

ClinicalTrials.gov Study Document

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Background and Rationale

Signing deaf children often do not receive explicit intervention to improve signed language skills. Strategic and Interactive Signing Instruction (SISI) is an intervention program that supports signing skills by having teachers guide children in planning, producing, and refining sign language videos in ways that elevate discourse structures. SISI draws on evidence-based practices adapted for a visual language modality, such as genre study, strategy instruction for composing, and gradual release through modeled, shared, and independent signing. Prior pilot work indicated that teachers could use SISI with support but reported needing clearer guidance, examples, and coaching to implement signing-based intervention with fidelity. High-quality professional development with embedded coaching is a plausible way to strengthen teachers' implementation of SISI.

Objectives and Hypotheses

Evaluate whether professional development in SISI increases teachers' fidelity of implementation of signing-based intervention practices with deaf children.

Secondary Objectives: (a) Estimate interrater reliability of the SISI Fidelity Tool.
(b) Document teachers' perceptions of the feasibility, usefulness, and acceptability of SISI (social validity).

Primary Hypothesis: Teacher fidelity to SISI will increase immediately following PD + coaching, relative to their baseline signing intervention routines

Secondary Hypothesis: Interrater agreement will fall in the good–excellent range; teachers will report positive social validity.

Study Design

Design: Nonconcurrent multiple-baseline single-case research design (SCRD) across four teachers (participants). The independent variable is PD + bi-weekly coaching; the dependent variable is teacher SISI fidelity. Staggered PD onset establishes experimental control.

Setting: Deaf education program (K-3).

Staggered PD Start Dates: Teacher 1: Oct 6, 2024; Teacher 2: Nov 9, 2024; Teacher 3: Dec 14, 2024; Teacher 4: Mar 1, 2025.

Duration: One academic year.

Participants and Eligibility

Teacher Participants (n=4): K-3 classroom teachers in a deaf education program; all are deaf and fluent ASL users (three White women; one Black man). Three hold master's degrees in deaf education; one holds a bachelor's degree (non-education) with provisional credential. Experience ranges 2-20+ years; classes serve 4-5 students.

Inclusion Criteria: Early-elementary classroom teacher in the program; ASL-fluent; agreement to video-record lessons and attend PD/coaching.

Exclusion Criteria: Inability to participate in PD/coaching or to allow instructional video capture.

Student Participants: Classroom students participate naturally as part of instruction; no student outcomes are formally analyzed in this protocol (focus is teacher outcomes).

Participant Flow

This study used a single-case research design (multiple baseline across participants) involving four teacher participants. Because the design focuses on individual replication rather than group-level enrollment, the standard concept of “participant flow” does not apply. All four teachers completed the study, and no attrition occurred.

Table:

Period	Started	Completed	Discontinued
Baseline Phase	4	4	0
Intervention Phase	4	4	0

The design involves repeated observations for each participant rather than cohort enrollment. No participants withdrew or were excluded after enrollment.

Interventions (Independent Variable)

Professional Development: 10 hours across two days, in classrooms, led by the PI, focusing on the SISI manual’s 45 indicators..

Coaching: Bi-weekly virtual coaching sessions post-PD: review recent instruction (uploaded videos), plan upcoming lessons, troubleshoot implementation.

Curricular Integration: SISI is woven into school-mandated American Reading Company (ARC) pacing guides (e.g., narrative units on animals; informational units on bugs), maintaining required topics while targeting sign language skills.

Procedures and Data Collection

Video Capture: Daily lessons recorded via iPads and uploaded to a secure cloud platform (Swivl) for observation and fidelity scoring.

Units:

- Baseline phase- Teachers maintain typical language arts routines. For each teacher, ≥ 7 baseline instructional “units” are sampled. If no composing unit is present, a single language arts class is scored per the protocol fallback rule.
- Intervention phase- After PD, teachers implement full SISI composing units; ≥ 2 intervention units per teacher are sampled.

Fidelity Tool: 45 indicators, scored 0 (not implemented), 0.5 (partial), 1 (full). Indicators require engagement in sign language composing using videos for credit. Total scores are converted to percentages per unit.

Interrater Reliability: A trained, independent rater double-codes a stratified random sample of units (baseline and intervention). Disagreements adjudicated for analytic data; IRR computed on unreconciled ratings.

Outcome Measures

Primary Outcome: Teacher SISI Fidelity (%), computed per unit from the 45-item instrument. Visual analysis examines level, trend, variability, immediacy, and maintenance across phases.

Secondary Outcomes:

- Interrater Reliability: item-level exact agreement and quadratic-weighted κ on unit totals.
- Social Validity: Semi-structured end-of-year interviews (30 minutes, in ASL) on value, feasibility, coaching satisfaction, improvement suggestions, and future intentions.

Sample Size and Replications

Four participants (teachers) with staggered baseline lengths provide ≥ 3 demonstrations of effect required for functional relation decisions in SCRD.

Statistical/Analytic Plan

Primary Analysis: Visual analysis per SCRD standards (Kratochwill et al., 2010): changes in level/trend/variability; immediacy following intervention onset; maintenance; and three replications across baselines. Baseline points represent single lessons sampled non-sequentially (x-axis spacing nominal). Intervention points represent composing units spanning multiple weeks (x-axis spacing approximates unit duration).

Effect Sizes: Log response ratio (increasing; LRRi) calculated for each teacher (Pustejovsky, 2018; Single-Case Effect Size Calculator v0.7.3). Benchmarks: small 0.5, medium 1.0, large ≥ 1.5 .

IRR: Item-level agreement (%) and quadratic-weighted κ with 95% CI on unit-level totals.

Social Validity: Thematic summary of interview responses.

Results Summary

Fidelity: Baseline near-zero (no sign language composition on videos); immediate post-PD jump to 45-60% on first unit; three teachers rose to 80-90% by study end; one maintained 60%. Baseline variability minimal; intervention variability low when fidelity $\geq 80\%$, with maintenance across final two units for each teacher.

Effect Sizes (LRRi): Teacher 1 = 3.72 (SE 0.05); Teacher 2 = 3.71 (0.06); Teacher 3 = 2.04 (0.22); Teacher 4 = 3.36 (0.04) - all large, consistent gains.

Interrater Reliability: Item-level exact agreement 90.8%; quadratic-weighted κ = 0.88 (95% CI 0.85-0.91). Teacher-specific κ : 0.86 (T1), 0.99 (T2), 0.90 (T3), 0.80 (T4).

Social Validity: All teachers valued SISI, reported feasibility, and intended to expand use next year; coaching and sign language composition on videos were highlighted as helpful. Technology (video editing) required extra support for some.

Adverse Events

Serious Adverse Events: None reported.

Other (Non-Serious) Adverse Events: None reported.

This was a minimal-risk, educational intervention involving professional development and instructional coaching for teachers. No physical, psychological, or social adverse events occurred. No participants withdrew due to adverse experiences. Monitoring was conducted by the Principal Investigator through bi-weekly meetings.

Risk/Benefit Assessment

Risk: Minimal risk related to confidentiality of instructional videos.

Mitigation: De-identification (alphanumeric IDs); restricted, password-protected storage and access; removal of direct identifiers; no public posting of identifiable content.

Benefit: Teachers receive PD and coaching likely to improve evidence-based language intervention; potential indirect benefit to child engagement and more sign language opportunities.

Data Management and Confidentiality

- Secure cloud upload (in transit/at rest encryption).
- Access limited to named research personnel.
- Linkage file with identifiers stored separately on restricted volume.
- Analytic datasets de-identified.
- Retention per institutional policy; destruction per policy after retention period.

Monitoring

Given the minimal-risk, education-focused design, no independent DSMB is constituted. The PI monitors protocol adherence, data quality, and privacy protections.

Ethics

IRB approval obtained from the University of Tennessee. Teacher and family consent procedures are documented in separate consent forms. Participation is voluntary; withdrawal permitted at any time without penalty.

Dear Parent or Guardian:

Project Information

The purpose of this research project is to investigate the impact of signing instruction on deaf students' sign language skills. This project will be conducted during this academic year. Your consent will make it possible for your child to participate in the research project.

Data Collection

- **From the teacher:** (1) Video-recorded instructional sessions and (2) Teacher demographic survey; Family and child demographic survey (e.g., hearing level, language use)
- **From your child:** (1) Video-recorded signed responses and written responses to questions (e.g., what is your favorite thing to do?).

Videotaping in Classrooms

In order to capture aspects of your child and their teacher's involvement in SISI, instructional sessions during signing instruction time will be video recorded. Videos will be uploaded and stored on a secure server that can only be accessed by me. Therefore, if you decline for your child to be videotaped, your child may not participate in the research. With added consents from you and your child's teacher (optional), classroom video footage may be used for conferences and professional development purposes.

Confidentiality & Potential Risks

This is a federally funded grant program, and as such, final research data will be publicly accessible to others for a minimum of 10 years on the University of Tennessee Research and Creative Exchange. Data may be used for future studies or shared with other researchers for use in future studies without obtaining additional informed consent from you or others. However, any identifiable information will not be shared or revealed. This means the names of your school, teachers, and students will not ever be shown to respect confidentiality.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

While the breach of confidentiality of data is always a potential risk to research, I will take steps to minimize this. Participants and their associated data will be represented with pseudonyms or alphanumeric IDs that do not contain identifying information. Video data will be viewed only by researchers involved in this project. Further, specific information, such as names or programs, will not be disclosed in published papers or presentations. Data with identifying information will only be shared within the researchers. These data will be saved on password-protected computers and a password-protected server. Any paper documents will be scanned and uploaded and then immediately destroyed.

Potential Benefits

This study presents potential benefits to your child, and to the field of deaf education and language development. Your child has potential to make gains in sign language skills. The analysis of student progress made while engaged in signing instruction could provide the field with valuable information about the effectiveness of this instructional approach.

Discontinuing Participation

At any time, you may request to withdraw your consent or discontinue your child's participation. Your requests will be honored promptly and unconditionally without penalty, and any data collected from you will be immediately destroyed.

Questions

If you have any questions about this study, please contact Leala Holcomb, Principal Investigator, email: lholcom5@utk.edu. If you have any questions or concerns regarding your rights as a study participant, or if you are dissatisfied at any time with any aspect of this study, you may contact the UT Office of Research IRB Compliance Officer at (865) 974-7697 or at utkirb@utk.edu.

Sincerely,

Leala Holcomb, Ph.D.
University of Tennessee

Name of child: _____

Your name (please print): _____

Your signature below indicates your consent to have your child participate in this study.

Signature: _____ Date: _____

Optional: Your signature below indicates your consent to have your child's video footage shown in future professional development given to other teachers.

Signature: _____ Date: _____



COLLEGE of EDUCATION, HEALTH, & HUMAN SCIENCE

Department of Theory & Practice in

Teacher Education

A204 Jane & David Bailey Education Complex

Knoxville, Tennessee 37996-3442

Phone: 865-974-6228

865-974-6302

Dear Teacher:

Project Information

The purpose of this 2-year research project is to investigate the impact of signing instruction on deaf students' sign language skills. This project will be conducted during an academic year. Your consent will enable you and your students to participate in the research project.

Teacher Participation

- You will receive a two-day professional development on signing instruction followed by bi-weekly coaching sessions to implement signing instruction with deaf students.

Year 1 and Year 2 Data Collection

- **From the teacher:** (1) Video-recorded instructional sessions and (2) Teacher demographic survey; Family and child demographic survey (e.g., hearing level, language use)
- **From the students:** (1) Video-recorded signed compositions after each instructional session.

Videotaping in Classrooms

In order to capture aspects of your involvement in signing instruction, all instructional sessions will be video recorded. Videos will be uploaded and stored on a secure server that can only be accessed by me. Therefore, if you decline to be videotaped, you may not participate in the research. With added consents from you and your students (optional), classroom video footage may be used for conferences and professional development purposes.

Confidentiality & Potential Risks

This is a federally funded grant program, and as such, final research data will be publicly accessible to others for a minimum of 10 years on the University of Tennessee Research and Creative Exchange. Data may be used for future studies or shared with other researchers for use in future studies without obtaining additional informed consent from you or others. However, any identifiable information will not be shared or revealed. This means the names of your school, teachers, and students will not ever be shown to respect confidentiality.

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Compensation

I will offer you a \$1,000 stipend for participating in 2-day professional development and \$50 for each bi-weekly coaching session in the first year of study and another \$1,000 stipend and \$50 for each bi-weekly coaching session for your involvement in the second year of study.

Discontinuing Participation

At any time, you may request to withdraw your consent or discontinue participation. Your requests will be honored promptly and unconditionally without penalty, and any data collected from you will be immediately

destroyed. Stipends will be prorated.

Questions

If you have any questions about this study, please contact Leala Holcomb, Principal Investigator, email: lholcom5@utk.edu. If you have any questions or concerns regarding your rights as a study participant, or if you are dissatisfied at any time with any aspect of this study, you may contact the UT Office of Research IRB Compliance Officer at (865) 974-7697 or at utkirb@utk.edu.

Sincerely,

Leala Holcomb, Ph.D.
University of Tennessee

Your name (please print): _____

Your signature below indicates your consent to participate in this study.

Signature: _____ Date: _____

Your signature below indicates your consent to have your classroom video footage shown in future professional development given to other teachers (optional).

Signature: _____ Date: _____