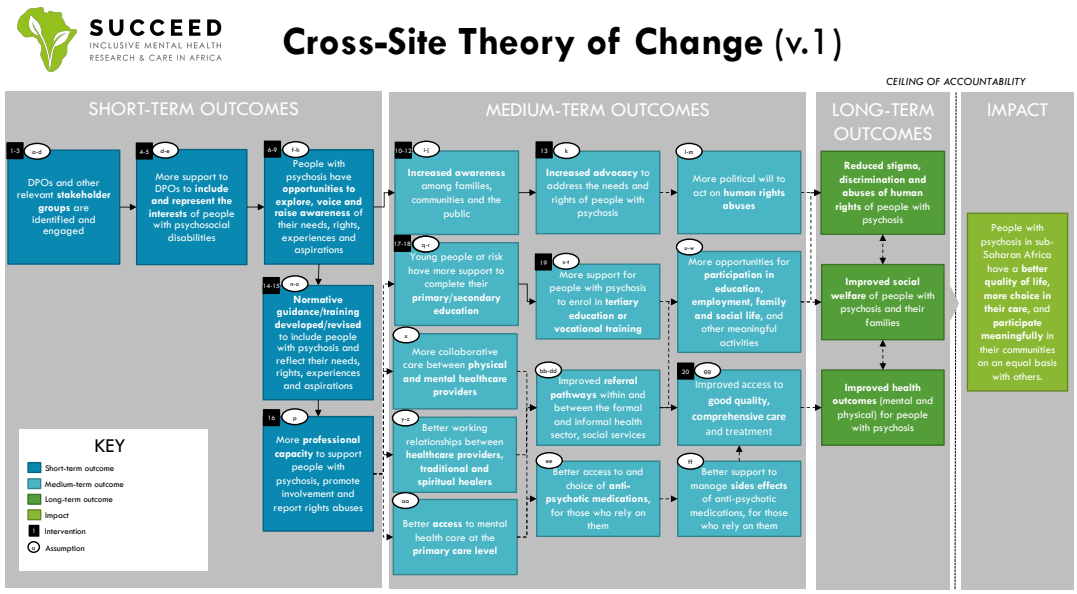
Additional File #1: Cross-Site Theory of Change



Assumptions

1. DPOs and other key stakeholders are willing and able to participate
2. Resources are sufficient to support accessible and effective meetings and communications
3. Virtual meetings and communications can provide an equally accessible and effective alternative to face-to-face meetings, where required (e.g., due to Covid-19 restrictions)
4. DPOs do not face operational challenges/threats (e.g., lack of funding) that inhibit their functioning
5. There are no barriers to people with psychosocial disability participating in DPOs
6. People with psychosocial disabilities and their families are willing and able to participate in self-help groups
7. People with psychosocial disabilities and other stakeholders are willing to collaborate effectively and share power for the purposes of co-production and co-delivery
8. People with psychosocial disabilities can safely self-disclose/participate in awareness-raising, despite stigma and discrimination, including from families
9. Families, communities, and the public at large will be receptive to messaging
10. Competing priorities in the media (e.g., Covid-19) do not drown out/dilute messaging
11. Key stakeholders will be willing and able to translate advocacy training into action, without expecting further incentives
12. Political will isn't diluted by more urgent issues (e.g., Covid-19, conflict, etc.)
13. Environment of relative political stability (election cycle doesn't interfere) and receptivity to advocacy
14. SUCCEED teams/advisors have sufficient technical knowledge and skills to adapt/produce high-quality trainings

15. SUCCEED teams are willing to collaborate effectively and share power for purposes of co-production and co-delivery
16. Professionals will be willing and able to participate in training
17. Teachers and other professionals in schools are willing to work with us to make change
18. Health/social services exist that have the capacity and willingness to receive referrals of young people with psychosis
19. Appropriate opportunities for tertiary education/vocational training exist in the area
20. SUCCEED team have or can partner with other organisations that have the skills/expertise and resources to establish livelihoods activities
21. These opportunities for participation exist, even for people without psychosocial disabilities but perhaps other disadvantages
22. SUCCEED's resources/influence are sufficient to ensure these opportunities can be made accessible to people with psychosocial disabilities
23. Improved participation yields positive experiences for people with psychosocial disabilities (does not simply expose them to new situations of adversity in difficult environments).
24. Physical/mental healthcare providers will be willing to work together and with SUCCEED
25. Traditional/spiritual healers and healthcare providers will be willing to work together and with SUCCEED
26. People with psychosocial disabilities and their families are comfortable with both biomedical and traditional/spiritual healing approaches
27. Some prior integration of mental health into primary care has already taken place
28. Barriers to access do not interrupt participants' uptake of referrals
29. Services are willing and able to handle possible increase in demand through referrals
30. Relationships between services do not deteriorate
31. It is possible to make drugs available (especially second-line drugs) at affordable prices
32. It is possible to effectively manage side effects, with the resources available (human resources, drugs, special accommodations, e.g., at work/home)
33. Factors beyond our control do not negatively impact quality (e.g., hospital strikes)

Additional File #2: SPIRIT Checklist

		Reporting Item	Page Number
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial Registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
Trial Registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	1
Protocol version	#3	Date and version identifier	1
Funding	#4	Sources and types of financial, material, and other support	38
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	38
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	1
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	38
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	6, 7
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	5
Objectives	#7	Specific objectives or hypotheses	9

Trial design	#8	Description of trial design including type of trial (e.g., parallel group, crossover, factorial, single group), allocation ratio, and framework (e.g., superiority, equivalence, non-inferiority, exploratory)	8
Study setting	#9	Description of study settings (e.g., community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	10
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (e.g., surgeons, psychotherapists)	11,12,13,14
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	14, 15
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (e.g., drug dose change in response to harms, participant request, or improving / worsening disease)	13
Interventions: adherence	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (e.g., drug tablet return; laboratory tests)	15
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	15
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (e.g., systolic blood pressure), analysis metric (e.g., change from baseline, final value, time to event), method of aggregation (e.g., median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	16, 17,18,19
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	20
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	20

Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	21, 22
Allocation: sequence generation	#16a	Method of generating the allocation sequence (e.g., computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (e.g., blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	N/A
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (e.g., central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	N/A
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	N/A
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (e.g., trial participants, care providers, outcome assessors, data analysts), and how	N/A
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (e.g., duplicate measurements, training of assessors) and a description of study instruments (e.g., questionnaires, laboratory tests) along with their validity, if known. Reference to where data collection forms can be found, if not in the protocol	22,23,24,25
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	24
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (e.g., double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	25, 26

Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	26
Statistics: additional analyses	#20b	Methods for any additional analyses (e.g., subgroup and adjusted analyses)	N/A
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol nonadherence (e.g., as randomised analysis), and any statistical methods to handle missing data (e.g., multiple imputation)	N/A
Data monoriting: interim analysis	#21a	a Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	25
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	25,26
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	9,18,27,36
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	34
Protocol amendments	#25	Plans for communicating important protocol modifications (e.g., changes to eligibility criteria, outcomes, analyses) to relevant parties (e.g., investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	30
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	328,29,30
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A

Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in 13 order to protect confidentiality before, during, and after the trial	25,26
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	34
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	35
Ancillary and post-trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	30
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (e.g., via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	31
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	35
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	31
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	28,29,30
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A