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

Submission date 23/01/2026	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 26/01/2026	**Overall study status** Ongoing	
Last Edited 13/03/2026	**Condition category** Other	

Plain English summary of protocol
Not provided at time of registration

Contact information

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

Type(s)
Principal investigator, Public

Contact name
Dr Edgar Miguel López Álvarez

ORCID ID
https://orcid.org/0000-0002-6619-4149

Contact details
Ciudad de Guatemala
Guatemala
Guatemala
9999
+502 (0)40173026
emlopeza@url.edu.gt

Type(s)
Principal investigator, Public

Contact name
Dr Ronald Fernando Tapia Pijuan

ORCID ID
https://orcid.org/0000-0002-8545-3636

Contact details
Santa Cruz de la Sierra
Santa Cruz de la Sierra
Bolivia
999
+591 (0)78510007
ronaldfernandotp@hotmail.com

Type(s)
Scientific

Contact name
Ms Ana Lorena Guerrero Abascal

ORCID ID
https://orcid.org/0009-0000-1604-6319

Contact details
Guatemala
Guatemala
Guatemala
9999
+502 (0)49494943
algatabush-nihr@url.edu.gt

Type(s)
Scientific

Contact name
Ms Lucia Elena Alvarado-Arnez

ORCID ID
https://orcid.org/0000-0002-3537-6361

Contact details
Cochabamba
Cochabamba
Bolivia
9999
+591 (0)63913548
lucia.alvarado@unifranz.edu.bo

Additional identifiers

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
Ethics approval required

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 Commitee 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
23/03/2026

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