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Authors

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Mechanisms of Change for a Family Intervention in Kenya: An Integrated Clinical and Implementation Mapping Approach

Ali Giusto^{a,b,*}, Elsa A. Friis-Healy^{c,b}, Bonnie N. Kaiser^{d,b}, David Ayuku^e, Wilter Rono^f, Eve S. Puffer^{b,g}

^{a.}New York State Psychiatric Institute, Columbia University, Department of Psychiatry, New York, NY 10032, USA

b. Duke Global Health Institute, Durham, NC, USA

^{c.}Department of Psychiatry Duke University School of Medicine, Durham, NC, USA

^{d.}University of California San Diego, Anthropology Department and Global Health Program, La Jolla, CA, USA

e.Moi University, Academic Highway, Eldoret, Usain Gishu County, Kenya

f. Moi Teaching & Referral Hospital, Eldoret, Rift Valley, Kenya

g-Department of Neuroscience and Psychology, Duke University, Durham, NC, USA

Abstract

To increase cultural relevance and maximize access for historically underserved populations, there is a need to explore mechanisms underlying treatment outcomes during piloting. We developed a mixed-method approach, Integrated Clinical and Implementation Mapping (ICIM), to explore clinical and implementation mechanisms to inform improvements in content and delivery. We applied ICIM in a pilot of Tuko Pamoja, a lay counselor-delivered family intervention in Kenya (10 families with adolescents ages 12-17). ICIM is a 3-phase process to triangulate data sources to analyze how and why change occurs within individual cases and across cases. We synthesized data from session and supervision transcripts, fidelity and clinical skills ratings, surveys, and interviews. Outputs included a comprehensive narrative and visual map depicting how content and implementation factors influenced change. For Tuko Pamoja, ICIM results showed common presenting problems, including financial strain and caregivers' distress, triggering negative interactions and adolescent distress. ICIM demonstrated that active treatment ingredients included communication skills and facilitated, prescribed time together. Families improved communication, empathy, and hope, facilitated improved family functioning and mental health. Key implementation mechanisms included provider clinical competencies, alliance-building, treatment-aligned adaptations, and consistent attendance. Results guided manual and training refinements and generated hypotheses about mechanisms to test in larger trials.

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 $[\]hbox{*Corresponding Author: Ali Giusto, ali.giusto@nyspi.columbia.edu.}\\$

Keywords

implementation science; mechanisms; family therapy; global mental health; mixed methods

Introduction

The fields of intervention research and implementation science share a major priority of reducing the mental health treatment gap among historically underserved populations globally. (We use the term historically underserved populations to refer to communities globally that have been excluded and/or underserved due to structural and systematic factors, such as racism or classism; (Kohn et al., 2004; Mongelli et al., 2020). To do this, intervention research focuses on designing more culturally and contextually relevant interventions, and implementation science includes the adaptation of existing evidencebased treatments (EBTs) and how they are delivered (Baumann, Cabassa,, & Wiltsey Stirman, 2017; Cabassa & Baumann, 2013). While great strides are being made to systematize adaptation and implementation processes for scaling treatments for diverse populations (Miller et al., 2021; Stirman et al., 2019), major gaps remain in understanding clinical- and implementation-related mechanisms of change (Kazdin, 2007; Lewis et al., 2020). Being able to systematically explore mechanisms of change from both a clinical and implementation perspective during piloting stages would allow for early, critical insight for refining treatments and implementation strategies. This would be particularly valuable when adapting or designing interventions, providing rich information for meaningful adaptation, and ultimately making the research-to-practice pipeline more efficient (Benish et al., 2011; Heim & Kohrt, 2019).

From the start of behavioral therapy, intervention science has sought to answer, "What treatment, by whom, is most effective for this individual with that problem, under which set of circumstances, and how does it come about?" (Paul, 1969, p.44). Many factors have been identified as mediating and moderating change. Clinically, these include therapeutic alliance (Baier et al., 2020; Wampold, 2015), specific treatment strategies (Hundt et al., 2013), and cultural alignment (Shehadeh et al., 2016). On the implementation side, factors such as the political-economic context, clinical context, delivery method, and provider characteristics have emerged as important (Aarons et al., 2011; Damschroder et al., 2009). There is a need for strategies that can be applied early in research to understand how such clinical and implementation factors influence outcomes. Such findings could guide refinement of adapted content before manuals and implementation plans are finalized and evaluated in resource-intensive trials. This is especially true for interventions with underserved populations because (1) the majority of EBTs have not been developed for, or tested with, these populations, and (2) newer, less-studied implementation approaches (e.g., task shifting; Barnett et al., 2018)) are often applied to interventions with historically underserved populations facing structural barriers to care (Brownson et al., 2021; Padmanathan & De Silva, 2013; Vellakkal & Patel, 2015). By moving beyond pre-post piloting results to identify potential mechanisms supporting both clinical change and successful implementation of adapted interventions, we can begin to identify pitfalls and capitalize on positive synergies to increase chances of success.

Early exploration of clinical and implementation mechanisms requires systematic ways to capture the richness of processes and of patient experiences. Qualitative and mixed-methods approaches provide powerful tools to do this (Hennink et al., 2020). Conversely, a solely quantitative approach can curtail or miss nuanced interactions and inadvertently exclude experiences of underreached populations for whom most quantitative measures were not developed nor tested (Zuberi & Bonilla-Silva, 2008). Qualitative and mixed-methods approaches can both amplify patient and provider voices that are often excluded and capture the interrelationships among clinical and implementation elements (Buchanan et al., 2020). These methods provide a level of understanding that makes it possible to identify key ingredients—of clinical content and implementation strategies—as well as nonessential ingredients that could be removed.

Exploring potential mechanisms of change during intervention development and initial piloting can also allow an early understanding of how implementation elements intersect with clinical elements, allowing for dual refinement and setting the stage for full hybrid implementation-effectiveness trials (Curran et al., 2012). Critical barriers and facilitators of implementation to explore include training and supervision processes, fidelity, provider engagement, implementation setting, implementing organization culture, and community engagement (Aarons et al., 2011; Dorsey et al., 2017; Glasgow et al., 2019; Meza et al., 2021; Shelton et al., 2018). Key clinical elements include intervention content, theoretical orientation, clinical competencies such as common factor elements (e.g., therapeutic alliance), and skill engagement. In addition to examining these individually, there might be important interactions. For example, specific intervention content may be more or less effective when delivered by specific types of providers with a certain set of clinical competencies (Campbell et al., 2013). Or a delivery setting's organizational climate may influence clinician buy-in and the formation of therapeutic alliance or intervention delivery (Aarons et al., 2011b; Cox et al., 2020; Lyon et al., 2018). Together, these examples could inform everything from counselor recruitment to delivery setting selection. Understanding these types of clinical-implementation interactions could help address barriers to care earlier while honing treatment—barriers that often disproportionately affect marginalized populations. If we can reduce these barriers at the outset, treatments could become accessible during the testing phases rather than expanding to underserved populations only after effectiveness has been supported in samples who are confronted with fewer barriers to care (Woodward et al., 2021).

When developing interventions that require more flexible application, such as community-embedded or family-based approaches, early and in-depth exploration of mechanisms may be particularly beneficial (blinded). In the case of family therapy, many clinical and implementation elements are at play that ultimately shape family outcomes (Liddle et al., 2001). For instance, having multiple family members in treatment together can lead to more treatment barriers specific to each family member. Similarly, achieving multiple clinical outcomes, such as improving family relationships and individual mental health, requires a provider to balance fidelity and flexibility to meet clinical needs, as is often the case in real-world clinical practice; this can lead to in-vivo adaptions that are important to understand early on (Kaiser et al., 2019; Lau et al., 2017).

In the current study, we present a novel approach for exploring clinical and implementation mechanisms of change, termed **Integrated Clinical and Implementation Mapping** (**ICIM**). ICIM builds on existing methodological and measurement tools drawn from implementation and intervention science, resulting in an integrated, mixed-methods approach. ICIM entails triangulating, synthesizing, and diagramming multiple data sources to understand mechanisms of change from clinical and implementation perspectives simultaneously. It aligns with case conceptualization processes used in clinical practice for decades, with added considerations of implementation elements (Scholten et al., 2021; Sperry & Sperry, 2020). ICIM is designed to complement the standard analysis of post-treatment clinical outcomes by examining mechanisms leading to those outcomes using in-depth process data, such as therapeutic session transcripts.

Here, we describe the ICIM approach and apply it to understand mechanisms of change in families participating in a pilot study of Tuko Pamoja (TP), a family-therapy intervention implemented in Kenya. TP is a community-based family intervention delivered by lay providers to improve family functioning and mental health. Family therapy approaches with the whole family are under-implemented in Kenya (Patterson et al., 2018). Yet, they may be particularly well suited for treating both youth and caregiver mental health because they can simultaneously address key family-level factors closely tied to both individual well-being and the surrounding context (Carr, 2019). We demonstrate in detail the procedures of ICIM to facilitate its application to other interventions.

Methods

We used ICIM to explore clinical- and implementation-related change mechanisms in ten family therapy cases included in the first pilot study of the *Tuko Pamoja* (TP) intervention. ICIM followed the collaborative development of the intervention and implementation (Puffer et al., 2019) and our analysis of pre-post outcomes (Puffer et al., 2020). In the ICIM analyses described below, we used multiple data sources to examine why changes may (or may not) have occurred.

Setting and Ethics

The pilot trial was conducted in two peri-urban communities surrounding the city of Eldoret in the Rift Valley Province of Kenya. The study was conducted in partnership with Moi Teaching and Referral Hospital (MTRH). In this setting, mental healthcare access is limited, with some inpatient and outpatient care primarily for serious mental illness and severe substance use problems provided through MTRH (Jaguga & Kwobah, 2020). While access is growing, treatments for youth mental health and families continue to be very limited. All study procedures were approved by the Institutional Research and Ethics Committee at Moi University and Moi Teaching and Referral Hospital and Duke University's Institutional Review Board. Participants received small, non-monetary tokens of appreciation (e.g., tea, sugar) for participating in the treatment study (See Puffer et al., 2019 for details).

Participant Recruitment: Lay Counselors and Families

Counselors—We recruited community members with no previous mental health training but who were already sought out by families for informal support with problems related to family relationships or mental health. These individuals served as 'natural counselors' in their communities(Wall et al., 2020). Community leaders recruited the potential counselors, identifying trusted individuals, often from local religious congregations and civic leadership roles (n=23). This group was interviewed, and 14 were invited for a training. Following training, a final group of 8 counselors (including one husband-wife pair) were selected based on clinical skills and treatment knowledge demonstrated during training. Half of the counselors were women, and the mean age was 45. The majority of counselors had completed at least some secondary school and were engaged in some part-time work (e.g., pastor, youth group leader). Counselors carried 1-2 cases at a time to attempt to match the time they were already engaging with families informally prior to becoming a TP study counselor. A full description of this process can be found in Puffer et al. 2019.

Families—Counselors recruited families in their communities who showed problems in family relationships and had an adolescent aged 12-17 years with suspected emotional or behavioral distress. Counselors were asked to use their typical informal methods for identifying families who need help for these problems in order to mirror local practices. Counselors typically drew from families who had already approached them with concerns or who had exhibited observable concerning indicators (e.g., child dropping out of school). Interested families then completed formal screening and consent with the research team. For assessment, up to two caregivers and one adolescent were included per family, though additional family members could participate in treatment. We defined a caregiver to be any adult providing care for the child, and if the family had more than one eligible adolescent, families identified one with the most significant concerns. Families were also screened for immediate danger to any individual, especially related to violence against children or intimate partner violence, though no families were excluded for these reasons. For a more in-depth description of procedures, please see (Puffer et al., 2020).

Intervention: Tuko Pamoja

Tuko Pamoja (TP, "We are together" in Kiswahili), is a family therapy that addresses family functioning and individual mental health outcomes by strengthening family system characteristics, including relationship quality and communication, as well as individual coping skills. Details on the development of TP as well as pre-post pilot outcomes have been previously reported (See Puffer et al., 2019, 2020). TP was developed through a collaborative process of exploratory research involving US and Kenyan partners to match evidence-based strategies with community needs, strengths, and existing approaches (Puffer et al., 2019 details the development process). This resulted in a modular treatment rooted in evidence-based therapies, including solution-focused, cognitive-behavioral, and family system therapies (D'Zurilla et al., 2010; Kaminski et al., 2008; Kerr, 1981; Schmit et al., 2016). The Tuko Pamoja intervention includes principles and strategies from these approaches that best aligned with intervention targets and natural counseling practices. For instance, solution-focused strategies fit with the existing practices in the community of providing problem-specific advice; TP then focused on creating action plans through client-

led processes (Puffer et al., 2019). TP is guided by a written and digital manual, including video-based role plays to illustrate concepts. Activities are not time-limited, meaning there are no strict limits on numbers of sessions or session length, mirroring local norms around flexible scheduling and pacing of natural counseling practices.

Table 1 outlines the content, structure, and core underlying clinical strategies of TP. TP is organized by modules, with families receiving only the modules they need. For all families, TP begins with an assessment of needs and goals, a mapping of problem cycles, and orientation to TP. Counselors and families collaboratively choose a module based on presenting concerns. All modules follow 10 core steps (Table 1) that are completed sequentially, with flexibility to return to earlier steps as needed. After completion of a module, the counselor and family again collaborate to determine if an additional module is needed and, if so, which one. While the manualized content is very structured, counselors were also trained on core strategies underlying the treatment that are not attached to any of the specific 10 steps. We refer to these as Tuko Pamoja "Spirit" principles to connote the flexibility with which they can be implemented.

Broadly, the hypothesized theory of change posits that the family-based processes included in TP content will improve relationship functioning, including communication, emotional connectedness, and overall unity, which will in turn improve individuals' mental health; simultaneously, for some, directly addressing individual distress through coping skills training will improve mental health, in turn also improving relationship functioning (See Puffer et al., 2019 for more details). This theory of change is informed by evidence-based family therapy approaches, such as solution-focused family therapy and cognitive behavioral therapy, as well as formative qualitative work that informed intervention development. Family systems theory also informed the overall theory of change and intervention strategies, positing that a family is a complex system in which individuals interact to influence each other's behavior and well-being and vice versa (Kerr, 1981).

Procedures

Lay Counselor Training and Supervision—Two clinical psychologists, one from Kenya and one from the US, as well as a US-based doctoral student, led counselors in a 10-day training (approximately 60 hours) focused on general clinical skills, such as validation and active listening, and TP-specific information, skills, and procedures. Approximately halfway through the study (6 months after study initiation), a 40-hour refresher training was conducted. Supervision followed a tiered model similar to those previously used in task-shifting projects globally (Murray et al., 2014). Local supervisors were four university students in their third year of medical psychology training, an undergraduate major with clinical practica. They were trained to supervise lay counselors, providing one-on-one supervision in person or by phone after each session. The local supervisors received weekly consultation from the clinical psychology team described above, in person or via Skype.

Data Collection, Sources, and Measures—Table 2 presents the specific data sources, constructs and outcomes they measured, collection procedures, and source-specific analysis that allowed for ICIM. Data were gathered at many levels to understand different

family member perspectives on implementation and clinical change (quantitatively and qualitatively), provider perspectives (qualitatively), interaction content and provider fidelity and competencies (qualitatively), and participation through process tracking. Assessments were completed in Swahili and all tools were adapted to, or developed for, the local context. Most data sources were analyzed previously for the pre-post pilot analyses and ready to extract for the ICIM analysis. See Puffer et al., 2019, 2020 for measurement details including translation and adaptation processes.

New data sources used for this study included the session-specific data from (a) each session transcript and (b) structured session and supervision notes.

Analysis

Overview—ICIM is a mixed-methods multiple case series approach to identify clinical and implementation mechanisms of change by describing pathways that drove or hindered change processes within and across individual cases. To do this, ICIM allows for triangulation, synthesis, and diagramming of multiple data sources. It draws on clinical case conceptualization processes (Ridley & Jeffrey, 2017; Sperry, 2005) to build a narrative to tell the story, as well as systems-thinking processes such as causal loop and interrelationship diagramming to show the story (de Pihno, 2015; similar to mechanism mapping (Geng et al., 2022). Importantly, ICIM is distinct from Intervention Mapping (Bartholomew et al., 1998) that focuses on developing behavior change interventions in a proactive manner whereas ICIM focuses on clinical mapping to depict the synthesized data over time. Across both, the term mapping is used to connote the systematic process for plotting data.

In this study, we began ICIM by identifying presenting problems of families and describing the changes—or lack of change—they exhibited by the end. We then filled in the rest of the story, asking: What happened in between, during the intervention, that led to the eventual outcome? What were the drivers and barriers to change? To answer, we examined how the family interactions changed over time. We then examined how the modules they received and how counselor delivery practices seemed to play a role in whether and how change happened.

There are three stages in ICIM: (1) developing an intervention-specific structured case report template based on available data sources, (2) conducting case-level analysis to assess and map integrated change pathways within each case, and (3) conducting group-level analysis to identify and map patterns across cases. The stages are outlined in Figure 1, designed to be used as a relatively comprehensive guide to the process.

Stage 1: Develop and Build Structured Case Report—Similar to qualitative analysis approaches, a pillar of ICIM is the structured organization of data to support triangulation and synthesis. In this 3-step stage, we focused on structuring and describing what has occurred within a case from a clinical and implementation lens. In *Step 1*, the research and clinical team outlined a structured case report template based on the intervention theory of change, outcomes of interest, key delivery elements, available data sources, and mechanisms of interest. The template includes pre-treatment, session by session, and post-treatment data to facilitate causal hypothesis generation. See Figure 1

for specific sections of our template relevant to the TP family intervention. In *Step 2*, data were extracted for each family from the data sources previously analyzed as pilot outcomes, including pre-post change and basic implementation variables (Table 2). We input these into the appropriate sections structured case report template. Next, in *Step 3*, we conducted an in-depth analysis of session transcripts and structured session and supervision notes to fill in the report sections with richer data to describe what happened over time. This included developing a <u>visual depiction of the presenting problem</u> of each family to capture clinical targets for change and contextual factors that may worsen outcomes or interfere with engagement (referred to in Figure 1 as Presenting Problem Cycles). We completed these steps for each case.

Stage 2: Map Integrated Change Pathways within Cases—In Stage 2, we focused on how and why change occurred using case conceptualization processes (Step 4) and visual pathway diagramming (Step 5). In Step 4, we developed a narrative describing changes over time. Similar to memoing (Birks et al., 2008), we took reflective notes on what we learned from multiple data sources concerning: (1) sequences of how family interaction patterns and individual behaviors changed over time, (2) clinical and implementation facilitators of specific changes, and (3) clinical and implementation barriers to change. We then synthesized the notes into a narrative summary. The summaries were then presented to the US and Kenyan team and were refined through collaborative discussion, similar to a case presentation process.

In Step 5, we distilled information from steps 1-4 to depict change mechanisms for each family using visual pathway diagramming to identify relationships among multiple outcomes, mechanisms, and aspects of treatment alongside barriers and facilitators to change. We created two pathways for each case representing change across treatment: a detailed case pathway diagram specific to that family and a "macro" pathway diagram referring to more general domains.

We began with the detailed case pathway diagram for each family using a collaborative team process (See Figure 3 for reference). We organized the diagram into three panels on a whiteboard, leaving space on the top and bottom, and filled in the map from right to left—starting with the end of treatment and working backwards to describe the pathway that led to those outcomes, First, we diagrammed Post-TP Treatment Outcomes (in Panel 3)—the new family behavioral patterns at the end of treatment—using post-treatment data. To diagram, we drew boxes with our main treatment outcomes (e.g., family functioning) and arrows showing relationships between those outcomes. This anchored the rest of the analysis. Next, we diagrammed Clinical Mechanisms of Change (Panel 2) that occurred during treatment. Clinical mechanisms were family behaviors that mediated outcomes that we had described in the narrative synthesis. We drew arrows showing relationships between these clinical mechanisms and treatment outcomes. Third, we diagrammed **TP Content** and Strategies (Panel 1) we identified in steps 3 and 4 that emerged as drivers of changes and drew arrows showing relationships between treatment elements and changes listed in Panel 2. Lastly, we diagrammed **Implementation Mechanisms** above and below the three panels, including drivers and barriers to change. We listed counselor-related (i.e., fidelity, adaptations) and family-related (e.g., engagement) mechanisms driving or interfering with

change that were identified from session specific data (e.g., transcripts). For each step, we consulted data sources and case reports as needed to validate diagrams (Hennink et al., 2020).

Next, we drew "macro-level" pathway diagrams for each case, in which we converted the very detailed, family-specific elements into broader domain categories that would allow comparison across families. For example, the detailed family pathway may say "mother begins praising child for chores," and the macro would be broadened to "improved positive parent-child communication." These macro pathways were foundational for Stage 3. We appended the final pathways to the Case Report.

Stage 3: Map Patterns Across Cases—The final phase of ICIM explores patterns across cases. In Step 6, we held team discussions of all cases side-by-side to explore patterns across families. We first identified typical problems across families to develop a common presenting problem cycle that showed behavioral patterns across multiple families at baseline, as well as contextual factors that seemed to impact behavior and engagement (e.g., poverty, gender norms). We also looked for patterns of mechanisms of change and barriers and facilitators to change and delivery across families.

In Step 7, we compiled all macro pathway diagrams to identify common pathways of change across cases, including shared barriers and facilitators to change. From those, we created a composite pathway diagram (See Results Figure 3 for reference). To do this, we used a high-level and concrete diagramming approach. We first organized a white board using the structure above: 3 Panels with space on the top and bottom. For every family, we wrote down each macro pathway step on a sticky note and placed the notes in the appropriate sections on the board. As above, we added arrows linking the treatment content, mechanisms, and treatment outcomes. We then counted how many times the same links (arrows) and steps occurred, with those occurring fewer than three times excluded from the composite diagram. Finally, we consolidated the redundant arrows and steps and drew the final composite digitally. The result was a diagram showing the pathway from most 'active' treatment ingredients to the clinical and implementation mechanisms to treatment outcomes (Figure 3). Links that were observed fewer than three times were still examined, but separately as unique patterns or cases.

Results

We present the ICIM results for Tuko Pamoja beginning with a brief description of the families and courses of treatment, followed by the overall across-case findings—the final products of the ICIM process. We then present a case study of one family to illustrate treatment mechanisms and the use of ICIM Steps 1 through 5.

Participants and Course of Treatment

Eighteen families were referred to TP, and 10 families completed treatment; three were not eligible, two dropped out before beginning, and three withdrew after beginning for logistical reasons. Among the completers, eight cases included two caregivers and a target adolescent, and the other two included a single female caregiver and a target adolescent.

Adolescents ranged in age from 12 to 17 (M = 14, SD = 1.79); four were male. Caregivers ranged in age from 26 to 61 years (M = 39, SD = 8.11); one caregiver was a non-biological parent (step-father). On average, families received 15 sessions lasting a mean of 39 minutes, totaling an average of approximately 9 treatment hours. The time period over which the intervention was delivered varied greatly (range: 15-48 weeks), reflecting that sessions often did not happen weekly. Most families completed two modules, most commonly the marriage and parent-child relationship modules.

Common Presenting Problem Cycles (Step 6)

Figure 2 depicts the common cycles of problems present across multiple families in Tuko Pamoja (Figure 2). Prior to treatment, families described three intersecting triggers for dysfunctional patterns that began with individual caregivers: financial strain, caregiver mental health symptoms, and, in several cases, alcohol use. These were dynamic and cyclical. For instance, financial stress often led to feelings of purposelessness, shame, or worry, especially among men and single mothers. For men, this often contributed to alcohol use, which increased their negative emotions and left less money for basic family needs after spending on drinking. These triggers led to problems in couple and parent-child relationships, characterized by conflict, poor or absent communication, and low trust. These relationship problems contributed to child emotional and behavioral symptoms, including sadness, anxiety, social withdrawal, academic issues, externalizing behaviors, and potentially dangerous behaviors, like running away from home.

Patterns of Clinical and Implementation Mechanisms

Figure 3 depicts the composite pathway diagram (Step 7) showing key pathways of change across all families. Panel 1 shows the manualized TP content and underlying strategies that emerged as important across pathways. Panel 2 shows clinical mechanisms (changes in family behaviors) that mediated outcomes. The outcomes in family functioning and mental health—new patterns after treatment—are depicted in Panel 3. Finally, Panels A and B present the implementation drivers and barriers that influenced change across cases. Below, we describe each section, including how elements interacted.

Panel 1: TP Content and TP Strategies—The five TP content and strategies most consistently involved in initiating change were: (1) strengthening communication through skills training and practice, (2) counselors teaching and modeling solution-focused problem solving and reinforcing families' solution-focused responses, (3) increasing family time together through sessions and homework, (4) building empathy and understanding between members, and (5) increasing individuals' knowledge and skills related to parenting and youth coping skills. These were helpful both because of prescribed steps in the manual and core underlying strategies not associated with manualized steps that counselors applied flexibly. For instance, after teaching communication skills (manualized content), counselors returned to these skills at other times to encourage families to talk with one another (underlying strategy) using these skills.

Panel 2 → 3: Clinical Mechanisms of Change and Outcomes—We observed five common clinical mechanisms—proximal drivers of change leading to treatment outcomes

(*Panel 2*, Figure 3). Three mechanisms were seen in all families: (1) improved and increased communication; (2) improved and increased perspective-taking, empathy, and understanding; and (3) increased hope, self-efficacy, and shared family values. In two-parent families, these changes often happened first in the couple relationship, leading to treatment outcomes of improved couple relationship quality and caregiver mental health; these were both connected with improved financial planning and more household resource sharing. An improved couple relationship was also associated with reduced adolescent emotional distress and externalizing behaviors. In single-parent families, these changes also were seen within the parent-child dyad, improving caregiver mental health, the parent-child relationship, and child distress.

In families presenting with parent-child relationship problems or child mental health symptoms as primary concerns, all the above mechanisms were important, in addition to: (1) clearer family expectations and new behavioral parenting skills and (2) youths' increased recognition and use of coping skills. As shown in Panel 3, mechanisms led to positive treatment outcomes: understanding and emotional openness in the parent-child relationship, as well as improved child well-being, both directly and through the parent-child relationship. This pattern was most common for single-mother households who were often faced with fulfilling dual roles of caretaker and financial provider.

Implementation Mechanisms of Change—Panels A and B at the top and bottom of Figure 3 list implementation-level drivers and barriers to change. Across all families, implementation mechanisms, or facilitators, first included qualities and abilities of the lay providers, including general clinical competencies and skills modeling. Mechanisms also included effective ways that counselors tailored the content through "ad-hoc" adaptations that were aligned with TP content but further contextualized the treatment; examples included use of appropriate self-disclosure and integrating hopeful local examples. Additionally, for youth, counselor alliance with the child and efforts to help the child to be heard in joint sessions were common among families who experienced change. At the family level, multiple family members consistently attending sessions seemed critical to facilitating and enhancing TP content, in part through the act of spending time together and practicing communicating during sessions.

Implementation barriers at the counselor level included counselors providing excessive advice or speaking in a harsh tone, with both seeming to reduce families' participation in session. While most counselors softened their tone and reduced advice-giving to some extent following coaching and role play-based supervision, a minority continued to dominate the sessions. Additionally, some counselors struggled with specific TP content, including cognitive coping skills, and using videos correctly, which did not seem to block progress but certainly slowed it. At the family level, severe alcohol use by caregivers on session days interfered with attendance and participation, which hindered progress and counselor ability to deliver treatment.

Case Example

Here we describe one case that exemplifies the pathways that emerged in the overall Composite Pathway Diagram presented above and illustrates the case-specific analysis steps of ICIM. In Figure 4, we show this family's detailed ICIM results. This family is composed of a male and female caregiver and five children. The mother, one adolescent daughter, and the stepfather to the daughter were referred to treatment because the daughter was missing school and running away from home; it was also suspected that the stepfather was treating the stepdaughter harshly, with the daughter reporting he was "always against what she does." At the start of treatment, conflict within the couple about roles and responsibilities appeared to be the driver of family problems, with the couple reporting a recent, contentious separation (Figure 4, Presenting Problem Cycle). The stepfather felt frustrated and ashamed that he could not provide for his family, leading him to become angry and uncommunicative quickly when his wife confronted him about finances. The mother simultaneously felt angry and dissatisfied with the husband's inability to provide and thought the father was not being 'responsible.' Their dual dissatisfaction triggered arguments that sometimes led the husband to leave home. When this occurred, the daughter felt afraid and the emotional climate at home worsened. At the same time, the daughter reported her stepfather discriminated against her, including disciplining her more harshly than the other children, who were biologically related to him; she felt like a burden to the family.

Given the family's most salient concern was conflict in the couple, treatment began with the couples-focused module (10 sessions), followed by three parent-child relationship sessions (Figure 4 Steps 1-3). The couple's goals included reducing quarrels, increasing emotional closeness, and living together; for stepfather and daughter, goals included reducing harsh discipline discrimination and improving emotional closeness. Most goals were met. The couple learned communication skills, used those skills in session, set clear goals, and completed their homework to talk, plan, and spend time together. The counselor's abilities seemed to drive the family's willingness and success in engaging with the content. These included: coaching the family to use skills in the moment; building a strong alliance that engendered trust in the couple to practice communication; and modeling effective communication and emotion regulation. Together, these clinical and implementation mechanisms led to increases in the stepfather's insight, awareness, and ability to communicate feelings about difficulty finding work and shame about not being able to provide. These was a salient driver for improving the couple's relationship and extended to improving the parent-child relationships as well. In the parent-child module, psychoeducation also increased the stepfather's knowledge related to parenting and discipline and directly improved his empathy and communication with the daughter, helping reduce discrimination and harsh treatment. Notably the counselor's self-disclosure of parenting challenges in the first parent-child session facilitated the stepfather's improved perspective-taking. This was illustrated in a session when the stepfather said to the daughter: "If you are having any burden in your heart, you can say it here so that we see how we can solve it." Improvements in the couple's interactions and stepfather behavior helped alleviate mother and adolescent emotional distress.

The family noted these changes during post-treatment qualitative interviews. The mother reported, "Changes are big because we can now sit down to talk, he brings home food, which he used never to bring...in the past he used to leave at 4am and come back home at 11pm at night and [didn't] care about us. We can now sit down to talk, and we are grateful." After treatment, the father described how communication played a key role in change. He noted: "Our marriage did not have any order at all. We used to throw words at each other, and no one would listen to the other. When someone [began] talking, the other one starts. We had problems and a difficult time. Now I think at least this marriage is going to stand because there is now that chance that we give each other [space] to speak out, and [that person] is understood and listened to."The daughter also reported improved outcomes, describing: "Changes are big... I am not stressed anymore ... my father and mother are no longer quarreling like in the past and there are big changes that we help one another; everyone is listening to the other."

Discussion

We developed and applied Integrated Clinical and Implementation Mapping (ICIM) to explore clinical and implementation mechanisms of change underlying Tuko Pamoja (TP), a family therapy intervention delivered by lay providers in Kenya. ICIM is a unique mixed-methods approach that allowed us to identify pathways of change for each family and then across families considering the treatment itself, how family interactions changed over time, how lay counselors delivered the treatment, and how external factors and real-world stressors affected the process. We are now using results to refine the treatment and implementation strategies, and to generate hypotheses about mechanisms to test in larger sample trials.

In this study, we aimed to address two gaps in the literature. First, we contribute to the understanding of how lay provider-delivered family therapies may lead to improvements in families' functioning and individual members' mental health through an in-depth example of Tuko Pamoja. Second, we propose ICIM as a way to go beyond the data that we, as researchers, typically analyze in intervention pilot studies to measure preliminary findings. These pilot findings often provide only surface-level understandings, and we wait for larger studies to examine clinical and implementation mechanisms. We posit that taking a deep dive into session-by-session data from small samples provides a valuable chance to identify subtle change patterns and potential mechanisms that can help hone treatments earlier for effectiveness and successful implementation simultaneously. Many researchers are also clinicians and implementation scientists who do this deep dive in other contexts; we suggest bringing these practices to pilot studies as well. These approaches may facilitate our ability to tailor treatments in ways that make them more accessible for underserved populations more quickly in the research to practice pipeline (Bernal et al., 2009).

Family Intervention Mechanisms of Change and Application to Intervention and Implementation

While family therapy has a long theoretical history pointing to hypothesized mechanisms of change (Nichols & Schwartz, 1984), the present study narrows to mechanisms of change

for adapted family interventions delivered by lay providers in low-resource settings. Some findings were certainly similar to well-established mechanisms in the literature, while others are more unique to these contexts and delivery methods. Here we also discuss how we refined TP based on these results.

External Stressors—External stressors shaped presenting problems and the course of treatment in ways that need to be considered for treatments in resource constrained contexts. Presenting problems were often inextricably linked with experiences of financial strain stemming from poverty. Unsurprisingly, lack of resources and conflict related to resources then continued as a theme, with families often developing goals closely related to improving their economic situation. Resource-related problems were also often at the core of children's distress and conflict with their parents. This fits with the broader clinical literature, including The Family Stress Model, which posits that caregiver distress triggered by a lack of economic opportunities leads to a cascade of problems in the family that ultimately impact child mental health (Masarik & Conger, 2017).

For Tuko Pamoja, based on findings, we expanded our assessment of financial strain, as well as other salient contextual stressors. We also integrated more explicit practice on applying skills to these problems during counselor training —helping families identify how relationship-related goals could help with financial problem-solving, facilitating communication about finances during sessions, and helping families connect with community resources while allowing them to take the lead in the problem-solving. Many of the lay counselors did this during the pilot, and their approaches we learned from transcripts laid the foundation for what was included in the subsequent trainings. We also recognized the importance of collaborating with existing community social structures who could provide more wraparound support (Puffer & Ayuku, 2022). In future work, integrating direct financial interventions should also be considered (Lund et al., 2010).

Prominence of Couples Functioning Across Outcomes—As hypothesized, improvements in relationship functioning were key to change, but couple relationship functioning specifically was central for changing multiple outcomes. This included change at the child level, which often centered on needs related to child distress, behavior, or even parental relationships, which improved significantly following the couples-focused module such that much less intervention was needed in those domains than expected. These findings align with the literature on family and couples' therapy showing that improvements in relationships can improve individual mental health (Baucom et al., 2012; Burstein et al., 2012; Lam et al., 2009). We also observed direct links from couples functioning to adolescent well-being. Longitudinal developmental psychopathology studies, typically in the US, have demonstrated a similar pathway with child adjustment mediated by the couple relationship when a caregiver experiences distress (Goeke-Morey et al., 2007; Schacht et al., 2009). In low-resource contexts, a specific mechanism to study may be improvement in couples' problem-solving applied directly to finances, leading to more provision to children and reduced stress and leading to more open, supportive communication about finances even with children, again reducing stress even without immediate increases in resources.

In TP, we revisited the key treatment ingredients driving couple change identified in ICIM, specifically noting the importance of improving communication as soon as possible. We therefore moved the concrete communication skills content earlier in manualized steps and emphasized the "sharing thoughts and feelings" step in couples' sessions because empathy and understanding had such impacts on reducing conflict and improving individual adult mental health. We made more time for this by reducing some content that was used less frequently or proved confusing, such as cognitive coping skills that were less helpful than the more straightforward behavioral skills. We also made some steps optional (i.e., solutions tried, exceptions) to allow for more space for couples and families to talk more during sessions and to get more quickly to goalsetting.

Lay Provider Clinical Skills and Ad-hoc Adaptations—It was clear how valuable lay providers' application of the manualized content was to the process of change. This went well beyond fidelity to how developed their general clinical skills were and how counselors contextualized steps in the moment—their "ad-hoc adaptations." This is consistent with the literature. As an example, a study in the US showed that modifications to Cognitive Processing Therapy (CPT) that were consistent with core CPT functions drove the largest reductions in posttraumatic stress and depressive symptoms (Marques et al., 2019).

More work is needed examining these constructs at the provider level with lay providers specifically and outside of US settings (Barnett et al., 2018; Dorsey et al., 2019; Magidson et al., 2019; Puffer et al., 2019). This is a goal that can be facilitated through ICIM and emphasis on the session-specific data, including the measurement of core underlying strategies and of ad-hoc adaptations, rather than only checklist-type measurement of step completion (Forgatch et al., 2005; Kaiser et al., 2019). Our findings fit with literature demonstrating the importance of flexibility within fidelity (Kendell & Frank 2018; Marques et al. 2019), as well as with the increasing focus in intervention science on treatments targeting mediators versus single-disorder protocols (Hofmann & Hayes, 2019). From an implementation lens, this nuanced measurement can help interventionists delineate core treatment strategies, consistent with calls in implementation science to clarify intervention elements that implementers can and cannot adapt when scaling to larger more diverse populations (Brownson et al., 2021).

In response to these findings, we began to emphasize the core underlying strategies even more and earlier in training. These strategies were termed "TP Spirit" to connote practices that were valuable to apply flexibly—sticking to the "spirit" of Tuko Pamoja, to enhance steps or to apply even when the steps might get off course. To do this, we increased training on the treatment rationale—the theory of change—and noted during role plays how these could be woven in. This also increases the likelihood that ad-hoc adaptations more broadly will promote change in ways that are consistent with the core strategies.

Applications of ICIM: Methodological Considerations

ICIM is designed to be applicable to any mental health or psychosocial intervention, though specifics will be tailored. It is most relevant for use during early or iterative piloting stages following development or deep adaptation of a treatment, or piloting of new implementation

strategies. ICIM is also intended to promote early refinement of interventions in ways that improve relevance and accessibility for historically underserved populations. However, using ICIM for in-depth analysis of a subsample following a large trial would also provide rich complementary data. Further, ICIM may serve as a helpful foundation on which to layer other implementation focused extensions. For instance, researchers could more extensively apply determinant frameworks, such as CFIR, or implementation strategy taxonomies and specification model (Proctor et al., 2013) Similarly, specific methods such as causal model building for implementation strategies could also be incorporated within this approach (Lewis et al., 2018). Lastly, while we focused on counselor-related and family-related mechanisms, one can include other levels such as training, supervision, or other implementation strategies.

For others considering ICIM, it is helpful to consider what the essential pieces of data are in order to use ICIM, as studies may not have all of the sources we used in this study. At minimum, data sources would include (1) baseline descriptions of presenting problems, (2) a source describing treatment and implementation *over time*, ideally transcripts or detailed treatment notes, (3) clinical and implementation indicators set *a priori* that can be rated (e.g., fidelity, provider competency), and (4) reliable outcome sources, ideally mixed methods (e.g., survey data, qualitative interviews). While ICIM is purposefully a deep and thoughtful analysis that takes time, only a small sample is needed, making it feasible and analogous to processes undertaken routinely in clinical settings for case conceptualization and in implementation science-related interventions, such as organizational assessment and coaching (Aarons et al., 2011b; Lewis et al., 2018).

Limitations

While this study presents a new method and preliminary mechanistic data for a lay delivered family therapy in Kenya, findings come from a small pilot trial and are not intended to be generalizable. Larger studies are needed to fully test multi-level mediator and moderator models reflective of potential mechanisms observed. Next, although steps were taken to minimize bias during analysis through an iterative group process, potential for bias in interpretation still exist. Future studies may benefit from teaching ICIM methods to blinded assessors who can then analyze the data. Additionally, we focused on families who completed treatment to assess mechanistic treatment elements, yet this limits conclusions about implementation factors that may have been at play for families who never began, or did not complete, treatment.

Conclusion

This paper presents Integrative Clinical and Implementation Mapping (ICIM) as a novel approach to understanding clinical and implementation mechanisms of change early in the piloting treatments to refine interventions and implementation strategies to improve effectiveness and access for diverse populations. ICIM proved an effective strategy for understanding mechanisms of change for a family intervention delivered in a low-resource setting in Kenya, allowing for refinements that better considered contextual challenges and key considerations for lay provider delivery.

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APPENDIX

Table A.1Description of the Minimum Data Types for ICIM

Data Source Needed	Description	Examples
	PRE AND POST TREATMENT DATA SOURCE	S
Baseline Problem Descriptions (pre)	Indicator of baseline problems. Preferably includes both quantitative and qualitative descriptions, though not necessary.	Survey; Qualitative Interviews; Session 1 Assessment/ Transcript
Clinical and Implementation Indicators	Indicators measured with some quantitative rating element. Can be other-rated or self-rated.	Fidelity Checklist; Provider Competency; EBI Competency or Adherence
Reliable Outcome Description (post)	Reliable indicator of post-treatment change, likely include both quantitative and qualitative data, but possible to map with one or other if change is corroborated by another sources (e.g., treatment notes with qualitative interviews)	Pre-Post Quantitative Surveys; Qualitative Interviews post- intervention
TREA	IMENT IMPLEMENTATION OVER TIME DATA	SOURCE*
Treatment and implementation Indicators over course of delivery period	Qualitative-based source providing descriptions of the course of treatment and/or delivery overtime. Preferably include sources at patient-level and provider-supervisor or training level, though not necessary.	Audio recordings of Sessions; Case Reports; Supervision Notes; Treatment Notes; Periodic Delivery Reflections

Notes:

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STAGE 1	Step 1. Create Structured Case Report Template based on domains and outcomes of interest, data, and theory. See example Structure Case Domains to the Right.	PRE-TREATMENT Characteristics & Problems Family Structure Reason for Referral	MECHANISMS: SESSION BY SESSION Clinical Elements Treatment Goals (List), Session type & # TP Strategies Used (List) Family: Behaviors, Engagement, Goals,	POST-TREATMENT Post-Treatment Outcomes Quantitative outcomes: Family Functioning & Individual MH
Develop and Build Structed Case Report	Step 2. Extract and input pre-post data.	Family Functioning & Individual MH (All Members, Survey)	Progress, Change Counselor-Family Interactions Implementation Elements Session Frequency; Barriers to engagement Counselor supervision engagement	Qualitative process and outcome data: Family and Provider Perceived Change,
Synthesis	Step 3: Analyze and input session specific data (e.g., transcripts, case/supervision notes) to identify potential drivers and barriers to change. Draw presenting problem cycles.	Contextual problems impacting functioning (Assessment Sessions) Presenting problem cycle	Implementation & Clinical Elements Counselor: Fidelity; Competencies: TP & General; Adaptations (List) Family Barriers & Facilitators to Change Pathways of Change/Mechanisms Specific: 1) TP Content & Strategies; 2) Clinical; 3) Implementation Integrated Pathways of Change	Perceived Pathways of Change
STAGE 2	Step 4. Narrative Case Conceptualization: and drivers on family outcomes; discuss nar		rnamic change pathways that integrate clinical arch and clinical teams	and implementation barriers
Map Integrated Change Pathways Case Level Analysis	left diagraming at each step. Then diag	ims. Diagram Post-TP Outcome gram Implementation Mechani	s, then Clinical Mechanisms, then TP Content	2.50 S.50
Case Level Output		STRUCTURED	REPORT PER CASE	
STAGE 3 Map Patterns Across Cases	explore all macro pathways side by side.	•	oss each family to develop a <u>common presenti</u> oathway diagram of each family's macro-pathw	
Across Case Analysis		trategies & Content; Clinical M	echanisms; Outcomes, and above/below Pane	
Group Level Output	COMMON PE	RESENTING PROBLEM CYCLE, C	COMPOSITE PATHWAY DIAGRAM ACROSS CASE	ES

Figure 1. Integrated Clinical and Implementation Mapping Approach

Note: Each row refers to steps used to guide integrated clinical and implementation mapping in the study.

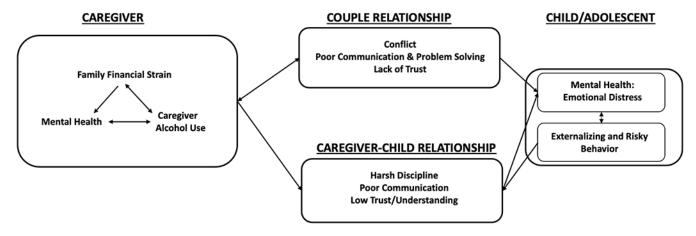


Figure 2. Common Presenting Problem Cycles Across Families

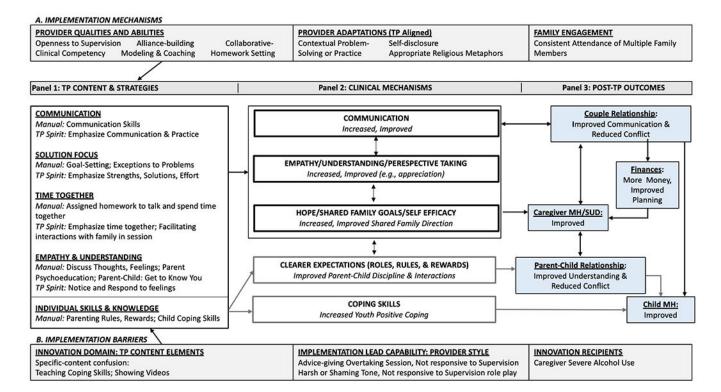


Figure 3. Composite Pathway Diagram Across Families

Note: TP= Tuko Pamoja; MH= Mental Health; SUD=Substance use disorders; Grey path indicate these paths most salient for families who presented with parent-child relationship problems or youth distress problems. We organized Barriers within the Consolidated Framework for Implementation Research (CFIR) 2.0 domains (L. Damschroder et al., 2022).

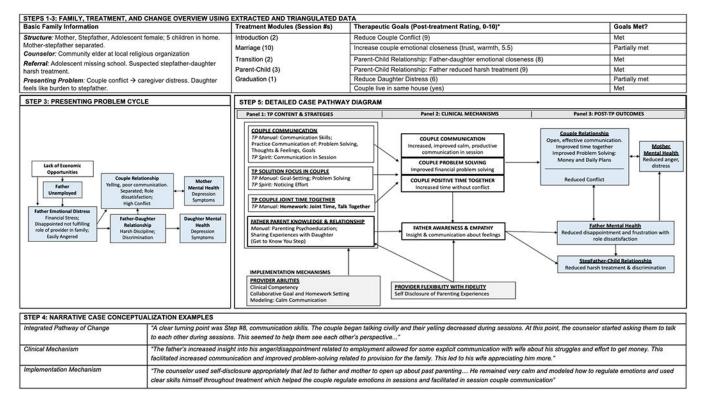


Figure 4. Family Structured Case Report Steps 1 through 5

Note: *=Goal ratings were based on data triangulated from transcripts, qualitative posttreatment interviews, and pre-post outcomes, across respondents, to what degree goals were met; TP= Tuko Pamoja

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Table 1

Tuko Pamoja Intervention Modules, Content, and Core Underlying Strategies

TP MODULES AND CONTENT Manualized Step	TP MODULES AND CONTENT: SOLUTION-BASED AND SYSTEMS-FOCUSED Manualized Steps, assessed using a fidelity checklist	CORE UNDERLYING STRATEGIES: TP 'SPIRIT' Measured as an indicator of counselor clinical competencies
Modules	10 Steps Used in Modules	TP-aligned strategies that occur throughout delivery (Not specific to any step)
A. Introduction B. Family C. Marriage/Couple Relationship D. Parent-child Relationships General Relationship Concerns Severe Behavioral Problems E. Caregiver Psychological Distress F. Youth Psychological Distress G. Transitions [After Module]	1. Get The Story: Understand Family System 2. Scaling Question: Assess Problem Severity 3. Communication Skills: Teach, Model, Practice 4. Build Empathy: Share Thoughts & Feelings 5. Identify Previous Solutions 6. Identify When the Problem Does Not Occur 7. Miracle Question: View of Life, Behavioral Changes 8. Set Specific Relationship Goal 9. Develop Action Plan 10. Track Propress and Continue	Practicing Skills Within and Outside of Sessions Facilitating All Family Member Engagement Developing and Monitoring Goals A Solution Focus to Identify and Change Problem Patterns Assessing, Tracking, and Reinforcing Progress on Goals Psychoeducation and New Skill Development

Note: TP=Tuko Pamoja

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Table 2

Data Sources and Description

Data Source	Constructs Assessed	Measures/ Data Collection Procedures	Analysis
	PRE AN	PRE AND POST TREATMENT DATA SOURCES ¹²	
Pre-Post TP Survey * (Caregivers & Target Adolescent)	Family Functioning (System-Level) ³ Relationship Quality (Dyads) ⁴ Youth Mental Health ⁵ Caregiver Mental Health & Alcohol Use ^{6.7,8} Harsh Family Interactions ^{9,10}	Self-report measures administered verbally by Kenyan research assistants $^{\it f}$	Estimated average treatment effects based on pre-post data by fitting linear mixed models. Calculated pre-post change in domain scores per family member. 2
Post-treatment * Qualitative Interviews (Family & Counselors)	Clinical Change (Family, Individual) Clinical Change Facilitators, Barriers, Pathways Implementation Barriers and Facilitators	Semi-structured interviews by trained Kenyan research assistants 2	Thematic content analysis using inductive and deductive codes. Transcripts coded in Dedoose 11.0 after 80% agreement between raters. Thematic summaries developed by code to synthesize themes.
Fidelity Checklists	Adherence to manual Quality of delivery	Ratings from session recordings: Steps completed correctly (yes/no) Quality rating per step (1-5; very poor to excellent) 1.2	Adherence: % of correct steps completed per steps attempted per session; Average % correct across case. Quality: Average of ratings per session; Average of all ratings across all sessions.
Clinical Competency Assessment ⁺	Use of TP "Spirit": Core Underlying TP Strategies Use of General Clinical Skills ³	Ratings of counselor competency with underlying TP strategies from session recordings from 1: does not meet needs to 4: skillfully meets needs, optimal outcome ²) Ratings (1.4) using adapted ENACT scale ³ from sessions recordings ^{1,2}	Average rating per session and per case. Average rating per session and per case.
Tracking Sheet ⁺	Family Engagement	Counselor-reported family member attendance; Entered in tracking spreadsheet. 1.2 SESSION-BY-SESSION DATA SOURCES	Case Level: Number of sessions completed overall and per month; treatment length; across case averages.
Session Transcripts (All sessions; All cases)	Family Presenting Problems, Problem Cycles Family Member Behaviors, Engagement Family Goals, Progress, Change Counselor Behavior and Skills Counselor Adaptations, Deviations, Style Counselor-Family Interactions and Alliance Integrated Pathways of Change during TP	All sessions audio recorded and transcribed verbatim from Kiswahili into English by Kenyan RA	Reviewed and synthesized as part of ICIM steps, including qualitative case conceptualization and synthesis of each construct into the Structured Case Reports, as well as diagramming integrated change pathways.
Structured Supervision Notes (All sessions; All cases)	Counselor Responsiveness to Supervision Counselor Engagement with Clinical Content Adaptations or Deviations from Treatment Course of Treatment Guidance Family Goals, Progress, and Change Barriers and Facilitators to Change	Structured Supervision Session by Session Case Notes: • Supervisors' structured summary of each session distilled from audio recordings or transcripts • Summary of supervision provided	Reviewed and synthesized alongside transcript data as part of ICIM. Notes informed qualitative case conceptualization and synthesis of each construct into the Structured Case Reports, as well as diagraming of integrated change pathways.

	Constructs Assessed	Measures/ Data Collection Procedures	Analysis
	PRE	PRE AND POST TREATMENT DATA SOURCES $^{\it 12}$	
	(clinical/implementation) Integrated Pathways of Change during TP	 List of key clinical and implementation barriers/ facilitators per session 	
s: PA=Previously Analyze	Notes: PA=Previously Analyzed; TP= Tuko Pamoja; ENACT= ENhancing Assessment of Common Therapeutic factors ⁹ ;	essment of Common Therapeutic factors 9 ;	
I Puffer et al., 2019;			
² Puffer et al., 2020;			
$^{\mathcal{S}}$ Khort et al, 2016.			
l description of measures	* =full description of measures can be found in Puffer et al., 2020;		
ll description of measures	$^+$ =full description of measures can be found in Puffer et al. 2019,;		
$\frac{\mathcal{J}}{=}$ Puffer et al., 2021);			
⁴ = Spanier, 1976);			
$\frac{\mathcal{S}}{=}$ Achenbach et al., 2011);			
$\stackrel{o}{=}$ Goldberg, 1972);			
7 =Watson et al., 2020);			
${\cal S}=$ Babor et al., 2001);			
$= \frac{g}{g}$ Straus & Douglas, 2004);			
10 , 01			