ISRCTN46897021 https://doi.org/10.1186/ISRCTN46897021

An exploratory study in primary care to test the feasibility of an intervention called DIALOG+, designed to improve quality of life for people in primary care with poor mental and physical health

Submission date
01/03/2021

Recruitment status
No longer recruiting

Registration date
15/03/2021

Overall study status
Completed

Last Edited
20/09/2023

Condition category
Other

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

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 an area to discuss in more depth with their health professional. The clinician then discusses the area, using four steps that focus on solutions to the identified problems. This study aims to find out how patients and health professionals experience DIALOG+ when it is used in primary care. They also want to find out if DIALOG+ improves outcomes like quality of life and other symptoms.

Who can participate?
Adults in primary care who have mental health and/or long-term physical health problems (such as diabetes, high blood pressure, lung disease, heart disease, etc).

What does the study involve?
DIALOG+ will be adapted to primary care settings to enable wider use with patients with mental health and or long-term physical health problem with assessments before and 3 months after the intervention. The results will provide insight to suggest further refining of the intervention and training.
DIALOG+ consists of a patient-centred assessment where the clinician invites the patient to rate their satisfaction with different life domains and treatment aspects. This is followed by a four-step solution-focused approach to identify the patient's resources and develop solutions to deal with the patient's concerns. The intervention will be delivered via an iPad. Each session begins with the patient using the tablet to rate their satisfaction with eight life domains (mental health,

physical health, job situation, accommodation, leisure activities, friendships, relationship with family/partner, personal safety) and three experience of treatment domains (medication, practical help, meetings with professionals). Due to changes during the COVID-19 pandemic, practices may choose to see patients remotely. Depending on their usual care staff may use the tablet via phone/video calls or use their existing IT systems to collect the scale ratings via text message responses which will be recorded on the patient electronic record. The ratings are followed by a four-step approach, based on the principles of solution-focused therapy, whereby the patient is encouraged to consider existing resources that can be used to address the concerns raised. The intervention period will be 3 months, there is no minimum amount of time staff are required to use the intervention and there is no limit to how many times they can use the intervention during the 3-month period. Patients will continue to receive any treatment as usual including medication and psychological therapies.

What are the possible benefits and risks of participating?
DIALOG+ is a resource-oriented and evidence-based intervention which makes use of existing personal and social resources to improve the quality of life of patients with mental illness. The intervention is low cost using routine meetings between patients and clinicians without the need for additional referrals or services. The researchers will adapt DIALOG+ for primary care to improve reach and enable a larger patient population to benefit. Additionally, the study focuses on a new and vulnerable population – those with long-term physical health problems. Research has shown that physical and mental health problems often occur together, are resource-intensive and result in a poor quality of life for billions of people worldwide.
A potential benefit for all participants involved in the study is that their suggestions and experiences might be incorporated into further adaptations, which will tailor the intervention to the needs of patients and clinicians in the context of the primary care system. Additionally, for patients who will be involved in testing DIALOG+, this might lead to improved quality of life and symptoms. The study will also benefit clinicians involved in terms of the training they will receive. Clinicians involved in the DIALOG+ study will be provided with training and supervision to enable them to implement the intervention.
The researchers do not foresee any significant ethical, legal or management issues arising from this study. Within the assessments and interviews that will 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 new interventions. Throughout the intervention-testing period, participants will continue to receive their routine care, including any medication, in addition to the intervention. The intervention can be stopped at any point. The use of DIALOG+ in mental health care settings has an evidence base for effectiveness and the researchers believe this is easily transferable across to physical health care too without any additional risks. To minimise the impact of potential risks, risk management strategies have been outlined in the study protocol.

Where is the study run from?
Queen Mary University of London (UK)

When is the study starting and how long is it expected to run for?
January 2021 to December 2022

Who is funding the study?
Barts Charity (UK)

Who is the main contact?
Franziska Mosler
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
294469

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 294469

Study information

Scientific Title
DIALOG+ in primary care: a proof of concept study

Study objectives
1. To assess the feasibility of DIALOG+ in primary care.
2. To assess the implementation of the DIALOG+ intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 13/01/2022, Wales Research Ethics Committee 1 (Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road East Cardiff, CF11 9AB; +44 (0)2920 785738; Wales.REC1@wales.nhs.uk), ref 21/WA/0389

Study design
Multi-centre interventional mixed-methods study

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Improving quality of life for patients with mental health and/or long-term physical health problems

Interventions
DIALOG+ consists of a patient-centred assessment whereby the clinician invites the patient to rate their satisfaction with different life domains and treatment aspects. This is followed by a four-step solution-focused approach to identify the patient's resources and develop solutions to deal with the patient's concerns. The intervention will be delivered via an iPad.
Each session begins with the patient using the tablet to rate their satisfaction with eight life domains (mental health, physical health, job situation, accommodation, leisure activities, friendships, relationship with family/partner, personal safety) and three experience of treatment domains (medication, practical help, meetings with professionals).
Due to changes during the COVID-19 pandemic, practices may choose to see patients remotely. Depending on their usual care staff may use the tablet via phone/video calls or use their existing IT systems to collect the scale ratings via text message responses which will be recorded on EMIS (patient electronic record).
The ratings are followed by a four-step approach, based on the principles of solution-focused therapy, whereby the patient is encouraged to consider existing resources that can be used to address the concerns raised.
The intervention period will be 3 months, there is no minimum amount of time staff are required to use the intervention and there is no limit to how many times they can use the intervention with during the three-month period. Patients will continue to receive any treatment as usual including medication and psychological therapies.

Intervention Type
Behavioural

Primary outcome(s)
Quality of life measured using the Manchester Short Assessment of Quality of Life (MANSA) at baseline and 3 months

Key secondary outcome(s))
Clinical:
1. Mental distress measured using CORE-10 at 3 months
2. General health status measured using EQ-5D-5L at 3 months

Feasibility:
3. Participants experience explored using semi-structured interviews at 3 months
4. Number of patients screened, recruited and drop-out measured using an Excel spreadsheet at 3 months

Implementation:
5. Treatment fidelity measured using DIALOG+ Adherence Scale from session recordings over the 3-month intervention period
6. App/intervention data recorded by the app over the 3-month intervention period

Completion date
31/12/2022

Eligibility

Key inclusion criteria
1. Formal diagnosis of mental health condition AND/OR long-term physical health condition
2. Able to communicate verbally in English
3. Over 18 years of age
4. Willing to have sessions recorded
5. Capacity to give consent

For remote delivery:
1. Has an email account

Staff:
1. Qualification as a mental health or healthcare professional
2. Experience of working in healthcare for at least 6 months
3. Based in a primary care setting
4. Willing to have sessions recorded
5. Not due to leave their post within the study period
6. Clinical contact with included patient group

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
12

Key exclusion criteria
1. Insufficient command of English to provide written informed consent and understand the questions in the research interviews
2. Lack of capacity to provide informed consent

Date of first enrolment
17/01/2022

Date of final enrolment
31/08/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
East London NHS Foundation Trust
United Kingdom
E1 8DE

Sponsor information

Organisation
Queen Mary University of London

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Charity

Funder Name
Barts Charity

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			20/09/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes