

A study to improve the quality of life among people with non-communicable diseases in Bolivia and Guatemala using DIALOG+

Submission date	Recruitment status	<input checked="" type="checkbox"/> Prospectively registered
23/01/2026	Not yet recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
26/01/2026	Ongoing	<input type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
26/01/2026	Other	<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

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Study information

Scientific Title

A hybrid type I effectiveness-implementation trial of DIALOG+ to improve quality of life among people with non-communicable diseases (diabetes, hypertension and obesity) and mental health conditions (anxiety, depression and alcohol consumption) in Bolivia and Guatemala

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 both Guatemala and Bolivia, implementation strategies are lacking. Given the social disparities in the health system in both countries and considering the lack of integration between the primary health system, there is a need to implement interventions that are culturally and locally adapted to the already existing health structures. DIALOG+ can adapt to use by health professionals in general, representing a promising strategy to tackle such deficiencies.

This research proposal aims to explore, culturally adapt, and test the feasibility of DIALOG+ for use with patients with mental disorders and/or non-communicable diseases (diabetes, hypertension, and obesity) in Bolivia and Guatemala. The objective is to evaluate its efficacy, acceptability, feasibility, and potential for integration into routine care in low-resource settings. Given the intervention's success in high-income settings, its low-cost model, and its reliance on existing human resources, it is well-suited for adaptation in low-income communities with diverse sociocultural contexts.

The study will provide essential evidence to guide the future implementation and scaling up of digital mental health interventions in Bolivia and Guatemala. Furthermore, by identifying contextual factors that influence implementation—such as cultural beliefs, technological barriers, and provider preparedness—it will inform the broader development of sustainable, community-based mental health care strategies.

The study's main objective is to evaluate the effectiveness of the DIALOG+ intervention to improve the quality of life of patients with NCDs (diabetes, hypertension and obesity) and mental health disorders (anxiety, depression and alcohol use) living in Bolivia and Guatemala.

Ethics approval required

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Ethics approval(s)

1. approved 14/10/2025, Ethics Committee of the Health Sciences Faculty from Rafael Landivar University (Vista Hermosa III, Zona 16, Edificio "L", Oficina L-308 3er Nivel, Guatemala, 010116, Guatemala; +502 (0)24262558; jlguzman@url.edu.gt), ref: CE-FCCSS/URL-(NIHR-QMUL-DIALOG+13102025)

2. approved 27/10/2025, Institutional Committee of Bioethics in Research (Calle Santa Barbara, Buenos Aires y Seoane, Santa Cruz de la Sierra, 9999, Bolivia; +591 (0)3371110; carvamon@yahoo.com), ref: FWA0002426

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

Non-communicable diseases: diabetes, hypertension, obesity; mental health conditions: anxiety, depression, alcohol consumption

Interventions

Healthcare professionals from selected health centers will be recruited, and their cases will be assessed to identify patients who may meet the inclusion criteria. The randomization unit will be

the group, defined as a healthcare professional with a maximum of 18 and a minimum of 10 patients (with a mean group size of 13). Groups will be randomly assigned to either the DIALOG+ intervention or the control group. Patients diagnosed with non-communicable diseases (diabetes, hypertension, and obesity) or those screened for mental health conditions (anxiety, depression, and alcohol use) will be referred. Patients with concurrent non-communicable diseases and/or mental health disorders will be recruited and confirmed in the corresponding group. Physicians randomly assigned to the intervention will use DIALOG+ with their recruited patients at least once a month for 6 months during their routine meetings (Intervention Phase I). Subsequently, for the following 6 months, patients and clinicians may continue using DIALOG+ (Intervention Phase II).

Patient outcome measures will be assessed at baseline, 6 months, and 12 months. Feasibility will be assessed at the 6-month follow-up.

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. Alcohol consumption measured using Alcohol Use Disorders Identification Test (AUDIT-C) at baseline, 6 months, and 12 months

Completion date

30/03/2027

Eligibility

Key inclusion criteria

1. Men and women aged 18 to 75 years
2. Understanding of Spanish (speaking and reading)
3. Have a residency in the country in which they were recruited
4. Report a low quality of life based on MANSA test score ≤ 5
5. A diagnosis of a physical NCD (diabetes, hypertension and obesity)
6. A diagnosis or a positive screening for at least one mental health condition (anxiety, depression and alcohol consumption)

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

75 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. Being hospitalized at the time of recruitment, irrespective of the cause

Date of first enrolment

15/02/2026

Date of final enrolment

30/06/2026

Locations

Countries of recruitment

Bolivia

Guatemala

Sponsor information

Organisation

Queen Mary University of London

ROR

<https://ror.org/026zzn846>

Organisation

Universidad Rafael Landívar

ROR

<https://ror.org/03jzm5a44>

Organisation

Universidad Privada Franz Tamayo

ROR

<https://ror.org/00nw66q03>

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