PHARMACOVIGILANCE AND CLINICAL TRIALS DIVISION

CLINICAL TRIAL APPLICATION PUBLIC ASSESSMENT REPORT

PART 1: ADMINISTRATIVE DETAILS

Title of Study and Protocol Version: Combining antidepressants with psychological therapy to improve depression outcome in Zimbabwe - the Friendship Bench Plus trial (FB+Trial), Protocol version 1.5, dated 29/10/2024	**Study Ref:** CT280/2024
Date of receipt of the application: 19 July 2024	
Clinical trial phase: IV	
Study site(s): The City of Harare clinics in Kambuzuma, Braeside, Mabvuku, Tafara, Hatcliffe, Warren Park, Belvedere, Kuwadzana, Mufakose, Glen View, Budiriro, Southerton, Highfields, Waterfalls, Mbare, Sunningdale, Hatfield, Ruwa, Stoneridge and Hopley.	
Applicant/Principal Investigator name and address: Prof. Dickson Chibanda, 4 Weale Road, Milton Park, Harare, Zimbabwe	
Sponsor name and address: University Hospital of Psychiatry and Psychotherapy Bern, Bolligenstrasse 111, CH-300 Bern 60	
Study duration: 51 months	
Date of Commencement (Expected or Actual):	
Clinical trial authorisation validity period: 8 January 2025 to 31 March 2029	

PART 2: SUMMARY OF EVALUATION

Study design:
This is an individually randomised, open-label, superiority trial comparing the Friendship Bench Plus Intervention (FB+) with the Friendship Bench (FB) intervention.

Population:
Adults ≥18 years with moderate to severe depression defined as PHQ-9 ≥ 11 who are treatment naïve to the FB at the time of recruitment. The total number of participants to be enrolled is 296.

Study Objectives:

1. Primary objectives:
   The primary objective is to evaluate the effect of the Friendship Bench Plus Intervention (FB+) on treatment response defined as ≥ 50% improvement on depression scores after four months as compared to usual care consisting of the Friendship Bench stand-alone.

2. Secondary Objectives:

2.1 To evaluate the feasibility of nurse-led antidepressant prescription in primary care in a LMIC for patients with moderate to severe depression

2.2 To explore barriers and enablers of antidepressant use among adults attending primary care

2.3 To compare two treatment strategies being parallel treatment (counselling plus antidepressants from the beginning) and sequential treatment (counselling followed by antidepressants in case of non-response)

Eligibility Criteria:

1. Inclusion Criteria

Adults ≥18 years with moderate to severe depression defined as PHQ-9 ≥ 11 who are treatment naïve to the FB at the time of recruitment.

2. Exclusion Criteria

Exclusion criteria will be: mild depression defined as PHQ-9 <11; receiving specialist mental health care including antidepressants at the time of recruitment; pregnancy (urine pregnancy test will be performed) or clear intention of pregnancy during the study period; not willing to be on effective contraception during the study period, history of serious physical health problem (kidney failure, liver failure, serious heart disease, cancer, end-stage AIDS) or currently presenting with these; presenting with high suicidal risk; presenting with psychotic symptoms; or unable to comprehend the nature of the study in either English or Shona (local language).

Vulnerable/High Risk Groups:

The study includes adults with moderate to severe depression and therefore is conducted in a vulnerable population. The justification provided by the P.I to conduct the study in this population was adequate. Additionally, adequate provisions were made to ensure the vulnerable population is not being exploited.

Informed Consent, Decision-making & Confidentiality

Shona and English Informed Consent Forms were provided which were satisfactory. Adequate proof of participant insurance was provided.

Scientific and Technical Issues

The study design was found to be scientifically sound, the justification for the study was acceptable and follow up procedures were satisfactory. All the scientific and technical aspects were satisfactory.

Other materials, documents and study instruments (Patient recruitment materials, Questionnaires)

The study -related questionnaires and documents were satisfactory.

Clinical Trials/Study Medicines

1. Fluoxetine 20mg capsules manufactured by Torrent Pharma
2. Sertraline 50mg tablets manufactured by Lupin Pharmaceuticals

The justification for the products was acceptable.

Summary of review of:

1. Quality
2. Safety
3. Efficacy

Quality, safety, efficacy and risk benefit analysis data was assessed and was satisfactory.

Application Review Process

The application was reviewed under the normal pathway.

Status after review:

The clinical trial application was authorised on the 8th of January 2025.

PART 3: OVERALL COMMENTS AND CONCLUSION:

The Principal Investigator (PI) was required to address queries by raised by the MCAZ Pharmacovigilance and Clinical Trials Committee after the review of the application. The PI managed to respond and addressed all the queries and submitted revised documentation, including an amended protocol. The PI was subsequently authorised, with the approval of the Secretary for Health and Child Care, to conduct the trial subject to the contents of the application and the following conditions:

1. Reporting of all serious adverse events to MCAZ;
2. Submission of all amendments to the protocol for approval by MCAZ;
3. Submission of a progress report of the clinical trial by the 31st of January annually;
4. Submission of the final report and copy of any publication of the clinical trial prior to publication of results;
5. In compliance with the current Good Clinical Practices (cGCP) and all other relevant MCAZ guidelines;
6. Submission of the completed indemnity form for conducting clinical trials to the Director-General prior to commencement of the clinical trial;
7. Expiry date of the authorisation is 31 March 2029.

Name of Evaluator: Rutendo P. Chaitezvi Signature  Date 3/9/2025

Name of 2nd Evaluator L. Chirinda Signature  Date 4/9/2025