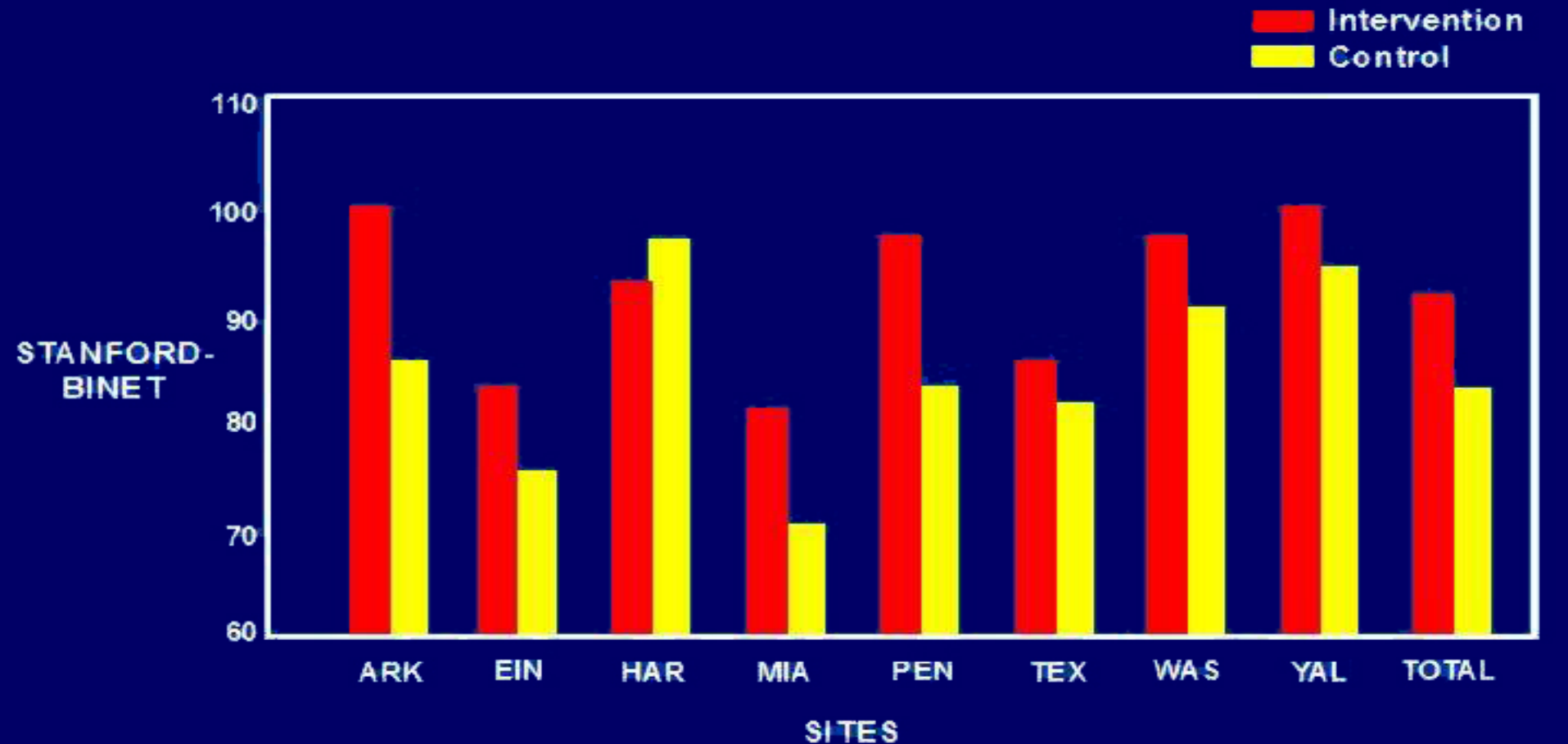


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Stanford-Binet IQ Scores at 36 Months

Lighter LBW Group (<2000gm)

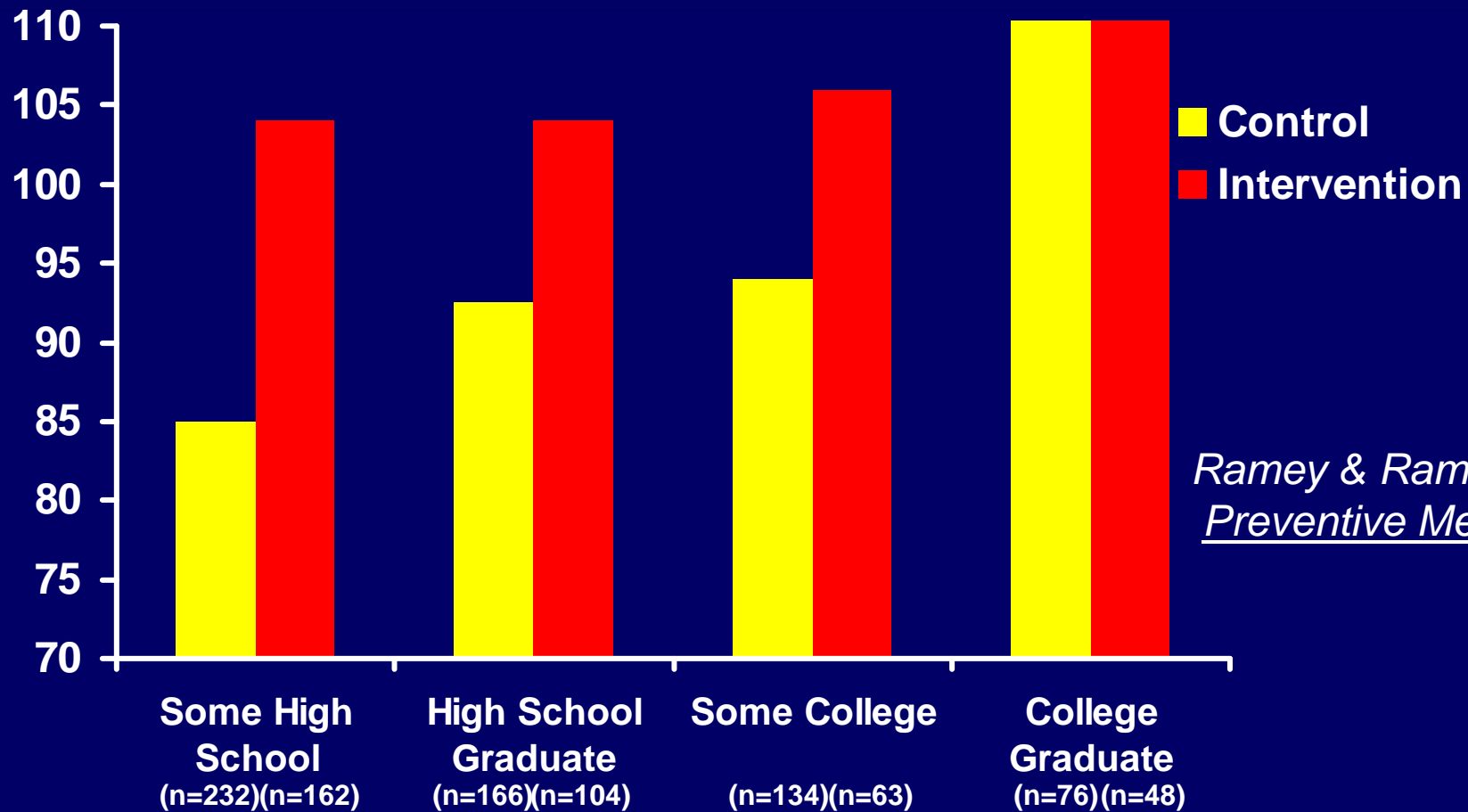
Infant Health and Development, JAMA, 1990 Ramey, AAAS, 1996



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Infant Health and Development Program

Children's IQ at 36 months: Maternal Education X Treatment Group



*Ramey & Ramey (1998),
Preventive Medicine*

Principle of Environmental Maintenance

- Benefits of early intervention are sustained longer when children continue to receive strong, appropriate environmental supports after intervention ends

Limitation: Almost impossible to separate effects of subsequent depriving or harmful environments (which could reverse benefits of early intervention) from the need for true “maintenance”

Some Implications of Principles for Service Settings

1. Develop flexible alternative compounds of services for benefit/cost studies rather than evaluate single service comparisons
2. Expect and plan to discover subgroups of participants who exhibit differential levels of risk and who may show differential levels of response to treatment
3. Develop an explicit model for population and subpopulation characteristics; intended primary pathways through which services are intended to have an impact on specific outcomes which are themselves monitored in an ongoing fashion

Some Implications of Principles for Service Settings

4. Develop adequate data systems to document frequency and quality of service availability and service utilization at the individual level
5. Conduct analyses and report them publicly at least on a yearly basis
6. Do not assume that appropriate control group participants are, or should be, an untreated group
7. When possible, establish explicit partnerships with relevant agencies