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Developing Innovative PTSD Treatment for Children: Reconsolidation of Traumatic Memories Protocol™ for Children (RTM-C Protocol)

Research Protocol for a Mixed-Methods Pilot Study

Sponsor, Implementers, and Partners

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Partners: Charitable Foundation Voices of Children (Ukraine) and Quresta, Inc. (USA).

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Background and Rationale

Post-traumatic stress disorder (PTSD) in children is a serious mental health problem that can develop after exposure to traumatic events such as war, violence, displacement, accidents, loss of loved ones, or abuse. PTSD in children is associated with intrusive memories, nightmares, physiological hyperarousal, avoidance of reminders, irritability, concentration difficulties, and impairments in family life, schooling, and social relationships. Although evidence-based psychological treatments exist for adults, there remains a major gap in effective, developmentally appropriate, and scalable interventions for children.

The Reconsolidation of Traumatic Memories (RTM) Protocol™ is a brief, non-pharmacological intervention originally developed for adults with PTSD. It is based on cognitive and neurobiological models of memory reconsolidation and dissociation. The RTM Protocol™ uses imagery to help individuals safely reprocess traumatic memories through a series of dissociative and imaginative steps (e.g., replaying memories in black-and-white, running them backwards, speeding them up). This process reconsolidates the traumatic memory in a less distressing form, leading to a reduction in flashbacks, nightmares, and distress responses. The RTM Protocol™ in adults has demonstrated strong clinical effectiveness across several clinical trials, with high acceptability and minimal risk of re-traumatisation.

The children's version (RTM-C Protocol) has not yet been formally evaluated and is being adapted and piloted in Ukraine, with training and implementation pathways planned through 2028. This research protocol outlines the pilot effectiveness and feasibility study for the RTM-C Protocol

scheduled for September 2025 – February 2026 using standardised outcome measures and ethically robust consent/data-protection procedures.

Aims and Hypothesis

Primary aim: Evaluate change in post-traumatic stress symptoms among children receiving RTM-C Protocol.

Secondary aims: (1) Assess functional impairment change across key domains (relationships, leisure, learning, happiness). (2) Assess acceptability/feasibility of RTM-C delivery and the value of auxiliary tools (animated instructions; cardboard cinema models). Generate qualitative feedback from trained specialists to refine language, tools, and procedures.

The study hypothesises that the RTM-C Protocol will significantly reduce PTSD symptoms in children, with effects maintained at 1- and 6-month follow-ups, and that children, parents, and therapists will find the intervention safe, acceptable, and feasible.

Study Design

This pilot study involves a mixed-methods evaluation.

A single-arm pilot with approximately 40–48 children, each treated by one of 20–24 trained RTM Protocol specialists. Children will complete six RTM-C Protocol sessions (plus parental sessions and diagnostic follow-ups). Outcomes will be measured at baseline, post-treatment, 1 month, and 6 months after treatment. Qualitative feedback will also be collected from specialists through structured focus groups.

This is a non-randomized, single-arm interventional pilot study. All participants will receive the Reconsolidation of Traumatic Memories in Children (RTM-C). Following the parent session (for consent and orientation), children will complete six structured RTM-C sessions, followed by diagnostic assessments at 1 and 6 months. This pilot study uses an open-label design with no masking, as the intervention requires active therapist and child engagement. The primary purpose is treatment: to test whether RTM-C reduces post-traumatic stress symptoms and improves child functioning, while also assessing feasibility and acceptability among children, parents, and providers.

Participants

The pilot targets 40-48 children (20–24 providers × 2 clients). This is adequate to estimate recruitment/retention, feasibility, and preliminary within-subject effect sizes (Cohen's d) to inform Stage-2/3 scaling and any future controlled trials.

Inclusion Criteria: (1) Age 6–14 years at enrolment. (2) PTSD symptoms present: CATS-2 (Parent) total ≥15 at screening. (3) Functional impact: impairment endorsed in ≥1 CATS-2 domain (relationships, leisure, learning, happiness). (4) Consent/assent: written parent/guardian consent and child assent obtained. (5) Availability: child and caregiver can attend parent session + 6 treatment sessions and complete 1- and 6-month follow-ups. (6) Language/comprehension: child can understand session instructions and participate in tasks (with supports as needed). (7) Therapist

check of readiness: during Session 1 practice, child demonstrates reliable break state (disengages from imagery, re-orients to present, maintains eye contact, relaxed affect).

Exclusion Criteria: (1) Acute comorbid mental disorder. (2) Concurrent trauma-focused psychotherapy planned or ongoing during the study period. (3) Inability to understand/follow instructions due to cognitive impairment or other reasons that preclude participation. (4) Medical/neurological condition or situational factors (e.g., inability to commit to visits) that, in the investigator's judgment, would make participation unsafe or compromise study integrity.

Intervention

The children's version of the RTM Protocol™ (RTM-C Protocol) retains the essential procedural components of the adult method but is carefully adapted to meet developmental needs. Adaptations include:

- Child-friendly language and explanations.
- The use of play-based and imaginative exercises.
- Animated instructional videos and a cardboard "cinema" and "skreen" models to guide children through visualisation steps.
- Additional therapist strategies for emotional support, grounding, and engagement.
- Structured parental involvement before, during and after treatment sessions.

Outcomes and Measures

Primary: CATS-2 total scores at baseline, post-treatment, 1- and 6-month follow-ups. Secondary: Functional impairment, acceptability, feasibility, and provider focus groups.

The study uses the CATS-2 (Child and Adolescent Trauma Screen) as the primary outcome measure. Both child self-report and parent-report versions will be administered. The CATS-2 provides scores for PTSD symptoms and functional impairment in relationships, learning, leisure, and happiness. An additional focus group interview will assess acceptability and feasibility from providers. Data will be collected at baseline, post-treatment, and at 1- and 6-month follow-ups.

Procedures and Timeline

RTM-C Protocol administration involves six structured sessions with the child, preceded by a parent session and followed by diagnostic follow-ups (at 1 month and 6 months after treatment), with both children and parents, to assess sustained outcomes.

Each session lasts approximately 60 minutes and follows a detailed, structured protocol. Animated instructions and cardboard "cinema" and "skreen" models are used as supportive tools only when verbal instructions are insufficient. Therapists are trained to avoid unnecessary use of tools that could prolong the session or burden the child. Children are rewarded at the end of sessions with small positive reinforcements (stickers, drawings, short games) to enhance engagement.

1. Screening & parent session (consent, parent CATS-2).
2. Session 1 (child assent, baseline CATS-2).
3. Sessions 2–6 (RTM-C Protocol administrations).
5. Follow-ups at 1 and 6 months.

Additional Documents

- **Parent/guardian informed consent** (voluntary; withdrawal without consequences; anonymisation; data rights; optional items for publication use, follow-up, archiving).
- **Child assent** (age-appropriate language; confidentiality; right to stop; option to bring a trusted adult/toy).
- **Parent memo** (what RTM-C is; expected reactions; home and in-session support; FAQs; safety; session count).
- **Information notice on personal data processing** (lawful basis; anonymisation; storage; rights).

Data Management and Protection

All identifying information will be anonymised using codes. Personal data will be securely stored in locked cabinets and password-protected computers in Ukraine. Anonymised datasets will be transferred via secure, certified platforms. Only trained RTM specialists have access to identified data. Researchers analyse only anonymised data.

Individual participant data (IPD) will not be shared outside the therapists who will collect data. This decision is based on the high sensitivity of the data, which involves trauma histories and mental health information from children. Even with de-identification, the small sample size and the vulnerability of the population create a risk of re-identification. For these reasons, only anonymised data will be shared with researchers, and only aggregated results will be shared through publications and presentations.

Training and Fidelity

All providers are certified RTM specialists. They receive additional one-day training in the RTM-C Protocol. Fidelity is supported through the use of protocol texts, animations, and visual tools, and monitored by session checklists and coaching. Feedback from therapists on usability, language, and feasibility will be used to refine the protocol before larger rollout.

Statistical Analysis Plan

Mixed models for CATS-2 change. Secondary analysis of functional impairment. Qualitative thematic analysis of provider feedback.

Ethical and Safety Considerations

The RTM-C Protocol emphasises “stress-free recall.” Children are not asked to provide detailed verbal descriptions of traumatic events. The therapist interrupts immediately if distress arises and redirects the child’s focus to a safe, neutral task. Work with traumatic material proceeds only once the child has demonstrated the ability to switch states reliably during practice (clear disengagement from imagery, reorientation to the present, ability to make eye contact, relaxed affect). These safeguards minimise the risk of re-traumatisation.

- **Minimal distress procedures** (stop/ground on first signs of discomfort; stress-free recall; parent presence when helpful).
- **Voluntariness and withdrawal** at any time without adverse consequences.

- **Child safeguarding and referral** where risk is detected; exclusion of acute comorbidities or concurrent trauma-focused therapy.
- **Independent ethical review** prior to data collection.

Significance

If effective, the RTM-C Protocol will provide an innovative, scalable, and low-burden treatment for PTSD in children. It could address a major unmet need in child mental health, particularly in humanitarian and post-conflict contexts. The pilot study in Ukraine is a first step toward larger implementation and evaluation, and findings will contribute to global knowledge on child-appropriate trauma interventions.