Evidence Table 11. Randomized Controlled Trials in LBW Neonates for Growth Outcomes
Part I

Author, Year UI#	Demographics	Inclusion Criteria	Exclusion Criteria	Disease/Condition Type (N)	Study Design (Duration)
Wauben 1998 98387708	Location: Canada Years of Birth: ND Mean GA (range), wk: Sample 1: 29.9±1.9 Sample 2: 30.1±1.5 Sample 3: 29.7±1.7 Mean BW (range), g: Sample 1: 1400±200 Sample 2: 1300±200 Controls: 1200±200 Male: ND Race: ND Enrolled: 37 Evaluated: 37 Number of sites: 1	BWT<1800 AGA >1 week old Full feed 5x5d Established weight gain No GI disease No long malformation	ND	Sample 1: Milk + Fortifier (12) Sample 2: Milk + Calcium phosphorus (13) Sample 3: Preterm formula-fed (12)	Randomized controlled trial (3 and 6 months)

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Morley 2000 20167446	Location: UK Years of Birth: ND Mean GA (range), wk: Trial 1: Group A: 31.1 Group B: 31 Trial 2: Group A: 31 Group B: 31.2 Mean BW (range), g: Trial 1: Group A: 1397±297 Group B: 1387±278 Trial 2: Group A: 1399±301 Group B: 1416±306 Male: Trial 1: Group A: 53% Group B: 52% Trial 2: Group A: 47% Group B: 46% Race: ND Enrolled: 833 Evaluated: 781 Number of sites: 5	Premature BW< 1850 g Survivors of participants in the two RCTs with 2 parallel arms each (assessing effect of different neonatal diets of growth) Age 7.5-8 yrs	Lost to follow-up	Trial 1: Group A: Premature infants, breast-fed until weight 2000 g or discharge (207) Group B: Premature infants, preterm formula-fed (213) Trial 2: Group A: Premature infants, standard term formula-fed until weight 2000 g or discharge (181) Group B: Premature infants, premature formula-fed (213)	RCT: Trial 1 and 2, with 2 parallel arms in each trial (at 9 months, 18 months, 7.5-8 years)

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Part II

Author, Year	Predictors	Predictor Measures	Outcomes	Outcome Measures
Wauben 1998 98387708	Other: Feedings: Breast, Milk+ multinutrient fortifier or breast milk + Ca + P supplement only, or preterm formula	ND	Growth: 1) Weight, length, head circumference 2) Body mass + body composition	ND
Morley 2000 20167446	Trial 1: Type of diet in early neonatal period: Banked donor breast milk vs Preterm formula (with or without supplementation with its mother's milk) Trial 2: Preterm formula vs term formula (with or without supplementation with mother's milk)	Not further specified	Trial 1: Growth: Assessment at 9 and 18 months post-term: Weight (kg), Length (cm), HC, Subscapular skinfold thickness, Body mass index Assessment at 7.5 –8 yrs: All of the above, Also weight to hip ratio Trial 2: Growth at 18 mo Growth at 7.5-8 yrs	Not further specified

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Part III

Author, Year	Associations found				Potential Biases	Comments
Wauben, 1998		*MM+MNF*	*MM+CaCP*	*PTF*	Used a "New multinutrient fortifier" design to their specifications. Generalizability?	Study was privately funded
	Term:					
	Weight (kg):	3.3±0.3	3.2±0.4	3.5±0.4	No relation examined between feeding + neurodevelopment. Unclear that their findings have or had any potential for clinical significance.	
	Length (cm):	49.6±1.3	48.4±1.8	49.4±2.3		
	12 months:					
	Weight (kg):	9.0±0.9	9.0±0.9	9.6±1.4		
	Length (cm):	74.9±3.7	75.9±2.5	76.0±2.8	Small study- unlikely to find anything other than major differences	
	Head circumference (cm)	46.9±3.9	46.8±?	6.8±2.0		
	Whole body BMC (g)	209.9±27.1	223.0±29.2	243.9±40.6	Post-discharge crossover between breast fed→ formula fed, further dilutes effect or small #'s	
	Lean mass (%):	74.0±5.0	73±4.7	73.8±5.6		
	Fat mass (%):	23.6±5.0	24.3±4.7	23.9±5.6		
					No correction for multiple comparison, although it is desperately needed	
Morley, 2000	Trial 1: There was no association between the neonatal diet (banked donor milk vs preterm formula) and the 6 anthropometrics at any follow up point (9 mo, 18 mo and 7.5-8 yrs) Trial 2: There was no association between neonatal diet (term vs preterm formula) and the Weight, Height, HC and skinfold thickness at any follow up point (18 mo and 7.5 yrs). Except for a significantly lower waist to hip ratio at 7.5 yrs in infants fed preterm vs term formula solely (without supplementation with mother's milk) (0.86 vs 0.89, p<0.001)				(None)	? Funding