ISRCTN26008944 https://doi.org/10.1186/ISRCTN26008944

Peer support for people with severe mental illness: a pragmatic multicentre randomised controlled trial

Submission date
30/09/2019

Recruitment status
No longer recruiting

Registration date
30/10/2019

Overall study status
Completed

Last Edited
27/06/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Peer support is an established intervention involving a person in recovery from mental illness being engaged to offering support to others with mental illness. There are significant gaps in the evidence base for peer support in low-/middle-income and in non-Anglophone countries. Building upon comprehensive formative research, UPSIDES-RCT will explore the implementation and effectiveness of peer support delivered in a range of high-, middle- and low-income country contexts. Main objectives are: (1) To evaluate the outcomes of delivering peer support, for service users, peer support workers and organisations, through a multi-centre pragmatic parallel-group randomised controlled trial and additional qualitative methods. (2) To assess the value for money of peer support for persons with severe mental illness, by carrying out a cost-effectiveness study. (3) To evaluate the process of implementing the UPSIDES peer support intervention, with special attention to differences in context across the study sites, using both quantitative and qualitative methods with peer support workers, service users, mental health workers and wider stakeholders

Who can participate?
Adults (18 -60 years) with mental illness

What does the study involve?
Participation in UPSIDES-RCT means that participants will meet with an UPSIDES research worker four times over one year (every four months) to give him/her general information about themselves (e.g. age, gender, family situation, work) and about their mental health problems. These interviews will last for about 1 1/2 hours each. This is a randomised controlled trial which means that, if they consent to participation, participants will be allocated per chance (50:50) to the intervention or control group. If they are allocated to the intervention group, they will receive UPSIDES peer support. This service will be provided by a trained UPSIDES peer support worker who has also experienced mental ill health and will support their recovery. If they are allocated to the control group, their participation will involve data as-sessment as described above. As this is a waiting list design, control group participants will receive the intervention in one year

What are the possible benefits and risks of participating?
Participants will be asked questions on their health and mental health during our four meetings in one year. Four meetings will require their time as per interview schedule. This could potentially place a burden on participants. If they are allocated to the intervention group, participants will receive the intervention immediately. If they are in the control group, they will receive the intervention in one year. See participant information sheet at https://www.upsides.org/wp-content/uploads/UPSIDES-RCT-informed-consent-forms.pdf for further information

Where is the study run from?
Ulm University, Germany

When is the study starting and how long is it expected to run for?
January 2020 to July 2022

Who is funding the study?
1. European Union Horizon 2020
2. Indian Council for Medical Research

Who is the main contact?
Prof. Bernd Puschner,
bernd.puschner@bkh-guenzburg.de

Study website
http://www.upsides.org

Contact information

Type(s)
Public

Contact name
Prof Bernd Puschner

ORCID ID
https://orcid.org/0000-0002-2929-4271

Contact details
Ulm University, Department of Psychiatry II
Section Process-Outcome-Research
Reisensburger Str. 32
Günzburg
Germany
89312
+49 8221 962866
bernd.puschner@bkh-guenzburg.de

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Peer support for people with severe mental illness versus usual care: a pragmatic multicentre randomised controlled trial

Acronym
UPSIDES-RCT

Study objectives
The aim of UPSIDES-RCT is to explore the implementation and effectiveness of peer support delivered in a range of high-, middle- and low-income country contexts. The main objectives are:
1. To evaluate the outcomes of delivering peer support, for service users, peer support workers and organisations, through a multi-centre pragmatic parallel-group randomised controlled trial (UPSIDES-RCT) and additional qualitative methods.
2. To assess the value for money of peer support for persons with severe mental illness, by carrying out a cost-effectiveness study.
3. To evaluate the process of implementing the UPSIDES peer support intervention, with special attention to differences in context across the study sites, using both quantitative and qualitative methods with PSWs, service users, mental health workers and wider stakeholders.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 21/08/2019, Ulm University Ethics Commission (Room 1.03, Helmholtzstraße 20 [Oberer Eselsberg], 89081 Ulm, Germany; +49 (0) 731 500-22050; ethik-commission@uni-ulm.de), ref: 254/19
2. Approved 02/03/2018, Indian Law Society (ILS Law College Campus, Chiplunkar Road, Pune - 411 004, India; +91 (0)20-25656780; deepapaturkar@ilslaw.in), ref: ILS/37/2018
3. Approved 01/09/2019, Human Subjects Research Committee of Ben-Gurion University (P.O.B 653, Beer Sheva 84105, Israel; +972 (0)86461932; hsrCommittee@bgu.ac.il), ref: 1787-1
4. Approved 21/05/2019, Uganda National Council for Science and Technology (UNCST) (Plot 6 Kimera Rd, Kampala, Uganda; +256 41 4705500; info@uncst.co.ug), ref: SS 4990
5. Approved 31/01/2020, National Institute for Medical Research, Dar es Salaam, and Ministry of Health, Community Development, Gender, Elderly & Children, Dodoma, Tanzania; +255 (0)26 2963341/42/46; ps@communitydevelopment.go.tz), ref: NIMR/HQ/R.8a/Vol. IX/3328
6. Approved 04/12/2020, Local Psychological Ethics Commission at the Centre for Psychosocial Medicine, Hamburg, Germany; +49 (0)40 7410 5520; skuehn@uke.de); ref: LPEK-0095

Study design

Pragmatic parallel-group multi-centre randomised controlled trial with four measurement points over 1 year (baseline, 4-, 8-, and 12-month follow-up), and embedded process evaluation and cost-effectiveness analysis

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
https://www.upsides.org/wp-content/uploads/UPSIDES-RCT-informed-consent-forms.pdf

Health condition(s) or problem(s) studied
Severe mental illness

Interventions
This is a pragmatic parallel-group multi-centre randomised controlled trial with four measurement points over one year (baseline, 4-, 8-, and 12-month follow-up), and embedded process evaluation and cost-effectiveness analysis.

All participants will receive treatment as usual as provided at the respective study site. Participants allocated to the intervention group will additionally receive the UPSIDES peer support, which is a direct service that is delivered by a person who has personal experience of mental health problems to a person or a group of persons with a serious mental illness. UPSIDES peer support workers will be using these personal experiences, along with UPSIDES training and supervision, to facilitate, guide, and mentor another person's recovery journey. UPSIDES peer support will be delivered for up to six months, with a minimum of three contacts. Weekly or biweekly meetings are recommended, but frequency may vary. The intervention has been developed by all UPSIDES partners, and will be delivered in line with the UPSIDES peer support intervention manual.
Participants will be randomly assigned to either control or intervention group with a 1:1 allocation as per a computer-generated randomisation schedule stratified by site using permuted blocks of random sizes.

Intervention Type
Other

Primary outcome measure
Social inclusion at t2 (8 months) measured with the Social Inclusion Scale (SIS)

Secondary outcome measures
Measured at baseline, 4-, 8-, and 12-month follow-up:
1. Empowerment (Empowerment Scale, ES)

2. Hope (HOPE scale)
3. Recovery (Stages of Recovery, STORI-30)
4. Health and social functioning (Health of the Nations Outcome Scales, HoNOS)

Overall study start date
06/03/2017

Completion date
30/09/2023

Eligibility

Key inclusion criteria
1. Adult age (18-60 years) at intake
2. Mental disorder of any kind as main diagnosis established by case notes, staff communication or self-label
3. Presence of severe mental illness (Threshold Assessment Grid ≥5 points and illness duration ≥2 years)
4. Sufficient command of the host country's language
5. Capable of giving informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
N= 558; N = 93 per site

Total final enrolment
615

Key exclusion criteria
1. Main diagnosis of learning disability, dementia, substance disorder or organic brain disorder
2. Cognitive impairment severe enough to make it impossible to give informed consent or complete study measures

Date of first enrolment
01/01/2020

Date of final enrolment
30/09/2021

Locations

Countries of recruitment
Germany

India

Israel

Tanzania

Uganda

Study participating centre
Ulm University Department of Psychiatry II
Reisensburger Str. 32
Günzburg
Germany
89312

Study participating centre
University Medical Centre Hamburg- Eppendorf Department of Psychiatry
Martinistraße 52
Hamburg
Germany
20246

Study participating centre
Butabika National Referral Hospital
Butabika Road
Kampala
Uganda
P.O. Box 7017

Study participating centre
Ifakara Health Institute
Plot 463, Kiko Avenue Mikocheni
Dar es Salaam
Tanzania
P.O. Box 78 373

Study participating centre
Ben Gurion University of the Negev, The Charlotte B. and Jack J. Spitzer Department of Social Work
Yitzhack I. Rager Blvd
Beer Sheva
Israel
84105

Study participating centre
Centre for Mental Health Law and Policy, Indian Law Society
Law College Road
Pune
India
411004

Sponsor information

Organisation
University of Ulm

Sponsor details
Department of Psychiatry II
Ludwig-Heilmeyer-Str. 2
Günzburg
Germany
89312
+49 8221 962866
bernd.puschner@bkh-guenzburg.de

Sponsor type
University/education

Website
https://www.uniklinik-ulm.de/psychiatrie-und-psychotherapie-ii/english-version/section-process-outcome-research.html

ROR
https://ror.org/032000t02

Organisation
University Medical Centre Hamburg-Eppendorf, Department of Psychiatry

Sponsor details
Martinistraße 52.
Hamburg
Germany
20246
+49 40-7410-58933
c.mahlke@uke.de

Sponsor type
University/education

Website
https://www.uke.de/kliniken-institute/kliniken/psychiatrie-und-psychotherapie/forschung/ab-partizipation.html

Organisation
Butabika National Referral Hospital

Sponsor details
Butabika Road
Kampala
Uganda
P.O. Box 7017
+256 41 4504376
jnakku2013@gmail.com

Sponsor type
Hospital/treatment centre

Website
https://www.butabikahospital.go.ug/

Organisation
Ifakara Health Institute, Department of Health Systems, Impact Evaluation and Policy

Sponsor details
Mikocheni, Kiko Avenue
Dar es Salaam
Tanzania
P.O. Box 78 373
+255 22 2774756
dshamba@ihi.or.tz

Sponsor type
Research organisation

Website
http://ihi.or.tz/health-systems-impact-evaluation-and-policy/

Organisation
Ben Gurion University of the Negev, The Charlotte B. and Jack J. Spitzer Department of Social Work

Sponsor details
Yitzhack I. Rager Blvd
Beer Sheva
Israel
84105
08-6472322
galia.moran@gmail.com

Sponsor type
University/education

Website
https://in.bgu.ac.il/en/humsos/social/Pages/staff/galia-moran@gmail-com.aspx

Organisation
Centre for Mental Health Law and Policy, Indian Law Society

Sponsor details
Law College Road
Pune
India
411004
020-25656775
jasmine@cmhlp.org

Sponsor type
Research organisation

Website
https://cmhlp.org/

Funder(s)

Funder type
Government

Funder Name
Horizon 2020

Alternative Name(s)
EU Framework Programme for Research and Innovation, Horizon 2020 - Research and Innovation Framework Programme, European Union Framework Programme for Research and Innovation

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Funder Name
Indian Council for Medical Research

Results and Publications

Publication and dissemination plan
Research results will be disseminated in Open Access, peer-reviewed journals and shared through oral and poster presentations at international conferences. All resources (policy briefs, research summaries, training tools, manuals, etc.) will be uploaded to an online knowledge management platform (updated 16/09/2022: https://www.upsides.org/output/), to increase exposure and ensure accessibility beyond the life of this project.

Intention to publish date
30/09/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository.
- Repository name/weblink: https://oparu.uni-ulm.de/xmlui/.
- Type of data that will be shared: Fully anonymized aggregated participant data.
- When the data will become available and for how long: After the last publication, scheduled for late 2023, for 10 years. (updated from scheduled for late 2022, for 10 years on 16/09/2022).
- By what access criteria the data will be shared including with whom: Open access, publicly available.
- For what types of analyses and by what mechanism: Open Data Commons (e.g. ODC-ODbl).
- Whether consent from participants was obtained: Only data of participants who have given informed consent will be collected.
- Comments on data anonymization: Only aggregated answers and limited sociodemographic data will be made open access to ensure anonymization.
- Any ethical or legal restrictions: Data sharing in this study will adhere to regulations of all IRB and Ethics Commissions involved. In addition, other regulations of authorities in countries of the study sites, e.g. with regard to data protection, may apply.
- Any other comments: UPSIDES adheres to the Horizon 2020 Pilot on Open Research Data.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/05/2020	04/05/2020	Yes	No
Other publications	Methodology development and implementation	20/01/2022	24/01/2022	Yes	No
Other publications	Qualitative focus group study on the societal and organisational influences on peer support work	23/05/2023	25/08/2023	Yes	No
Other publications	Theory of change implementation map	18/04/2024	22/04/2024	Yes	No
Other publications	Qualitative focus group study on mental health workers experiences	15/05/2024	21/05/2024	Yes	No
Other publications	Development and psychometric evaluation of a SU- and PSW-rated fidelity scale for manualised peer support	11/10/2024	15/10/2024	Yes	No
Results article		27/06/2025	27/06/2025	Yes	No