Prolonged, exclusive breastfeeding & adiposity, stature & blood pressure: Promotion of Breastfeeding Intervention Trial (PROBIT III)

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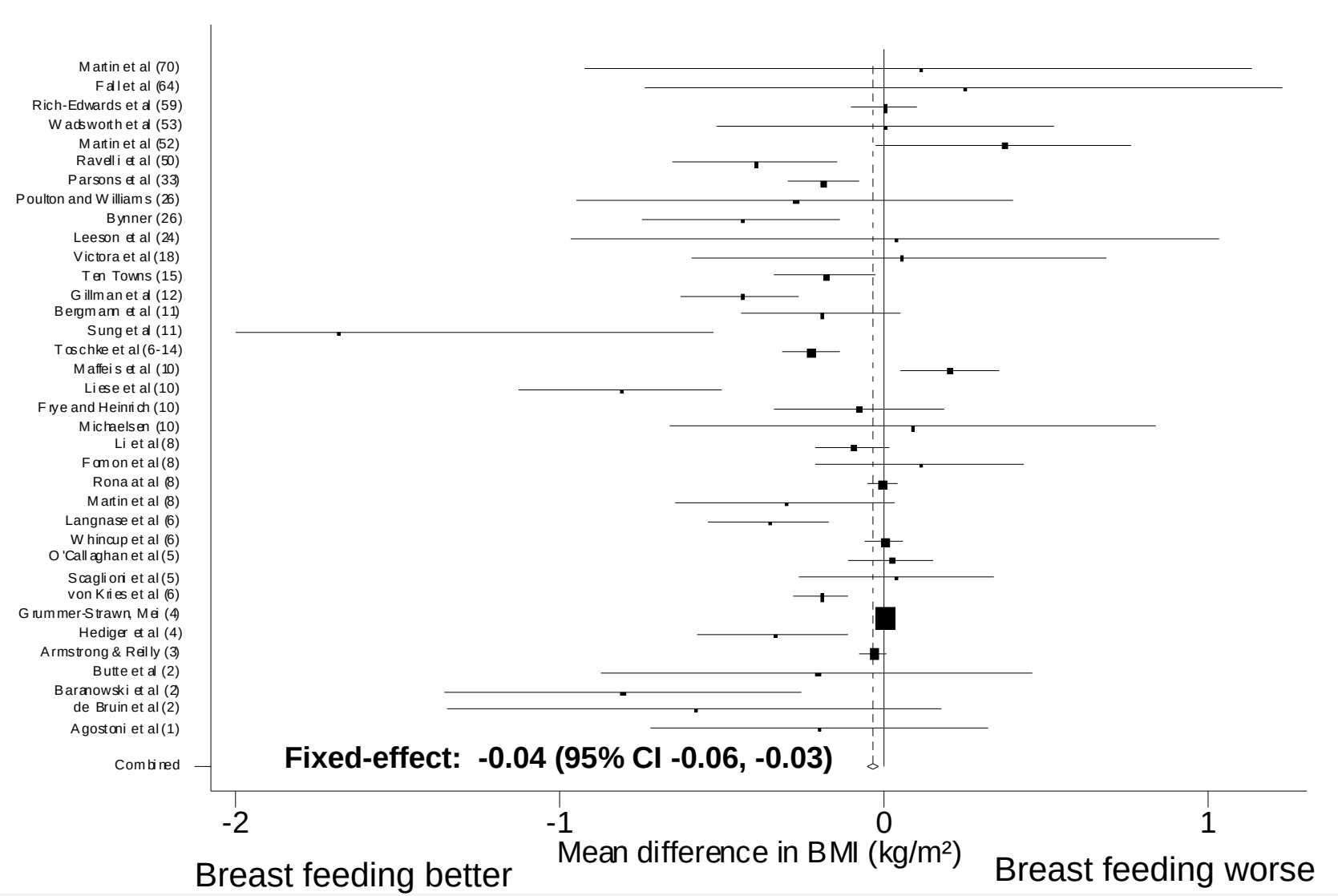
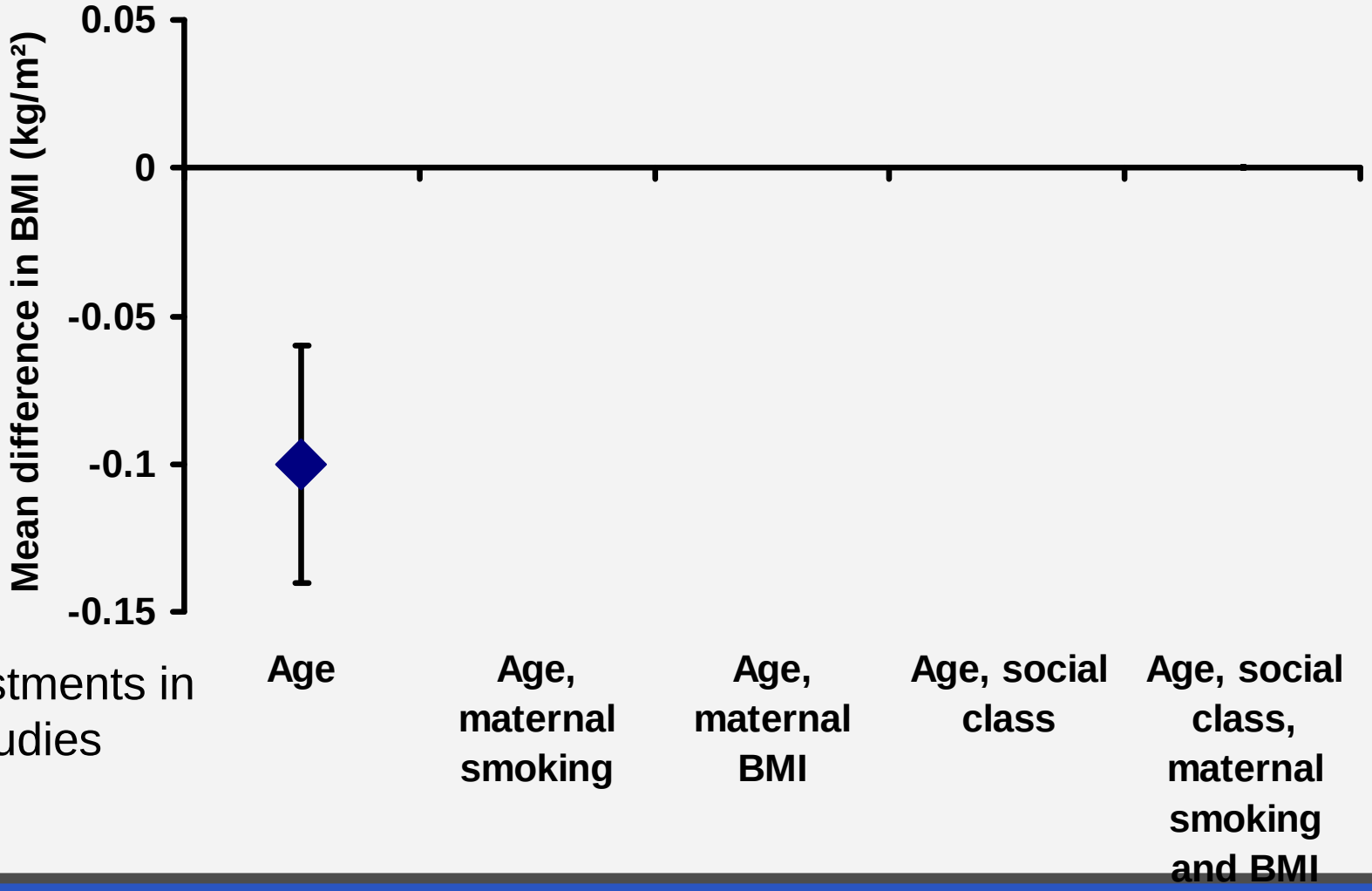
Potential child health benefits of breastfeeding

- Increased stature
- Protection against :
  - Obesity
  - CVD risk factors
    - blood pressure, insulin resistance, hyperlipidaemia
- Problems with the evidence base
  - Based on observational studies
  - Residual confounding
  - Selection bias
  - Publication bias

Mean difference in BMI: BF v formula fed (36 studies)



Mean difference in BMI: effect of adjustment for important confounders



Adjustments in 11 studies

Owen et al, AJCN, 2005;82:1298-307

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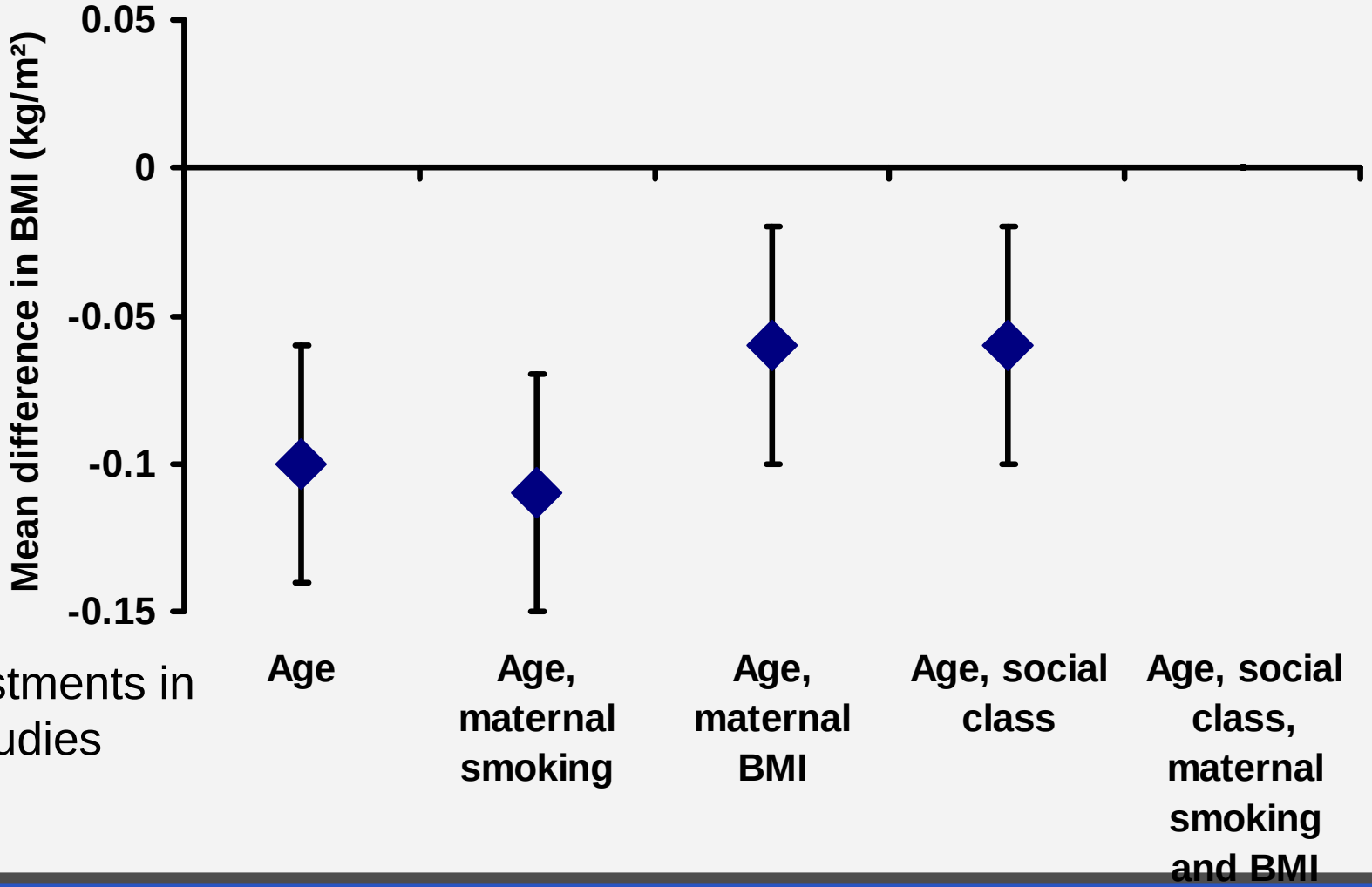

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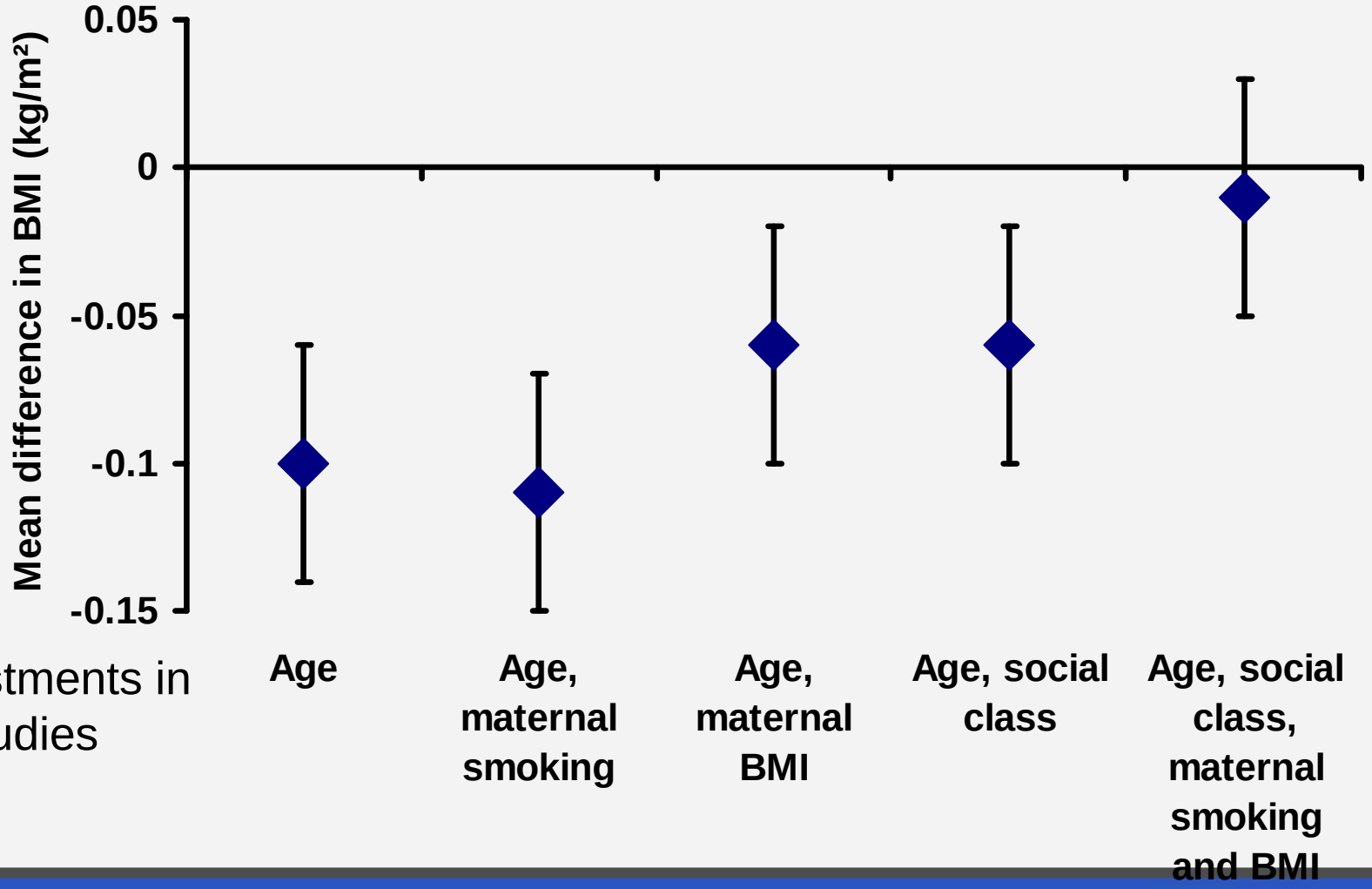

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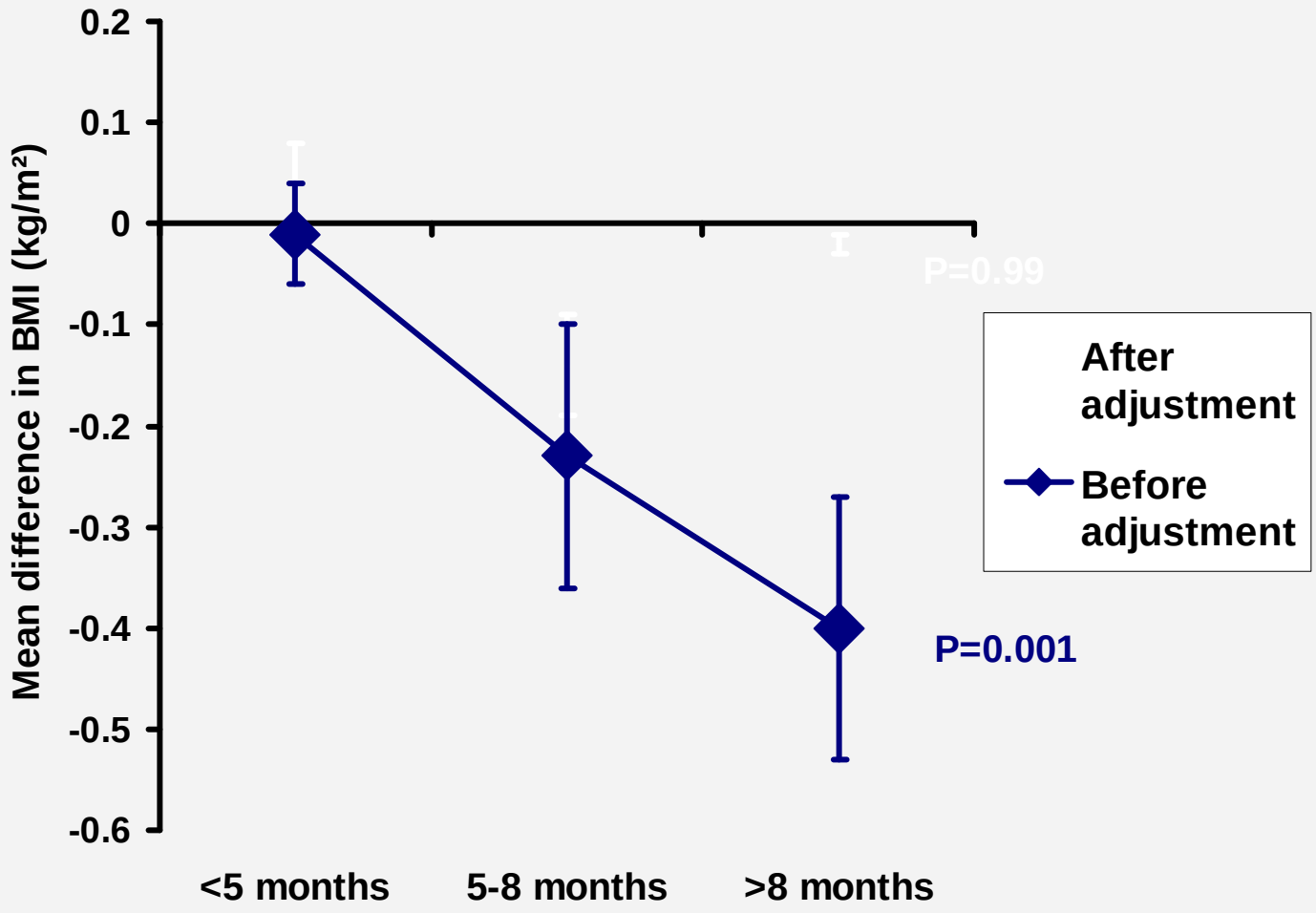
Mean difference in BMI: effect of breast feeding duration (6 studies)



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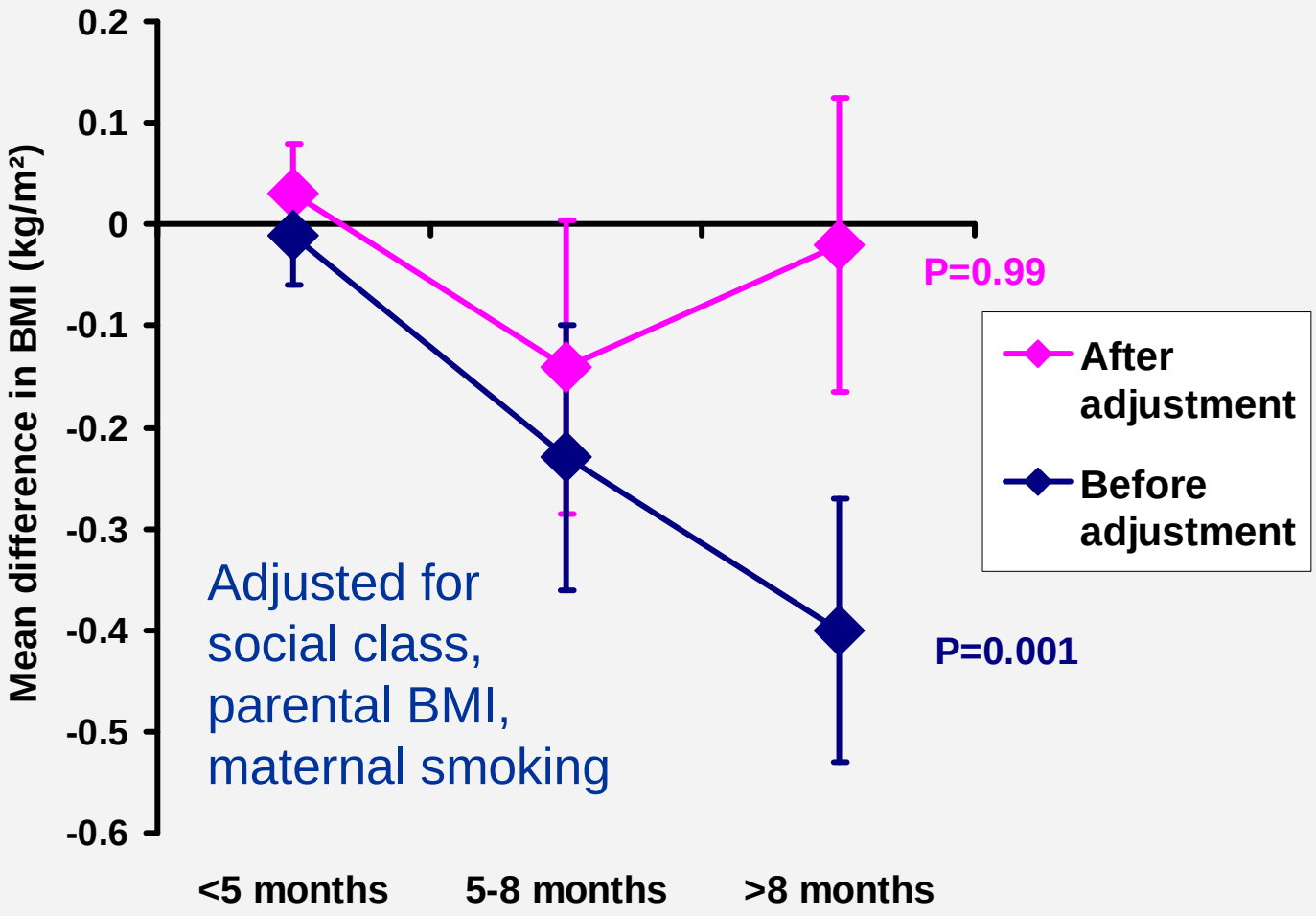

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Solution: RCT with analysis by "intention to treat"

- Best way to minimize multiple biases
- Randomization to breast *vs* artificial feeding is not feasible / ethical
- The solution is a RCT of an intervention to promote BF <u>exclusivity & duration</u>
- Overlap of BF behaviors requires very large sample size

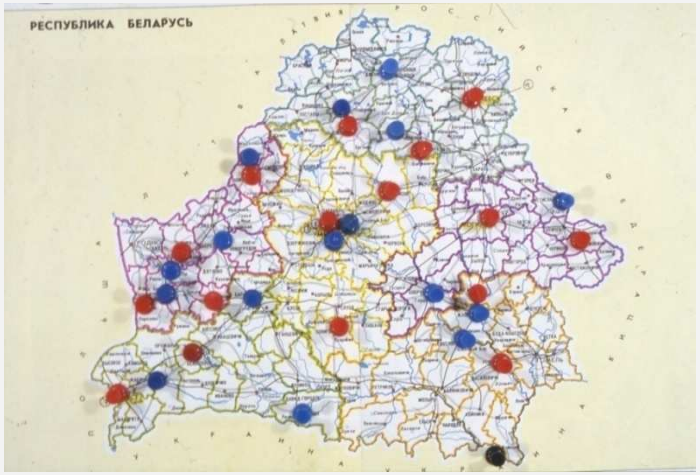
PROBIT

PROmotion of Breastfeeding Intervention Trial

Follow-up of A Cluster-Randomized Trial in the Republic of Belarus

Trial design

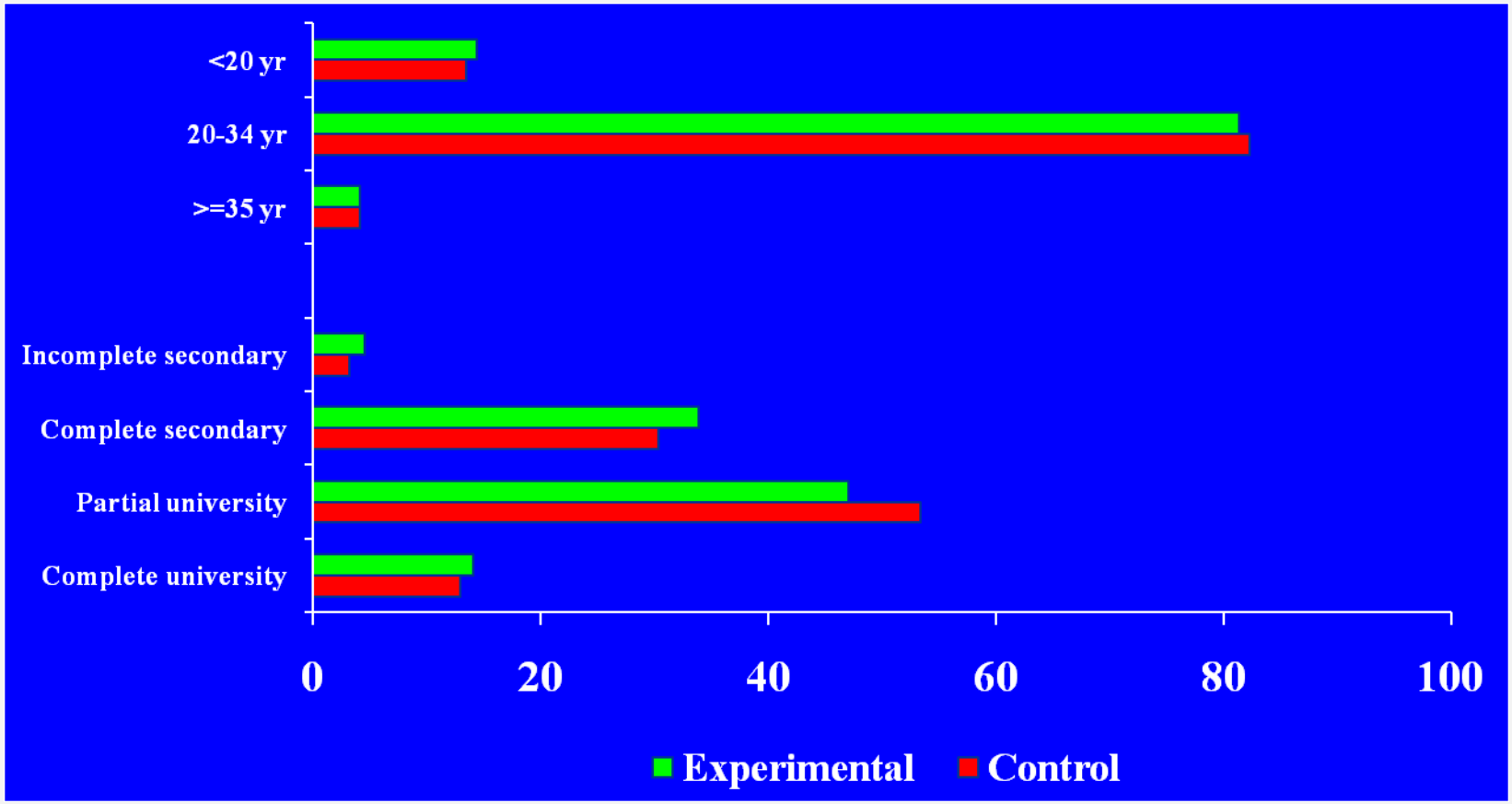
- RCT to promote breastfeeding exclusivity & duration, based on WHO/UNICEF BFHI
- Stratified, cluster randomization of 31 maternity hospitals & one affiliated polyclinic per hospital



- In 1996-7, 17,046 healthy BF newborns ≥37 wks & ≥2500g enrolled during postpartum stay

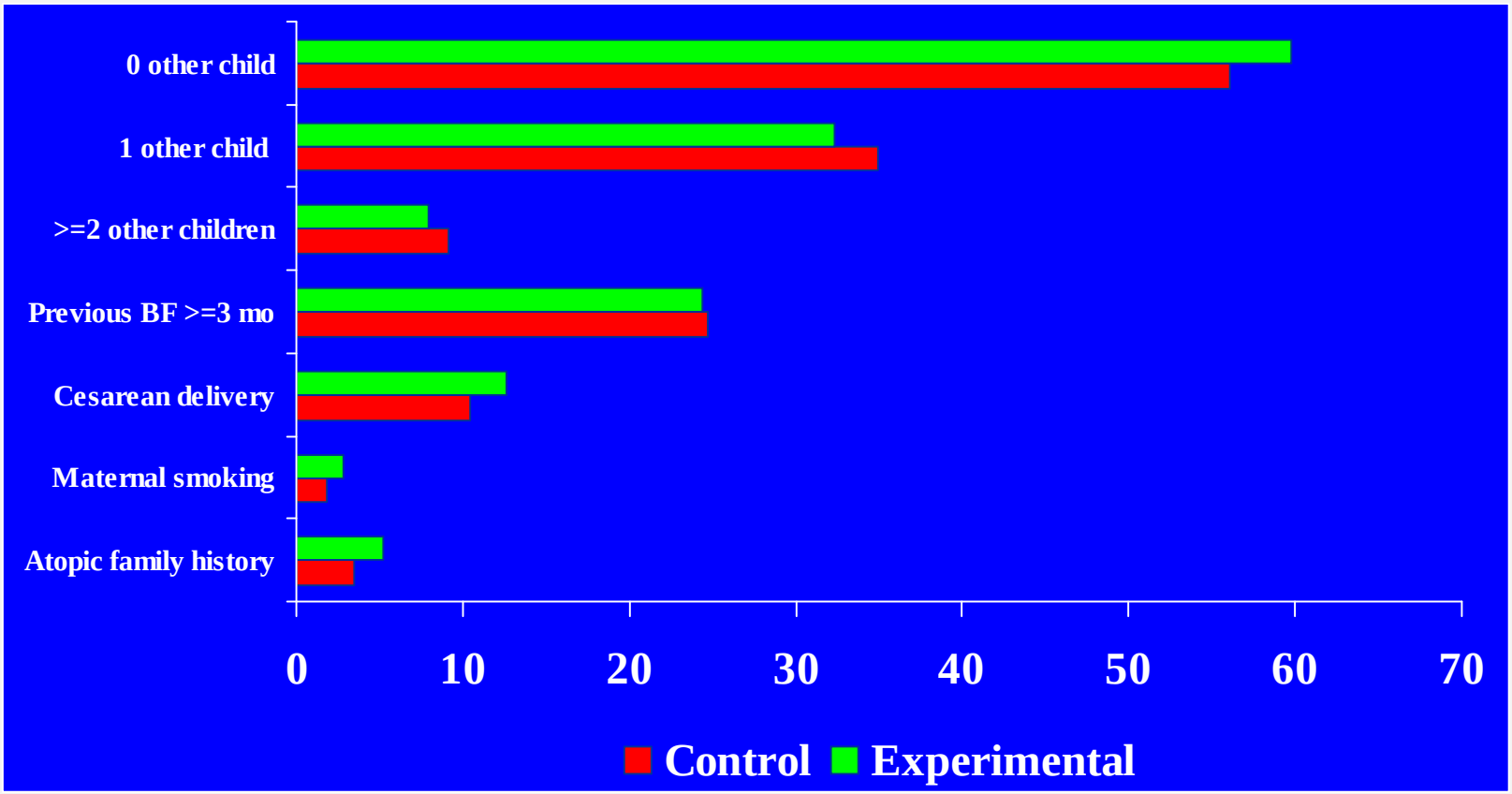
Baseline Comparison

Maternal Age & Education (%)

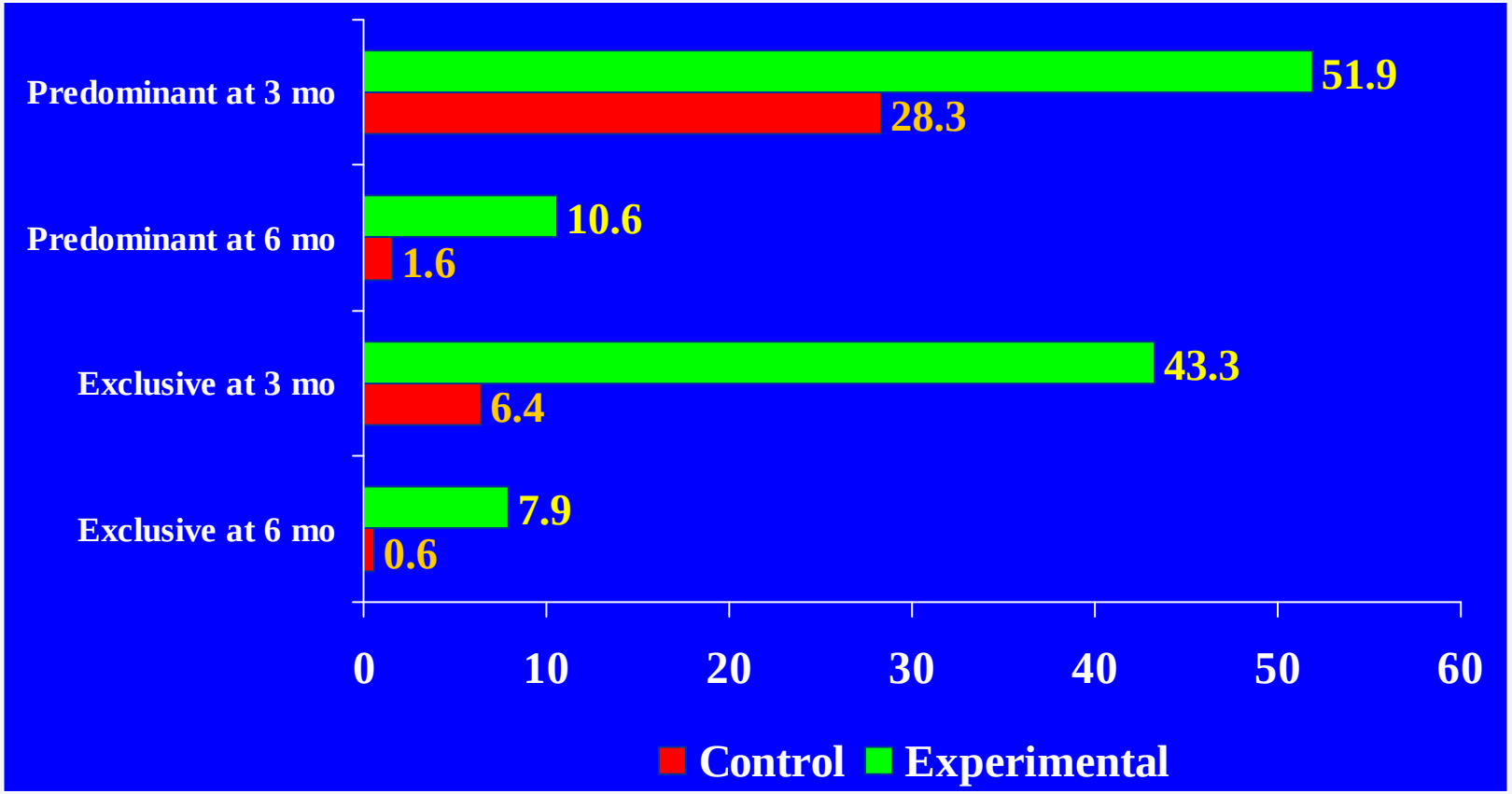


Baseline Comparison

No. of siblings, prev BF, CS, smoking, atopic FH (%)



Degree of Breastfeeding (%)



Long-term follow-up of PROBIT

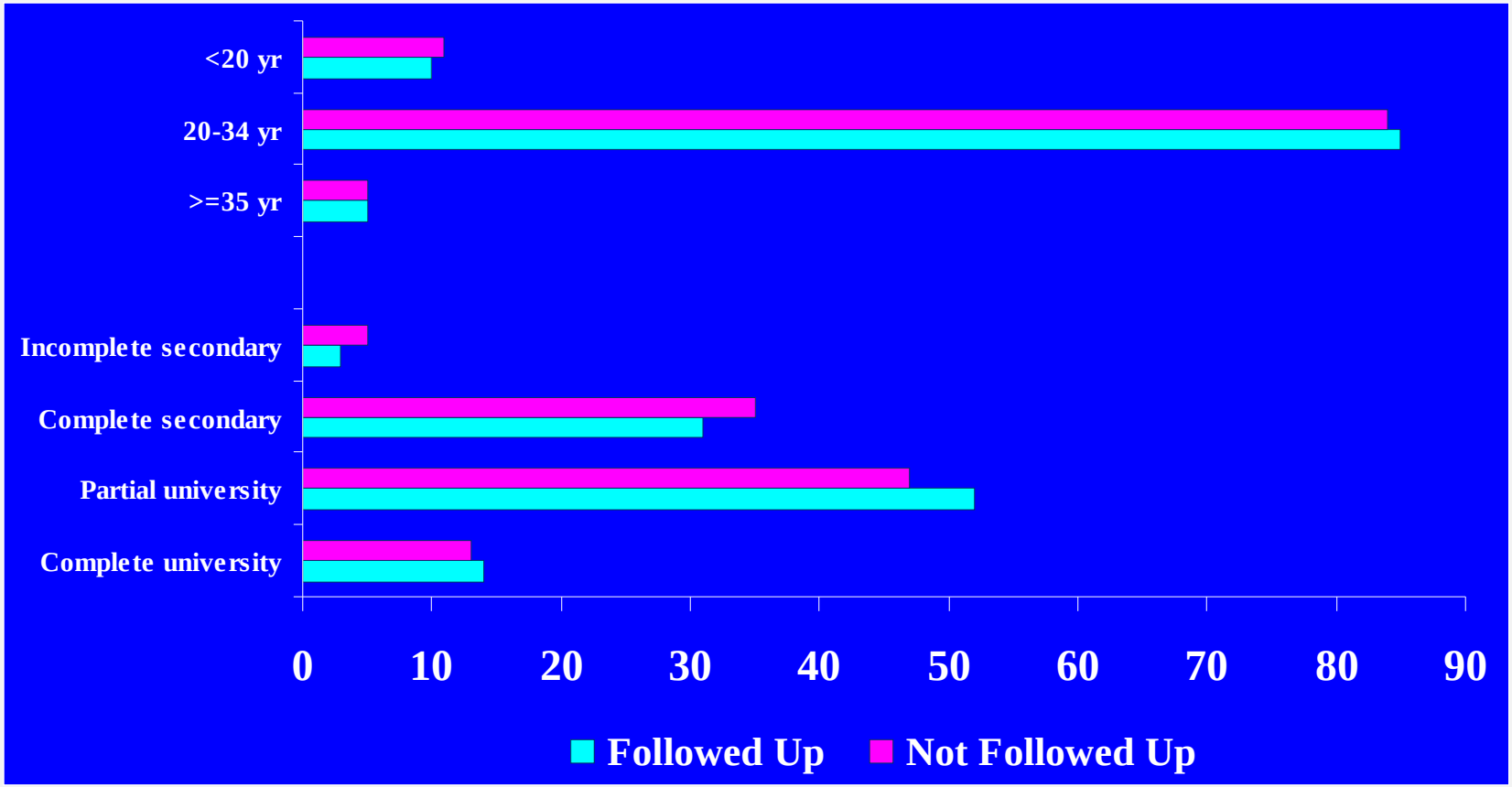
- Created two ***randomized*** cohorts differing substantially in exclusivity / duration of BF
- Analysis by intention to treat enables ***strong causal inferences*** with respect to BF effects on long-term outcomes
- Intervention had significant benefits on:
  - GI infection in infancy (PROBIT I)
  - Atopic eczema in infancy (PROBIT I)
  - IQ at 6.5 years (PROBIT II)

PROBIT III

- Follow-up at 11.5 yrs between Jan 2008 to June 2010
  - Anthropometry
  - CVD risk factors (*BP; glucose; insulin; adiponectin; apo A1; apo B; IGF-I)*
- > 13,500 children have been seen (80%)
- 11,674 (68%) have data entered to date
- Interim results are presented today, as still over 2000 records to enter

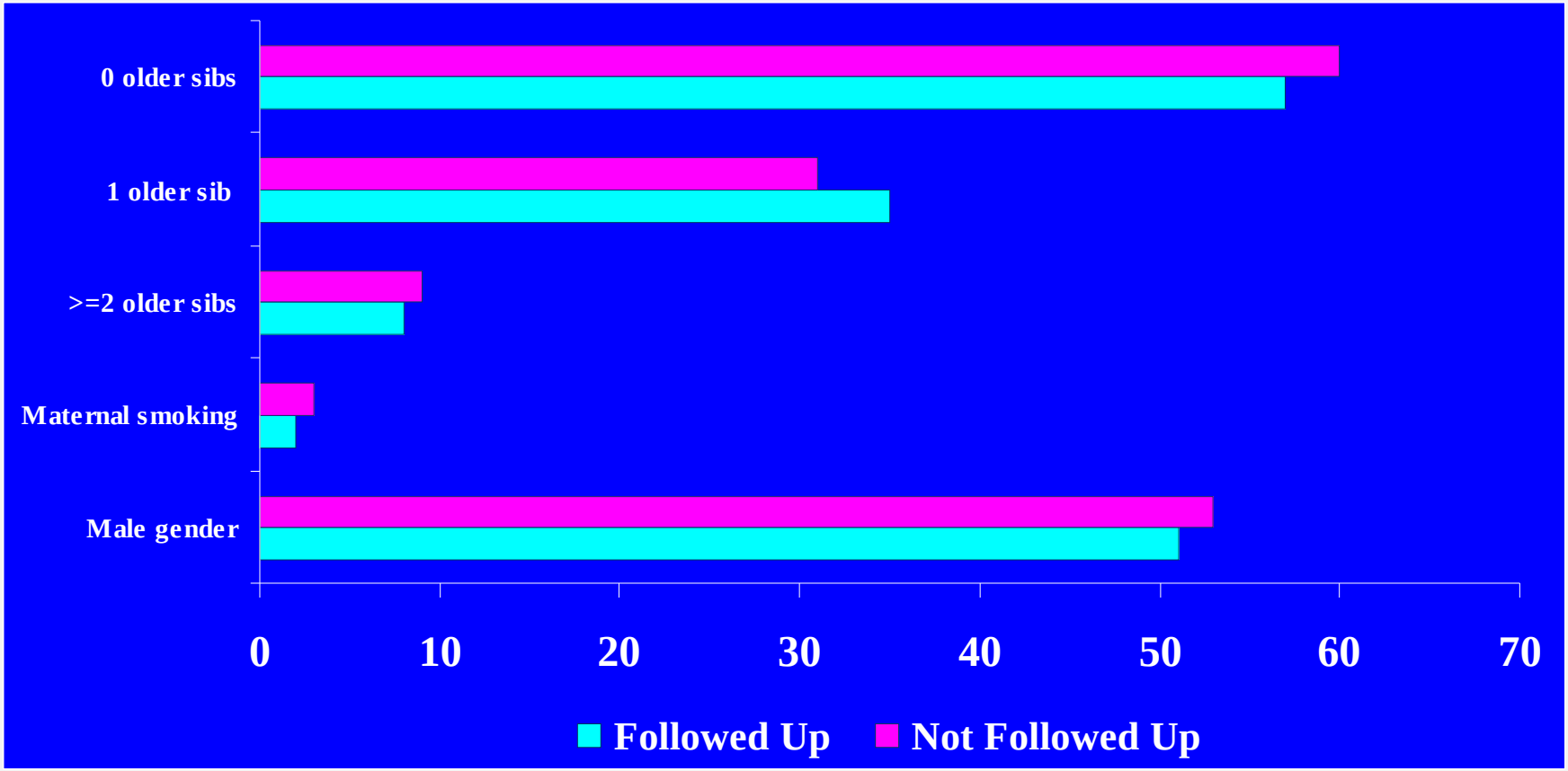
Comparison By Follow-Up: Probit III

Maternal Age & Education (%)



Comparison By Follow-Up : Probit III

Older Sibs, Maternal Smoking, & Gender (%)



Interim conclusions – prolonged/exclusive BF at 11.5 yrs:

- Stature: Small positive ass'n with height (leg-length)
- Adiposity: No important reduction in adiposity
- Blood pressure: No important reduction in BP
- In this interim analysis, the 95%CIs indicate that small beneficial or adverse effects cannot be ruled out
- These results are not due to selection bias or confounding, unlike observational studies
- Breastfeeding improves IQ and protects against GI infections and atopic eczema in infancy

Спасибо

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