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Psycho-social treatment for people with psychosis in south eastern Europe

Submission date
21/03/2019

Recruitment status
No longer recruiting

Registration date
29/03/2019

Overall study status
Completed

Last Edited
08/04/2024

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
People with psychosis sometimes hear voices, and don't understand what is real and what is not, for example, they can think that family or friends are part of a conspiracy to harm them. They can also experience low mood, isolation and lack of hope and initiative. People with psychosis die 15-20 years earlier than other citizens due to under diagnosed physical illnesses, poor access to healthcare and suicide. In countries with low income up to 50% of people with psychosis do not receive care for their condition. Available treatment is largely focused on anti-psychotic medication which neglects people's social needs and resources. The aim of this study is to test a psycho-social treatment for people with psychosis in south eastern Europe.

Who can participate?
Patients aged 18 or older with psychosis

What does the study involve?
Participants are allocated by chance to either an intervention called Dialog+ or treatment as usual for 12 months. Dialog+ is used during routine clinical meetings. The clinician asks the patient to talk about their satisfaction with different areas of life, such as mental health, physical health, medication, family life, etc. In this way the patient identifies problems and in the next step the patient is guided by the clinician to identify solutions to these problems. Clinicians and patients use computer tablets to engage in this conversation. It is expected that Dialog+ will improve the quality of life and mental health of patients with psychosis.

What are the possible benefits and risks of participating?
Possible benefits for patients include feeling less distressed and having better quality of life. No risks of participating have been reported. However, some participants might become upset due to recalling distressing personal experiences. Appropriate support will be provided to distressed individuals.

Where is the study run from?
1. Universiteti i Prishtines (Kosovo)
2. Klinicki Centar Univerziteta U Sarajevu (Bosnia and Herzegovina)
3. Faculty of Medicine, University of Belgrade (Serbia)

4. University Clinic of Psychiatry Skopje (Macedonia)
5. Clinical Centre of Montenegro (Montenegro)

When is the study starting and how long is it expected to run for?
April 2019 to June 2020

Who is funding the study?
European Commission

Who is the main contact?
1. Tamara Pemovska
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Contact information

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
779334

Study information

Scientific Title
Implementation of an effective and cost-effective intervention for patients with psychotic disorders in low and middle income countries in south eastern Europe

Acronym
IMPULSE

Study objectives
The intervention (Dialog+) is effective in reducing clinical symptoms, improving quality of life and in reducing treatment costs for people with psychosis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/10/2018, Queen Mary Ethics of Research Committee (Queen Mary, University of London, Room W117, Queen's Building, Mile End Road, London E1 4NS; Tel: +44 (0)20 7882 7915; Email: h.covill@qmul.ac.uk), ref: QMREC2204a

The study has been approved by institutional ethics committees in all participating countries: Bosnia and Herzegovina (Klinicki Centar Univerziteta U Sarajevu), Former Yugoslav Republic of Macedonia (University Clinic Of Psychiatry, Skopje), Kosovo (Universiteti I Prishtines), Montenegro (Clinical Centre Of Montenegro, Podgorica), and Serbia (Klinicki Centar Univerziteta U Beogradu).

Study design
Hybrid type 2 effectiveness/implementation, multi-centre study; effectiveness will be studied in a pragmatic, parallel-group, cluster-randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
After baseline assessments, clinicians will be randomized to the intervention (DIALOG+ for 12 months) or control (TAU for 12 months), with an allocation ratio of 1:1.

The intervention group will receive DIALOG+, an evidence-based, technology-assisted intervention designed to make routine meetings between clinicians and patients patient-centred, structured and more therapeutically effective.

The control group will include routine meetings offering treatment as usual. This includes consultations on medication, psychological support and discussion on other aspects of care. After 12 months, clinicians in the control groups will be trained to deliver DIALOG+ and the intervention will be offered to patients in the control group.

Intervention Type
Mixed

Primary outcome(s)
Subjective quality of life measured by Manchester Short Assessment of Quality of Life (MANSA) at baseline, 6 months and 12 months

Key secondary outcome(s))
Measured at baseline, 6 months and 12 months:
1. Treatment satisfaction measured using Client Satisfaction Questionnaire (CSQ)-8
2. Clinical symptoms measured using Brief Symptom Inventory (BSI), Brief Psychiatric Rating Scale (BPRS), and Clinical Assessment Interview for Negative Symptoms (CAINS)

Completion date
26/06/2020

Eligibility

Key inclusion criteria
Clinicians:
1. Having a professional qualification in mental health care
2. More than 6 months' experience of working in mental health care
3. No plans to leave their post within the study period

Patients:
1. Primary diagnosis of psychosis or related disorder (i.e.: ICD-10 F20-29, F31)
2. Aged 18 years or older
3. Attending the outpatient clinic or day hospital
4. History of at least one hospital admission in their lifetime
5. There should not be plans to be discharged from mental health care services for the next 12 months
6. Capacity to provide informed consent

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
549

Key exclusion criteria
Clinicians:
1. No exclusion criteria

Patients:
1. Having a diagnosis of organic brain disorders
2. Having severe cognitive deficits (unable to provide information to study instruments). This will be based on the clinical judgement

Date of first enrolment
01/02/2019

Date of final enrolment
01/09/2019

Locations

Countries of recruitment
Bosnia and Herzegovina

Kosovo

Montenegro

North Macedonia

Serbia

Study participating centre
Universiteti i Prishtines
Street Nena Tereze
Prishtina
Kosovo
10000

Study participating centre
Klinicki Centar Univerziteta U Sarajevu
Bolnicka 25
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71000

Study participating centre
Faculty of Medicine, University of Belgrade
Dr Subotica, 8
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11000

Study participating centre
University Clinic of Psychiatry Skopje
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10000

Study participating centre
Clinical Centre of Montenegro
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81000

Sponsor information

Organisation
European Commission, Directorate-General for Research and Innovation

ROR
https://ror.org/01ef4as46

Funder(s)

Funder type
Government

Funder Name
European Commission

Alternative Name(s)
European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, EC, EU

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan
Anonymised dataset will be available on request from April 2021. Requests can be sent to Dr Nikolina Jovanovic, (n.jovanovic@qmul.ac.uk). The researchers will not share analysed data as they want to have them published in an open access peer reviewed journal. All patients and clinicians participating in the study signed informed consent approved by the relevant ethics committees.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		01/01/2020	20/09/2021	Yes	No
Basic results		21/01/2022	21/01/2022	No	No
Interim results article	Physical health of individuals with psychosis - a mixed method study	16/01/2023	17/01/2023	Yes	No
Other publications	Economic evaluation	26/08/2022	08/04/2024	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes