

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

<b>Submission date</b> 04/12/2025	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 23/01/2026	<b>Overall study status</b> Ongoing	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 11/03/2026	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

Dr Adriana Buitrago

### ORCID ID

<https://orcid.org/0000-0002-2840-0781>

### Contact details

Tv. 5 # 42A-65

Bogota

Colombia

110231

+57 13208320 ext 2811

[buitrago\\_d@javeriana.edu.co](mailto:buitrago_d@javeriana.edu.co)

### Type(s)

Principal investigator

### Contact name

Dr Carlos Gómez-Restrepo

### ORCID ID

<https://orcid.org/0000-0002-9013-5384>

**Contact details**

7th Avenue No. 40-62  
9th Floor  
Bogota  
Colombia  
110231  
+57 13208320 Ext.2770-2766  
cgomez@javeriana.edu.co

**Type(s)**

Principal investigator

**Contact name**

Prof Victoria Bird

**ORCID ID**

<https://orcid.org/0000-0002-2053-7679>

**Contact details**

Wivenhoe Park  
Colchester  
United Kingdom  
CO4 3SQ  
-  
v.bird@essex.ac.uk

## Additional identifiers

## 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, Psychosocial 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 MANSAs 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 Assessment 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  $\leq 5$ .
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**

23/03/2026

**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?
<a href="#">Protocol file</a>	version 2.0	24/10/2025	08/12/2025	No	No