

# Investigating physical comorbidity in people with severe mental illness in South Asia

<b>Submission date</b> 22/05/2019	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 03/06/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 15/12/2023	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

People with mental illness die on average 10-20 years earlier than the general population. Studies from low- and middle-income countries also show a similar pattern but with an even greater reduction in life expectancy.

The vast majority of these excess deaths are due to preventable physical health problems, such as heart disease and diabetes. Almost all physical conditions are more common and their outcomes are poorer for people with mental illness. Reasons for this include a complex combination of the underlying mental disorder, its treatment, socioeconomic inequalities and crucially, disparities in accessing healthcare and lack of effective treatments.

The physical health of people with mental illness has been largely neglected by health professionals. For example, they do not receive screening for health problems, do not get illnesses such as diabetes diagnosed, or get help to stop smoking. To compound the problem, there has been limited research in this area. Current gaps in knowledge and availability of effective treatments for physical health problems in people with mental illness are simply indefensible and contravene their basic human right to health.

Responding to this complex challenge requires strong international research partnerships and collaborations. We have established a collaboration between policy makers, clinicians and researchers from the UK and South Asia (Bangladesh, India and Pakistan) – the IMPACT Group. The aim is to develop expertise and carry out research to understand how to prevent physical health problems, improve health and improve health services for one of the world's most vulnerable populations- people with mental illness in South Asia.

### Who can participate?

Anyone aged 18 or over with a diagnosis of severe mental illness (i.e. schizophrenia, schizoaffective disorder, bipolar affective disorder, severe depression with psychosis), attending included institutions during the study period can participate.

### What does the study involve?

Participants will be interviewed about their health and lifestyle.

### What are the possible benefits and risks of participating?

As a non-interventional study, there is very little risk of adverse events associated with the

study. Due to the frailty of the population, some questions or the burden of the assessments may cause distress on the participants or the carers. However, if any of these happens, the participant can stop participating at any time during the assessments.  
If a physical condition or blood test abnormality (outside the normal range for age and sex) is detected as a part of the research assessments, the research team will inform the clinician responsible for the patient.

Where is the study run from?

1. The National Institute of Mental Health and Neuro-Sciences, Bangalore, India
2. National Institute of Mental Health, Dhaka, Bangladesh
3. Institute of Psychiatry & WHO Collaborating Center, Rawalpindi, Pakistan

When is the study starting and how long is it expected to run for?

July 2019 to December 2020

Who is funding the study?

National Institute of Health Research, UK

Who is the main contact?

Dr Gerardo Zavala Gomez,  
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## Contact information

**Type(s)**

Public

**Contact name**

Dr Gerardo Zavala Gomez

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## Additional identifiers

**Clinical Trials Information System (CTIS)**

Nil known

**Protocol serial number**

002

# Study information

## Scientific Title

Investigating mental and physical comorbidity: survey in people with severe mental illness in South Asia

## Acronym

IMPACT SMI survey

## Study objectives

The prevalence of physical disorders and related lifestyle health risk behaviours in people with severe mental illness (SMI) in South Asia is higher than in the general population.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

1. Approved 02/08/2017, Health Sciences Research Governance Committee from the University of York (Heslington, York, YO10 5DD; (01904) 323253; smh12@york.ac.uk), ref: nil known
2. Approval pending, National Centre for Injury Prevention and Rehabilitation Bangladesh (House: B 162, Rd No 23, Dhaka, Bangladesh; +880 2-58814988; info@ciprb.org), ref: nil known
3. Approval pending, Indian Medical Research Council (P.O. Box No. 4911, Ansari Nagar, New Delhi - 110029, India; 91-11-26588980; icmrhqds@sansad.nic.in), ref: nil known
4. Approved 19/09/2018, National Bioethics Committee Pakistan (Institutional research and ethics forum, Rawalpindi medical university, Tipu Rd, Chamanzar Colony, Rawalpindi, Punjab 46000, Pakistan; +92 51 9290755; info@rmur.edu.pk), ref: R-32/RMU/20

## Study design

Cross-sectional study

## Primary study design

Observational

## Study type(s)

Prevention

## Health condition(s) or problem(s) studied

Severe mental illness

## Interventions

We will conduct a cross-sectional survey among SMI patients in wards, outpatient clinics and specialist mental health institutions in Bangladesh, India and Pakistan. In Bangladesh, the survey will take place initially at the National Institute of Mental Health (NIMH), Dhaka. In India, the survey will be conducted initially at the National Institute of Mental Health and Neurosciences (NIMHANS), Bangalore, a tertiary care neuropsychiatric institute. In Pakistan, the survey will be initiated at Institute of Psychiatry (IoP), Rawalpindi. Once the procedures and resource requirements have been established in the three sites, the survey will expand to other specialist mental health institutes.

## Intervention Type

Other

**Primary outcome(s)**

Prevalence of self-reported communicable and non-communicable diseases and lifestyle health-risk behaviors measured by patient interviews at baseline.

**Key secondary outcome(s)**

Identify lifestyle advice, health-related quality of life and common mental disorders (depressive and anxiety symptoms) measured by patient interviews at baseline

**Completion date**

01/03/2021

**Eligibility**

**Key inclusion criteria**

1. Diagnosis of severe mental illness (i.e. schizophrenia, schizoaffective disorder, bipolar affective disorder, severe depression with psychosis)
2. Aged 18 years and over
3. Able to provide informed consent, or for whom carer agreement can be obtained
4. Attending included institutions during the study period
5. Able to be seen by study researchers during working hours

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

3989

**Key exclusion criteria**

Patients who are assessed to lack capacity by their local physician

**Date of first enrolment**

01/07/2019

**Date of final enrolment**

01/12/2020

# Locations

## Countries of recruitment

Bangladesh

India

Pakistan

## Study participating centre

### **The National Institute of Mental Health and Neuro-Sciences**

368 8th Main Rd 2nd Block

Someshwara Nagar

Jayanagar

Bengaluru

India

560029

## Study participating centre

### **National Institute of Mental Health**

Mirpur Rd

Near Shyamoli Sheeshu Mela

Dhaka

Bangladesh

1207

## Study participating centre

### **Institute of Psychiatry & WHO Collaborating Center**

Benazir Bhutto Rd

Chah Sultan

Rawalpindi

Pakistan

46000

# Sponsor information

## Organisation

University of York

## ROR

<https://ror.org/04m01e293>

# Funder(s)

## Funder type

Government

## Funder Name

National Institute for Health Research

## Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during the current study will be available upon request from the IMPACT data management group. Ownership of the data is carefully managed, in accordance with the IMPACT Collaboration Agreement (between the partners) and the Main Contract (between the University of York, as the co-ordinator, and the NIHR, as funder) and IP policy. Guidance and regulations governing the collection and secure storage of research data at participating organisations and the University of York will be followed.

Consent will be provided by all participants. All consent forms will be stored separately from survey data in locked cabinets in locked offices at study research offices in each study site. All coded data will be transferred to and stored as anonymous data at the University of York who will act as data curator. A secure password protected and encrypted electronic database will be set up to store the data. All trackable information records will be destroyed at the end of the standard archiving period (i.e. 10 years after study approval) in line with the University of York policies.

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		23/02/2023	19/07/2023	Yes	No
<a href="#">Results article</a>		14/12/2023	15/12/2023	Yes	No

<a href="#">Protocol article</a>	protocol	10/10/2020	13/10/2020	Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes