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A study to improve quality of life of people with long term conditions in Colombia using Dynamic DIALOG+

Submission date
04/12/2025

Recruitment status
Not yet recruiting

Registration date
23/01/2026

Overall study status
Ongoing

Last Edited
23/01/2026

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Not provided at time of registration

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Study information

Scientific Title
Building on Dynamic DIALOG+ for non-communicable diseases: a hybrid type I effectiveness-implementation trial of Dynamic DIALOG+ to improve quality of life among people with non-communicable diseases in Colombia

Acronym
BOND+

Study objectives
Chronic non-communicable diseases (NCDs) represent a growing public health challenge in low- and middle-income countries (LMICs). There is a well-documented bidirectional relationship between chronic physical illnesses and mental health conditions. Individuals with co-existing disorders face increased disability, reduced quality of life, greater healthcare use, and elevated mortality rates. Despite this, integrated approaches to addressing mental and physical health are rare in LMICs. As a result, health systems often fail to detect and treat mental health problems among patients with NCDs, contributing to poor health outcomes and increased systemic costs. The World Health Organisation has emphasised the need for scalable, evidence-based interventions to address mental health in LMICs, particularly in regions like Latin America, where resource constraints and high unmet need intersect.

Digital health technologies have emerged as promising, scalable tools to bridge the treatment gap for mental health care. These technologies are low-cost, can be delivered by non-specialist providers, and offer flexible, user-centred approaches tailored to resource-constrained settings. One such intervention is DIALOG+. Evidence from high-income countries (HICs), including randomised controlled trials in the UK and implementation studies in Europe, shows that DIALOG+ is effective in improving quality of life, reducing psychiatric symptoms, and enhancing communication between patients and providers. Despite the proven effectiveness of DIALOG+, mainly for patients with mental NCDs in Colombia, implementation strategies are lacking. Evidence is primarily oriented towards effectiveness in mental health conditions in particular contexts, such as school settings, victims of armed conflict, or adolescents.

Although exploratory data suggest the utility, feasibility, and effectiveness of DIALOG+ for patients with physical NCDs, and the impact of such conditions on mental health and quality of life is well recognised, no controlled trial has yet provided effectiveness data for DIALOG+ in patients with co-existing physical and mental health conditions.
Previous data from a recent pilot study conducted in Colombia by the NIHR LatAm Centre identified key system-level barriers to implementation. These include the additional consultation time required to deliver the intervention, which may increase costs due to clinician time and reduce capacity to meet primary care demand. Another barrier is the high turnover of health professionals, particularly in remote regions, which disrupts the continuity of DIALOG+ delivery and affects the therapeutic alliance between patient and provider.

To address these challenges while acknowledging the known limitations of the original intervention in the Colombian context, the NIHR LatAm Centre has proposed an adaptation of the original DIALOG+ intervention based on previous pilot studies. Modifications include adjustments to the app's structure and language, as well as the way the intervention is delivered, with contracted professionals or staff providing the intervention in appointments exclusively assigned for this purpose. Given these modifications, the adapted intervention will be referred to as Dynamic DIALOG+ (DD+). Therefore, given the absence of an implementation strategy for DD+, a Hybrid I effectiveness-implementation trial will be conducted. This design will allow simultaneous testing of both effectiveness and implementation outcomes of the modified intervention in patients with co-existing physical and mental NCDs in Colombia.

The Primary Effectiveness aim is to evaluate the effectiveness of (Dynamic DIALOG +) DD+ intervention for improving QoL of patients with co-existing physical and mental NCDs in Colombia. The Secondary Implementation aim is to analyse the implementation context for DD + intervention for patients with co-existing physical and mental NCD to improve their QoL in local Colombian contexts.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 13/11/2025, Institutional Research and Ethics Committee of the Faculty of Medicine of the Pontificia Universidad Javeriana and the Hospital Universitario San Ignacio (42nd Street No. 4-49 5th Floor, Office 507, Bogota, 110231, Colombia; +57 15946161 Ext. 2470; ciei@husi.org.co), ref: FM-CIE-1144-25

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Single

Purpose
Health services research, Supportive care, Psicosocial Intervention Implementation

Study type(s)

Health condition(s) or problem(s) studied
Diabetes, anxiety, depression, diabetes, obesity, hypertension,hazardous alcohol consumption

Interventions
Dynamic DIALOG+ (DD+) is an adaptation of the original DIALOG+ intervention, developed to address limitations identified in the Colombian context. It is a patient-centred, resource-oriented, and technology-assisted approach that supports structured communication between patients and healthcare professionals. The intervention is delivered by trained practitioners during appointments explicitly scheduled for this purpose, at least once per month, for a minimum of 6 months.

During each session, patients use a tablet/computer to rate their satisfaction across different life domains. Together with the clinician, they identify and prioritise areas to focus on. The conversation is then guided through a structured four-step process: understanding the current situation, envisioning a preferred future, exploring available options, and agreeing on concrete actions. This structured dialogue promotes solution-focused care, helps patients draw on personal and external resources, and enables progress to be tracked digitally across sessions. By embedding these features, DD+ aims to enhance patient engagement, improve continuity of care, and address both physical and mental health needs in individuals living with non-communicable diseases (NCDs).

Recruitment will take place in primary health care centres, outpatient psychiatric facilities, or outpatient services at hospitals in three Colombian cities (Bogotá, Cali, and Leticia).
DD+ deliverers will be part of the study personnel
Participants must have at least one long-term chronic disease (diabetes, high blood pressure, or obesity) and one mental health condition (anxiety, depression, or hazardous alcohol use). Screening includes MANSA for quality of life, followed by PHQ-8, GAD-7, AUDIT-C, and assessments for diabetes, blood pressure, and obesity to confirm eligibility. Additional Baseline Assessmente measures include: Objective Social Outcomes Index (SIX), EQ5D, WHOQOL-BREF, and CSRI

The unit of randomisation will be the individual participant. Site-stratified blocked randomisation with variable block sizes of two to four will be applied on a rolling basis during recruitment. A randomisation schedule will be generated for each health centre, and

participants within each stratum will be assigned 1:1 to either the DD+ or the control group, using REDCap or by phone, according to the schedule.

Due to the nature of the intervention, participants cannot be blinded to allocation. Researchers involved in recruitment, screening, baseline assessment, and scheduling will also be unblinded. Outcome assessors, however, will remain blinded, and participants will be instructed not to reveal their allocation. Blinded statisticians will conduct statistical analyses, while unblinded researchers will conduct qualitative interviews and analyses.

Implementation outcomes will be assessed at 6 months, effectiveness outcomes will be assessed at 6 and 12 months.

Intervention Type
Behavioural

Primary outcome(s)
1. Quality of Life measured using Manchester Short Assessment of Quality of Life (MANSA) at Baseline , 6 months, and 12 months

Key secondary outcome(s))
1. Implementation Context measured using Qualitative Interviews, Feasibility of Intervention Measure (FIM), Intervention Appropriateness Measure (IAM), Acceptability of Intervention Measure (AIM) at Baseline, 6 months, and 12 months

2. Social Functioning measured using Objective Social Outcomes Index (SIX) at Baseline, 6 months, and 12 months

3. Depressive symptoms measured using Patient Health Questionnaire-8 (PHQ-8) at Baseline, 6 months, and 12 months

4. Anxiety symptoms measured using Generalised Anxiety Disorder- 7(GAD-7) at Baseline, 6 months, and 12 months

5. HbA1c (Glycated hemoglobin) measured using HbA1c Capillary Sample at Baseline, 6 months, and 12 months

6. Blood pressure measured using Blood pressure cuff assessment at Baseline, 6 months, and 12 months

7. Abdominal circumference measured using Standard measuring tape at Baseline, 6 months, and 12 months

Completion date
15/03/2027

Eligibility

Key inclusion criteria
1. Men and women aged 18 to 65 years
2. Speak and understand Spanish
3. Hold legal residency in Colombia.

4. Report a low quality of life, defined as a MANSA score ≤5.
5. A diagnosis of a physical NCD (Diabetes, Obesity or Hypertension) and positive screening for a mental health condition(Anxiety, depression or hazardous alcohol consumption); or
A diagnosis of a mental health condition and positive screening for a physical NCD, or a diagnosis of both a mental health condition and a physical NCD

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Diagnosis of dementia or cognitive impairment
2. Clinical diagnosis of schizophrenia or other psychotic disorders
3. An inpatient at the time of recruitment, irrespective of the cause
4. Absence of health insurance or inactive health insurance at the moment of recruitment

Date of first enrolment
02/03/2026

Date of final enrolment
30/06/2026

Locations

Countries of recruitment
Colombia

Sponsor information

Organisation
Queen Mary University of London

ROR
https://ror.org/026zzn846

Organisation
Pontificia Universidad Javeriana

ROR
https://ror.org/03etyjw28

Funder(s)

Funder type

Funder Name
National Institute for Health and Care 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

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2.0	24/10/2025	08/12/2025	No	No