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A research study in Bosnia and Herzegovina to test a Family Involvement intervention, designed to improve care for people living in the community with severe mental illness

Submission date
09/11/2018

Recruitment status
No longer recruiting

Registration date
20/11/2018

Overall study status
Completed

Last Edited
06/12/2022

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
The Family Involvement intervention has been developed from existing approaches called Trialogue and psycho-education. A key part of these approaches is bringing together several people living with mental health difficulties, their family members and mental health professionals into regular meetings. These different groups meet as equals to discuss topics that they have previously agreed on, share experiences and to learn from one another. This study aims to find out whether Family Involvement can help to improve care for people living with severe mental illness in Bosnia and Herzegovina. More specifically, the researchers want to find out how patients, family members/friends, and health professionals experience Family Involvement when it is used on a regular basis. They also want to find out if Family Involvement improves outcomes like quality of life and symptoms.

Who can participate?
Patients aged 18 and older with severe mental illness

What does the study involve?
All patients are randomly allocated into two groups: one group receives Family Involvement and one group (the control) does not receive Family Involvement (both groups receive their usual treatment). Patients in the Family Involvement group attend meetings once per month over a 6 month period. In each group, there will be 5 patients, 1-2 family members/friends for each patient and 1-2 mental health professionals. The two groups of patients are compared to see if Family Involvement makes a difference to outcomes like quality of life and symptoms. Patients in the Family Involvement group are also interviewed to see how they experienced the intervention.

What are the possible benefits and risks of participating?
For patients, they will be taking part in testing an intervention which might lead to improved quality of life, social functioning and symptoms. Participating family members may benefit from

sharing experiences and learning from others patients and family members/friends, which may help them to manage their own wellbeing and to provide better care for their relatives. The study will benefit clinicians who take part in terms of the training and supervision they will receive to enable them to implement the intervention. For all participants involved in the study, their suggestions and experiences might be incorporated into further adaptations of Family Involvement, so that it is tailored to the needs of patients, carers and clinicians in the context of the mental health care system in Bosnia and Herzegovina. Severe mental illnesses cause a high burden for societies with high levels of distress and high costs to individuals who are affected. This is particularly worse in low and middle-income countries such as Bosnia and Herzegovina, where there is a lack of human and financial resources for specialised mental health services in the community. The testing of Family Involvement will provide evidence for interventions for people with severe mental illness in the community. It is unlikely that any significant ethical, legal or management issues will arise from this study, but some potential risks might be: within the research assessments and interviews that take place across both studies, questions will be raised with participants that might trigger feelings of distress or anxiety. Participants may experience anxiety in trying a new intervention. Throughout the intervention-testing period, individuals will continue to receive their routine care, including any medication, in addition to the test intervention. The intervention can be stopped at any point. The intervention to be tested (Family Involvement) has an evidence base for effectiveness.

Where is the study run from?
Clinical Centre University of Sarajevo (Bosnia and Herzegovina)

When is the study starting and how long is it expected to run for?
August 2017 to March 2021

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

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
16/137/97

Study information

Scientific Title
Testing the effectiveness, acceptability and feasibility of Family Involvement in severe mental illness in Bosnia and Herzegovina: a randomised controlled trial

Study objectives
To test the acceptability, feasibility and effectiveness of Family Involvement against usual treatment.
The specific research questions are:
1. How can Family Involvement be used to support community mental health care in Bosnia and Herzegovina?
2. How is Family Involvement experienced by patients, family members/friends and professionals?
3. How do outcomes change when Family Involvement is used?

Ethics approval required
Old ethics approval format

Ethics approval(s)

1. Clinical Centre University of Sarajevo School of Medicine Research Ethics Committee (Eticki komitet), 18/09/2018
2. Queen Mary Ethics of Research Committee, 30/10/2018, ref: QMERC2018/66

Study design
Interventional single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Patients with severe mental illness (including psychosis)

Interventions
72 patients will be recruited. Each patient will be randomly allocated to either a control or intervention group. Randomisation will be done by UK based research team using STATA statistical software and allocations communicated to the unmasked researchers in the Bosnia team. Patients will be randomised to either the intervention or control groups so that each patient will be either receiving the Family Involvement intervention OR receiving their usual treatment.

Masking: randomisation will take place after recruitment of participants and completion of baseline assessments. Follow-up assessments at 6 and 12 months will be completed with participants by masked researchers. Measures are in-place to ensure that researchers completing follow-up research assessments remain masked to participant allocation.

Patients allocated to the intervention group will receive Family Involvement at their routine clinic or agreed community location once per month over a 6 month period. 1-2 family members /friends will be recruited for each patient who is randomly allocated to the intervention group. These participants will attend the monthly Family Involvement meetings with their relatives. 6-12 clinicians will be recruited to help facilitate the Family Involvement meetings. The Family Involvement intervention is based on principles of Trialogue and psychoeducation. It involves bringing together several patients (5), 1-2 of their family members/friends, and 1-2 mental health professionals in monthly meetings, as equals, so that they may discuss pre-agreed topics, share experiences and for mutual learning.

Patients allocated to the control group will receive their usual treatment over the 6 month period.

Intervention Type
Mixed

Primary outcome measure
Quality of life, measured using the Manchester Short Assessment of Quality of Life (MANSA) at baseline, 6 months (post intervention) and 12 months

Secondary outcome measures
1. Objective social functioning, measured using Objective social outcome index (SIX) at baseline, 6 and 12 months
2. Symptoms, measured using Brief Psychiatric Rating Scale (BPRS) at baseline, 6 and 12 months
3. Service use, measured using adapted Client Service Receipt Inventory (CSRI) at baseline, 6 and 12 months
4. Client satisfaction, measured using Client Satisfaction Questionnaire (CSQ-8) at 6 and 12 months
5. Self esteem, measured using Self-esteem rating scale at baseline, 6 and 12 months
6. Insight and Treatment Attitudes, measured using ITAQ at baseline, 6 and 12 months

Overall study start date
01/08/2017

Completion date
03/08/2020

Eligibility

Key inclusion criteria
1. Patients with a primary diagnosis of severe mental illness (ICD-10 F2)
2. Aged 18 years and older
3. Capacity to provide informed consent
4. Scores 5 or below on the MANSA scale
5. Illness of over 6 months

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
72 patients (72 family members/friends, 6-12 clinicians)

Total final enrolment
72

Key exclusion criteria
1. Does not meet inclusion criteria
2. Primary diagnosis of substance-use disorder, learning disability, dementia, organic psychosis
3. Diagnosis of bipolar disorder
4. Participating in another study conducted by this or another research group

Date of first enrolment
01/12/2018

Date of final enrolment
30/04/2019

Locations

Countries of recruitment
Bosnia and Herzegovina

Study participating centre
Clinical Centre University of Sarajevo
Bolnička 25
Sarajevo
Bosnia and Herzegovina
N/A

Sponsor information

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Queen Mary University of London

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Sponsor type
University/education

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ROR

https://ror.org/026zzn846

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 statistical analysis plan is being written and the trialists are planning publication(s) of a large protocol paper describing the work of their Research Group, including this study, and are considering writing more detailed protocol papers. They intend to publish the quantitative and qualitative findings from this study by August 2020. Regarding dissemination, this study is part of a research group which also aims to build sustainable research capacity. The dissemination plan therefore aims to inform research, policy and practice. The trialists plan to disseminate findings across Bosnia and Herzegovina and across the wider region of South Eastern Europe. Dissemination will include publications, attending conferences, and using platforms like Twitter and the Group website.

Intention to publish date
01/09/2021

Individual participant data (IPD) sharing plan
The trialists will ensure that the study dataset is available for sharing on request following the publication of the main research papers. This is to ensure the scientific impact of the project is maximised. Prior to making the dataset available to interested individuals, the dataset will be pseudonymised and any potentially identifiable data removed. For publications that require data to be accessible, they will comply with this as guided by FAIR principles.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/02/2022	01/03/2022	Yes	No
Protocol article		14/06/2019	11/08/2022	Yes	No