

ORIGINAL ARTICLE

Advisory Panel Review on the Feasibility of Three Intervention Programmes for Children with Autism Spectrum Disorder

Farahiyah Wan Yunus¹, Michelle Bissett², Stefania Penkala³, Muhammad Hibatullah Romli⁴, Karen P.Y Liu^{3,5}

¹ Centre for Rehabilitation and Special Needs, Occupational Therapy Programme, Faculty of Health Sciences, Universiti Kebangsaan Malaysia, Jalan Raja Muda Abdul Aziz, 50300 Kuala Lumpur, Malaysia.

² School of Allied Health Sciences, Gold Coast Campus, Griffith University. QLD 4222. Australia

³ Western Sydney University, School of Science and Health, Locked Bag 1797. Penrith NSW 2751, Australia

⁴ Department of Nursing & Rehabilitation, Faculty of Medicine and Health Sciences, Universiti Putra Malaysia, 43400 Serdang, Selangor, Malaysia

⁵ Western Sydney University, Translation Health Research Institute, Locked Bag 1797, Penrith NSW 2751, Australia

ABSTRACT

Introduction: The prevalence of children with autism spectrum disorder is increasing each year. Intervention programmes towards improving the occupational needs such as daily activities of these children are limited. This study aimed to collect opinions from advisory panel for the content validation of the three developed intervention programmes to be implemented among children with autism spectrum disorder aged between 6 to 12 years. The intervention programmes are; i) self-regulated learning, ii) sensory integration intervention and iii) activity-based intervention. **Methods:** A cross-sectional study was conducted. Twenty occupational therapists with more than three years' experience working with children with autism spectrum disorders were recruited as advisory panel members. Researchers-developed questionnaire was used. The questionnaire consists of nine to eleven items. Each item consists of a five-point Likert scale for quantitative responses and open-ended questions for qualitative responses. **Results:** Advisory panel ratings of 'Good' to 'Excellent' was reported across most items in all three intervention programmes. Overall results suggested that the intervention programmes content was rated to be suitable for children with autism spectrum disorder. Constructive comments were adopted to clarify the activities and structure of the intervention programmes. Final development of the intervention programmes is presented. **Conclusion:** This study provides confidence for the interventions to be incorporated into the future randomised controlled trial.

Keywords: Occupation-driven, Self-regulated learning, Sensory integration, Activity-based, Questionnaire

Corresponding Author:

Farahiyah Wan Yunus, PhD
Email: farahiyahwanyunus@ukm.edu.my
Tel: +603-92897609

INTRODUCTION

Autism Spectrum Disorder (ASD) is defined as having difficulties with social interactions and social communication, and restrictive and repetitive patterns of behaviours, interests or activities (1) that affect their performances in everyday lives. With the increase prevalence of children with ASD (2), it is essential to provide an effective intervention programme to overcome numerous problems related to these children and increase their performances in everyday activities.

Occupational therapy is a profession with a wide range of services to offer for children with ASD. The most common used of intervention for children with ASD includes behavioural intervention (3) sensory

integration and sensory-based intervention (4), activity-based intervention (4) and social skills and social communication training (5).

With the common used of intervention applied for children with ASD, it seems that intervention which emphasis on occupational-driven activities and cognitive approaches of activities remained limited. Occupation-driven activities is defined as interventions that are specifically focused on the purposeful activities of the person, which are goal directed and meaningful to the person (6). Cognitive approaches of intervention are applying techniques reflecting on one's thinking patterns and the connections between thoughts, feelings, and behaviours (7). This approach was found to show improvements in children's adaptive behaviours and social participation (8). However, most cognitive approaches of intervention were targeting social skills and suitable to be implemented for older children (8). According to Bandura (9), lack of cognitive control might prevent a person from modifying or inhibiting

their behaviour problems. Therefore, using a cognitive approach in children with ASD may stimulate their cognitive abilities to understand their own problems. Children with ASD in majority have good intellectual ability (10), therefore intervention using a cognitive approach focusing on the children’s occupational needs and suitable for younger children should be developed as an alternative intervention.

Three interventions were developed to address the needs of children with ASD, these are the i) sensory integration intervention (SI) as a commonly used intervention, ii) the activity-based intervention (AB) as a commonly used conventional occupational therapy intervention and iii) self-regulated learning (SRL) as a cognitive approach intervention emphasizing on occupation-driven activities. The process of participant enrolment and group allocation are shown in the CONSORT diagram (Figure 1).

Before the three interventions can be applied in practice, a feasibility study needs to be implemented first. A feasibility study needs to be conducted to ensure

the instruments used in the study are appropriate and interventions developed are safe and beneficial for the participants that can derived a desired outcome for research (11). Preliminarily, the SRL, SI and AB interventions were developed based on a review of literature. Therefore, the developed interventions are needed to be validated by advisory panel members to facilitate a planned randomised controlled trial in evaluating the effectiveness of the developed interventions. This process is essential to test the integrity of the study protocol for the future trial and determine the suitability of the intervention for children with ASD aged 6 to 12 years old (5, 12). Therefore, this study aimed to collect opinions from advisory panel for the content validation of the three developed intervention programmes to be implemented among children with autism spectrum disorder aged between 6 to 12 years.

MATERIALS AND METHODS

Study design of the advisory panel

The advisory panel members were recruited in a cross-sectional study design to assess the feasibility of the

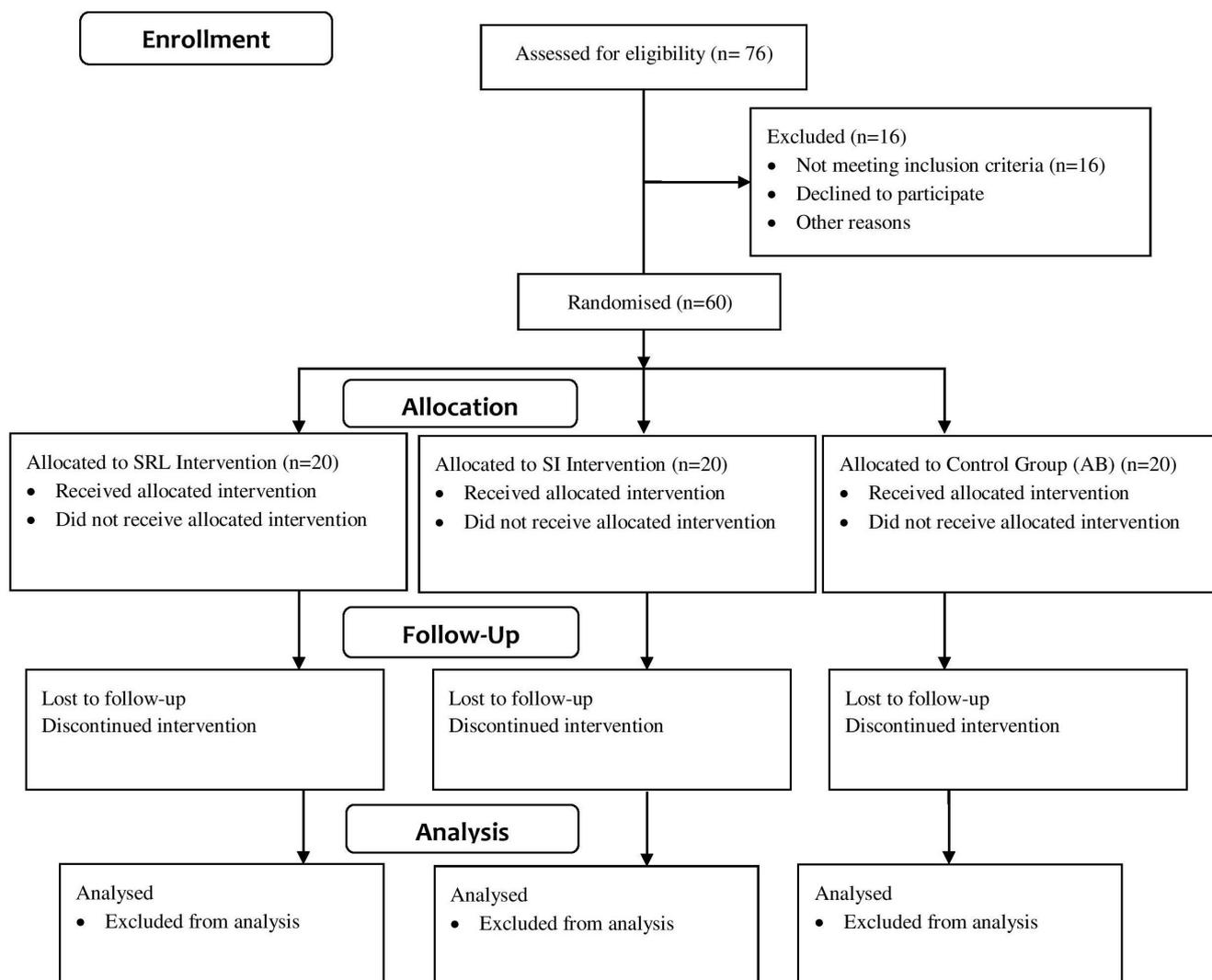


Figure 1: CONSORT flow diagram

three intervention programmes on children with ASD aged 6 to 12 years old. Recruiting an advisory panel is commonly conducted to establish agreement and provide solution for a topic with insufficient information or relatively new challenges (13). The method is relevant as decision is provided by individuals with similar interest and expertise. Therefore, the outcome is considered trustworthy and credible to be applied in practice. Ethical approval was obtained from the Western Sydney University Human Ethics Committee (H10816), the Economic Planning Unit of the Prime Minister's Department of Malaysia (UPE: 40I2OOI19/3128) and Universiti Kebangsaan Malaysia (NN-162-2014).

Participants and recruitment

Advisory panel members from Australia and Malaysia were purposively recruited by directly contacting experienced occupational therapists. Inclusion criteria included i) occupational therapists, and ii) have experience working with children with ASD. Advisory panel were excluded if they have less than three years of experience working with children with ASD. Consent was obtained prior to their participation in the study.

Intervention programs

Three intervention programs were developed to address the needs of children with ASD aged 6 to 12 years old. The SRL program was designed based on the approached originated from Bandura (9) social-cognitive theory. SRL involves self-monitoring and self-modification of one's behaviour (14). The intervention in the SRL program are more towards occupation-driven activities (e.g. daily activities, school tasks). The SI program was developed based on Ayres (15) theory in addition to Parham, Roley (16) 10 fidelity measures. The AB program was adapted from Pfeiffer and colleagues (17) study which included three main activities: i) construction, ii) drawing and iii) crafts. All three programs will be implemented in a 60-minute session per week for a total of 12 weeks' duration. The intervention protocol is described in Table I.

Questionnaire for advisory panel review

A questionnaire was developed to determine the feasibility of the interventions. The questionnaire was developed by the first and fifth author. There is no standard guideline to design and evaluate the

Table I: Protocol of the randomised controlled trial study

Design	Three-armed parallel randomised controlled trials
Randomisation	Computer generated randomisation table
Blinding	<ul style="list-style-type: none"> i) A clerical staff are responsible to allocate the clients into a randomisation table without knowing which intervention groups ii) Pre-evaluation is conducted randomly by accident by two research assistant with an occupational therapy background without knowing which participant in which group. There is no specific client on specific assessor iii) The post-evaluation is conducted randomly by accident by two research assistant with an occupational therapy background. There is no specific client on specific assessor iv) Only one therapist is responsible to one intervention group
Participants	Inclusion <ul style="list-style-type: none"> i) Aged 6 to 12 years ii) Diagnosed with ASD in accordance with the DSM-5 iii) Overall raw scores >10 on the maladaptive behaviour index in VABS-II iv) IQ ≥50 (moderate intellectual disability to normal intelligence)
	Exclusion <ul style="list-style-type: none"> i) Diagnosed with Asperger syndrome or any other pervasive developmental disability or dual diagnosis. ii) Children who did not attend school or were home schooled
	Recruitment <p>An initial advertisement about the study was distributed at the local centres and schools in Greater Kuala Lumpur area. All interested participants contacted the primary researcher and appointments were made at the location setting to screen the child's eligibility by the primary researcher. Study detail is explained in written and oral to the participants. Parents were asked to sign the consent form on behalf of their children. Once consent was obtained, the children were randomly allocated to one of the three interventions.</p>
Sample size	Sample size of 60 children – with 20 children per group (80% power, $\alpha \leq 0.05$, effect size of 5%,) with consideration on 15% dropout rate was calculated using G*power software (19) based on the clinical, meaningful self-regulation results from Liu and Chan (20)
Location and setting	One day-clinic of occupational therapy centre
Data collection point	i) Pre-intervention, ii) Post-intervention, iii) Follow-up after one month post- intervention
Outcome measurement	i) Vineland Adaptive Behaviour Scale 2nd Edition (VABS-2), ii) School Function Assessment (SFA), iii) Behaviour Rating Inventory of Executive Function (BRIEF), iv) Sensory Profile (SP), v) Sensory Processing Measure (SPM), vi) Walker-McConnell Scale (WMS)
Intervention procedure	Self-regulated learning <p>Client is shown a model video depicting a person performing one daily task. The child then performs the task while being recorded using a camcorder. Then, the recording is transferred to a laptop/tablet where both model and the child's video played simultaneously. The child needs to compare and recognize any mistake with the assistance of the therapist.</p>
	Sensory integration <p>Based on 10 fidelity measures of Sensory Integration (16) where the child is guided to a playful 8-stations of sensory challenging activities in a clinic environment. The activities involve physical activities rich on vestibular, tactile and proprioceptive stimulation.</p>
	Activity-based <p>The child performs regular therapy involving interactive table task activities with the therapist. Focused on three main activities; i) construction, ii) drawing and iii) crafts</p>
Duration of the intervention	Once a week for the duration of 12 weeks
Trial registry	NCT02496819
Funding	Western Sydney University HDR Candidature Support Funding, School of Science and Health
Ethics approval	Ethical approval was obtained from the Western Sydney University Human Ethics Committee (H10816), the Economic Planning Unit of the Prime Minister's Department of Malaysia (UPE: 40I2OOI19/3128) and Universiti Kebangsaan Malaysia (NN-162-2014).

feasibility studies from the literature (18). Therefore, the item generated for the questionnaire is based on the suggestion by Bowen and colleagues (18) which needs to focus on eight aspects: i) acceptability, ii) demand, iii) implementation, iv) practicality, v) adaptation, vi) integration, vii) expansion and viii) limited efficacy. The questions were tailored to suit the eight aspects without the needs to specify each of the aspect. After the initial development, the questionnaire was validated by all authors until consensus were reached.

Procedure

Each advisory panel member was invited to review one intervention programme. The intervention programme provided to the panel are the initial protocol developed of the intervention programmes. The assignment of interventions to panel members was random. The programme was mailed to the panel members with the corresponding review questionnaire. Each intervention programme has its separate questionnaire. The questionnaire contains seven sections on specific tasks/activities, durations, instructions, procedures and physical layouts. Advisory panel members were asked to rate the suitability of the intervention for children with ASD aged 6 to 12 years old on a five-point Likert scale (where 1 = poor, 2 = fair, 3 = good, 4 = very good and 5 = excellent). Open-ended feedback was also requested. After one month, the panel is contacted by the researcher via email and telephone as a reminder to return the completed questionnaire. If the panel have not completed the questionnaire, two weeks additional duration is given before the second reminder was given. The panel members were to return the completed questionnaire via a prepaid envelope provided.

Analyses

Data were analysed descriptively using frequencies (n) and percentages (%) for quantitative response. Internal consistency of the rating on each intervention group was analysed using Cronbach’s Alpha. The open-ended responses were synthesised narratively for the qualitative feedback.

Patient involvement

No patient was involved in any stages of this study; neither contributing ideas, designing the study, constructing the questionnaire, involves as a participant nor writing the manuscript.

RESULTS

In total, 20 occupational therapists from Australia and Malaysia reviewed the proposed SRL (n=7), SI (n=6) and AB (n=7) interventions. The demographic data of advisory panel members for each intervention programme is presented in Table II.

Quantitative findings

For the feasibility analysis, the Likert scale response

Table II: Demographic data of the advisory panel members

		Self-Regulated Learning (N=7) number (%)	Sensory Integration (N=6) number (%)	Activity-Based (N=7) number (%)
Gender	Male	-	-	1 (14.3)
	Female	7 (100)	6 (100)	6 (85.7)
Education level	Bachelor	2 (28.6)	5 (83.3)	6 (85.7)
	Master	5 (71.4)	1 (16.7)	1 (14.3)
Country	Australia	3 (37.5)	2 (25.0)	3 (37.5)
	Malaysia	4 (33.3)	4 (33.3)	4 (33.3)
Years of clinical experiences	3 to < 5 years	4 (57.1)	3 (50.0)	3 (42.9)
	5 to < 10 years	-	1 (16.7)	1 (14.2)
	10+ years	3 (42.9)	2 (33.3)	3 (42.9)
Working sector	Private	1 (14.3)	4 (66.7)	3 (42.9)
	Government	4 (57.1)	1 (16.7)	3 (42.9)
	University	1 (14.3)	1 (16.7)	-
	Not for profit	1 (14.3)	-	1 (14.3)

were collapsed from a 5-point to a 2-point scale for ease of analysis (21). The response of ‘1=poor’ and ‘2=fair’ was considered as ‘unfavourable’ response. A score of ‘3=good’, ‘4=very good’ and ‘5=excellent’ was considered as ‘favourable’. The ‘favourable’ responses on each question for each intervention programme are presented in Table III. All the three proposed interventions received over 70 percent of the ratings as ‘favourable’. However, a noticeable amount of ‘unfavourable’ ratings was provided in the SI intervention (34.4%).

The internal consistency of questionnaire response for SRL is $\alpha = 0.928$, for SI is $\alpha = 0.903$ and for AB is $\alpha = 0.848$. This indicates that the responses are strongly consistent for each question from all advisory panel members.

Qualitative findings

A review on written feedback was conducted. Several of the comments were addressed in order to improve the intervention programmes and to maintain the robustness of the future study. Summary of the significant qualitative findings on each intervention for further improvement were provided below and example of pertinent qualitative comments from the advisory panel is provided in Table IV.

Self-Regulated Learning

Some advisory panel members questioned the acceptability of the activities as appropriate interventions for the children as during the initial development of the intervention, 30 activities were included – some activities are more advanced for the age range of the children and some are less relevant for daily activities of the children. Several panel members requested for the steps of the activities to be broken down further.

Sensory Integration

Several panel members were concerned on how the

Table III: Percentage of ‘favourable’ response on the three developed interventions

Question	Intervention			
	Self-Regulated Learning (n=7)	Sensory Integration (n=6)	Activity-Based (n=7)	
General questions for all interventions				
Content of the intervention	Are the activities/interventions provided in the intervention program suitable for use with children with ASD between the ages of 6–12?	71.5%	100%	71.5%
	Are the activities/interventions provided in the intervention program suitable to be used for children with ASD with normal to moderate IQs?	71.5%	100%	85.7%
Duration of the intervention	Is the length of the intervention program appropriate?	71.5%	83.4%	100%
Instructions	Are the instructions provided clear and easy to understand?	71.5%	100%	100%
	Are the activity procedures for weeks 1–12 of the intervention program easy to follow and clearly stated?	100%	100%	71.5%
Physical layout	Is the physical layout of the intervention program appropriate?	100%	100%	100%
On specific intervention				
Self-Regulated Learning	Are the targeted tasks set in the intervention program appropriate?	71.5%	Not Applicable	Not Applicable
	Are the task steps appropriate for application in children with ASD aged 6–12 with normal to moderate intelligence?	100%	Not Applicable	Not Applicable
Sensory Integration	Does the intervention program meet the requirements of Parham’s et al. (2011) 10 fidelity measures of SI?	Not Applicable	66.6%	Not Applicable
	Is the composition of the intervention program appropriate?	Not Applicable	100%	Not Applicable
	Do the suggested activities meet with the proposed rationale?	Not Applicable	83.4%	Not Applicable

Table IV: Qualitative comments from the advisory panel members

Intervention	Selected pertinent qualitative response
Self-Regulated Learning	<p><i>“I am concerned whether these skills could be generalised to apply to a real-life context”.</i></p> <p><i>“May need to break down further and presented visually”.</i></p> <p><i>“Some activities are not suited to age group of 6-12 years; this all depends on how well the verbal and visual instructions are used”.</i></p>
Sensory Integration	<p><i>“The activities are age appropriate; however, the degree of structure runs the risk of the activity not being aligned with the SI approach”.</i></p> <p><i>“If the same activities are to be repeated for 12 weeks, children might get bored and the effectiveness will be reduced”.</i></p> <p><i>“This will provide sensory experiences, but it will be important to respond to the individual child’s responses to achieve a sensory integrative outcome”.</i></p> <p><i>“Needs to take note of the child’s health. For example, if the child has asthma, the 60-minutes intervention needs to be cut down or the child needs to take frequent breaks”.</i></p>
Activity-Based	<p><i>“I am concerned with the length of time required to sit at the table focused on these activities. Some of the craft items will need grading for younger or older participants’, these activities usually take longer”.</i></p> <p><i>“Not clear on the specific duration of stimulation”, or “Rating indicators needed to be clarified more” or “Need more explanation on the checklists”, or “Some tasks are practiced more than others”.</i></p> <p><i>“Be prepared that if the child is older, they may not want to do the craft activities as they may not be interested or exhibit sensory defensiveness to glue and messy play”</i></p> <p><i>“I do not see a link between these activities and a reduction of behavioural problems”.</i></p>

intervention fulfils the Ten Fidelity Measure of Sensory Integration framework and how to ensure the sensory experiences by the children is at ‘the right challenge’ as in the initial development of the SI intervention protocol, no specific description on each fidelity was provided in the manual. Duration and dosage of the SI intervention is also a concern among the panel as the initial development of the SI protocol proposed for the SI to be conducted in a full 60-minutes session, three times per week for 12 weeks.

Activity-Based

Common concern from the panel is about the efficacy of the intervention as the panel identified that the activities may be meaningful but may provide little to negligible therapeutic values to improve the performance of the children with ASD. Other comments on the activities included that some of the activities might bore the children due to lack of variety and are too simple. Initial development of the AB intervention is by therapist-driven on providing only one table-top activity for one

intervention session without the possibility to grading the intensity and challenges of the activities.

Final development of the intervention programmes

The initial intervention programmes were revised by addressing the comments made by the advisory panel.

Self-regulated learning

The activities described in the SRL were maintained and explicit descriptions of the activities were provided. To address the advisory panel's comments, the activities in the SRL were re-evaluated and they covered the major activities required for the children resulted to the final 15 occupation-driven activities (pick up rubbish and throw it in the rubbish bag; pour water in the water bottle for school; tidy up after play activity; organise pencil case for school; pack own lunchbox for school; organise backpack for school; clean up after meals; cut along lines using scissors; glue and paste on paper; place books on bookshelves; erase pencil marks from books; write letters between lines in a book; keep clothing cupboard tidy; make own sandwich for school; buy snacks from school canteen). With the SRL strategies used in these commonly performed activities, the intervention could possibly enhance the generalisation of skills learned necessary for their daily life. In the future study, generalisation of skills learned will be one of the objectives to be addressed.

The SRL intervention consists of nine steps; i) watch a video of the person completing a specific task, ii) name the steps involved in the task, iii) remember the steps, iv) perform the same task in a room while the performance in being videotaped, v) review own recorded performance and compare it with the original video to identify any errors vi) find appropriate solutions to identified errors, vii) perform the tasks again with identified solutions while the performance is being videotaped, viii) evaluate the effectiveness of the self-identified solution and ix) practice the rectified tasks performance.

Sensory integration

The eight developed activity stations were maintained. Eight stations of activities were provided to suit the needs of children with ASD (jumping on a trampoline; walking on a balance beam; searching items in a ball pool; throwing an item into a basket while balancing on a therapy ball; crawling in a tunnel; swinging on a swing; climbing stairs; sticking stickers on a chart at a table). Further refinement of the procedure was provided. The SI intervention programme now consisted of a 10-minute warm-up session for the children to explore the SI equipment. The children are encouraged to complete as many cycles as possible within 30 minutes—taking 15 minutes for each cycle, and a five-minute break between them. Afterwards, specific sensory stimulations are provided for a further five minutes. Cool down activities are conducted at the end of the session. All the interventions are monitored and

observed by the therapist to ensure that no injury occurs during the one-hour session for each child. An upgrade or downgrade of each intervention is initiated by the therapist to ensure that the activity performed in the SI intervention is suitable ('a just-right challenge') for each child's needs. To address the comments provided by the advisory panel, the intervention will be run by SI-trained therapist. Before and after every session, the activities will be reviewed and evaluated to align them with the 10 fidelity measure stated by Parham and colleagues (16). The SI intervention was developed based on the 10 fidelity measures of SI as described by Parham and colleague (16) (Table V).

Activity-based

Activities for the AB group were reviewed. The AB intervention was adapted from the study of Pfeiffer and colleagues (17). It focused on three main activities: i) construction (e.g. completing jigsaw puzzles; building shapes with Lego; using blocks and bricks to create shapes/buildings), ii) drawing (e.g. drawing with crayons and pencils; painting), and iii) crafts (e.g. using variety of materials to create an artwork). In order to cater for children with different functioning, therapist providing this intervention is given a variety of possible activities to choose for easy up- and down-grading. The programme consists of a 20-minute construction activity, a 15-minute drawing activity, a five-minute rest and a 20-minute craft activity. Frequent flexible free-activities are also provided during the session to minimise boredom. As the AB group is planned to be a control group, any effort of feedback to enhance its effectiveness is addressed at minimal.

DISCUSSION

The results of the feasibility study provided an important role towards the robustness of each of the intervention programmes. According to French and colleagues (22), the potential reasons for a varied unsuccessful management in an intervention is due to lack of feasibility testing of the proposed intervention. Lack of testing in an intervention may lead to the intervention being inapplicable, not practical, not addressing the needs of the practitioners and clients, and not feasible for real-life implementation and practice (5, 12). Moreover, lack of fidelity may result in an inappropriate use of instruments failing to measure the changes in the outcome. As indicated in this study, feasibility studies provided an opportunity to identify any practical problems and enable researchers to rectify the issue and refine the research protocol ensuring methodological rigor and scientific validity (23, 24). Therefore, this feasibility study is used to estimate the important parameters that are needed to design a primary randomised controlled trial study and explicitly described the intervention for practice.

van Teijlengen and Hundley (24) stated the majority

Table V: The SI intervention addressing Parham's et al. (2011) 10 fidelity measures

10 fidelity measures	Description
Ensuring physical safety by ensuring that the child is safe throughout the intervention.	The therapist will observe and supervise the children to ensure physical safety throughout the activities. Any injury or accident that occurs during the sessions will be reported immediately by the therapist to the attendant and therapist in charge
Providing sensory opportunities by presenting various experiences of more than one sensory modality (e.g., tactile, vestibular and/or proprioceptive).	Intervention design providing various sensory experiences of tactile, proprioceptive and vestibular stimulations
Providing 'just-right challenges' by choosing activities that are neither too difficult nor too easy.	All the activities will be upgraded and downgraded to provide 'just right challenges' based on the children's capabilities
Collaborating when making activity choices	The intervention begins with a warm-up activity for the children to explore the sensory integration room/equipment for 10 minutes' duration. Therapist encourages the children to be part in decision making of each activity at the eight stations where sequences, equipment, materials is determined by the child and negotiated with the therapists
Challenges postural, ocular, oral or bilateral motor control	Therapist supports and challenges the child's postural, ocular, oral or bilateral motor control. A 30 minutes' duration will be given to the child to ensure the challenges are fulfilled.
Supporting optimal arousal by providing changes in the environment or activities to support the level of the child's alertness	The therapist will need to ensure that the activities create fun while helping to attain and maintain level of alertness and an affective state supporting engagement and comfort in the activities
Challenges praxis and organization of behaviour	The intervention will provide challenges to the child's ability to conceptualised and plan own motor tasks using tactile, proprioceptive and vestibular stimulations in addition organization of own child's behaviour in time and space will be supported by the therapist
Ensuring successful activities	All the activities will be modified based on the children's experience to success involving response to challenge (sensory modulation or discrimination; postural, ocular or oral control; or praxis)
Supporting intrinsic motivation to play	The room will be arranged to ensure play in fully utilised by the child
Fostering therapeutic alliance by respecting the child's emotions, conveying positive regard and being connected with the child to gain the child's trust.	Therapist builds a connection with the child in an enjoyable friendship. Therapist work together with the child in achieving one or more goals. Encouragement, prompting and motivation will be given by the therapist to the children throughout the session

of the pilot and feasibility studies provide a simple conclusion on justification of the instruments or methods selected. In addition, many pilot and feasibility studies vaguely comments "had learnt from the pilot study and made the necessary changes" (p.36) but failed to provide the detail on what had been learnt. This feasibility study indicated new interventions are open to comments and can be improved. The SRL approach is different to what is currently being applied in practice. Therefore, new intervention such as the SRL requires clear explanation to provide good understanding to the practitioners. Additional information was provided on the relevancy of the chosen tasks, breakdown of the intervention session (i.e. watch the video, recording session, replay session, precaution measure – rest) and provide clear instructions to assist therapists with running the intervention.

Established interventions were also critiqued for improvement. Although the SI intervention programme received 'favourable' ratings on almost every question, queries were raised on whether the intervention could fulfil the 10 fidelity measure of Parham et al. (16). These limitations were constantly voiced in other studies related to SI intervention (17, 25-27). Following the concerns from the advisory panel members, an objective and description regarding how the SI intervention addresses the 10 components of the fidelity measure are described. Changes were also made in relation to the repetition of activities. This was addressed by including a detailed description of the modifications of the activities to ensure that every child would be provided with 'just-

right-challenge'. These modifications enhanced the robustness of the SI intervention programme.

The majority of the advisory panel members perceived the activities in the AB intervention were relevant but questioned the efficacy of the AB in relation to the research objectives. This outcome was expected as the advisory panel members were blinded to which group was the intervention and which was the control. This indicated that the AB programme was a suitable control group. A good control group should provide a sham intervention to prevent any improvement that can be devoted toward placebo effect and has not enough therapeutic value to provide significant improvement, and using active placebo intervention as a control group is more ethical than no treatment (28). Therefore, the developed AB programme fulfils these criteria.

The evidence of most aspects receiving a 'favourable' rating overall indicates that the interventions are relevant to be applied for future study. This has increased the confidence for conducting future research (29). Validation and positive response received from the advisory panel ratings from Australia and Malaysia confirmed that all three intervention programmes have potential to be generalised for international use.

This feasibility study is limited to validating the intervention programmes and the research design from the perspective of advisory panel. Further studies are required to observe the practice application of

the intervention and the use of instruments in the real setting (12, 23, 24). A separate study investigating the application and validity of some of the instruments used in this study has been published elsewhere (30). A study investigating the acceptance of the interventions among other stakeholders such as the children with ASD, parents, teachers and other allied health professionals is desirable.

CONCLUSION

This feasibility study provides support for three developed intervention programmes to be incorporated into a full clinical trial. Outcomes from this feasibility study enhances the acceptance and robustness of the intervention. Success of an intervention study depends on the ability to minimise challenges when conducting the full trial. Therefore, this study is hoped to provide a guideline of how occupational therapy intervention can be conducted in the future.

ACKNOWLEDGEMENTS

The authors would like to thanks participants, parents and therapists on the feedback for this protocol. This work was supported by the Western Sydney University HDR Candidature Support Funding, School of Science and Health.

REFERENCES

- American Psychiatric Association. Diagnostic and statistical manual of mental disorders. 5th ed. Washington DC: American Psychiatric Association; 2013.
- Centre of Disease Control. Prevalence of autism spectrum disorders, Autism and Developmental Disabilities Monitoring Network, 11 sites, United States (2010). *MMWR Surveillance Summary*. 2014;63(2):1-21.
- Devlin S, Healy O, Leader G, Hughes BM. Comparison of behavioural intervention and sensory-integration therapy in the treatment of challenging behavior. *J Autism Dev Disord*. 2011;41(10):1303-20. doi:10.1007/s10803-010-1149-x
- Case-Smith J, Arbesman M. Evidence-based review of interventions for autism used in or of relevance to occupational therapy. *Am J Occup Ther*. 2008;62(4):416-29. doi: 10.5014/ajot.62.4.416
- Tanner K, Hand BN, O'Toole G, Lane AE. Effectiveness of interventions to improve social participation, play, leisure, and restricted and repetitive behaviors in people with autism spectrum disorder: A systematic review. *Am J Occup Ther*. 2015;69(5):6905180010p1-p12. doi:10.5014/ajot.2015.017806
- McHugh-Pendleton H, Schultz-Krohn W. Pedretti's occupational therapy: Practice skills for physical dysfunction. 7th ed. St Louis, Missouri: Elsevier; 2013.
- Corcoran J. Building strengths and skills: a collaborative approach to working with clients. Oxford, UK: Oxford University Press; 2004.
- Gevers C, Clifford P, Mager M, Boer F. Brief report: A theory-of-mind-based social-cognition training program for school-aged children with pervasive developmental disorders: An open study of its effectiveness. *J Autism Dev Disord*. 2006;36:567-71. doi:10.1007/s10803-006-0095-0
- Bandura A. Social foundations of thought and action: A social-cognitive theory Englewood Cliffs, NJ: Prentice-Hall; 1986.
- Crespi BJ. Autism as a disorder of high intelligence. *Front Neurosci*. 2016;10:1-17. doi: 10.3389/fnins.2016.00300
- Arain M, Campbell MJ, Cooper CL, Lancaster GA. What is a pilot or feasibility study? A review of current practice and editorial policy. *BMC Med Res Methodol*. 2010;10(67):1-7. doi: 10.1186/1471-2288-10-67
- Lancaster GA, Dodd S, Williamson PR. Design and analysis of pilot studies: recommendations for good practice. *J Eval Clin Pract*. 2004;10(2):307-12. doi: 10.1111/j.2002.384.doc.x
- Fink A, Kosecoff J, Chassin M, Brook RH. Consensus methods: Characteristics and guideline for use. *Am J Public Health Res*. 1984;74(9):979-83. doi: 10.2105/ajph.74.9.979
- Dinsmore DL, Alexander PA, Loughlin SM. Focusing the conceptual lens on metacognition, self-regulation, and self-regulated learning. *Educ Psychol Rev*. 2008;20(4):391-409. doi: 10.1007/s10648-008-9083-6
- Ayres AJ. Sensory integration and learning disorders. edition s, editor. Los Angeles, CA: Western Psychological Services; 1972.
- Parham LD, Roley SS, May-Benson TA, Brett-Green B, Burke JP et al. Development of a fidelity measures for research on the effectiveness of the Ayres Sensory Integration Intervention. *Am J Occup Ther*. 2011;65:133-142. doi: 10.5014/ajot.2011.000745
- Pfeiffer BA, Koenig KP, Kinnealey M, Sheppard MC, Henderson L. Effectiveness of sensory integration interventions in children with autism spectrum disorders: a pilot study. *Am J Occup Ther*. 2011;65(1):76-85. doi: 10.5014/ajot.2011.09205
- Bowen DJ, Kreuter M, Spring B, et al. How we design feasibility studies. *Am J Prev Med*. 2009;36(5):452-457. doi:10.1016/j.amepre.2009.02.002
- Faul F, Erdfelder E, Buchner A, et al. Statistical power analyses using G*Power 3.1: Tests for correlation and regression analyses. *Behav Res Methods*. 2009;41:1149-60. doi: 10.3758/BRM.41.4.1149
- Liu KPY, Chan CCH. A pilot randomized controlled trial of self-regulation in promoting function in acute post-stroke patients. *Arch Phys Med*. 2014;95:1262-67. doi: 10.1016/j.apmr.2014.03.018

21. Grimbeek P, Bryer F, Beamish W, D'Netto M. Use of data collapsing strategies to identify latent variables in CHP questionnaire data. Stimulating the "action" as participants in participatory. Griffith University; 2005 [cited 2018 December 18]. Available from: <http://hdl.handle.net/10072/2534>
22. French CT, Diekemper RL, Irwin RS. Assessment of intervention fidelity and recommendations for researchers conducting studies on the diagnosis and treatment of chronic cough in the adult: CHEST guideline and expert panel report. *Chest*. 2015;148(1):32-54. doi:10.1378/chest.15-0164
23. Feeley N, Cossette S, Cote J, Heon M, Stremler R, Martorella G, et al. The importance of piloting an RCT intervention. *Can. J. Nurs. Res.* 2009;41(2):85-99.
24. van Teijlingen E, Hundley V. The importance of pilot study. *Nurs Stand*. 2002;16(40):33-6. doi:10.7748/ns2002.06.16.40.33.c3214
25. Barton EE, Reichow B, Schnitz A, Smith IC, Sherlock D. A systematic review of sensory-based treatments for children with disabilities. *Res Dev Disabil*. 2015;37:64-80. doi: 10.1016/j.ridd.2014.11.006
26. May-Benson TA, Koomar JA. Systematic review of the research evidence examining the effectiveness of interventions using a sensory integrative approach for children. *Am J Occup Ther*. 2010;64(3):403-14. doi: 10.5014/ajot.2010.09071
27. Watling R, Hauer S. Effectiveness of Ayres Sensory Integration® and sensory-based interventions for people with autism spectrum disorder: a systematic review. *Am J Occup Ther*. 2015;69(5):6905180030p1-p12. doi:10.5014/ajot.2015.018051
28. Temple R, Ellenberg SS. Placebo-controlled trials and active-control trials in the evaluation of new treatments. part 1: Ethical and scientific issues. *Ann. Intern. Med.* 2000;133(6):455-63. doi: 10.7326/0003-4819-133-6-200009190-00014
29. Simkhada P, Bhatta P, Teijlingen ER. Importance of piloting a questionnaire on sexual health research. *Wilderness Environ Med*. 2006;17:295-6. doi:10.1580/1080-6032(2006)17[295:IOPAQO]2.0.CO;2
30. Wan Yunus F, Bissett M, Penkala S, Kadar M, Liu K. Malaysian parents' feedback on three proxy-rated assessments used in pediatric rehabilitation. *Mal J Public Health Med*. 2018;18:64-9.