**Effectiveness of Peer Support for People with Severe Mental Health Conditions in High-, Middle- and Low-Income Countries:**

**The UPSIDES Multicenter Randomized Controlled Trial**

**Online supplement**

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Trial procedures

Names of the relevant local ethics review bodies and approval numbers: (i) Ulm: Ulm University’s Ethics Commission, Germany (approval #: 254/19); (ii) Hamburg: Local Psychological Ethics Commission at the Centre for Psychosocial Medicine, Hamburg, Germany (approval #: LPEK-0095); (iii) Butabika: Uganda National Council for Science and Technology (approval #: SS 4990); (iv) Dar es Salaam: National Institute for Medical Research, Dar es Salaam, and Ministry of Health, Community Development, Gender, Elderly & Children, Dodoma, Tanzania (approval #: NIMR/HQ/R.8a/Vol. IX/3328); Be’er Sheva: Human Subjects Research Committee of Ben-Gurion University, Israel (approval #: 1787-1); Pune: Indian Law Society (approval #: ILS/37/2018).

Key time points in the trial’s participant timeline were enrolment, baseline (t0), immediate allocation, and 4-month (t1) and 8-month (t2) follow-up. Fulfilment of inclusion criteria was established at enrolment, and all outcome measures were completed at measurement points t0–t2. Data collection was carried out by trained research workers at all study sites, in line with standard operating procedures describing tasks to be carried out at each point on the participant timeline.

Recruitment for the UPSIDES-RCT started in January 2020 at all six study sites, as scheduled, and was initially planned to last 12 months. Starting in March 2020, recruitment had to be paused at all sites due to the COVID-19 pandemic. Duration of pause due to lockdowns was around three months at four sites (Ulm: 74 days; Butabika: 80 days; Dar es Salaam: 84 days; Be’er Sheva: 76 days), five months at one site (Hamburg: 112 days), and one site was particularly badly affected (Pune: 257 days), so that recruitment could not be resumed until the end of 2020. To compensate for disruption, the recruitment period was adjusted, by adding the duration of pausing to the original recruitment end-date at each site, up to a maximum of seven months. Recruitment was completed in August 2021. Intensive risk management took place during the COVID-19 lockdowns to balance safety of study staff and participants with the need to continue research tasks and maintain methodological rigor. The coordinating centre (Ulm), in close collaboration with the Ethics Advisor and consortium partners, provided guidance on crisis management and restart. The consortium’s standard procedure was to pause all study activities (recruitment, data collection, and delivery of face-to-face peer support) during lockdowns, while maintaining contact with existing participants and PSWs either online or by phone. After the restart, parts of the study were allowed to be carried out online while crucial elements of the study were excluded from remote delivery, e. g. obtaining informed consent and certain parts of the peer support intervention, because for these aspects personal contact was seen as essential.

Assessment of safety and adverse events

The members of the independent Trial Steering Committee (TSC) ensured that the trial was conducted in line with Good Clinical Practice. A serious adverse event (SAE) was defined as untoward occurrence that results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, or results in persistent or significant disability or incapacity. Within 24 hours after learning about a potential SAE, UPSIDES research workers reported it on a standardized form to the TSC chair and their site Principal Investigator, for the TSC to evaluate whether it was related to study participation.

Treatment-as-usual at each study site

Ulm: Psychiatric routine care in Germany is mainly provided by psychiatric hospitals, psychiatric outpatient clinics and office-based psychiatrists and psychotherapists. In addition, a broad spectrum of nonmedical vocational, residential and psychosocial services is provided by vocational rehabilitation centres, community mental health care centres and different types of residential facilities. The Department of Psychiatry and Psychotherapy II at Ulm University is responsible for the provision of mental health care in a large catchment area in rural Bavaria (North and Middle Swabia, population 671,000). Multidisciplinary teams (psychiatrists, psychologists, social workers, nurses, occupational therapists) offer the full range of pharmacological and psychosocial interventions in a large inpatient unit, two-day care units, an outpatient clinic, and a home treatment team (mobile crisis intervention). The Department collaborates closely with office-based psychiatrists and psychotherapists in the area.

Hamburg: For routine psychiatric care in Germany, see Ulm above. The University Medical Centre Hamburg-Eppendorf (UKE) is one of the largest hospitals in the City of Hamburg. The Department of Psychiatry and Psychotherapy has multidisciplinary teams who provide inpatient, outpatient and outreach (Crisis Resolution Teams, Assertive Community Treatment) mental health services in a large catchment area of several districts in Hamburg and cooperates closely with various service providers in the region.

Butabika: Psychiatric services in Kampala are provided in the form of outpatient clinics at general hospitals as well as inpatient and outpatient care at the National Referral Hospital at Butabika. Physical health care, psychotherapies as well as social interventions and reintegration are provided at Butabika before service users are discharged back to their homes. Rehabilitation is provided at the Occupational Therapy department at Butabika, as there are no public community-based mental health rehabilitation facilities. Treatment as usual will therefore comprise psychopharmacological as well as regular psychosocial care and occupational therapy provided on an inpatient or outpatient basis at Butabika Hospital.

Dar es Salaam: Mental health services in Tanzania are decentralised, starting from primary care facilities which often serve as an entry point into the mental health system. At district hospitals, psychiatric nurses do triaging, referring and refilling prescriptions for people with mental ill-health who are considered to be in stable condition. People with severe and complicated mental ill-health are referred to tertiary care for specialised treatment. Tanzania experiences a considerable shortage of psychiatrists, and most psychiatrists work in tertiary care. At the Department of Psychiatry and Mental Health at Muhimbili National Hospital, Dar es Salaam, both inpatient and outpatient mental health services are available. Providers include psychiatrists, occupational therapists, social workers, psychiatric nurses and clinical psychologists. Mental health services provided include psychotherapy, psychosocial rehabilitation, vocational skills training, family intervention, cognitive enhancement therapy and psychoeducation.

Be’er Sheva: Mental health care in Israel is provided by psychiatric hospitals, psychiatric outpatient clinics and office-based psychiatrists and psychotherapists. Psychiatric rehabilitation services are provided through the mandatory rehabilitation basket law and include a wide range of services in the community: vocational, residential and psychosocial services and programs and community mental health care centres. The Yozma Derech Halev program specializes in supporting consumers who wish to work in rehabilitation or clinical services. It is independent of other services and supports consumers in numerous organisations who are employed in multidisciplinary mental health teams.

Pune: Mental health care in India is broadly delivered through public and private mental health facilities with in-patient and out-patient departments. Community -based services are limited and generally based on a medical model of care. Services at public mental health facilities are provided at a nominal cost; however, these services are typically overburdened and under-resourced. Mental health care is often not available, accessible, acceptable nor of good quality, leading to a large treatment gap. The Hospital for Mental Health in Ahmedabad, Gujarat, caters to the city of Ahmedabad (8 million population approximately), with an in-patient facility of 300 clients, and outpatient unit serving 150 clients per day. Peer support volunteers are financially supported by the State at this site. Treatment-as-usual therefore comprises psychopharmacological as well as regular psychosocial care and occupational therapy provided by the hospital on an inpatient or outpatient basis.

Table S1: Key baseline characteristics by site

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Ulm**  **(*n*=72)** | **Hamburg**  **(*n*=98)** | **Butabika**  **(*n*=138)** | **Dar es Salaam**  **(*n*=109)** | **Be’er Sheva**  **(*n*=106)** | **Pune**  **(*n*=92)** | **Total**  **(n=615)** | **Difference** |
| Age (years), mean (SD) | 39.4 (13.8) | 40.0 (12.2) | 34.5 (9.5) | 34.2 (8.6) | 45.2 (10.4) | 38.5 (9.2) | 38.3 (11.2) | F(5;609)=16.7, p < 0.001 |
|  |  |  |  |  |  |  |  |  |
| Gender, female, N (%) | 43 (59.7) | 79 (80.6) | 59 (42.8) | 59 (54.1) | 53 (50.0) | 44 (47.8) | 337 (54.8) | χ2(10)=43.5, p < 0.001 |
|  |  |  |  |  |  |  |  |  |
| Schooling in general education (years), mean (SD) | 10.6 (1.8) | 12.6 (1.6) | 11.2 (4.6) | 11.0 (4.2) | 12.0 (1.2) | 9.3 (3.6) | 11.1 (3.5) | F(5;503)=10.9, p < 0.001 |
|  |  |  |  |  |  |  |  |  |
| Employment, N (%) |  |  |  |  |  |  |  |  |
| Paid or self-employment | 30 (41.7) | 23 (23.5) | 53 (38.4) | 25 (22.9) | 10 (9.4) | 14 (15.2) | 155 (25.2) | χ2(35)=561.0, p < 0.001 |
| Voluntary employment | 1 (1.4) | 1 (1.0) | 2 (1.4) | 0 (0.0) | 1 (0.9) | 19 (20.7) | 24 (3.9) |
| Sheltered employment | 4 (5.6) | 2 (2.0) | 3 (2.2) | 0 (0.0) | 62 (58.5) | 5 (5.4) | 76 (12.4) |
| Unemployed | 21 (29.2) | 25 (25.5) | 69 (50.0) | 76 (69.7) | 7 (6.6) | 47 (51.1) | 245 (39.8) |
| Student | 3 (4.2) | 19 (19.4) | 5 (3.6) | 1 (0.9) | 0 (0.0) | 1 (1.1) | 29 (4.7) |
| Housewife/husband | 3 (4.2) | 2 (2.0) | 5 (3.6) | 1 (0.9) | 11 (10.4) | 6 (6.5) | 28 (4.6) |
| Retired | 9 (12.5) | 14 (14.3) | 0 (0.0) | 1 (0.9) | 0 (0.0) | 0 (0.0) | 24 (3.9) |
| Other | 1 (1.4) | 12 (12.2) | 1 (0.7) | 5 (4.6) | 15 (14.2) | 0 (0.0) | 34 (5.5) |
|  |  |  |  |  |  |  |  |  |
| Kind of mental illness, N (%) |  |  |  |  |  |  |  |  |
| Depression | 38 (52.8) | 38 (38.8) | 1 (0.7) | 16 (14.7) | 47 (44.3) | 41 (44.6) | 181 (29.4) | χ2(35)=398.7, p < 0.001 |
| Psychosis | 10 (13.9) | 13 (13.3) | 54 (39.1) | 58 (53.2) | 47 (44.3) | 20 (21.7) | 202 (32.8) |
| Other | 24 (33.3) | 47 (48.0) | 83 (60.1) | 35 (32.1) | 12 (11.3) | 31 (33.7) | 232 (37.7) |
|  |  |  |  |  |  |  |  |  |
| Duration of illness (years), mean (SD) | 15.4 (11.9) | 28.9 (93.0) | 10.1 (7.9) | 9.7 (7.8) | 17.8 (9.1) | 9.7 (7.5) | 14.9 (38.4) | F(5;609)=4.0, p < 0.001 |
|  |  |  |  |  |  |  |  |  |
| Social Inclusion (SIS), mean (SD) | 39.1 (8.6) | 39.8 (7.1) | 45.6 (7.5) | 40.0 (7.3) | 44.5 (6.8) | 36.7 (9.3) | 41.4 (8.4) | F(5;608)=21.2, p < 0.001 |
|  |  |  |  |  |  |  |  |  |
| Empowerment (ES), mean (SD) | 65.2 (10.1) | 64.5 (11.0) | 59.1 (8.9) | 58.2 (7.6) | 61.2 (9.7) | 67.3 (12.0) | 62.1 (10.3) | F(5;597)=13.6, p < 0.001 |
|  |  |  |  |  |  |  |  |  |
| Hope (HOPE), mean (SD) | 39.9 (11.5) | 39.3 (12.6) | 48.9 (8.6) | 48.2 (11.2) | 42.7 (12.2) | 36.6 (18.0) | 43.3 (13.2) | F(5;607)=17.5, p < 0.001 |
|  |  |  |  |  |  |  |  |  |
| Recovery (STORI), mean (SD) | 3.0 (1.3) | 2.8 (1.4) | 3.8 (1.3) | 3.5 (1.3) | 3.1 (1.2) | 3.5 (1.6) | 3.3 (1.4) | F(5;608)=8.0, p < 0.001 |
|  |  |  |  |  |  |  |  |  |
| Health and social functioning (HoNOS), mean (SD) | 18.8 (7.0) | 20.8 (5.9) | 6.8 (6.0) | 13.7 (7.5) | 16.0 (6.8) | 18.1 (8.2) | 14.9 (8.4) | F(5;604)=62.4, p < 0.001 |

Table S2. Detailed statistics of outcome analyses (intention-to-treat)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **β** | **SE** | **df** | **t** | **p** | **CI 95%**  **lower upper** | |
| **SIS tot** |  |  |  |  |  |  |  |
| Intercept | 43.56 | 0.72 | 1043 | 60.22 | <.0001 | 42.14 | 44.98 |
| Slope | 0.18 | 0.06 | 1043 | 3.23 | 0.001 | 0.07 | 0.29 |
| Intercept x allocation | 0.68 | 0.61 | 607 | 1.11 | 0.266 | -0.52 | 1.88 |
| Slope x allocation | 0.16 | 0.08 | 1043 | 1.95 | 0.052 | 0.00 | 0.31 |
|  |  |  |  |  |  |  |  |
| **SIS SI** |  |  |  |  |  |  |  |
| Intercept | 11.10 | 0.26 | 1044 | 42.03 | <.0001 | 10.58 | 11.61 |
| Slope | 0.04 | 0.02 | 1044 | 1.85 | 0.065 | 0.00 | 0.08 |
| Intercept x allocation | 0.13 | 0.23 | 608 | 0.55 | 0.581 | -0.33 | 0.59 |
| Slope x allocation | 0.07 | 0.03 | 1044 | 2.42 | 0.016 | 0.01 | 0.13 |
|  |  |  |  |  |  |  |  |
| **SIS SR** |  |  |  |  |  |  |  |
| Intercept | 23.11 | 0.41 | 1043 | 56.43 | <.0001 | 22.31 | 23.91 |
| Slope | 0.10 | 0.03 | 1043 | 2.93 | 0.004 | 0.03 | 0.16 |
| Intercept x allocation | 0.51 | 0.34 | 607 | 1.49 | 0.137 | -0.16 | 1.18 |
| Slope x allocation | 0.03 | 0.05 | 1043 | 0.62 | 0.535 | -0.06 | 0.12 |
|  |  |  |  |  |  |  |  |
| **SIS SA** |  |  |  |  |  |  |  |
| Intercept | 15.06 | 0.30 | 1041 | 50.64 | <.0001 | 14.47 | 15.64 |
| Slope | 0.07 | 0.02 | 1041 | 3.12 | 0.002 | 0.03 | 0.12 |
| Intercept x allocation | 0.18 | 0.26 | 607 | 0.67 | 0.502 | -0.34 | 0.70 |
| Slope x allocation | 0.09 | 0.03 | 1041 | 2.76 | 0.006 | 0.03 | 0.16 |
|  |  |  |  |  |  |  |  |
| **Empowerment** |  |  |  |  |  |  |  |
| Intercept | 78.53 | 0.90 | 1020 | 87.52 | <.0001 | 76.77 | 80.29 |
| Slope | -0.01 | 0.06 | 1020 | -0.19 | 0.853 | -0.14 | 0.11 |
| Intercept x allocation | 0.64 | 0.80 | 606 | 0.80 | 0.425 | -0.93 | 2.20 |
| Slope x allocation | 0.24 | 0.09 | 1020 | 2.59 | 0.010 | 0.06 | 0.42 |
|  |  |  |  |  |  |  |  |
| **Hope** |  |  |  |  |  |  |  |
| Intercept | 40.10 | 1.08 | 1034 | 37.25 | <.0001 | 37.99 | 42.21 |
| Slope | 0.05 | 0.08 | 1034 | 0.68 | 0.495 | -0.10 | 0.21 |
| Intercept x allocation | 0.36 | 0.98 | 608 | 0.37 | 0.712 | -1.56 | 2.29 |
| Slope x allocation | 0.32 | 0.11 | 1034 | 2.77 | 0.006 | 0.09 | 0.54 |
|  |  |  |  |  |  |  |  |
| **STORI** |  |  |  |  |  |  |  |
| Intercept | 2.84 | 0.12 | 1035 | 24.60 | <.0001 | 2.62 | 3.07 |
| Slope | 0.03 | 0.01 | 1035 | 3.14 | 0.002 | 0.01 | 0.05 |
| Intercept x allocation | 0.04 | 0.11 | 608 | 0.33 | 0.743 | -0.17 | 0.24 |
| Slope x allocation | 0.02 | 0.02 | 1035 | 1.42 | 0.157 | -0.01 | 0.05 |
|  |  |  |  |  |  |  |  |
| **HoNOS** |  |  |  |  |  |  |  |
| Intercept | 17.37 | 0.63 | 1035 | 27.42 | <.0001 | 16.13 | 18.62 |
| Slope | -0.39 | 0.05 | 1035 | -7.88 | <.0001 | -0.49 | -0.29 |
| Intercept x allocation | -0.77 | 0.55 | 608 | -1.40 | 0.163 | -1.86 | 0.31 |
| Slope x allocation | -0.08 | 0.07 | 1035 | -1.11 | 0.266 | -0.22 | 0.06 |

*Notes:* SE=standard error; df=degrees of freedom; CI=confidence interval 95%. Effects on intercept for site as control variable not shown.

Table S3. Detailed statistics of outcome analyses (per-protocol)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **β** | **SE** | **df** | **t** | **p** | **CI 95%**  **lower upper** | |
| **SIS tot** |  |  |  |  |  |  |  |
| Intercept | 43.31 | 0.74 | 1003 | 58.62 | <.0001 | 41.86 | 44.76 |
| Slope | 0.18 | 0.06 | 1003 | 3.23 | 0.001 | 0.07 | 0.29 |
| Intercept x allocation | 0.50 | 0.64 | 557 | 0.78 | 0.435 | -0.76 | 1.76 |
| Slope x allocation | 0.18 | 0.08 | 1003 | 2.17 | 0.031 | 0.02 | 0.34 |
|  |  |  |  |  |  |  |  |
| **SIS SI** |  |  |  |  |  |  |  |
| Intercept | 11.01 | 0.27 | 1004 | 40.78 | <.0001 | 10.48 | 11.54 |
| Slope | 0.04 | 0.02 | 1004 | 1.85 | 0.065 | 0.00 | 0.08 |
| Intercept x allocation | 0.05 | 0.25 | 558 | 0.20 | 0.841 | -0.44 | 0.53 |
| Slope x allocation | 0.08 | 0.03 | 1004 | 2.69 | 0.007 | 0.02 | 0.14 |
|  |  |  |  |  |  |  |  |
| **SIS SR** |  |  |  |  |  |  |  |
| Intercept | 22.96 | 0.42 | 1003 | 55.02 | <.0001 | 22.15 | 23.78 |
| Slope | 0.10 | 0.03 | 1003 | 2.93 | 0.003 | 0.03 | 0.16 |
| Intercept x allocation | 0.41 | 0.36 | 557 | 1.14 | 0.255 | -0.29 | 1.11 |
| Slope x allocation | 0.03 | 0.05 | 1003 | 0.67 | 0.504 | -0.06 | 0.13 |
|  |  |  |  |  |  |  |  |
| **SIS SA** |  |  |  |  |  |  |  |
| Intercept | 15.01 | 0.30 | 1001 | 49.53 | <.0001 | 14.42 | 15.61 |
| Slope | 0.07 | 0.02 | 1001 | 3.15 | 0.002 | 0.03 | 0.12 |
| Intercept x allocation | 0.14 | 0.28 | 557 | 0.51 | 0.607 | -0.40 | 0.69 |
| Slope x allocation | 0.10 | 0.03 | 1001 | 3.02 | 0.003 | 0.04 | 0.17 |
|  |  |  |  |  |  |  |  |
| **Empowerment** |  |  |  |  |  |  |  |
| Intercept | 78.47 | 0.90 | 980 | 87.39 | <.0001 | 76.71 | 80.23 |
| Slope | -0.01 | 0.07 | 980 | -0.20 | 0.839 | -0.14 | 0.11 |
| Intercept x allocation | 0.41 | 0.83 | 556 | 0.50 | 0.619 | -1.22 | 2.04 |
| Slope x allocation | 0.26 | 0.10 | 980 | 2.66 | 0.008 | 0.07 | 0.45 |
|  |  |  |  |  |  |  |  |
| **Hope** |  |  |  |  |  |  |  |
| Intercept | 40.16 | 1.10 | 994 | 36.58 | <.0001 | 38.00 | 42.31 |
| Slope | 0.05 | 0.08 | 994 | 0.67 | 0.506 | -0.10 | 0.21 |
| Intercept x allocation | 0.18 | 1.03 | 558 | 0.17 | 0.863 | -1.85 | 2.21 |
| Slope x allocation | 0.34 | 0.12 | 994 | 2.83 | 0.005 | 0.10 | 0.57 |
|  |  |  |  |  |  |  |  |
| **STORI** |  |  |  |  |  |  |  |
| Intercept | 2.85 | 0.12 | 995 | 24.05 | <.0001 | 2.62 | 3.09 |
| Slope | 0.03 | 0.01 | 995 | 3.12 | 0.002 | 0.01 | 0.05 |
| Intercept x allocation | 0.01 | 0.11 | 558 | 0.12 | 0.903 | -0.21 | 0.24 |
| Slope x allocation | 0.02 | 0.02 | 995 | 1.46 | 0.146 | -0.01 | 0.05 |
|  |  |  |  |  |  |  |  |
| **HoNOS** |  |  |  |  |  |  |  |
| Intercept | 17.38 | 0.65 | 996 | 26.79 | <.0001 | 16.11 | 18.65 |
| Slope | -0.39 | 0.05 | 996 | -7.88 | <.0001 | -0.49 | -0.29 |
| Intercept x allocation | -0.92 | 0.59 | 558 | -1.58 | 0.115 | -2.07 | 0.23 |
| Slope x allocation | -0.07 | 0.07 | 996 | -1.01 | 0.313 | -0.22 | 0.07 |

*Notes:* SE=standard error; df=degrees of freedom; CI=confidence interval 95%. Effects on intercept for site as control variable not shown.