**Table S1 – Number and proportion of babies who were LGA by each definition at birth, presented by trial arm and phase, and by gestational age at birth (imputed data)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | Pre-randomisation phase | | Outcome phase | |
|  |  | **Standard Care**  **(n=29,404)** | **GAP (n=26,546)** | **Standard Care**  **(n=13,810)** | **GAP (n=11,096)** |
| LGAboth | | 5.7% | 5.5% | 4.8% | 5.0% |
| LGApop, not LGAcust | | 1.4% | 1.3% | 1.6% | 1.4% |
| LGAcust, not LGApop | | 3.0% | 3.2% | 2.7% | 3.1% |
| Proportion of LGA babies born during each gestational period (LGA defined by intervention allocation)\* | **24+1-27+6** | 0.1% | 0.6% | 0.1% | 0.7% |
| **28+0-31+6** | 0.6% | 0.8% | 0.8% | 1.6% |
| **32+0-35+6** | 2.9% | 3.6% | 3.7% | 3.6% |
| **36+0-37+6** | 13.2% | 13.0% | 15.8% | 13.1% |
| **38+0-39+6** | 50.3% | 46.9% | 53.6% | 48.2% |
| **40+0-42+6** | 33.0% | 35.0% | 26.0% | 32.8% |
| \*LGApop in both arms during the pre-randomisation phase and the standard care arm during the outcome phase, and LGAcust in the intervention arm during the outcome phase. | | | | | |

| Table S2- Clinical and sociodemographic characteristics of pregnancies in which the baby was born LGA during the outcome comparison trial phase, presented by trial arm (available case data where not already presented). | | Standard Care | GAP |
| --- | --- | --- | --- |
|  | | LGAboth  (n=633) | LGAboth  (n=497) |
| Imputed data | | | |
| Age at estimated conception, years | **Median (IQR)** | 33.1  (29.3-36.3) | 32.6  (28.8-36.4) |
| **Missing, n(%)** | 0  (0.00%) | 0  (0.00%) |
| Ethnicity, n(%) | **White** | 407  (64.3%) | 286  (57.5%) |
| **Black** | 102  (16.1%) | 63  (12.7%) |
| **Asian** | 54  (8.5%) | 74  (14.9%) |
| **Mixed** | 9  (1.4%) | 4  (0.8%) |
| **Other** | 40  (6.3%) | 33  (6.6%) |
| **Missing** | 21  (33.2%) | 37  (7.4%) |
| Index of Multiple Deprivation Quintiles, n(%) | **1 (Least deprived)** | 143  (22.6%) | 43  (8.7%) |
| **2** | 89  (14.1%) | 60  (12.1%) |
| **3** | 92  (14.5%) | 116  (23.3%) |
| **4** | 160  (25.2%) | 155  (31.2%) |
| **5 (Most deprived)** | 140  (22.1%) | 113  (22.7%) |
| **Missing** | 9  (1.4%) | 10  (2.0%) |
| Body Mass Index | **Median (IQR)** | 27.2  (23.6-32.0) | 26.9  (23.8-31.8) |
| **Missing, n(%)** | 79  (12.4%) | 117  (23.5%) |
| Parity, n(%) | **Nulliparous** | 171  (27.0%) | 176  (35.4%) |
| **1** | 207  (32.7%) | 191  (38.4%) |
| **2** | 74  (11.7%) | 71  (14.3%) |
| **3** | 36  (5.7%) | 26  (5.2%) |
| **4 +** | 25  (3.9%) | 20  (4.0%) |
| **Missing, n(%)** | 120  (19.0%) | 13  (2.6%) |

**Table S3 - Ultrasound utilisation amongst pregnancies in which the baby was born LGAboth at or after 36+0 weeks of gestation, presented by trial arm and phase (available case data)**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | Pre-randomisation phase | | Comparison phase | | Intervention effect size - unadjusted (95%CI) | Intervention effect size - adjusted (95%CI) | p-value |
|  | **Standard Care** | **GAP** | **Standard Care** | **GAP** |
| Proportion of pregnancies with at least one scan, % | 72.4% | 88.1% | 94.0% | 91.0% | -1.3%  (-10.4, 7.8) | -0.7%  (-9.7, 8.4) | 0.86 |
| Number of all scans, mean (SD) | 3.2  (3.0) | 3.5  (2.3) | 4.7  (2.9) | 3.8  (2.2) | -0.9  (-2.4, 0.7) | -0.9  (-1.4, -0.4) | 0.002 |
| Proportion of pregnancies with scans ≥34+0 weeks, % | 39.9% | 56.7% | 73.0% | 62.2% | -8.5%  (-26.4, 9.5) | -9.8%  (-25.8, 6.2) | 0.19 |
| Number of scans ≥34+0 weeks, mean (SD) | 0.9  (1.2) | 0.9  (0.8) | 1.2  (1.2) | 1.0  (1.0) | -0.2  (-0.9, 0.6) | -0.2  (-0.6, 0.3) | 0.38 |
| Proportion of pregnancies with scans ≥34+0, including EFW, %\* | 38.3% | 57.3% | 71.1% | 59.1% | -11.8%  (-33.2, 9.7) | -12.9%  (-31.6, 5.9) | 0.13 |
| Number of scans ≥34+0 with EFW, mean (SD)\* | 0.5  (0.7) | 0.7  (0.7) | 0.9  (0.7) | 0.7  (0.7) | -0.2  (-0.5, 0.1) | -0.2  (-0.4, 0.02) | 0.07 |
| Of women with EFW recorded ≥34+0 weeks, mean (SD) duration in days between the last growth scan and the birth | 18.3  (12.9) | 17.7  (10.8) | 17.7  (11.5) | 18.2  (10.4) | 1.0  (-4.2, 6.1) | 0.0  (-5.3, 5.4) | 0.99 |
| *\*Values for the intervention arm exclude two cluster sites at which data on estimated fetal weight was not available during both trial phases for non-SGA babies.* | | | | | | | |

**Table S4 – Number and proportion of babies who were LGA by each definition at birth, presented by trial arm and phase (available case data)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | | Pre-randomisation phase | | Outcome comparison phase | |
|  | | **Standard Care**  **(n=29,404)** | **Intervention (n=26,546)** | **Standard Care**  **(n=13,810)** | **Intervention (n=11,096)** |
| LGAboth, n (%) | | 1693  (5.76%) | 1395  (5.3%) | 665  (4.8%) | 532  (4.8%) |
| LGApop, n (%) | | 369  (1.3%) | 303  (1.1%) | 203  (1.5%) | 146  (1.3%) |
| LGAcust, n (%) | | 852  (2.9%) | 726  (2.7%) | 357  (2.6%) | 307  (2.8%) |
| LGA (defined by intervention allocation)\* , n (%) born during each gestational period. | **24+1-27+6** | 1  (0.1%) | 7  (0.3%) | 1  (0.1%) | 4  (0.5%) |
| **28+0-31+6** | 11  (0.5%) | 14  (0.7%) | 7  (0.8%) | 10  (1.2%) |
| **32+0-35+6** | 57  (2.8%) | 69  (3.3%) | 31  (3.6%) | 27  (3.2%) |
| **36+0-37+6** | 273  (13.2%) | 282  (13.3%) | 136  (15.7%) | 111  (13.2%) |
| **38+0-39+6** | 1038  (50.3%) | 1010  (47.6%) | 466  (53.7%) | 411  (49.0%) |
| **40+0-42+6** | 682  (33.1%) | 738  (34.8%) | 227  (26.2%) | 275  (32.8%) |
| **Missing gestational age** | 0  (0.0%) | 1  (0.1%) | 0  (0.0%) | 1  (0.1%) |

**Table S5- Clinical and sociodemographic characteristics of pregnancies in which the baby was born LGA during the outcome comparison trial phase, presented by trial arm (available case data where not already presented)**

|  | | Standard care | GAP |
| --- | --- | --- | --- |
|  | | LGAboth  (N=618) | LGAboth  (N=506) |
| Age at estimated conception, years,  median (IQR) | | 33.1  (29.3-36.3) | 32.6  (28.8-36.4) |
| Missing age, n (%) | | 0  (0.0%) | 0  (0.0%) |
| Ethnicity, n (%) | **White** | 407  (66.5%) | 286  (62.2%) |
| **Black** | 102  (16.7%) | 63  (13.7%) |
| **Asian** | 54  (8.8%) | 74  (16.1%) |
| **Mixed** | 9  (1.5%) | 4  (0.9%) |
| **Other** | 40  (6.5%) | 33  (7.2%) |
| **Missing** | 21  (3.3%) | 37  (7.4%) |
| Index of Multiple Deprivation Quintiles, n (%) | **1 (Least deprived)** | 143  (22.9%) | 43  (8.8%) |
| **2** | 89  (14.3%) | 60  (12.3%) |
| **3** | 92  (14.7%) | 116  (23.8%) |
| **4** | 160  (25.6%) | 155  (31.8%) |
| **5 (Most deprived)** | 140  (22.4%) | 113  (23.2%) |
| **Missing** | 9  (1.4%) | 10  (2.0%) |
| Body Mass Index, median (IQR) | | 27.2  (23.6-32.0) | 26.9  (23.8-31.8) |
| Body Mass Index, n (%) | **<18.5** | 3  (0.6%) | 5  (1.3%) |
| **18.5-25** | 155  (33.2%) | 124  (32.6%) |
| **25-30** | 155  (33.2%) | 123  (32.4%) |
| **30-35** | 95  (20.3%) | 71  (18.7%) |
| **35-40** | 33  (7.1%) | 41  (10.8%) |
| **40+** | 26  (5.6%) | 16  (4.2%) |
| **Missing** | 166  (26.2%) | 117  (23.5%) |
| Parity, n (%) | **0** | 171  (33.3%) | 176  (36.4%) |
| **1** | 207  (40.4%) | 191  (39.5%) |
| **2** | 74  (14.4%) | 71  (14.7%) |
| **3** | 36  (7.0%) | 26  (5.4%) |
| **4 +** | 25  (4.9%) | 20  (4.1%) |
| **Missing** | 120  (19.0%) | 13  (2.6%) |
| NB. Mothers and babies with missing data have been excluded from the denominator of available case results, rates of missing values presented for information. | | |

**Table S6 - Rate of detection of LGA by each definition, presented by trial arm and phase (available case analysis)**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | Pre-randomisation phase | | Comparison phase | | Intervention effect size - unadjusted (95%CI) | Intervention effect size - adjusted (95%CI) | p-value |
|  | **Standard**  **Care** | **GAP** | **Standard Care** | **GAP** |
| Primary outcome |  |  |  |  |  |  |  |
| LGA at birth by customised and population centiles, %(n/N) | 5.8%  (1,633/28,298) | 5.6%  (1,081/19,302) | 4.8%  (633/13,111) | 4.9%  (388/7,941) |  |  |  |
| Antenatal detection, %(n/N) | 24.1%  (393/1,633) | 40.8%  (441/1,081) | 47.9%  (303/633) | 39.4%  (153/388) | -5.6%  (-23.0, 11.8) | -5.2%  (-29.6, 19.3) | 0.61 |
| False positive rate, %(n/N) | 3.3% | 2.8% | 7.2% | 4.9% | -2.8%  (-7.0, 1.4) | -2.6%  (-6.5, 1.3) | 0.14 |
| Secondary outcomes\* | |  |  |  |  |  |  |
| LGA at birth by customised centiles (<10th centile) , %(n/N) | 8.7%  (2,464/28,301) | 8.3%  (1,611/19,341) | 7.5%  (984/13,111) | 7.5%  (598/7,976) |  |  |  |
| Antenatal detection, %(n/N) | 19.2%  (474/2,464) | 32.3%  (521/1,611) | 39.0%  (384/984) | 37.8%  (226/598) | 1.1%  (-16.9, 19.0) | -0.8%  (-23.8, 22.3) | 0.94 |
| False positive rate, %(n/N) | 3.1%  (805/25,837) | 2.6%  (394/15,274) | 6.7%  (817/12,127) | 4.0%  (264/6,638) | -3.1%  (-7.2, 1.0) | -2.6%  (-6.2, 1.0) | 0.12 |
| LGA at birth by population centiles (<10th centile) , %(n/N) | 7.0%  (1,993/28,302) | 6.7%  (1,301/19,305) | 6.3%  (829/13,111) | 6.3%  (497/7,941) |  |  |  |
| Antenatal detection, %(n/N) | 23.3%  (464/1,993) | 39.2%  (510/1,301) | 45.7%  (379/829) | 34.8%  (173/497) | -9.6%  (-22.5, 3.3) | -7.1%  (-26.5, 12.4) | 0.39 |
| False positive rate, %(n/N) | 3.1%  (816/26,309) | 2.6%  (404/15,542) | 6.7%  (822/12,282) | 4.7%  (318/6,718) | -2.4%  (-6.3, 1.5) | -2.3%  (-5.9, 1.3) | 0.15 |
| *\*One site did not contribute data on screening outcomes for the pre-randomisation phase, so excluded from all secondary outcomes* | | | | | | | |

**Table S7 - Secondary outcomes for mothers who gave birth to LGAboth babies at or after 36+0 weeks of gestation, presented by trial arm and phase (available case data where not already presented).**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | Pre-randomisation phase | | Comparison phase | | Intervention effect size - unadjusted (95%CI) | Intervention effect size - adjusted (95%CI) | p-value |
|  | **Standard Care (n=1633)** | **GAP (n= 1320)** | **Standard Care**  **(n= 633)** | **GAP (n= 497)** |
| Induction of Labour, n/N(%) | 396/1629 (24.3%) | 322/1151 (28.0%) | 158/632 (25.0%) | 148/479 (30.9%) | 8.2% (-5.0, 21.5) | 0.8% (-9.4, 11.0) | 0.86 |
| Mode of birth, n/N (%) |  |  |  |  |  |  |  |
| Spontaneous vaginal delivery | 747/1632 (45.8%) | 603/1231 (49.0%) | 274/633 (43.3%) | 200/472 (42.4%) | 1.7% (-11.8, 15.2) | -8.1% (-22.4, 6.1) | 0.21 |
| Instrumental delivery | 155/1632 (9.5%) | 142/1231 (11.5%) | 62/633 (9.8%) | 43/472 (9.1%) | 0.4% (-5.6, 6.3) | -3.8% (-7.9, 0.4) | 0.07 |
| Elective caesarean section | 412/1632 (25.3%) | 308/1231 (25.0%) | 187/633 (29.5%) | 143/472 (30.3%) | -2.4% (-17.7, 12.9) | -5.6% (-20.6, 9.5) | 0.40 |
| Emergency caesarean section | 317/1632 (19.4%) | 176/1231 (14.3%) | 110/633 (17.4%) | 86/472 (18.2%) | 0.3% (-4.3, 5.0) | -3.0% (-7.3, 1.3) | 0.14 |
| Estimated blood loss, mls  mean (SD) | 625.5 (483.5) | 640.0 (486.0) | 651.4 (551.2) | 647.3 (455.6) | -26.7 (-124.8, 71.3) | 2.1 (-84.2, 88.5) | 0.95 |
| Post-partum haemorrhage (>1500mls), n/N(%) | 90/1621 (5.6%) | 58/1291 (4.5%) | 38/630 (6.0%) | 20/475 (4.2%) | -2.4% (-5.5, 0.7) | -2.4% (-4.8, -0.0) | 0.048 |
| 3rd/4th degree tears, n/N (%) | 35/1633 (2.1%) | 40/1320 (3.0%) | 8/633 (1.3%) | 11/497 (2.2%) | 1.4% (-1.5, 4.3) | 0.7% (-1.4, 2.8) | 0.46 |
| Epidural, n/N (%) | 458/1435 (31.9%) | 375/1318 (28.5%) | 177/556 (31.8%) | 141/496 (28.4%) | -5.2% (-26.7, 16.3) | -5.7% (-18.7, 7.3) | 0.33 |
| Episiotomy, n/N (%) | 165/1358 (12.2%) | 167/909 (18.4%) | 76/558 (13.6%) | 46/319 (14.4%) | 14.0% (-11.2, 39.1) | -5.7% (-12.2, 0.8) | 0.08 |

**Table S8 - Secondary outcomes for LGAboth babies born at or after 36+0 weeks of gestation, presented by trial arm and phase (available case data).**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | Pre-randomisation phase | | Comparison phase | | Intervention effect size - unadjusted (95%CI) | Intervention effect size - adjusted (95%CI) | p-value |
|  | **Standard Care (n=1633)** | **GAP**  **(n= 1320)** | **Standard Care (n= 633)** | **GAP (n= 479)** |
| Gestational age at birth, weeks , mean (SD) | 39.3 (1.3) | 39.2 (1.3) | 39.2 (1.3) | 39.3 (1.3) | 0.1 (-0.1, 0.2) | 0.1 (-0.1, 0.3) | 0.20 |
| Babies born before 39+0 weeks, n/N (%) | 594/1633  (36.4%) | 513/1320  (38.9%) | 248/633  (39.2%) | 185/497  (37.2%) | -2.1%  (-10.7, 6.5) | -6.4%  (-19.6, 6.7) | 0.28 |
| Birthweight, grams,  mean (SD) | 4207.2 (351.8) | 4180.4 (372.3) | 4183.94 (337.0) | 4196.8 (334.3) | 17.3 (-27.3, 61.8) | 32.7 (-18.0, 83.3) | 0.167 |
| Apgar score < 7 at 5 minutes, n/N (%) | 28/1633 (1.7%) | 22/1320 (1.7%) | 15/633 (2.4%) | 5/497 (1.0%) | -1.1% (-2.6, 0.3) | -1.1% (-3.0,0.9) | 0.23 |
| Arterial cord pH < 7.1, n/N (%) | 38/1404 (2.7%) | 42/1320 (3.2%) | 16/552 (2.9%) | 15/497 (3.0%) | -0.1% (-2.3, 2.2) | -0.3% (-2.0, 1.4) | 0.67 |
| Neonatal unit admission, n/N (%) | 216/1333 (16.2%) | 146/1320 (11.1%) | 104/514 (20.2%) | 46/497 (9.3%) | -10.3% (-31.8,11.2) | -6.4% (-14.4, 1.6) | 0.10 |
| Hypoxic-Ischaemic encephalopathy, n/N (%) | 1/1633 (0.1%) | 2/1320 (0.2%) | 2/633 (0.3%) | 2/497 (0.4%) | 0.1% (-0.5, 0.7) | 0.3% (-0.5, 1.1) | 0.35 |
| Hypoglycaemia, n/N (%) | 37/1633 (2.3%) | 41/1320 (3.1%) | 20/633 (3.2%) | 10/497 (2.0%) | -0.6% (-3.2, 2.0) | -0.4% (-3.7, 2.9) | 0.77 |
| Nasogastric tube feeding, n/N (%) | 16/1333 (1.2%) | 38/1320 (2.9%) | 8/514 (1.6%) | 13/497 (2.6%) | 0.9% (-1.4, 3.1) | 0.8% (-1.4, 2.9) | 0.40 |
| Stillbirth, n/N (%) | 0/1633 (0.0%) | 2/1320 (0.2%) | 1/633 (0.2%) | 0/495 (0.0%) | -0.2% (-0.5, 0.2) | # | 0.39\* |
| Neonatal death, n/N (%) | 0/1633 (0.0%) | 0/1320 (0.0%) | 0/633 (0.0%) | 0/497 (0.0%) | 0.0% (0.0, 0.0) | # | 1.00\* |
| Perinatal mortality, n/N (%) | 0/1633 (0.0%) | 2/1320 (0.2%) | 1/633 (0.2%) | 0/495 (0.0%) | -0.2% (-0.5, 0.2) | # | 0.39\* |
| *# Cannot be calculated due to too few events*  *\*Unadjusted p-value* | | | | | | | |