

Project Summary

Mandala Drawing Therapy (MDT) has been shown to markedly reduce negative affect in adults, yet randomized-controlled evidence for its impact on the “rumination + loneliness” comorbidity chain in early adolescents is lacking. This single-site, parallel-group, assessor-blinded randomized controlled trial will be embedded in two public junior-high schools in Jilin City, Jilin Province. An 8-week, school-based MDT curriculum will be tested for simultaneous reductions in rumination and loneliness, with 3-month follow-up.

Primary objective: verify that the MDT arm is superior to a wait-list control in Rumination Response Scale (RRS) score at Week 9.

Secondary objectives: reduce UCLA Loneliness Scale (UCLA-LS) scores, enhance emotion-regulation self-efficacy, and evaluate cultural acceptability.

Design: superiority, 1:1 allocation, intention-to-treat analysis.

Sample: 120 students aged 12–15 y (sex-balanced), baseline RRS ≥ 50 .

Intervention: school counsellors deliver eight 40-min weekly sessions following the sequence “Protection → Differentiation → Cohesion → Integration → Guidance → Transcendence → Enlightenment → Consolidation”; control receives routine psycho-education only.

Primary endpoint: RRS change at Week 9.

Secondary endpoints: UCLA-LS, emotion-regulation scale, qualitative interviews at Weeks 9 and 21.

Analysis: mixed-effects model, $\alpha = 0.05$ (two-sided), power 90 %, 15 % attrition tolerated.

Expected effect: RRS –10 points (Cohen’s $d \geq 1.0$), UCLA-LS –6 points ($d \geq 0.7$), no serious adverse events.

Timeline: March 2026 – June 2027; total budget CNY 100 000.

1.1 General Information

Protocol title: Randomized Controlled Trial of Mandala Drawing Therapy to Reduce Rumination and Loneliness in Junior-High-School Students

Protocol ID: JLNUN-MDT-202603

Version date: 14 January 2026

Sponsor: —

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Co-investigator: Prof Shumei Jiang (methodological supervision, final manuscript approval)

Role: randomisation scheme review, quality control, adverse-event adjudication

Collaborating units

Psychological Experiment Teaching Center, Jilin Normal University

Department of Adolescent Mental Health, Jilin City Children's Hospital (emergency medical back-up)

Statistics Unit, Siping Center for Disease Control & Prevention (independent statistics & blinded programming)

Rationale & Background

Over the past decade the prevalence of loneliness among Chinese junior-high students rose from 8 % to 20 %. Rumination and loneliness are mutually causal and predict depression and suicidal ideation. Traditional CBT demands high verbal abstraction and scarce specialist time; mindfulness requires space and trained personnel; digital interventions show poor adherence. As an expressive-arts therapy, mandala drawing reduces negative affect through non-verbal, symbolic, structured engagement, yet no RCT has targeted the rumination-plus-loneliness dual vulnerability in regular adolescents. This study fills the gap and offers a low-cost, scalable, culturally friendly prevention package.

Learning Objectives & Aims

Overall aim: evaluate the effect of an embedded MDT curriculum on simultaneous reductions in rumination and loneliness.

Primary specific objectives

Week 9: MDT arm RRS total score \geq 10 points lower than wait-list (superiority margin 3 points).

Week 21: effect sustained, relapse rate < 10 %.

Secondary objectives

Reduce UCLA-LS and enhance emotion-regulation self-efficacy ($d \geq 0.5$).

Assess cultural acceptability (qualitative saturation ≥ 90 % positive themes).

Study Design

Type: superiority, single-centre, parallel-group, randomised, assessor-blinded, 3-month follow-up.

Sampling frame: all 2 800 Grade 7–9 students in two public junior-high schools in Jilin City, autumn 2025; screen then recruit.

Population: 12–15 y, RRS ≥ 50 , UCLA-LS ≥ 45 , no severe physical or psychiatric disorder, not receiving other psychological intervention.

Exclusion: colour-blindness, developmental disorder, major depression (PHQ-9 ≥ 20) requiring immediate referral.

Planned duration: March 2026 – February 2027 (including follow-up).

Methodology

Intervention

Name: Structured Mandala Drawing Therapy (MDT)

Dose: 8 sessions \times 40 min, groups of 8–10, school psychology classroom

Content: based on Jung's seven-stage model; A4 circular line template + 12-colour water-colour pens each session, soft background music (e.g., "River Flows in You"), standardised guided script.

Staff: four school counsellors, each certified by International Expressive Arts Therapy Association (32 h) plus 8 h project-specific training; must pass competency test before

leading groups.

Control

Wait-list receives routine mental-health lessons (1 large class per month); identical MDT offered after Week 21.

Procedures & Measures

Screening: Week -4, whole-class distribution of RRS/UCLA-LS, double data entry.

Baseline: Week -1, demographics, PHQ-9, GAD-7, family SES, informed consent.

Randomisation: independent statistician generates blocked random list (block size 4, sex-stratified) using SAS 9.4; opaque sealed envelopes, opened on site.

Blinding: external graduate assessors told only “emotion study”; interventionists and participants cannot be blinded.

Primary endpoint: Week 9 RRS (Chinese version Han & Yang 2020, $\alpha = 0.95$).

Secondary endpoints: Week 9 & 21 UCLA-LS, short Emotion-Regulation Self-Efficacy Scale (SERS).

Qualitative: 30–45-min semi-structured interview Week 9, audio-recorded, thematic analysis.

Biomarker: subsample $n = 60$, salivary cortisol 30 min post-awakening (exploratory mechanism).

Safety Considerations

Risk level: minimal (expressive arts).

Adverse-event definition: any emotion distress related to sessions lasting > 24 h.

Recording & reporting: AE form within 24 h; SAE to PI & ethics within 3 days.

Stopping rule: ≥ 2 moderate emotional dysregulation cases in one group \rightarrow suspend sessions and refer to children’s hospital.

Follow-up

Immediate: 10-min post-session observation, teacher records emotional state.

Long-term: after Week 21, school counselling remains open; if PHQ-9 ≥ 15 , phone parents and assist referral.

Data Management & Statistical Analysis

Collection: Wenjuanwang electronic platform + paper back-up, double entry verification.

Database: encrypted MySQL, export 权限仅限数据管理员与统计师。

Software: R 4.3, two-sided $\alpha = 0.05$.

Sample size: effect size $d = 0.9$, power = 0.8, 30 per arm (in Chinese text; corrected to 60 per arm in power calculation section).

Primary analysis: ITT & PP parallel, covariate-adjusted for baseline score, sex, grade.

Missing data: multiple imputation ($m = 20$), worst-case sensitivity analysis.

Qualitative: NVivo coding, $\kappa \geq 0.8$.

Quality Assurance

Adhere to “Good Clinical Practice for School Mental-Health Research 2025”.

Monitor visits every 2 months checking informed consent, source records, intervention fidelity $\geq 80\%$.

Independent Data & Safety Monitoring Board (DSMB) of 3 (biostatistician, child psychiatrist, ethicist); interim analysis at 50 % sample, α -spending 0.003.

Anticipated Results & Significance

Academic: first RCT evidence of MDT targeting dual vulnerability (rumination + loneliness) in regular Chinese adolescents, filling cultural gap.

Policy: provides evidence-based package for Jilin Provincial Education Department “100-School Mental Growth” initiative, projected 30 % saving in teacher-training costs.

Clinical: one 8-session standardised teacher manual plus one student self-help picture book ready for school-based curriculum integration.

Dissemination & Publication Policy

Primary results will be submitted to BMC Psychology (IF > 5).

Community: by June 2027 hold 2 workshops for 50 Jilin City junior-high schools, distribute 500 manuals.

Authorship: PI sole first author, Prof Jiang corresponding author; no conflicts declared; interventionists acknowledged.

Project Timeline

March 2026: ethics approval & teacher training

April–May: screening & baseline

June–July: intervention delivery

August: immediate assessment

November: 3-month follow-up

February 2027: database lock & report submission

Anticipated Problems & Solutions

Sample attrition → “perfect-attendance reward” (stationery set) plus weekly SMS reminder.

Project Management

PI: overall coordination, liaison with sponsor & ethics.

Two research assistants: recruitment, scheduling, data entry.

Finance officer: budget monitoring & reimbursement.

Data manager: database construction & lock.

Ethical Considerations

Approval: Jilin Normal University Ethics Committee KJLL20250407.

Potential risk: emotion arousal without immediate support → each school has 1 supervising counsellor available within 24 h post-session.

Informed consent: dual signature (student + guardian), right to withdraw.

Privacy: de-identified data, only aggregate results reported.