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A research study in Bosnia and Herzegovina to test an intervention called DIALOG+, 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
DIALOG+ is an intervention delivered on a tablet or smartphone using an app. It is designed to help mental health professionals to improve the structure of their routine meetings with patients. It also helps to improve communication with patients during these meetings. Patients are first asked about how satisfied they are with eight areas of their lives (e.g. physical health, family relationships, leisure activities) and three areas of the treatment they are receiving (e.g. practical help, meetings), which is called the DIALOG scale. The patient then chooses up to three areas to discuss in more depth with their health professional. The clinician then discusses each area chosen by patients, using four steps that focus on solutions to the identified problems. This study aims to find out whether DIALOG+ 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 and health professionals experience DIALOG+ when it is used during their routine meetings. They also want to find out if DIALOG+ improves outcomes like quality of life and symptoms.

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

What does the study involve?
All patients are randomly allocated into two groups. Patients in the DIALOG+ group use the app with their clinicians once per month for a period of 6 months. The other group (the control) do not use DIALOG+ (both groups receive their usual treatment). The two groups of patients are compared to see if DIALOG+ makes a difference to outcomes like quality of life and symptoms. Patients in the DIALOG+ 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. The study will also 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 research, their suggestions and experiences might be incorporated into further adaptations of DIALOG+, 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 DIALOG+ 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 (DIALOG+) 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)
Scientific

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Type(s)
Public

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Additional identifiers

Protocol serial number
16/137/97

Study information

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

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

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. The 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 cluster randomised controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Patients with a diagnosis of severe mental illness: includes diagnoses of severe depression and anxiety

Interventions
14 clinicians will be recruited. For each clinician, the research team will recruit 5-6 of their patients and then each clinician-patient cluster will be randomly allocated to a control or intervention group. Randomisation will be done by the UK based research team using STATA statistical software and communicated to the unmasked researchers in Bosnia and Herzegovina. Clinician-patient clusters (5-6 patients per clinician) will be randomised to either the intervention or control groups so that each clinicians will be either delivering DIALOG+ OR delivering usual treatment with their recruited patients.

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 and to minimise risk of contamination in clinicians allocated to the control group.

Patients allocated to the intervention group will receive DIALOG+ at their routine outpatient clinic appointments once per month. This will be delivered by their usual clinician using an app on a tablet computer. The intervention will be over 6 months during which patients will receive 6-7 DIALOG+ sessions. DIALOG + is a technology mediated intervention, which involves a structured patient assessment covering satisfaction with eight life domains and three treatment domains (DIALOG scale) and a four-step solution focused therapy approach to address patient concerns (+). DIALOG+ aims to make routine meetings between clinicians and patients therapeutically effective.

Patients allocated to the control group will receive their usual treatment at routine outpatient clinic appointments once per month over a 6 month period.

Intervention Type
Mixed

Primary outcome(s)
Quality of life, measured using the Manchester Short Assessment of Quality of Life (MANSA), collected by masked researchers using a case report form as part of a research assessment at baseline, 6 months and 12 months

Key secondary outcome(s)
1. Symptoms, measured using the Brief Psychiatric Rating Scale (BPRS) at baseline, 6 and 12 months
2. Objective social functioning, measured using the Objective social outcome index (SIX) at baseline, 6 and 12 months
3. Service use, measured using adapted Client Service Receipt Inventory (CSRI) at baseline, 6 and

12 months
4. Therapeutic relationship in community mental health care, measured using STAR-P at baseline, 6 and 12 months
5. Client satisfaction, measured using client satisfaction questionnaire (CSQ-8) at 6 and 12 months
6. Symptoms, measured using Hospital Anxiety and Depression Scale (HADS) at baseline, 6 and 12 months
7. Self esteem, measured using self-esteem rating scale at baseline, 6 and 12 months

Completion date
21/07/2020

Eligibility

Key inclusion criteria
1. Primary diagnosis of severe mental illness (ICD-10 F3 or F4)
2. Attending the outpatient clinic or day hospital at Clinical Center University of Sarajevo
3. Aged 18 years or older
4. Capacity to provide informed consent
5. Scores 5 or below on the MANSA scale
6. Illness of over 6 months

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
86

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. An inpatient at the time of recruitment
5. Participating in another study conducted by this or another research group

Date of first enrolment
01/12/2018

Date of final enrolment
01/09/2019

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

Organisation
Queen Mary University of London

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

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		03/11/2021	06/01/2022	Yes	No
Protocol article		14/06/2019	11/08/2022	Yes	No