IPMH PPW RCT Survey Weekly Report

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# Enrollment Status

Altogether, we currently have data for 980 participants.

## Consort Diagram

## Enrollment Per Facility

Table 1: Summary of Study Enrollment by Facility

Showing Participants enrollments

| Facility | Screened | Eligible | Enrolled | % Enrolled (of Eligible) |
| --- | --- | --- | --- | --- |
| **Overall** | **1649** | **1035** | **980** | **94.7** |
| Nyalenda Health Centre | 120 | 68 | 63 | 93.0 |
| Ndiru Level 4 Hospital | 107 | 58 | 56 | 97.0 |
| Akala Health Centre | 93 | 55 | 55 | 100.0 |
| Airport Health Centre (Kisumu) | 131 | 55 | 55 | 100.0 |
| Usigu Health Centre | 60 | 54 | 54 | 100.0 |
| Miriu Health Centre | 60 | 53 | 52 | 98.0 |
| Gita Sub County Hospital | 61 | 53 | 52 | 98.0 |
| Sigomere Sub County Hospital | 53 | 51 | 51 | 100.0 |
| Mbita Sub-County Hospital | 84 | 56 | 51 | 91.0 |
| Madiany Sub County Hospital | 54 | 49 | 49 | 100.0 |
| Rwambwa Sub-county Hospital | 106 | 58 | 48 | 83.0 |
| Ukwala Sub County Hospital | 91 | 56 | 48 | 86.0 |
| Kabondo Sub County Hospital | 95 | 49 | 47 | 96.0 |
| Simenya Health Centre | 97 | 53 | 47 | 89.0 |
| Nyandiwa Level IV Hospital | 130 | 47 | 46 | 98.0 |
| Uyawi Sub County Hospital | 64 | 50 | 45 | 90.0 |
| Ramula Health Centre | 89 | 46 | 45 | 98.0 |
| Mirogi Health Centre | 54 | 43 | 41 | 95.0 |
| Got Agulu Sub-District Hospital | 48 | 38 | 38 | 100.0 |
| Ober Kamoth Sub County Hospital | 52 | 43 | 37 | 86.0 |

## Follow-up Tracking Per Facility

# Baseline Information

## PPW Demographics

Table 1: Basic Demographic Summary

| **Characteristic** | **N** | **N = 980***1* |
| --- | --- | --- |
| **Age (Years)** | 980 | 25.0 [IQR: 21.0, 30.0] |
| **Ever been pregnant (Yes)** | 980 | 703 (72%) |
| **Total Pregnancies (incl.current)** | 980 | 2.0 [IQR: 1.0, 4.0] |
| **Do you currently have a partner (Yes)** | 978 | 828 (85%) |
| **Currently Married (Yes)** | 980 | 738 (75%) |
| **Marriage(Monogamous)** | 738 | 657 (89%) |
| **Shares residence with partner (Yes)** | 829 | 690 (83%) |
| **Currently in School** | 980 | 96 (9.8%) |
| **Completed years in School** | 980 | 12.0 [IQR: 9.0, 14.0] |
| **Do you have regular employment (Yes)** | 980 | 90 (9.2%) |
| **Number of people in Household** | 980 | 4.0 [IQR: 3.0, 5.0] |
| **Number of people sleep in same house** | 980 | 3.0 [IQR: 2.0, 5.0] |
| **Rooms in the house most often sleep in** | 980 | 2.0 [IQR: 1.0, 3.0] |
| **Time to the Clinic (Minutes** | 980 | 30.0 [IQR: 20.0, 45.0] |
| *1*Median [IQR: Q1, Q3]; n (%) | | |

# Treatment Tracking (Routine Databases)

## PM+ and Telepsychiatry Referrals

Table 1: Study Participants Who Received PM+

Showing Study Participants Who Received PM+

| **Characteristic** | **N = 107***1* |
| --- | --- |
| Facility |  |
| Kabondo SCH | 18 (17%) |
| Ndiru Level 4 | 18 (17%) |
| Uyawi SCH | 18 (17%) |
| Airport HC (Kisumu) | 10 (9.3%) |
| Miriu HC | 10 (9.3%) |
| Usigu HC | 9 (8.4%) |
| Ramula HC | 8 (7.5%) |
| Rwambwa SCH | 7 (6.5%) |
| Got Agulu SCH | 5 (4.7%) |
| Ober Kamoth SCH | 4 (3.7%) |
| Pre-intervention PSYCHLOPS measurement | 100 (93%) |
| Session 1 content | 80 (75%) |
| Session 2 content | 65 (61%) |
| Session 3 content | 61 (57%) |
| Session 4 content | 53 (50%) |
| Session 5 content | 42 (39%) |
| Post-intervention PSYCHLOPS measurement | 42 (39%) |
| *1*n (%) | |

Table 1: None study Participants Who Received PM+

Showing None Study Participants Who Received PM+

| **Characteristic** | **N = 47***1* |
| --- | --- |
| Facility |  |
| Rwambwa Sub-county Hospital | 16 (34%) |
| Ndiru Level 4 Hospital | 8 (17%) |
| Ramula Health Centre | 7 (15%) |
| Airport Health Centre (Kisumu) | 5 (11%) |
| Uyawi Sub County Hospital | 4 (8.5%) |
| Got Agulu Sub-District Hospital | 3 (6.4%) |
| Kabondo Sub County Hospital | 3 (6.4%) |
| Miriu Health Centre | 1 (2.1%) |
| Pre-Intervention Psychlops | 30 (64%) |
| Session 1 content | 22 (47%) |
| Session 2 content | 16 (34%) |
| Session 3 content | 13 (28%) |
| Session 4 content | 9 (19%) |
| Session 5 content | 6 (13%) |
| Post-intervention PSYCHLOPS measurement | 5 (11%) |
| *1*n (%) | |

Table 1: Participants Referred to Telepsychiatry

Showing Participants Referred to Telepsychiatry

| **Characteristic** | **N = 11***1* |
| --- | --- |
| Facility |  |
| 17, Ramula Health Centre | 4 (36%) |
| 07, Kabondo Sub County Hospital | 3 (27%) |
| 13, Ober Kamoth Sub County Hospital | 3 (27%) |
| 16, Usigu Health Centre | 1 (9.1%) |
| *1*n (%) | |

## Overall PM+ Retention

PM+ Session Tracking for Study Participants

| pm\_session | round | delay | on time | early attendance |
| --- | --- | --- | --- | --- |
| Post-intervention PSYCHLOPS measurement | 1 | 14 (33.3%) | 28 (66.7%) | - |
| Pre-intervention PSYCHLOPS measurement | 1 | 4 (4%) | 94 (94%) | 2 (2%) |
| Session 1 content | 1 | 16 (20%) | 64 (80%) | - |
| Session 2 content | 1 | 19 (29.2%) | 46 (70.8%) | - |
| Session 3 content | 1 | 19 (31.1%) | 42 (68.9%) | - |
| Session 4 content | 1 | 15 (28.3%) | 37 (69.8%) | 1 (1.9%) |
| Session 5 content | 1 | - | 42 (100%) | - |
| Post-intervention PSYCHLOPS measurement | 2 | - | 2 (100%) | - |
| Pre-intervention PSYCHLOPS measurement | 2 | 2 (66.7%) | 1 (33.3%) | - |
| Session 1 content | 2 | - | 1 (100%) | - |
| Session 2 content | 2 | 1 (50%) | 1 (50%) | - |
| Session 3 content | 2 | 2 (66.7%) | 1 (33.3%) | - |
| Session 4 content | 2 | 2 (66.7%) | 1 (33.3%) | - |
| Session 5 content | 2 | - | 2 (100%) | - |
| Session 1 content | 3 | - | 1 (100%) | - |
| Session 3 content | 3 | - | 1 (100%) | - |
| Notes: On time is defined as within a 14 day window since last attendance | | | | |

# Severe Adverse Events (SAEs)

## Percent of SAEs reported to ERC

| Event | Number of Events | SAE Reported | % Reported |
| --- | --- | --- | --- |
| Death (Infant or Maternal) (SAE) | 11 | 11 | 100 |
| Miscarriage or stillbirth (loss of pregnancy) (SAE) | 7 | 7 | 100 |
| New/prolonged hospitalization (SAE) | 1 | 1 | 100 |

# Follow-up Data (PPW Longitudinal Survey)

## Pregnancy Outcomes

| **Pregnancy Outcome** | **N** | **N = 621***1* |
| --- | --- | --- |
| **Live birth** | 610 | 607 (100%) |
| **Gestational age at birth (weeks)** | 579 | 39.3 (37.7, 40.9) |
| **Place of delivery** | 607 |  |
| Health Facility |  | 599 (99%) |
| Home |  | 7 (1.2%) |
| Other |  | 1 (0.2%) |
| **Mode of delivery** | 607 |  |
| Cesarian Section (C-section) |  | 66 (11%) |
| Vaginal delivery |  | 541 (89%) |
| *1*n (%); Median (Q1, Q3) | | |

## Infant Outcomes

| **Infant Outcome** | **N** | **N = 621***1* |
| --- | --- | --- |
| **Infant status** | 608 |  |
| Alive |  | 598 (98%) |
| Dead |  | 10 (1.6%) |
| **Infant sex** | 606 |  |
| Female |  | 317 (52%) |
| Male |  | 289 (48%) |
| **Birth weight (kg)** | 547 | 3.20 (3.00, 3.60) |
| **Birth length (cm)** | 353 | 49.0 (45.0, 52.0) |
| **Twin birth** | 604 | 8 (1.3%) |
| **Infant illness prior to today's visit** | 606 | 41 (6.8%) |
| **Infant hospitalization prior to today's visit** | 606 | 5 (0.8%) |
| **Currently breastfeeding** | 599 | 596 (99%) |
| **Fed infant any drink or food other than breastmilk** | 596 | 43 (7.2%) |
| **Infant HIV status** | 480 |  |
| Negative |  | 473 (99%) |
| Positive |  | 7 (1.5%) |
| **Infant given ARV prophylaxis** | 7 |  |
| Yes |  | 7 (100%) |
| **Infant on given cotrimoxazole prophylaxis** | 7 | 5 (71%) |
| *1*n (%); Median (Q1, Q3) | | |

| **Infant Outcome** | **N** | **N = 222***1* |
| --- | --- | --- |
| **Infant status** | 222 |  |
| Alive |  | 213 (96%) |
| Dead |  | 9 (4.1%) |
| **Infant illness prior to today's visit** | 221 | 22 (10.0%) |
| **Infant hospitalization prior to today's visit** | 221 | 3 (1.4%) |
| **Currently breastfeeding** | 213 | 208 (98%) |
| **Fed infant any drink or food other than breastmilk** | 208 | 28 (13%) |
| **Infant HIV status** | 167 |  |
| Negative |  | 162 (97%) |
| Positive |  | 5 (3.0%) |
| **Infant given ARV prophylaxis** | 5 | 4 (80%) |
| **Infant on given cotrimoxazole prophylaxis** | 5 | 4 (80%) |
| *1*n (%) | | |

## Clinical Outcomes

| **Clinical Outcome** | **N** | **Enrollment** N = 980*1* | **6 Weeks** N = 621*1* | **14 Weeks** N = 222*1* | **6 Months** N = 0*1* |
| --- | --- | --- | --- | --- | --- |
| **PHQ-9 Total Score** | 1,823 | 7.0 (5.0, 9.0) | 4.0 (1.0, 6.0) | 3.0 (0.0, 6.0) | NA (NA, NA) |
| **PHQ-9 High Score (>=10)** | 1,823 | 151 (15%) | 13 (2.1%) | 2 (0.9%) | 0 (NA%) |
| **GAD-7 Total Score** | 1,823 | 6.0 (4.0, 8.0) | 3.0 (1.0, 6.0) | 3.0 (0.0, 6.0) | NA (NA, NA) |
| **GAD-7 High Score (>=10)** | 1,823 | 105 (11%) | 14 (2.3%) | 4 (1.8%) | 0 (NA%) |
| **WHOQOL Overall Score (Scaled)** | 1,810 | 63 (50, 75) | 75 (63, 75) | 75 (63, 75) | NA (NA, NA) |
| **WHOQOL Physical Domain Score (Scaled)** | 1,810 | 64 (57, 71) | 75 (68, 82) | 75 (71, 82) | NA (NA, NA) |
| **WHOQOL Psychological Domain Score (Scaled)** | 1,810 | 63 (54, 71) | 71 (63, 79) | 75 (67, 79) | NA (NA, NA) |
| **WHOQOL Social Domain Score (Scaled)** | 1,809 | 67 (50, 75) | 67 (58, 75) | 75 (58, 75) | NA (NA, NA) |
| **WHOQOL Environmental Domain Score (Scaled)** | 1,810 | 56 (47, 66) | 59 (50, 66) | 63 (56, 69) | NA (NA, NA) |
| *1*Median (Q1, Q3); n (%) | | | | | |

| **Clinical Outcome** | **N** | **N = 621***1* |
| --- | --- | --- |
| **Miscarriage** | 610 |  |
| FALSE |  | 610 (100%) |
| TRUE |  | 0 (0%) |
| **Stillbirth** | 610 |  |
| FALSE |  | 607 (100%) |
| TRUE |  | 3 (0.5%) |
| **Late Stillbirth (>=28 weeks)** | 610 |  |
| FALSE |  | 609 (100%) |
| TRUE |  | 1 (0.2%) |
| **Preterm Birth (<37 weeks)** | 579 |  |
| FALSE |  | 479 (83%) |
| TRUE |  | 100 (17%) |
| **Low Birth Weight (<2.5 kg)** | 547 |  |
| FALSE |  | 523 (96%) |
| TRUE |  | 24 (4.4%) |
| **Small for Gestational Age** | 518 |  |
| FALSE |  | 468 (90%) |
| TRUE |  | 50 (9.7%) |
| **Infant Death** | 621 |  |
| FALSE |  | 620 (100%) |
| TRUE |  | 1 (0.2%) |
| **Any Adverse Outcome** | 621 |  |
| FALSE |  | 468 (75%) |
| TRUE |  | 153 (25%) |
| *1*n (%) | | |

## Psychosocial Scales

| **Psychosocial Correlates** | **N** | **Enrollment** N = 980*1* | **6 Weeks** N = 621*1* | **14 Weeks** N = 222*1* | **6 Months** N = 0*1* |
| --- | --- | --- | --- | --- | --- |
| **Reducing Tension Checklist (Score)** | 1,823 | 13 (8, 18) | 15 (10, 21) | 17 (13, 21) | NA (NA, NA) |
| **Parenting Stress (Score) (6 weeks and 6 months)** | 1,823 | 0 (0, 0) | 15 (14, 16) | 0 (0, 0) | NA (NA, NA) |
| **Intimate Partner Violence (Score)** | 1,823 | 0 (0, 1) | 0 (0, 0) | 0 (0, 0) | NA (NA, NA) |
| **Intimate Partner Violence High Score (>=10)** | 1,823 |  |  |  |  |
| No |  | 977 (100%) | 619 (100%) | 221 (100%) | 0 (NA%) |
| Yes |  | 3 (0%) | 2 (0%) | 1 (0%) | 0 (NA%) |
| **Social Support (Score) (Baseline and 14 weeks)** | 1,823 | 9 (8, 10) | 0 (0, 0) | 9 (8, 10) | NA (NA, NA) |
| **Social Support Category** | 1,201 |  |  |  |  |
| Moderate |  | 494 (50%) | 0 (NA%) | 131 (59%) | 0 (NA%) |
| Poor |  | 426 (44%) | 0 (NA%) | 70 (32%) | 0 (NA%) |
| Strong |  | 59 (6%) | 0 (NA%) | 21 (9%) | 0 (NA%) |
| **Adverse Childhood Experiences (Number) (14 weeks)** | 1,823 | 0 (0, 0) | 0 (0, 0) | 2 (0, 3) | NA (NA, NA) |
| *1*Median (Q1, Q3); n (%) | | | | | |

## Mental Health Utilization

|  |  | **Visit Type** | | | |
| --- | --- | --- | --- | --- | --- |
| **Variable** | **Overall** N = 1,823*1* | **Enrollment** N = 980*1* | **6 Weeks** N = 621*1* | **14 Weeks** N = 222*1* | **6 Months** N = 0*1* |
| **Screened by PHQ-2** | 1,117 (61.9%) | 780 (80.1%) | 245 (40.2%) | 92 (41.4%) | 0 (NA%) |
| **Screened by GAD-2** | 1,116 (61.8%) | 782 (80.3%) | 241 (39.6%) | 93 (41.9%) | 0 (NA%) |
| **Screened by PHQ-9** | 857 (47.5%) | 603 (61.9%) | 181 (29.7%) | 73 (32.9%) | 0 (NA%) |
| **Screened by GAD-7** | 856 (47.5%) | 603 (62.1%) | 180 (29.6%) | 73 (32.9%) | 0 (NA%) |
| **Accessed Mental Health Providers** | 6 (3.0%) | 1 (5.3%) | 3 (3.0%) | 2 (2.5%) | 0 (NA%) |
| **Mental Health Referral Made** | 2 (1.0%) | 1 (5.3%) | 1 (1.0%) | 0 (0.0%) | 0 (NA%) |
| **Used Telepsychiatry** | 6 (1.1%) | 0 (0.0%) | 5 (1.9%) | 1 (1.0%) | 0 (NA%) |
| *1*n (%) | | | | | |

|  |  | **Visit Type** | | |
| --- | --- | --- | --- | --- |
| **Variable** | **Overall** N = 843*1* | **6 Weeks** N = 621*1* | **14 Weeks** N = 222*1* | **6 Months** N = 0*1* |
| **PM+ Participation** | 66 (17.8%) | 43 (16.2%) | 23 (22.1%) | 0 (NA%) |
| **PM+ Sessions Completed** |  |  |  |  |
| 0 | 12 (18.2%) | 7 (16.3%) | 5 (21.7%) | 0 (NA%) |
| 1 | 8 (12.1%) | 7 (16.3%) | 1 (4.3%) | 0 (NA%) |
| 2 | 6 (9.1%) | 3 (7.0%) | 3 (13.0%) | 0 (NA%) |
| 3 | 6 (9.1%) | 5 (11.6%) | 1 (4.3%) | 0 (NA%) |
| 4 | 7 (10.6%) | 4 (9.3%) | 3 (13.0%) | 0 (NA%) |
| 5 | 27 (40.9%) | 17 (39.5%) | 10 (43.5%) | 0 (NA%) |
| **Stopped PM+** | 28 (3.3%) | 19 (3.1%) | 9 (4.1%) | 0 (NA%) |
| **Restarted PM+** | 26 (3.1%) | 15 (2.4%) | 11 (5.0%) | 0 (NA%) |
| **No PM+ Changes** | 12 (1.4%) | 9 (1.4%) | 3 (1.4%) | 0 (NA%) |
| *1*n (%) | | | | |