Study Protocol

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Protocol Title: Transfer effects of dual n-back training in children and adolescents with autism spectrum disorder: a randomized controlled trial

Summary:
Autism spectrum disorders are characterized by executive dysfunction, which is contributing to ASD symptomatology and social skill. Working memory comprises one core component of executive function and recent evidence shows that working memory is impaired in individuals with ASD and interventions related working memory may have implications in these individuals. Working memory training in children and adolescents with ASD demonstrates evidence in improving executive functions and social communication. Dual n-back task as a frequently used computerized cognitive training in research, involves both spatial and verbal WM with combination of maintenance and manipulation. Training-related improvement has been reported in untrained WM tasks, fluid intelligence and emotional cognitive control in healthy individuals. However, the evidence of the effects of dual n-back training in ASD individuals remains unclear. The objective of this study is to investigate the near and far transfer effects of dual n-back training in children and adolescents with autism spectrum disorder.

Backgrounds:

Autism Spectrum Disorder: an overview
Autism Spectrum Disorder (ASD) is a complex neurodevelopmental disorder characterized by persistent challenges in social communication and interaction, as well as restricted and repetitive patterns of behavior, interests, or activities. It is diagnosed based on a range of symptoms that manifest across different developmental domains. The prevalence of ASD has been steadily increasing, with recent estimates indicating 1.4% children are diagnosed with ASD in Hong Kong.

ASD is a heterogeneous condition, meaning that individuals with this disorder can display a wide range of abilities, challenges, and clinical presentations. Individuals with ASD often face difficulties in various aspects of social communication. They may struggle with understanding and using verbal and nonverbal communication cues, such as gestures, facial expressions, and tone of voice. Challenges in social interactions can include difficulties with initiating and maintaining conversations, sharing interests or emotions, and understanding social norms and expectations. Restricted and repetitive behaviors and interests are another hallmark feature of ASD. Individuals with ASD may display repetitive movements (e.g., hand flapping, rocking), adherence to strict routines or rituals, intense fixations on specific topics or objects, and resistance to changes in their environment. Sensory sensitivities, such as being overly sensitive or under-responsive to sensory stimuli (e.g., sound, touch), are also common in individuals with ASD.

Cognitive functioning in ASD varies widely, ranging from intellectual disability to above-average intelligence. Many individuals with ASD exhibit executive function deficits, which refer to a set of cognitive processes responsible for goal-directed behavior and

self-regulation. Executive function impairments can manifest as difficulties in planning, organizing, inhibitory control, cognitive flexibility, and problem-solving.

The impact of ASD extends beyond the core symptoms, affecting various aspects of an individual's life. Challenges in social communication and interaction can lead to difficulties in forming and maintaining relationships, participating in social activities, and adapting to new social situations. Individuals with ASD may also experience academic and learning difficulties, requiring specialized educational support tailored to their unique needs.

Understanding the complexities of ASD is essential for providing effective interventions and support for individuals with this disorder. Early diagnosis and intervention can help optimize outcomes and enhance the quality of life for individuals with ASD.

Executive function deficit in Autism Spectrum Disorder

Executive function deficit in individuals with Autism Spectrum Disorder (ASD) has been a topic of extensive research and investigation. Recent studies aim to analyze executive function performance in individuals with ASD, explore the fractionation of executive function subdomains, evaluate the clinical utility of executive function measures, and examine the influence of various moderators.

The meta-analysis of fMRI studies by Demetriou et al. (2020) included 235 studies comprising 14,081 participants. The results indicated a moderate overall effect size for reduced executive function in ASD, with similar effect sizes observed across each executive function domain. The findings suggest that individuals with ASD exhibit broad executive dysfunction that remains relatively stable across development. Another meta-analysis by Demetriou et al. (2018) focused on executive function in ASD and included studies published between 1980 and 2016. The analysis encompassed a wide range of executive function subdomains and explored the influence of moderators such as age, gender, diagnosis, and measure characteristics. The results demonstrated a moderate effect size for executive dysfunction in ASD, indicating impairments in goal-directed behavior, abstract reasoning, decision making, and social regulation.

Overall, these studies provide important evidence for the presence of executive function deficits in individuals with ASD. The findings support the notion that executive dysfunction plays a significant role in the core behaviors and impairments associated with ASD, including social communication, social cognition, and restricted and repetitive patterns of behavior. The research suggests that executive dysfunction in ASD is not limited to a specific cognitive domain but rather encompasses a broad range of executive processes.

Working memory impairment in Autism Spectrum Disorder

Working Memory Impairment in Autism Spectrum Disorder (ASD) is a topic of significant research interest, as it has implications for understanding the cognitive profile and daily functioning of individuals with ASD. The meta-analysis conducted by Wang et al. (2017) and Habib, Harris, Pollick, and Melville (2019) aimed to determine the extent of working memory impairments in individuals with ASD and identify specific domains of working memory that are affected.

The findings of the meta-analyses indicated that individuals with ASD demonstrate significant impairments in working memory across both phonological and visuospatial domains when compared to typically developed individuals. The results showed that working memory scores were consistently lower for individuals with ASD compared to typically developed controls. The effect size (Cohen's d) was estimated to be -0.61, indicating a moderate impairment in working memory abilities.

In the visuospatial domain, both accuracy and error rates were found to be significantly impaired in individuals with ASD. Similarly, in the phonological domain, accuracy showed impairments, although the difference was not statistically significant. However, error rates were significantly higher in individuals with ASD, indicating difficulties in maintaining and manipulating phonological information.

The meta-analyses also explored potential moderators such as age and intelligence quotient (IQ). Interestingly, age and IQ did not explain the differences in working memory impairments in individuals with ASD. This suggests that working memory deficits are present across the lifespan and are not solely attributable to variations in age or intellectual abilities.

The implications of working memory impairments in ASD are significant. Working memory plays a crucial role in various cognitive processes, such as language comprehension, reasoning, problem-solving, and social interactions. Therefore, the observed impairments in working memory can have a profound impact on the daily functioning and quality of life of individuals with ASD.

Working memory training: methods and implications

Working memory training is a topic of great interest in cognitive neuroscience and psychology, as it holds promise for enhancing cognitive abilities and potentially aiding in the rehabilitation of cognitive deficits. The below research papers provide valuable insights into different aspects of working memory training, including its effects on neural activation patterns, cognitive performance, and potential applications for specific populations.

Redick et al. (2020) conducted a meta-analysis of working memory training studies that examined transfer to other measures such as nonverbal ability, verbal ability, word decoding, reading comprehension, and arithmetic. The results showed that while there were immediate improvements on measures of intermediate transfer, there was no convincing evidence of reliable improvements on measures of far transfer. While the study suggests that working memory training has limited effects on broader cognitive skills and intelligence, it is important to note that there may be individual differences in response to training. Some individuals may benefit more from working memory training than others, depending on factors such as baseline working memory capacity, age, and specific cognitive demands.

A research conducted by Li, et al. (2019) focused on the potential benefits of working memory training for individuals with schizophrenia. The authors investigated the effects of training on cognitive performance and found that working memory training led to significant improvements in working memory capacity and executive functions in schizophrenia patients. These findings suggest that working memory training may serve as a promising intervention for cognitive remediation in individuals with schizophrenia.

Furthermore, the papers on working memory training in the context of anhedonia (Li, et al., 2016) and cognitive rehabilitation in schizophrenia patients (Li, al, 2019) shed light on the potential applications of working memory training in specific clinical populations. These studies suggest that working memory training may have positive effects on cognitive functioning and potentially contribute to the treatment and management of cognitive impairments associated with these disorders.

A meta-analysis conducted by Li et al. (2015) employed an activation likelihood estimation (ALE) meta-analysis to examine the neural changes associated with working memory training in healthy volunteers and patients with schizophrenia. The results demonstrated widespread distribution of activation changes in the frontal and parietal regions, indicating the engagement of the dorsolateral prefrontal cortex, medial frontal cortex, and precuneus during working memory tasks. These findings provide a better understanding of the neuroplastic changes that occur as a result of working memory training.

Additionally, Dentz et al. (2017) investigated the effects of working memory training specifically in adults with ADHD. The study found that working memory training led to improvements in working memory capacity and attentional control in this population. These findings highlight the potential benefits of working memory training as a targeted intervention for individuals with ADHD.

While some studies provide a nuanced perspective, highlighting the limited transfer effects to other cognitive domains, some studies demonstrate the potential benefits of working memory training in terms of neural activation changes, cognitive performance improvements, and cognitive rehabilitation. Further research exploring individual differences in response to training is needed.

Working memory training in children

Working memory training in children has been a topic of significant research interest, as it has the potential to improve cognitive performance and enhance various cognitive skills. Several studies have investigated the effects of working memory training in typically developing children and those with specific cognitive impairments. Most showed improvement in working memory after training in this population.

A study (Jones, Adlam, Benattayallah, & Milton, 2022) investigated the underlying neural mechanisms of working memory training in typically developing children. The study used magnetic resonance imaging (MRI) to examine the structural and functional changes in the brain following working memory training. The findings revealed increased intrinsic functional connectivity between brain regions involved in working memory tasks, suggesting that repeated engagement of fronto-parietal regions during training may enhance their activity and functional connectivity over time, leading to improved working memory performance.

A meta-analysis (Sala, G., & Gobet, F.,2020) examined the overall impact of working memory training on typically developing children. The findings revealed that working memory training had a positive effect on cognitive performance in untrained tasks. This suggests that working memory training can lead to generalized improvements in cognitive abilities beyond the specific tasks trained. A randomized controlled trial (Roording-Ragetlie et al., 2019) focused on children with borderline intellectual functioning and neuropsychiatric disorders.

The study found that working memory training had a significant positive impact on cognitive performance in these children, highlighting its potential as an intervention for improving cognitive functioning in clinical populations. Furthermore, another randomized control trial (Roque-Gutierrez & Ibbotson, 2023) investigated the relationship between working memory training and syntactic ability in children. The results showed that working memory training led to improvements in syntactic ability, suggesting a specific link between working memory and language processing skills in children.

However, a study (Liu et al., 2023) explored the transfer effects of working memory training on inhibitory control in primary school children. The study found that working memory training had specific effects on improving working memory capacity but did not significantly enhance inhibitory control skills.

Overall, these studies collectively indicate that working memory training in children can have positive effects on cognitive performance in children across various domains, including language processing, cognitive abilities in clinical populations, and specific cognitive functions such as inhibitory control.

Working memory training in Autism Spectrum Disorder

Regarding working memory training in individuals with Autism Spectrum Disorder (ASD), several studies have explored the efficacy of different interventions aimed at improving working memory performance in children and adolescents with ASD. One such study is the systematic review and meta-analysis conducted by Cavalli et al. (2022) titled "The efficacy of executive function interventions in children with autism spectrum disorder: a systematic review and meta-analysis."

The review by Cavalli et al. examined various interventions targeting executive function (EF) in individuals with ASD, including working memory training. The review highlighted different approaches used in working memory training for individuals with ASD. Computer-based interventions, cognitive-behavioral therapy, and assisted-animal therapy were among the main approaches identified. Of particular interest, statistically significant results were found in the use of exergames as an intervention for working memory improvement in children with ASD.

Furthermore, a randomized controlled trial conducted by a different research team (de Vries, Prins, Schmand, & Geurts, 2015) investigated the effectiveness of working memory and cognitive flexibility training in children with ASD. The study found that the training interventions led to significant improvements in working memory and cognitive flexibility skills in children with ASD.

Additionally, another randomized controlled trial (Roording-Ragetlie et al., 2023) explored the impact of working memory training on children with neurodevelopmental disorders and intellectual disabilities. Although this study did not solely focus on ASD, it provided valuable insights into the potential benefits of working memory training in a population with overlapping cognitive challenges. The results showed that working memory training, with the support of coaching, resulted in significant improvements in working memory performance in the intervention group compared to the control group.

Overall, the research papers reviewed indicate that working memory training interventions can be effective in improving working memory performance in individuals with ASD. The findings suggest that various approaches, such as computer-based interventions and exergames, can be utilized to target working memory deficits in this population. These interventions have the potential to positively impact working memory, behavior, and flexibility, contributing to improved cognitive functioning and overall adaptive skills in individuals with ASD.

Dual n-back task

The dual n-back task is a cognitive training method that has gained attention in research studies focused on enhancing working memory and fluid intelligence in healthy adults. The task involves responding to visual and/or auditory stimuli that match stimuli presented "n" presentations prior. Several studies have investigated the effects of dual n-back training on cognitive performance and its potential for transfer to other tasks.

In a randomized controlled trial by Lawlor-Savage and Goghari (2016), the researchers compared the effects of dual n-back training to processing speed training in healthy adults aged 30-60. The results indicated that there were no significant improvements in working memory, processing speed, or fluid intelligence after the training period. However, in a meta-analysis conducted by Au et al. (2017) aggregated data from 20 n-back training studies and found a small but statistically significant overall effect of n-back training on working memory performance. However, the transfer to other cognitive domains, such as fluid intelligence, was inconsistent across studies.

These findings highlight the need for further investigation into the efficacy of dual n-back training and its potential benefits for different populations. It is worth noting that methodological inconsistencies, such as small sample sizes, variations in control groups, and differences in training settings, may have contributed to the mixed results observed in the literature. In order to fully understand the impact of dual n-back training, additional factors should be considered. A study by Lawlor-Savage and Goghari (2016) suggested that the effectiveness of working memory training might depend on individual factors such as emotional vulnerability and perceived cognitive impact. Therefore, it is important to explore the moderating roles of such factors in the context of cognitive training interventions.

The clinical utility of the Dual n-back task in schizophrenia has been explored in a study conducted by Xu et al. (2021). They used functional magnetic resonance imaging (fMRI) to investigate the neural correlates of WM impairments in schizophrenia patients during the Dual n-back task. The results revealed significant positive correlations between performance in the Dual 2-back condition and another measure of WM capacity and IQ estimates.These findings support the clinical relevance of the Dual n-back task in assessing WM impairments in schizophrenia and suggest potential implications for cognitive training interventions targeting the neural substrates associated with WM deficits in this population.

A research paper (Salmi et al., 2020) investigated the effects of dual n-back task-based working memory (WM) training on adults with ADHD. The study used fMRI to assess brain activity during the task and found aberrant patterns in ADHD individuals. WM training led to a redistribution of brain activity, partially restoring the aberrant patterns. The findings

highlight the potential of WM training using the dual n-back task to improve cognitive functioning in adults with ADHD.

In conclusion, while the dual n-back task has shown promise in enhancing working memory performance in some studies, the evidence for its transfer effects to other cognitive domains, such as fluid intelligence, is inconclusive. Further research is needed to clarify the potential benefits of dual n-back training in different clinical populations and to identify the factors that may influence its effectiveness.

Towards current study

Building upon the existing literature on dual n-back working memory training, the current study aims to investigate the effects of this training method on a specific population. While previous research has explored the impact of dual n-back training on healthy adults, individuals with attention-deficit hyperactivity disorder (ADHD) and individuals with schizophrenia, and the moderating roles of emotional vulnerability and perceived cognitive impact, there is still a need to examine its effects in a different context.

The current study seeks to fill this gap by examining the effects of dual n-back working memory training on children and adolescents with Autism Spectrum Disorder. By focusing on a specific population, the study aims to provide targeted insights into the potential benefits and limitations of dual n-back training for this particular group.

Objectives:

Primary objective

1. To examine the impact of dual n-back training on near transfer effect on working memory performance in children and adolescents with ASD.

Secondary objective

1. To assess the far transfer effects of dual n-back training on cognitive functioning in children and adolescents with ASD.
2. To investigate the long-term maintenance of any observed training effects in the follow-up period after the completion of the dual n-back intervention.
3. To explore potential moderators and mediators of the training effects in children and adolescents with ASD.

Null hypothesis in this study

There will be no significant impact of dual n-back training on near transfer effect on working memory performance in children and adolescents with ASD.

Methods:

Study design

The study will employ a randomized controlled trial (RCT) design following the CONSORT guideline to investigate the impact of dual n-back training on children and adolescents with Autism Spectrum Disorder (ASD). Participants will be randomly assigned to either the intervention group, which will receive the dual n-back training (2-back task), or an active

control group, which will receive an alternative intervention (0-back task) for 2 weeks. Data obtained at baseline, immediately after intervention and 3-month post intervention will be analyzed for any transfer effects of the intervention.

Randomization

Participants will be randomly assigned to either the intervention group or the control group using a computer-generated randomization sequence. The randomization process will be conducted by a researcher who is not directly involved in the assessment or intervention.

Blinding

To ensure objectivity of the study results, a double-blind procedure will be implemented. Both participants and outcome assessors will be blinded to the group assignments. The computer-based training program will be identical in appearance and interface for both groups, differing only the cognitive load for the tasks. This approach will prevent bias in reporting and assessing the outcomes of the study.

Subject selection and recruitment

Participants will be recruited from the child and adolescent psychiatric out-patient clinic of Queen Mary Hospital. Informed consent will be obtained.

Inclusion criteria:

1. Age range of 10-15 years;
2. Diagnosis of DSM-V ASD, or DSM-IV Asperger's syndrome or ICD-10 Childhood autism, atypical autism or Asperger syndrome;

Exclusion criteria:

1. Diagnosed with comorbid active mood or psychotic disorder;
2. Diagnosed with mental retardation;
3. Visual or hearing impairment;
4. Serious medical illness;
5. Substance misuse in the past 6 months

Diagnostic tool

Developmental, Dimensional, and Diagnostic Interview

3di is a comprehensive, semi-structured interview used for assessing autism spectrum disorders (ASD) in children and adolescents. It covers a broad range of developmental domains and provides a dimensional assessment of ASD-related symptoms. The 3di incorporates diagnostic criteria from various classification systems and assesses social communication, repetitive behaviors, and restricted interests. It is administered by trained clinicians to gather detailed information about an individual's developmental history and current functioning, aiding in the accurate diagnosis and characterization of ASD.

Conners Rating Scale

Conners 3-P is a comprehensive assessment tool that measures ADHD symptoms and associated behavioral difficulties in children and adolescents aged 6 to 18 years, which is completed by parents. The Conners 3-P assesses a wide range of domains, including inattention, hyperactivity/impulsivity, executive functioning, learning problems, aggression, and emotional distress.

Trial Intervention

Dual n-back training is a cognitive training task designed to specifically target and improve working memory abilities. It has been utilized in research studies and has shown promising results in enhancing working memory performance in children and adolescents.

During the dual n-back training, participants will engage in a computer-based task that requires them to simultaneously remember and recall two different types of stimuli, including spatial and auditory stimuli. The training sessions will be conducted on a daily basis for 2 consecutive weeks. Each training session would involve five blocks with a 10+n trial in each block. The 2-back task would be utilized as the experiment intervention while the 0-back task would be the control group.

To monitor participants' compliance with the dual n-back training, the computerized program will include a built-in usage log. This log will track participants' engagement with the training, including the frequency and duration of the training sessions. Reminders will be given to participants with low log time to enhance compliance. Additionally, parents or guardians will be asked to report on their child's compliance, providing additional information on adherence to the training protocol.

Psychometric measurements

Dual N-back Task

Digit Span Test

The Digit Span Test is a cognitive assessment tool used to measure an individual's WM capacity. It involves the repetition and recall of a series of digits in either forward or backward order. In the forward version, the individual repeats the digits in the same sequence presented. In the backward version, the individual recalls the digits in reverse order. The test provides insights into an individual's ability to temporarily store and manipulate information, which is important for various cognitive processes.

Operation Span Task

This task combines WM and arithmetic operations. Participants are presented with a series of math equations and simultaneously asked to remember a series of unrelated words. They must solve the math equations while recalling the words in the correct order. It assesses the individual's ability to maintain and manipulate information in both verbal and numerical WM domains.

Corsi Block Tapping Test

In this task, participants are presented with a sequence of blocks that light up in a specific order. They are then asked to reproduce the same sequence by tapping the blocks in the correct order. This test assesses spatial WM and the individual's ability to remember and manipulate spatial information.

Sternberg Test

A cognitive psychology experiment used to measure WM capacity. In this test, participants are presented with a list of items to remember for a short period. Following this, a single item is presented, and participants must indicate whether this item was part of the original list. The test assesses the speed and accuracy of information retrieval from working memory.

Go No-Go Test

A cognitive assessment tool that measures response inhibition and impulsivity. In this test, participants are required to respond to certain stimuli (Go stimuli) while refraining from responding to others (No-Go stimuli). The test evaluates an individual's ability to inhibit prepotent responses and maintain focus on relevant tasks.

Tower of London

A neuropsychological assessment used to measure executive functioning, specifically planning and problem-solving skills. In this task, participants are presented with a board containing a configuration of colored balls on three pegs. The goal is to rearrange the balls to match a specified target configuration using the fewest possible moves. This test provides insights into an individual's ability to plan ahead, think strategically, and solve complex problems.

Behavior Rating Inventory of Executive Function

BRIEF is a widely used questionnaire that assesses executive function skills in children and adolescents. It provides valuable information about a child's ability to plan, organize, inhibit impulses, shift between tasks, and regulate emotions. It consists of parent and teacher versions with items covering various domains of executive functioning.

Child Behavior Checklist

CBCL is a widely used parent-report questionnaire that assesses behavioral and emotional problems in children. It covers a range of issues such as internalizing and externalizing problems, social difficulties, attention problems, and thought problems. It is useful for assessing children's behavioral and emotional functioning in clinical and research settings.

Sample size calculation

The sample size was calculated to ensure a power of 80% and a statistical significance of 0.05. From a previous study of n-back training in the healthy population, the effect size was 1.85 (Jaeggi et al., 2008).

Assuming a 10% of incomplete data input, a total number of 66 subjects, 33 per arm, are needed.

Plan of statistical analyses

The statistical analysis employs a rigorous approach to examine intervention effects while accounting for repeated measurements and multiple comparisons. For baseline characteristics, independent samples t-tests will compare continuous variables between groups, with chi-square tests used for categorical variables. These analyses will verify successful randomization by demonstrating comparable groups at baseline. Homogeneity of variance will be confirmed through Levene's test.

Primary analyses will utilize repeated measures ANOVA (RM-ANOVA) with a 2×3 factorial design (Group × Time) to evaluate intervention effects. This approach allows simultaneous examination of within-subjects changes across three time points (baseline, post-intervention, and 3-month follow-up) and between-group differences. The RM-ANOVA will specifically test

three key effects: the main effect of time (indicating overall changes regardless of group), the main effect of group (showing overall differences between intervention and control conditions), and most critically, the group × time interaction effect that reveals whether patterns of change differ significantly between groups.

Assumption testing will precede all RM-ANOVA analyses. Mauchly's test will evaluate sphericity, with Greenhouse-Geisser corrections applied when the sphericity assumption is violated ($\varepsilon < 0.75$). For cases where ε exceeds 0.75, Huynh-Feldt corrections will be implemented. These adjustments protect against inflated Type I error rates that can occur with violated sphericity assumptions. Within-subjects contrasts will examine specific time point comparisons, while between-subjects effects will assess overall group differences.

For significant interaction effects, post-hoc analyses will employ Bonferroni-adjusted pairwise comparisons to identify specific time points where group differences emerge. Simple effects analysis will further decompose significant interactions by examining group differences at each individual time point. Effect sizes will be reported as partial eta-squared (ηp^2) for ANOVA effects and Cohen's d for pairwise comparisons, following conventional benchmarks for small, medium and large effects.

Supplementary analyses will explore potential moderating variables through mixed-effects models incorporating three-way interaction terms (Group × Time × Moderator). Sensitivity analyses will compare intention-to-treat results with per-protocol findings. Missing data will be handled using multiple imputation after assessing missingness patterns through Little's MCAR test. All analyses will be conducted using SPSS v30 with alpha set at 0.05 (two-tailed), employing robust methods to ensure valid conclusions about the intervention's efficacy.

Data Handling and Record Keeping:
Since patient records will be used in this study, the data are required by law to be securely stored for privacy reasons. All data will be stored in an encrypted hard disk and secured locker. Only the investigator has access to these.

Timetable:
Jun 2024: Submission for ethics approval
Aug 2024 - Apr 2025: Case recruitment and collection of data
May-Aug 2025: Analysis of data and report write-up
Sep 2025: Submission of report

Ethical issue:
All participants gave written informed consent and all investigations will be conducted in accordance with the Declaration of Helsinki. Ethical approval of this research will be obtained from the Hospital Authority Hong Kong West Cluster Institutional Review Board.

Staffing and Resources:
No grant has been applied. The training program is provided by the Institute of Psychology of the Chinese Academy of Science.

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