

Appendices

Appendix A: Baseline characteristics of women who do versus do not have 6-month post-childbirth outcome data for the primary endpoint analysis.

| | Have 6-month outcome data for the primary endpoint analysis | | p-value [2] |
|---|---|-----------------|-------------|
| | No (n=117) [1] | Yes (n=453) | |
| Age, years (mean (SD)) | 27 (5.1) | 27 (4.7) | 0.54 |
| Marital status (n (%)) | | | - |
| Married | 117 (100%) | 453 (100%) | |
| Occupation (n (%)) | | | 0.77 |
| Does not work | 109 (93%) | 424 (94%) | |
| Manual worker | 6 (5%) | 25 (6%) | |
| Non-manual worker | 2 (2%) | 4 (1%) | |
| Education status (n (%)) | | | 0.16 |
| None | 30 (26%) | 77 (17%) | |
| Primary | 26 (22%) | 113 (25%) | |
| Secondary | 39 (33%) | 194 (43%) | |
| Higher secondary | 10 (9%) | 36 (8%) | |
| Graduate/above | 12 (10%) | 33 (7%) | |
| Participant's expectation of usefulness of counselling (n (%)) | | | 0.70 |
| Not useful | 1 (1%) | 3 (1%) | |
| A little useful | 4 (3%) | 22 (5%) | |
| Somewhat useful | 26 (22%) | 88 (19%) | |
| Moderately useful | 52 (44%) | 194 (43%) | |
| Very useful | 33 (28%) | 145 (32%) | |
| Missing | 1 (1%) | 1 (<1%) | |
| Chronicity of depression, weeks (median (IQR)) | 22 (13-32) | 24 (16-39) | 0.43 |
| Missing * | 25 (21%) | 146 (32%) | |
| Chronicity of depression category (n (%)) | | | 0.72 |
| <12 weeks | 19 (16%) | 54 (12%) | |
| ≥12 weeks | 73 (62%) | 253 (56%) | |
| Missing | 25 (21%) | 146 (32%) | |
| Median PHQ-9 score (SD; IQR) | 15 (3.7; 12-17) | 14 (3.7; 12-17) | 0.38 |
| PHQ-9 score category (n (%)) | | | 0.19 |
| 10-14 (moderate) | 56 (48%) | 256 (57%) | |
| 15-19 (moderately severe) | 43 (36%) | 144 (32%) | |
| 20-27 (severe) | 18 (15%) | 53 (12%) | |
| PHQ question 10 (n (%)) [3] | | | 0.69 |
| Not difficult at all | 10 (9%) | 43 (9%) | |
| Somewhat difficult | 28 (24%) | 129 (28%) | |
| Very difficult | 51 (44%) | 181 (40%) | |
| Extremely difficult | 28 (24%) | 100 (22%) | |

| | Have 6-month outcome data for the primary endpoint analysis | | |
|--|---|-------------|-------------|
| | No (n=117) [1] | Yes (n=453) | p-value [2] |
| MSPSS score (mean (SD)) (3) | 3.9 (1.3) | 3.9 (1.4) | 0.61 |
| Parity (n (%)) | | | 0.76 |
| Primiparous | 22 (19%) | 80 (18%) | |
| Multiparous | 95 (81%) | 373 (82%) | |
| Previous miscarriage (n (%)) | | | 0.94 |
| None (not first pregnancy) | 22 (19%) | 80 (18%) | |
| None (first pregnancy) | 60 (51%) | 232 (51%) | |
| One/more | 35 (30%) | 141 (31%) | |
| Previous still birth (n (%)) | | | 0.25 |
| None (not first pregnancy) | 22 (19%) | 80 (18%) | |
| None (first pregnancy) | 86 (74%) | 355 (78%) | |
| One/more | 9 (8%) | 18 (4%) | |
| Any domestic violence in last 3 months (n (%)) | | | 0.93 |
| No | 102 (87%) | 384 (85%) | |
| Yes | 15 (13%) | 56 (12%) | |
| Missing | 0 | 13 (3%) | |
| Time between screening and birth of child, months (mean (SD)) | | | 0.07 |
| Missing [4] | 3.4 (1.36) | 3.0 (1.20) | |
| | 85 (73%) | 0 | |

SD=standard deviation. IQR=interquartile range. PHQ-9=Patient Health Questionnaire (nine items). MSPSS=Multidimensional Scale of Perceived Social Support [1] Mainly lost for the 6-month visit. [2] P-values were calculated using logistic generalised estimating equation models with outcome of whether had 6-month outcome data or not, the baseline variable in question as the dependent variable (continuous variables assumed linear) and village-cluster as the panel variable. Women with missing data for a given variable were omitted for the test on that variable. [3] If you checked off any problems (PHQ questions 1-9), how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people? [4] Women who did not attend any follow up visits have missing information relating to the date of birth of the child.

*Chronicity was missed being asked in about 1/3rd of the sample

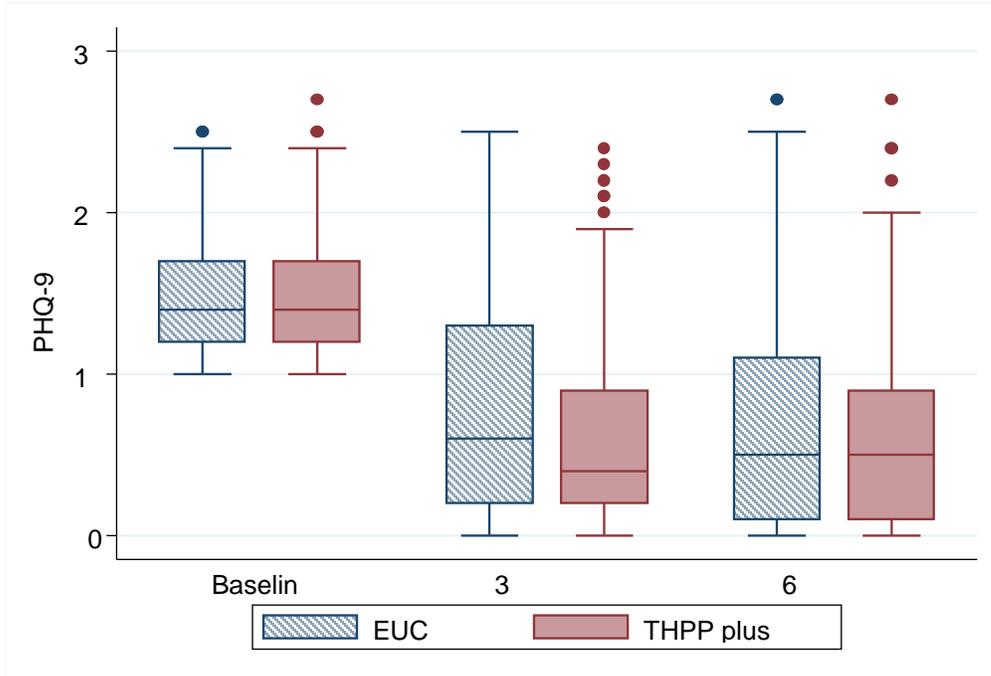
Appendix B: Baseline characteristics of women who did versus did not have their 6-month post-childbirth visit within the protocol-defined +/- 2 week visit window.

| | Participants seen within the protocol-defined +/- 2 week visit window | | p-value [2] |
|---|---|-------------|-------------|
| | No (N=156) [1] | Yes (N=297) | |
| Age, years (mean (SD)) | 27 (5.1) | 27 (4.5) | 0.63 |
| Marital status (n (%)) | | | - |
| Married | 156 (100%) | 297 (100%) | |
| Occupation (n (%)) | | | 0.97 [3] |
| Does not work | 146 (94%) | 278 (94%) | |
| Manual worker | 10 (6%) | 15 (5%) | |
| Non-manual worker | 0 | 4 (1%) | |
| Education status (n (%)) | | | 0.22 |
| None | 35 (22%) | 42 (14%) | |
| Primary | 37 (24%) | 76 (26%) | |
| Secondary | 63 (40%) | 131 (44%) | |
| Higher secondary | 12 (8%) | 24 (8%) | |
| Graduate/above | 9 (6%) | 24 (8%) | |
| Participant's expectation of usefulness of counselling (n (%)) | | | 0.57 |
| Not useful | 2 (1%) | 1 (<1%) | |
| A little useful | 7 (5%) | 15 (5%) | |
| Somewhat useful | 35 (22%) | 53 (18%) | |
| Moderately useful | 65 (42%) | 129 (43%) | |
| Very useful | 47 (30%) | 98 (33%) | |
| Missing | 0 | 1 (<1%) | |
| Chronicity of depression, weeks (median (IQR)) | 25 (16-41) | 24 (15-37) | 0.16 |
| Missing* | 54 (35%) | 92 (31%) | |
| Chronicity of depression category (n (%)) | | | 0.74 |
| <12 weeks | 17 (11%) | 37 (12%) | |
| ≥12 weeks | 85 (54%) | 168 (57%) | |
| Missing | 54 (35%) | 92 (31%) | |
| Median PHQ-9 score (IQR) | 14 (12-17) | 14 (11-18) | 0.77 |
| PHQ-9 score category (n (%)) | | | 0.97 |
| 10-14 (moderate) | 87 (56%) | 169 (57%) | |
| 15-19 (moderately severe) | 51 (33%) | 93 (31%) | |
| 20-27 (severe) | 18 (12%) | 35 (12%) | |
| PHQ question 10 (n (%)) [4] | | | 0.70 |
| Not difficult at all | 12 (8%) | 31 (10%) | |
| Somewhat difficult | 48 (31%) | 81 (27%) | |
| Very difficult | 60 (38%) | 121 (41%) | |
| Extremely difficult | 36 (23%) | 64 (22%) | |
| MSPSS score (mean (SD)) | 3.9 (1.4) | 4.0 (1.4) | 0.28 |
| Parity (n (%)) | | | 0.54 |

| | Participants seen within the protocol-defined +/- 2 week visit window | | p-value [2] |
|--|---|-------------|-------------|
| | No (N=156) [1] | Yes (N=297) | |
| Primiparous | 30 (19%) | 50 (17%) | |
| Multiparous | 126 (81%) | 247 (83%) | |
| Previous miscarriage (n (%)) | | | 0.41 |
| None (first pregnancy) | 30 (19%) | 50 (17%) | |
| None (not first pregnancy) | 73 (47%) | 159 (54%) | |
| One/more | 53 (34%) | 88 (30%) | |
| Previous still births (n (%)) | | | 0.83 |
| None (first pregnancy) | 30 (19%) | 50 (17%) | |
| None (not first pregnancy) | 120 (77%) | 235 (79%) | |
| One/more | 6 (4%) | 12 (4%) | |
| Any domestic violence in last 3 months (n (%)) | | | 0.91 |
| No | 134 (86%) | 250 (84%) | |
| Yes | 19 (12%) | 37 (12%) | |
| Missing | 3 (2%) | 10 (3%) | |
| | | | |
| Time between screening and birth of child, months (mean (SD)) | 2.8 (1.24) | 3.1 (1.17) | 0.02 |

Appendix B includes women who had a visit according to the analysis-defined window (-1 month + 2 months relative to the expected visit date), categorized by whether that visit was within the protocol-defined window or not (the protocol-defined window being narrower ie +/- 2 weeks than the analysis-defined window). SD=standard deviation. IQR=interquartile range. PHQ-9=Patient Health Questionnaire (nine items). MSPSS=Multidimensional Scale of Perceived Social Support. [1] 38 and 51 women in the THPP plus EUC and EUC-alone groups, respectively, came too early; 32 and 35 women in the THPP plus EUC and EUC-alone groups, respectively, came too late. [2] P-values were calculated using logistic generalised estimating equation models with outcome of whether seen within the protocol-defined window at 6 months or not, the baseline variable in question as the dependent variable (continuous variables assumed linear) and village-cluster as the panel variable. Women with missing data for a given variable were omitted for the test on that variable. [3] Manual and non-manual workers combined for the test, since there were no non-manual workers in the "no" column. [4] If you checked off any problems (PHQ questions 1-9), how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?
* Chronicity was missed being asked in about 1/3rd of the sample

Appendix C: PHQ-9 score over 6 months post-childbirth.



PHQ-9=Patient Health Questionnaire (nine items), THPP=Thinking Healthy Program Peer-delivered, EUC=Enhanced Usual Care. The central line shows the median score, the length of the box is the interquartile range, the lines are the most extreme values within 1.5 times the interquartile range, and points outside this range are shown individually.

Appendix D: Symptom severity (PHQ-9 score) at 6 months post-childbirth by potential effect modifiers.

| | N | | Mean (SD) | | Adjusted mean difference for THPP Plus EUC versus EUC-alone (95% CI) [1] | Adjusted SMD for THPP Plus EUC versus EUC-alone (95% CI) [1] | P value for effect modification [1] |
|-------------------------------------|---------------|-----------|---------------|--------------|--|--|-------------------------------------|
| | THPP Plus EUC | EUC-alone | THPP Plus EUC | EUC-alone | | | |
| Age, years | | | | | | | |
| 18-24 | 71 | 63 | 5.9 (6.6) | 6.9 (6.2) | -1.09 (-2.97 to 0.78) | -0.14 (-0.48 to 0.19) | 0.73 |
| ≥25 | 156 | 163 | 6.1 (5.6) | 6.8 (6.2) | -0.68 (-1.79 to 0.43) | -0.11 (-0.33 to 0.11) | |
| Chronicity of depression [2] | | | | | | | |
| <12 weeks | 30 | 24 | 5.1 (4.9) | 6.8 (5.0) | -1.88 (-4.94 to 1.18) | -0.20 (-0.73 to 0.34) | 0.80 |
| ≥12 weeks | 129 | 124 | 6.4 (6.2) | 8.0 (6.7) | -1.44 (-2.68 to -0.21) | -0.21 (-0.45 to 0.04) | |
| Missing | 68 | 78 | 5.6 (5.8) | 4.9 (5.3) | | | |
| Baseline PHQ-9 severity | | | | | | | |
| 10-14 | 123 | 133 | 4.9 (5.5) | 5.7 (5.5) | -0.77 (-2.06 to 0.51) | -0.09 (-0.34 to 0.15) | 0.97 |
| ≥15 | 104 | 93 | 7.3 (6.1) | 8.5 (6.8) | -0.82 (-2.34 to 0.69) | -0.07 (-0.35 to 0.21) | |
| Treatment expectations [3] | | | | | | | |
| None/somewhat | 54 | 59 | 5.7 (5.4) | 7.2 (7.3) | -1.13 (-3.14 to 0.88) | -0.14 (-0.51 to 0.23) | 0.71 |
| Moderate/very useful | 172 | 167 | 6.2 (6.1) | 6.7 (5.8) | -0.68 (-1.73 to 0.38) | -0.11 (-0.32 to 0.11) | |

SD=standard deviation. CI=Confidence Interval. PHQ-9=Patient Health Questionnaire (nine items). THPP=Thinking Healthy Program Peer-delivered, EUC=Enhanced Usual Care. [1] Results from generalised estimating equation models, adjusted for union council, baseline PHQ-9 score, chronicity of depression, and time between screening and childbirth. [2] Models include missing chronicity category, but interaction effects are presented only among those with non missing chronicity. [3] Missing for 1 woman, who is excluded here.

Appendix E: Remission (PHQ-9 <5) at 6 months post-childbirth by potential effect modifiers.

| | N | | N with remission (%) | | Adjusted odds ratio [95% CI] for THPP Plus EUC versus EUC-alone [1] | Adjusted PR [95% CI] for THPP Plus EUC versus EUC-alone [1] | P value for effect modification [1] |
|-----------------------------------|---------------|-----------|----------------------|-----------|---|---|-------------------------------------|
| | THPP Plus EUC | EUC-alone | THPP Plus EUC | EUC-alone | | | |
| Age, years | | | | | | | |
| 18-24 | 71 | 63 | 41 (58%) | 31 (49%) | 1.48 (0.75 to 2.93) | 1.19 (0.83 to 1.54) | 0.57 |
| ≥25 | 156 | 163 | 71 (46%) | 70 (43%) | 1.16 (0.77 to 1.75) | 1.08 (0.85 to 1.31) | |
| Chronicity of depression | | | | | | | |
| <12 weeks | 30 | 24 | 14 (47%) | 8 (33%) | 1.85 (0.60 to 5.68) | 1.42 (0.49 to 2.34) | 0.60 |
| ≥12 weeks | 129 | 124 | 58 (45%) | 49 (40%) | 1.32 (0.91 to 1.92) | 1.16 (0.93 to 1.40) | |
| Missing [2] | 68 | 78 | 40 (59%) | 44 (56%) | | | |
| Baseline PHQ-9 severity | | | | | | | |
| 10-14 | 123 | 133 | 72 (59%) | 68 (51%) | 1.48 (0.93 to 2.35) | 1.19 (0.94 to 1.43) | 0.37 |
| ≥15 | 104 | 93 | 40 (38%) | 33 (35%) | 1.02 (0.58 to 1.79) | 1.02 (0.68 to 1.35) | |
| Treatment expectations [3] | | | | | | | |
| None/somewhat | 54 | 59 | 27 (50%) | 28 (47%) | 1.07 (0.52 to 2.23) | 1.03 (0.69 to 1.38) | 0.62 |
| Moderate/very useful | 172 | 167 | 84 (49%) | 73 (44%) | 1.34 (0.90 to 1.98) | 1.16 (0.93 to 1.38) | |

SD=standard deviation. CI=Confidence Interval. PHQ-9=Patient Health Questionnaire (nine items). THPP=Thinking Healthy Program Peer-delivered, EUC=Enhanced Usual Care. [1] Results from generalised estimating equation models, adjusted for union council, baseline PHQ-9 score, chronicity of depression, and time between screening and childbirth. [2] Not included in the effect modification model. [3] Missing for 1 woman, who is excluded here.

Appendix F: PHQ-9 score and remission at 6 months post-childbirth with data restricted to sensitivity window.

| | THPP Plus EUC (n=227) | EUC-alone (n=226) | Adjusted mean difference or odds ratio (95% CI) for THPP Plus EUC versus EUC-alone [1] | Adjusted SMD or PR (95% CI) for THPP Plus EUC versus EUC-alone [1] | P-value [1] |
|--|------------------------------|--------------------------|---|---|--------------------|
| PHQ-9 score at 6 months, mean (SD) | 6.0 (5.9) | 6.8 (6.2) | -0.80 (-1.65 to 0.06) | -0.13 (-0.31 to 0.06) | 0.07 |
| Restricted to sensitivity window [2] | 6.0 (5.8) | 6.8 (6.2) | -0.71 (-1.68 to 0.25) | -0.11 (-0.31 to 0.09) | 0.15 |
| Remission (PHQ-9 <5) at 6 months, number (%) | 112 (49%) | 101 (45%) | 1.26 (0.92 to 1.73) | 1.12 (0.95 to 1.29) | 0.14 |
| Restricted to sensitivity window [2] | 97 (49%) | 88 (46%) | 1.16 (0.79 to 1.69) | 1.07 (0.88 to 1.27) | 0.46 |

SD=standard deviation. CI=Confidence Interval. PHQ-9=Patient Health Questionnaire (nine items). THPP=Thinking Healthy Program Peer-delivered, EUC=Enhanced Usual Care. [1] Results from generalised estimating equation models, adjusted for union council, baseline PHQ-9 score, chronicity of depression, and time between screening and childbirth. [2] Windows of -1 to +2 months were permitted for the follow-up visits; in sensitivity analyses these were restricted to -0.5 to +1 months. N=199 and 190 the THPP Plus EUC and EUC-alone groups, respectively.

Appendix G: Alternative models for PHQ-9 score at 6 months post-childbirth.

| Model | Mean difference (95% CI) for THPP Plus EUC versus EUC-alone | P value |
|---|---|---------|
| Main result as reported (linear GEE, adjusted for baseline PHQ-9 score, union council, time between screening and delivery, chronicity) [1] | -0.80 (-1.65 to 0.06) | 0.07 |
| As above but adjusted only for baseline PHQ-9 score, union council | -0.81 (-1.67 to 0.05) | 0.07 |
| As above but adjusted only for baseline PHQ-9 score, union council, time between screening and delivery | -0.80 (-1.67 to 0.06) | 0.07 |
| Random effects model (adjusted for baseline PHQ-9 score, union council, time between screening and delivery, chronicity) | -0.83 (-1.91 to 0.25) | 0.13 |
| Linear GEE with multiple imputation for missing outcome data [2] | -0.93 (-1.87 to 0.02) | 0.06 |

| Model | Ratio of mean PHQ-9 score (95% CI) for THPP Plus EUC versus EUC-alone | P value |
|-----------------|---|---------|
| Poisson GEE [3] | 0.89 (0.78 to 1.01) | 0.08 |

| | Ratio of mean PHQ-9 score (95% CI) for THPP Plus EUC versus EUC-alone | P value |
|---|---|---------|
| Poisson random effects with gamma distribution for random effects [3] | 0.89 (0.78 to 1.00) | 0.05 |

| | Ratio of mean PHQ-9 score (95% CI) for THPP Plus EUC versus EUC-alone | P value |
|--|---|---------|
| Poisson random effects with normal distribution for random effects [3] | 0.88 (0.77 to 1.01) | 0.07 |

| | Ratio of mean PHQ-9 score (95% CI) for THPP Plus EUC versus EUC-alone | P value |
|-----------------------|---|---------|
| Negative binomial GEE | 0.91 (0.77 to 1.07) | 0.25 |

| | Ratio of mean PHQ-9 score (95% CI) for THPP Plus EUC versus EUC-alone | P value |
|----------------------------------|---|---------|
| Negative binomial random effects | 0.86 (0.72 to 1.02) | 0.09 |

SD=standard deviation. CI=Confidence Interval. PHQ-9=Patient Health Questionnaire (nine items). THPP=Thinking Healthy Program Peer-delivered, EUC=Enhanced Usual Care. GEE=generalised estimating equations. [1] P values for the adjustment variables are: baseline PHQ-9 score, p<0.001; union council, p=0.03; time between screening and birth of the child, p=0.47; chronicity of depression, p=0.17. [2] Multiple imputation performed using treatment arm, union council, baseline PHQ-9 score, chronicity and village cluster, with 20 replications (GEE). [3] Poisson models with robust standard errors to allow for over dispersion.

Appendix H: Alternative models for remission at 6 months post-childbirth.

| Model | Odds ratio (95% CI) for THPP Plus EUC versus EUC-alone | P value |
|---|---|----------------|
| Main result as reported (logistic GEE, adjusted for baseline PHQ-9 score, union council, time between screening and delivery, chronicity) [1] | 1.26 (0.92 to 1.73) | 0.14 |
| As above but adjusted only for baseline PHQ-9 score, union council | 1.24 (0.90 to 1.71) | 0.18 |

| Model | Odds ratio (95% CI) for THPP Plus EUC versus EUC-alone | P value |
|---|---|----------------|
| As above but adjusted only for baseline PHQ-9 score, union council, time between screening and delivery | 1.24 (0.90 to 1.71) | 0.18 |

| Model | Odds ratio (95% CI) for THPP Plus EUC versus EUC-alone | P value |
|--|---|----------------|
| Random effects model (adjusted for baseline PHQ-9 score, union council, time between screening and delivery, chronicity) [2] | 1.27 (0.86 to 1.86) | 0.23 |

| Model | Odds ratio (95% CI) for THPP Plus EUC versus EUC-alone | P value |
|--|---|----------------|
| Logistic GEE with multiple imputation for missing outcome data [3] | 1.28 (0.91 to 1.79) | 0.15 |

SD=standard deviation. CI=Confidence Interval. PHQ-9=Patient Health Questionnaire (nine items). THPP=Thinking Healthy Program Peer-delivered, EUC=Enhanced Usual Care. GEE=generalised estimating equations. [1] P values for the adjustment variables are: baseline PHQ-9 score, p=0.009; union council, p=0.02; time between screening and birth of the child, p=0.96; chronicity of depression, p=0.09. [2] Problems identified with the quadrature integration. [3] Multiple imputation performed using treatment arm, union council, baseline PHQ-9 score, chronicity and village cluster, with 20 replications (GEE).

Appendix I: Serious adverse events (SAEs).

| | THPP plus EUC (n=283) | EUC-alone (n=287) | P-value [1] | Total (n=570) |
|--------------------------------------|--------------------------|----------------------|-------------|---------------|
| Participants with at least one SAE | 43 (15%) | 47 (16%) | 0.72 | 90 (16%) |
| Participants with at least one: | | | | |
| Death of participants | 0 | 0 | - | 0 |
| Loss of child | 24 (8%) | 25 (9%) | 0.92 | 49 (9%) [2] |
| Suicide attempt | 2 (1%) | 0 | - | 2 (<1%) |
| Hospitalisation [3] | 9 (3%) | 11 (4%) | 0.66 | 20 (4%) |
| Victimisation [4] | 7 (2%) | 9 (3%) | 0.63 | 16 (3%) |
| Infant abuse/neglect [5] | 2 (1%) | 2 (1%) | 0.98 | 4 (1%) |
| Stigmatisation [6] | 1 (<1%) | 0 | - | 1 (<1%) |
| Reported violence towards others [7] | 0 | 1 (<1%) | - | 1 (<1%) |

SAE= Severe Adverse Events. THPP=Thinking Healthy Program Peer-delivered. EUC=Enhanced Usual Care. Values are number of women experiencing this event at least once (not the total number of events) and column % of those enrolled. Each woman could have more than one type of SAE and therefore could be counted more than once in the table (aside from the first row): one woman had victimisation, infant abuse; one woman had suicide attempt; one woman had victimisation and stigmatisation; one woman had suicide attempt and (child) hospitalisation; one woman had victimisation and violence towards others. [1] P-values were calculated from logistic generalised estimating equation models with outcome of each respective SAE, treatment arm as the dependent variable and village-cluster as the panel variable. [2] Including two still births; excluding one abortion. There were no miscarriages. All child deaths occurred before 3 months old (and therefore the women were discontinued from the trial). [3] Includes unplanned mother hospitalisations, and all child hospitalisations. Of the 20 hospitalisations shown, 1 was of the mother (EUC-alone group) and 19 were of the child (9 in THPP Plus EUC group and 10 in EUC-alone group). [4] Based on responding "yes" at the 3 or 6 month visits to the question "Have you experienced any physical violence e.g. being hit or slapped, since you joined the study?". [5] Based on responding "yes" at the 3 or 6-month visits to the question "Has there been any indication during the assessment that the infant might have been physically abused or neglected? Examples of this are: Violent shaking of a crying baby, Child being very ill/dehydrated/sluggish/crying excessively and is not being attended by the TP". [6] Based on responding "a little", "somewhat" or "a lot" at the 3 or 6 month visits to any of the four questions "Did you feel uncomfortable or worried because you thought other people might find out about your problem, make negative comments or treat you differently since you joined the study?", "Did your family members feel uncomfortable or worried because they thought other people might find out about your problem, make negative comments or treat you differently since you joined the study?", "Did you feel uncomfortable or worried because you felt other people were making negative comments or treating you differently since you joined the study?", "Did your family members feel uncomfortable or worried because they felt other people were making negative comments or treating you differently since you joined the study?". The single stigmatisation SAE was a woman who responded "a lot" to the final of the four questions indicated above at her month 6 visit (she responded "not at all" to the other three questions at the 6-month visit, and to all four questions at the 3 month visit). [7] Based on responding "a little", "somewhat" or "a lot" at the 3 or 6 month visits to the question "From the time you began participating in our study, have you hurt somebody else, for example, by slapping your other children?".

Appendix J: Health system service utilisation costs comparison between THPP plus EUC and EUC-alone arms over total trial period (3rd trimester to 6 months post childbirth) (US\$, 2015)

| Type of Service Utilised | THPP plus EUC Mean cost (SD) [CI 95%] | EUC-alone Mean cost (SD) [CI 95%] | Difference in (SD, CI 95%) (THPP plus EUC – EUC-alone) |
|---|---|---|---|
| PHC Doctor (Primary Health Care) | 0.17 (1.23) [-0.03 to 0.37] | 0.21 (0.94) [0.04 to 0.37] | -0.036 [-0.23 to 0.302] |
| Lady Health Visitor – | 4.97 (8.92) [0.54 to 9.40] | 6.18 (14.39) [-1.71 to 14.1] | -1.20 [-7.09 to 9.52] |
| Community Midwife – CMW | 8.23 (12.09) [-1.79 to 18.41] | 6.11 (6.09) [1.43 to 10.81] | -2.17 [11.9 to 7.55] |
| Vaccinator** | 16.62 (4.51) [17.40 to 18.53] | 6.82 (4.77) [8.38 to 9.54] | 9.79 [-34.76 to 54.36] |
| Specialist Doctor (Public Hospital) *** | 1.44 (5.23) [0.49 to 0.24] | 2.55 (8.45) [0.9 to 4.2] | -1.11 [-0.72 to 2.94] |
| Specialist Doctor (Private Hospital) | 10.3 (11.92) [8.56 – 12] | 11.18 (14.57) [9.02 to 12.97] | -0.9 [-1.83 to 3.63] |
| Traditional healers or Traditional birth attendant | 0.82 (1.32) [0.37 – 1.272] | 1.27 (2.23) [0.35 to 2.19] | -0.45 [-0.46 to 1.36] |
| Inpatient/In- door/admission | 66.62 (96.17) [45.62 – 87.62] | 86 (112.21) [60.87 to 111.14] | -19.38 [-12.9 to 51.75] |
| Intervention costs | 133.55* | 0 | |
| Total Health System Costs (incl. intervention) In US\$ | 150.02 [144.30 to 155.75] | 136.69 [131.29 to 142.09] | 19.19 [-22.98 to 61.37] |
| Productivity Cost In US\$ | 51.69 [49.50 to 53.89] | 53.01 [51.04 to 54.97] | -1.71 [-4.27 to 6.77] |
| Total Societal Cost (Heath System + Productivity Cost) In US\$ | 201.73 [197.14 to 206.31] | 189.70 [184.90 to 194.51] | 17.48 [-33.28 to 68.25] |

Note: Average value of exchange rates from Oct 2014 to Feb 2017 were taken to be @ \$1=Rs105 (implementation duration). SD=standard deviation. CI=Confidence Interval. PHQ-9=Patient Health Questionnaire (nine items). THPP=Thinking Healthy Program Peer-delivered, EUC=Enhanced Usual Care. US\$= United States Dollar. PHC=Primary Health Care

*The cost of intervention included the development costs (sketches, formatting etc), printing costs for 66 peers and about 300 participants in the intervention arm, training costs, travel costs of peer to attend training and supervisions, hand bags for the peers, mobile phones and monthly top-up for the peers to help stay in touch with their supervisors

** Cost of vaccinator does not include the cost of vaccines. *** Includes Gynaecologist, Obstetrician and/or General Surgeon

Appendix K: 3rd month post-childbirth health system service utilisation costs comparison between THPP plus EUC and EUC-alone (from 3rd trimester to 3rd month post-childbirth) (US\$, 2015)

| Type of Services Utilised | THPP plus EUC Mean cost (SD) [CI 95%] | EUC Mean cost (SD) [CI 95%] | Difference in (SD, CI 95%) (THPP plus EUC – EUC- alone) |
|---|---|-------------------------------------|--|
| PHC Doctor (Primary Health Care) | 0.16 (1.23) [-0.06 to 0.384] | 0.13 (0.65) [0.008 to 0.252] | 0.03 [-0.31 to 0.25] |
| Lady Health Visitor | 5.77(11.73) [-2.89 to 13.89] | 11.21 (20.46) [-7.5 to 30.14] | -5.44 [-8.92 to 18.86] |
| Vaccinator | 4.04 (4.14) [-2.54 to 10.63] | 0.47 (1 obs**) | 3.57 |
| Community Midwife – CMW | 8.29 (12.10) [-1.82 to 18.41] | 6.65 (6.30) [1.38 to 11.91] | 1.65 [-11.99 to 8.69] |
| Specialist Doctor*** (Public Hospital) | 1.45 (5.55) [0.36 to 266.68] | 2.65 (8.82) [0.84 to 4.45] | -1.19 [-0.86 to 3.25] |
| Specialist Doctor (Private Hospital) | 8.44 (11.82) [6.59 to 10.28] | 10.21 (14.84) [7.77 to 12.67] | -1.77 [-1.24 to 4.79] |
| Traditional healers or traditional birth attendant | 0.97 (1.49) [0.32 to 1.61] | 1.72 (2.69) [0.29 to 3.16] | -0.75 [-0.61 to 2.12] |
| Inpatient/In-door/admission | 67.52 (96.51) [46.31 to 88.73] | 90.98 (113.46) [64.88 to 117.09] | 23.46 [-9.6 to 56.59] |
| Total Health System Costs | 143.96 [138.06 to 149.86] | 140.15 [134.68 to 145.61] | 9.95 [-35.29 to 55.20] |
| Total productivity costs | 35.02 [33.28 to 36.75] | 37.92 [36.39 to 39.44] | -3.39 [-20.67 to 13.87] |
| Societal cost | 178.97 [174.30 to 183.65] | 178.07 [173.44 to 182.69] | 6.56 [-44.02 to 57.13] |

Note: Average value of exchange rates from Oct 2014 to Feb 2017 taken to be @ \$1=Rs105 (implementation duration); Obs**: Observation. Cost of vaccinator does not include the cost of vaccines

*** Includes Gynaecologist, Obstetrician and/or General Surgeon

SD=standard deviation. CI=Confidence Interval. PHQ-9=Patient Health Questionnaire (nine items). THPP=Thinking Healthy Program Peer-delivered, EUC=Enhanced Usual Care. US\$= United States Dollar. PHC=Primary Health Care

Appendix L: 6-month post-childbirth health system service utilisation costs comparison between THPP plus EUC and EUC-alone (from 3rd to 6 months post-childbirth)(US\$, 2015)

| Type of Services Utilised | THPP plus EUC Mean cost (SD) [CI 95%] | EUC Mean cost (SD) [CI 95%] | Difference in (SD, CI 95%) (THPP plus EUC – EUC- alone) |
|--|---|-----------------------------------|--|
| PHC Doctor (Primary Health Care) | 0.09 (0.36) [-0.01 to 0.204] | 0.42 (1.06) [0.008 to 0.85] | -0.34 [-0.015 to 0.69] |
| Lady Health Visitor – | 3.09 (3.04) [-1.75 to 7.94] | 1.58 (1.45) [-2.02 to 5.2] | 1.50 [-6.47 to 3.47] |
| Vaccinator* | 3 (0.87) [-4.86 to 10.86] | 2.26 (1.95) [-0.85 to 10.86] | 0.74 [-4.94 to 3.47] |
| Specialist Doctor** (Public Hospital) | 0.73 (1.82) [0.047 to 1.41] | 0.56 (1.17) [0.07 to 1.41] | 0.16 [-1.01 to 0.68] |
| Specialist Doctor (Private Hospital) | 5.88 (5.45) [4.8 to 6.97] | 5.18 (5) [4.12 to 6.18] | 0.702 [-2.16 to 0.75] |
| Traditional healers or traditional birth attendant | 0.48 (0.89) [-0.006 to 0.93] | 0.47 (0.47) [0.11 to 0.84] | 0.012 [-0.68 to 0.65] |
| Inpatient/In- door/admission | 18.32 (12.85) [2.36 to 34.28] | 16.02 (24) [-4.04 to 36.09] | 2.29 [-28.22 to 23.62] |
| Health System Costs | 17.32 [16.96 to 17.68] | 13.16 [12.84 to 13.47] | 4.08 [-1.97 to 10.13] |
| Productivity costs | 22.3667 [21.50 to 23.23] | 24.10 [23.29 to 24.91] | -1.76 [-18.45 to 14.91] |
| Societal costs | 39.69 [38.49 to 40.89] | 37.26 [36.17 to 38.36] | 2.32 [-18.04 to 22.68] |

Note: Average value of exchange rates from Oct 2014 to Feb 2017 taken to be @ \$1=Rs105 (implementation duration). SD=standard deviation. CI=Confidence Interval. PHQ-9=Patient Health Questionnaire (nine items). THPP=Thinking Healthy Program Peer-delivered, EUC=Enhanced Usual Care. US\$= United States Dollar. PHC=Primary Health Care. * Cost of vaccinator does not include the cost of vaccines. ** Includes Gynaecologist, Obstetrician and/or General Surgeon

Appendix M: Mean Outdoor and In-Patient Visits

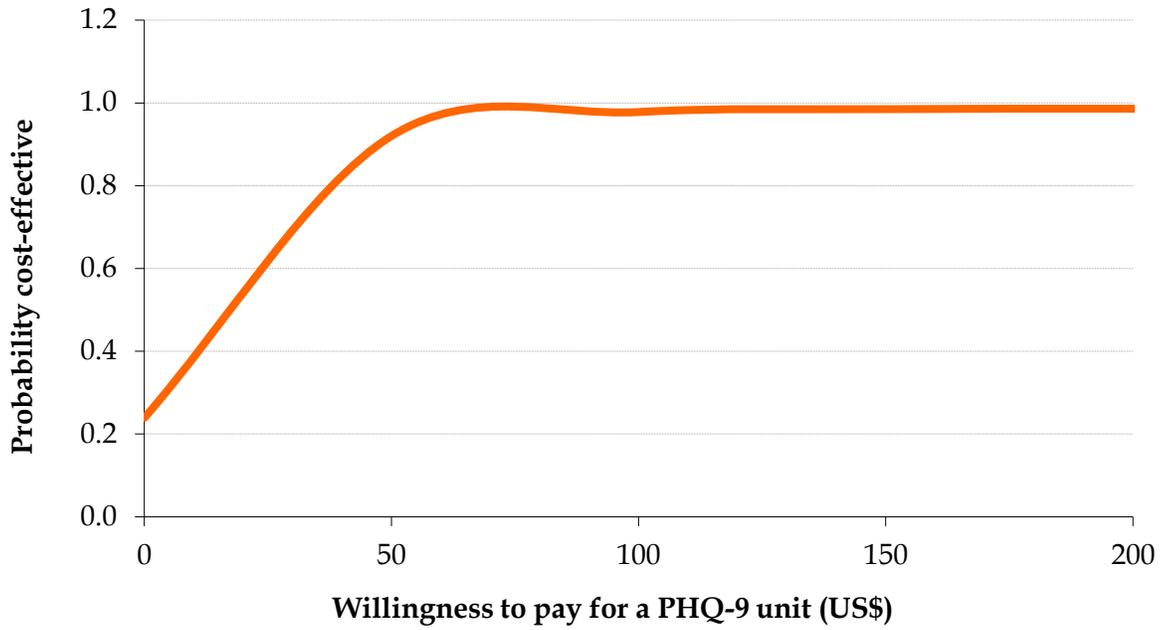
| Hospital Mean Outdoor (OPD) & In-patient Visits from 3 rd trimester to 6-month post childbirth period | | |
|--|---|---------------------------------------|
| Category | THPP plus EUC Mean visits (SD) [CI 95%] | EUC Mean Visits (SD) [CI 95%] |
| Outdoor (OPD) visits | N=104 3.81 (2.82) [3.26 to 4.35] | N=94 3.58 (2.54) [3.06 to 4.11] |
| In-patient visits | N=79 1.05 (0.22) [1.00 to 1.10] | N=72 1.11 (0.46) [1.00 to 1.22] |
| Hospital Mean Outdoor (OPD) & In-patient Visits from 3 rd trimester to 3-month post childbirth period | | |
| Category | THPP plus EUC Mean visits (SD) [CI 95%] | EUC Mean Visits (SD) [CI 95%] |
| Outdoor (OPD) visits | N=95 3.63 (2.58) [3.11 to 4.16] | N=87 3.46 (2.30) [2.97 to 3.95] |
| In-patient visits | N=78 1.04 (0.19) [0.99 to 1.08] | N=72 1.05 (0.28) [0.99 to 1.12] |
| Hospital Mean Outdoor OPD & In-patient Visits from 3 rd month post childbirth to 6 th month post childbirth period | | |
| Category | THPP plus EUC Mean visits (SD) [CI 95%] | EUC Mean Visits (SD) [CI 95%] |
| Outdoor (OPD) visits | N=18 2.83 (2.18) [1.75 to 3.91] | N=13 2.77 (1.79) [1.69 to 3.85] |
| In-patient visits | N=2 1 (0) [1.00 to 1.00] | N=2 2 (1.41) [-10.71 to 14.71] |

Appendix N: Summary of unit costs used in cost estimations

| Category | Unit cost (in US\$) | Source |
|--------------------------------------|----------------------------|----------------------------|
| LHWs | 0.07 per minute | Unit Cost study conducted* |
| LHVs | 0.057 per minute | Unit Cost study conducted* |
| Doctor Consultation | 0.234 per minute | Unit Cost study conducted* |
| Vaccinator | 0.074 per minute | Unit Cost study conducted* |
| CMW | 0.072 per minute | Unit Cost study conducted* |
| Compounder/dispenser | 0.078 per minute | Unit Cost study conducted* |
| Psychologist/Counsellor | 0.125 per minute | Unit Cost study conducted* |
| Gynaecologist Consultation | 0.451 per day | Unit Cost study conducted* |
| Hospital in-patient bed (government) | 28.57 per day | Unit Cost study conducted* |
| Hospital in-patient bed (private) | 47.61 per day | Unit Cost study conducted* |
| Productivity Costs | | |
| | Unit cost (in US\$) | |
| LHWs | 0.24 per contact | Unit Cost study conducted* |
| LHVs | 0.79 per contact | Unit Cost study conducted* |
| Doctor Consultation | 0.99 per contact | Unit Cost study conducted* |
| Vaccinator | 0.33 per contact | Unit Cost study conducted* |
| CMW | 0.66 per contact | Unit Cost study conducted* |
| Compounder/dispenser | 0.99 per contact | Unit Cost study conducted* |
| Psychologist/Counsellor | 2.64 per contact | Unit Cost study conducted* |
| Gynaecologist Consultation | 3.14 per contact | Unit Cost study conducted* |
| **Hospital in-patient (per day) | 5.13 per day | Unit Cost study conducted* |

*Note: Unit cost study was conducted specifically for SHARE trial. Information was collected from district and provincial level programs (through official reports and key informant interviews with program personnel) as well as private sector ad-hoc surveys to document the costs. ** Hospital in-patient unit cost of lost productivity calculated per day, while all other services calculated as per contact

Appendix O: Cost Effectiveness Acceptability Curve for PHQ-9



NOTE: Over a willingness-to-pay threshold of US\$ 60 per unit improvement on PHQ-9, THPP+EUC was found to have an 98% probability of being a cost-effective choice compared to EUC alone

Appendix P: Primary outcome PHQ-9 score and remission at 6 months post-childbirth with Adjusted Mean Differences & Odds Ratio for future reference (not referred to in the main paper).

| | THPP plus EUC (n=227) | EUC-alone (n=226) | Adjusted mean difference or odds ratio (95% CI) for THPP plus EUC versus EUC-alone | Adjusted SMD or PR (95% CI) for THPP plus EUC versus EUC-alone | p-value [1] |
|---|------------------------------|--------------------------|---|---|--------------------|
| PHQ-9 score at 6 months, mean (SD) | 6.0 (5.9) | 6.8 (6.2) | -0.80 (-1.65 to 0.06) | -0.13 (-0.31 to 0.06) | 0.07 |
| Remission (PHQ-9<5) at 6 months, number (%) | 112 (49%) | 101 (45%) | 1.26 (0.92 to 1.73) | 1.12 (0.95 to 1.29) | 0.14 |

[1] Results from generalised estimating equation models, adjusted for union council, baseline PHQ-9 score, chronicity of depression, and time between screening and childbirth THPP= Thinking Healthy Programme delivered by peers. EUC=enhanced usual care. PHQ-9=Patient Health Questionnaire 9. PR=Prevalence Ratio. SD=Standard Deviation. SMD=Standardised Mean Difference.

Appendix Q: Secondary outcomes with Adjusted Mean Differences & Odds Ratio for future reference (not referred to in the main paper).

| | N | | Mean (SD) or n (%) | | Adjusted mean difference or OR (95% CI) for THPP plus EUC vs EUC-alone [1] | Adjusted SMD or PR (95% CI) for THPP plus EUC vs EUC-alone [1] | p-value |
|--|---------------|-----------|--------------------|-------------|--|--|---------|
| | THPP plus EUC | EUC-alone | THPP plus EUC | EUC-alone | | | |
| Categorical variables | | | | | | | |
| Remission (PHQ-9<5) at 3 months | 223 | 211 | 112 (50%) | 93 (44%) | 1.39 (1.13 to 1.71) | 1.18 (1.06 to 1.29) | 0.002 |
| Response (PHQ-9 <10) at 3 months | 223 | 211 | 169 (76%) | 139 (66%) | 1.74 (1.21 to 2.50) | 1.17 (1.05 to 1.29) | 0.003 |
| Response (PHQ-9 <10) at 6 months | 227 | 226 | 172 (76%) | 156 (69%) | 1.39 (0.98 to 1.98) | 1.09 (0.99 to 1.19) | 0.07 |
| Recovery (PHQ-9<5 at both 3 and 6 months) | 209 | 197 | 74 (35%) | 51 (26%) | 1.62 (1.19 to 2.21) | 1.36 (1.09 to 1.63) | 0.002 |
| Response I (PHQ-9<10 at both 3 and 6 months) | 209 | 197 | 132 (63%) | 102 (52%) | 1.60 (1.15 to 2.22) | 1.21 (1.05 to 1.37) | 0.005 |
| Response II (≥50% reduction from baseline in PHQ-9 at both 3 and 6 months) | 209 | 197 | 111 (53%) | 78 (40%) | 1.67 (1.19 to 2.33) | 1.30 (1.08 to 1.53) | 0.003 |
| Exclusive breastfeeding in last 24 hours | | | | | | | |
| 3 months | 223 | 211 | 99 (44%) | 98 (46%) | 0.89 (0.66 to 1.23) | 0.94 (0.77 to 1.10) | 0.48 |
| 6 months | 227 | 226 | 18 (8%) | 19 (8%) | 0.87 (0.45 to 1.68) | 0.89 (0.38 to 1.40) | 0.69 |
| Continuous variables | | | | | | | |
| PHQ-9 score at 3 months | 223 | 211 | 6.1 (5.6) | 7.8 (6.9) | -1.96 (-2.71 to -1.21) | -0.30 (-0.48 to -0.11) | <0.001 |
| WHO-DAS complex score | | | | | | | |
| 3 months | 223 | 210 [2] | 15.5 (19.0) | 17.5 (18.3) | -3.03 (-4.56 to -1.50) | -0.15 (-0.34 to 0.03) | <0.001 |
| 6 months | 227 | 226 | 15.8 (19.8) | 18.2 (21.8) | -2.36 (-6.22 to 1.50) | -0.11 (-0.29 to 0.08) | 0.23 |
| Number of days unable to work in past 30 days | | | | | | | |
| 3 months | 223 | 210 [2] | 1.3 (4.4) | 1.5 (4.7) | -0.33 (-1.00 to 0.35) | -0.07 (-0.26 to 0.12) | 0.35 |
| 6 months | 227 | 226 | 1.1 (4.0) | 1.0 (3.6) | 0.07 (-0.31 to 0.45) | 0.02 (-0.17 to 0.20) | 0.71 |
| MSPSS score | | | | | | | |
| 3 months | 223 | 211 | 4.5 (1.2) | 4.4 (1.3) | 0.13 (-0.04 to 0.30) | 0.10 (-0.08 to 0.29) | 0.12 |
| 6 months | 227 | 226 | 4.7 (1.3) | 4.4 (1.4) | 0.29 (0.07 to 0.50) | 0.20 (0.02 to 0.39) | 0.007 |

| | | | | | | | |
|---|------------|------------|-----------------|-----------------|-----------------------|-----------------------|------|
| Height for age z score | | | | | | | |
| 3 months | 220 [3] | 210 [3] | 0.20 (1.73) | 0.05 (1.78) | 0.09 (-0.21 to 0.40) | 0.05 (-0.14 to 0.24) | 0.55 |
| 6 months | 226 [4] | 223 [4] | 0.26 (1.70) | 0.07 (1.92) | 0.15 (-0.13 to 0.42) | 0.08 (-0.11 to 0.26) | 0.29 |
| Height for age z score – sensitivity [16] | | | | | | | |
| 3 months | 217 | 207 | 0.14 (1.65) | 0.01 (1.69) | 0.09 (-0.21 to 0.40) | - | 0.55 |
| 6 months | 223 | 220 | 0.29 (1.69) | 0.14 (1.74) | 0.13 (-0.13 to 0.40) | - | 0.33 |
| Weight for age z score | | | | | | | |
| 3 months | 220 [5] | 209 [5] | -1.25 (1.25) | -1.17 (1.22) | -0.11 (-0.32 to 0.11) | -0.08 (-0.28 to 0.11) | 0.32 |
| 6 months | 226 [6] | 224 [6] | -0.90 (1.24) | -0.85 (1.18) | -0.07 (-0.28 to 0.14) | -0.06 (-0.24 to 0.13) | 0.50 |

[1] Adjusted for union council, baseline PHQ-9 score, chronicity of depression, and time between screening and childbirth. MSPSS=Multidimensional Scale of Perceived Social Support. THPP= Thinking Healthy Programme delivered by peers. EUC=enhanced usual care. PHQ-9=Patient Health Questionnaire 9. WHO-DAS=WHO -Disability Assessment Schedule. PR=Prevalence Ratio. SD=Standard Deviation. SMD=Standardised Mean Difference. [2] WHO-DAS responses missing for one woman at month 3 visit (woman refused to continue the interview). [3] Height at 3 months missing for 3 and 1 children in THPP plus EUC and EUC-alone, respectively (THPP plus EUC: 1 child ill and 2 no plain surface available; EUC-alone: child unsettled). [4] Height at 6 months missing for 1 and 3 children in THPP plus EUC and EUC-alone, respectively (THPP plus EUC: child not present; EUC-alone: 1 child unsettled, 1 no place available, 1 mother refused). [5] Weight at 3 months missing for 3 and 2 children in THPP plus EUC and EUC-alone, respectively (THPP plus EUC: 1 child ill and 2 equipment not working; EUC-alone: 2 equipment not working). [6] Weight at 6 months missing for 1 and 2 children in THPP plus EUC and EUC-alone, respectively (THPP plus EUC: child not present; EUC: 1 child unsettled, 1 equipment not working).