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Developing culturally-relevant family interventions for people with psychosis in Indonesia

Submission date
30/11/2021

Recruitment status
No longer recruiting

Registration date
03/12/2021

Overall study status
Completed

Last Edited
13/02/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Mental illnesses comprise the single largest source of health-related economic burden globally and low-and middle-income countries are disproportionately affected. The majority of people with schizophrenia who need treatment do not receive it and are often wholly reliant on family caregivers for daily care and support. Family interventions have an exceptionally robust evidence base for their effectiveness in high-resource settings, but it is unknown whether they can produce equivalent effects in some low-resource settings where cultural beliefs, explanatory models of illness and contextual socio-economic issues differ. The aim of this study is to assess the feasibility and acceptability of implementing an adapted, co-produced intervention via task-shifting in primary care settings evaluated using the Medical Research Council framework for complex interventions.

Who can participate?
For the feasibility trial, people with schizophrenia and family members or carers of people with schizophrenia aged over 18 years can participate. The development and preliminary testing will also involve people with schizophrenia, family members or carers of people with schizophrenia, healthcare professionals and people who can inform decisions about implementing interventions in primary care.

What does the study involve?
The study will involve delivering family interventions to carers and relatives of people with schizophrenia and may potentially involve people with schizophrenia in parts of the intervention. The intervention will be delivered by mental health workers in primary care settings and will contain up to 10 sessions delivered over 12 weeks and comprises therapeutic elements to enhance family skills and knowledge, communication skills training, enhancing skills in problem-solving and goal-setting underpinned by cognitive models and framed by collaborative partnerships to enhance supportive therapeutic relationships. The intervention is based on a widely used cognitive-behavioural model and is approved by the National Institute for Clinical Excellence. Half of the participants who take part in the study will not receive the intervention and will continue to attend treatment as normal in their primary care centre. All participants,

whether receiving the intervention or not, will take part in assessments of symptoms, wellbeing, social functioning and families and carers will be asked to answer questions about their experiences as a carer, knowledge and the consequences of being a carer or family member.

What are the possible benefits and risks of participating?
Participants consenting involvement in this study will contribute to the production of knowledge for the advancement of mental health practice and policy and building capacity for research in their areas. Though the aim of this research is not to directly benefit the participants, some may find beneficial effects from participating in talking therapies including gaining insight, emotional relief and feelings of being supported. Similarly, those involved in the delivery of interventions will gain skills and knowledge in this mode of intervention delivery. There are no known negative side-effects to family interventions though some participants may find it emotionally upsetting to discuss their personal experiences.

Where is the study run from?
1. University of Manchester (UK)
2. Universitas Indonesia (Indonesia)

When is the study starting and how long is it expected to run for?
March 2021 to September 2023

Who is funding the study?
The study is funded by the Joint Global Health Trials Initiative which is managed by the Medical Research Council (UK)

Who is the main contact?
1. Dr Laoise Renwick, laoise.renwick@manchester.ac.uk
2. Dr Herni Susanti, herni-s@ui.ac.id

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Reducing relapse for people with schizophrenia in Indonesia: developing a culturally-relevant, evidence-based family intervention

Acronym
FUSION

Study objectives
The aim of this study is to adapt and refine an evidence-based family intervention for relatives and carers of people with schizophrenia in Java, Indonesia. Schizophrenia presents a major public health problem in this region. Large treatment gaps are a key contributor; the majority for whom treatment would be of benefit, do not receive any and consequently, much of the care people with schizophrenia receive is delivered by their families. In low-resource settings, family interventions are one of only three types of interventions recommended for schizophrenia by the World Bank's third edition of disease priorities. Family interventions for psychosis (FIp) have strong evidence for their efficacy in high-income countries. FIp significantly reduce relapse, re-hospitalization, increase adherence to medication regimes, enhance patient functioning and improve family environments.

The researchers propose to use an existing intervention that is currently approved for widespread use in the NHS (according to National Institute for Clinical Excellence Guidelines) and adapt and refine the intervention to produce a culturally relevant psychosocial intervention. FIp require adaptation to different cultural contexts allowing cultural beliefs, explanatory models of illness and contextual socio-economic issues to be incorporated into the content and delivery of such interventions. This enhances acceptability, increases engagement and can enhance the efficacy of the intervention. The researchers will explore stakeholder priorities for the intervention using an empirically-derived heuristic framework for cultural adaptation of psychosocial therapies and gain consensus from stakeholders on the components, format and delivery of this evidence- based intervention.

The objectives are:
1. Explore preferences and priorities for delivering family interventions for relatives and carers of people with schizophrenia in Java, Indonesia
2. Synthesise findings from stakeholder interviews with an existing evidence-based intervention
3. Gain consensus on the components, format and delivery of the intervention
4. Identify the training needs of healthcare workers for delivering the intervention
5. Produce a manual to support the delivery of the culturally-adapted intervention
6. Explore wider factors that may hinder or facilitate the adoption, reach and effectiveness of the intervention for delivery
7. Train healthcare professionals to deliver the intervention in primary care settings
8. Assess the feasibility of testing the intervention in a full trial and explore the acceptability of the intervention to a wide group of stakeholders

The researchers will produce a manual to support delivery of a co-produced, culturally-relevant intervention and assess the training needs of community workers to promote scalability for a future trial to reduce the risk of relapse in schizophrenia. Using the Medical Research Council framework for complex interventions the researchers will conduct this study in three phases. Following adaptation and refinement of the intervention, they will produce a manual to guide intervention implementation, develop training resources, train healthcare professionals to deliver the intervention and explore the acceptability of this intervention to a wide group of stakeholders. The researchers will assess the feasibility of taking the intervention to full trial considering key aspects including recruitment, the willingness of participants to be randomised, retention in the trial, intervention fidelity and completeness of outcome assessment. They will explore participants and healthcare workers views of receiving and delivering the intervention and wider implementation issues from key informants to ascertain factors affecting the reach and scalability of the intervention for a future trial. The key objective is to assess the feasibility of testing this intervention in a randomised, single-blind trial to determine the effectiveness of a culturally adapted version of FIp versus standard care in a primary care setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/03/2021, University of Manchester University Research Ethics Committee (UREC 1) (Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, UK; switchboard +44 (0)161 306 6000; urec1@manchester.ac.uk), ref: 2021-8041-18032

Study design
Randomized feasibility trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Over 12 months, the researchers will recruit a convenience sample of 60 service-user and family member dyads to i) compare recruitment and retention in different settings and delivered by different health professionals, ii) assess the feasibility of collecting participant outcome measures at study entry, post-intervention and 6 months later, iii) assess the usability and acceptance of the intervention manual by non-specialist healthcare workers in primary care, iv) measure fidelity to the model and healthcare workers adherence to the intervention model and v) assess the acceptability of the intervention to recipients.

Participants will be randomised to receive family interventions or to continue with treatment as usual at a ratio of 1:1. Randomisation will be carried out remotely using randomisation software according to the International Conference on Harmonization E9 Statistical Principles Guidelines and will be implemented by the trial manager.

The intervention is based on a widely used cognitive-behavioural model of family interventions developed by Barrowclough and Tarrier and adopted as the model of choice in NICE-approved interventions. The family intervention will offer therapeutic elements to enhance family skills and knowledge, communication skills training, enhancing skills in problem-solving and goal-setting underpinned by cognitive models and framed by collaborative partnerships to enhance supportive therapeutic relationships. The intervention is typically delivered over 12 weeks and will consist of up to 10 sessions. The intervention adaptation will be co-produced locally synthesising stakeholders' preferences and priorities for intervention delivery and using consensus methods to determine the mode and delivery of the intervention.

Intervention Type
Behavioural

Primary outcome(s)
1. Acceptability and satisfaction with the intervention will be measured quantitatively by attendance and retention in the intervention and qualitatively using in-depth interviews with carers and family members of those with schizophrenia post-intervention
2. Recruitment and retention will be measured using numbers of participants identified by healthcare workers, numbers approached to participate, numbers consenting to take part, numbers randomised and numbers of participants who complete the intervention and are retained in both arms post-intervention and 3 months
3. Recruitment and retention will also be measured using numbers of complete outcome measures described in the secondary outcome measures below post-intervention
4. Fidelity to the intervention and experience of delivering the intervention will be measured using items drawn from the adapted manualised intervention and measured using therapist report and therapy diaries post-intervention

Key secondary outcome(s))
1. Symptom severity and relapse rates will be measured by administering the Positive and Negative Syndrome Scale (PANSS) to participants with schizophrenia at baseline, post-intervention and at 3 months follow-up
2. Social functioning will be measured by administering the Personal and Social Performance Scale (SPS) to participants with schizophrenia at baseline, post-intervention and at 3 months follow-up
3. Family environment and functioning will be measured using the Family Questionnaire administered at baseline, post-intervention and at 3 months follow-up
4. Therapeutic engagement will be measured quantitatively using attendance levels, number of sessions attended and completion of the intervention post-intervention

Completion date
01/09/2023

Eligibility

Key inclusion criteria
Carers/relatives will be included if they are:
1. Living with or spending at least 10 hours per week in face-to-face contact with an individual with schizophrenia and assuming a caring role

2. Over the age of 18 years
3. Resident of Bogor or Jakarta
4. Able to give informed written consent

Participant type(s)
Carer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Sex
All

Key exclusion criteria
The researchers will exclude potential participants if they have:
1. A drug or alcohol dependence alongside a diagnosis of schizophrenia, according to the Diagnostic and Statistical Manual of Mental Disorders (DSM-V) criteria
2. Unstable residential arrangements such that the likelihood of being available for the duration of the trial is low

Date of first enrolment
01/09/2022

Date of final enrolment
01/03/2023

Locations

Countries of recruitment
Indonesia

Study participating centre
Universitas Indonesia
Faculty of Nursing
Jl. Prof. DR. Sudjono D. Pusponegoro, Kukusan, Kecamatan Beji, Kota Depok, Jawa Barat
Depok
Indonesia
16425

Sponsor information

Organisation
University of Manchester

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Unidentifiable participant data is available from the study team upon request from Laoise Renwick (laoise.renwick@manchester.ac.uk) and Herni Susanti (herni-s@ui.ac.id).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		30/03/2023	13/02/2025	Yes	No
Protocol (preprint)		19/10/2021	01/12/2021	No	No