ISRCTN15571919 https://doi.org/10.1186/ISRCTN15571919

Investigating the impact of COVID-19 and its response, on people with severe mental illness in South Asia

Submission date
25/05/2020

Recruitment status
No longer recruiting

Registration date
28/05/2020

Overall study status
Completed

Last Edited
28/05/2020

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The current global COVID-19 pandemic has affected almost all aspects of life for a large proportion of the world's population, including people living in low- and middle-income (LMIC) countries in South Asia. In preparing a response to the pandemic, it is important that the needs of vulnerable groups, such as people with severe mental illness (SMI; i.e. disorders such as schizophrenia, bipolar disorder) are not neglected to avoid widening existing health and healthcare inequalities. There are reasons to suggest people with SMI may be disproportionately affected by the outbreak and/or its response.
The aim of the study is to investigate the impact of the COVID-19 pandemic and its response (e. g. health promotion messaging, lockdown and social distancing) on persons with SMI.

Who can participate?
Adults with SMI.

What does the study involve?
Researchers will administer the survey by telephone and record responses directly using a tablet or PC. We will collect information about participants' knowledge, attitudes and responses to public health measures to prevent COVID-19; symptoms, symptoms, diagnosis and testing for COVID-19 amongst participants and their families; participants' wellbeing and mental health, health risk behaviours, quality of life and access to healthcare; and their housing (including urban /rural location), employment, finances, food security and social support.

What are the possible benefits and risks of participating?
The participants will be remunerated for their time, they will receive calling credit for their cell-phones. The procedures are not invasive and we don't expect any harm to the participants however, If a subject during the interview reveals symptoms of COVID-19 or self-harm, the interviewer will report the findings to the PI, so the patient can be referred to a clinician for risk assessment and further management, according to protocols in place in each site.

Where is the study run from?
University of York (UK) and mental health hospitals in India, Pakistan, and Bangladesh.

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

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Gerardo Zavala, g.zavala@york.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Gerardo Zavala

ORCID ID
https://orcid.org/0000-0002-9825-8725

Contact details
University of York
Heslington
York
United Kingdom
YO10 5DD
+44 (0)1904 321333
g.zavala@york.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Investigating the impact of COVID-19 and its response, on people with severe mental illness in South Asia

Acronym

IMPACT SMI-COVID-19 Survey

Study objectives
People with severe mental illness are more likely to be affected by the COVID-19 pandemic than people without severe mental illness

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 29/04/2020, Health Sciences Research Governance Committee from the University of York (Heslington, York, YO10 5DD, UK; +44 (0)1904 323253; smh12@york.ac.uk), ref: n/a
2. Approved 27/04/2020, National Centre for Injury Prevention and Rehabilitation Bangladesh (House: B 162, Rd No 23, Dhaka, Bangladesh; +880 2-6995004; info@ciprb.org), ref: n/a
3. Approved, National Institute of Mental Health and Neurosciences ethics committee (P.O. Box No. 2900, Hosur Road, Bangaluru – 560 029, India; 91-11-26588980; drgrimaji@gmail.com), ref: n/a
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: n/a

Study design
Longitudinal study

Primary study design
Observational

Study type(s)
Other

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

Interventions
We will contact IMPACT SMI survey participants who have provided consent to contact will be contacted by telephone (n=2,500). Verbal informed consent will be obtained. Researchers will administer the survey by telephone and record responses directly using a tablet or PC. We will collect information about participants' knowledge, attitudes and responses to public health measures to prevent COVID-19; symptoms, symptoms, diagnosis and testing for COVID-19 amongst participants and their families; participants' wellbeing and mental health, health risk behaviours, quality of life and access to healthcare; and their housing (including urban/rural location), employment, finances, food security and social support.

Intervention Type
Other

Primary outcome(s)
Depression, anxiety and wellbeing are measured via a telephone survey using the validated GAD7, PHQ9, and WEMWBS scales at baseline and possible follow-ups (depending on the evolution of the pandemic)

Key secondary outcome(s))
Beliefs and knowledge about COVID-19, Knowledge of, and response to government measures and public health advice to prevent the spread of COVID-19, Key sources and levels of trust for information about COVID-19, COVID-19 symptoms, Access to treatment for COVID-19, access to food, Problems with employment, income and finances, Social isolation, loneliness and limited social support will be measured via a telephone survey at a single time point

Completion date
01/02/2022

Eligibility

Key inclusion criteria
Consenting adults aged 18 years and above with severe mental illness (schizophrenia, bipolar disorder, schizoaffective disorder and depression with psychotic symptoms) from the IMPACT survey. The IMPACT survey randomly selected and recruited eligible patients attending a mental health institute in Dhaka, Rawalpindi or Bangalore.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Lack of capacity

Date of first enrolment
05/05/2020

Date of final enrolment
01/01/2022

Locations

Countries of recruitment
Bangladesh

India

Pakistan

Study participating centre
National Institute of Mental Health and Hospital
Dhaka 1207
Dhaka
Bangladesh
N/A

Study participating centre
Institute of Psychiatry
Benazir Bhutto Rd
Chah Sultan
Punjab
Rawalpindi
Pakistan
46000

Study participating centre
National Institute of Mental Health and Neuro-Sciences
368, 8th Main Rd, 2nd Block
Someshwara Nagar,
Jayanagar
Karnataka
Bangaluru
India
560029

Sponsor information

Organisation
University of York

ROR
https://ror.org/04m01e293

Funder(s)

Funder type
Government

Funder Name
National Institute of Health Research

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes