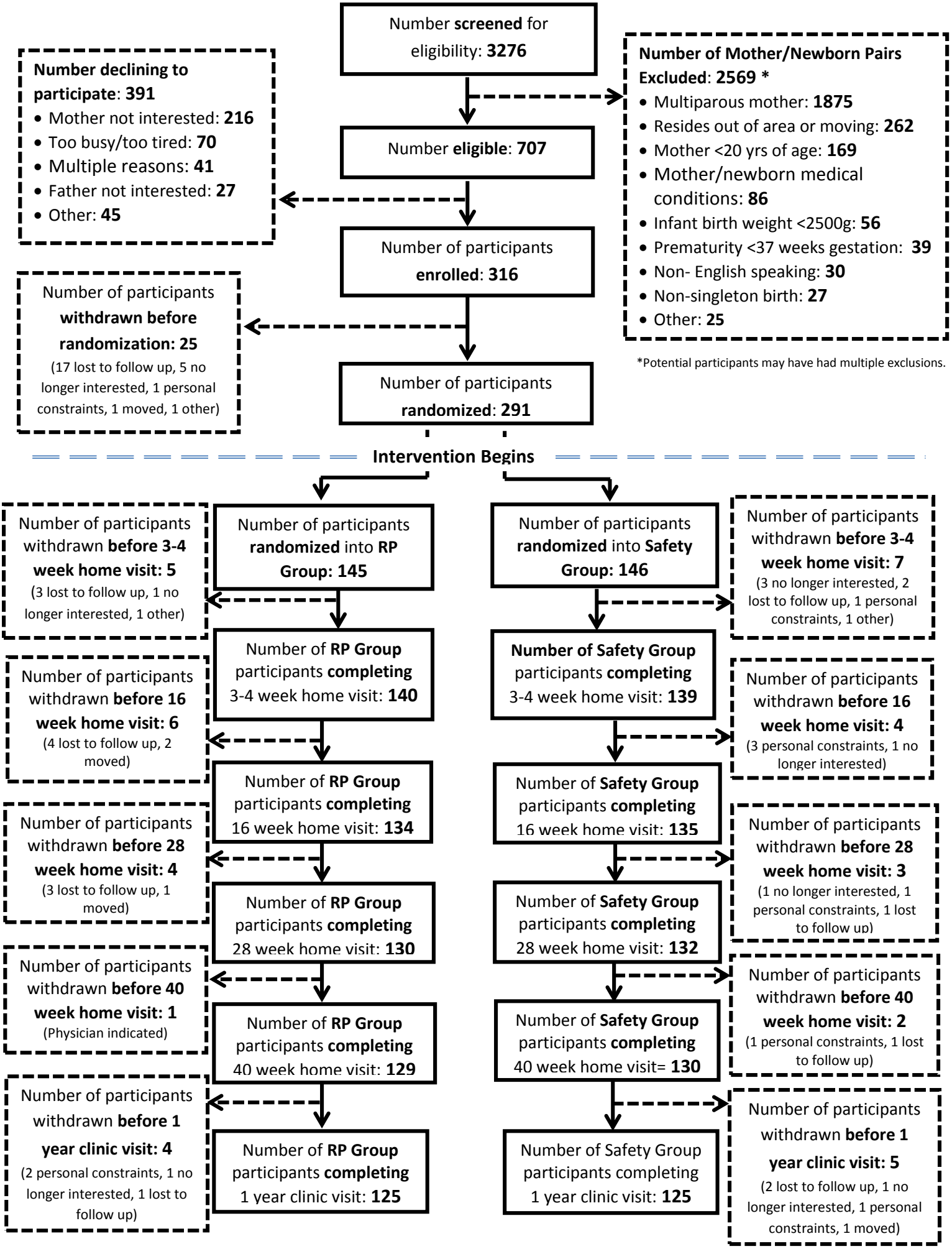
Number screened for eligibility: 3276
Number eligible: 707
Number of participants enrolled: 316
Number of participants randomized: 291
Number declining to participate: 391
• Mother not interested: 216
• Too busy/too tired: 70
• Multiple reasons: 41
• Father not interested: 27
• Other: 45
Number of Mother/Newborn Pairs Excluded: 2569 *
• Multiparous mother: 1875
• Resides out of area or moving: 262
• Mother <20 yrs of age: 169
• Mother/newborn medical conditions: 86
• Infant birth weight <2500g: 56
• Prematurity <37 weeks gestation: 39
• Non- English speaking: 30
• Non-singleton birth: 27
• Other: 25
*Potential participants may have had multiple exclusions.
Number of participants withdrawn before randomization: 25
(17 lost to follow up, 5 no longer interested, 1 personal constraints, 1 moved, 1 other)
Intervention Begins
Number of participants randomized into RP Group: 145
Number of participants withdrawn before 3-4 week home visit: 5
(3 lost to follow up, 1 no longer interested, 1 other)
Number of RP Group participants completing 3-4 week home visit: 140
Number of participants withdrawn before 16 week home visit: 6
(4 lost to follow up, 2 moved)
Number of RP Group participants completing 16 week home visit: 134
Number of participants withdrawn before 28 week home visit: 4
(3 lost to follow up, 1 moved)
Number of RP Group participants completing 28 week home visit: 130
Number of participants withdrawn before 40 week home visit: 1
(Physician indicated)
Number of RP Group participants completing 40 week home visit: 129
Number of participants withdrawn before 1 year clinic visit: 4
(2 personal constraints, 1 no longer interested, 1 lost to follow up)
Number of RP Group participants completing 1 year clinic visit: 125
Number of participants randomized into Safety Group: 146
Number of participants withdrawn before 3-4 week home visit: 7
(3 no longer interested, 2 lost to follow up, 1 personal constraints, 1 other)
Number of Safety Group participants completing 3-4 week home visit: 139
Number of participants withdrawn before 16 week home visit: 4
(3 personal constraints, 1 no longer interested)
Number of Safety Group participants completing 16 week home visit: 135
Number of participants withdrawn before 28 week home visit: 3
(1 no longer interested, 1 personal constraints, 1 lost to follow up)
Number of Safety Group participants completing 28 week home visit: 132
Number of participants withdrawn before 40 week home visit: 2
(1 personal constraints, 1 lost to follow up)
Number of Safety Group participants completing 40 week home visit= 130
Number of participants withdrawn before 1 year clinic visit: 5
(2 lost to follow up, 1 no longer interested, 1 personal constraints, 1 moved)
Number of Safety Group participants completing 1 year clinic visit: 125