Medicines Control Authority of Zimbabwe

Clinical Trials Registry

PUBLIC TITLE/ACRONYM	The Friendship Bench Plus trial (FB+Trial)
Scientific Title	Combining antidepressants with psychological therapy to improve depression outcome in Zimbabwe - the Friendship Bench Plus trial (FB+Trial)

Primary Sponsor Details

Sponsors *	University Hospital of Psychiatry and Psychotherapy Bern

Secondary Sponsor Details

Sponsors	Swiss National science Foundation

Contact for Public Queries

Name *	Rukudzo Mwamuka
Designation *	Study coordinator
Email *	ruemwamuka.tsungu@gmail.com
Phone number *	0777065549
Postal Address*	4 Cuba Avenue Mt Pleasant Harare
Affiliation	University of Bern

Contact for Scientific Queries

Name *	Dickson Chibanda
Designation *	Principal Investigator
Email *	dixon.chibanda@frienshipbench.io
Phone number *	0712204107
Postal Address*	4 Weale Road Milton Park
Affiliation	University of Zimbabwe

Countries of Recruitment *

Zimbabwe

Source of Funds	Foreign
Health Condition(s) or Problem(s) Studied *	Depression
Medicine Name *	Fluoxetine
Quantity of medicine required *	40000 tablets

7.0 PRINCIPAL INCLUSION CRITERIA *

We will include 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.

7.1 PRINCIPAL 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); history of serious physical health problem (kidney failure, liver failure, serious heart disease, cancer, end-stage AIDS); 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).

7.2 PRIMARY END POINTS *

Our primary outcome will be treatment response after four months defined as ≥ 50% improvement in the PHQ-9 score as compared to baseline

Remission after four months defined as PHQ-9<5 will be our key secondary outcome.

9.0 DESIGN OF THE TRIAL

Type of trial *	Controlled
If controlled	
Randomised	Yes
Single Blind	No
Double Blind	No
Parallel group	No
Cross over	No
Other	No
If yes to other, specify	
If controlled, specify the comparator	The Friendship Bench psychological intervention
Other medicinal product(s)	No
Placebo	No
Other	No
If yes to other, specify	
Other	No

Expected Number of participants in Zimbabwe *	296
Total enrolment in each site: (if competitive enrolment, state minimum and maximum number per site.) *	296
Total participants worldwide *	296

Time period for the trial *	August 2024 to 31 December 2028