

## **EFFECTIVENESS OF THE OCCUPATIONAL THERAPY HANDWRITING INTERVENTION GUIDELINE ON HANDWRITING SKILLS FOR CHILDREN: A PROTOCOL FOR CLUSTERED- RANDOMISED CONTROL TRIAL**

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*Occupational therapy may have essential benefits in handwriting intervention for children with handwriting difficulties (CwHD). This study aims to evaluate the effectiveness of the Occupational Therapy Handwriting Interventions Guidelines (OTHIG) in enhancing handwriting performance among children. However, this manuscript will only highlight the protocol for a clustered-randomised controlled trial (c-RCT) which was conducted before the intervention. Forty-two children with occupational therapy indications and handwriting issues, aged five to nine years, recruited from private centres, were assigned to the experimental and control groups. Participants received a total of 10-week sessions, including training, intervention, and outcome measures. The experimental group received the developed OTHIG during handwriting skills intervention. Meanwhile, the control group received conventional interventions without being exposed to the OTHIG. Two outcome measures, The Print Tool and Test of Visual Perceptual Skills 4th edition were measured at baseline and post-intervention levels. The effectiveness of the developed OTHIG was investigated using covariance analysis. Effects on both outcome measures were calculated by the difference between mean group scores, accounting for baseline scores. This study is expected to provide evidence for the effectiveness of using the developed OTHIG to Occupational Therapists (OTs) in delivering their services, targeting on 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 an issue in learning problems, academic performance, and school-related tasks (Engel et al., 2018; Zwicker et al., 2018). Handwriting skills such as holding a pencil and associated motor skills such as cutting and colouring are difficult for children with handwriting issues (Zainol & Abdul Majid, 2013). For decades, these handwriting skills were included in 30-60% of tasks for children in schools (McHale & 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 et al., 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., 2022). 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 received 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 et al., 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 programme could be the factor or medium to accelerate handwriting performance (Zainol et al., 2022). Provided with an intervention programme, 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., 2022). A prominent study in 2011 stated that the most efficient handwriting intervention is six weeks' duration, three times a week with a minimum of twenty sessions (Hoy et al., 2011). However, a pretty recent study has proven 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).

### **STATEMENT OF PROBLEM**

Most of the studies used different handwriting skills, visual perceptual skills, and motor function assessments to measure handwriting intervention efficacy by analysing the scores before and after intervention (Güneş & 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 & Torrez, 2019; Taverna, Tremolada, Dozza, et al., 2020), visual perceptual skills (Baldi et al., 2015), and sensory skills (Marquardt et al., 2016). Visual and perceptual skills should be the essential sub-skills component for handwriting performance (Baldi et al., 2015; Havaei et al., 2018). Therefore, the visual-motor function is another sub-skill incorporated into the handwriting task; handwriting activity was impossible to be carried out without vision.

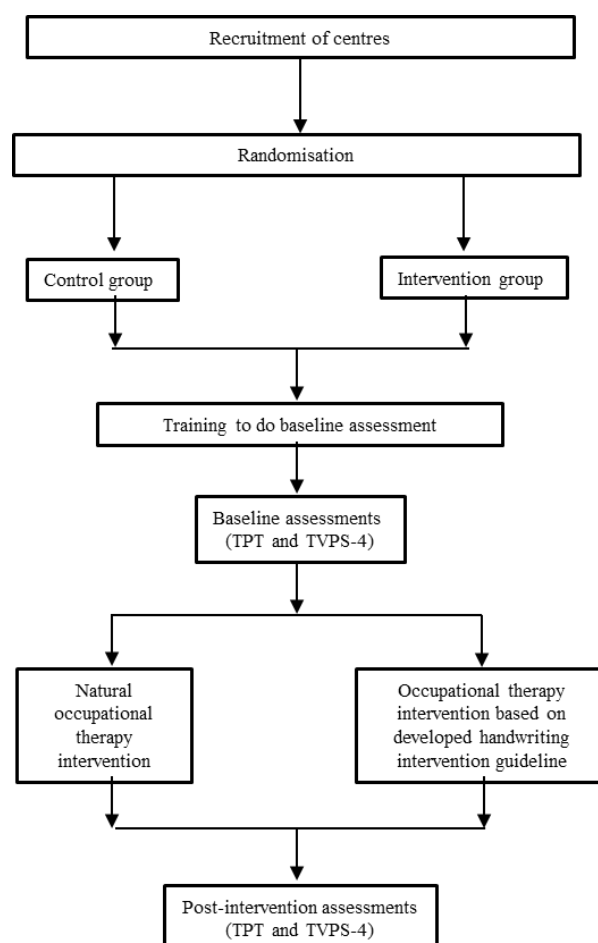
Since OTs contribute to handwriting skills intervention, a guideline considering the intervention that may affect handwriting performance and visual perception skills needs to be proposed. Therefore, this study primarily aims to evaluate the effectiveness of the Occupational Therapy Handwriting Interventions Guidelines (OTHIG) developed for OTs to improve handwriting skills performance among children with handwriting difficulties (CwHD) by using two outcome measures to assess handwriting and visual perception performance.

## METHODOLOGY

### Research Design

The study is a Cluster Randomised Controlled Trial (C-RCT) that systematically clusters the centres into treatment and control groups. Four main centres have other branches making a total of 10 centres will be involved in this study. In general, all centres provide early intervention programmes for children who receive OT intervention, including handwriting skills intervention. The pre-test was conducted at the baseline level and will take two weeks which all the children from the centres will have an assessment using The Print Tool (TPT) and Test of Visual Perceptual Skills-4 (TVPS-4). The clustering of all ten centres was allocated 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 were conducted. The treatment groups received the OTHIG for handwriting skills intervention. Meanwhile, the control groups received the conventional handwriting skills intervention from the OTs of the centres. The intervention process occurred in five weeks for both intervention and control groups. Upon that, a post-test was conducted within two weeks using the same assessments. A flow chart of the study design is presented in Figure 1.

**Figure 1**  
*Flowchart of Study Design*

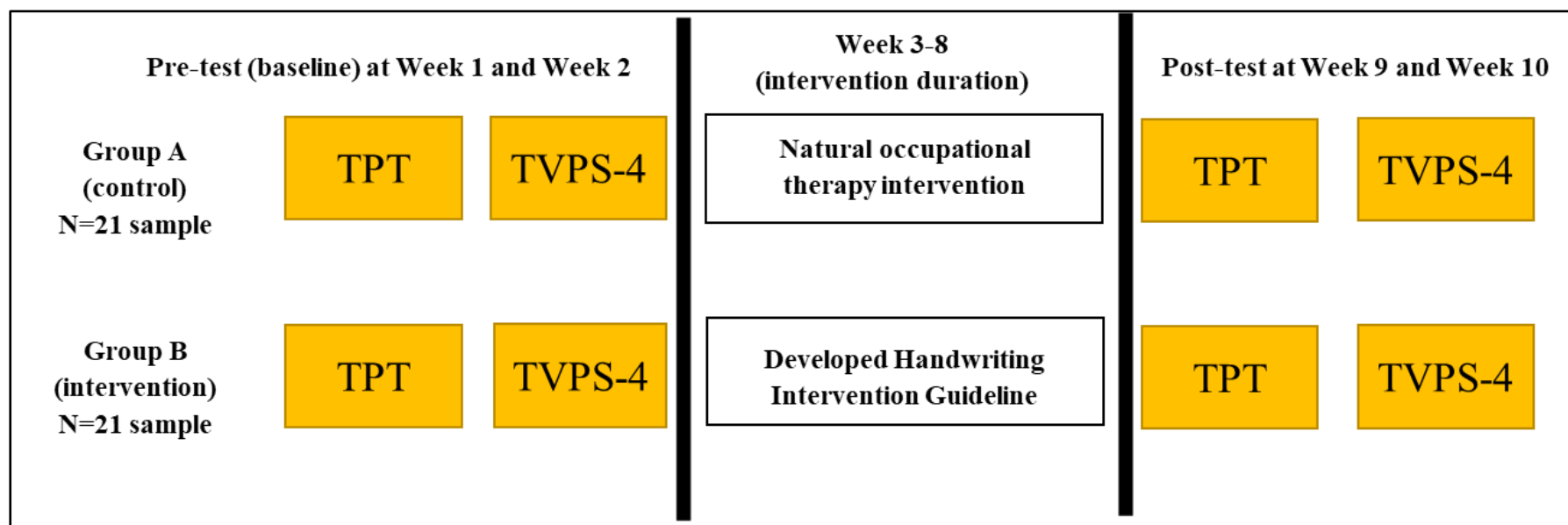


\*TPT: The Print Tool

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

The Print Tool (TPT) and Test of Visual Perceptual Skills-4 (TVPS-4) were applied to all children in this study for baseline data. Centres in the treatment group received 10-week handwriting intervention and training. In contrast, the participants in the remaining centres in the control group received 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.

**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 centre were between five to nine years old. These children received OT intervention for handwriting skills regardless of any other learning difficulties. They may receive OT intervention on an individual or group basis at the respective centres. Before the study begun, all children and parents were provided with a written informed consent form. In addition, a formal invitation letter from the centre owners attached to an information sheet about the research was given to children and parents. Parents completed the consent form and returned it to the centre owners. Provided with the returned consent form, the children were assessed. All OTs from the respective centres were assigned as facilitators for this study. Each facilitator had 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 OT intervention either in an individual or group session, and (3) scored 75% and below in handwriting assessment (namely The Print Tool, Test of Handwriting Skills-Revised, Minnesota Handwriting Assessment, or other standardised handwriting assessment). 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 a physical diagnosis such as Down Syndrome, (4) 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 recognised university in Malaysia and (2) is 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.

## **Randomisation**

Ten early intervention and development centres were recruited and have similar characteristics such as (1) hiring graduated occupational therapists from recognised universities in Malaysia, (2) having occupational therapists working daily at the centre, and (3) having children aged five to nine years who receive OTs intervention. After the assessment using the TPT and TVPS-4 were conducted, the children were randomised into treatment and control groups using a randomly generated number, one and two. This randomisation will be allocated based on the list of the centres that give an early submission of a signed consent form. The randomisation was carried out with a mechanism that neither the researcher nor children or centre owners will know which group of intervention they will be assigned.

## **Blinding**

This study involved the provision of training and handwriting intervention for children. It was not feasible to blind both facilitators and children. However, the facilitators were blinded to the randomisation procedure to reduce ascertainment bias. All centres had undergone the same training and outcome measures at baseline and post-intervention levels. The difference is that the facilitators and children in the control group received the training module and the developed OTHIG after both groups finish their post-intervention measures.

## **Intervention**

The intervention was delivered at the same frequency and duration of 30 minutes per session, 2-3 times a week (Brevoort, 2018). The same facilitators carried out intervention for all children from the beginning until the end of this study duration. Children from treatment groups received OTHIG during handwriting skills intervention. On the other hand, children in the control groups did not receive OTHIG but followed 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 programme strictly follows the given guidelines 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 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 was used as a handwriting skills intervention for ten weeks. Table 1 shows the content summary of the OTHIG validity result.

**Table 1**

*Content Summary of Handwriting Intervention Guideline*

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

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**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 were 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 activities were delivered weekly through a virtual platform, namely, Google Meet, conducted by the researcher. Each training session had its task to be completed by the children. The researcher uploaded and monitored all assignments through the Google Drive application. Apart from that, an online group was set up with all facilitators from each centre to monitor progression, deal with issues, or have any further inquiries or problems regarding the weekly assignments that needed to be completed.

The training format consists of two parts. The first part was the explanation of the OTHIG. The second part was 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 explains the intervention and training schedule over ten weeks.

**Table 2**

*Intervention and Training Schedule Over a 10-Week Study Duration*

Week	Training to facilitators	Intervention to children for treatment group	Intervention to children for control group	Data Collection
1	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)

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3	Introduction to Handwriting Skills	Session 1: Development of Handwriting Skills Activities	Natural OT intervention: Gross, fine motor skills, handwriting tasks such as copying and colouring.	-
4	Basic Component in Handwriting Skills	Session 2: Pre-writing Skills Activities	Natural OT intervention: Gross, fine motor skills, handwriting tasks such as copying and colouring.	-
5	Readiness in Handwriting Skills	Session 3: Gross and Fine Motor Skills Activities	Natural OT intervention: Gross, fine motor skills, handwriting tasks such as copying and colouring.	-
6	Handwriting Skills Intervention	Session 4: Writing Capital Letters	Natural OT intervention: Gross, fine motor skills, handwriting tasks such as copying and colouring.	-
7	Copying Skills	Session 5: Writing Lowercase Letters	Natural OT intervention: Gross, fine motor skills, handwriting tasks such as copying and colouring.	-
8	Speed of Handwriting Skills	Session 6: Writing Numbers	Natural OT intervention: Gross, fine motor skills, handwriting tasks such as copying and colouring.	-



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)

## Sample Size Calculation

The sample size calculation was estimated with G-Power analysis software (version 3.1.9.2). Regardless the OTHIG is newly developed, and no studies has yet to use 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)  $\alpha$  level is 0.05, (4) group number is 2, (5) number of measurements is two (6) 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 had included 10 clusters to cover the total sample size. Each cluster had about four to five children, making it 42 children in total.

## Outcome Measures

All outcome measures were assessed at baseline before the intervention begins (at week 1 and 2) and post-intervention (at week 9 and 10). The primary outcome is The Print Tool (TPT), and the secondary outcome is Test of Visual Perceptual Skills version 4 (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 pre-school to primary school, depending on their grades (Olsen & 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 programme 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 & 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 programmes (Chrisman et al., 2013; Donica et al., 2018; Donica & Holt, 2019; Randall, 2018). TPT has indicated good concurrent validity based on the psychometric properties of handwriting assessment studies (Donica & Holt, 2019) and higher sensitivity than specificity in handwriting components (Chrisman et al., 2013). However, the researcher is aware that TPT

is only used for measuring handwriting skills. Therefore, another outcome measure is needed to assess the visual perception aspect of handwriting.

#### ***Test of Visual Perceptual Skills-4***

Test of Visual Perceptual Skills-4 (TVPS-4) is a standardised, 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 were presented using Microsoft PowerPoint Presentation software with strict adherence to the administration instruction manual. The child was shown the digital test plates and answer them by pointing or verbalising the correct answer. Their responses were recorded on the assessment form and analysed.

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 significant correlation of total scale raw scores compared to other similar visual perceptual tests (Colosimo & Brown, 2022; Martin, 2017). It is beneficial to use TVPS-4 to investigate visual perceptual 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 were performed using Statistical Package for the Social Sciences (SPSS) software (version 26.0, IBM Corporation, Chicago, IL). Data was analysed for normality, expressed mean, and standard deviation (SD). To assess the normal distribution of quantitative data, the Shapiro-Wilk test was employed ( $p > 0.05$ ). Continuous variables were presented as the mean for normal distributions and median for non-normal distributions, and categorical variables was presented as frequencies or percentages. Means, standard deviation, and frequencies were used to describe the outcome, background, and baseline variables. A descriptive analysis was performed for the quantitative data on the scores from both outcome measures, TPT and TVPS-4.

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

A mixed repeated measures ANOVA, between and within groups, was performed to examine the effectiveness of the OTHIG among school children with handwriting problems. A two-way repeated-measures analysis of variance (ANOVA) was 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 were 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 was treated to protect the confidentiality and anonymity of all participants at any level.

All data were collected virtually. Electronic data were kept safe in 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 programmes have positively impacted a child's handwriting performance. However, those handwriting programmes are not easily and readily accessible within Malaysia. If it is accessible, it is very costly for an institution to take up all the programmes. Moreover, the programme'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 of 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 applied a randomisation strategy in which all the centres were assigned either into treatment or control groups on equal chance. In addition, all centres were unaware of which group they have been assigned to. All materials, including the handwriting guidelines, training, modules, and handwriting kit, were given to all the centres at different times. This means the treatment group will receive the materials earlier within week 10, 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 were used to statistically measure handwriting performance in 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 & Brown, 2022). These two assessments are ideal at this time of the study; due to the current pandemic Covid-19, the researchers administered and monitored via the online platform called Google Meet to reduce physical contact. However, it is suggested that any future study should include motor or physical skills assessment together with handwriting (Adams et al., 2016; Smits-Engelsman et al., 2013).

## **LIMITATIONS OF THE STUDY**

This study has some limitations. None of the occupational therapy facilitators in this study had 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 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 et al., 2018). Many studies suggested that a 6-week duration is sufficient for a handwriting intervention to be effective (Engel et al., 2018; Waelvelde et al., 2017; 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.

## **IMPLICATIONS**

This study contributes to the development of a handwriting intervention guideline for children with handwriting difficulties in Malaysia. This study had proven an effective and relevant handwriting intervention programme for children with handwriting difficulties. Moreover, this study with a large number of participants and a strong study design using RCT to prove its effectiveness to be used among children with handwriting difficulties. The research impact are on the occupational therapy practice intervention in terms of motor function, and visual and perceptual skills to improve handwriting skills. The developed intervention guideline also showed positive implications on child motivation, involvement of parents, child behaviour, and child participation in handwriting activities.

## **CONCLUSION**

In conclusion, this study evaluates the developed handwriting intervention guideline effectiveness and explores the relationship between 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.

### **Research ethics**

Full ethical approval has been granted by the ethics committee, granted by the Sekretariat Etika Penyelidikan, Universiti Kebangsaan Malaysia UKM PPI/111/8/JEP-2020-491. Permission to conduct the study was also granted by the Educational Planning and Research Development (EPRD), Ministry of Education Malaysia KPM.600-3/2/3-eras(8087). This study protocol was registered with ClinicalTrials.gov, ID number NCT05217394.

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**Conflict of Interest Statement**

The authors declared no potential conflicts of interest for the research and/or publication of this article. The authors report no declaration of interest. The authors declare that the research was conducted in the absence of any risk or harmful situation to the researchers and participants.

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**Patient and public involvement data**

During the progress and reporting of the submitted manuscript, Patient and Public Involvement in the research was included in the conduct of the research.

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