

**Study Identification Unique Protocol ID:** FRGS/1/2020/SSI0/UKM/03/2 **Brief Title:** Effectiveness of the Occupational Therapy Handwriting Intervention Guideline on Children  
**Official Title:** Evaluating the Effectiveness of the Occupational Therapy Handwriting Intervention Guideline on Handwriting Skills for Children: A Protocol for Clustered-Randomised Control Trial  
**Secondary IDs:**

**Study Status Record Verification:** January 2022 **Overall Status:** Completed **Study Start:** October 1, 2021 [Actual] **Primary Completion:** December 1, 2021 [Actual] **Study Completion:** February 28, 2022 [Actual]

**Sponsor/Collaborators Sponsor:** National University of Malaysia **Responsible Party:** Sponsor Collaborators: Ministry of Education, Malaysia

**Study Description Brief Summary:**

This study aims to evaluate the effectiveness of the Occupational Therapy Handwriting Interventions Guidelines (OTHIG) in enhancing handwriting performance among children. **Method:** Forty-two children recruited from private centers with occupational therapy indications and with handwriting issues, aged five to nine years, will be assigned to the experimental and control groups. Participants will receive a total of 10-week sessions, including training, intervention, and outcome measures. A total of 10 centers will be involved in this study. The clustering of all ten centers will allocate randomly into the treatment and control groups based on submitting the consent letter to the researcher and after an assessment of TPT and TVPS-4 are conducted. Ten early interventions have similar characteristics such as (1) hiring graduated occupational therapists from recognized universities in Malaysia, (2) having occupational therapists working daily at the centre, (3) having children aged five to nine years who receive OTs intervention. This randomization will be allocated based on the list of the centers that give an early submission of a signed consent form. The randomization will be carried out with a mechanism that neither the researcher nor children or center owners will know which group of intervention they will be assigned.

**Conditions Conditions:** Difficulty Writing **Keywords:** handwriting intervention effectiveness children study protocol clustered randomized controlled trial.

**Study Design Study Type:** Interventional Primary Purpose: Health Services Research Study  
Phase: N/A Interventional Study Model: Parallel Assignment Number of Arms: 2 Masking:  
Double (Participant, Care Provider) Allocation: Randomized Enrollment: 42 [Actual]

**Arms and Interventions Arms Assigned Interventions Experimental:**

**OTHIG Occupational Therapy Handwriting Intervention Guideline - this is the experimental guideline to be tested in this study.**

Section C:

Intervention for Handwriting Readiness Skills

- Handwriting development
- Pre-writing skills
- Gross motor skills activities
- Fine motor skills activities
- Motor visual skills activities

Section D:

Intervention for Handwriting Skills

- Handwriting tools
- Pencil grasp
- Posture and position
- Hand dominance
- Writing capitals, lowercase, and numbers
- Handwriting speed

Section E: Handwriting Intervention Module

- Session 1: Development of Handwriting Skills Activities
- Session 2: Pre-writing Skills Activities
- Session 3: Gross and Fine Motor Skills Activities

- Session 4: Writing Capital Letters
- Session 5: Writing Lowercase Letters
- Session 6: Writing Numbers

**OTHIG Occupational Therapy Handwriting Intervention Guideline No Intervention:  
NOTi Natural Occupational Therapy Intervention - this means, the participants in this  
group are not exposed to the OTHIG.**

They receive natural OT intervention without exposure to the OTHIG. The natural OT intervention includes: Gross motor skills, fine motor skills, pre-writing skills, basic handwriting tasks such as copying, tracing, imitating and colouring.

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**Outcome Measures Primary Outcome Measure:**

1. The Print Tool Handwriting assessment [Time Frame: 2 weeks] Secondary Outcome Measure:
2. Test of Visual Perceptual Skills-4 Visual perceptual skills assessment [Time Frame: 2 weeks]