

# 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

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| <b>Submission date</b><br>01/03/2021   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>15/03/2021 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>20/09/2023       | <b>Condition category</b><br>Other                | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> 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

## Contact name

Ms Franziska Mosler

## ORCID ID

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## Contact details

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# Additional identifiers

## EudraCT/CTIS number

Nil known

## IRAS number

294469

## ClinicalTrials.gov number

Nil known

## Secondary identifying numbers

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

## **Secondary study design**

Non randomised study

## **Study setting(s)**

GP practice

## **Study type(s)**

Quality of life

## **Participant information sheet**

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

## **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 measure**

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

**Secondary outcome measures**

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

**Overall study start date**

01/01/2021

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

10

**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**

England

United Kingdom

**Study participating centre**

East London NHS Foundation Trust

United Kingdom

E1 8DE

**Sponsor information****Organisation**

Queen Mary University of London

**Sponsor details**

Research & Development Governance Operations Manager

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+44 (0)20 7882 7275/6574  
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**Sponsor type**

University/education

**Website**

<http://www.qmul.ac.uk/>

**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**

**Publication and dissemination plan**

The researcher intends to publish the quantitative and qualitative findings from this study by 2022. Findings will also be presented at relevant conferences and shared on social media. Finally, the study will form a chapter in the researcher's PhD thesis. No additional documents will be available.

**Intention to publish date**

31/12/2023

## 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? |
|--------------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">HRA research summary</a> |         |              | 20/09/2023 | No             | No              |