

RESEARCH PROTOCOL

Protocol Title: From Pilot to RCT: Scaling Up a Multi-Domain Training Programme for Enhancing Language and Speech Skills in Jordanian Children – A Randomised Controlled Trial

Protocol Date: 4 March 2026

Version: 1.0 (Final)

1. PROJECT SUMMARY

Background: Language delay affects approximately 7–10% of children globally, yet there is a scarcity of standardised, culturally-adapted interventions for Arabic-speaking populations.

Objective: To evaluate the efficacy of a multi-domain training programme (targeting auditory rehabilitation, cognitive skills, language, speech, and oral muscular strength) compared to standard care in improving language and speech capabilities among Jordanian children aged 3–8 years with language delay.

Methods: Randomised controlled trial with parallel-group design, 1:1 allocation ratio. Sixty-four participants will be randomly assigned to either experimental (intensive 48-week programme, 140 sessions) or control (standard care) groups. Primary outcome: Language and Speech Capabilities Scale (LSCS) total score. Secondary outcomes: Amayreh Articulation Test and Oral Motor Assessment Protocol scores.

Expected Outcomes: Significant improvement in language and speech capabilities in the experimental group compared to control, with large effect sizes.

Duration: 48 weeks intervention + 3 months follow-up.

Sponsor: Zarqa University, Jordan.

2. GENERAL INFORMATION

Item	Details
Protocol Title	From Pilot to RCT: Scaling Up a Multi-Domain Training Programme for Enhancing Language and Speech Skills in Jordanian Children – A Randomised Controlled Trial
Protocol ID	[ISRCTNXXXXXX – to be added after registration]
Protocol Date	24 February 2026
Sponsor/Funder	Zarqa University, P.O. Box 2000, Zarqa 13110, Jordan
Principal Investigator	Dr. Dhia'a Y. AbuEswailem, Assistant Professor, Department of Applied Speech Language Pathology and Audiology, Zarqa University, Jordan. Email: dhiaaslpresearch@gmail.com

Co-Investigators	Dr. Zaidan Alkhamaiseh (Zarqa University) Dr. Athar MR Abdallatif (Zarqa University) Prof. Nader A. Jaradat (Zarqa University) Dr. Mohammad A. Al-Momani (Dr. Mohammad Momani Center for Consulting and Child Development, Amman, Jordan)
Research Sites	Speech and language centres in Amman, Jordan

3. RATIONALE & BACKGROUND INFORMATION

Problem Statement: Language delay constitutes one of the most impactful developmental challenges, profoundly affecting an individual's social integration, academic achievement, and quality of life. Global estimates indicate that 7–10% of school-aged children experience language disorders (Bishop et al., 2017).

Gap in Knowledge: In the Arab context, there is a conspicuous absence of standardised, culturally-adapted assessment tools and intervention programmes. Existing interventions are often fragmented, focusing on isolated language components rather than adopting a comprehensive, multi-domain approach.

Preliminary Work: This trial builds upon a systematic development phase (Phase I) and a pilot feasibility study (Phase II) conducted with eight Jordanian children, which confirmed the programme's acceptability, feasibility, and initial promise (AbuEswailem et al., 2026).

Rationale: A multi-domain intervention simultaneously addressing auditory, cognitive, linguistic, articulatory, and oral motor skills may produce synergistic effects and greater improvements than single-domain approaches.

4. STUDY GOALS AND OBJECTIVES

Primary Objective: To evaluate the efficacy of a multi-domain training programme compared to standard care in improving language and speech capabilities among Jordanian children aged 3–8 years with language delay.

Secondary Objectives:

1. To assess the programme's effectiveness on specific subdomains: auditory rehabilitation, cognitive skills, language, speech, and muscular strength
2. To evaluate improvements in articulation skills using the Amayreh Articulation Test
3. To assess changes in oral motor function using a structured Oral Motor Assessment Protocol

5. STUDY DESIGN

Type of Trial: Interventional, parallel-group, randomised controlled trial with 1:1 allocation ratio

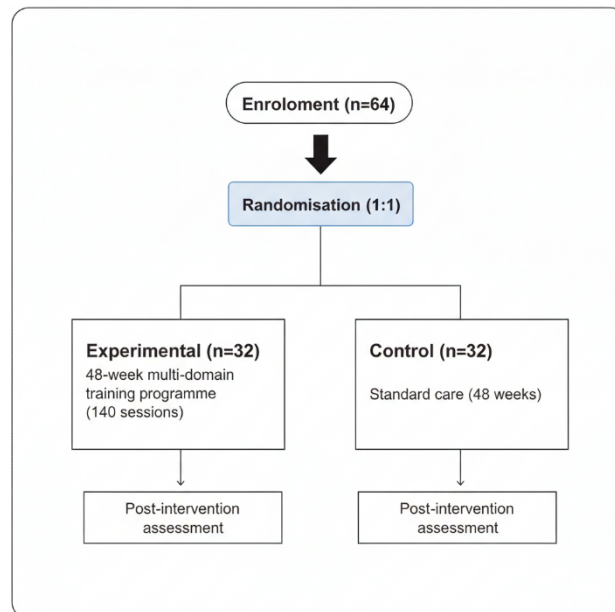
Framework: Superiority trial

Study Population: Children aged 3–8 years with confirmed language delay

Setting: Community-based speech and language centres in Amman, Jordan

Duration: 48 weeks of intervention + immediate post-intervention assessment

Flow Diagram:



6. METHODOLOGY

6.1 Eligibility Criteria

Inclusion Criteria:

- Confirmed diagnosis of language delay by a certified speech-language pathologist
- Age 3–8 years
- Absence of comorbid neurodevelopmental disorders (e.g., autism spectrum disorder, intellectual disability, global developmental delay)
- No prior exposure to specialised language interventions similar to the experimental programme in the past 12 months
- No hearing impairments, neurological disorders, or significant physical disabilities interfering with participation

Exclusion Criteria:

- Presence of any of the comorbid conditions listed above
- Prior exposure to similar interventions

6.2 Interventions

Experimental Group:

- **Intervention:** Multi-domain training programme
- **Components:**
 - Auditory Rehabilitation (25 sessions): sound discrimination and processing
 - Cognitive Training (30 sessions): memory, attention, executive functions
 - Language Development (45 sessions): phonology, syntax, morphology, semantics, pragmatics
 - Speech Production (25 sessions): articulation, fluency, voice quality
 - Oral Motor Skills (15 sessions): muscular coordination and function
- **Frequency:** 5 sessions per week
- **Duration:** 30 minutes per session
- **Total sessions:** 140 over 48 weeks
- **Provider:** Certified speech-language pathologist
- **Parental Involvement:** Structured in-session coaching and home practice assignments

Control Group:

- Standard speech therapy services following conventional protocols currently employed in participating centres
- No exposure to specialised components of the experimental intervention

Primary Outcome:

- **Variable:** Language and speech capabilities
- **Measurement:** Language and Speech Capabilities Scale (LSCS) total score
- **Description:** 125-item clinician-administered instrument measuring five domains (auditory rehabilitation: 40 points; cognitive skills: 80 points; language: 102 points; speech: 6 points; muscular strength: 22 points)
- **Range:** 0–250 (higher scores indicate better capabilities)
- **Timepoint:** Baseline and immediately post-intervention (48 weeks)

Secondary Outcomes:

- **Articulation skills:** Amayreh Articulation Test score (baseline and post-intervention)
- **Oral motor function:** Oral Motor Assessment Protocol score (baseline and post-intervention)

6.4 Sample Size

Sample size was calculated using G*Power software. With $\alpha = 0.05$, power = 0.99, and expected large effect size ($d = 0.8$), a total of 64 participants (32 per group) is required.

6.5 Randomisation

- **Sequence generation:** Computer-generated random numbers
- **Allocation concealment:** Sequentially numbered, opaque, sealed envelopes
- **Implementation:** Independent researcher generated sequence; centre staff enrolled and assigned participants

6.6 Blinding

- Outcome assessors blinded to group allocation
- Participants and intervention providers not blinded due to nature of intervention

6.7 Statistical Methods

- Primary analysis: Two-way mixed ANOVA (group × time interaction)
- Adjustment for baseline: ANCOVA with pre-test scores as covariate
- Effect sizes: Partial eta squared (η^2) and Cohen's d
- Robustness verification: Wilcoxon Signed-Rank and Mann-Whitney U tests
- Significance level: $\alpha = 0.05$ (two-sided)
- Analysis population: Intention-to-treat

7. SAFETY CONSIDERATIONS

- No serious adverse events anticipated as intervention is non-invasive behavioural/educational programme
- Any unintended emotional distress during sessions will be documented and addressed
- Participants free to withdraw at any time without penalty

8. DATA MANAGEMENT AND STATISTICAL ANALYSIS

- Data entered into SPSS version 28
- Double-data entry with verification for accuracy
- Missing data handled using available-case analysis (low expected due to complete follow-up)
- All data anonymised with participant codes

9. QUALITY ASSURANCE

- Treatment fidelity: Random video monitoring of 20% of sessions using standardised checklist (adherence >90%)
- Weekly supervision sessions for intervention providers
- Manualised protocols for consistent implementation

10. ETHICAL CONSIDERATIONS

- **Approval:** Approved by Ethics Committee for Scientific Research (ECSR) at Zarqa University, Jordan (1 March 2024)
- **Consent:** Written informed consent obtained from parents/guardians of all participants
- **Confidentiality:** All personal identifiers removed; data stored securely with encryption

11. INFORMED CONSENT FORM

Attached as separate document – includes both English and Arabic versions

12. DISSEMINATION OF RESULTS

- Results will be published in peer-reviewed scientific journals

- Findings presented at national and international conferences
- Lay summary provided to participating families and centres
- Policy briefs shared with Ministry of Health and Ministry of Education, Jordan

13. DURATION OF THE PROJECT

Phase	Timeline
Protocol development and ethical approval	January–February 2024
Participant recruitment	March 2024
Intervention delivery	March 2024 – March 2025
Post-intervention assessments	March–June 2025
Data analysis and manuscript writing	June–December 2025

14. PROBLEMS ANTICIPATED

Potential Problem	Mitigation Strategy
Participant dropout	Regular follow-up, flexible scheduling, parental engagement
Treatment fidelity	Video monitoring, supervision, manualised protocols
Blinding compromise	Independent assessors, strict protocols

15. PROJECT MANAGEMENT

Team Member	Role and Responsibility
Dr. Dhia'a Y. AbuEswailem	Principal Investigator: study design, supervision, data analysis, manuscript writing
Dr. Zaidan Alkhamaiseh	Co-investigator: study design, data interpretation, manuscript review
Dr. Athar MR Abdallatif	Co-investigator: data collection, parent coordination
Prof. Nader A. Jaradat	Co-investigator: theoretical framework, literature review
Dr. Mohammad A. Al-Momani	Co-investigator: participant recruitment, programme implementation

16. FUNDING AND SUPPORT

Funder: Zarqa University (article processing charge only)

Other Support: No external funding received

17. DECLARATIONS

Conflicts of Interest: The authors declare no conflicts of interest.

Data Availability: De-identified participant data available from corresponding author upon reasonable request, subject to ethical approvals.