**Participant Flow**

|  |
| --- |
|  |

Source: Consort Flow Chart. Own Elaboration

a Once in the field for data collection, it was realized that some towns did not have any FAMI units as they had made the transition to other models (MF)

b Towns not originally assigned to the sample were randomly ranked and used as replacements. However, there were not enough in all randomization strata.

**Baseline Characteristics**

**Table 1. Baseline characteristics of children and their households by randomization status**

|  |  |  |  |
| --- | --- | --- | --- |
|   | ITT=1 | ITT=0 |   |
|   | Mean | SD | Mean | SD |   |
| **Sociodemographic characteristics** |  |  |  |  |  |
| Child's age in months | 5.76 | (3.44) | 5.54 | (3.29) |  |
| Boys (%) | 0.52 | (0.50) | 0.51 | (0.50) |  |
| First Born (%)  | 0.47 | (0.50) | 0.45 | (0.50) |  |
| Child's birth weight (gr) | 3,190 | (572) | 3,156 | (500) |  |
| Low birth weight (%)  | 0.07 | (0.26) | 0.07 | (0.26) |  |
| Mother's age (number of years) | 26.16 | (6.95) | 26.48 | (6.81) |  |
| Mother's education (years) | 8.85 | (3.42) | 8.40 | (3.31) |  |
| Father present (%) | 0.70 | (0.46) | 0.75 | (0.43) | \*\* |
| Mother present (%) | 1.00 | (0.06) | 1.00 | (0.07) |  |
| Mother single (%) | 0.24 | (0.43) | 0.21 | (0.41) |  |
| Mother divorced (%) | 0.01 | (0.11) | 0.03 | (0.16) | \* |
| Teenage mothers (%) | 0.25 | (0.44) | 0.21 | (0.41) | \* |
| Household wealth index a | 0.06 | (0.96) | -0.06 | (1.04) | \*\* |
| Home ownership | 0.37 | (0.48) | 0.39 | (0.49) |  |
| SISBEN survey b | 0.71 | (0.45) | 0.70 | (0.46) |  |
| Household size | 4.08 | (1.47) | 4.10 | (1.43) |  |
| No. of observations | 702 | 758 |   |
| **Caregiver Characteristics** |  |  |  |  |  |
| Peabody Picture Vocabulary Test (raw score) | 22.33 | (8.53) | 19.76 | (8.8) | \*\* |
| Personality Traits by Big Five |  |  |  |  |  |
|  Extroversion (raw score) | 3.33 | (0.54) | 3.35 | (0.54) |  |
|  Agreeableness (raw score) | 3.88 | (0.57) | 3.86 | (0.61) |  |
|  Conscientiousness (raw score) | 3.92 | (0.60) | 3.73 | (0.60) | \*\*\* |
|  Emotional Stability (raw score) | 2.73 | (0.61) | 2.77 | (0.56) |  |
|  Openness (raw score) | 3.80 | (0.60) | 3.78 | (0.57) |  |
| No. of observations | 702 | 758 |   |
| **Intermediate Outcomes** |   |   |   |   |   |
| FCI No. of adult books, magazines and newspapersc | 2.57 | (3.08) | 2.76 | (3.17) |  |
| FCI No. of toy sources | 1.35 | (0.94) | 1.38 | (0.97) |  |
| FCI No. of varieties of play materials | 1.42 | (1.41) | 1.42 | (1.45) |  |
| FCI No. of varieties of play activities over past 3 days | 2.53 | (1.56) | 2.53 | (1.57) |  |
| FCI No. of parental care activities over past 3 days | 4.75 | (1.04) | 4.72 | (1.06) |  |
| Exclusive breastfeeding at least 6 months (%)  | 0.72 | (0.45) | 0.73 | (0.44) |  |
| Social support DUKE UNC-11 scale total (raw score) | 41.22 | (8.26) | 42.21 | (8.89) |  |
| Self-efficacy in the Caregiver Role Test – Modifiedd | 26.47 | (5.60) | 26.45 | (4.76) |  |
| Mothers with depression symptoms CESD-10 (%) | 0.15 | (0.36) | 0.13 | (0.33) |  |
| Use of verbal or physical abuse in the household (%) | 0.02 | (0.15) | 0.01 | (0.11) |   |
| No. of observations | 702 | 758 |   |
| Note: \*\*\*p<0.01; \*\*p<0.05; \*p<0.1 |   |   |   |   |   |
| Standard errors clustered by town in parenthesis |  |  |  |  |  |
| a The wealth index was computed as the principal component of a set of dichotomous variables that describe characteristics of the household, ownership of durable goods, and access to public utilities.b Colombia’s proxy means testc FCI: UNICEF’s family care indicator (Frongillo, Sywulka and Kariger, 2003).d Pedersen et al. (1989) and Porter and Hsu (2003) |

**Outcome measures**

 **Table 2. Outcomes of children at baseline and end of intervention by randomization status**

|  |  |  |  |
| --- | --- | --- | --- |
|   | ITT=1 | ITT=0 |   |
|   | Mean | SD | Mean | SD |   |
| **Baseline** |  |
| *Nutrition* |   |   |   |   |   |
| Height (cm) | 64.98 | (6.85) | 63.99 | (7.05) | \* |
| Weight (kg) | 7.38 | (1.97) | 7.34 | (2.02) |  |
| Weight for age Z-score | 0.25 | (1.40) | 0.27 | (1.42) |  |
| Length for age Z-score | -0.02 | (1.70) | -0.21 | (1.74) |  |
| Weight for length Z-score | 0.37 | (1.59) | 0.55 | (1.65) |  |
| Global Malnutrition (Underweight) | 0.07 | (0.25) | 0.05 | (0.22) |  |
| Acute Malnutrition (Wasting) | 0.06 | (0.24) | 0.07 | (0.25) |  |
| Chronic Malnutrition (Stunting) | 0.10 | (0.30) | 0.14 | (0.35) |  |
| Overweight by BMI | 0.10 | (0.29) | 0.09 | (0.28) |  |
| ELCSA food insecurity | 0,50 | (0,50) | 0,42 | (0,50) |  |
| ELCSA food insecurity (Moderate or Severe) | 0,04 | (0,21) | 0,03 | (0,175) |  |
| No. of observations | 702 | 758 |   |
| *Motor Development* |   |   |   |   |   |
| No. of WHO motor milestones achieved | 2,70 | (1,661) | 2,78 | (1,870) |  |
| No. of observations | 344 | 361 |   |
| **End of the Intervention** |  |  |  |  |   |
| *Nutrition* |  |  |  |  |   |
| Height (cm) | 84.34 | (4.50) | 84.30 | (4.59) |  |
| Weight (kg) | 12.05 | (1.69) | 11.94 | (1.66) |  |
| Weight for age Z-score | 0.02 | (1.09) | -0.06 | (1.03) |  |
| Length for age Z-score | -0.82 | (1.15) | -0.89 | (1.18) |  |
| Weight for length Z-score | 0.59 | (1.22) | 0.52 | (1.23) |  |
| Global Malnutrition (Underweight) | 0.02 | (0.14) | 0.04 | (0.19) |  |
| Acute Malnutrition (Wasting) | 0.01 | (0.09) | 0.02 | (0.15) |  |
| Chronic Malnutrition (Stunting) | 0.16 | (0.37) | 0.16 | (0.37) |  |
| Overweight by BMI | 0.26 | (0.44) | 0.22 | (0.42) |  |
| ELCSA food insecurity | 0,49 | (0,50) | 0,65 | (0,48) | \*\* |
| ELCSA food insecurity (Moderate or Severe) | 0,05 | (0,22) | 0,07 | (0,25) |  |
| No. of observations | 628 | 707 |   |
| *Socio-emotional Development* |   |   |   |   |   |
| ASQ:SE Raw Scores Total | 44,30 | (26,02) | 48,44 | (28,69) |  |
| No. of observations | 628 | 707 |   |
| *Bayley-III Raw Scores* |  |  |  |  |  |
|  Cognition | 59,37 | (7,95) | 59,47 | (7,53) |  |
|  Receptive language | 24,34 | (5,25) | 24,67 | (5,06) |  |
|  Expressive language | 25,78 | (5,76) | 25,47 | (5,49) |  |
|  Gross motor | 54,58 | (4,74) | 54,37 | (4,44) |  |
|  Fine motor | 38,18 | (4,18) | 38,06 | (3,80) |  |
| No. of observations | 628 | 707 |   |
| Note: \*\*\*p<0.01; \*\*p<0.05; \*p<0.1 |   |   |   |   |   |
| Standard errors clustered by town in parenthesis |  |  |  |  |  |

|  |
| --- |
| **Table 3. Secondary outcomes of participant children at the end line by randomization status** |
|   | ITT=1 | ITT=0 |   |
|   | Mean | SD | Mean | SD |   |
| **End of the Intervention** |  |  |  |  |   |
| FCI No. of adult books, magazines and newspapers | 6,01 | (3,97) | 4,77 | (3,80) | \*\*\* |
| FCI No. of toy sources | 2,73 | (0,50) | 5,56 | (0,37) | \*\*\* |
| FCI No. of varieties of play materials | 3,98 | (1,67) | 4,00 | (1,76) |  |
| FCI No. of varieties of play activities over past 3 days | 5,87 | (0,49) | 5,84 | (0,42) |  |
| FCI No. of parental care activities over past 3 days | 7,89 | (2,36) | 7,96 | (2,51) |  |
| Use of verbal or physical abuse in the household (%) | 0,10 | (0,30) | 0,13 | (0,33) |  |
| Social support DUKE UNC-11 total (raw score) | 39,77 | (9,02) | 37,45 | (8,61) | \* |
| Self-Efficacy Score Above Median | 0,30 | (0,46) | 0,24 | (0,43) |  |
| Mothers with depressive symptoms (%) | 0,18 | (0,39) | 0,19 | (0,39) |  |
| Parental Knowledge (Raw Score) | 29,27 | (3,61) | 29,49 | (3,44) |  |
| No. of observations | 628 | 707 |   |
| Note: \*\*\*p<0.01; \*\*p<0.05; \*p<0.1 |   |   |   |   |   |
| Standard errors clustered by town |  |  |  |  |  |

**Adverse events**

There were no adverse events associated with this trial.