Evaluating the Effects of StrongMinds Community-Based Group Interpersonal Therapy on Depression and Secondary Outcomes in Uganda:
A Cluster Randomized Controlled Trial

Study Protocol

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Abstract

Background

Depression is a significant public health concern in Uganda, with high prevalence rates and limited access to mental health care due to resource constraints, stigma, and a shortage of trained professionals. Group Interpersonal Therapy (IPT-G) has been identified as an effective, scalable intervention for addressing depression in low-resource settings. However, most evaluations of IPT-G have been conducted in controlled research settings or with longer intervention durations, leaving a gap in understanding its effectiveness when implemented as part of a real-world program. The StrongMinds model, a six-week adaptation of IPT-G designed for community settings, offers a promising, more accessible alternative to the standard eight-week model. The StrongMinds model is designed to be scalable within government health systems.

Objective

This study aims to evaluate the impact of the StrongMinds IPT-G model on depressive symptoms (primary outcome) and measures related to quality of life, social, economic, educational outcomes, and within-household spillover effects (secondary outcomes). The study draws lessons from a smaller pilot RCT conducted in 2025 to inform its protocols, outcome metrics, and optimal design.[1]

Methods

A randomized controlled trial (RCT) will be conducted in Luuka and Buikwe districts in Uganda. The team will sample 40 villages in Luuka and 60 villages in Buikwe (100 villages total). To minimize contamination and ethical concerns regarding offering treatment to some eligible individuals within a village and not to others, the study will randomly allocate half of the villages in each district to the intervention cluster and half to the control cluster: 20 villages to intervention and 20 to control in Luuka, and 30 villages to intervention and 30 to control in Buikwe. Eligible participants from villages will be pre-screened using the PHQ-4 by StrongMinds program staff and then assessed using the PHQ-9 by research assistants. Those who score 10 or higher on the PHQ-9 will be invited to enroll in the study. Participants from the intervention villages will receive 6-week IPT-G immediately. Participants from the control villages will receive Enhanced Treatment as Usual (ETAU), involving psychoeducation and referral to a Psychiatric nurse.

Research assistants will obtain informed consent and administer baseline, two-week post-treatment, and follow-ups over time (six-month post-treatment, which is the current study endpoint, but with the possibility of adding 12-month, and 24-month follow-ups to the study protocol). During follow-up rounds post treatment, surveys will be conducted with two

[1] The pilot RCT was approved by Mildmay Uganda (IRB Approval: MUREC-2025-799) and Uganda National Council for Science and Technology (IRB Approval: SS3945ES)

non-participant household members, one adolescent and one adult per enrolled household to measure spillover.

The primary outcome will be the reduction in depressive symptoms measured by the PHQ-9. Secondary outcomes will include Anxiety (GAD-7), Externalization of Depression (MDRS-7) Functioning (WHODAS), Subjective Well-being (Cantril Ladder, WHO-5), Social Support (MSPSS), Perceived stress (SOS-4), Nutrition and Food security, Economic (Labor supply/Income), and Consumption measures. Quantitative and qualitative data will be collected from the participants, and programmatic cost data will be used to calculate cost-effectiveness.

Expected Outcomes

The study is expected to provide evidence on the effectiveness of the StrongMinds' model in reducing depression in a real-world program setting. Findings will inform the scalability and integration of IPT-G into community-based mental health programs and national health policies in Uganda and similar low-resource settings.

Conclusion

By being the first rigorous evaluation of a six-week IPT-G model in a programmatic setting, this study will fill a critical gap in the evidence base for community-based mental health interventions. The results could contribute to efforts to scale up mental health services and improve access to effective depression treatment in Uganda and other LMICs.

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1. Introduction

1.1 Background and Rationale

Depression is a leading contributor to the global burden of disease, accounting for a substantial share of years lived with disability worldwide (WHO, 2023). The burden falls disproportionately on low- and middle-income countries (LMICs), where approximately 80% of affected individuals reside, yet where access to evidence-based mental health care remains severely limited (Patel et al., 2018). In Uganda specifically, the prevalence of depression is alarmingly high, with a systematic review and meta-analysis estimating a pooled prevalence of 30.2% across studied populations (Kaggwa et al., 2022). This burden is compounded by intersecting vulnerabilities, including poverty, gender-based violence, HIV/AIDS, and displacement, all of which elevate both the risk of developing depression and the barriers to accessing treatment.

Despite the magnitude of the problem, a vast treatment gap persists. Uganda has fewer than 42 psychiatrists serving a population of over 45 million, and mental health receives less than 1% of the national health budget (WHO, 2020). Stigma surrounding mental illness further discourages care-seeking, particularly in rural communities. As a result, the vast majority of individuals experiencing depression in Uganda receive no treatment whatsoever. This gap underscores the urgent need for scalable, cost-effective interventions delivered by non-specialist providers within existing community structures.

Group Interpersonal Therapy (IPT-G) has emerged as one of the most promising approaches for addressing depression at scale in resource-constrained settings. IPT-G is a structured, time-limited psychotherapy that focuses on resolving interpersonal difficulties such as grief, role disputes, role transitions, and social isolation. These difficulties are causally linked to the onset and maintenance of depressive episodes. A seminal cluster-randomized trial in rural Uganda demonstrated that IPT-G delivered by trained lay health workers produced large, clinically significant reductions in depressive symptoms compared with a control condition, with effects sustained at 6 months post-treatment (Bolton et al., 2003; Bass et al., 2018). Subsequent studies in Uganda and other LMIC settings have replicated these findings, confirming that task-shifting IPT-G delivery to community health workers is both feasible and effective (Verdeli et al., 2003; Mutamba et al., 2018; Lewandowski et al., 2016).

To facilitate scalability, StrongMinds, an organization dedicated to treating depression with IPT-G, implements an adapted version of IPT-G tailored to the Ugandan context. It involves a six-week program where trained lay workers facilitate weekly group therapy sessions under supervision of trained staff. Preliminary evaluations suggest that the model not only reduces depressive symptoms but also delivers secondary benefits, such as enhanced labour supply and improved subjective well-being. The intervention's community-based nature allows it to

address cultural and logistical barriers to mental health care, fostering greater accessibility and sustainability.

Despite promising observational findings, rigorous evaluations of the StrongMinds model are needed to confirm its effectiveness and broader impacts, including on secondary outcomes such as quality of life and economic well-being. To inform the design and feasibility of a full-scale efficacy trial, StrongMinds conducted a pilot cluster-randomized controlled trial in Mayuge District, Uganda, in 2025. The pilot enrolled about 200 female participants (adults and out-of-school adolescents aged 13 and above) across 20 villages, with 10 villages randomized to receive IPT-G immediately and 10 assigned to a control group that received IPT-G after the study period. Data were collected at baseline, 2 weeks, 4 weeks, and 3 months post-treatment.

The pilot yielded several important findings. The intervention produced large and statistically significant reductions in depressive symptoms. At 3 months post-treatment, participants in the treatment group had a mean PHQ-9 score of 5.33, compared to 10.96 in the control group, a difference of 5.63 points ($p < 0.001$). The remission rate (PHQ-9 < 5) was 51.5% in the treatment sample versus 7.4% in the control group. Significant treatment effects were also observed for anxiety (GAD-7: 4.82 vs. 9.70, $p < 0.001$), subjective well-being (Cantril Ladder: 6.70 vs. 4.11, $p = 0.003$), functional impairment (57.6% vs. 88.9% reporting any difficulty, $p < 0.001$), WHO Disability score (0.92 vs. 1.57, $p = 0.001$), social support (MSPSS: 5.16 vs. 4.34, $p = 0.011$), and depression stigma (1.05 vs. 1.64, $p = 0.026$). Several other secondary outcomes were not statistically significant, perhaps due to the small sample size.

Despite the encouraging pilot results, several important gaps remain that motivate this full-scale randomized controlled trial:

1. **Statistical power and generalizability**. The pilot was designed primarily to test protocols and refine parameters, not to provide definitive evidence of efficacy. The pilot's estimates, while encouraging, lack the precision needed to draw definitive conclusions. The full-scale trial will enroll a substantially larger sample across two districts (Luuka and Buikwe), providing adequate statistical power to detect clinically meaningful effects on the primary outcome and key secondary outcomes.
2. **Longer-term follow-up.** The pilot's final assessment was at 3 months post-treatment. Global evidence suggests that treatment effects diminish over time (McGuire et al., 2023), but the trajectory in the StrongMinds context remains unknown. The full-scale trial will include follow-up at 2 weeks and 6 months post-treatment to characterize the durability of effects. We may add follow-ups at 12 months and/or 24 months, depending on findings from the earlier follow-ups and funding availability. We will also assess the impact of treatment on household economic outcomes, which tend to take at least several months to manifest.
3. **Male participants.** The pilot was restricted to females. StrongMinds serves both women and men, and approximately 25% of its current caseload in Uganda is male.

The full-scale trial will include male participants to assess whether the intervention is similarly effective across genders.

4. **Geographic and contextual variation**. The pilot was conducted in a single district (Mayuge). The full-scale trial will be conducted in two districts, Luuka and Buikwe, that differ in urbanization, volunteer infrastructure, and operational maturity, providing greater external validity.
5. **Cost-effectiveness**. Policymakers increasingly require not only evidence of effectiveness but also demonstration that an intervention represents good value for money. The full-scale trial will incorporate a cost-effectiveness analysis to estimate the cost per unit of depression reduction and, where possible, cost per quality-adjusted or disability-adjusted life year.
6. **Rigorous independent evaluation.** The pilot was conducted by StrongMinds' internal research team. The full-scale trial will be independently led by IDinsight, with scientific oversight from Dr. Victoria Baranov (University of Melbourne), ensuring methodological independence and credibility.
7. **Refined protocols to minimize social desirability bias**. During the pilot, StrongMinds refined and tested protocols to minimize social desirability bias. The full-scale trial will employ these improved protocols for the full sample to capture accurate data.
8. **Household spillovers.** The existence and magnitude of within-household spillovers is uncertain in current cost-effectiveness estimates of IPT-G. GiveWell's (2023) model assumes a 15% household spillover but flags low confidence; HLI (2025) rates the underlying evidence as "very low quality." By surveying non-participant household members at follow-up, this trial will generate evidence on this parameter.

This study will be the first large-scale, independently evaluated, cluster-randomized trial of a 6-week IPT-G model delivered within a real-world program in a low-income country. Its findings will inform StrongMinds' and Ministry of Health decisions about whether to continue aggressively scaling its current model, and will contribute to the global evidence base on task-shifted psychotherapy for depression in LMICs.

1.2 Relevance and Significance

Depression is a significant mental health problem in Uganda, affecting individuals, families, and communities. Despite its high prevalence, many people do not have access to effective treatments due to a lack of trained mental health professionals, limited resources, and widespread stigma. Addressing this gap requires solutions that are not only evidence-based but also practical and scalable in low-resource settings like Uganda (Mutamba et al., 2018).

Group Interpersonal Therapy (IPT-G) has shown promise as a culturally adaptable and cost-effective intervention to reduce depressive symptoms in low-resource settings (Lewandowski et al., 2016; Verdeli et al., 2003). It has been successfully adapted in Uganda for delivery by lay health workers, with studies demonstrating its feasibility and impact on specific populations, such as caregivers of children with nodding syndrome (Mutamba et al., 2018).

By compressing the intervention from the WHO-recommended 8-weeks to a 6-week model, the StrongMinds program offers a practical and scalable adaptation for community-based settings. This shorter duration reduces logistical challenges, such as time away from income-generating activities, while allowing greater reach and resource efficiency (Verdeli et al., 2003).

This study will evaluate whether this programmatic approach can achieve outcomes comparable to those of longer interventions, while addressing depression and improving secondary outcomes such as social support and labour supply. This study will generate critical evidence on the effectiveness, feasibility, and scalability of IPT- G in a programmatic setting. By focusing on real-world implementation, the findings will inform the integration of scalable mental health interventions into routine health systems in Uganda and similar contexts.

1.3 Theory of Change

The theory of change for this research demonstrates how implementing the StrongMinds Group Interpersonal Therapy (IPT-G) model can lead to improved mental health outcomes and broader social and economic benefits for individuals and communities in Uganda. This framework connects the intervention's activities to its anticipated short- and long-term outcomes, grounded in evidence and contextual understanding.

This intervention begins with critical inputs, including trained lay health workers and peer counsellors who are equipped to deliver the StrongMinds program. These volunteers provide a structured, culturally-tailored six-week therapy program that addresses interpersonal triggers of depression. The program also leverages community engagement to recruit participants and reduce stigma surrounding mental health issues, alongside resources such as funding, logistics, and program oversight to ensure successful implementation and evaluation.

Activities within the program focus on training lay health workers and peer counsellors to deliver IPT-G effectively and on conducting community-based therapy sessions. These sessions are designed to foster interpersonal skills and coping mechanisms in a group setting. Outreach and recruitment activities aim to mobilize communities and encourage individuals experiencing depressive symptoms to participate. Additionally, robust monitoring and evaluation mechanisms are implemented to collect data on outcomes, including improvements in mental health, social support, and labour supply.

The immediate outputs of these activities include the successful delivery of the six-week IPT-G intervention, increased capacity among lay health workers to provide mental health care, and participants' engagement in structured therapy sessions. Furthermore, the program generates valuable data on the intervention's effectiveness and feasibility in low-resource settings.

In the short term, participants are expected to experience a reduction in depressive symptoms due to the interpersonal and emotional skills gained through therapy. Social support within therapy groups is also anticipated to increase, fostering greater cohesion among participants. Simultaneously, community awareness and acceptance of mental health care are likely to improve, reducing stigma and creating a more supportive environment.

Over time, these immediate gains are expected to translate into intermediate outcomes, including an enhanced quality of life for participants, better social relationships, and increased labour supply due to improved mental health and motivation. Participants are also expected to sustain their gains by continuing to utilize the skills learned in therapy. At the community level, reductions in mental health stigma will facilitate ongoing acceptance and engagement with similar interventions.

In the long term, the StrongMinds model aims to contribute to sustained improvements in mental health at both the individual and community levels. By demonstrating its effectiveness and scalability, the integration of this intervention could be fasttracked into Uganda's primary healthcare system as a standard approach to addressing depression at a national scale. Furthermore, the findings from this study will contribute to global evidence on task-shifting models for mental health care, providing valuable insights for other low-resource settings.

This theory of change assumes that the six-week model can deliver results comparable to those of longer interventions when implemented with high fidelity. It also relies on the premise that lay health workers and peer counsellors, with appropriate training and supervision, can effectively deliver the program, and that participants will remain engaged throughout the intervention. Moreover, the intervention's success depends on community acceptance and support, which are fostered through targeted outreach and engagement.

1.4 Main Objective

To estimate the causal impact of StrongMinds' community-based, 6-week Group Interpersonal Therapy (IPT-G) model on depression severity and secondary well-being outcomes among adults and adolescents in two districts in Uganda, using a cluster-randomized controlled trial with independent evaluation.

1.5 Specific Objectives

1. Estimate the effect of IPT-G on depressive symptoms (PHQ-9) at 2 weeks and 6 months post-treatment, and possibly later follow-ups, relative to an Enhanced Treatment as Usual (ETAU) control condition.

2. Estimate effects on secondary mental health and well-being outcomes, including anxiety (GAD-7), functional disability (WHODAS), subjective well-being (Cantril Ladder), and perceived social support (MSPSS).

3. Estimate effects on downstream economic outcomes, including labor supply, income, and household consumption.

4. Assess the cost-effectiveness of the intervention by estimating the cost per remission, cost per depression free day and, where feasible, the cost per Disability Adjusted Life Years (DALYs) and Wellbeing Adjusted Life Years (WELLBYs) averted.

5. Examine heterogeneity of treatment effects by participant baseline depression severity, gender and age group (adults vs. adolescents).

6. Estimate within-household spillover effects of IPT-G on the depressive symptoms (PHQ-9), subjective well-being (Cantril Ladder), and stress load of non-participant household members.

1.6 Hypotheses

Primary hypothesis: Participants in villages randomized to receive IPT-G will exhibit a significantly greater reduction in PHQ-9 depression scores at 6 months post-treatment compared to participants in ETAU villages.

Secondary hypotheses: Relative to the ETAU control group, participants in the IPT-G treatment group will:

1. Show greater reductions in anxiety symptoms (GAD-7) and functional disability (WHODAS).
2. Report higher subjective well-being (Cantril Ladder) and perceived social support (MSPSS).
3. Demonstrate improvements in economic outcomes, including labor supply, income, and consumption expenditure.
4. Exhibit higher rates of clinical remission (PHQ-9 < 5), treatment response (≥ 50% reduction in PHQ-9) and Minimal Clinically Important Difference or MCID (≥5-point reduction in PHQ-9) from baseline to follow-up.
5. Non-participant members of treatment households will show lower PHQ-9, higher subjective well-being, and lower stress overload.

1.7 Measuring Consumption Efficiently Sub-study

This sub-study, conditional on external extended funding, forms part of a learning agenda to develop guidelines for efficiently measuring consumption. The team proposes to add extended consumption modules to a sub-sample of enrolled participants (approximately 16% of the total sample in this study) in planned data collection activities (including this trial) that already measure consumption as one of their outcomes. Consumption is a more stable, comprehensive, and accurate welfare metric than income, but traditional methods for measuring consumption are costly and time-intensive. The team seeks to design and validate more efficient methods for measuring consumption. The goal is to produce and publicly

share guidelines and a tool that allow other research teams to prepare customized shortened consumption modules. If validated by research, this tool could enable research teams to reduce the time spent on consumption modules from over three hours to under half an hour, with minimal loss to accuracy.

Main Objective: validate efficient approaches to measuring household consumption by administering a comprehensive consumption module to a random sub-sample of participants and comparing shortened-module estimates against it.

2. Study Design and Methods

2.1 Study Design

This study is a two-arm, parallel, cluster-randomized controlled trial (RCT) in which villages serve as the unit of randomization. Approximately 100 villages across two districts in Uganda, Luuka and Buikwe, will be randomly assigned in equal proportion to one of two conditions: (1) a treatment arm, in which eligible participants receive StrongMinds' 6-week community-based Group Interpersonal Therapy (IPT-G), or (2) a control arm, in which eligible participants receive ETAU, involving psychoeducation and referral to a nurse. Within each district, villages will be selected and randomized in equal proportion to treatment and control: 40 villages in Luuka (20 treatment, 20 control) and 60 villages in Buikwe (30 treatment, 30 control). Within each village, we will randomly select a subset of approximately 12 eligible participants to enroll. The villages will further be stratified by four target groups: Adult males, adult females, out of school adolescent-boys and out-of-school adolescent-girls. At each follow-up wave, an additional sample of up to two non-participant members per enrolled household will be sampled to measure spillover effects. Wherever available, the non-participant household members will be stratified into adolescents (aged 15 to 17) and adults (aged 18+) and a member will be selected randomly from both stratas.

Village-level randomization was chosen over individual-level randomization for two reasons. First, cluster randomization substantially reduces the risk of contamination: because therapy sessions take place in community settings and participants interact with neighbors, randomizing individuals within a village would risk exposing control participants to therapeutic content and social support effects, underestimating the effects. Second, village-level assignment avoids the ethical difficulty of visibly denying treatment to some individuals within a community while providing it to their neighbors, which could undermine trust and retention. The pilot RCT in Mayuge District confirmed the feasibility of village-level randomization and informed the parameters used to power this trial.

Participants in control villages will receive a brief sensitization session about depression and a referral to the nearest government health facility nurse. This comparator was chosen over a pure waitlist design on both ethical and methodological grounds. Ethically, it ensures all study participants receive a minimum level of support. The ETAU condition also guards against nocebo effects in the control group where, receiving no support can adversely impact the control group participants. Details of the ETAU condition are described in Section 2.3.3.

Justification for ETAU comparator: Standard depression care is limited in rural Uganda under the WHO recommended mhGAP. ETAU (psychoeducation + nurse referral) provides more than current access, not less. Kinyanda et al. (2026) found 44% remission after a single psychoeducation session, confirming ETAU is an active comparator. A delayed-intervention control would require denying treatment to severely depressed individuals (PHQ-9 ≥ 10) as

learnt from our pilot study approved under reference# MUREC-2025-799. A stronger comparator is not feasible in rural Uganda and would not answer the policy-relevant question of how StrongMinds compares to the current reality of minimal to no care.

2.2 Study Setting and Sites

The study will be conducted in the districts of Luuka (Eastern Region) and Buikwe (Central Region), both in Uganda. These districts were selected based on StrongMinds operational presence, availability of trained volunteers and absence of prior saturation.

Within each district, approximately 2 to 3 sub-counties will be selected, yielding a combined pool of eligible villages from which the final sample of 40 villages in Luuka and 60 villages in Buikwe can be drawn. Sub-county selection will prioritize areas where StrongMinds has not previously worked and where sufficient eligible volunteers reside nearby.

Village eligibility will be assessed using a list compiled and validated by StrongMinds field staff in collaboration with district officials. Villages will be excluded if they: (a) have previously hosted a StrongMinds therapy group; (b) are located in flood-prone or otherwise inaccessible areas; or (c) have insufficient population to support a therapy group of 8–12 participants. Intervention will be clustered at the village level to prevent any risk of contamination.

2.3 Intervention

2.3.1 Shared Baseline Activities (All Study Villages)

The mobilization, screening, and baseline enrollment process is identical in treatment and control villages. This ensures that the populations enrolled in each arm are subject to the same recruitment procedures, and that enumerators remain blind to treatment status throughout data collection. Chronologically, the procedure is as follows

1. **Screening phase.** StrongMinds community volunteers conduct door-to-door mobilization to sensitize community members about depression and identify individuals who self-identify with symptoms. Interested individuals are invited to a community sensitization event, during which StrongMinds program staff administer the PHQ-4. Those scoring 5 or above are considered potentially eligible for the study. At this stage, StrongMinds volunteers have not yet been informed whether their village is assigned to treatment or control.
2. **Village assignment notification.** After the screening phase is complete and potentially eligible individuals have been identified, StrongMinds volunteers are informed of their village's treatment assignment. IDinsight research assistants are not informed of this assignment.
3. **Enrollment phase.** Approximately one week later, independent IDinsight research assistants visit each potentially eligible individual at their home. The research

assistants obtain informed consent for the research study, administer the PHQ-9 to confirm eligibility (score ≥ 10), and conduct the full baseline questionnaire with eligible individuals. StrongMinds program staff are not present during any part of the baseline survey to ensure independence of data collection. If the research assistant identifies a participant as being at risk of suicidal ideation (revealed by item-9 on PHQ-9 module), they will refer the case to the Mental Health Coach present on the field for further action (see Section 2.10.2 for details). The Mental Health Coach (MHC) is responsible for coaching and mentoring therapy facilitators to deliver depression treatment using IPT-G. They ensure quality assurance and support safety planning for participants throughout the intervention. The MHC must hold at least a diploma or undergraduate degree in psychology or a related field, along with specialized training in counselling psychology, and at least 2 years of experience.

4. **Handoff.** Following the completion of the baseline survey, the research assistant communicates each eligible participant's PHQ-9 score to the assigned StrongMinds volunteer through a structured handoff procedure. This handoff is the same in both arms. The volunteers give all enrolled participants a referral card with information on the nearest government facility / psychiatric nurse. At this point, the process diverges for treatment and control villages.

2.3.2 Treatment Village Baseline Activities

1. **Pre-group phase**: The research assistant communicates the participant's PHQ-9 score to the assigned StrongMinds volunteer through a structured handoff procedure. The StrongMind volunteer meets eligible individuals, invites them to participate in the psychotherapy program, and prepares them for the sessions.
2. **Session 1, Initial phase**. Group members are introduced to each other and establish ground rules. The facilitator provides psychoeducation about depression, its symptoms, and the four interpersonal problem areas. Participants review their therapy goals.
3. **Sessions 2–5, Middle phase**. Participants focus on addressing their identified interpersonal problem areas. With the support of the facilitator and fellow group members, each participant develops and practices strategies for resolving interpersonal difficulties. Weekly homework reinforces between-session learning and application of skills.
4. **Session 6, Termination phase**. The group reviews skills acquired during therapy, assesses progress toward goals, discusses relapse prevention strategies, and plans for maintaining gains after the program ends.

Sessions are held weekly, last approximately 90 minutes each, and take place in a community setting (e.g., school, church, or community center). Groups comprise 8–12 participants. Sessions are facilitated by trained StrongMinds community volunteers who have completed the organization's standardized IPT-G delivery training curriculum.

Facilitators are lay community health workers who have completed at least three program delivery cycles and have been rated as "Intermediate," "Competent," or "Proficient" on StrongMinds' Volunteer Quality Assurance (VQA) assessment. Each facilitator will be assigned to lead at least 2 therapy groups and receive regular supervision from StrongMinds staff, including direct observation visits.

Fidelity monitoring and supervision: Each facilitator will receive weekly group supervision from the MHC, including a debrief session and session roll out to go through the IPTG session task list for the week. A minimum of 20% of therapy sessions will be directly observed by a supervisor using a standardized IPT-G fidelity checklist (Appendix A). Facilitators will complete the fidelity checklist during the sessions to assess the strength and areas of improvement and provide training during the weekly debrief sessions. A random sample of 20% of groups, all 6 sessions, will be audio-recorded. The audio will be transcribed, translated, compared to protocols and rated by MHCs.

Confidentiality within therapy groups: At the start of Session 1, the facilitator will explain that group members must keep each other's personal information private and not discuss what is shared outside the group. Each participant will verbally agree to this ground rule and members will agree on which consequence to tag to any member that breaks confidentiality. The facilitator will also explain the limits of confidentiality e.g. if a participant discloses intent to harm themselves or others, or discloses abuse of a minor, the facilitator is required by therapy and ethical standards to report this to a supervisor or relevant authorities. Participants will be informed that while the facilitator will enforce group confidentiality rules, the study team cannot guarantee that other group members will not disclose information outside the session. This risk will be clearly communicated during the informed consent process. The facilitator will remind group members to maintain confidentiality at the start of all other sessions.

2.3.3 Control Village Baseline Activities

1. **Referral phase**: The StrongMinds volunteer meets with eligible participants and refers them to a qualified nurse or mental health professional at a nearby government health facility (see Section 2.10.2 for referral protocols). Participants are provided with the contact information for the referred nurse

Each facilitator will be assigned to at least 2 control villages. ETAU participants will not receive IPT-G, any other structured psychotherapy, or ongoing contact with StrongMinds facilitators during the study period. They will not be prevented from independently seeking mental health care through the public health system or other channels.

The ETAU condition was selected over a pure no-treatment control for the following reasons: (a) providing depression sensitization and a referral pathway ensures that all participants receive a minimum standard of care, consistent with the principle of beneficence; (b) the ETAU condition represents a realistic approximation of the care that would be available to

individuals in the absence of the StrongMinds program, making the comparison policy-relevant; and (c) referral to existing government services avoids creating an artificial control condition that is worse than what participants could ordinarily access. In the pilot RCT, 13% of ETAU participants reported independently seeking care from the referred nurse, confirming that the referral mechanism does facilitate some care-seeking.

2.4 Participant Eligibility

2.4.1 Inclusion Criteria

An individual will be eligible for enrollment if they meet **all** of the following criteria:

1. Score ≥ 10 on the Patient Health Questionnaire-9 (PHQ-9) at screening, indicating at least moderate depressive symptoms.
2. Are aged 15 and above.
3. Are a permanent resident of the study village.
4. Provide written informed consent (or assent with parental/guardian consent, in case of a non-emancipated minor).

The study will include both women and men. Approximately 75% of groups will be composed of women and 25% of men, reflecting the gender distribution of StrongMinds' current caseload in Uganda. Likewise, approximately 75% of the groups will be composed of adults while remaining 25% will be out-of-school adolescents. Both adults and out-of-school adolescents who meet the age criterion will be eligible and assigned to age-appropriate therapy groups.

2.4.2 Exclusion Criteria

An individual will be excluded from participation if they meet **any** of the following criteria:

1. Report active suicidal ideation (assessed via PHQ-9 item 9). Individuals excluded on this basis will be immediately referred for care in accordance with the protocol described in Section 2.10 and Annex H.
2. Are identified as currently experiencing gender-based violence (GBV) requiring immediate safety intervention and referral.
3. Are unable to provide informed consent due to cognitive impairment, severe distress, or other factors as assessed by the research assistant.
4. Have previously participated in a StrongMinds IPT-G group.

Individuals excluded due to suicidal ideation or GBV will be referred to appropriate services (see Section 2.10) and will not be enrolled in the study. Individuals with active suicidal ideation will be excluded because group IPT-G cannot provide the individualized monitoring and crisis response that acute suicidality requires.These exclusions are intended to ensure

participant safety and do not preclude individuals from receiving StrongMinds services outside the study context.

2.4.3 Spillover (non-participant) Sample

At the end of the participant's follow-up survey, they will provide a household roster, with details on each person's age, the participant's relationship with that person.

Eligibility:

- Is a resident household member of an enrolled participant, aged 15 or above.
- Has been cleared by the participant, who has no concerns about the study team speaking with them.

Selection: random draw of two members from the roster, one each from the list of adolescents and adults in the household, after the participant has vetted and (optionally) excluded members. If one subgroup does not have any eligible individuals, we would randomly select 2 from the other subgroup.

2.4.4 Consumption Sub-study Sample

The team will invite a random sub-sample of enrolled participants, two per village across both arms (~200 total), at the 2-week follow-up, and will follow the same 200 individuals at the 6-month follow-up to measure changes over time.

Protocol: Enumerators will survey each of these 200 respondents as usual at the 2-week follow-up and, in the same visit, ask whether the respondent is willing to complete an extended survey requiring an additional 1–2 hours. The study will offer these respondents an additional incentive to compensate for their added time. The enumerator will ask whether the respondent prefers to complete the additional module during the first visit, immediately after the main survey, or on a return visit the following day or later.

2.5 Randomization

The village is the unit of randomization. All eligible individuals within a given village will be assigned to the same study arm. Randomization will be stratified by district (Luuka vs. Buikwe). Within each district, 2 to 3 subcounties will be selected. A total of 100 eligible villages will be randomly selected from these sub-counties and assigned to a group, such as adult males, adult females, and out-of-school adolescent males and females. Each program facilitator will receive about 4 villages, 2 from the treatment arm and 2 from the control arm.

Randomization will be conducted using computer-generated random assignment by the IDinsight research team. Within each stratum, villages will be randomly assigned to treatment or control in a 1:1 ratio. Randomization will occur after village selection is finalized but before baseline data collection begins. Field staff (enumerators and supervisors) will not be

informed of village assignments until after baseline surveys are complete. StrongMinds facilitators will not know which villages are in treatment or control during the mobilization and pre-screening phase; treatment status will be revealed only after baseline enrollment is confirmed.

Randomization will be conducted pre-baseline. While post-baseline randomization (stratifying on baseline outcomes) could increase statistical power, the narrow operational window between baseline completion and program start could make this approach infeasible for this study.

The randomization procedure and analysis plan will be pre-registered on a public trial registry (e.g., AEA RCT Registry or ClinicalTrials.gov) after baseline and before the first follow-up data collection begins.

2.6 Blinding

Blinding is not feasible for participants and StrongMinds volunteers. Participants will be aware of whether they receive IPT-G sessions, and StrongMinds facilitators will necessarily know which villages are assigned to the treatment group. Research assistants and enumerators will be blinded to the treatment status as same survey instruments will be used in both treatment and control villages. It is possible that unintentionally people's treatment status could be revealed, we're going to take the following measures to mitigate this. These include:

- Training of enumerators on why blinding is important
- Standardised introductory scripts that do not reveal treatment status
- Clear protocols on what and how to communicate between enumerators and coordinators

2.7 Sample Size and Power

2.7.1 Primary outcome and target parameters

The primary outcome is depression severity measured by the PHQ-9 score at baseline and post-treatment. The study is designed to detect a clinically meaningful difference in mean PHQ-9 scores between the treatment and control arms.

2.7.2 Pilot-derived parameters

The power calculations draw on estimates from the pilot RCT in Mayuge District. Key parameters from the pilot include:

- **Intra-cluster correlation coefficient (ICC):** 0.21 for PHQ-9 scores at 3 months post-treatment
- **Baseline-to-follow-up correlation:** 0.13 for PHQ-9

- **Standardized effect size (SES) at 3 months:** 0.9 SES for subsample following least social desirability bias protocol

2.7.3 Design parameters

- **Number of clusters (villages):** 100 total (40 in Luuka: 20 treatment + 20 control; 60 in Buikwe: 30 treatment + 30 control)
- **Participants per cluster:** 12 (target: 12 eligible participants per village at baseline, and 10 enrolled per village at endline, assuming some attrition)
- **Total target enrollment:** approximately 1,200 participants
- **Significance level:** $\alpha = 0.05$ (two-sided)
- **Power:** 80%
- **Attrition assumption**: 15% loss to follow-up by the 6-month assessment, with projected cumulative attrition of up to 25% by 12 months and 30% by 24 months (based on pilot retention rates of approximately 87% at 3 months and attrition patterns from comparable longitudinal studies in LMICs)

2.7.4 Minimum detectable effect size (MDES)

Based on the power calculations using pilot data, with 100 villages and approximately 10 respondents per village, the minimum detectable effect size (MDES) for PHQ-9 at 3 months post-treatment is approximately 0.30 standard deviation units. This is smaller than the effect observed in the pilot's unbiased sample (SES = 0.9), indicating that the study is well-powered to detect the primary treatment effect in the whole sample and in various subgroups (baseline depression severity, gender, age, etc.).

The study is also adequately powered (MDES < pilot SES) for key secondary outcomes at 3 months, including GAD-7 anxiety (MDES = 0.28 vs. pilot SES = 1.49), subjective well-being (MDES = 0.28 vs. pilot SES = 1.55), social support (MDES = 0.27 vs. pilot SES = 0.84), and WHO disability (MDES = 0.30 vs. pilot SES = 1.26). The study also likely has adequate power for other secondary economic outcomes such as monthly income (MDES = 0.18 vs. pilot SES = 0.41) and days worked (MDES = 0.19 vs. pilot SES = 0.22).

2.7.5 Sub-group analyses

The study aims to examine heterogeneity by gender, age group (adults vs. adolescents), and baseline depression severity. Power for subgroup analyses will depend on the final sample composition. Preliminary calculations suggest that subgroup-specific MDES will be approximately 1.5–2 times the overall MDES, and power to detect subgroup differences may be limited for small subgroups (e.g., male participants, who are expected to comprise ~25% of the sample).

2.7.6 Spillover power

The spillover sample comprises approximately two non-participant household members per enrolled household, drawn from both treatment and control villages (see Section 2.4.3).

Based on the same pilot-derived parameters and power-calculation workbook used for the primary outcome, the minimum detectable effect size (MDES) for the spillover analysis is approximately 0.28 standard deviation units when both the spillover subgroups are pooled together, and approximately 0.30 standard deviation units specific subgroups (adults or adolescents). The study is designed to measure spillover effects among both subgroups, household adolescents and adults, separately.

2.8 Enrollment and Consent Procedures

2.8.1 Community mobilization and pre-screening

Mobilization of participants will be supported by StrongMinds program therapy facilitators. Facilitators will walk door to door, sensitizing residents about depression. Potential participants who express interest will be consented for the StrongMinds program and pre-screened using the PHQ-4, a patient health questionnaire with two questions on depression and two on anxiety. A week later, IDinsight Research Assistants will visit the households of potential participants to seek consent for enrollment in the study, screening using PHQ-9 and baseline survey. The first stage of consent to participate in the StrongMinds program will be done by the StrongMinds staff and the second stage consent to participate in the study will be done by IDinsight Reseachers, with each request for consent being clear and explicit about what is being consented to. Only those who consent for the study and score more than 10 on PHQ-9 scale will be enrolled in the study.

2.8.2 Informed consent

Informed consent will be obtained by facilitators at the pre-screening stage, before using the PHQ-4, and by trained research assistants at the screening stage , prior to PHQ-9 administration. The consent process will include:

- A clear explanation of the study's purpose, procedures, risks, and potential benefits, delivered orally in the participant's preferred language (Lusoga in Luuka; Luganda in Buikwe).
- Explicit information that participation is voluntary, that participants may withdraw at any time without consequences, and that their decision will not affect their access to StrongMinds services or any other services.
- An explanation of random assignment: that their village has been selected by chance to receive either the therapy program or a referral to a government nurse, and that they cannot choose which group they are in.

- Information about data collection procedures, including the use of audio recording of surveys (for data quality purposes), and assurance that all data will be kept confidential and de-identified.
- Opportunity to ask questions and receive answers before providing consent.

Written informed consent will be obtained from all participants aged 18 and above and emancipated adolescents aged 15 to 17. For non-emancipated participants aged 15 to 17, written consent will be obtained from a parent or guardian and written assent from the participant. Consent and assent forms will be available in English, Lusoga, and Luganda. We will obtain verbal consent from individuals with limited literacy skills and allow use of thumbprints or use witnesses to help the individuals give written consent as appropriate.

Consent and assent procedures for non-participant (spillover) respondents including adolescents aged 15–17, remain the same as those of the enrolled participant outlined above.

2.9 Data Collection

2.9.1 Data Collection Points

Data will be collected from all enrolled participants (treatment and control) at the following time points. Spillover interviews occur at the 2week and 6-month **follow-ups rounds only**

Wave	Timing	Approximate Date
Baseline	Before intervention begins	May – June 2026
2-week follow-up	2 weeks after completion of the 6-week intervention	August – September 2026
6-month follow-up	6 months after completion of the intervention	February – March 2027
12-month follow-up (possible)	12 months after completion of the intervention	August – September 2027
24-month follow-up (possible)	24 months after completion of the intervention	August – September 2028

The 6-month follow-up is the **primary endpoint** for this study. Follow-up data collection at 12 months and 24 months post-treatment may be conducted to assess the persistence of treatment effects and capture treatment effects on longer-term economic outcomes. The 12-month and 24-month survey instruments will mirror the 6-month instrument, with additional modules on sustained behavior change and long-term economic trajectories as appropriate. The 2-week follow-up will capture immediate post-treatment effects and inform comparisons with the pilot RCT findings.

2.9.2 Survey Instruments

Primary outcome measure:

- **Patient Health Questionnaire-9 (PHQ-9):** A validated 9-item self-report measure of depression severity over the past two weeks, scored 0–27. The PHQ-9 is widely used in LMIC settings and was used in the pilot RCT, enabling direct comparison. A neutralizing prompt will be read aloud immediately before the PHQ-9 is administered to reduce social desirability bias (see Section 2.9.3).

Secondary outcome measures:

- **Generalized Anxiety Disorder-7 (GAD-7):** A 7-item measure of anxiety severity (0–21).
- **Male Depression Risk Scale (MDRS-7):** A 7-item multidimensional depression rating scale capturing other behaviors associated with depression.
- **Stress Overload Scale (SOS):** A 4-item scale measuring perceived stress and feelings of being overwhelmed.
- **WHO Disability Assessment Schedule (WHODAS 2.0, 12-item):** A measure of functional impairment across six domains (cognition, mobility, self-care, getting along, life activities, participation).
- **Cantril Self-Anchoring Ladder:** A single-item measure of subjective well-being (0–10).
- **WHO-5 Well-Being Index:** A 5-item positive-affect wellbeing measure on mood, calmness, energy, sleep quality, and daily interest.
- **Multidimensional Scale of Perceived Social Support (MSPSS):** A 12-item measure of perceived support from family, friends, and significant others (1–7).
- **Economic outcomes:** Labor supply (days worked in the past week, hours worked yesterday), monthly income, poverty-related outcomes and household consumption expenditure.
- **Nutrition:** Number of meals consumed in the past 24 hours (self and children), food insecurity.
- **Consumption**: As part of a cross-country methodological learning agenda on efficient consumption measurement, a randomly selected sub-sample of participants will, receive an extended (~170-item) consumption module at the 2-week and 6-month follow-ups.

- **Decision-making and self efficacy:** A measure of indecision and choice avoidance and self efficacy.

The **Non-participant (spillover) instrument will include**, Patient Health Questionnaire-9 (PHQ-9), Cantril Self-Anchoring Ladder, and the four-item Stress Overload Scale discussed above.

The complete draft instrument is linked in the annex.

2.9.3 Data Collection Procedures

All surveys will be administered by trained IDinsight research assistants who are fully independent of StrongMinds. No StrongMinds program staff, facilitators, or supervisors will be present during any survey administration. This separation of research and program staff is a design feature informed by the pilot RCT, which demonstrated that the presence of facilitators may potentially inflate treatment effect due to social desirability bias.

Baseline surveys will be conducted at central community locations, however, all follow-up surveys will be conducted at participants' households. Household-based interviewing was chosen to: (a) maximize privacy and reduce social desirability bias; (b) reduce differential attrition between treatment and control groups (control participants, who lack regular contact with facilitators, may be less likely to attend centralized sessions); and (c) allow enumerators to conduct follow-up visits more flexibly.

At the beginning of each interview the enumerator will request the interview be conducted in a private space (preferably outdoors). Immediately before administering the PHQ-9 at each follow-up wave, enumerators will read a standardized neutralizing prompt informing participants that the interviewer is from an independent research organisation, that responses are confidential and will have no bearing on eligibility or receipt of any government or non-governmental programs, that the participation incentive is guaranteed regardless of responses, and that there are no right or wrong answers.

For the spillover interviews, enumerators will use neutral framing so as not to mention group therapy, "mental health," or "depression". The enumerators will also be trained to end a non-participant interview quickly and professionally if it risks revealing confidential information or endangering the participant.

Surveys will be programmed and administered using SurveyCTO on Android tablets. Computer-Assisted Personal Interviewing (CAPI) will incorporate built-in skip logic, validation checks, and real-time data quality flags.

A separate consent will be sought for audio recording the surveys. Participants who decline audio recording will still be surveyed; the interview will proceed without recording, and their refusal will not affect their participation in the study or any benefits they are entitled to. Audio

recordings will be encrypted, stored on password-protected devices, and then uploaded to a secure SCTO server. A random sample of recordings will be reviewed by the IDinsight field team to verify enumerator adherence to protocols.

Survey instruments will be administered orally in the participant's preferred local language (we anticipate this will mainly be Lusoga in Luuka; Luganda in Buikwe). All instruments will be translated, back-translated, and reviewed for cultural appropriateness and mental health terminology. Instruments will be piloted with a small sample of community members and refined before deployment.

The target survey duration is 45–60 minutes per interview. If the full set of secondary outcomes exceeds this target during pilot testing, the team will consider randomizing modules across respondents.

Data quality will be assured through: (a) a comprehensive enumerator training of approximately 5–7 days, including classroom instruction, role-play, and supervised field practice; (b) daily debriefing sessions between enumerators and supervisors; (c) high-frequency data quality checks (e.g., monitoring interview duration, response distributions, and skip-pattern adherence); (d) back-check surveys on a random 10–15% of respondents; and (e) supervisor spot-checks and audio audits of surveys during fieldwork.

2.10 Referral Protocols

The study involves a population with moderate-to-severe depression, and some participants may present with suicidal ideation, gender-based violence, or acute psychological distress. The following referral protocols will be in place to ensure participant safety:

2.10.1 Identification of at-risk participants

All research assistants will receive training on: recognition of suicidal ideation and GBV indicators; appropriate and sensitive response techniques; use of the referral directory; documentation procedures; and self-care for staff working with distressed populations. Research assistants will be trained to identify participants at risk through:

- **PHQ-9 tool:** The ninth question of the PHQ-9 tool will be used to determine if respondent is experiencing any thoughts of self harm. If there is any risk of self-harm, the research assistant will stop the survey and immediately reach out to field supervisors and Mental Health Coach (MHC) on the ground for further management.
- **Routine observation:** Research assistants will be trained to recognize signs of acute distress, including persistent crying, agitation, verbal expressions of hopelessness, disorientation, or disclosure of GBV, during any stage of the interview. In any such case, they will reach out to the MHC on ground.

The MHC will conduct an independent suicide risk assessment and determine whether the case requires escalation and referral to appropriate services according to the suicide management protocol in Annex H. In cases of emotional distress, the MHC will engage with the participant to provide emotional support and ensure the participant is stable before any further steps are taken. In the event of suspected GBV, the MHC will assess the risk of harm or abuse. Where the risk is high or poses a danger to life, the MHC will discuss referral options with the participant to identify the help with which the participant is comfortable. These options include the district child protection officer, the community development officer, and other local leaders. The participant will be supported in accessing the needed services, and a follow-up will be conducted within 48 hours to ensure they were assisted.

2.10.2 Referral process

1. **Immediate response.** If a participant is identified as at-risk, the research assistant will: (a) pause the interview; (b) offer the participant a private space; (c) provide emotional first aid using the WHO's Psychological First Aid framework; (d) assess the level of urgency, and (e) Reach out to MHCs for at-risk cases.
2. **Referral.** The research team will prepare a referral directory prior to study implementation that includes mental health professionals, public health facilities, and community-based services. Participants requiring support will be referred to the most appropriate and accessible provider, and where necessary, the study team will assist with logistical arrangements such as transportation. Healthcare providers will also be informed about the referrals. In all cases, participants will be asked for their informed consent before the referral is made, and confidentiality will be strictly maintained.
3. **Communication and follow-up.** The MHC will confirm with facility staff that the participant has been seen. Within 48 hours, the MHC will contact the participant by phone or home visit to confirm ongoing safety. If care was not received, the MHC will facilitate an alternative referral.
4. **Documentation.** All referral cases will be documented using participant codes only, with no identifying information recorded in shared datasets. This process will ensure that participants' mental health needs are addressed promptly and ethically, while also upholding the integrity of the study.

3. Data Analysis Plan

3.1 Analytical Model

To estimate program effects, the primary analysis follows an intention-to-treat (ITT) framework, comparing the outcomes of IPT-G eligible individuals (and their households) in

villages assigned to treatment or control. An ordinary least squares (OLS) model will be used to estimate the treatment effect at each time point:

$$Y_{1ij} = \beta_1 T_j + \beta_2 Y_{0ij} + X'_i\gamma + \alpha'_s + \varepsilon_{ij}$$

Where:

- Y_{1i} denotes the outcome variable (mental health, economic well-being, etc.) for individual *i* in village *j* at follow-up (2 weeks, 6 months, possible additional follow-ups)
- T_j denotes whether village *j* was assigned to the treatment group or not. β_1 is the estimated treatment effect of being an eligible household in a village assigned to receive the StrongMinds program.
- Y_{0i} denotes the outcome variable at baseline. For outcomes that were not collected at baseline, this variable will be omitted from the regression.
- X'_i is a vector of individual-level and household-level covariates measured at baseline. To determine the appropriate list of covariates to include, we will estimate double-lasso regressions (Chernozhukov et al., 2018) with PHQ-9 at the 2-week follow-up on the full range of baseline covariates. We use the same list of covariates for all outcomes at all follow-up rounds for consistency, with the exception that each regression also includes the baseline value of the outcome variable.
- α'_s is a vector of categorical factors corresponding to the stratum that the village is found in. Villages were assigned to 4-village strata, and each stratum was assigned to a StrongMinds volunteer for mobilization of their specific target population (adult females, adult males, adolescent females, adolescent males). Thus treatment is implicitly stratified by area and target population.
- ε_{ij} denotes the household error term *i.* Standard errors will be clustered at the village level to account for within-cluster correlation.

A secondary treatment-on-treated (TOT) analysis will be conducted to estimate effects of participating in IPT-G. In this analysis, we will define treatment as attending at least one therapy session, per StrongMinds' administrative records. We will use randomized treatment assignment as an instrumental variable for treatment receipt. In addition, we will estimate dose-response correlations between the number of sessions completed and change in depression severity - with the caveat that session attendance is endogenous and thus this analysis will be considered exploratory rather than causally identified.

All analyses will be conducted using Stata and/or R, with significance levels set at $p < 0.05$ for the primary outcome. The full analysis plan, including outcome definitions, model specifications, and subgroup analyses, will be pre-registered on a public RCT registry before data collection for the first follow-up round (2-weeks post-intervention) begins.

3.2 Primary Analysis

The primary outcome is the PHQ-9 depression severity score at 6 months post-treatment, controlling for baseline scores. Depending on funding availability and other considerations, we may reassess the same outcome at 12 months and 24 months post-treatment to evaluate the persistence of treatment effects.

3.3 Secondary Analyses

We will also present treatment effects on additional depression outcomes from the PHQ-9 data, including three binary variables: 1) remission, defined as PHQ-9 <5; 2) response, defined as a reduction of at least 50% from baseline; and 3) minimal clinically important difference (MCID), defined as a reduction of at least 5 points from baseline.

Secondary outcomes include anxiety (GAD-7), functional disability (WHODAS), subjective well-being (Cantril Ladder), perceived social support (MSPSS), economic outcomes (labor supply, income, consumption), nutrition, and depression stigma (adaptations from Corrigan's Self-Stigma of Mental Illness Scale (SSMIS) and the Inventory of Attitudes Toward Seeking Mental Health Services (IASMHS)).

For secondary outcomes, linear regression models will be estimated with the same specification as the primary analysis. To address multiple testing across secondary outcomes, family-wise error rate corrections (e.g., Westfall-Young stepdown) will be applied and reported alongside unadjusted p-values.

3.4 Subgroup Analyses

The following subgroup analyses are pre-specified:

- **Age group:** Adults vs. adolescents
- **Gender:** Women vs. men
- **Baseline depression severity:** Moderate (PHQ-9 10–14) vs. moderately severe/severe (PHQ-9 15+). Depending on the sample size, we may further split the moderately severe (PHQ-9 15-19) and severe category (PHQ-9 20+)
- **District:** Luuka vs. Buikwe

Subgroup effects will be estimated by interacting the treatment indicator with the subgroup variable. These analyses are exploratory; the study is not powered to detect statistically significant differences between all subgroups and outcomes, and results will be interpreted with appropriate caution.

3.5 Missing Data and Attrition

Missing baseline data will be handled using indicator variables (i.e., replacing missing values with zero and including a binary missingness indicator as a covariate), preserving sample size without imputing unobserved values.

Attrition will be minimized through the collection of detailed contact information at baseline (two phone numbers, next of kin, GPS coordinates); participation incentives; and use of independent mobilizers and local council chairpersons to trace participants at follow-up.

At each follow-up wave, the analysis will: (a) test whether attrition rates differ by treatment status; and (b) check baseline balance among the retained sample. If differential attrition is detected, Lee (2009) attrition bounds will be estimated to provide upper and lower bounds on the treatment effect under conservative assumptions about selection.

3.6 Cost-Effectiveness Analysis

A cost-effectiveness analysis (CEA) will estimate the cost per unit of depression reduction (PHQ-9 point), cost per depression-free case (remission), and, where feasible, cost per DALYs and WELLBYs averted. Intervention costs will be estimated using StrongMinds' administrative cost data. Research costs will be excluded.

Results will be compared with cost-effectiveness benchmarks and with cost-effectiveness estimates from comparable psychotherapy interventions in LMICs reported in McGuire et al. (2023). The conversion of PHQ-9 effects into WELLBYs will follow established disability weight mappings for depressive episodes from the Global Burden of Disease study.

3.7 Dissemination Plan

The primary findings will be submitted to a peer-reviewed journal (target: *The Lancet Psychiatry*, *BMJ Global Health*, or a comparable outlet). Findings may also be shared through: policy briefs prepared for the Uganda Ministry of Health and district health authorities; presentations to relevant stakeholders and at conferences; and an internal findings report for StrongMinds' operational use.

3.8 Data Sharing

Only de-identified data will be shared. Data sharing will be possible six months after publication of the study's main findings, to allow time to complete the initial analysis and report. Researchers wishing to access the data will be required to submit a request that describes the purpose of the data use, provides an overview of the proposed research, and includes a data management plan. Requests will be reviewed by StrongMinds Research Department to ensure they meet scientific, ethical, and qualification standards. Approved researchers will sign a Data Sharing Agreement outlining terms of use, security requirements, acknowledgment rules, and restrictions on onward sharing, in compliance with applicable Ugandan data protection laws.

4. Ethical Considerations

4.1 Ethics Approvals

Administrative clearance will be sought from the participating districts. StrongMinds has signed a memorandum of understanding with the Ministry of Health and the district in which it operates. Ethical approval will be obtained from the Mildmay Uganda Research Ethics Committee and the Uganda National Council for Science and Technology.

4.2 Informed Consent and Assent

Written informed consent will be obtained from all participants prior to enrollment. The consent process will be conducted by trained IDinsight research assistants in a private setting, in the participant's preferred language (Lusoga or Luganda). Consent forms will also be available in English.

Before providing consent, participants will receive a clear oral explanation of: the study's purpose and procedures; the randomization process and what it means for their village; the data collection schedule; risks and potential benefits of participation; confidentiality protections; the use of audio recording; and their right to withdraw at any time without consequences to their access to services.

Adults (18+): Written informed consent will be obtained directly from the participant.

Minors ([15–17]): In this study, an "emancipated minor" is as an adolescent aged 15–17 years who meets one or more of the following criteria: (a) is currently married; (b) has a biological child and is the primary caregiver; (c) is the head of their household and economically independent without reliance on parents or guardians. Verification will be conducted in private to ascertain these criteria. Eligible emancipated minors will provide written informed consent directly, without parental consent or additional assent. The minor will be explicitly informed that participation is voluntary and they may withdraw at any time. Non-emancipated minors will be required to provide assent in addition to informed consent from their parent/guardian.

All emancipated minors will be placed in age-appropriate therapy groups. Any disclosure of abuse will be reported to the district probation officer within 24 hours.

Audio recording: A separate consent will be sought for audio recording of survey interviews. Participants who decline audio recording will still be surveyed; the interview will proceed without recording, and their refusal will not affect their participation in the study or any benefits they are entitled to.

Participation is entirely voluntary. Participants may withdraw from the study at any time, for any reason, without penalty or loss of access to StrongMinds services or any other services.

4.3 Confidentiality and Data Security

All data collected during the study will be de-identified to protect participant privacy. Identifiable information (names, addresses, phone numbers) will be replaced with unique participant codes during data entry. A master linking file connecting codes to identifiers will be stored separately from the research dataset in an encrypted folder accessible only to authorized members of the research team.

Data security measures include:

- Survey data will be collected using SurveyCTO on password-protected tablets and uploaded to encrypted cloud servers at the end of each day. Raw data will be deleted from local devices.
- Audio recordings will be encrypted, stored on password-protected devices, and then uploaded to a secure server. Access will be restricted to authorized supervisors conducting quality assurance reviews.
- Physical documents (consent forms, referral logs) will be stored in locked cabinets, with access restricted to authorized personnel.
- Any data transfer between institutions will use secure, encrypted methods.
- Any personally identifiable data will be retained up to maximum of 12 months after the final follow-up (Whether the final follow up is at 6 months, 12 months or 24 months). In whichever scenario, all identifiable data will be carefully destroyed within 12 months after the follow up.

4.4 Safety and Safeguarding

Individuals identified as experiencing active suicidal ideation (via PHQ-9 item 9 or clinical judgment) or gender-based violence requiring immediate intervention will be excluded from the study and immediately referred to appropriate services using the protocol described in Section 2.10. Follow-up with referred individuals will occur within 48–72 hours.

All adverse events (AEs) and serious adverse events (SAEs) occurring during the study period will be documented and reported in accordance with IRB requirements. Adverse events include any unfavorable or unintended experience reported by or observed in a participant, whether or not it is related to the study. Serious adverse events, including hospitalization, suicidal behavior, or death, will be reported to the IRB within 24–48 hours of the study team becoming aware.

The reporting hierarchy for adverse events is as follows.

- Research assistants, as the first point of detection, are trained to identify AEs through PHQ-9 Item 9 responses, participant disclosures, or behavioral observation; upon detection, they will immediately pause the interview, provide psychological first aid, and escalate to the Field Supervisor.
- The Field Supervisor will report the incident to the Principal Investigator within 24 hours of detection.
- The PI will classify each event as an AE or a SAE, assess relatedness to study procedures, and is responsible for all regulatory reporting. For SAEs, the PI will notify the IRB (MUREC) within 48 hours of becoming aware. The StrongMinds Team will also be notified of all AEs within 24 hours of the PI becoming aware to activate any organizational safeguarding protocols

All AE documentation will use participant codes only. No identifying information will be included in shared reports.

The non-participant (spillover) interviews may introduce a safeguarding risk where interviewing a participant's household members could inadvertently reveal that the participant is enrolled in the study or, by extension, disclose their depression status or involvement in IPT-G. To manage this risk,

- The participant interview is always conducted first and in private, and participants are reminded that their responses are confidential and will not be shared with anyone in the household.
- The household roster is collected at the end of the interview, and for each member the participant is asked whether they are comfortable with the study team speaking to that person; any member the participant asks us to exclude is removed from the eligible roster, and these exclusions are recorded (both to respect the participant's wishes and because exclusion may itself moderate spillover effects).
- Enumerators use neutral study framing when approaching non-participants and do not mention “StrongMinds”, “IPT-G”, "mental health," "depression", or any other information about the intervention.
- Enumerators are trained in "interruption protocols" enabling them to end a non-participant interview quickly and professionally if they perceive any risk of disclosure or discomfort to the participant.
- All non-participant interviews are conducted in privacy.
- Should a non-participant themselves screen positive for depressive symptoms or acute risk (via PHQ-9 item 9), the same referral pathway and Mental Health Coach escalation described in Section 2.10 will apply.

Research assistants conducting household visits will work in pairs or maintain regular check-ins with supervisors. Field protocols will include procedures for managing unsafe situations, and enumerators will be provided with emergency contact numbers.

All study activities will comply with StrongMinds' organizational safeguarding policy, which protects participants, staff, and community members. IDinsight will integrate StrongMinds' clinical safeguarding standards, including suicide risk escalation protocols and referral pathways, into enumerator training and field manuals.

4.5 Participant Compensation

Study participants will receive compensation of 15,000 UGX (given in kind-support as soap, sugar etc. or mobile money) per completed survey round.The spillover respondents in the same households as the study participants will receive a smaller token (e.g. packet of biscuits). Respondents in the consumption sub-study (Section 2.4.4) who complete the extended module will receive an additional 15,000 UGX to compensate for the additional 1–2 hours required. Compensation is intended to reimburse participants for their time.

Compensation will be **decoupled from survey responses**. Participants will receive the incentive for completing the interview regardless of what answers they provide. The neutralizing prompt read before the PHQ-9 explicitly reminds participants that their incentive is guaranteed.

The compensation amount is set at a level sufficient to acknowledge participants' time without being so high as to constitute undue inducement to participate.

4.6 Risks and Discomforts

Participation in this study is expected to involve minimal risks. However, discussing personal mental health experiences during the intervention or assessments may cause emotional discomfort for some participants. If any participant experiences psychological distress at any point during the interview, they will be given the opportunity to interrupt or discontinue participation.

The respondents in the consumption sub-study (Section 2.4.4) who consent to the extended module face an additional time burden of approximately 1–2 hours; participation is voluntary, and compensated. The respondent will also have the option to take the ended module at a later time.

To mitigate the risk of unauthorized access to participant data, any audio recordings will be encrypted and stored on password-protected devices. Participant data will be anonymized during all stages of handling, ensuring that identifying information is removed. Any physical documents, such as consent forms, will be securely stored in locked cabinets to prevent unauthorized access and protect confidentiality. These measures are in place to safeguard participants' privacy and ensure their data remains secure.

There are no anticipated physical risks associated with participation. The IPT-G intervention is a talking therapy that does not involve medication, medical procedures, or physical contact.

4.7 Community Engagement

The community engagement process will begin by involving the Ministry of Health, the participating district(s), local leaders, community health workers, and key stakeholders during the planning and implementation phases. Their input will help tailor the intervention and research to align with cultural practices, local needs, and community priorities.

Throughout the study, regular meetings and workshops will be conducted with community leaders and stakeholders to provide updates on the study's progress and to gather feedback. These sessions will ensure transparency and foster trust between the study team and the community. Participants will also be informed about the study's purpose, benefits, and potential risks through sensitization sessions, including community gatherings and open dialogue sessions.

Local health workers and community members will play an active role in implementing the intervention, particularly in recruitment and follow-up activities. Training sessions for lay health workers will build local capacity and also ensure the sustainability of the intervention after the study concludes.

At the end of the study, findings will be shared with the community through accessible formats, such as summary reports, community presentations, and interactive workshops. These efforts will ensure that participants and local stakeholders understand the study's outcomes and its potential benefits for improving mental health in their communities. By actively involving the community at every stage, this engagement plan aims to build trust, enhance collaboration, and ensure the intervention is both culturally relevant and impactful.

5. Study Timeline

Study timeline from February 2026 to November 2028

Activity	2026											2027												2028									
	02	03	04	05	06	07	08	09	10	11	12	01	02	03	04	05	06	07	08	09	10	11	12	04	05	06	07	08	09	10	11	12
1. Protocol Development, IRB and Pre analysis plan	X	X	X																													
2. Study Preparation (Village selection, enumerator training)			X	X																												
3. Baseline Data Collection (Screening with PHQ-4 and PHQ-9)					X	X																										
4. Intervention (6 weeks IPT-G sessions)						X	X	X																								
5. Follow-Up Data Collection (2 weeks, 6 months, 12 months post)									X				X						X	X												
7. Analysis & Dissemination (Journal articles, policy briefs and presentations)														X	X						X	X										
8. Follow-Up Data																											X	X				

Collection (24 months post-intervention)																																
9. Analysis & Dissemination (Journal articles, policy briefs and presentations)																												X	X			

6. Budget

Budget head	Year 1	Year 2	Year 3
IDinsight Staff	$484,219	$72,500	$72,500
Temp Staff Cost	$79,170	$26,910	$26,910
Staff Costs Subtotal	$563,389	$99,410	$99,410
International Travel	$4,200	$1,400	$1,400
Regional Travel	$32,880	$11,010	$11,010
Equipment and Supplies	$2,910	$630	$630
General & Administrative	$25,776	$6,924	$6,924
Subcontracts	$0	$0	$0
Others	$0	$0	$0
Travel and Supplies Subtotal	$65,766	$19,964	$19,964
Tax	$0	$0	$0
Tax: CGST Output	$0	$0	$0
Tax: SGST Output	$0	$0	$0
Tax: IGST Output	$0	$0	$0
Tax Subtotal	$0	$0	$0
GRAND TOTAL	**$629,155**	**$119,374**	**$119,374**

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8. Appendices

APPENDIX A - FIDELITY CHECK LISTS

A. QUALITY ASSURANCE TOOL PREGROUP PHASE

Date of Assessment:	Cycle No:	Name of Facilitator
Phase:	Supervisor/Assessor Name:	Role of Assessor:
Region;	District;	Group Name;
Program;		

I. Fidelity to the therapy Process (Please tick the most appropriate rating for the facilitators for each of the areas below)

Rating Key: 0 (Poorly delivered) 1 (Fairly Delivered) 2 (Good) 3 (Very Good) 4(Excellently Delivered)- *Rate the facilitator's delivery on this 0-4 scale*.

Focus Area	Fidelity Checkpoint	Score (0-4)
1.Preparation & Consent	All necessary tools/logistics handled (quiet space, attendance, therapy aids).	
	Informed Consent sought and documented	
	Confidentiality and risk limits discussed	
	Session plan documented and followed	
2. Initial Assessment/Symptom Check	Initial screening/assessment for depression and anxiety was completed (using PHQ-9, GAD-7)	
	Psychoeducation on depression/Anxiety	

3.Setting and Review of Treatment Goals	Mutually agreed SMART goals, which are actively focused on and reviewed during therapy.	
	Avoiding practices contradictory to the therapy intervention	

II. Facilitator Skills & Competence (How it was delivered)

Focus Area	Skill Checkpoint	Score (0-4)
1. Rapport & Active Listening	• Demonstrates genuine empathy and builds therapeutic alliance.	
	• Active Listening utilized (paraphrasing, summarizing, tracking narrative).	
2. Questioning & Focus	• Uses open-ended, non-judgmental questions/probing.	
	• Maintains focus on the therapeutic task; avoids giving advice.	
4. Safety & Documentation	• Identifies and manages warning signs/risk concerns; follows referral pathway.	
	• Documentation completed accurately (attendance, referrals).	

III.Overall efficacy: Observer's overall impression

Facilitator Strengths: Areas for Growth.

1. 1.

2. 2.

Supervisor's Recommended Support Plan (Check all that apply):

Tick: Mentoring and Coaching, Training on new skills, Peer-to-Peer Support, Reading, Session Roll-out, Other (Specify:

B. QUALITY ASSURANCE TOOL- INITIAL PHASE

Date of Assessment:	Cycle No:	Name of Facilitator
Phase:	Supervisor/Assessor Name:	Role of Assessor:
Region;	District;	Group Name;
Does the group exist; Yes/No	Program;	

I. Performance scale (Fidelity to the therapy Process (Please tick the most appropriate rating for the facilitators for each of the areas below)

Rating Key: 0 (Poorly delivered) 1 (Fairly Delivered) 2 (Good) 3 (Very Good) 4(Excellently Delivered)- *Rate the facilitator's delivery on this 0-4 scale.*

Focus Area	Fidelity Checkpoint	Score (0-4)
1.Preparation & Consent	● All necessary tools/logistics handled (quiet space, attendance, therapy aids).	
	● Informed Consent sought and documented	
	● Confidentiality and risk limits discussed	
	● Session plan documented and followed	

2. Initial Assessment/Symptom Check	● Initial screening/assessment for depression and anxiety was completed (using PHQ-9, GAD-7)	
	● Symptom check-in/burden rating completed	
	● Facilitator notices clients emotions and feelings and connects it to what is happening in his/her life	
	● Psychoeducation on depression/Anxiety	
3.Treatment Goals & Review	● Mutually agreed SMART goals, which are actively **focused on and reviewed** during therapy.	
	● Avoiding practices contradictory to the therapy intervention	
4. Core intervention Techniques	● Appropriate core techniques utilized (e.g. skills building, mood rating, communication analysis, decision analysis)	
	● Review of homework/home practice assigned from the previous session.	

II. Facilitator Skills & Competence (How it was delivered)

Focus Area	Skill Checkpoint	Score (0-4)
1. Rapport & Active Listening	• Demonstrates genuine empathy and builds therapeutic alliance.	

	• Active Listening utilized (paraphrasing, summarizing).	
2. Questioning & Focus	• Uses open-ended, non-judgmental questions/probing.	
	• Maintains focus on the therapeutic task; avoids giving advice.	
3. Group Management (If applicable)	• Manage group dynamics well (equitable participation, conflict resolution).	
	• Ensures emotional safety and promotes mutual support/cohesion.	
4. Safety & Documentation	• Identifies and manages warning signs/risk concerns; follows referral pathway.	
	• Documentation completed accurately (attendance, summary of symptom checks and rating, referrals).	

III. Overall efficacy: **Observer's overall impression**

Facilitator Strengths: **Areas for Growth.**

1. 1.

2. 2.

Supervisor's Recommended Support Plan (Check all that apply):

Tick: Mentoring and Coaching, Training on new skills, Peer-to-Peer Support, Reading, Session Roll-out, Other (Specify:

C. QUALITY ASSURANCE TOOL- MIDDLE PHASE

Date of Assessment:	Cycle No:	Name of Facilitator
Phase:	Supervisor/Assessor Name:	Role of Assessor:
Region;	District;	Group Name;
Does the group exist; Yes/No	Program;	

I. Performance scale (Fidelity to the therapy Process (Please tick the most appropriate rating for the facilitators for each of the areas below)

Rating Key: 0 (Poorly delivered) 1 (Fairly Delivered) 2 (Good) 3 (Very Good) 4(Excellently Delivered)- *Rate the facilitator's delivery on this 0-4 scale.*

Focus Area	Fidelity Checkpoint	Score (0-4)
1.Preparation & Consent	● All necessary tools/logistics handled (quiet space, attendance, therapy aids).	
	● Informed Consent sought and documented	
	● Confidentiality and risk limits discussed	
	● Session plan documented and followed	
2. Initial Assessment/Symptom Check	● Initial screening/assessment for depression and anxiety was completed (using PHQ-9, GAD-7)	
	● Symptom check-in/burden rating completed	
	● Facilitator notices clients emotions and feelings and connects it to what is happening in his/her life	

	● Psychoeducation on depression/Anxiety	
3.Treatment Goals & Review	● Mutually agreed SMART goals, which are actively **focused on and reviewed** during therapy.	
	● Avoiding practices contradictory to the therapy intervention	
4. Core intervention Techniques	● Appropriate core techniques utilized (e.g. skills building, mood rating, communication analysis, decision analysis)	
	● Review of homework/home practice assigned from the previous session.	

II. Facilitator Skills & Competence (How it was delivered)

Focus Area	Skill Checkpoint	Score (0-4)
1. Rapport & Active Listening	• Demonstrates genuine empathy and builds therapeutic alliance.	
	• Active Listening utilized (paraphrasing, summarizing).	
2. Questioning & Focus	• Uses open-ended, non-judgmental questions/probing.	
	• Maintains focus on the therapeutic task; avoids giving advice.	

3. Group Management (If applicable)	• Manage group dynamics well (equitable participation, conflict resolution).	
	• Ensures emotional safety and promotes mutual support/cohesion.	
4. Safety & Documentation	• Identifies and manages warning signs/risk concerns; follows referral pathway.	
	• Documentation completed accurately (attendance, summary of symptom checks and rating, referrals).	

III. Overall efficacy: **Observer's overall impression**

Facilitator Strengths: **Areas for Growth.**

1. 1.

2. 2.

Supervisor's Recommended Support Plan (Check all that apply):

Tick: Mentoring and Coaching, Training on new skills, Peer-to-Peer Support, Reading, Session Roll-out, Other (Specify:

D. QUALITY ASSURANCE TOOL- TERMINATION PHASE

Date of Assessment:	Cycle No:	Name of Facilitator
Phase:	Supervisor/Assessor Name:	Role of Assessor:
Region;	District;	Group Name;

Does the group exist; Yes/No	Program;	

I. Performance scale (Fidelity to the therapy Process (Please tick the most appropriate rating for the facilitators for each of the areas below)

Rating Key: 0 (Poorly delivered) 1 (Fairly Delivered) 2 (Good) 3 (Very Good) 4(Excellently Delivered)- *Rate the facilitator's delivery on this 0-4 scale.*

Focus Area	Fidelity Checkpoint	Score (0-4)
1.Preparation & Consent	● All necessary tools/logistics handled (quiet space, attendance, therapy aids).	
	● Informed Consent sought and documented	
	● Confidentiality and risk limits discussed	
	● Session plan documented and followed	
2. Initial Assessment/Symptom Check	● Initial screening/assessment for depression and anxiety was completed (using PHQ-9, GAD-7)	
	● Symptom check-in/burden rating completed	
	● Facilitator notices clients' emotions and feelings and connects it to what is happening in his/her life	
	● Psychoeducation on depression/Anxiety	
3.Treatment Goals & Review	● Mutually agreed SMART goals, which are actively **focused on and reviewed** during therapy.	

	● Avoiding practices contradictory to the therapy intervention	
4. Core intervention Techniques	● Appropriate core techniques utilized (e.g. skills building, mood rating, communication analysis, decision analysis)	
	● Review of homework/home practice assigned from the previous session.	
5. Termination/Relapse planning	● Reviewing goal reached and closure of session	
	● Relapse prevention strategies discussed/rehearsed (for final phase sessions).	
	● Referral of clients that need support at closure	

II. Facilitator Skills & Competence (How it was delivered)

Focus Area	Skill Checkpoint	Score (0-4)
1. Rapport & Active Listening	• Demonstrates genuine empathy and builds therapeutic alliance.	
	• Active Listening utilized (paraphrasing, summarizing).	
2. Questioning & Focus	• Uses open-ended, non-judgmental questions/probing.	
	• Maintains focus on the therapeutic task; avoids giving advice.	

3. Group Management (If applicable)	• Manage group dynamics well (equitable participation, conflict resolution).	
	• Ensures emotional safety and promotes mutual support/cohesion.	
4. Safety & Documentation	• Identifies and manages warning signs/risk concerns; follows referral pathway.	
	• Documentation completed accurately (attendance, summary of symptom checks and rating, referrals).	

III. Overall efficacy: **Observer's overall impression**

Facilitator Strengths: **Areas for Growth.**

1. 1.

2. 2.

Supervisor's Recommended Support Plan (Check all that apply):

Tick: Mentoring and Coaching, Training on new skills, Peer-to-Peer Support, Reading, Session Roll-out, Other (Specify:

9. Annexes

Annex A: Informed Consent/ Assent Form (English)

[To be attached]

Annex B: Informed Consent/ Assent Form (Lusoga / Local Language Translation)

[To be attached]

Annex C: Survey Instruments

[PHQ-9, GAD-7, WHODAS, MSPSS, Cantril Ladder, economic modules — to be attached]

Annex D: CVs of Principal and Co-Investigators

[To be attached]

Annex E: Letters of Support

Annex F: Ethics/ Good Clinical Practice Certificates

[For all investigators — to be attached]

Annex G: Risk Mitigation Plans

[COVID-19, Ebola, MPOX, Natural disaster, and contextual risk plan; data security plan]

Annex H: Suicide Protocol

[To be attached]