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

Submission date
22/05/2019

Recruitment status
No longer recruiting

Registration date
03/06/2019

Overall study status
Completed

Last Edited
15/12/2023

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
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 Institue of Health Research, UK

Who is the main contact?
Dr Gerardo Zavala Gomez,
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Study website
https://www.york.ac.uk/igdc/research/impact/

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

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

Overall study start date
01/05/2018

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
4,500

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

Sponsor details
Heslington
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United Kingdom
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Sponsor type
University/education

Website
https://www.york.ac.uk/

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

Publication and dissemination plan
The protocol of the survey will be sent for publication
The second manuscript of the survey will be a prevalence study addressing the physical h Physical co-morbidities in patients with severe mental illness in south Asia: a cross-sectional study in India Pakistan and Bangladesh. Exploring the inequalities, sex, age and country related differences in the prevalence.
The third will provide an overview of the prevalence of “unhealthy behaviours” (i.e. smoking, alcohol consumption, physical activity, sleeping patterns) and study the relationship between modifiable lifestyle behaviours, and their relationship with infectious and non-communicable diseases in South Asia.
The fourth will explore the experiences of seeking healthcare (including out of pocket expenditure) for physical health problems and b) the offer, receipt and engagement with lifestyle behaviour change interventions for this group.

Intention to publish date
01/01/2021

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?

Protocol article	protocol	10/10/2020	13/10/2020	Yes	No
Results article		23/02/2023	19/07/2023	Yes	No
Results article		14/12/2023	15/12/2023	Yes	No