METADATA: COHORT STUDIES

Overview

The cohort studies are treatment cohorts which assessed the clinical, social and economic outcomes of patients who have received a diagnosis of depression, alcohol use disorder (AUD), psychosis or epilepsy. In some countries a control group (patients who screen positive for a disorder but were undiagnosed by a clinician) were also followed up. Key research themes included social, health and economic outcomes, equity of access, and stigma, discrimination, adherence and retention in care. After the baseline data collection, patients were followed-up after 3 or 6 months (midline visit), and again 12 months after the baseline (endline visit). A detailed description of the cohort methods has been published in BMC Psychiatry (https://bmcpsychiatry.biomedcentral.com/articles/10.1186/s12888-018-1642-x). Below is a brief overview of the design, recruitment and data collection methods.

If you wish to access the cohort dataset, please complete an expression of interest form at https://docs.google.com/forms/d/e/1FAIpQLSfp9sVy_OKV18AWJfUlBGVnC_QuLyCalR4xVJR4tAMRR5g1wg/viewform.

Objectives

Primary objectives

1. To **estimate the change in the severity of symptoms** among adults 12 months after being diagnosed with depression/AUD/psychosis/epilepsy by a primary health care provider in in the PRIME implementation areas.
2. To **estimate the change in the severity of disability** among adults 12 months after being diagnosed with depression/AUD/psychosis/epilepsy by a primary health care provider in in the PRIME implementation areas.

Secondary objectives

3. To **estimate the change in social functioning** among adults 12 months after being diagnosed with depression/AUD/psychosis/epilepsy by a primary health care provider in the PRIME implementation areas.
4. To **estimate the change in productivity** (e.g. housework functioning, employment) and economic status (e.g. income, health care expenditures) among adults 12 months after being diagnosed with depression/AUD/psychosis/epilepsy by a primary health care provider in the PRIME implementation areas.
5. To **identify the predictors of primary outcomes** (i.e. symptom and disability severity after 12 months), the moderators (e.g. baseline symptom severity and socio-demographic factors) of the primary outcomes, and mediating factors (e.g. adherence to interventions and social support) of the primary outcomes among adult who have been diagnosed with depression/AUD/psychosis/epilepsy by a health care provider in the PRIME implementation areas.
6. To **estimate the equity** (e.g. by gender and by socioeconomic status) **of treatment provision and of primary outcomes** (i.e. disability and symptom severity after 12 months) among adults who were diagnosed with depression/AUD/psychosis/epilepsy by a primary health care provider in the PRIME implementation areas.
7. To **estimate the change in internalized stigma and discrimination** experienced among adults (and their caregivers) 12 months after being diagnosed with psychosis by a health care provider in the PRIME implementation areas.

Outcomes

Data collected by questionnaire	Depression			Alcohol use disorders			Psychosis			Epilepsy		
Months of follow-up*	0	3*	12	0	3	12	0	6	12	0	6	12
DEMOGRAPHICS CHARACTERISTICS	✓			✓			✓			✓		
CLINICAL MEASURES												
WHO Disability Assessment Schedule (WHODAS 2.0)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Patient Health Questionnaire (PHQ-9)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Alcohol Use Disorder Identification Test (AUDIT)	✓			✓	✓	✓	✓	✓	✓	✓		
Short Inventory of Problems – Recent (SIP 2-R)				✓	✓	✓						
Suicidality (Composite International Diagnostic Interview - suicidality module)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Epilepsy severity (developed by PRIME)										✓	✓	✓
Brief Psychiatric Rating Scale (BPRS-E)							✓	✓	✓			
Positive and Negative Syndrome Scale (PANSS)							✓	✓	✓			
HEALTH SERVICE USE												
Group/community interventions (developed by PRIME)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Mental health services received (developed by PRIME)		✓	✓		✓	✓		✓	✓		✓	✓
Health Service use and costs (adapted from the Client Service Receipt Inventory)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
MEDICATION ADHERENCE												
Morisky Medication Adherence Scale (4-item)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Medication adherence (adapted from Care for People with Schizophrenia in India)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
SOCIAL AND ECONOMIC MEASURES												
Economic activity (adapted from WHODAS 2.0, added items by PRIME)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Severe Adverse Events (developed by PRIME)		✓	✓		✓	✓		✓	✓		✓	✓
Oslo 3-item Social Support Scale	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Caregiver work burden - WHO Family Interview Schedule (Impact)							✓	✓	✓	✓	✓	✓
Caregiver economic activity (adapted from WHODAS 2.0, items added by PRME)							✓	✓	✓			
STIGMA AND DISCRIMINATION												
Discrimination and Stigma Scale							✓		✓	✓		✓
Caregiver stigma & discrimination - WHO Family Interview Schedule (Stigma)										✓		✓
Human rights abuse by caregiver (developed by PRIME)							✓	✓	✓	✓	✓	✓

* 6

months for depression in Ethiopia

Questionnaire

A link to the cross-country cohort questionnaire can be found here. Several secondary outcomes were optional, and each country also included country-specific sections:

Ethiopia:

- Treatment gap questionnaire – Access to treatment and support from community (Depression, Psychosis and Epilepsy)
- Burden on caregiver (IEO caregiver) (psychosis & epilepsy)
- Human rights abuse (psychosis)
- For Epilepsy only
    - Epilepsy quality of life (QOLIE-10-P)
    - Seizure severity (NHS3)
    - Epilepsy Screening (PSQ)

India:

- Substance use
- Internalized Stigma of Mental Illness (ISMI)

Nepal:

- Heart/mind (depression and AUD)
- Training and Supervision Common Therapeutic Factors Rating (TASC-R) Scale

South Africa

- Internalized Stigma of Mental Illness (ISMI)
- Chronic illnesses
- Violence against women (VAW)

Uganda

- Abuse assessment scale (AAS)

Sample size

	DEPRESSION		AUD		PSYCHOSIS		EPILEPSY	
	Treatment	Comparison	Treatment	Comparison	Patient	Caregiver	Patient	Caregiver
Ethiopia	92	39	51	-	300	300[a]	304	304 [a]
India	281	158	218	147	22	21[b]	-	-
Nepal	137	72	175	57	-	95	42	-
South Africa	217	236	-	-	47	12 [a]	-	-
Uganda	64	-	-	-	51	50 [a]	181	171 [a]

[a] Patients and caregivers are paired; [b] Either patient or caregiver recruited – not paired;

Recruitment and data collection

	Sodo district, Ethiopia	Sehore district, India	Chitwan district*, Nepal	Dr Kenneth Kaunda, SA	Kamuli district, Uganda
District population	143,507 (total) [70]	318,314 (total)[71]	579,984 [72]	695 933 [73]	490,255 (total) [74]
Number of clinics involved in recruitment	9 facilities (8 health centres, 1 hospital)	3 community health centres	10 clinics	4 clinics	13 facilities (12 health centres, 1 hospital)
Recruitment period					
Depression	Feb 2015 – Dec 2015	Nov 2014 – July 2015	Aug 2014 – Sept 2015	Aug 2014 – July 2015	Jan 2015 - Sept 2015
AUD	Aug 2015 – Nov 2015	Nov 2014 – Aug 2015	Aug 2014 – Sept 2015	-	-
Psychosis	Dec 2014 – Jul 2015	Nov 2014 – Aug 2015	Aug 2014 – Sept 2015	Aug 2014 – Sept 2014 Aug 2015 – Sept 2015	Jan 2015 - Sept 2015
Epilepsy	Dec 2014 – March 2015	-	Aug 2014 – Sept 2015	-	Jan 2015 - Sept 2015
Recruitment and group allocation					
Depression	Recruitment done by PRIME researcher; Group allocation: • Diagnosis made by nurse or health officer: diagnosed cohort • No diagnosis but screen positive on PHQ-9: comparison cohort	Recruitment done by PRIME researcher; Group allocation: • Diagnosis made by Medical officer (MO): diagnosed cohort • No diagnosis but screen positive on PHQ-9 or AUDIT: depression or AUD comparison cohorts	Recruitment done by PRIME researcher; Group allocation: • Diagnosis made by primary health care (PHC) worker: diagnosed cohort • No diagnosis but screen positive on PHQ-9 or AUDIT: depression or AUD comparison cohorts	Recruitment done by PRIME researcher; Group allocation: • Diagnosis made by nurse or doctor: diagnosed cohort • No diagnosis but screen positive on PHQ-9: comparison cohort	Recruitment done by PRIME researcher; • Group allocation: Diagnosis made by nurse: diagnosed cohort • No participants recruited in the comparison cohort
AUD	Diagnosis and recruitment done by PRIME researcher; • Screen positive on AUDIT: diagnosed cohort • No participants recruited in a comparison cohort			n/a	n/a
Psychosis	Diagnosis and recruitment done by psychiatric nurse; Diagnosed patient recruited, together with caregiver	Recruitment done by PRIME researcher; Diagnosis made by MO: diagnosed patient or caregiver recruited	Recruitment done by PRIME researcher; Diagnosis made by trained PHC worker or MO: caregivers of diagnosed patients recruited	Recruitment done by PRIME researcher: patient recruited; where possible, caregiver also recruited	Recruitment done by PRIME researcher; Diagnosis made by nurse: diagnosed patient recruited, together with caregiver
Epilepsy	Diagnosis and recruitment done by nurse or health officer;	n/a	Diagnosis given by PHC worker or MO: diagnosed patient recruited	n/a	

	Diagnosed patient recruited, together with caregiver				
Assessments					
Location and timing of baseline assessment	All cohorts: Facility-based; if participants too unwell to leave their home, completed at home	All cohorts: Initiated at facility, finalised at home	All cohorts: Initiated at facility, finalised at home	All cohorts: Facility-based	Depression: Facility or home-based (participant-dependent). Psychosis and epilepsy: Facility-based for participant, home-based for caregiver, or vice versa.
Location and timing of midline assessment	• Facility-based - if participants too unwell to leave their home, completed at home • Depression, psychosis and epilepsy: 6 months post-baseline • AUD: 3 months post-baseline	• Home-based • Depression and AUD: 3 months post-baseline • Psychosis: 6 month post-baseline	• Home-based • Depression and AUD: 3 months post-baseline • Psychosis and epilepsy: 6 month post-baseline	• Facility/Home-based • Depression: 3 months post-baseline • Psychosis: no midline	• Home-based • Depression: 3 months post-baseline • Psychosis and epilepsy: 6 month post-baseline
Location and timing of endline assessment	• Facility-based - if participants too unwell to leave their home, completed at home; • 12 months post-baseline	Home-based; 12 months post-baseline		• Facility/Home based; 12 months post-partum	Home-based; 12 months post-baseline

*The implementation area includes 10 of the 36 Village Development Committees in Chitwan District; PHC=Primary health care; PHQ-9=Patient Health Questionnaire – 9 item; AUDIT=Alcohol Use Disorder Identification Test.