

Official Title: Evaluating the Effectiveness of the Occupational Therapy Handwriting Intervention Guideline on Handwriting Skills for Children: A Protocol for Clustered-Randomised Control Trial

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Abstract

Background: Occupational therapy may have essential benefits in handwriting intervention for children with handwriting difficulties. This study aims to evaluate the effectiveness of the Occupational Therapy Handwriting Interventions Guidelines (OTHIG) in enhancing handwriting performance among children.

Method: A clustered-randomized controlled trial (c-RCT) will be conducted before and after the intervention. 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. The experimental group will receive the developed OTHIG during handwriting skills intervention. Meanwhile, the control group will receive conventional interventions which not exposed to the OTHIG.

Results: Two outcome measures, The Print Tool and Test of Visual Perceptual Skills 4th edition will be measured at baseline and post-intervention levels. The effectiveness of the developed OTHIG will be investigated using covariance analysis. Effects on both outcome measures will be calculated by the difference between mean group scores, accounting for baseline scores.

Conclusion: This study is expected to provide evidence for the effectiveness of using the developed OTHIG to OTs in delivering their services, targeting children struggling with handwriting skills.

Keywords: Handwriting intervention, effectiveness, children, study protocol, clustered-RCT

Introduction

The prevalence of children experiencing handwriting difficulties varies in the literature between 5-35% (Overvelde & Hulstijn 2011; Volman et al. 2006; Brossard-Racine et al. 2011; Duiser et al. 2020). Handwriting difficulties might be the issue in learning problems, academic performance, and school-related tasks (Zwicker *et al.*, 2017; Engel, Lillie, Zurawski and Brittany G Travers, 2018). Handwriting skills such as holding a pencil and associated motor skills such as cutting and coloring are difficult for children with handwriting issues (Zainol and Abdul Majid, 2013). For decades, these handwriting skills were included in 30-60% of tasks for children in schools (McHale and Cermak, 1992; Sakamat *et al.*, 2019). Handwriting legibility is the main issue among children with handwriting problems (Lam *et al.*, 2011; Shih *et al.*, 2018). It became the main reason for referral to occupational therapy intervention (Engel, Lillie, Zurawski and Brittany G Travers, 2018).

Occupational therapy intervention would positively impact handwriting skills among children (Farhat *et al.*, 2016). Handwriting intervention usually focuses on visual perception skills, motor skills, visual-motor skills, and sensory-motor activities (Zainol *et al.*, 2021). A previous study investigated the effects of occupational therapy services on handwriting performance and found that handwriting legibility increased by 14.2% for students who receive occupational therapy and by only 5.8% for the group of students who did not receive the service (Case-Smith 2002). Studies on the effects of handwriting intervention have varied in purposes, such as focussing on handwriting legibility, speed, or fluency. However, there was little evidence on the impact of handwriting fluency in which fluency reflected the entire handwriting ability in children (Engel, Lillie, Zurawski and Brittany G Travers, 2018).

Handwriting ability may improve due to several factors such as life routine, other indirect interventions outside occupational therapy sessions, or individual maturation (Havaei *et al.*, 2018). However, an intervention program could be the factor or medium to accelerate handwriting performance (Zainol *et al.*, 2021). Provided with intervention program, other several factors and characteristics may influence the effectiveness of OTs intervention such as (1) time frame, (2) age range, (3) type of intervention, (4) targeted outcomes, and (5) involvement of other support during an intervention (Zainol *et al.*, 2021). A prominent study in 2011 stated that the most efficient handwriting intervention is of six weeks' duration, three times a week with a minimum of twenty sessions (Hoy, Egan and Feder, 2011). However, a pretty recent study has proved that handwriting intervention is perfectly effective with a

minimum of 15 minutes per session, 3-5 times a week, with 15 therapy sessions in total (Brevoort, 2018).

Most of the studies used different handwriting skills, visual perceptual skills, and motor function assessments to measure the handwriting intervention efficacy by analyzing the scores before and after intervention (Güneş and Söylemez, 2018; Taverna, Tremolada, Tosetto, *et al.*, 2020). OTs need to apply evidence-based interventions that have a substantial impact on handwriting skills, such as fine motor skills (Piller and Torrez, 2019; Taverna, Tremolada, Dozza, *et al.*, 2020), visual perceptual skills (Baldi, Nunzi and Brina, 2015) and sensory skills (Marquardt *et al.*, 2016). It is advisable that visual and perceptual skills are the essential sub-skills component for handwriting performance (Baldi, Nunzi and Brina, 2015; Havaei *et al.*, 2018). Therefore, the visual-motor function is another sub-skill incorporated in the handwriting task; handwriting could not be carried out without vision.

Since OTs contribute to handwriting skills intervention, a guideline considering the intervention that may affect handwriting performance and visual perception skills need to be proposed. Therefore, this study primarily aims to evaluate the effectiveness of the OTHIG developed for OTs to improve handwriting skills performance among CwHD children by using two outcome measures to assess handwriting and visual perception performance.

Methods

Study Design

The study is a Cluster Randomised Controlled Trial (C-RCT) that systematically clusters the centers into the treatment and control groups. Four main centers have other branches that make a total of 10 centers will be involved in this study. In general, all centers provide early intervention programs for children that receive OTs intervention, including handwriting skills intervention. The pre-test will be conducted at the baseline level and will take two weeks which all the children from the centers will have an assessment using The Print Tool (TPT) and Test of Visual Perceptual Skills-4 (TVPS-4). The clustering of all ten centers will allocate randomly into the treatment and control groups based on a submission of the consent letter to the researcher and after an assessment of TPT and TVPS-4 are conducted. The treatment groups will receive the Occupational Therapist Handwriting Interventions Guideline (OTHIG) for handwriting skills intervention. Meanwhile, the control groups will receive conventional handwriting skills intervention from the OTs of the centers. The interventions process will

occur in five weeks for both intervention and control groups. After that, a post-test will be conducted within two weeks using the same assessments. A flow chart of the study design is presented in Figure 1.

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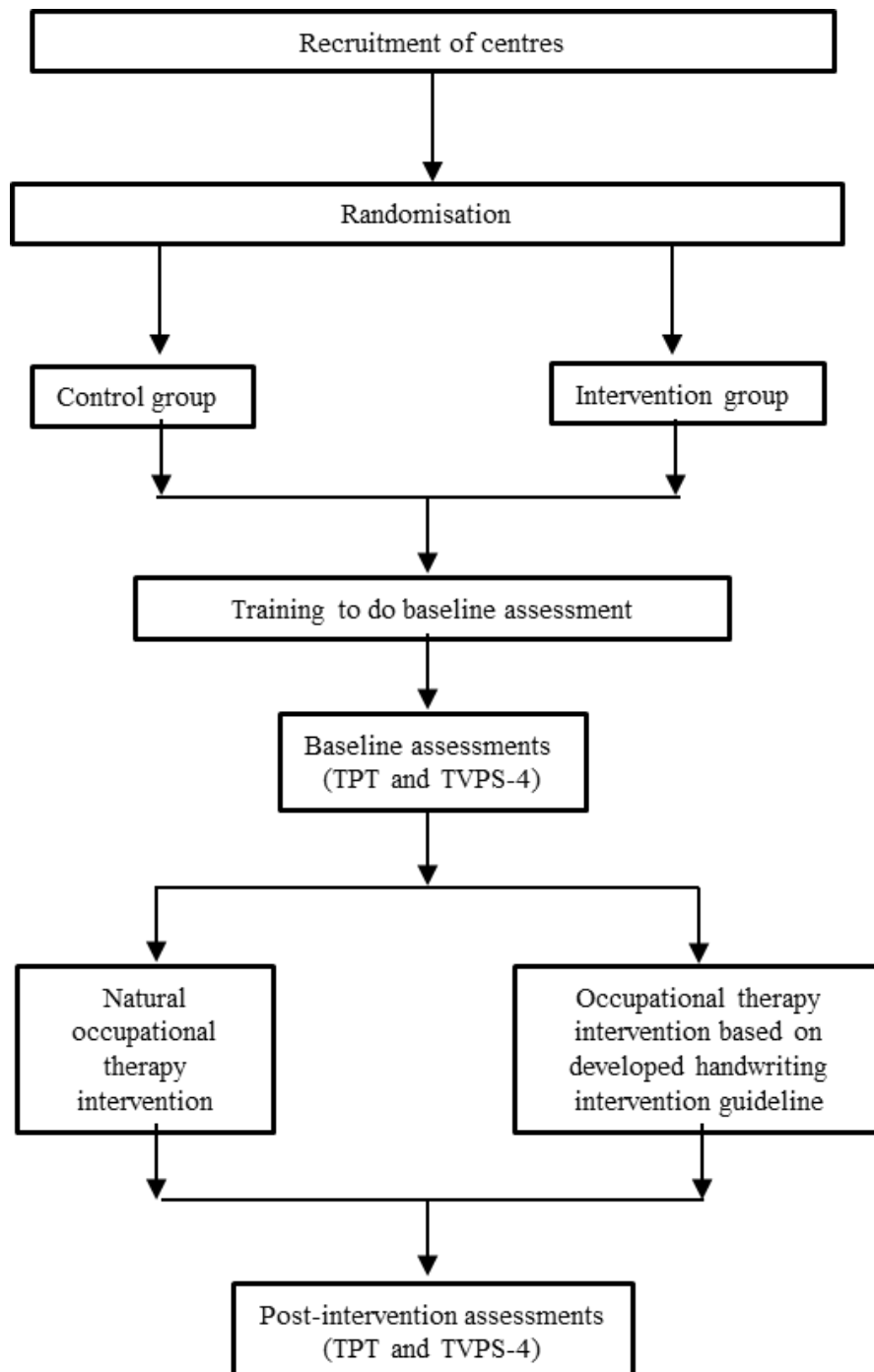


Figure 1. Flowchart of study design

*TPT: The Print Tool

**TVPS-4: Test of Visual Perceptual Skills-4

The Print Tool (TPT) and Test of Visual Perceptual Skills-4 (TVPS-4) will be applied to all children in this study for baseline data. Centers in the treatment group will receive 10-week handwriting intervention and training. In contrast, the participants in the remaining centers in the control group will receive two sessions of training to do pre-outcome measures in the first two weeks (Week 1 and 2), then continue the occupational therapy intervention as usual, and finally, another two sessions of training to do post-outcome measures after the ten weeks (Week 9 and 10). Figure 2 is the diagram of the study design for both control and treatment groups.

<< Insert Figure 2 here >>

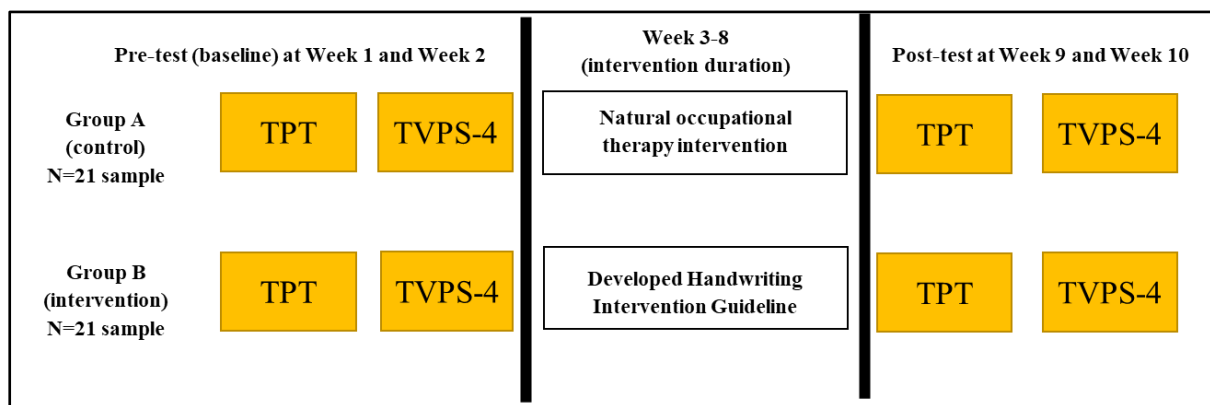


Figure 2. Diagram of study design

*TPT: The Print Tool

**TVPS-4: Test of Visual Perceptual Skills-4

Participant recruitment

The eligible children from each center are between five to nine years old. Naturally, these children received OT intervention for handwriting skills on an individual or group basis at the respective centers. Before the study begins, all children and parents will be provided a written informed consent form. In addition, a formal invitation letter from the center owners that will attach with an information sheet about the research will be given to children and parents. Parents will complete the consent form and return it to the center owners. Provided with the returned consent form, the children will be assessed. All OTs from the respective centers will be assigned as facilitators for this study. Each facilitator will have one to four qualified children as participants.

There are specific criteria for including and excluding children and facilitators in this study. The inclusion criteria for children are as follows: (1) age between five and nine years, (2) engaged in OTs intervention either in an individual or group session. Meanwhile, the exclusion criteria are as follows: (1) refuse to participate in the study, (2) fail to comply with the whole intervention process during the study, (3) present severe sensory problems, and (4) present poor behavior.

For the facilitators, the inclusion criteria are as follows: (1) possesses a minimum academic background in Occupational Therapy degree from a recognized university in Malaysia and (2) employed as a full-time occupational therapist. Meanwhile, the exclusion criteria are as follows: (1) refuses to participate in the study, (2) does not have intervention children who meet the criteria for this study, and (3) is unable to complete the whole process of intervention during the study.

Randomization

Ten early intervention and development centers will be recruited and have similar characteristics such as (1) hiring graduated occupational therapists from recognized universities in Malaysia, (2) having occupational therapists working daily at the center, (3) having children aged five to nine years who receive OTs intervention. After the assessment using the TPT and TVPS-4 are conducted, the children will be randomized into treatment and control groups using a randomly generated number, one and two. 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.

Blinding

This study involves the provision of training and handwriting intervention for children. It is not feasible to blind both facilitators and children. However, the facilitators will be blinded to the randomization procedure to reduce ascertainment bias. All centers will undergo the same training and outcome measures at baseline and post-intervention levels. The difference is that the facilitators and children in the control group will receive the training module and the developed OTHIG after both groups finish their post-intervention measures.

Intervention

The intervention will be delivered at the same frequency and duration of 30 minutes per session, 2-3 times a week (Brevoort, 2018). The same facilitators will carry out intervention for all children from the beginning until the end of this study duration. Children from treatment groups will receive OTHIG during handwriting skills intervention. On the other hand, children in the control groups will not receive OTHIG and follow the conventional interventions provided by OTs with the exact duration of intervention.

The content of the intervention includes specific materials and techniques in handwriting intervention such as activities on handwriting development phases, pre-writing skills, gross and fine motor skills, writing capitals, lowercase, and numbers using proposed strategies and materials. The intervention program strictly follows the given guideline as in OTHIG to meet the occupational goals in handwriting skills. The OTHIG had been designed and developed by the researcher, and it was conducted in a previous study. Eleven OTs and two clinical psychologists completed developing and validating the OTHIG. The validation procedure for OTHIG had used a Content Validity Index (CVI), and the score was gained from all thirteen experts. The face and content validity reported a convincing value ranging from 0.99 to 1.00 of S-CVI values on four aspects – relevance, clarity, simplicity, and ambiguity. These four aspects were the validity contents that covered each of the sections in the OTHIG. For this study, OTHIG will be used as a handwriting skills intervention in ten weeks. Table 1.0 shows the content summary of the OTHIG validity result.

<< Insert Table 1 here >>

Table 1. Intervention arm.

Content Summary of Handwriting Intervention Guideline
Section A: Introduction to Handwriting Skills
- Problems related to handwriting
- Factors in handwriting issues
- Suggested frequency for handwriting intervention
- Target group
Section B: Occupational Therapy Service Procedure for Handwriting Intervention
- Screening
- Checklist
- Assessment
- Planning
- Intervention
- Re-evaluation

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

Delivery and Training

The overall delivery process to and training of the facilitators will be executed within ten weeks. The table demonstrates the schedule of training and intervention for the facilitators and children for both treatment and control groups. All activity will be delivered weekly through a virtual platform, namely, Google Meet, conducted by the researcher. Each training session will have its task to be completed by the children. The researcher will upload and monitor all assignments through the Google Drive application. Apart from that, an online group will be set up with all facilitators from each center to monitor progression, deal with issues, or have any further inquiries or problems regarding the weekly assignments that need to be completed.

The training format will consist of two parts. The first part is the explanation of the OTHIG. The second part is the weekly assignment derived from the OTHIG, and it needs to be completed as a one-to-one intervention between the children and OTs. Table 2.0 explains the intervention and training schedule over ten weeks.

<< Insert Table 2 here >>

Table 2. Intervention and training schedule over 10-week study duration

<i>Week</i>	<i>Training to facilitators</i>	<i>Intervention to children for treatment group</i>	<i>Intervention to children for control group</i>	<i>Data Collection</i>
<i>1</i>	How to do The Print Tool assessment?	None	None	The Print Tool score (baseline)

2	How to do Test of Visual Perceptual Skills – 4?	None	None	Test of Visual Perceptual Skills – 4 score (baseline)
3	Introduction to Handwriting Skills	Session 1: Development of Handwriting Skills Activities	Natural intervention: Gross, fine motor skills, handwriting tasks such as copying and colouring.	OT -
4	Basic Component in Handwriting skills	Session 2: Pre-writing Skills Activities	Natural intervention: Gross, fine motor skills, handwriting tasks such as copying and colouring.	OT -
5	Readiness in Handwriting Skills	Session 3: Gross and Fine Motor Skills Activities	Natural intervention: Gross, fine motor skills, handwriting tasks such as copying and colouring.	OT -
6	Handwriting Skills Intervention	Session 4: Writing Capital Letters	Natural intervention: Gross, fine motor skills, handwriting tasks such as copying and colouring.	OT -
7	Copying Skills	Session 5: Writing Lowercase Letters	Natural intervention: Gross, fine motor skills, handwriting tasks such as copying and colouring.	OT -
8	Speed of Handwriting Skills	Session 6: Writing Numbers	Natural intervention: Gross, fine motor skills, handwriting tasks such as copying and colouring.	OT -
9	How to Score The Print Tool Assessment?	None	None	The Print Tool score (post-intervention)
10	How to do Scoring in Test of Visual Perceptual Skills-4?	None	None	Test of Visual Perceptual Skills – 4 score (post-intervention)

Analyses

Sample size calculation

The sample size calculation is estimated with G-Power analysis software (version 3.1.9.2). Regardless the OTHIG is newly developed, and no studies using the outcome measures of TPT and TVPS-4 to assess the effectiveness of OTHIG for handwriting performance among CwHD. This study protocol will use these parameters: (1) small effect size is 0.25 (Cohen, 1988), (2) power ($1 - \beta$) is 0.80, (3) α level is 0.05, (4) group number is 2, (5) number of measurements is two (4) ANOVA repeated measures by determining a sample size of 34. Assuming the same for a dropout rate of 20%, this study will need 42 children across each cluster. Due to this study being a C-RCT, we will include 10 clusters to cover the total sample size. Each cluster will have about four to five children, making 42 children in total.

Outcome measures

All outcome measures will be assessed at baseline before the intervention begins (at week 1 and 2) and post-intervention (at week 9 and 10). The primary outcome is TPT, and the secondary outcome is TVPS-4.

The Print Tool

An occupational therapist has intentionally developed the Print Tool (TPT) to evaluate capital, lowercase, and number writing skills in children from preschool to primary school, depending on their grades (Olsen and Knapton, 2006). TPT focused on assessing seven handwriting components: memory, orientation, placement, size, start, sequence, and spacing. The findings from this assessment tool are beneficial in planning an appropriate handwriting intervention program for the child. The TPT assessment requires fifteen to twenty minutes to administer for each child; however, it is not necessary to record the time taken in the evaluation.

TPT is a criterion-based handwriting assessment used by occupational therapists to assess children's handwriting skills, examine specific areas of handwriting problems and offer a relevant intervention plan (Olsen and Knapton, 2006). This study does not assess spacing between words in handwriting skills because it requires other samples from a previous handwriting worksheet of the child. The scores for this assessment will be calculated in percentages for capital letter writing, lowercase writing, number writing, and for an overall score of the handwriting assessment. Many experimental studies have been using TPT as a handwriting outcome measure to investigate the effectiveness of handwriting intervention programs (Chrisman *et al.*, 2013; Donica, Massengill and Gooden, 2018; Randall, 2018;

Donica and Holt, 2019). TPT has indicated good concurrent validity based on the psychometric properties of handwriting assessment studies (Donica and Holt, 2019) and higher sensitivity than specificity in handwriting components (Chrisman *et al.*, 2013). However, the researcher is aware that TPT is insufficient to measure handwriting skills. Therefore, another outcome measure is needed to assess the visual perception aspect in handwriting.

Test of Visual Perceptual Skills-4

Test of Visual Perceptual Skills-4 (TVPS-4) is a standardized, norm-referenced, and motor-free assessment test for individuals aged between five and twenty-one years (Martin, 2017). It was initially revised from Test of Visual Perceptual Skills-3 (TVPS-3) (Martin, 2006) with seven sub-tests; namely, (1) visual discrimination, (2) visual memory, (3) spatial relationship, (4) form constancy, (5) sequential memory, (6) figure-ground and (7) visual closure. TVPS-4 digital test plates will be presented using Microsoft Powerpoint Presentation software with strict adherence to the administration instruction manual. The child will be shown the digital test plates and answer them by pointing or verbalizing the correct answer. Their responses will be recorded on the assessment form and be analyzed.

Recent studies have successfully conducted validity tests, and it was evident that TVPS-4 is an accurate measure of motor-free perceptual skills and demonstrated a great significant correlation of total scale raw scores compared to other similar visual perceptual tests (Martin, 2017; Colosimo and Brown, 2021). It is beneficial to use TVPS-4 to investigate visual perceptual's impact on children's handwriting skills. TVPS-4 acts as a complementary instrument to be used with TPT in this study to measure the effectiveness of the developed OTHIG.

Proposed statistical analysis

All statistical analyses will be performed using Statistical Package for the Social Sciences (SPSS) software (version 26.0, IBM Corporation, Chicago, IL). Data will be analyzed for normality, expressed mean and standard deviation (SD). To assess the normal distribution of quantitative data, the Shapiro-Wilk test will be employed ($P > 0.05$). Continuous variables will be presented as the mean (SD) for normal distributions and median for non-normal distribution, and categorical variables will be presented as frequencies or percentages. Means, standard deviation, and frequencies will describe the outcome, background, and baseline variables. A

descriptive analysis will be performed for the quantitative data on the scores from both outcome measures, TPT and TVPS-4.

Baseline data between groups will be compared using t-test for continuous variables and the chi-square or Fisher's exact tests for categorical variables. The significance value will be set up at $p < 0.05$. Within-group differences will be assessed using paired t-tests for the normality distributed data and Wilcoxon-signed ranked test for a non-parametric equivalent test.

A mixed repeated measures ANOVA, between and within groups, is performed to examine the effectiveness of the OTHIG among school children with handwriting problems. A two-way repeated-measures analysis of variance (ANOVA) will be conducted to explore the treatment group interaction, with time as the within-group variable and the treatment group as the between-group variable. Correlations between TPT and TVPS-4 will be investigated to identify any relationships between both outcome measures.

Data Management

The researcher is responsible for data confidentiality and security. All the data gathered for this study is treated to protect the confidentiality and anonymity of all participants at any level. All data will be collected virtually. Electronic data will be kept safe at a secured database, namely Google Drive, that can be protected and accessible by the researcher and facilitators. Moreover, the raw data in the study will be stored securely for an appropriate period and will be destroyed once the research has been completed. Due to the research subject, there is no potential risk or harm to the researcher or participants in this research study.

Discussion

Research suggests that many occupational therapy handwriting programs have positively impacted a child's handwriting performance. However, those handwriting programs are not easily and readily accessible within Malaysia. If it is accessible, it is very costly for an institution to take up all the programs. Moreover, the program's content may not suit our handwriting curriculum, culture, and educational system. Therefore, this study aims to investigate the potential of a developed handwriting guideline that suits our background. Other than that, we expect this study's outcome to demonstrate evidence for practicing occupational therapists working with children. Previous studies support the concept that visual perception

skills contribute to handwriting performance. Accordingly, this study uses two outcome measures that comprehensively assess the components in visual perception alongside handwriting skills. To ensure the efficiency of the intervention delivery, a relatively high number of occupational therapy facilitators will be involved (Sturkenboom *et al.*, 2013). This means that the number of participants seen by each facilitator during this study is low. The average ratio of facilitator to participant is 1:2. Each facilitator will be monitored and coached through an online discussion platform to assure protocol adherence throughout the study.

The study design will apply a randomization strategy in which all centers will be assigned either into treatment or control groups on equal chance. In addition, all centers are unaware of which group they have been given. All materials, including the handwriting guideline, training, modules, and handwriting kit, will be given to all centers at different times. This means the treatment group will receive the materials earlier within the ten weeks, while the control group will get the materials after week 10 when all the pre- and post-outcome measures have been completed.

For the outcome measure aspect, two assessment tools are used to statistically measure the handwriting performance in the capital, lowercase, and number writing. It also evaluates the sub-skills in the visual perception components, ranging from memory, discrimination, spatial relationship, form constancy, and visual closure (Colosimo and Brown, 2021). These two assessments are ideal at this time of the study; due to the current pandemic Covid-19, the researchers will probably administer and monitor via the online platform called Google Meet to reduce physical contacts. However, it is suggested that any future study should include motor or physical skills assessment together with handwriting (Smits-Engelsman *et al.*, 2013; Adams *et al.*, 2016).

Study Limitations

Nevertheless, this study has some limitations. None of the occupational therapy facilitators in this study have had previous experience using both outcome measures (TPT and TVPS-4). Though the researchers offer training to conduct these two outcome measures for this study, this might be a potential limitation for the data collection. To address this, all facilitators must provide a video recording during the assessment session using both outcome measures to ensure the validity and reliability of the data collected.

Another limitation is the intervention period of this study; the more extended period of ten weeks is a little demanding. Some children may not commit and could withdraw before the intervention is completed. The effectiveness of the intervention given might be affected by the time and the child's skills (Engel, Lillie, Zurawski and Brittany G. Travers, 2018). Many studies suggested that a 6-week duration is sufficient for a handwriting intervention to be effective (Waelvelde *et al.*, 2017; Engel, Lillie, Zurawski and Brittany G. Travers, 2018; Wuang *et al.*, 2018). Interestingly, a study reported a low-intensity, high frequency, and short duration handwriting intervention to be efficient, with a minimum of 15 minutes for 15 therapy sessions 3-5 times a week (Brevoort, 2018). Nevertheless, this present study has been developed to fulfill the specific intervention guideline; thus, it requires more than six weeks of intervention.

Finally, this study evaluates the developed handwriting intervention guideline effectiveness and explores the relationship of visual perceptual skills in handwriting performance. It is hoped that the findings from this study will contribute to the evidence-based practice of handwriting intervention for occupational therapists. This study is the beginning documentation of a thorough handwriting intervention guideline for occupational therapists in Malaysia; thus, an efficacy report is essential to evidence the quality of professional practice for a child's occupational goal in our unique culture and educational system. Future research that uses the developed OTHIG needs to expand and should focus on considerations such as different target groups of the population.

Study status

The status of the trial is ongoing at the time of manuscript submission. The recruitment of participants through centers has been completed in the first week of October 2021. At the time of submission, 42 children have been enrolled in this study and are undergoing the intervention. This study is due to finish in February 2022.

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