



# **A Systematic Review of Non- Pharmacological Interventions for Children with Intellectual Disabilities**

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40 credits

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## Abstract

**Purpose/Aims:** A systematic review was conducted as part of the Special Needs Education Master's Thesis, to identify non-pharmacological interventions using RCT designs for children with intellectual disability (ID); measure the methodological quality of identified studies; identify intervention categories. This area was selected as it was proposed that in order to best support children with ID effectively, with well-informed, evidence-based practice, a sound research base must be available for practitioners and policy makers. The study design was limited to RCTs to identify the highest standard of research possible. While the extended summary provides greater theoretical and legislative backgrounds and perspectives, the article (provided at the end of the thesis) provides a more concise version of this. *Disability and Rehabilitation* was the journal selected for submission for purposes, and the article follows the layout and referencing guidelines accordingly.

**Materials & methods:** Further consideration was given to the benefits of conducting systematic reviews, in terms of evaluating evidence, and in consideration of the various levels of evidence. The study was registered in PROSPERO (CRD42021239599); followed PRISMA reporting guidelines. RoB2.0 was used to evaluate study methodological quality. Five databases were searched.

**Inclusion criteria:** Randomized controlled trials (RCTs); children, 5-18 years, with ID; non-pharmacological interventions; original, peer-reviewed English-language articles.

**Results:** 878 records identified; 24 studies included. Data extracted using pre-specified forms. Meta-analysis could not be performed due to heterogeneity. Studies categorized into groups relating to cognitive or adaptive functioning according to intervention focus.

**Conclusions:** Further research suggested in the areas of social skills and communication, and in relation to adolescents. Developing procedures to measure outcomes appropriate for individuals with ID across ages and abilities may support/promote the inclusion of people with more severe ID within RCTs.

**Title of the article:** A systematic review of non-pharmacological interventions for children and adolescents with Intellectual Disabilities

**Journal:** *Disability & Rehabilitation*

## Preface

The authors of this paper would like to thank the lecturers of the Special Needs Education course at UiO for their support and teaching over the previous two years, during a very strange time in history. Particular thanks to our thesis supervisor.

Catriona would like to thank her friends and family who have kindly tolerated the complaints about fighting with words on Word, and various other technological difficulties. Thanks to Nico for fixing the printer. Mainly thanks to the people I know with heavy labels they carry casually for teaching me so much.

Tingwei would like to thank her friends who heard the complaints all the time and supported her.

The extended summary and article have been written in their entirety by both authors, as opposed to each author writing specific chapters. The paper reflects an entirely joint effort, and therefore both parties should be graded the same.

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## Foreword

The discipline of Special Needs Education is broad, however, the area of how best to support the learning of children with special needs is of concern to teachers and special needs educators (Ferriday & Cantali, 2020). The diagnosis of Intellectual Disabilities (ID) is similarly broad and may be applied to a number of children, including those with other diagnoses (i.e. Fragile X Syndrome; Down Syndrome). A systematic review was completed to explore what RCT study designs had been conducted implementing non-pharmacological interventions with children and adolescents. The extended summary provides more background and information in relation to ID and RCTs than a peer-reviewed article would permit, includes more background on the rationale for the need for such a systematic review, and explores theoretical perspectives. The article is a more concise, condensed summary of this, explicitly following PRISMA guidelines. As two reviewers are required to adhere to PRISMA guidelines, the authors collaborated on the process. The extended summary and article have been written in their entirety by both authors, as opposed to each author writing specific chapters. The thesis reflects a common product reflecting cooperation on all levels, and therefore both parties should receive the same grade.

In selecting a journal to submit the article to, the authors looked at options that were of a relevant discipline and accepted systematic reviews. From those found, the one with the highest Impact Factor was selected: *Disability & Rehabilitation*. This journal publication may not explicitly relate to education, however, its focus on enablement and strengths-based approaches is consistent with the values and principles of special needs educators.

As per UiO Master's Thesis requirements, the Extended Summary follows APA7 guidelines for referencing; this was also used for formatting headings. The *Disability & Rehabilitation* journal requires submissions to follow a TF-Standard NLM referencing format, and the article manuscript reflects this. The TF-Standard NLM referencing format is also used in the attachments to prevent tables from becoming larger than required; the tables contain separate reference lists below them as a result of this. There are hyperlinks within both the extended summary and article manuscript that navigate the reader to the relevant figure or table without the same attachments chapter.

# Introduction

## Background and Rationale

The conceptualization and treatment of people with intellectual disabilities (IDs) has existed for centuries, from the Ancient Egyptian civilization's emphasis on finding solutions to treat people with disabilities, to the Ancient Roman approaches that promoted the earliest iterations of eugenics (Roth et al., 2019). More contemporary changes have been observed in recent decades as knowledge and understanding around ID has evolved, shifting it from being considered as a mental disorder (Roth et al., 2019) to a neurodevelopmental disorder (Association, 2013; Organization, 2020; Schalock et al., 2021). This coincided with ID shifting from being considered exclusively within the medical model, to the incorporation of the social model, moving the issue from being an individualistic issue to placing emphasis on the impact of culture and society (Matheis, 2019). Subsequently, while continuing to acknowledge the contribution of the medical evidence base, there was an increase in demand for research focusing on more biopsychosocial theories of disabilities, given the impact theory and research have on the support available to those with disabilities (Oliver, 1998).

In addition to constructs of how ID was perceived, a framework of international legislation has been growing since the 1980s. Following the International Year of Disabled Persons, the World Program of Action concerning Disabled Persons was implemented by the UN General Assembly (WHO, 1982); one of the overarching principles of this Program was that of the “Equalization of opportunities.” Since the Salamanca Statement (United Nations Educational & Organization, 1994) advocated the inclusion of children with disabilities within an ethos of “education for all,” there has been an increase in focus on how to meet the learning needs of children with special educational needs (SEN), including those with ID, within inclusive settings. This goal brought with it a need to develop a sound evidence base on which to establish best teaching-learning practices.

In order to embed theory and research into professional practice, evidence-based practice



(EBP) is often used to promote the use of high-quality research into treatment and support plans, including those with ID (Nicole M. DeRosa et al., 2019). Systematic reviews are one method by which research can be gathered and presented to promote best practice by highlighting treatments and interventions that have been found to be effective (Nicole M. DeRosa et al., 2019). This chapter will discuss factors relating to ID and outline the principles of randomized control trials (RCTs), prior to outlining the rationale for the current literature review exploring RCT research designs with people with ID.

## Intellectual Disabilities

### **Definition**

Currently, there is no consensus on the definition of ID, although definitions are available from the Diagnostic and Statistical Manual of Mental Disorders (5<sup>th</sup> Edition, DSM5), International Classification of Disorders, (11th edition, ICD11), and the American Association for Intellectual and Developmental Disabilities (AAIDD). According to ICD11, ID is described as:

“a group of etiologically diverse conditions originating during the *developmental period* characterized by **significantly below average intellectual functioning and adaptive behavior**” (Organization, 2020).

Similarly, the AAIDD defines ID as

“a disability characterized by **significant limitations in both intellectual functioning and in adaptive behavior**, which covers many everyday social and practical skills. This disability originates *before the age of 22*.” (Schalock et al., 2021).

In the DSM5 (Association, 2013), ID is classified as “Intellectual Developmental Disorder”, and is defined as:

“a disorder with onset during the *developmental period* that includes **both intellectual and adaptive functioning deficits** in conceptual, social, and practical domains”.

Although there are slight differences, all characterize ID as involving substantial

impairments of both cognitive functioning and adaptive behaviors, with onset during the developmental period. “Significant limitations” are defined as two or more standard deviations below the mean on standardized measurements of cognitive function and adaptive behaviors. However, scores in assessments are not the only diagnostic considerations, with clinical judgment also considered an important contributor to the assessment process (Association, 2013; Organization, 2020; Schalock et al., 2021). Generally, ID is diagnosed in children over the age of five when standardized measurements for cognitive and adaptive functioning to assess ID become more valid and reliable. Prior to the age of five, the diagnosis of global developmental delay (GDD) may be made, defined as a significant delay in two or more developmental domains (i.e. cognitive, gross or fine motor, social or personal, activities of daily living, speech or language). It is considered a potential indicator of a future diagnosis of ID, particularly where delays are shown in language or speech to a moderate or severe degree (van Karnebeek, 2018). However, children with GDD, especially mild, may “catch up” developmentally, with appropriate supports in place (Moeschler & Shevell, 2014). The upper age limit of the developmental period is less clear. Neither the DSM-5 nor the ICD-11 specify upper age limits for the developmental period (Association, 2013; Organization, 2020), while AAIDD specifies that ID originates prior to the age of 22 (Schalock et al., 2021). Moreover, when the ID assessment cannot be achieved for individuals over the age of five due to associated sensory or physical impairments, or co-occurring mental disorders, the diagnosis of unspecified intellectual disability is used and requires reassessment (Association, 2013).

### ***Severity and Prevalence***

Historically, the severity of ID was determined only on the basis of intelligence quotient (IQ) test scores to measure cognitive function, ranging from mild (IQ55-69), moderate (IQ36-51), severe (IQ20-35), and profound (IQ < 20) (Shree & Shukla, 2016). When ascribing severity level: ICD-11 uses both cognitive and adaptive functioning; DSM-5 only utilizes adaptive functioning; AAIDD-2021 uses the intensity of required support needs (Association,

2013; Organization, 2020; Schalock et al., 2021). Ideally, classification is assessed by appropriate standardized tests, however, when these tests are not available, assessments rely on clinical judgment (Organization, 2020).

Due to differences in methodological selection, sampled population, and diagnostic criteria, the reported prevalence varies. DSM-5 estimates the prevalence rate of ID to be approximately 1% and it varies across age ranges (Association, 2013). Recent systematic reviews supported this estimate (Maulik et al., 2011; McKenzie et al., 2016), however, rates vary among countries. The prevalence in low- and middle-income countries is twice as high as in high-income countries (Maulik et al., 2011). The overall prevalence rate is slightly higher in males than in females (Association, 2013; Maulik et al., 2011; McKenzie et al., 2016; Organization, 2020; Shree & Shukla, 2016), with an estimated male-female ratio of 1.6:1 for mild ID, and 1.2:1 for moderate ID (Association, 2013).

### ***Etiology***

The etiology of ID has been associated with both biological and environmental factors (Association, 2013; Organization, 2020; Patel et al., 2018; Schalock et al., 2021). Biological causes are more likely to be found in individuals with severe or profound ID with a rate of 75%, compared to only 50% for mild ID (Moeschler & Shevell, 2014; Patel et al., 2018; Shree & Shukla, 2016). One example of a biological cause is a chromosomal abnormality, the identified cause of Down syndrome and Fragile X Syndrome (Shree & Shukla, 2016). Environmental factors mainly relate to the exposure of deprivation due to, for instance, poverty, domestic violence, and severe neglect (Patel et al., 2018; Shree & Shukla, 2016). However, identification of causes is complex as ID can be diagnosed for multiple reasons; among all cases of ID, it has been estimated that only half can identify specific causes (Shree & Shukla, 2016). It has also been found that individuals with ID also experience co-occurring mental health problems, medical conditions, and challenging behaviors (Association, 2013; Matson & Cervantes, 2013). For instance, some disorders, including mental disorders, epilepsy, and cerebral palsy, appear

three to four times higher than that in the general population (Association, 2013, p. 40).

### ***Evaluation and Diagnosis***

The comprehensive evaluation of ID requires considerable time and effort, from the collaboration between various healthcare staff, rather than a single physician, to confirm the diagnosis. From this, individualized rehabilitation plans can be developed, with consideration given to the person's age, the severity of clinical presentations, strengths, and other relevant factors (Moeschler & Shevell, 2014; Patel et al., 2018; Shevell, 2008). Such an assessment process often begins with a family history investigation on pregnancy, medical background, and environmental factors. This includes child-parent relationships and interaction, economic conditions, and other factors related to the development of the child, to determine their current developmental stage and identify possible comorbid features (Shevell, 2008). In addition to the general physical assessment, further neurological examination, and detailed laboratory tests on genetics and metabolism may be required (Patel et al., 2018; Shevell, 2008). Of note, visual and auditory assessments are also necessary as impairments in vision and hearing can substantially hinder the developmental process (Patel et al., 2018; Shevell, 2008).

The assessments of cognitive and adaptive functioning require reliable and valid standard tools. Wechsler scales are most commonly used in intellectual measurement while the Vineland Adaptive Behavior scales are mostly used in assessing adaptive abilities (Flanagan & Alfonso, 2017; Patel et al., 2018; Schalock et al., 2021; Tassé et al., 2012). Diagnosis must consider both aspects; IQ tests alone cannot determine the diagnostic result (Association, 2013; Organization, 2020). Due to the limited sensitivity of IQ tests, where the score is at, or slightly higher than, the upper limit for mild ID (IQ 70), the diagnosis of borderline intellectual disability (IQ 71–84) is met (Association, 2013).

### ***Principles of Management and Theoretical Background***

Despite the somewhat disparate nature of ID definitions, diagnostic methods, and terminology used internationally, there are some generally accepted principles of management,

for instance, most people with ID will require support from multi-disciplinary teams, including input from health, social and psychological professionals from childhood into adulthood (Patel et al., 2018). Principle aims of supporting people with ID have been proposed as promoting the development of cognitive and adaptive skills, maintaining positive health outcomes, and behavior management strategies (Patel et al., 2018). Emphasis should also be placed on incorporating community involvement, ensuring individualized education and transition plans are in place while accounting for developmental progress. Communication should also be promoted between the multi-disciplinary team and family members where appropriate (Patel et al., 2018). Similarities can be observed between these recommendations and bioecological models of human development, in considerations of individual abilities within their contexts and relationships, over time (Bronfenbrenner & Morris, 2007). While the individual needs of the person with ID should be coordinated to address a range of factors specific to them, frequent areas that may require support include cognitive abilities, areas of adaptive functioning, behavior management support.

**Cognitive Abilities.** Historically, it was perceived that people with ID did not possess the ability to learn and develop cognitive skills (Downing, 2010). As knowledge and understanding of the condition increased, different theoretical perspectives of learning have dominated at different times, with initial emphasis placed on behavioral interventions to support learning (Ainscow & Tweddle, 1979). This involved establishing clear learning goals and laid the foundations for the development of Applied Behavioral Analysis (ABA), an empirically supported, albeit often debated, support intervention designed to encourage positive, and reduce negative, behaviors in the application of operant conditioning principles (Roth et al., 2019). These approaches came under criticism in relation to the increasingly directive nature of teaching strategies, with reduced expectations on learners with ID, and an increase in behaviors that suggested learned helplessness in students (Watson, 2000). Cognitive theories perceive learning processes as developing and building on an individual's existing knowledge and understanding of their world (Anderson et al., 1996). While some researchers

and educators may support one approach as superior to the other, it has been suggested that drawing on principles from both theories can best support learners with ID (Algahtani, 2017). For instance, ensuring learning activities have explicitly explained applications to the real world to support the generalizability of information from cognitive approaches, combined with ensuring information is broken down into manageable amounts so as not to overwhelm a student with information overload, from behavioral principles (Algahtani, 2017).

**Adaptive functioning.** The importance of supporting people with ID to learn, develop and maintain life skills has been recognized as invaluable, with a high volume of research published in the 1980s and 1990s, potentially related to the move toward independent living models at that time (King et al., 2017). While practical, self-help skills or activities of daily living (ADLs) cover a broad range of abilities, recurring approaches have demonstrated positive outcomes for people with ID, including, modeling behaviors, spoken or gestural prompts, providing verbal feedback, and social, or other desirable, reinforcers (Matson & Hong, 2019). The level to which such approaches achieve efficacy is also dependent on factors such as intrinsic motivation of the individual, level of cognitive functioning, and task complexity (Matson & Hong, 2019). It has been noted that the development of these skills can be incorporated within curriculums (Chiang & Kemp, 2019).

The promotion of positive social skills has been another focus of intervention strategies. A common characteristic of people with ID has been described as a deficit in socialization, either in terms of social withdrawal, or excessive gullibility (Little et al., 2019). This area has been influenced by Bandura's social cognitive learning theory, which identified necessary skills that would facilitate learning from modeling (Bandura & McClelland, 1977). An individual must be able to attend to and recall behaviors being modeled; have the capacity to transfer those behaviors to different settings appropriately, and again, be motivated to engage (Bandura & McClelland, 1977). The complex interplay of different intellectual and adaptive functioning abilities can be seen from this example: cognitive abilities impact the capacity an individual has to concentrate on and recall a behavior; social skills impact the capacity an individual has

to learn from role modeling. Another important consideration would be in how much access an individual with ID would have to environments within which to practice social skills, considering evidence of their increased experiences of social isolation (Louw et al., 2020). One main reason is that from a young age people with ID, particularly severe ID, are less exposed to opportunities for social interaction than their typically developing peers; with limited socialization opportunities, comes a limited ability to practice and generalize social skills (Feldman et al., 2016).

**Behavior management.** Behavior problems have also been recognized as a barrier to people with ID engaging in learning, ADLs, or social activities (Bowring et al., 2019). While deficits in social skills in some areas are considered characteristic in people with ID (Little et al., 2019), the prevalence of behavioral problems is less clear. Estimates suggest they occur three times more often in children and young people with ID than in their peers without (Baker & Blacher, 2015), and while it is known that these issues may persist into adulthood without appropriate support, reported prevalence rates among adults with ID vary. Conservative estimates suggest they affect 4-20% of the population with ID, while other estimates suggest prevalence as high as 80% within some sub-populations (Bowring et al., 2019). Behavioral approaches, specifically ABA, have received the most empirical evidence of psychosocial interventions in supporting the management of behavior problems (Lang et al., 2019), although there are also high rates of anti-psychotic medication prescribed to people with ID (Charlot et al., 2019). Connections between increased behavioral difficulties, and more limited cognitive abilities and adaptive functioning have been observed as predictors of increased challenging behavior include higher ID severity, and lower communication abilities (Bowring et al., 2019). In terms of accessing support for such difficulties, it has been observed that where challenging behaviors were externalized, i.e. resulting in injury to others or property damage, service provision was more frequent and longer than where challenging behavior was self-directed, i.e. self-injurious (Adams et al., 2018).

## ***Terminology and Stigmatization***

In addition to generally aligned, albeit slightly distinct, definitions and diagnostic tools, the terminology has also varied over time (World Health, 2007), and continues to vary between countries (Cluley, 2018). This is particularly true of the UK where learning disability remains the more commonly used term, despite the increasing use of the term ID within some professional settings (Cluley, 2018). While discussions on the semantics of terminology may appear superficial, the impact of labels are considerable to the life trajectories of those who receive them; especially in relation to those most likely to result in the stigmatization of people, as is the case with “learning disabilities” or ID (Green et al., 2005). The importance of monitoring and explaining changes in terminology use is important to ensure a shared understanding between those people who are labeled, professionals, and in disseminating research findings internationally (Cluley, 2018).

The AAIDD (Schalock et al., 2007) supported the change in terminology from “mental retardation” to ID within the US, viewing it as a more inclusive, less stigmatizing label, that accounted for the impact of societal obstacles in addition to individualistic limitations. Despite efforts to reduce stigmatization through careful consideration of labels, people with ID continue to experience negative impacts of discriminatory attitudes throughout their lives across education, health, and social settings. In a review of students without ID’s attitudes toward their peers with disabilities, it was found that the type of disability acted as a predictor, with more negative attitudes observed toward their peers with ID than toward their peers with physical disabilities (de Boer et al., 2012). This likely has an impact on the experiences of children with ID, who report having fewer and lower quality friendships, and recounted incidents of rejection and prejudiced behavior, increasing their sense of social exclusion (Louw et al., 2020).

These findings were found to persist into adulthood (Alexandra et al., 2018). In addition to findings that indicate ongoing issues with social isolation and oppressive attitudes toward people with ID, other reviews have observed issues in relation to self-determination and



employment. People with ID living in residential settings were found to experience difficulties in having their wants and desires heard and respected (Gjermestad et al., 2017), while workers with ID were found to earn less than their colleagues without ID and reported increased rates of negative social encounters and prejudices in the workplace (Kocman & Weber, 2018).

Identifying the underlying reasons for this may be especially challenging; people without ID may not be aware of holding biases, as can occur in unconscious biases toward other often oppressed groups (Agarwal, 2020). While one study, using self-report measures, found that people stated that they would be comfortable meeting and employing a person with ID (Slater et al., 2020), a review of studies using the Implicit Association Test (IAT) found contradictory results (Wilson & Scior, 2014). From a meta-analysis of 17 studies that used the IAT (Lane et al., 2007), a computer program to measure implicit bias, it was found that people held moderate to strong negative implicit attitudes toward people with disabilities. They also found that results from the IAT did not correlate to self-reported views, raising concerns about the validity of studies using these measures.

These potentially, implicitly held biases may contribute to the disadvantages people with ID experience within healthcare settings; they have been reported as having poorer health outcomes compared to people without ID (Hatton & Emerson, 2015), and while life expectancy has increased at a similar rate to the general population it remains over 10 years lower (Coppus, 2013). These outcomes do not reflect the financial costs invested within services for people with ID. Overall annual healthcare costs for people with ID are higher than for those without in Canada (Lunsky et al., 2019) and Australia (Arora et al., 2020). In attempts to find solutions to these trends, a literature review explored reasons that people with ID have difficulties in accessing healthcare support, and what could be implemented to resolve these (Doherty et al., 2020). Emphasis was placed on increased training opportunities for healthcare professionals to increase knowledge and awareness of ID, particularly in relation to communication needs (Doherty et al., 2020). This seems especially significant in the context of previous findings whereby mainstream health care professionals tended to over or underestimate the abilities of

people with ID, and reported a range of negative, stress-related emotions in relation to treating people with ID (Pelleboer-Gunnink et al., 2017). In addition to likely connections with stigmatizing attitudes, it could therefore be suggested that a lack of training hinders the treatment that people with ID receive, and that addressing this may improve both their health outcomes and the confidence of those tasked with supporting them. The increased financial expenditure in relation to people with ID, alongside their lower health outcomes, suggests that services are either under-resourced, resources are not currently being used optimally, or a combination of the two.

In addition to healthcare services, individuals with ID also experience challenges in psychiatric comorbidity. In a recent review of comorbid psychiatric symptoms in young people with ID, higher rates were found than in similarly aged children without ID (Buckley et al., 2020). They raised issues around communication limitations, and in ensuring diagnostic accuracy was achieved, noting that some practitioners may inaccurately assign symptoms as a further indicator of ID rather than recognizing them as symptoms of a mental health disorder (“diagnostic overshadowing”) (Buckley et al., 2020, p. 981). There has also been limited research in relation to suicidal behavior and thoughts with people with ID (Dodd et al., 2016), and it was found that people with ID experience difficulties in accessing mental health support (Whittle et al., 2018). These combined observations are particularly problematic given that people with ID are at an increased risk of experiencing mental health difficulties. In a review of people with ID’s experiences in seeking support for mental health problems, barriers were noted at organizational levels, with low service availability and quality, especially impacted by low knowledge among professionals (Whittle et al., 2018). In addition to the importance of training and education of professionals again being emphasized, it was highlighted that effective multi-disciplinary working could have a facilitative impact on people with ID’s experiences of accessing mental health support (Whittle et al., 2018). Another area of potential interest was identified by a systematic review whereby ID syndromes more frequently associated with higher social skill capacity were less likely to display psychiatric comorbidity

(Glasson et al., 2020). This potentially demonstrated that at least some populations with ID experienced the protective factors of strong social connections against mental health problems as observed within the general population (Ozbay et al., 2007).

The Covid pandemic has further highlighted social inequalities, with people with worse health and increased contact with others at higher risk of infection, or other negative, economic impacts (Stiglitz, 2020). People with ID experience lower levels of general health, and while they may have restricted social interactions, they are more likely to have increased contact with others as a result of requiring support (Courtenay & Perera, 2020). These supports have been disrupted, and medical professionals have observed increases in people seeking pharmacological support to manage challenging behaviors associated with these disruptions (Courtenay, 2020). There has also been an increase in the general population experience of feeling socially disconnected as a consequence of needing to socially distance (Hwang et al., 2020); a trend that had been increasing prior to the pandemic to such an extent it had been described as a “behavioral epidemic” (Jeste et al., 2020, p. 533). People with ID already experience increased social isolation, potentially as a result of prejudice and stigmatization, alongside lower health outcomes and difficulties in accessing health services. Ensuring appropriate, robustly examined, interventions and treatments, aiming to support people with ID in developing their life skills to increase their resiliency, could support them in improving their quality of life. RCTs have been acknowledged as an important, robust research design to examine and identify effective interventions.

## **Randomized Controlled Trial**

The scientific design of randomized controlled trials (RCTs) was introduced by Charles Sanders Peirce in 1747, and was first, published in British Medical Journal in 1948 (Jastrow & Peirce, 1884; Saxena et al., 2012; Yoshioka, 1998). The RCT study design consists of assigning participants randomly to two or more groups (Nicole M DeRosa et al., 2019). Participants within the “experimental group” receive the intervention under investigation, while the

“control group” participants receive no intervention, a placebo, or an alternative intervention. This allows the effectiveness of an intervention to be assessed by comparing the outcomes of participants allocated to different groups (Akobeng, 2005; DeRosa et al., 2019). They can be applied to interventions under optimal, highly controlled conditions, or under more flexible conditions, as required (Saxena et al., 2012; Zwarenstein et al., 2008). The key elements of RCTs involve random allocation, allocation concealment, and blinding (Bhide et al., 2018).

Random allocation refers to the process of assigning participants to intervention or control groups at random, in such a way that each participant has an equal opportunity to be allocated to each group (Akobeng, 2005; Bhide et al., 2018). The main purpose is to ensure that participant characteristics of each group remain as similar, and therefore comparable, as possible, and to reduce the bias in the assignment (Akobeng, 2005). The main methods of random allocation include simple/complete randomization, fixed randomization, stratified randomization, and cluster randomization (Akobeng, 2005; Saxena et al., 2012).

In simple or complete randomization, a “coin flip” style method determines participant group assignment (Saxena et al., 2012). It can be easily achieved but may result in each group containing a different number of participants, and has more use where samples are small (Saxena et al., 2012). Fixed randomization uses random digits or software like SPSS to generate random numbers to assign each participant to a group (Saxena et al., 2012). When participants’ baseline characteristics may influence the outcomes of the intervention, random allocation processes may consider these factors by using stratified randomization (Akobeng, 2005). Achieved in two stages, participants with the same characteristics, especially certain prognostic factors, are divided into one group, with all subgroups defined as strata; each stratum is then randomized (Akobeng, 2005). Block randomization is often used in this second stage, where participants are randomized into blocks to ensure that the number of participants within each group is similar (Akobeng, 2005; Saxena et al., 2012). When it is not feasible to randomize each individual, participants may be randomized by hospitals or geographic districts, known as

cluster randomization (Bhide et al., 2018).

After randomization, allocation concealment can be used to prevent researchers, participants, or other professional staff involved in interventions from knowing the allocation sequence; particularly important when blinding is not practical (Bhide et al., 2018; Saxena et al., 2012). Allocation concealment supports the limitation of selection bias and confounding factors. A recent study found that estimates of treatment effect were inflated by approximately 41% where no allocation concealment was possible (Schulz, 2001). A common method of allocation concealment uses opaque, sealed envelopes (Saxena et al., 2012). Alternatively, it can be achieved by delivering the allocation process to an independent party, known as distance randomization (Akobeng, 2005).

Blinding refers to a procedure that ensures the results of an intervention's assignment are unknown to participants, care providers, and researchers (Saxena et al., 2012). The importance of blinding relates to how the knowledge of an assignment can influence the outcome, thus creating bias. For example, participants who receive their preferred interventions may report better outcomes; care providers might pay more attention to an intervention group; researchers might over-analyze the data to support treatment groups (Akobeng, 2005). "Single-blind" refers to the blinding of only participants, while "double-blind" involves both participants and care providers being unaware of the group assignments. Less commonly used, "triple-blind" involves participants, care providers and researchers all being blinded to the assignment procedures (Akobeng, 2005).

When conducting RCTs, multiple factors such as time, funding, and ethical issues must be taken into consideration (Saxena et al., 2012). RCTs are also not feasible for rare circumstances in which sample sizes are relatively small and can only evaluate one variable at one time (Saxena et al., 2012). However, these weaknesses do not counteract the advantages. In RCTs, confounding factors are more carefully controlled for, and results can be applied to larger populations as relatively large sample sizes, and the random allocation procedures employed,

create more external validity (Nicole M DeRosa et al., 2019). Furthermore, RCTs have been regarded as the “gold standard” for assessing effectiveness and are highly advocated by research organizations (Bickman & Reich, 2015; Hariton & Locascio, 2018). For example, the National Health and Medical Research Council (NHMRC) considers the design of RCT as the highest evidence among all types of study designs (Merlin et al., 2009). Moreover, various state institutions in the US use RCT as the “gold standard” when determining funding, evaluation, and even launching and decessing program (Bickman & Reich, 2015; Brass et al., 2006).

## **Systematic review**

A systematic review utilizes approaches that support methodical search strategies, identification, appraisal, and analysis of relevant studies in order to address one or more research questions (Gopalakrishnan & Ganeshkumar, 2013). It is valued due to its comprehensive and transparent approach (Siddaway et al., 2019). The use of such systematic methods limits bias and can provide a more comprehensive picture of current research (Gopalakrishnan & Ganeshkumar, 2013). Further, as the eligibility criteria must be explicitly stated, other researchers can assess the results and may update or extend such reviews (Siddaway et al., 2019). Moreover, as systematic reviews focus on various studies rather than individual studies, more robust and generalized conclusions may be made. Therefore, they can provide directions for researchers, practitioners, and policy makers, thereby narrowing the gap between research and clinical implementation (Akobeng, 2005; Gopalakrishnan & Ganeshkumar, 2013; Siddaway et al., 2019). However, systematic reviews are constrained by previous research. Additionally, one inherent limitation of systematic reviews is publication bias whereby studies with significant results are more likely to be published (Gopalakrishnan & Ganeshkumar, 2013). Taking these limitations into consideration, the systematic review of RCT is deemed as the highest evidence by the National Health and Medical Research Council (NHMRC) (Merlin et al., 2009) and The Scottish Intercollegiate Guidelines Network (SIGN) (Harbour & Miller, 2001).

## **Current Research**

It has been suggested that there is less evidence produced from RCTs in relation to people with ID than for those in non-ID populations, despite there being ongoing issues in long-term outcomes for people with ID (Mulhall, 2018). These discrepancies in equality can be observed from childhood within education settings, when children with ID are at higher risk of exclusion both from school and socially (UNESCO, 2020). It has also been highlighted that the teachers of children with the highest needs should be provided with sufficient support and training (UNESCO, 1994, 2020). As such, the need for robust, reliable information on what works best, for whom, and in which settings can be seen.

From previous systematic reviews, it was noted that few RCTs were used in interventions for people with ID. In a recent systematic review of self-regulation interventions, of 36 studies identified, all reporting significant improvements, only eight studies were RCTs; most were case studies and contained small sample sizes (Sandjojo, 2020). A further systematic review, assessing the effectiveness of psychotherapeutic interventions for ID, found only one-third of identified studies were RCTs; the authors concluded that this limited the evidence, and suggested more well-designed RCTs were required to consolidate current evidence (Oshodi & Turk, 2016). Another systematic review assessing the effectiveness of non-specialist psychosocial interventions found similar results, with only half of the included studies following RCT designs (Reichow, 2013).

Although previous systematic reviews focused on non-pharmacological interventions for ID, they were limited to: the effectiveness of a specific intervention approach, i.e., mindfulness-based (Singh, 2020), psychotherapeutic (Oshodi & Turk, 2016), and cognitive-behavioral (Felce, 2015); a particular aspect of daily living skills, such as self-management (Sandjojo, 2020), oral hygiene (Waldron, 2019) and lifestyle change (Willems, 2018); a particular age group or ID severity (Kok et al., 2016; Oshodi & Turk, 2016; Vereenooghe, 2018). Reviews with a broad focus on non-pharmacological intervention, addressing all aspects of ADLs, and

across all ages and ID severity levels could not be identified.

## **Aims/objectives**

This systematic review aims to synthesize non-pharmacological interventions employing RCTs for children aged 5-18 years, with ID without limiting to one perspective, to provide potential directions for future research and practice with considerations of legislation and theoretical backgrounds. The age range 5-18 years was selected as ID is not diagnosed prior to 5 years, and the UN's Convention on the Rights of the Child defines children as being 18 years and under (UN, 1989).

### ***Research Aims***

- 1) Identify existing non-pharmacological interventions using RCT experimental designs for children with ID.
- 2) Measure the methodological quality of included studies.
- 3) Identify intervention categories, reported outcomes, and effectiveness of studies.



# Methods

## Theoretical perspectives

### *Evaluating evidence*

To narrow the gap between research and practice, institutions like The National Institute for Clinical Excellence (NICE) were established to provide clinical guidelines for practitioners to implement “evidence-based practice” (EBP) (Rycroft-Malone et al., 2004). “Evidence” in EBP refers to evidence from multiple sources including research, clinical expertise, patients, and local environments, rather than research evidence alone (Rycroft-Malone et al., 2004). However, research evidence is given priority in the delivery of EBP (Rycroft-Malone et al., 2004; Upshur, 2001). As research is changing, research evidence is also evolving; it is, therefore, important to regularly integrate the most recent research and develop manuals for practitioners from research evidence.

Emphasis on EBP has been the result of several factors. At times, some ineffective interventions are still in use (Burns & Ysseldyke, 2009; Courtade et al., 2014), and as EBP is based on high-quality experimental research it has been found to produce more effective outcomes (Baron, 2004; Cook et al., 2008; Courtade et al., 2014). However, the implementation of EBP still faces various challenges. There has been no consensus on the terminology used, or on what comprises an evidence-based intervention (DeRosa et al., 2019; Reed & Reed, 2008). Additionally, research evidence on the implementation of EBP remains limited (DeRosa et al., 2019; Detrich, 2008; Reed & Reed, 2008).

### *Level of evidence*

The level of evidence offers a framework to evaluate interventions using different study designs. They are ranked from most to least rigorous as:

“Level I is a systematic review of level II studies; level II is a randomized controlled trial (RCT); level III-1 is a pseudorandomized controlled trial; level III-2 is a comparative study

with concurrent controls including non-randomized experimental trial, cohort study, and case-control study; level III-3 is a comparative study without concurrent controls including historical control study and two or more single-arm study; level IV is case series.” (Merlin et al., 2009, p. 15).

Such a hierarchy of evidence implies that interventions using RCTs are more likely to be effective compared with other types of studies (Akobeng, 2005). Furthermore, the systematic review of RCTs can provide the most reliable evidence when evaluating interventions (Akobeng, 2005).

## **Protocol and registration**

As recommended by the journal “Disability & Rehabilitation”, this systematic review utilized the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Checklist as reporting guidelines (Page, McKenzie, et al., 2021; Page, Moher, et al., 2021), presented in [table 1](#). PRISMA provides a set of reporting items for reviewers to ensure that all aspects of systematic reviews can be reported transparently and completely (Page, McKenzie, et al., 2021). This systematic review was registered on PROSPERO, an international prospective register of a systematic review with the registration number: CRD42021239599.

## **Information sources and search strategy**

The electronic databases Cinahl, Embase, Eric (Proquest), APA PsycINFO, and PubMed were searched on 29<sup>th</sup> January 2021. Combinations of two categories of subject headings or free texts were used for searching: (1) condition (intellectual disability, ID); (2) randomized controlled trials. Specific search strategies per database are presented in [table 2](#). A manual search of the included studies’ reference lists was conducted to find potentially missing articles.

## **Eligibility criteria**

Included articles were to meet the following criteria: (1) participants are children aged 5-18 years with a diagnosis of ID (Association, 2013), including children with conditions known to have co-occurring ID, such as DS and FXS; (2) studies utilize RCTs as research designs; (3) interventions designed to improve social-behavioral functioning of children with ID; at least

one outcome measure focusing on non-physiological areas including behavioral, cognitive abilities, social abilities, and communication; (4) original articles published in English language, peer-reviewed journals.

Exclusion criteria consisted of: (1) pharmaceutical interventions; (2) outcomes focusing only on peers or caregivers; (3) interventions focusing only on physiological outcomes, i.e. blood pressure, heart rate, oxygen saturation, respiratory rate and temperature, blood sugar rate, BMI, weight change, posture, gait, and balance. No restrictions were placed on comparison groups; intervention settings or delivery agents; country; or publication year.

### **Selection process, data collection process, data items**

Titles and abstracts of included articles were screened by two reviewers independently to identify articles meeting the inclusion criteria. Reviewers conferred after screening to agree on articles to be retrieved in full. Selected articles were retrieved and read in full by two reviewers to determine whether they met inclusion criteria. When there was a disagreement, both reviewers discussed and came to a consensus. When an agreement could not be reached, a third reviewer was contacted to determine whether the article met inclusion criteria. The process is presented in [figure 1](#), by the PRISMA flow diagram (Page, Moher, et al., 2021).

After studies were identified, data were extracted from the studies using pre-specified data extraction forms. The following data on study and participant characteristics were extracted: (1) study (country, study design, and intervention category); (2) Methodological quality; (3) ID (definition, diagnosis criteria); (4) inclusion/exclusion criteria of the study population; (5) sample size (intervention and control group); (5) group descriptives (age, gender ratio, relevant medical diagnosis). Data on intervention characteristics were extracted by: (1) intervention goal; (2) intervention agent, delivery, and dosage; (3) materials and procedures; (4) outcome measures; (5) treatment outcomes. One reviewer extracted data relating to study characteristics and the other extracted data relating to intervention characteristics. Reviewers exchanged extraction results on completion and checked for accuracy. Disagreements were discussed to

reach a consensus. Meta-analysis was planned to be conducted dependent on the suitability of selected studies.

### **Study risk of bias assessment**

To assess methodological quality, the Cochrane Collaboration “Risk of bias tool” for randomized controlled trials (RoB 2.0) (Higgins et al., 2019) was used. RoB 2.0 contains five key specific domains: (1) bias resulting from the randomization process; (2) bias as a result of changes from planned interventions; (3) bias due to omitted outcome data; (4) bias caused by measurement of outcome; (5) bias in selective reporting of results. Two reviewers independently assessed five domains of each article and resolved disagreements by discussion until consensus was reached. The overall risk of bias judgment was determined by the guidelines of RoB 2.0 (Higgins et al., 2019) and assessments of both reviewers. The likelihood of bias within this review was also reduced by the two reviewers having no affiliations or interests with the included articles.

## Results

A total of 878 records were identified from the database searches, 130 were removed as they were duplicates. The titles and abstracts of the remaining 748 records were screened by two reviewers. Following consensus discussions, 656 records were excluded; 92 original articles were sought for retrieval. Ten of the 92 articles could not be retrieved following searches with access provided from two university libraries and contact made to authors. A further 66 records were excluded following the agreement between two reviewers (all excluded articles, including reasons for exclusion, presented in [table 3](#)). A further eight records were identified and assessed as eligible following manual reference list checks. [Figure 1](#) (PRISMA flow diagram) (Page, Moher, et al., 2021), provides information relating to the screening, retrieval, and inclusion process. This resulted in a total of 24 included studies; see [table 4](#) for details relating to participant characteristics (age, gender), and [table 5](#) for details relating to study characteristics (intervention details, outcomes), with citations. Meta-analysis could not be undertaken for a variety of reasons. There was a diverse range of participants involved within the studies, both in terms of ID severity, and in terms of additional diagnoses such as DS and FXS. Further to this, both intervention strategies, methods, and outcomes measured ranged across the 24 studies. Finally, the statistical analyses used and reported were heterogenous across the studies, with effect sizes reported inconsistently throughout.

### Risk of bias

The outcome of assessments of the included studies using RoB 2.0 (Higgins et al., 2019) is presented in [table 6](#). Of the 24 included studies, nine were rated “low risk,” five as “high risk” and ten as having “some concerns.” Within studies considered “high risk” and “some concerns,” the majority (11/15) were rated as such as they did not clearly state the randomization or concealment of the allocation sequence (Agbaria, 2020; Balthazar et al., 1971; Bennett et al., 2013; Boyce & Clinton, 1976; Burgoyne et al., 2012; Hong & Lee, 2012; Jacques

et al., 1998; Kantner et al., 1982; Litrownik et al., 1978; Maïano et al., 2001; Sepúlveda et al., 2013). Another study (Lanfranchi et al., 2015) was considered “high risk” due to baseline differences between the sample size in the intervention and control group, and a lack of description regarding allocation sequences. Three studies were assessed as having “some concerns” because of baseline differences in diagnosis (Janeslätt et al., 2019) and the total number of education hours participants received prior to intervention (Saint-Georges et al., 2020; Tanet et al., 2020). Two “some concerns” studies did not contain pre-specified statistical analysis plans (Kantner et al., 1982; Litrownik et al., 1978). Among studies assessed as “high risk,” two assessed outcomes without blinding assessors from the allocation result of the intervention (Balthazar et al., 1971; Boyce & Clinton, 1976). The assessment outcomes of one study (Jacques et al., 1998) were likely influenced by the non-blinding of assessors. Two studies were regarded as “high risk” because of utilizing measurement without established validity and reliability (Agbaria, 2020; Boyce & Clinton, 1976). One “high risk” study had no appropriate analysis for estimating the effect of intervention assignment (Balthazar et al., 1971).

## **Study & participant characteristics**

### ***Publication Year & Country***

The included studies ranged in publication year from 1971 – 2020; four of the 24 studies were published prior to the publication of the Salamanca Statement (UNESCO, 1994) in North America (Balthazar et al., 1971; Boyce & Clinton, 1976; Kantner et al., 1982; Litrownik et al., 1978). The remaining 20 studies were published after 1994, three in N. America (Hessl et al., 2019; McDuffie et al., 2018; Sepúlveda et al., 2013), and seven in Europe (Bagattoni et al., 2020; Bennett et al., 2013; Burgoyne et al., 2012; Drysdale et al., 2008; Janeslätt et al., 2019; Lanfranchi et al., 2015; Maïano et al., 2001). Of note, two of the European papers were from the same longitudinal study, published at different time points (Saint-Georges et al., 2020; Tanet et al., 2020). A further six studies were conducted in Asia (Agbaria, 2020; Hong & Lee, 2012; Lee et al., 2017; Lee et al., 2020; Wuang et al., 2013), one in New Zealand (Jacques et al.,

1998), one in Australia (McPherson et al., 2017), and one in Turkey (Baran et al., 2013).

### **Sample Size & Age**

The sample size of the studies ranged from 17 (Balthazar et al., 1971) to 445 (Lee et al., 2020). The median sample size of the 24 studies was 42 participants. Over half of the studies (13/24) included only primary/elementary-school-aged participants from 5-12 years (Agbaria, 2020; Bagattoni, 2020; Bennett et al., 2013; Boyce & Clinton, 1976; Burgoyne et al., 2012; Drysdale et al., 2008; Hong & Lee, 2012; Jacques et al., 1998; Kantner et al., 1982; Litrownik et al., 1978; Saint-Georges et al., 2020; Tanet et al., 2020; Wuang et al., 2013). Few studies (2/24) included only adolescent participants aged 12-18 years (Baran et al., 2013; Maïano et al., 2001). A single study described participants as “children” but did not report their age range (Balthazar et al., 1971), while the remaining (8/24) studies included children of various age ranges across the 5-18 years inclusion criteria.

### **Gender & diagnoses**

Most studies (17/24) reported the ratio of male and female participants, with just under half (10/24) consisting of reasonably balanced gender proportions across both treatment and control groups (50-65% male) (Bagattoni et al., 2020; Bennett et al., 2013; Burgoyne et al., 2012; Hessel et al., 2019; Janeslätt et al., 2019; Lanfranchi et al., 2015; Litrownik et al., 1978; McPherson et al., 2017; Sepúlveda et al., 2013; Wuang et al., 2013). Within the remaining (14/24) studies the proportion was not balanced, involved only one gender, or did not report the gender (Agbaria, 2020; Balthazar et al., 1971; Baran et al., 2013; Boyce & Clinton, 1976; Drysdale et al., 2008; Hong & Lee, 2012; Jacques et al., 1998; Lee et al., 2017; Maïano et al., 2001; McDuffie et al., 2018; Saint-Georges et al., 2020; Tanet et al., 2020).

In relation to diagnostic manuals, of the 24 studies, one referred to the ICD-10 (Bagattoni et al., 2020), two referred to the DSM (Agbaria, 2020; McPherson et al., 2017), and one referred to the AAIDD (Hong & Lee, 2012). Just under half of the studies (10/24) did not specify how diagnostics were determined, but highlighted the use of intelligence tests to determine IQ <70,

including: WISC (Jacques et al., 1998; Kantner et al., 1982; Maïano et a., 2001; Sepúlveda et al., 2013); alternative intelligence tests to measure IQ (Boyce & Clinton, 1976; Lee et al., 2020; Litrownik et al., 1978; McDuffie et al., 2018); use of the Vineland Adaptive Behavior Scales (VABS-II) to measure participant's Developmental Quotient (DQ) (Saint-Georges et al., 2020; Tanet et al., 2020). Few (5/24) studies did not specify how diagnostics were determined but reported: the presence of DS (Bennett et al., 2013; Burgoyne et al., 2012; Lanfranchi et al., 2015) or FXS (Hessl et al., 2019; McDuffie et al., 2018). The remaining (5/24) studies did not specify how diagnoses were made (Balthazar et al., 1971; Baran et al., 2013; Drysdale et al., 2008; Janeslätt et al., 2019; Lee et al., 2017; McPherson et al., 2017).

Most studies (17/24) reported ID severity explicitly or with the inclusion of IQ scores of participants. The majority (14/24) included participants with mild-moderate ID (Agbaria, 2020; Bagattoni et al., 2020; Baran et al., 2013; Drysdale et al., 2008; Hessl et al., 2019; Hong & Lee, 2012; Jacques et al., 1998; Janeslätt et al., 2019; Kantner et al., 1982; Lee et al., 2017; Lee et al., 2020; Maïano et al., et a., 2001; McDuffie et al., 2018; Wuang et al., 2013). The two studies published from the same cohort of participants at different time points recorded an average DQ of 30 (Saint-Georges et al., 2020; Tanet et al., 2020). The VABS-II takes into consideration adaptive behaviors and provides a composite DQ score from 20-160 (Sparrow, 2011); an average DQ of 30 could therefore be considered as low. While DQ does not correlate directly to an ID severity level, it has been found to be an acceptable approximation of intellectual capacity (Kawabe et al., 2016).

## **Intervention Sub-groupings**

The categorization of study interventions was based on the ID diagnostic criteria of the DSM-5 (Association, 2013): intellectual and adaptive functioning. Where interventions focused on intellectual functioning, they were categorized as “cognitive abilities”, and included studies with a focus on executive functioning, problem-solving, and learning academic skills such as literacy and mathematics. Adaptive functioning can be described as competencies



required for daily living, operationalized into the categories: “communication,” “social skills,” “activities of daily living,” (ADLs) “school or work functioning,” or “comprehensive.” Communication was defined as the ability to understand and be understood (Cervantes et al., 2019); social skills as the ability to relate with others in a culturally and contextually appropriate manner (Reynolds, 2021); this included sense of self and self-esteem, in consideration of the dialogical perspective, whereby identity is thought to be developed through social interactions with others (Shadden, 2005); ADLs as self-care abilities (Cervantes et al., 2019); school or work functioning as the ability to conform to school or vocational standards (Cervantes et al., 2019). “Comprehensive” was used for those studies which met multiple categories, resulting in the 24 studies being placed into one of:

- Intellectual functioning
  - Cognitive abilities
- Adaptive functioning
  - Activities of daily living
  - Communication skills & abilities
  - Social skills
  - School/work functioning
- Comprehensive (intervention could fulfill two or more categories).

The reported efficacy of interventions will be discussed under these categories: where the effect size is referred to, unless otherwise stated, Cohen’s *d* was used. Of 24 included studies, eight were grouped into the category of cognitive abilities, seven into activities of daily living, two studies into communication, three into social skills, one into school or work functioning. Three studies were grouped as comprehensive interventions.

### ***Cognitive Abilities***

The intervention aims of three articles on cognitive abilities were to improve executive functions including memory (Bennett, et al., 2013; Hessel et al., 2019) and attention (Hong &

Lee, 2012). The two studies aiming to improve memory made use of Cogmed (Cogmed, 2021), a paid-for downloadable computer program: one consisted of a large number of participants (N=100), however the differences between treatment groups were not statistically significant (Hessl et al., 2019). The other study (Bennett, et al., 2013) found significant differences between the treatment group (TG) and control group (CG), as did the study focusing on attention (Hong & Lee, 2012).

A further three studies targeted academic areas, all with children with DS. One study focused on developing math skills, (Lanfranchi et al., 2015), while the other two studies focused on language skills relating to reading (Burgoyne et al., 2012) and grammar (Sepúlveda et al., 2013). All three reported significant differences between TG and CGs; all consisted of one TG and one CG. In relation to developing math skills, statistically, significant differences were found on numerical and counting skills, written calculation, and number knowledge (Lanfranchi et al., 2015); TG effect sizes were medium while the CG effect sizes were very low. The language skills intervention with a focus on reading found significant between-group differences with a small effect size on single-word reading, letter-sound knowledge, phoneme blending, and taught expressive language (Burgoyne et al., 2012). The intervention with a focus on grammar reported significant differences in the outcomes measuring syntax, morphology, and semantics (Sepúlveda et al., 2013).

The two remaining studies were associated with experiential learning processes (Boyce & Clinton, 1976; Litrownik, 1978). One study found no between-group differences (Litrownik et al., 1978), while the other (Boyce & Clinton, 1976), reported a significant difference in how children with or without ID responded to informative or affective social reinforcement. Children with ID responded preferably to affective social reinforcement; effect sizes were not reported.

### ***Activities of Daily Living***

Following cognitive abilities, activities of daily living (ADLs) consisted of the most

studies (7/24). They were most frequently conducted within education settings by education (5/7). Overall, this category consisted of the largest sample sizes compared to the other categories (N = 40-445). Of these studies, approximately half (4/7) concentrated on health: handwashing techniques (Lee et al., 2020); behavioral management during dental restorations (Bagattoni et al., 2020); healthy lifestyle knowledge (Lee et al., 2017); health advocacy skills (McPherson et al., 2017). All reported statistically significant results, although one found this to be in favor of the control group (Bagattoni et al., 2020).

The study focusing on hand washing found statistically significant results relating to hand-washing technique, and to hand cleanliness with small effect sizes (Hedges'  $g < 0.5$ ) (Lee et al., 2020). The study that aimed to improve health advocacy skills also found significant results in relation to participants' self-determination in seeking medical support but did not report effect sizes (McPherson et al., 2017). The study focusing on healthy lifestyle knowledge found statistically significant results in relation to healthy lifestyle knowledge and psychosocial well-being including quality of life, self-esteem, and perceived body shape (Lee et al., 2017); no effect size was reported. The study conducted during the dental appointment (Bagattoni et al., 2020) found statistically significant results in favor of the control group in relation to negative behaviors displayed during the appointment. While the study involved a smaller number of participants (N=45) relative to the others within this category, it established and recruited the minimum required to calculate the effect size.

The other studies (3/7) focused on independent living skills: time management (Janeslätt et al., 2019), occupational performance (Wuang et al., 2013), and community living skills (Drysedale et al., 2008). The study with a focus on time management reported statistically significant between-group differences on time processing with a medium effect size (Janeslätt et al., 2019). In relation to occupational performance, significant differences were found on activity participation, and occupational performance (Wuang et al., 2013); effect sizes were not reported. The community living skills were measured by shopping skills and a telephone task. Statistically significant differences were reported between treatment and control groups for the

shopping skills, with a small effect size. No differences were reported between classroom only based intervention, compared with classroom-community combined intervention.

### ***Communication***

Of the two communication-focused interventions, one intended only to improve spoken language (McDuffie et al., 2018), while (Kantner et al., 1982) aimed to enhance multiple communicative abilities. The study with multiple language foci reported significant differences relating to intervention strategies and engagement time, with large effect sizes, however, no significant differences on language variables were found (McDuffie et al., 2018), possibly due to the relatively small sample size (N=20). The study focusing on spoken language found no significant between-group differences (Kantner et al., 1982); no effect size was reported.

### ***Social Skills***

The three social skills interventions focused on behavior support within a residential setting (Balthazar et al., 1971), and self-identity (Jacques et al., 1998; Maïano et al., 2001). The study focusing on behavior support (Balthazar et al., 1971) reported significant between-group differences but did not report effect size. The two studies related to self-identity focused on: children with ID's perceived competence and self-worth (Maïano et al., 2001); increasing the social acceptance and self-esteem of children with ID (Jacques et al., 1998). No significant results were reported in relation to competence and self-worth (Maïano et al., 2001); the study had a moderate number of participants (N=32). The study that aimed to increase the social acceptance of children with ID reported significant between-group effects both post-intervention and at a 5-week follow-up (Jacques et al., 1998). Neither study reported effect sizes.

### ***School or Work Functioning***

The only study included within this category aimed at soccer skills development (Baran et al., 2013), as developing specific skills can be considered necessary for functioning within school environments. Significant statistical differences on total soccer scores were found in

TGs for participants with ID compared with their CGs, with large effect sizes.

### ***Comprehensive Interventions***

Of the three interventions that could not be included within one category, one focused on both social skills and cognitive abilities (Agbaria, 2020) by supporting parents in a group work setting facilitated by social workers. They reported significant improvements in the outcome measures in the TG, although no effect size was reported. The other two consisted of one curricular intervention, published over two papers at different time points, aiming to improve cognitive abilities, communication, social skills, and school or work functioning (Saint-Georges et al., 2020; Tanet et al., 2020). The curricular intervention was an adapted instruction program aimed at improving multiple abilities including cognitive, communication skills, social skills, and school or work functioning. Nonsignificant differences were reported, while significant improvements over time were found in the TG at 18 and 24 months (Tanet et al., 2020). This outcome was replicated at the 36-month follow-ups (Saint-Georges et al., 2020). The effect sizes ranged from medium to large at months 18 and 24 (Tanet et al., 2020), while they were mostly large (except for two components regarding communication and behaviors with small effect sizes) at month 36 (Saint-Georges et al., 2020).

### **Other Intervention Characteristics**

#### ***Setting***

Few (4/24) studies were conducted in participant homes (Agbaria, 2020; Hessel et al., 2019; McDuffie et al., 2018; Wuang et al., 2013). One study was conducted in a residential school environment (Balthazar et al., 1971). Four of the 24 studies had a community-based component, one of which was at the dentist (Bagattoni et al., 2020), one combined class-based activities with community-based training (Drysdale et al., 2008), two of which were after-school, sports-based activities (Baran et al., 2013; Maïano et al., 2001). Nearly half (11/24) studies were conducted in school environments (Bennett et al., 2013; Burgoyne et al., 2012; Hong & Lee, 2012; Jacques et al., 1998; Janeslätt et al., 2019; Lanfranchi et al., 2015; Lee et al., 2017; Lee

et al., 2020; Saint-Georges et al., 2020; Tanet et al., 2020). It was unclear where the remaining 4 studies were conducted (Boyce & Clinton, 1976; Kantner et al., 1982; Litrownik et al., 1978; Sepúlveda et al., 2013).

### ***Delivery agent***

The intervention in four of the 24 studies was delivered by parents, with support from coaches (Hessl et al., 2019), speech and language therapists (McDuffie et al., 2018), occupational therapists (Wuang et al., 2013), or social workers (Agbaria, 2020). A third (8/24) of study interventions were implemented by education staff, including teachers, special education teachers, and teaching assistants (Bennett et al., 2013; Burgoyne et al., 2012; Hong & Lee, 2012; Janeslätt et al., 2019; Lanfranchi et al., 2015; McPherson et al., 2017; Saint-Georges et al., 2020; Tanet et al., 2020). The intervention delivery of four of the 24 studies involved a collaboration between teaching staff and: peers (Jacques et al., 1998); speech and language therapists (Sepúlveda et al., 2013); school nurses (Lee et al., 2020); school nurses and peers (Lee et al., 2017). One of the 24 study interventions was delivered by the experimenters (Litrownik, et al., 1978), one by the experimenter with occupational therapists (Drysdale et al., 2008), one by the experimenter with speech pathologists (Kantner et al., 1982), and one by a graduate student (Boyce & Clinton, 1976). Few (2/24) of the study interventions were delivered by health or social care professionals, including nurses and care staff (Balthazar et al., 1971) and special needs dentists (Bagattoni et al., 2020). Two of the 24 study interventions were delivered by sports coaches (Baran et al., 2013; Maïano et al., 2001).

### ***Frequency & duration***

Over half (14/24) of the studies reported the frequency of intervention delivery as sessions per week: three studies at 5 times per week (Hessl et al., 2019; McDuffie et al., 2018; Sepúlveda et al., 2013); three studies at 4 times per week (Jacques et al., 1998; Saint-Georges et al., 2020; Tanet et al., 2020); three studies at 3 times per week (Baran et al., 2013; Bennett et al., 2013; Hong & Lee, 2012); and four studies at twice per week (Drysdale et al., 2008; Kantner et al.,

1982; Lanfranchi et al., 2015; Sepúlveda et al., 2013). One study implemented the intervention 3 days per week, then 3 days per fortnight as per their protocol (Lee et al., 2020). One study initially implemented their intervention once per week, then fortnightly as per their protocol (Lee et al., 2017), while one study intervention was conducted during a single dental visit (Bagattoni et al., 2020).

Few (5/24) studies detailed frequency of intervention in terms of number and duration of sessions: 2 hours per week (Mañano et al., 2001); 4 x 20 minutes (A. J. C. Litrownik, C. P.; Lecklitner, G. L.; Franzini, L. R., 1978); 24 x 15 minutes (Boyce & Clinton, 1976); varying number of sessions at 15 minutes per session (Wuang et al., 2013); 15 sessions x 2.5 hours (Agbaria, 2020). Three of the 24 studies did not explicitly report on frequency due to the intervention approach being holistic in nature, i.e., adapted individual curricula or care plans, and as such the intervention frequency could not be precisely defined (Balthazar et al., 1971; G. A. Janeslätt et al., S. W.; Granlund, M., 2019; McPherson et al., 2017).

In relation to the duration of the intervention period, seven of the 24 studies were conducted over a 6–8-week period (Baran et al., 2013; Drysdale et al., 2008; Hessel et al., 2019; Jacques et al., 1998; G. A. Janeslätt et al., S. W.; Granlund, M., 2019; Kantner et al., 1982; Lanfranchi et al., 2015; Sepúlveda et al., 2013). Three of the 24 studies were conducted over a 10-12 week/3-month period (Bennett et al., 2013; Hong & Lee, 2012; McDuffie et al., 2018). Six studies were conducted over a 4–7-month period (Burgoyne et al., 2012; Lee et al., 2017; Lee et al., 2020; Mañano et al., 2001; McPherson et al., 2017; Wuang et al., 2013). The two studies based on the same cohort of participants were published after two years, reporting on 18 and 24 months of data (Tanet et al., 2020), and after three years, on completion of the study (Saint-Georges et al., 2020). Few of the studies (4/24) did not report on overall duration (Agbaria, 2020; Balthazar et al., 1971; Boyce & Clinton, 1976; Litrownik et al., 1978).

A small number of studies (3/24) reported follow-up data at 3-months/12 weeks (Bennett et al., 2013; Hessel et al., 2019); or at 6-months (Lee et al., 2020). The remaining 21 studies did not report follow-up data.

## **Comparators**

Most (18/24) studies consisted of treatment groups (TG) and treatment as usual (TAU) or waiting list (WL) control groups (CG): 12 consisted of one TG and one TAU-CG (Bagattoni et al., 2020; Balthazar et al., 1971; Baran et al., 2013; Jacques et al., 1998; Janeslätt et al., 2019; Lanfranchi et al., 2015; Lee et al., 2017; McDuffie et al., 2018; McPherson et al., 2017; Saint-Georges et al., 2020; Tanet et al., 2020; Wuang et al., 2013); three consisted of two TGs and one TAU-CG (Drysdale et al., 2008; Hong & Lee, 2012; Litrownik, 1978); two studies consisted of one TG and one WL-CG (Bennett et al., 2013; Burgoyne et al., 2012); one study consisted of three TGs and 1 TAU-CG (Maïano et al., 2001). Two of the 24 studies consisted of one (Sepúlveda et al., 2013) or two (Kantner et al., 1982) TGs while the CG received regular speech and language therapy, and one study involved one TG while the CG received art therapy (Agbaria, 2020). Three of the 24 studies consisted of two TGs without CGs (Boyce & Clinton, 1976; Hessel et al., 2019; Lee et al., 2020).



## Discussion

Following systematic searches to identify non-pharmacological interventions using RCT study designs with children with ID, a broad range of research, addressing a variety of cognitive and adaptive functioning domains were identified. The results obtained were diverse to such an extent that did not allow for meta-analysis. The research was conducted globally, across multiple decades and settings. The 24 included studies were categorized on the basis of intervention focus into cognitive abilities, and areas of adaptive functioning including ADLs, social skills, communication skills, school or work functioning, or comprehensive. The total number of studies included was relatively small, particularly considering the lack of limitation placed on the year of publication, although was likely due to restrictions placed on the study design. This further supports previous findings that RCT studies were performed less frequently with ID populations than with the general population (Mulhall, 2018; Northway, 2013). Within the article, the discussion was limited to the explicit research aims, commenting on interventions identified, methodological quality, effectiveness, and limitations. This discussion expands on those areas, including increased consideration of how terminology changes, theoretical perspectives, and legislation, may have impacted the research identified.

### Interventions

The terminology changes over time used to refer to people with ID were observed. Older studies published in the 1970-80s, in the USA, referred to participants as “retarded” (Balthazar et al., 1971; Boyce & Clinton, 1976; Kantner et al., 1982; Litrownik, et al., 1978). There was one more recent paper published in 2001, in France, that also referred to participants as having “mild to moderate mental retardation” (Maïano et al., 2001). The remaining 19 included studies referred either to ID or to other diagnosed conditions associated with ID, namely DS and FXS. This included those studies conducted in the UK, where the term “learning disability” continues

to be used more frequently than ID by health and social care professionals (Cluley, 2018). This possibly suggests a change in terminology used within academia in the UK, despite the ongoing preference toward learning disability within other disciplines (Cluley, 2018).

Most studies focused on either cognitive abilities or ADLs within adaptive functioning, with less evidence produced in relation to the other adaptive functioning areas of social skills, communication, school/work functioning, and comprehensive studies. The interest in cognitive abilities may relate to the previous emphasis placed on cognitive abilities within the assessment and diagnostic process (Roth et al., 2019). The increased interest in ADLs compared to other areas of adaptive functioning may relate to an ongoing drive toward increasing independent living skills within ID populations, as has been the trend since the 1980s following deinstitutionalization (King et al., 2017). Enhancing such abilities may help to reduce the intensity of support someone with ID requires on a daily or weekly basis (Curry, 2006).

Limited high-quality RCT design research conducted in relation to social skills, communication abilities, and school/work functioning were found. Given the significant impact these skills have on health, activity participation, and quality of life, these areas need to be addressed. Deficits in these areas can increase social isolation, loneliness, and mental health difficulties (Alexandra et al., 2018; Kocman & Weber, 2018; Louw et al., 2020), while enhancing social skills may contribute to lower rates of psychiatric comorbidity (Glasson et al., 2020). Furthermore, given that limited communication abilities are a predictor for increased challenging behaviors (Bowring et al., 2019), the presence of which results in poorer, less cost-effective, outcomes for people with ID, their caregivers, and communities (Buckley et al., 2020), it was equally concerning that limited studies were found in this area. Future high-quality research would therefore be beneficial in the adaptive functioning areas of social skill development, specifically communication and skills for school and work functioning.

As reported in a recent systematic review, there was a trend toward introducing digital devices into interventions (Moreno et al., 2021). It may be of interest to explore the use of

technology such as applications available on smartphones, to increase the involvement of parents and other caregivers within the education and support of their children with ID. One study (Lee et al., 2017) used this approach to involve participants' families in supporting the intervention and this may be a cost-effective way to increase collaboration between school and home settings.

### ***Theoretical perspectives***

The studies published during the 1970s referred to behavioral theories in the rationale for their interventions (Balthazar et al., 1971; Boyce & Clinton, 1976; Litrownik et al., 1978). There was a specific discussion of reinforcement and learning theory as related to behavior modification (Balthazar et al., 1971), social learning theory (Boyce & Clinton, 1976), and one with specific reference to Bandura's social learning theory (Litrownik, et al., 1978). This was consistent with the dominance of behaviorism during this period (Ainscow & Tweddle, 1979). This influence was particularly clear in the earliest study (Balthazar et al., 1971) where participants included children living within residential settings. Adaptations were made as part of the intervention approaches to improve living environments and to support staff's understanding of reinforcement techniques and nurturant approaches.

While other theories have increasingly been drawn from, behavioral approaches were acknowledged either as the basis of, or as a part of, an intervention in more recent years, 2017-2020. Lee and colleagues drew from Bandura's social learning theory when developing handwashing and weight management interventions in China (Lee et al., 2017; Lee et al., 2020). Behavior interventions were also considered alongside technological devices within the weight management intervention (Lee et al., 2017), and within a study aiming to support children with DS manage dental appointments (Bagattoni et al., 2020). The study exploring audio-visual distraction aids during dental appointments for children with DS did not support the intervention, finding significant issues in participant compliance with the intervention,

highlighting that traditional behavior management techniques can be as effective, if not more so, during times of increased stress for such participant groups.

There was also some evidence of studies drawing on multiple theories, particularly within those categorized as comprehensive. The two papers based on the same study (Saint-Georges et al., 2020; Tanet et al., 2020) drew on behaviorist principles, specifically referring to the use of ABA and other recognized, structured teaching strategies. They noted that they made adaptations to the environment, minimizing distractions, and creating a sense of routine within participant's schooldays over the course of the 3-year study. They also made reference to the importance of staff training and supervision, and of adopting a strengths-based approach in relation to both staff and participants. While they did not find significant improvements in the TG compared to the CG, they did highlight that the study had found the implementation of such approaches feasible.

### ***Research directions: past, present, future***

The World Health Organization (Emerson, 2012) highlighted research priorities nearly ten years ago, including to “ensure that good quality mental and physical health care is coordinated and sustained” (Emerson, 2012, p. 13) and “empower children and young people with intellectual disabilities to contribute to decision-making about their lives” (Emerson, 2012, p. 15). The need for increased support in relation to developing social skills and communication was also observed, especially in relation to improving the mental health of those with ID (Buckley et al., 2020; Whittle et al., 2018). Findings from the included studies suggest that there have been some moves toward addressing these. For instance, the paper exploring how to promote adolescents' independent engagement with healthcare services could be seen to be addressing both self-determination and improving health-related outcomes (McPherson, 2017). While promising, this was limited to only one study, and the area of self-determination, applied to contexts other than healthcare, requires further high-quality research to promote the self-advocacy capacity of people with ID.

Another study that aimed to improve health outcomes, did so by targeting the hand-washing techniques of children and adolescents with ID (Lee et al., 2020). This has become of international interest since the Covid-19 pandemic and was perhaps unsurprised that it was developed in Asia, where previous highly contagious epidemics had been most impactful. The study cited H1N1, among other diseases, as having resulted in a substantial loss of school days in children with ID, highlighting that these children were at particular risk of contracting and spreading diseases best managed with good preventative hand hygiene (Lee et al., 2020). As this was seen as likely related to children with ID experiencing difficulties in learning skills with such complex steps, they adapted a simplified hand-washing program from 7-steps to 5-steps. While the intervention did not find significant improvements in school absenteeism, the 5-step program was found to have significantly improved hand cleanliness and hand-washing techniques, compared to the 7-step programs. Of note, the program was only implemented within the school environment and did not involve parents or other caregivers. As this is where, and with whom, children spend most of their time, and as significant findings were found in improvements of technique and cleanliness while at school, absenteeism may be improved by including parents and families within such interventions, to promote good hand hygiene across environments. This could be promoted using mobile phone applications, such as mHealth, used in the study examining weight management interventions (Lee et al., 2017).

While those studies considered physical health care and improving self-determination capacity, there were no studies identified that measured psychological well-being as a primary outcome. While some studies included self-esteem as a secondary outcome, these were in the contexts of whether children with ID would be socially accepted by their peers (Jacques et al., 1998), and the efficacy of a weight management program (Lee et al., 2017). The inclusion of these important factors within diverse studies was valuable, however, they require further, more focused attention within high-quality studies.

While there was only one study that explicitly addressed self-determination (McPherson et al., 2017), other studies examined how to support children with ID to develop self-awareness

with respect to their abilities (Litrownik, et al., 1978; Maïano et al., 2001). The emphasis of one study was placed on ensuring children had realistic expectations of their abilities, referring to issues surrounding children with ID overestimating their capacity, and raised concerns around the impact of including children with ID on their peers without ID (Maïano et al., 2001). While such considerations are not unreasonable, the emphasis was not solution-focused and seemed less concerned with the empowerment of people with ID, and more concerned with the potential impact their inclusion may have on those without ID. This does not embrace the “education for all” principles outlined within the Salamanca Statement (UNESCO, 1994) only seven years earlier. Of interest this was the only included study that referred to children with ID as “mentally retarded” since 1994, potentially further highlighting the impact terminology use may have on perceptions.

## **Effectiveness**

The impact of the Salamanca Statement (UNESCO, 1994), and other disability legislation such as the United Nations Convention on the Rights of Persons with Disabilities (Nations, 2006), can be seen in the increase in higher quality study designs; most of the included studies were published between 1998 – 2020, and of those more recent studies, lower levels of risk of bias were found overall. However, few studies included follow-up measures to evaluate whether the effects of interventions were maintained. The inclusion of more follow-up measures is therefore recommended, as RCT evidence is often used to provide information on best practice and funding directions, and knowledge of long-term benefits could further support where best to use resources.

Most of the included studies reported statistically significant improvements. Among studies reporting effect sizes, most reported small to medium effect sizes. There has been some evidence that interventions may be more effective when implemented more frequently and for a longer duration (Bryant, 1999). Taking risk of bias and sample sizes into consideration alongside frequency and duration of the intervention, it was observed that studies with lower

risk of bias, larger sample sizes, and increased frequency and duration demonstrated increased efficacy (Baran et al., 2013; Lee et al., 2017; Lee et al., 2020; McDuffie et al., 2018; McPherson et al., 2017; Wuang et al., 2013).

## **Methodological quality**

There were several issues in the generalizability of the results found. Most studies were completed in economically developed countries, predominantly in the US or Europe. The sample size was often limited, with about a third of studies consisting of fewer than 30 participants. There was also more research conducted with children under 12 years, but few studies involved only adolescents. The lack of studies focusing on adolescents with ID may have a significant impact during this crucial transition period, where it is necessary to support the development of skills to live independently in later adulthood (Memisevic & Djordjevic, 2019). Therefore, more RCT evidence exploring how best to effectively support people during this time would be beneficial particularly within low-income countries and with reasonable sample sizes.

There was some evidence of studies incorporating multi-disciplinary practice, with intervention agents including specialists such as speech therapists and occupational therapists in some studies (Kantner et al., 1982; Sepúlveda et al., 2013; Wuang et al., 2013). However, there was limited use of examining whether skills developed from an intervention in one setting could transfer to another setting. The one exception was a study that examined whether language development skills were transferred from the home environment to an unfamiliar clinical setting (McDuffie et al., 2018). The scarcity of studies set within local communities, and the limited number of studies exploring how effectively skills can be transferred between settings, limited the generalizability of findings.

Another area that was not represented within the included studies was that of the use of peer support within interventions (Jacques et al., 1998; Lee et al., 2017), despite most studies

being set within school environments. Given the growing interest around the benefits of peer support both for children with ID (and other additional support needs), and to those children who act as “peers” (Cowie, 2019), it would be of interest to explore their application utilizing high-quality RCT research designs. This may also provide further support on the practical implementation of inclusive principles, an area in which teachers have expressed a desire for more information (Ferriday & Cantali, 2020; Scruggs & Mastropieri, 2017).

Outcomes and outcome measures, varied significantly between all studies, reflecting the diverse range of needs within the ID population, and the broad topics considered within intellectual and adaptive functioning. This resulted in difficulties in drawing comparisons and performing a meta-analysis. Furthermore, few measures target the two core deficits of ID directly, i.e., intellectual ability and adaptive function. Most measures target more specific skills such as communication and social skills. As supported in a recent article, this may be due to a lack of measurements appropriate for all ID severities and of measurements sufficiently sensitive to detect small, incremental changes during interventions (Thurm et al., 2020). Overall, these findings call for further development of appropriate measurements for ID across ages and abilities.

When extracting data in relation to diagnostic criteria and ID definitions, information was found to be sporadic and inconsistent. This may be related to the presence of three distinct manuals from which ID can be diagnosed and defined, with little to no global consensus on which should be applied within research. It may also be indicative of the more complex diagnosis procedure where IQ is not the only factor being considered, but adaptive functioning is also incorporated within the diagnosis. It would be impractical to suggest a uniform approach toward a global diagnostic tool, given the disparities between national resources, and the need to take into consideration socio-cultural impacts on ID. It may however be beneficial to ensure descriptions of how children received ID diagnoses be reported to allow for easier comparisons of intervention effectiveness. Additionally, there was a significant imbalance of studies in terms



of ID severity, with over half of the studies-focusing on children with mild ID. As those with mild ID account for 85% of the ID population (Cervantes et al., 2019), it was unsurprising that this group accounted for the majority of included studies. It has remained unclear whether intervention focuses and approaches for individuals with mild-moderate ID are appropriate or transferable for individuals with more severe ID (Gargiulo & Bouck, 2017; Lunsy et al., 2010), further supporting the need for RCTs that explore how best to support people with more severe ID.

## **Limitations**

One limitation was related to the age range. While it was selected as 5-18 years in line with the UN definition (Nations, 1989), arguments have been made for increasing the upper age limit denoting the beginning of adulthood to 21, or even 25 years, as supported by social and cultural shifts in some countries, and from neuropsychological research (Arnone, 2014). Furthermore, different diagnostic manuals contain conflicting information as they either do not state the upper age limit of the “development period” in which symptoms must appear (Association, 2013; Organization, 2020) or have placed the upper age limit at 22 years (Schalock et al., 2021). Another limitation of this review was that only English studies were included. This may have limited potentially relevant and useful findings and posed a further barrier in the dissemination of information between cultures (Morrison et al., 2012). Finally, a common theme among all literature reviews was the limitation of publication bias; it has been well documented that issues persist in this area, with studies that report no significant findings often not being published (Sun et al., 2018).

## **Conclusion**

This systematic review identified 24 studies that met the inclusion criteria. Most of these studies were in the areas of cognitive abilities and ADLs, with far less focus placed on social skills, communication, and school/work functioning. Most studies reported statistically

significant improvements and targeted children with mild ID in school settings, with less focus placed on adolescents. Therefore, there is a need for more RCTs conducted in different settings, involving adolescents, in areas such as social skills, communication, and school/work functioning.

As a result of the heterogeneity of participant characteristics, interventions used, and outcome measures, a meta-analysis was not possible. Some evidence from high-level, low risk of bias research, indicates effective non-pharmacological interventions. However, further exploration of how to develop procedures to measure outcomes explicitly related to changes in intellectual and adaptive functioning, particularly for people with severe-profound ID, would benefit further RCT research designs. This may support the increased involvement of people with more severe ID within RCTs, an area that is also in need of more high-level evidence to support best practice.

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Wuang, Y. P.; Ho., G. S.; Su, C. Y. (2013a). Occupational therapy home program for children with intellectual disabilities: A randomized, controlled trial. *Research in Developmental Disabilities*, 34(1), 528-537. <https://doi.org/http://dx.doi.org/10.1016/j.ridd.2012.09.008>

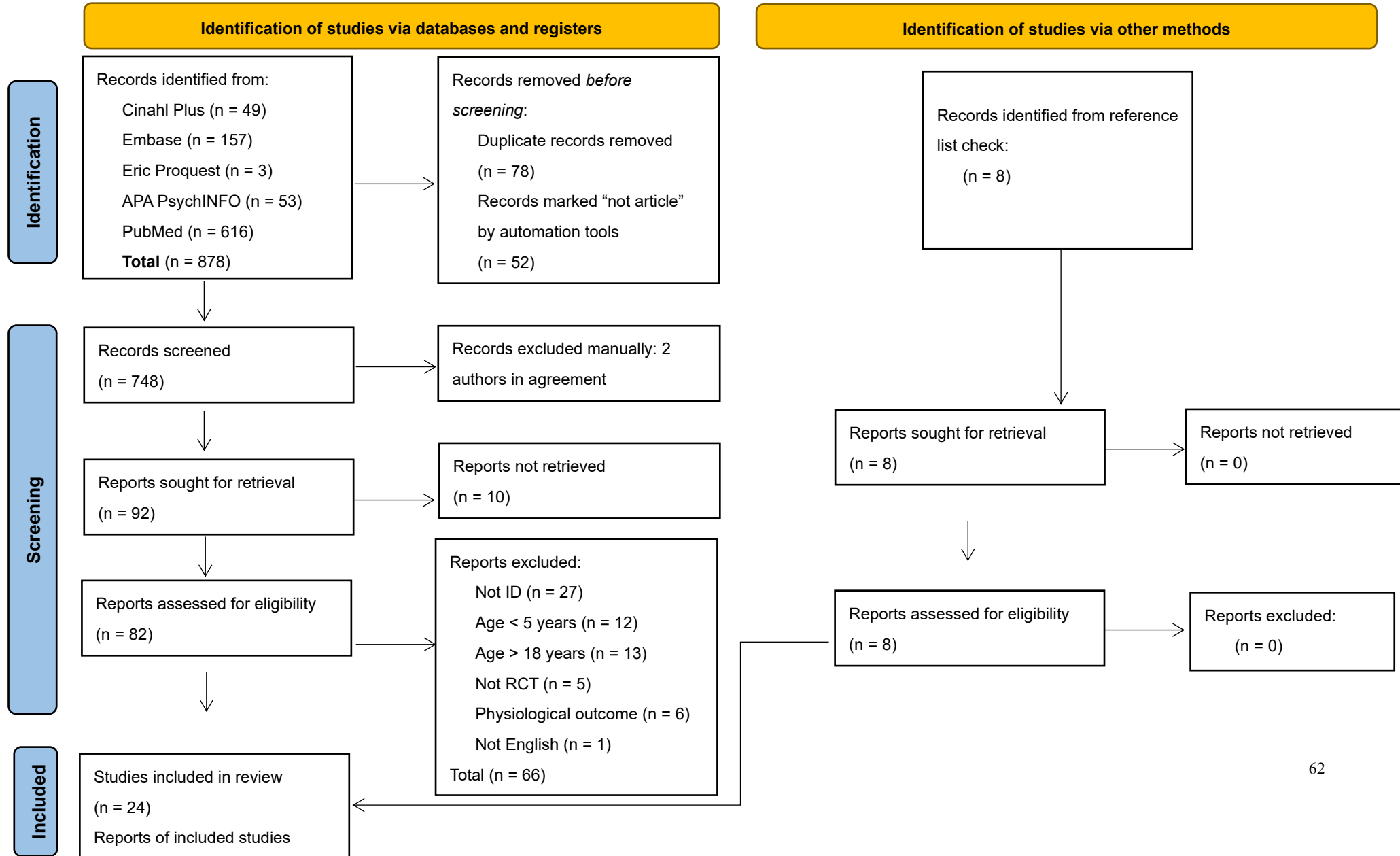
Yoshioka, A. (1998). Use of randomisation in the Medical Research Council's clinical trial of streptomycin in

pulmonary tuberculosis in the 1940s. *Bmj*, 317(7167), 1220-1223.

Zwarenstein, M., Treweek, S., Gagnier, J. J., Altman, D. G., Tunis, S., Haynes, B., Oxman, A. D., & Moher, D. (2008). Improving the reporting of pragmatic trials: an extension of the CONSORT statement. *Bmj*, 337.

# Attachments

Figure 1. PRISMA Flow Diagram



**Table 1. PRISMA Checklist**

Section & Topic	Item #	Checklist item	Location where item is reported
<b>TITLE</b>			
Title	1	Identify the report as a systematic review.	1
<b>ABSTRACT</b>			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	2
<b>INTRODUCTION</b>			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	4
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	4
<b>METHODS</b>			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	5
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	5
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	5 ( <a href="#">link</a> )
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	5-6 ( <a href="#">link</a> )
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	6
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	6
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	6
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	6
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	N/A
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	N/A
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	N/A
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	6
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	N/A
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	N/A

Section & Topic	Item #	Checklist item	Location where item is reported
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	N/A
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	N/A
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	N/A
<b>RESULTS</b>			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	6-7
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	6-7 ( <a href="#">link</a> )
Study characteristics	17	Cite each included study and present its characteristics.	6-7 ( <a href="#">link</a> )
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	7 ( <a href="#">link</a> )
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	7 ( <a href="#">link</a> )
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	N/A
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	N/A
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	N/A
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	N/A
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	7 ( <a href="#">link</a> )
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	N/A
<b>DISCUSSION</b>			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	12-15
	23b	Discuss any limitations of the evidence included in the review.	13-15
	23c	Discuss any limitations of the review processes used.	16
	23d	Discuss implications of the results for practice, policy, and future research.	13-15
<b>OTHER INFORMATION</b>			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	5
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	N/A
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	N/A



Section & Topic	Item #	Checklist item	Location where item is reported
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	2
Competing interests	26	Declare any competing interests of review authors.	2
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	N/A

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ* 2021;372:n71. doi: 10.1136/bmj.n71

**Table 2. Search Strategies**  
**Search strategies [Date 290121]**

Database and Search Terms	Number of records
<p><b>Cinahl Plus with Full Text:</b> (MH "Intellectual Disability") AND (MH "Randomized Controlled Trials")</p> <p>Limit to: infant, newborn: birth-1 month; infant: 1-23 months; all infant; child, preschool: 2-5 years; adolescent: 13-18 years; child: 6-12 years; all child</p>	49
<p><b>Embase (1974 to 2021 Jan 27):</b> (intellectual impairment/dm, pc, rh, th [Disease Management, Prevention, Rehabilitation, Therapy] OR mental deficiency/dm, pc, rh, th [Disease Management, Prevention, Rehabilitation, Therapy] OR cognitive defect/dm, pc, rh, th [Disease Management, Prevention, Rehabilitation, Therapy]) AND (randomization/ OR randomized controlled trial/ OR "randomized controlled trial (topic)"/ OR controlled clinical trial/)</p> <p>Limit to (infant &lt;to one year&gt; or child &lt;unspecified age&gt; or preschool child &lt;1 to 6 years&gt; or school child &lt;7 to 12 years&gt; or adolescent &lt;13 to 17 years&gt;)</p>	157
<p><b>Eric (Proquest):</b> (MAINSUBJECT.EXACT("Moderate Intellectual Disability") OR MAINSUBJECT.EXACT("Mild Intellectual Disability") OR MAINSUBJECT.EXACT("Intellectual Disability") OR MAINSUBJECT.EXACT("Severe Intellectual Disability")) AND (RCT OR (Randomized AND Controlled AND Trial) OR (Randomised AND Controlled AND Trial) OR (Randomized AND Clinical AND Trial) OR (Randomised AND Clinical AND Trial) OR (Controlled AND Clinical AND Trial))</p> <p>Limit to: Early childhood education, Elementary education, Elementary secondary education, Grade 1, Grade 2, Grade 3, Grade 4, Grade 5, Grade 6, Grade 7, Grade 8, Grade 9, Grade 10, Grade 11, Grade 12, High school equivalency programs, High schools, Intermediate grades, Junior high schools, Kindergarten, Middle schools, Preschool education, Primary education, Secondary education</p>	3
<p><b>APA PsycINFO (1806 to Dec week 2 2020):</b> (intellectual development disorder/ or "intellectual development disorder (attitudes toward)"/ OR *cognitive impairment/) AND (RCT OR (Randomized AND Controlled AND Trial) OR (Randomised AND Controlled AND Trial) OR (Randomized AND Clinical AND Trial) OR (Randomised AND Clinical AND Trial) OR (Controlled AND Clinical AND Trial)).ab,ti.</p> <p>Limit to childhood &lt;birth to age 12 yrs&gt; or adolescence &lt;age 13 to 17 yrs&gt;</p>	53
<p><b>PubMed:</b> (( "Intellectual Disability/education"[Mesh] OR "Intellectual Disability/nursing"[Mesh] OR "Intellectual Disability/prevention and control"[Mesh] OR "Intellectual Disability/psychology"[Mesh] OR "Intellectual Disability/rehabilitation"[Mesh] OR "Intellectual Disability/therapy"[Mesh] ) OR ( "Cognitive Dysfunction/diet therapy"[Mesh] OR "Cognitive Dysfunction/nursing"[Mesh] OR "Cognitive Dysfunction/prevention and control"[Mesh] OR "Cognitive Dysfunction/psychology"[Mesh] OR "Cognitive Dysfunction/rehabilitation"[Mesh] OR "Cognitive Dysfunction/therapy"[Mesh] )) AND ("Randomized Controlled Trial" [Publication Type] OR "Randomized Controlled Trials as Topic"[Mesh] OR "Controlled Clinical Trial" [Publication Type] OR "Pragmatic Clinical Trials as Topic"[Mesh])</p> <p>Limit to Child: birth-18 years</p>	616

**Total number of records (including duplicates): 878**

**Total number of records (excluding duplicates): 800**

**Export to Excel (articles only): 748**

**Table 3.** Excluded articles: “0” marked under reason for exclusion.

Reference	Age 5-18	ID	RCT	Behavior outcome	Full text in English	Available full text
1. Aeschleman SRH, A. F. Concept learning by retarded children: a comparison of three discrimination learning procedures. <i>J Ment Defic Res.</i> 1982 Dec;26 (Pt 4):229-38.		0				
2. Ainsworth MKE, A. S.; Behrmann, M.; Jerome, M. Teaching phonics to groups of middle school students with autism, intellectual disabilities and complex communication needs. <i>Res Dev Disabil.</i> 2016 Sep;56:165-76.			0			
3. Apache RR. Activity-based intervention in motor skill development. <i>Percept Mot Skills.</i> 2005 Jun;100(3 Pt 2):1011-20.		0				
4. Asmus JMC, E. W.; Moss, C. K.; Biggs, E. E.; Bolt, D. M.; Born, T. L.; Bottema-Beutel, K.; Brock, M. E.; Cattey, G. N.; Cooney, M.; Fesperman, E. S.; Hochman, J. M.; Huber, H. B.; Lequia, J. L.; Lyons, G. L.; Vincent, L. B.; Weir, K. Efficacy and Social Validity of Peer Network Interventions for High School Students With Severe Disabilities. <i>Am J Intellect Dev Disabil.</i> 2017 Mar;122(2):118-137.		0				
5. Bagner DME, S. M. Parent-child interaction therapy for disruptive behavior in children with mental retardation: A randomized controlled trial. <i>Journal of Clinical Child and Adolescent Psychology.</i> 2007;36(3):418-429.	0					
6. Baroody AJ. Number-comparison learning by children classified as mentally retarded. <i>Am J Ment Retard.</i> 1988 Mar;92(5):461-71.						0
7. Ben Itzhak EL, E.; Burgin, R.; Zachor, A. D. Cognitive, behavior and intervention outcome in young children with autism. <i>Res Dev Disabil.</i> 2008 Sep-Oct;29(5):447-58.		0				
8. Bordini DP, C. S.; Cunha, G. R.; Caetano, S. C.; Bagaiole, L. F.; Ribeiro, T. C.; Martone, M. C. C.; Portolese, J.; Moya, A. C.; Brunoni, D.; Bosa, C.; Brentani, H.; Cogo-Moreira, H.; de Jesus Mari, J. A randomised clinical pilot trial to test the effectiveness of parent training with video modelling to improve functioning and symptoms in children with autism spectrum disorders and intellectual disability. <i>Journal of Intellectual Disability Research.</i> 2020 01 Aug;64(8):629-643.	0					
9. Bossink LW, van der Putten AA, Waning A, et al. A power-assisted exercise intervention in people with profound intellectual and multiple disabilities living in a residential facility: a pilot randomised controlled trial. <i>Clinical rehabilitation.</i> 2017;31(9):1168-1178.	0					

10.	Buschert VCG, I.; Teipel, S. J.; Jolk, S.; Hampel, H.; Rujescu, D.; Buerger, K. Long-term observation of a multicomponent cognitive intervention in mild cognitive impairment. <i>J Clin Psychiatry</i> . 2012 Dec;73(12):e1492-8.		0				
11.	Devitt P. Research digest. <i>Paediatric Nursing</i> . 2011;23(1):10-10.						0
12.	Gates BN, R.; Wray, J. Behaviour modification and gentle teaching workshops: management of children with learning disabilities exhibiting challenging behaviour and implications for learning disability nursing. <i>Journal of advanced nursing</i> . 2001 Apr;34(1):86-95.	0					
13.	Hand AR, C. N.; Cuppage, J.; Coyle, S.; Sharry, J. A controlled clinical evaluation of the Parents Plus Children's Programme for parents of children aged 6-12 with mild intellectual disability in a school setting. <i>Clin Child Psychol Psychiatry</i> . 2013 Oct;18(4):536-55.		0				
14.	Harris SR. Effects of neurodevelopmental therapy on motor performance of infants with Down's syndrome. <i>Dev Med Child Neurol</i> . 1981 Aug;23(4):477-83.				0		
15.	Heal LWC, L. S.; Gross, J. C. A true experiment evaluating adult skill training for severely mentally retarded secondary students. <i>Am J Ment Defic</i> . 1984 Sep;89(2):146-55.						0
16.	Heitman RJG, W. F. Effects of blocked versus random practice by mentally retarded subjects on learning a novel skill. <i>Percept Mot Skills</i> . 1989 Oct;69(2):443-7.				0		
17.	Hemayattalab RM, A. Effects of different variations of mental and physical practice on sport skill learning in adolescents with mental retardation. <i>Research in Developmental Disabilities</i> . 2010 January 2010/February;31(1):81-86.				0		
18.	Hodes MWM, M.; de Moor, M.; Kef, S.; Schuengel, C. Alleviating Parenting Stress in Parents with Intellectual Disabilities: A Randomized Controlled Trial of a Video-feedback Intervention to Promote Positive Parenting. <i>J Appl Res Intellect Disabil</i> . 2017 May;30(3):423-432.	0	0				
19.	Hodes MWM, M.; de Moor, M.; Kef, S.; Schuengel, C. Effects of video-feedback intervention on harmonious parent-child interaction and sensitive discipline of parents with intellectual disabilities: A randomized controlled trial. <i>Child Care Health Dev</i> . 2018 Mar;44(2):304-311.	0	0				
20.	Holzapfel SDR, S. D.; Mulvey, G. M.; Sandoval-Menendez, A. M.; Cook, M. R.; Ganger, R. O.; Bennett, K. Improvements in manual dexterity relate to improvements in cognitive planning after assisted cycling therapy (ACT) in adolescents with down syndrome. <i>Res Dev Disabil</i> . 2015 Oct-Nov;45-	0					

	46:261-70.						
21.	Huang XY, Q.; Luo, Q.; Zeng, H.; Zheng, X.; Huang, X.; Yu, Y.; Wu, Y. [Clinical efficacy on mental retardation in the children treated with JIN's three scalp needling therapy and the training for cognitive and perceptual disturbance]. <i>Zhongguo Zhen Jiu</i> . 2015 Jul;35(7):651-6.						0
22.	Janeslätt GK, A.; Granlund, M. Evaluating intervention using time aids in children with disabilities. <i>Scand J Occup Ther</i> . 2014 May;21(3):181-90.		0				
23.	Jansen BRDL, E.; Van der Molen, M. J. Math practice and its influence on math skills and executive functions in adolescents with mild to borderline intellectual disability. <i>Res Dev Disabil</i> . 2013 May;34(5):1815-24.		0				
24.	Kahn JV. A comparison of sign and verbal language training with nonverbal retarded children. <i>J Speech Hear Res</i> . 1981 Mar;24(1):113-9.	0					
25.	Kaiser APR, M. Y. Parent-implemented enhanced milieu teaching with preschool children who have intellectual disabilities. <i>Journal of speech, language, and hearing research : JSLHR</i> . 2013 Feb;56(1):295-309.	0					
26.	Kanode JOP, V. G. Effects of variable practice on retention and motor schema development in Down syndrome subjects. <i>Percept Mot Skills</i> . 1989 Aug;69(1):211-8.	0					
27.	Karaaslan OM, G. Effectiveness of responsive teaching with children with Down syndrome. <i>Intellect Dev Disabil</i> . 2013 Dec;51(6):458-69.	0					
28.	Kiewik MV, J. E. L.; Kemna, L. E. M.; Engels, R. C. M E; DeJong, C. A. J. Substance use prevention program for adolescents with intellectual disabilities on special education schools: a cluster randomised control trial. <i>Journal of Intellectual Disability Research</i> . 2016;60(3):191-200.		0				
29.	Kirk HEG, K. M.; Ellis, K.; Taffe, J.; Cornish, K. M. Computerised attention training for children with intellectual and developmental disabilities: a randomised controlled trial. <i>J Child Psychol Psychiatry</i> . 2016 Dec;57(12):1380-1389.	0					
30.	Kirk HG, K.; Ellis, K.; Taffe, J.; Cornish, K. Impact of Attention Training on Academic Achievement, Executive Functioning, and Behavior: A Randomized Controlled Trial. <i>Am J Intellect Dev Disabil</i> . 2017 Mar;122(2):97-117.	0					

31.	Kleefman MJ, D. E. M. C.; Stewart, R. E.; Reijneveld, S. A. The effectiveness of Stepping Stones Triple P parenting support in parents of children with borderline to mild intellectual disability and psychosocial problems: A randomized controlled trial. BMC Medicine. 2014;12(1).	0				
32.	Klein AMS, E.; de Hullu, E.; Houtkamp, E.; Papa, M.; van der Molen, M. Cognitive Bias Modification Reduces Social Anxiety Symptoms in Socially Anxious Adolescents with Mild Intellectual Disabilities: A Randomized Controlled Trial. J Autism Dev Disord. 2018 Sep;48(9):3116-3126.	0				
33.	Ko EJS, I. Y.; Yuk, J. S.; Jang, D. H.; Yun, G. A tablet computer-based cognitive training program for young children with cognitive impairment: A randomized controlled trial. Medicine (Baltimore). 2020 Mar;99(12):e19549.	0				
34.	Leblanc LAM, J. L. A social skills training program for preschoolers with developmental delays. Generalization and social validity. Behav Modif. 1995 Apr;19(2):234-46.	0				
35.	MacDonald AM, P.; Murphy, G. An evaluation of staff training in positive behavioural support. Journal of applied research in intellectual disabilities : JARID. 2018 01 Nov;31(6):1046-1061.	0				
36.	Martin G, Costello H, Leese M, et al. An exploratory study of assertive community treatment for people with intellectual disability and psychiatric disorders: conceptual, clinical, and service issues [Article]. Journal of Intellectual Disability Research. 2005 Jul;49:516-524.	0				
37.	McCormack LAW, A.; Moultrie, R.; Furberg, R. D.; Wheeler, A. C.; Treiman, K.; Bailey, D. B., Jr.; Raspa, M. Supporting informed clinical trial decisions: Results from a randomized controlled trial evaluating a digital decision support tool for those with intellectual disability. PLoS One. 2019;14(10):e0223801.	0				
38.	McCubbin JC, C. S.; Jansma, P.; Decker, J. T.; Ersing, W. Personal health training and the severely handicapped: a curriculum based research investigation. Health Educ Q. 1988 Summer;15(2):217-23.	0				
39.	Morrison TLN, B. L. Effects of directive vs. nondirective play therapy with institutionalized mentally retarded children. Am J Ment Defic. 1975 May;79(6):666-9.					0
40.	Neman RR, P.; McCann, R. M.; Menolascino, F. J.; Heal, L. W. Experimental evaluation of sensorimotor patterning used with mentally retarded children. Am J Ment Defic. 1975 Jan;79(4):372-84.					0

41.	Nestler JG, L. A pilot study of social competence group training for adolescents with borderline intellectual functioning and emotional and behavioural problems (SCT-ABI). <i>J Intellect Disabil Res.</i> 2011 Feb;55(2):231-41.		0				
42.	Oliver PCP, J.; Tyrer, P.; Regan, A.; Dack, M.; Alexander, R.; Bakala, A.; Cooray, S.; Done, D. J.; Rao, B. Randomized controlled trial of assertive community treatment in intellectual disability: the TACTILD study. <i>J Intellect Disabil Res.</i> 2005 Jul;49(Pt 7):507-15.		0				
43.	Peters-Scheffer ND, R.; Mulders, M.; Korzilius, H. Low intensity behavioral treatment supplementing preschool services for young children with autism spectrum disorders and severe to mild intellectual disability. <i>Res Dev Disabil.</i> 2010 Nov-Dec;31(6):1678-84.		0				
44.	Piercy MW, K.; Townsend, M. Promoting the social acceptance of young children with moderate-severe intellectual disabilities using cooperative-learning techniques. <i>Am J Ment Retard.</i> 2002 Sep;107(5):352-60.		0				
45.	Plant KMS, M. R. Reducing problem behavior during care-giving in families of preschool-aged children with developmental disabilities. <i>Res Dev Disabil.</i> 2007 Jul-Sep;28(4):362-85.		0				
46.	Porretta DLS, P. R. Imagery and physical practice in the acquisition of gross motor timing of coincidence by adolescents with mild mental retardation. <i>Perceptual and motor skills.</i> 1995 Jun;80(3 Pt 2):1171-1183.				0		
47.	Ringebach SDH, S. D.; Mulvey, G. M.; Jimenez, A.; Benson, A.; Richter, M. The effects of assisted cycling therapy (ACT) and voluntary cycling on reaction time and measures of executive function in adolescents with Down syndrome. <i>J Intellect Disabil Res.</i> 2016 Nov;60(11):1073-1085.		0				
48.	Roberts JEB, M. R.; Bailey, D. B. Communication among preschoolers with and without disabilities in same-age and mixed-age classes. <i>Am J Ment Retard.</i> 1994 Nov;99(3):231-49.						0
49.	Roux GS, K.; Sanders, M. A randomized controlled trial of group stepping stones triple P: A mixed-disability trial. <i>Family Process.</i> 2013 September;52(3):411-424.		0				
50.	Schuiringa HvN, M.; Orobio de Castro, B.; Lochman, J. E.; Matthys, W. Effectiveness of an Intervention for Children with Externalizing Behavior and Mild to Borderline Intellectual Disabilities: A Randomized Trial. <i>Cognitive Therapy and Research.</i> 2017 01 Apr;41(2):237-251.		0				

51.	Schuermans AATN, Karin S.; Engels, Rutger C. M. E.; Granic, Isabela. Using a Videogame Intervention to Reduce Anxiety and Externalizing Problems among Youths in Residential Care: an Initial Randomized Controlled Trial. <i>Journal of Psychopathology &amp; Behavioral Assessment</i> . 2018;40(2):344-354.	0				
52.	Selanikyo EW, N.; Yalon-Chamovitz, S. Effectiveness of the Co-PID for Students With Moderate Intellectual Disability. <i>The American journal of occupational therapy : official publication of the American Occupational Therapy Association</i> . 2018 01 Mar;72(2):7202205090p1-7202205090p10.	0				
53.	Silliman LMF, R. Use of selected reinforcers to improve the ball kicking of youths with profound mental retardation. <i>Adapted Physical Activity Quarterly</i> . 1993;10(1):52-69.		0			
54.	Srija SSS, S.; Srinivasan, D. Efficacy of Social Stories in Coping with Bullying among Children with Childhood Psychiatry Conditions: A Randomized Controlled Interventional Study...56th All India Occupational Therapists' Association (AIOTA) Conference (OTICON'2019), February 8-10 2019, Chandigarh, India. <i>Indian Journal of Occupational Therapy (Wolters Kluwer India Pvt Ltd)</i> . 2019;51(2):52-56.	0				
55.	Stuttard LB, B.; Clarke, S.; Beecham, J.; Todd, S.; Bromley, J. Riding the rapids: living with autism or disability--an evaluation of a parenting support intervention for parents of disabled children. <i>Res Dev Disabil</i> . 2014 Oct;35(10):2371-83.	0				
56.	Townsend PWF, J. J. Experimental preadmission program to encourage home care for severely and profoundly retarded children. <i>Am J Ment Defic</i> . 1976 Mar;80(5):562-9.					0
57.	Turner LAD, E. M.; Dutka, S. Effect of strategy and attribution training on strategy maintenance and transfer. <i>American Journal on Mental Retardation</i> . 1994;98(4):445-454.					0
58.	Tzanakaki PH, Richard; Grindle, Corinna; Hughes, J.; Hoare, Zoë. An Individualized Numeracy Curriculum for Children with Intellectual Disabilities: A Single Blind Pilot Randomized Controlled Trial. <i>Journal of Developmental &amp; Physical Disabilities</i> . 2014;26(5):615-632.	0				
59.	Van der Molen MJVL, J. E. H.; Van der Molen, M. W.; Klugkist, I.; Jongmans, M. J. Effectiveness of a computerised working memory training in adolescents with mild to borderline intellectual disabilities. <i>Journal of Intellectual Disability Research</i> . 2010 May;54(5):433-447.	0				



60.	van der Putten AV, C.; Reynders, K.; Nakken, H. Children with profound intellectual and multiple disabilities: the effects of functional movement activities. Clin Rehabil. 2005 Sep;19(6):613-20.		0				
61.	Vasilevska Petrovska IT, V. Effects of a Computer-Based Intervention on Emotion Understanding in Children with Autism Spectrum Conditions. J Autism Dev Disord. 2019 Oct;49(10):4244-4255.		0				
62.	Vineet VB, K.; Swadia, N.; Mokashi, P.; Raj, A.; Mishra, R. Effectiveness of oral health intervention on the oral health knowledge and status of 6-14 years old intellectually disabled children - a randomised control trial. Journal of Disability & Oral Health. 2019;20(1):10-16.						0
63.	Warren SFF, M. E.; Finestack, L. H.; Brady, N. C.; Bredin-Oja, S. L.; Fleming, K. K. A randomized trial of longitudinal effects of low-intensity responsivity education/prelinguistic milieu teaching. J Speech Lang Hear Res. 2008 Apr;51(2):451-70.	0					
64.	Wiggs LS, G. Behavioural treatment for sleep problems in children with severe learning disabilities and challenging daytime behaviour: effect on daytime behaviour. J Child Psychol Psychiatry. 1999 May;40(4):627-35.		0				
65.	Wuang YPC, C. S.; Su, C. Y.; Wang, C. C. Effectiveness of virtual reality using Wii gaming technology in children with Down syndrome. Res Dev Disabil. 2011 Jan-Feb;32(1):312-21.				0		
66.	Wuang YPW, C. C.; Huang, M. H.; Su, C. Y. Prospective study of the effect of sensory integration, neurodevelopmental treatment, and perceptual-motor therapy on the sensorimotor performance in children with mild mental retardation. American Journal of Occupational Therapy. 2009 July/August;63(4):441-452.				0		
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**Table 4.** Data extraction results: study and participant characteristics

<b>Study</b> (first author & year) <ul style="list-style-type: none"> <li>Country</li> <li>Design</li> <li>Category</li> </ul>	<b>Methodological quality</b> (RoB_2.0)	<ul style="list-style-type: none"> <li><b>Definition ID</b>( How ID diagnosed)</li> <li><b>Diagnosis</b> (If applicable)</li> <li><b>Inclusion / exclusion criteria</b></li> </ul>	<b>Sample (N)</b> <ul style="list-style-type: none"> <li><b>Groups (n)</b></li> </ul>	<b>Group descriptive (Mean ± SD)</b> (Age, gender, relevant medical diagnoses)
<b>Cognitive Abilities (x10)</b>				
Hessl (2019) [1] <ul style="list-style-type: none"> <li>U.S.A. &amp; Canada</li> <li>Randomized, blinded, parallel two-arm controlled</li> </ul>	Low RoB	<b>Definition ID:</b> Fragile X Syndrome (FXS) <b>Diagnosis:</b> FMR1 full mutation, determined by DNA testing. <b>Inclusion/exclusion:</b> FXS, 8-18years, normal/corrected-to-normal vision/hearing, able to pass at least some items during Cogmed training at BL, English/Spanish speaking, parental consent & agreement to adhere to study. No significant brain trauma, previous Cogmed training, significant medical/bhvr problems that would disrupt the study.	N = 100 children with FXS recruited from various locations in U.S. & Canada randomized to: <ul style="list-style-type: none"> <li>Adaptive group (n= 50)</li> <li>Non-adaptive group (n= 50)</li> </ul>	Adaptive / Non-adaptive: mean(SD) <b>Age yr:</b> 13(3.11) / 12(3.04) <b>Male:</b> 64% / 62% <b>IQ:</b> 64.42 (17.73) / 64.79 (15.64)
Lanfranchi (2015) [2] <ul style="list-style-type: none"> <li>Italy</li> <li>RCT</li> </ul>	High RoB	<b>Definition ID:</b> IQ 25-79 (generally), most under 7-year-old mental age <b>Diagnosis:</b> DS <b>Inclusion/exclusion:</b> 10-15 years, diagnosis of DS, no diagnosis of psychiatric disorders, severe visual or hearing impairments.	N = 36 children with DS at the schools, clinical services, and through association contact randomized to: <ul style="list-style-type: none"> <li>Intervention group (n= 27)</li> <li>control group (n= 9)</li> </ul>	Intervention / Control: mean (SD) <b>Chronological age yr:</b> 11.9(2.1)/12.2(2.6) <b>Mental age yr:</b> 5.4(0.10)/5.7(0.9) <b>Male:</b> 55.6%/55.6%
Bennet (2013) [3] <ul style="list-style-type: none"> <li>UK</li> <li>RCT</li> </ul>	Some concerns	<b>Definition ID:</b> not reported <b>Diagnosis:</b> Down Syndrome <b>Inclusion/Exclusion:</b> 7-12years, DS, able to operate mouse effectively, normal/corrected-to-normal vision/hearing, able to recall a sequence of at least 3 items. No bhvr difficulties that would interfere with the study.	N = 21 from 5 counties in South England, randomized to: <ul style="list-style-type: none"> <li>Intervention group (n= 10)</li> <li>WL control group (n= 11)</li> </ul>	Intervention / Control: mean(SD) <b>Age mth:</b> 113.60(18.09) / 113.64(26.75) <b>Male:</b> 60% / 45%
Sepúlveda (2013) [4] <ul style="list-style-type: none"> <li>USA</li> <li>RCT</li> </ul>	Some concerns	<b>Definition ID:</b> moderate to severe ID <b>Diagnosis:</b> DS, WISC-IV <b>Inclusion/exclusion</b> aged 6 to 14 years, diagnosis of DS, native Spanish speaker (patients & parents), no hearing impairment.	N = 20 individuals with DS in Toledo Down Syndrome Association randomized to: <ul style="list-style-type: none"> <li>Intervention group (n= 10)</li> <li>Control group (n= 10)</li> </ul>	Intervention / Control: mean(SD) <b>Age yr;mth:</b> 10;5(1;11) / 10;9(2;5) <b>Male:</b> 60% / 50% <b>IQ, WISC-IV:</b> 45.5 (4.9) / 44.1 (3.1)

<p>Burgoyne (2012) [5]</p> <ul style="list-style-type: none"> <li>● UK</li> <li>● RCT</li> </ul>	<p>Some concerns</p>	<p><b>Definition ID:</b> not reported  <b>Diagnosis:</b> DS  <b>Inclusion/Exclusion:</b> Primary school, years 1-5</p>	<p>N = 56 children from North Yorkshire and south Hampshire in England, UK, randomized to:</p> <ul style="list-style-type: none"> <li>- Intervention group (n= 28)</li> <li>- WL control group (n= 26)</li> <li>-</li> </ul>	<p>Intervention / Control: mean(SD)  <b>Age mth:</b> 80.48(14.74) / 77.82(15.88)  <b>Age range mth:</b> 60-115 / 57-115  <b>Male:</b> whole sample: 50%  (data not provided for groups)</p>
<p>Hong (2012) [6]</p> <ul style="list-style-type: none"> <li>● Korea</li> <li>● RCT</li> </ul>	<p>Some concerns</p>	<p><b>Definition ID:</b> significant limitations both in intellectual functioning and in adaptive behavior, which covers a range of everyday social and practical skills  <b>Diagnosis:</b> AAIDD, 2010, IQ measured by WISC-III, Korean Version  <b>Inclusion/Exclusion:</b> Elementary school students, grades 3-6, mild ID.</p>	<p>N = 21 elementary school children, from Kyungnam Province, randomized to:</p> <ul style="list-style-type: none"> <li>- Neurofeedback (NFB) training group (n= 7)</li> <li>- Visual Perception (VP) training group (n= 7)</li> <li>- Control group (n= 7)</li> </ul>	<p>NFB / VP / Control: mean(SD)  <b>Age yr:</b> 10.57(1.25) / 10.43(1.13) / 9.86(0.90)  <b>Male:</b> Not reported  <b>IQ:</b> 67.4(4.3) / 65.2(2.7) / 66.6(4.7)</p>
<p>Litrownik (1978) [7]</p> <ul style="list-style-type: none"> <li>● USA</li> <li>● RCT</li> </ul>	<p>Some concerns</p>	<p><b>Definition ID:</b> not reported, IQ tested  <b>Diagnosis:</b> trainable mental retardation, Slosson Intelligence Test  <b>Inclusion/exclusion:</b> students from Fairhaven School in San Diego, California, aged 115.6 to 120 months, diagnosis of trainable mental retardation</p>	<p>N = 24 students with ID from Fairhaven School in San Diego, California randomized to:</p> <ul style="list-style-type: none"> <li>- Training 1 (n= 8)</li> <li>- Training 2 (n= 8)</li> <li>- Control (n= 8)</li> </ul>	<p>Training 1 / Training2 / Control: mean(SD)  Total sample  <b>Chronological age mth:</b> not reported  <b>Mental age mth:</b> 46.4  <b>Male:</b> 50%  <b>IQ:</b> 40.1  Each stratified group:  <b>Chronological age mth:</b> 115.6 – 120(17.8 – 24.4)  <b>Mental age mth:</b> 46.3 - 46.4(6.8 – 9.8)  <b>IQ:</b> 39.6 – 40.5(6.3 – 7.1)</p>
<p>Boyce (1976) [8]</p> <ul style="list-style-type: none"> <li>● USA</li> <li>● RCT</li> </ul>	<p>High RoB</p>	<p><b>Definition ID:</b> n/r  <b>Diagnosis:</b> Kuhlmann-Anderson Intelligence Test; provided measure of mental age (MA)  <b>Inclusion/Exclusion:</b> n/r</p>	<p>N = 40 children (20 ID, 20 non-ID) from 2 small, rural Midwestern school districts, randomized to fill cells of a fixed factor 2x2x2 multivariate ANOVA:</p> <ul style="list-style-type: none"> <li>- Dependent variable – direct / rule-governed imitation</li> <li>- Independent variables – population type (normal; ID); type of social reinforcement (affective; informative)</li> <li>- Each cell contained 10 children</li> </ul>	<p>Descriptive stats n/r per treatment groups. Non-ID / ID: mean (range)  <b>Age yr:</b> 8.0 (7.3 – 9.2) / 12.2 (9.10 – 14.6)  <b>MA yr:</b> 8.11 (8.2 – 9.9) / 9.0 (7.0 – 10.10)  <b>Male:</b> n/r</p>

<b>Communication Skills &amp; Abilities (x2)</b>				
McDuffie (2018) [9] <ul style="list-style-type: none"> <li>● USA</li> <li>● Small randomized group design</li> </ul>	Low RoB	<b>Definition ID:</b> IQ 40-55(most), nonverbal IQ <b>Diagnosis:</b> FXS, Leiter International Performance Scales-Revised <b>Inclusion/exclusion:</b> aged 10-16, FXS boys, daily use of min 3-word utterances, English primary language at home, no severe uncorrected sensory or motor impairments.	N = 19 boys with FXS randomized to: <ul style="list-style-type: none"> <li>- Intervention group (n= 10)</li> <li>- Control group (n=9)</li> </ul>	(N = 20) Intervention / Control: mean(SD) <i>Child</i> <b>Age yr:</b> 13.92(2.26) / 12.46(1.23) <b>Non-verbal IQ:</b> 41.80(8.72) / 41.20(8.23) <i>Mother</i> <b>Age yr:</b> 44.20(6.00) / 44.00(6.13) <b>Education yr:</b> 15.30(1.77) / 15.40(2.46) <b>IQ on KBIT-2:</b> 109.30(12.25) / 104.40(16.08)
Kantner (1982) [10] <ul style="list-style-type: none"> <li>● USA</li> <li>● RCT</li> </ul>	Some concerns	<b>Definition ID:</b> “mentally retarded” (MR) <b>Diagnosis:</b> IQ determined by school psychologists using WISC <b>Inclusion/Exclusion:</b>	N = 30 MR, language-delayed children, randomized to: <ul style="list-style-type: none"> <li>- Vestibular/specific speech therapy (VS-ST) (n= 10)</li> <li>- Specific ST (S-ST) (n= 10)</li> <li>- General ST (G-ST) (n= 10)</li> </ul>	VS-ST / S-ST / G-ST: mean <b>Age yr:</b> 9.3 / 7.7 / 10.6 <b>Male:</b> 50% / 60% / 70% <b>IQ:</b> 42.0 / 45.9 / 46.4
<b>Social Skills (x4)</b>				
Maïano (2001) [11] <ul style="list-style-type: none"> <li>● France</li> <li>● RCT</li> </ul>	Some concerns	<b>Definition ID:</b> IQ 40 to 78(mild to moderate mental retardation) <b>Diagnosis:</b> Revised Weschler Intelligence Scale for Children -of non-organic origin. <b>Inclusion/exclusion:</b> aged 13-17 males, diagnosis of mild or moderate mental retardation, 1-year placement in a specialized class, problems of non-organic origin, little or no experience of athletic competition.	N = 32 adolescent males with mild to moderate mental retardation in French specialized schools randomized to: <ul style="list-style-type: none"> <li>- B.B. Alt. group (n= 8)</li> <li>- Run Alt. group (n= 8)</li> <li>- A.P.A. group (n= 8)</li> <li>- Sedentary group(n= 8)</li> </ul>	B.B. Alt. / Run Alt. /A.P.A. / Sedentary: mean(SD) <b>Age yr:</b> 14.4(0.92) / 14.2(1.04) / 13.7(0.71) / 13.5(0.53) <b>IQ:</b> 63.5(2.39) / 60.9(3.56) / 60.0(3.51) / 59.2(3.49)
Jacques (1998) [12] <ul style="list-style-type: none"> <li>● New Zealand</li> <li>● RCT</li> </ul>	High RoB	<b>Definition ID:</b> IQ 50 to 70 <b>Diagnosis:</b> mild ID by educational psychologists, WISC full-scale <b>Inclusion/exclusion:</b> aged 9-11, mild ID diagnosis, mainstream special education at one of 21 primary schools, ½ attending special class/resource rooms previously, ½ attending regular classes full-time.	N = 22 children with mild ID currently attending regular primary schools in the Auckland, New Zealand, metropolitan area randomized to: <ul style="list-style-type: none"> <li>- Intervention group (n= 10) (4 former special class pupils)</li> <li>- Control (n= 12) (6 former special class pupils)</li> </ul>	Intervention / Control: <b>Age yr:</b> range from 9 to 11, no specific statistics reported <b>Male:</b> 90.9% (20/22) for the total sample, no specific statistics reported
Balthazar (1971) [13] <ul style="list-style-type: none"> <li>● USA</li> <li>● RCT</li> </ul>	High RoB	<b>Definition ID:</b> not reported <b>Diagnosis:</b> profound/severe mental retarded <b>Inclusion/exclusion:</b> profound/severe MR diagnosis, enrolled in specific School, psychometrically tested, presented with most difficulties in nursing & social management.	N = 17 severely retarded children showing self-destructive and disruptive behaviors randomized to: <ul style="list-style-type: none"> <li>- Intervention group (n= 9)</li> <li>- Control (n= 8)</li> </ul>	Intervention/control: mean(SD) <b>Age yr:</b> not reported, only described as “children” <b>Male:</b> not reported

<b>Activities of Daily Living: personal independence at home/in the community (x7)</b>				
Lee (2020) [14] ● China ● Cluster RCT	Low RoB	<b>Definition ID:</b> MID=IQ from 50-69 <b>Diagnosis:</b> Hong Chi Association, 2010 <b>Inclusion/exclusion:</b> 9-18 years old, abilities of written and spoken Chinese	N = 445 students with ID aged from 9 to 18, selected from 6 special schools in Central and Northern districts of Kowloon, randomized to: - 5-step group (n= 190) - 7-step group (n= 255)	5-step / 7-step: mean(SD) <b>Age yr:</b> 13.56(0.19) / 12.78(0.10) <b>Male:</b> 29.4% / 43.1%
Bagattoni (2020) [15] ● Italy ● Randomized case-control study	Low RoB	<b>Definition ID:</b> not severe or profound ID(ICD-10) <b>Diagnosis:</b> ICD-10(WHO), DS <b>Inclusion/exclusion:</b> 5-12 years old, at least one molar requiring a restoration, no history of seizures, nystagmus, vertigo, visual/hearing impairments, pain/swelling in cavity, no severe/profound ID (ICD-10), no need for pulp therapy	N= 45 DS outpatients requiring dental restorations in the Unit of Special Needs Dentistry & Paediatric Dentistry randomized to: - study group (n= 22) - control group (n= 23)	Study / Control: mean(SD) <b>Age yr:</b> 8.0(1.8) / 7.9(1.8) <b>Male:</b> 55% / 65% <b>Anaesthesia medication:</b> 68% / 78% <b>Dental treatment:</b> 50% / 61% <b>Dental trauma:</b> 22% / 13% <b>Orthodontics:</b> 31% / 17%
Janeslätt (2019) [16] ● Sweden ● Cluster randomized trial	Some concerns	<b>Definition ID:</b> mild (IQ 55–70) or moderate (IQ 40–55) ID <b>Diagnosis:</b> not reported <b>Inclusion/exclusion:</b> 10–17 years old, mild or moderate ID, low Time processing ability (the KaTid-Child), no diagnosis of autism severe multiple disabilities	N = 60 children with mild or moderate ID in special schools randomized to: - Intervention group (n= 27) - Control group (n= 33)	(N = 61) Intervention / Control: mean(SD) <b>Age yr; mth:</b> 13;1 / 13;2 <b>Male:</b> 50% / 52% <b>Mild ID:</b> 89.3% / 78.8% <b>KaTid scale:</b> 49.89(22.91) / 52.70(25.33)
Lee (2017) [17] ● Hong Kong ● RCT	Low RoB	<b>Definition ID:</b> IQ 50-69 <b>Diagnosis:</b> Mild ID. <b>Inclusion/exclusion:</b> 8-16years, mild IDs, grades 3-9 in special school in Hong Kong, overweight/obese, no phys impairment/cardiovascular disease based on school medical records, students able to follow instructions and u/stand teaching materials. No – mod/severe ID (IQ ≤49) or those w/ extreme difficulty in comprehension, memorizing and visualizing.	N = 115 from 4 special schools in Hong Kong, randomized to: - Intervention group (n= 63) - Control group (n= 52)	Intervention / Control: mean(SD) <b>Age yr:</b> 13.44(2.734) / 15.31(3.387) <b>Male:</b> 76.2% / 65.4%
McPherson (2017) [18] ● Australia ● Parallel-group cluster RCT	Low RoB	<b>Definition ID:</b> not reported <b>Diagnosis:</b> assessed by Education Queensland <b>Inclusion/exclusion:</b> aged 10–18, diagnosis of ID, registered at a Special Education School or a Special Education Unit in South East Queensland	N = 385 adolescents with ID in Special Education Schools or units in South East Queensland randomized to: - Intervention group (n= 205) - Control group (n= 180)	(N = 592) Intervention / Control: mean(SD) <b>Adolescent</b> <b>Age yr:</b> 15.4(1.7) / 15.8(1.5) <b>Male:</b> 53.9% / 55.5% <b>Carer</b> <b>Age yr:</b> 44.7(7.0) / 44.8(7.0) <b>Finished high school:</b> 30.1%/34.0%

Wuang (2013) [19] ● Taiwan ● RCT	Low RoB	<b>Definition ID:</b> characteristics of cognitive deficits, global developmental delay, sensorimotor difficulties, and perceptual dysfunction <b>Diagnosis:</b> DSM-IV criteria (American Psychiatric Association, 2000), WISC-IV <b>Inclusion/exclusion</b> aged 6 to 12 years, primary school enrolment, diagnosis of ID, waiting list for therapy services, written consent by one parent, no coexisting autism, cerebral palsy, blindness, deafness, or previous neurological impairments were excluded, not receive physical or occupational therapy in the year preceding the study	N = 83 children with ID from both school programs and hospitals in the Kaohsiung metropolitan area randomized to: - OTHP group (n= 43) - Non-OTHP group (n=40)	(N = 114) OTHP / Non-OTHP: mean(SD) <b>Age yr:</b> 9.70(1.92) / 10.10(2.41) <b>Female:</b> 42%/46% <b>IQ, WISC-IV:</b> 56.84(6.13) / 57.12(4.44)
Drysdale (2008) [20] ● UK ● Blinded, RCT	Low RoB	<b>Definition ID:</b> not reported <b>Diagnosis:</b> Identified by educational psychologist prior to/during attendance at the school <b>Inclusion/Exclusion:</b> All pupils in years 6-7 from 1 UK-based special school for children with mod ID invited to participate (n=60), informed consent from parents	N = 40 children from 1 UK based special school, randomized to: - Classroom based intervention (Class) (n= 12) - Classroom & Community based intervention (Class&Comm) (n= 12) - Control group (n= 16)	Class / Class&Comm / Control: mean <b>Age yr; mth:</b> 10;1 / 10;1 / 10;3 <b>Range yr; mth:</b> 9;4-11;0 / 9;2-11;0 / 9;4-11;1 <b>Male:</b> 91.7% / 75% / 62.5%
<b>School &amp; Work Functioning (x1)</b>				
Baran (2013) [21] ● Turkey ● Randomised comparative intervention design	Low RoB	<b>Definition ID:</b> “educable mentally retarded,” corresponds to mild ID, IQ>50. <b>Diagnosis:</b> Received from schools. <b>Inclusion/Exclusion:</b> 12-15year old males. No health problems interfering in ability to play sports, no secondary disability such as physical/visual/psychiatric/brain injury/DS, no previous training in soccer.	N = 76 participants recruited from a regional special education school and a secondary school from a large urban community in Turkey, randomized to: - Training group (n= 46) with ID (ID) (n= 23) without ID (WoID) (n= 23) - Control group (n= 30) with ID (ID) (n= 15) without ID (WoID) (n= 15)	Training / Control: mean (SD) <i>With ID</i> <b>Age yr:</b> 14.46(1.19) / 14.51(0.81) <b>Male:</b> 100% / 100% <i>WoID</i> <b>Age yr:</b> 13.22(0.79) / 13.78(0.49) <b>Male:</b> 100% / 100%
<b>Comprehensive: multiple domains addressed (x3)</b>				
Tanet (2020) [22] ● France ● Randomized, single-blind multicentric controlled ● Cognitive/Communication / Social skills / School or work functioning	Some concerns	<b>Definition ID:</b> mean DQ= 30 <b>Diagnosis:</b> Vineland developmental age and chronological age <b>Inclusion/exclusion:</b> 5 to 9 years old, ASD diagnosis (ICD-10 & ADI-R), 24 months communication development and under or a 3-year speech delay (VABS-II), impossible to attend mainstream or spl ed classroom.	N = (18 mth measurement) 66 children with ASD and ID in French outpatient healthcare institutions randomized to: - DSI-EI (n= 32) - TAU (n= 34) N= (at 24 month measurement) 63: - DSI-EI (n= 31) - TAU (n= 32)	DSI-EI / TAU (N= 72): mean(SD) <b>Age mth:</b> 82.4(19.1) / 87(19.5) <b>Male:</b> 86.1% / 83.3% <b>DQ:</b> 30(10) / 30(10) <b>Associated disorders(yes):</b> 16.7% / 25% <b>Psychotropic medication:</b> 13.9% / 16.7% <b>Education hrs:</b> 10 (3.3) / 3.1(4.3)

<p>Saint-Georges (2020) [23]</p> <ul style="list-style-type: none"> <li>● France. Follow-up study of Tanet et al. (2020)</li> <li>● Randomized, single-blind multicentric controlled</li> <li>● Cognitive / Communication / Social skills / School or work functioning</li> </ul>	<p>Some concerns</p>	<p><b>Definition ID:</b> mean DQ= 30  <b>Diagnosis:</b> Vineland developmental age and chronological age  <b>Inclusion/exclusion:</b> 5 to 9 years old, diagnosis of ASD (ICD-10 &amp; ADI-R), 24 months communication development and under or a 3-year speech delay (VABS-II), impossible to include in a mainstreamed or special education classroom.</p>	<p>N = 63 children with ASD and ID in French outpatient healthcare institutions randomized to:</p> <ul style="list-style-type: none"> <li>- DSI-EI (n= 31)</li> <li>- TAU (n= 32)</li> </ul>	<p>DSI-EI / TAU (N= 72): mean(SD)  <b>Age mth:</b> 82.4(19.1) / 87(19.5)  <b>Male:</b> 86.1% / 83.3%  <b>DQ:</b> 30(10) / 30(10)  <b>Associated disorders:</b> 16.7% / 25%  <b>Psychotropic medication:</b> 13.9% / 16.7%  <b>Education, hrs:</b> 10 (3.3) / 3.1(4.3)</p>
<p>Agbaria (2020) [24]</p> <ul style="list-style-type: none"> <li>● Israel</li> <li>● RCT</li> <li>● Cognitive / Social skills</li> </ul>	<p>High RoB</p>	<p><b>Definition ID:</b> multidimensional deficits to cognitive, behavioural, &amp;/or social functioning  <b>Diagnosis:</b> DSM-5, American Psychiatric Association, 2013  <b>Inclusion/exclusion:</b> parents of children, 8–12yr w/ minor IDD, attending special schools in the Haifa district of Israel</p>	<p>N = 50 Israeli parents with an aged 8–12 minor IDD child attending special schools in the Haifa district of Israel randomized to:</p> <ul style="list-style-type: none"> <li>- Experimental group (n= 25)</li> <li>- Control group (n= 25)</li> </ul>	<p>Experimental / Control: mean(SD)  <b>Age yr:</b> 43.13(9.76) / 45.23(11.12)  <b>Male:</b> 44% / 40%  <b>Education yr:</b> 13.45(4.23) / 14.13 (3.34)</p>

**Table 4 Notes.** AAIDD= American Association of Intellectual and Developmental Disabilities; ADHD= attention deficit hyperactivity disorder; A.P.A.= adapted physical activity; B.B. Alt.= basketball in Alternated sport competition; bhvr=behaviour; BL= baseline; Chron= chronological; CP= cerebral palsy; DS=Down Syndrome; DSM= Diagnostic and Statistical Manual of Mental Disorders; DQ= developmental quotient; FXS= Fragile X Syndrome; ICD= International Classification of Diseases; ID=Intellectual disabilities; KBIT-2= Kaufman Brief Intelligence Test –2nd Edition; MID= mild intellectual disability; MR= mental retardation; mth/s= month/s; multi= multiple; phys=physical; n/r= not reported; OTHP= occupational therapy home program; RCT= Randomised Control Trial; re= relating; RoB= Risk of Bias; Run Alt.= running in Alternated sport competition; spl ed= special education; ST= speech therapy; u/stand=understand; VABS-II= Vineland Adaptive Behaviour Scale II; WL= waiting list; WISC-III= Wechsler Intelligence Scale for Children-3rd edition; WISC-IV= Wechsler Intelligence Scale for Children-Fourth Edition; yr/s=year/s.



#### **Table 4. References – all included studies**

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**Table 5.** Data extraction results; intervention details and outcomes

Study 1 <sup>st</sup> author (year) [citation]	Intervention goal	Intervention agent, delivery, and dosage	Materials and procedures	Outcome measures	Treatment outcome (Confidence Interval 95% & effect size Cohen's <i>d</i> , unless otherwise stated)
<b>Cognitive Abilities (x8)</b>					
Hessl (2019) [1]	Evaluate efficacy of adaptive Cogmed training (compared to non-adaptive Cogmed) to enhance WM and EF in children and adolescents with FXS.	<p><b>Intervention agent:</b> - coaches provided training to parents. - parents supported participants with Cogmed training.</p> <p><b>Delivery/dosage:</b> 3 training activities / session; 15minutes sessions; 5 days/week for 5-6 weeks to achieve goal of 25 training sessions.</p>	<p><b>Adaptive intervention group:</b> measured three times (baseline, post-treatment, 3 months post-intervention), parents' training from coaches (weekly phone-calls), completion of training by children with support of parents (adapted to children's developmental age and responses, memory span continuously challenged).</p> <p><b>Non-adaptive control group:</b> measured three times (baseline, post-treatment, and 3 months after intervention), parents' training from coaches (weekly phone-calls), completion of training by children with support of parents (adapted to children's developmental age fixed span length, memory span less challenged).</p>	<p><b>Primary outcome</b> Working Memory (WM) - Visual (Leiter-R [2]) - Auditory WM (WISC-IV [3]).</p> <p><b>Secondary outcomes</b> Executive Function (EF) (KiTAP [4] including distractibility errors; alertness; flexibility; false alarms).</p> <p>Behaviour &amp; EF (Parent &amp; teacher-rated - Conners 3 [5]: assessment of ADHD related bhvr; BRIEF-P [6]: inattention &amp; hyperactivity/impulsivity sub-scales).</p>	Both groups significantly improved on WM visual ( $p = .003$ ), WM auditory ( $p < .0001$ ), two domains of EF (flexibility, $p = .001$ ; distractibility, $p = .021$ ) and parent- and teacher-reported attention and EF ( $p < .05$ ). Maintained effects (after 3 months): WM visual ( $p = .014$ ), WM auditory ( $p < .0001$ ), flexibility ( $p = .004$ ). Effect sizes for within-group differences were reported, but no significant between-group effects are found.
Lanfranchi (2015) [7]	Evaluation of a numerical skills training program on the basic mathematical skills and logical thinking for children with DS.	<p><b>Intervention agent:</b> trained instructor</p> <p><b>Delivery/dosage:</b> 30-min session twice a week for 2 months (16 sessions in total).</p>	<p><b>Intervention group:</b> material (visual workbook activities), 30-min training sessions including lexical processing, semantic processing, pre-syntactic processing, counting, and mental calculation.</p> <p><b>Control group:</b> no training sessions.</p>	<p><b>Outcomes</b> Numerical and counting skills measured by numerical Intelligence Scale [8], calculation abilities measured by CA-MT [9], logical thinking measured by LO [10], and CFA [11].</p>	Significant between group effects ( $p < .05$ ) on numerical Intelligence Scale, mental calculation, written calculation, number knowledge. Between group effect sizes not reported. Significant increase over time in TG on numerical Intelligence Scale ( $p < .001$ , $d = 0.52$ ), mental calculation ( $p < .001$ ), number knowledge ( $p < .001$ ), LO ( $p < .0001$ ), CFA ( $p < .05$ ). No significant effects on number writing.

Bennett (2013) [12]	Evaluate the feasibility of using Junior Cogmed Working Memory Training (JCWMT) with children with DS; investigate whether training leads to improvements in non-trained tasks of verbal and visuospatial short-term memory (STM) and working memory (WM).	<p><b>Intervention agent:</b> SENCos /TAs Research team provided training and support to SENCos &amp; TAs.</p> <p><b>Delivery / dosage:</b> Each task 6-10minutes 3 tasks per session. Total session approx 25minutes. 25 training sessions = 75 tasks completed. Program duration 10-12 weeks.</p>	<p><b>Both groups</b> – Software installed to school cpus. SENCos &amp; TAs trained to use program. Wk 1-4 – baseline (t1) assessments taken.</p> <p><b>Intervention group</b> – Wk 5-20 – full intervention: JCWMT – 7 different cpu’ed visuospatial (VS) memory training tasks. Every 5 days, 1 training task replaced. Motivational features provided, TA/SENCos provided continuous support during training. On avg training occurred 3 times/week. Research team provided support and monitored performance remotely. External rewards given approx. every 5 sessions. Wk 20-40 – TAU. Wk 21-23 – assessed (t2). Week 41-44 – final assessment (t3).</p> <p><b>WL control group</b> – wk 5-20 TAU. Wk 21-23 – assessed (t2). Wk 24-40 received full intervention described above. Wk 41-44 – final assessment (t3).</p>	<p><b>Outcomes</b> Working memory (AWMA [13]; x4 aspects of WM – verbal STM; verbal WM; visuospatial (VS) STM; VS WM. Measured by research team). Behavioural/emotional (BRIEF-P [6]; 5 subscales – inhibition; shift; emotional control; WM; planning. Measured by parental rating).</p>	<p>Intervention group significantly improved t1 - t2 for: VS STM (<math>p = .04</math>, <math>d = 0.59</math>), VS WM (<math>p = .03</math>, <math>d = 0.83</math>), shift (<math>p = .01</math>, <math>d = 1.22</math>), WM (<math>p = .04</math>, <math>d = 0.46</math>). Gains sustained at t3. Results replicated by WLCCG t2-t3 only for Verbal STM (<math>p = .04</math>, <math>d = 0.67</math>), and VS STM, (<math>p = .01</math>, <math>d = 0.70</math>) Significant group*time i/action for VS STM at t2 (<math>p = .02</math>) No significant group*time i/actions for BRIEF-P.</p>
Sepúlveda (2013) [14]	Effectiveness of a morphosyntactic intervention programme for children with DS.	<p><b>Intervention agent:</b> speech and language therapists.</p> <p><b>Dosage:</b> 30-min sessions twice a week for 3.5 months (30 sessions in total).</p>	<p><b>Intervention group:</b> materials for visual support, two preparatory sessions before intervention (three speech and language therapists), training sessions.</p> <p><b>Control group:</b> habitual speech and language treatment.</p>	<p><b>Outcomes</b> Language components (morphology, syntax, semantics and pragmatics) measured by BLOC-C [15].</p>	<p>Significant between group effects on syntax (<math>p = .001</math>), morphology (<math>p = .002</math>) and semantics (<math>p &lt; .05</math>). No significant between-group effects on morphology, syntax and pragmatic development.</p>
Burgoyne (2012) [16]	Evaluate program of interventions combining phonics-based reading instruction & vocab teaching for children with DS. Assess if intervention speeds progress in teaching & language.	<p><b>Intervention agent:</b> 2 TAs from each school: attended 2 days training prior to intervention &amp; 1 day after 10 weeks.</p> <p><b>Delivery / dosage:</b> 5 x 40-minute sessions/week. 20-week duration. Prescribed program; could tailor sessions to needs &amp; abilities of child.</p>	<p><b>Intervention group</b> – Program consisted of 2 components: reading strand and language strand_4 sessions/week focused on new teaching; 5<sup>th</sup> session focused on revising &amp; consolidating learning. TA received: comprehensive teaching manual; reading books; phonics resources; copy of “Letters &amp; Sounds” (DfES, 2007). Multiple context approach: use of visual supports &amp; simple games to reinforce learning. Parents involved in selecting target words not yet known/used by child. TAs supported through regular phone/email contact &amp; observed min x1/week to check fidelity/provide individualized feedback.</p> <p><b>WL control group</b> – intervention provided later.</p>	<p><b>Primary Outcomes</b> Letter-sound knowledge &amp; single-word reading (YARC [17]: extended alphabet knowledge; EWR test); phoneme blending (select 3 pictures to match word spoken); taught vocabulary.</p> <p><b>Secondary Outcomes</b> Non-word reading (test created; child to read names of 6 cartoons, i.e. “et”); phonetic spelling (10 pictures presented to be name &amp; spell); standardized tests of receptive &amp; expressive language/expressive grammar &amp; info.</p>	<p>Children in intervention group significantly increased progress in: single word reading (<math>p = .002</math>, <math>d = 0.23</math>), letter-sound knowledge (<math>p = .002</math>, <math>d = 0.42</math>), phoneme blending (<math>p = .022</math>, <math>d = 0.54</math>), taught expressive vocabulary (<math>p = .011</math>, <math>d = 0.47</math>) No significant effects on other measures of literacy / standardised test of language.</p>

Hong (2012) [18]	To investigate Neurofeedback (NFB) training effects on attention tasks for a group of children with ID, comparing to Visual Perception (VP) training group and a control group.	<p><b>Intervention agent:</b> 2 special ed teachers.</p> <p><b>Delivery:</b> NFB – NFB program system “Neuroharmony M” (Braintech Corp, Korea).</p> <p>VP – VP training program, adapted version.</p> <p><b>Dosage (both):</b> 30-minute sessions; 3 sessions/week; over 12 weeks, total of 36 sessions.</p>	<p><b>NFB Intervention group</b> – based in special classroom; 5 minutes relax time. Attached electrode headband; directions given; EEGs measured from the frontal lobe were used for NFB. Four programs used in study: painting program to select training mode; performance on attention/concentration mode compared – the weaker selected as training mode for 3 weeks; after 3 weeks brainwaves reanalysed &amp; training mode re-selected; 3 programs used for training; each training program performed for 3 weeks.</p> <p><b>VP Intervention group</b> – training consists of 5 parts: visual-motor integration; figure-ground; position in space; spatial relations &amp; form constancy. 30 tasks for each part selected &amp; reconstructed according to child’s developmental &amp; intellectual abilities.</p> <p><b>Control group</b> – TAU.</p>	<p><b>Outcomes</b></p> <p>Distributed attention &amp; dis/inhibition ability (CCTT-2, Korean Version, for children 8-15 [19])</p> <p>Attention – inhibition (SCWT, word-colour test only, Korean version, for children 5-14 [20])</p> <p>STM (WISC-R, digit span test, adapted version – different arrangement of numbers than in original test).</p>	<p>Post-intervention outcomes:</p> <p>NFB group scores significantly (<math>p &lt; .05</math>) higher than VP/control in CCTT-2</p> <p>NFB group significantly increased in SCWT, digital span (<math>p &lt; .05</math>).</p> <p>VP/control group showed no significant differences in SCWT, digital span.</p> <p>3-month follow-up:</p> <p>NFB group scores maintained in CCTT-2 (<math>p &lt; .01</math>), SCWT (<math>p &lt; .05</math>) and digital span (<math>p &lt; .01</math>).</p>
Litrownik (1978) [21]	Whether students with ID can acquire, retain, and generalize the concept as evidenced by the standards they set.	<p><b>Intervention agent:</b> experimenters- demonstrate the concept and assess results.</p> <p><b>Dosage:</b> one 20 min session in 1<sup>st</sup> section, 4 sessions in 2<sup>nd</sup> section (two 20 min training sessions, two assessment sessions).</p>	<p><b>Training1 group:</b> 1<sup>st</sup> section, set their standard after individually watched 10-minute colour videotape where five clown models set their standard at 6 on a bowling game; 2<sup>nd</sup> section, 1<sup>st</sup> day, individually observed a 12-minute colour videotape in which three clowns demonstrated the concept “between”, the ability to apply this concept was assessed. 2<sup>nd</sup> day, watched live demonstrations of this concept “between”, the ability to apply this concept was assessed; 6<sup>th</sup> day, standard setting was assessed; 7<sup>th</sup>, the transfer of concept “between” was assessed.</p> <p><b>Training2 group:</b> 1<sup>st</sup> section, the same as training 1 group; 2<sup>nd</sup> section, 1<sup>st</sup> day, the same as the second day of training 1 group. 2<sup>nd</sup> day, the same as the first day of training 1 group. 6<sup>th</sup> day, standard setting was assessed; 7<sup>th</sup> the transfer of concept “between” was assessed.</p> <p><b>Control group:</b> take the same tests as training groups without training.</p>	<p><b>Outcomes</b></p> <p>Standards set based on the concept "between", (picture-story trial, five bowling trials).</p>	<p>Both training groups acquired, retained, and generalized the concept as evidenced by the standards they set (<math>p &lt; .05</math>), whereas no differences between the training groups were found.</p>

Boyce (1976) [22]	Examine the influence of intellectual level and social reinforcement on imitation learning.	<p><b>Intervention agent:</b> Graduate student.</p> <p><b>Delivery / Dosage:</b> 15minute sessions, 24 sessions, 12 for each of 2 tasks.</p>	<p><b>Affective social-reinforcement group</b> – 4 distinct imitation tasks; 2 direct imitation &amp; 2 rule-governed imitation. 6 baseline demonstrations followed by 6 experimental phase trials, of which 2 included further demonstrations, 4 completed only by the pt with verbal feedback provided. Verbal feedback was only provided during the 4 experimental phases. Treatment script contained “good” and “fine.”</p> <p><b>Informative social-reinforcement group</b> – all sequences and procedures the same. Treatment script contained “right” and “correct.”</p>	<p><b>Outcomes</b></p> <p>Dependent variable: number of imitative bhvrs of given type, produced during the expmtal phase minus the number produced in baseline.</p>	<p>Informative social reinforcement effective in non-retarded population, and affective social reinforcement effective for retarded children <math>p &lt; .01</math>.</p>
<b>Communication Skills &amp; Abilities (x2)</b>					
McDuffie (2018) [23]	Evaluation of a parent-implemented intervention designed to improve the spoken language skills of school-aged and adolescent boys with FXS.	<p><b>Intervention agent:</b> Mothers (taught and guided by speech-language pathologists).</p> <p><b>Dosage:</b> 12 weeks, read one book per week.</p>	<p><b>Intervention group:</b> 2 hours of distance training on the behavioural support strategies before intervention, materials (scripts, wordless e-books in IPAD), equipment (laptop computer, distance video conferencing software), 5 sessions each week (sequences: parent education, coaching, homework, feedback, observation), interventionist (a licensed SLP for parent education, coaching, a licensed SLP assisted by two speech-language clinicians for homework and observation, speech-language clinicians for feedback).</p> <p><b>Control group:</b> 2 hours of distance training on the behavioural support.</p>	<p><b>Outcomes</b></p> <p>Language variables (transcription and coding with SALT), Child engagement (a coding software using a 5-sec partial interval coding system); both measured at three contexts: child-mother at home, child-mother at clinic, child and an unfamiliar examiner at clinic.</p>	<p>Significant between group effects (<math>p &lt; .05</math>, large effect sizes) on maternal intervention strategies usage (home and clinic), engagement time (mother involved home and clinic). Significant increase (<math>p &lt; .05</math>, large effect sizes) over time for child and maternal story-related utterances (mother involved home and clinic), lexical complexity (mother involved home and clinic). No significant between or within group effects on grammatical complexity in three contexts. Strong association between intervention gains and standard scores for receptive and expressive vocabulary (<math>p &lt; .05</math>).</p>

Kantner (1982) [24]	Explore the value of one component of the sensory-integrative or sensori-motor therapy in improving language ability of language-delayed mentally retarded children.	<p><b>Intervention agent:</b> Vestibular – senior author of paper. Specific/general – speech pathologist.</p> <p><b>Delivery / Dosage:</b> Vestibular – 2 days/week Specific/general – 4 days/week, 10-12 minute sessions Total duration 6 weeks.</p>	<p><b>Vestibular/specific treatment group</b> – stimulation of specific pairs of semicircular canals; delivered by hand-operated rotary chair, with predetermined angles and times, adjusted depending on child’s tolerance. + specific speech therapy:</p> <p><b>Specific treatment group</b> – Language Acquisition Program (LAP, Kent, 1974) – each child progressed through LAP sequential training format at their own rate. Each child’s teacher was given specific language activities to complete in class.</p> <p><b>General treatment group</b> – general speech and language stimulation; therapist read books and played records that were consistent with the child’s maturational age and classroom level.</p>	<p><b>Outcomes</b> Communicative skills (PICAC [25])</p>	No significant differences in scores between groups found when age, IQ and pre-test scores controlled for.
<b>Social Skills (x3)</b>					
Maiano (2001) [26]	Effectiveness of alternated sport competition and type of sport (basketball versus running) on domains of perceived competence and general self-worth for adolescents with ID.	<p><b>Intervention agent:</b> Specific sport instructors for each group.</p> <p><b>Dosage:</b> 2-hour training each week and six competitive meets over 7 months.</p>	<p><b>B. B. Alt. group:</b> adapted teaching &amp; coaching methods; fixed objectives &amp; precise calendar for basketball in forms of alternated sport competition (Classic SO and school comp).</p> <p><b>Run Alt. group:</b> adapted teaching &amp; coaching methods; fixed objectives and a precise calendar for running in forms of alternated sport competition (Classic SO &amp; school comp).</p> <p><b>A.P.A. (control) group:</b> traditional program of adapted physical activities (gymnastics) in a specialized centre by the same A.P.A. instructor.</p> <p><b>Sedentary (Control) group:</b> sedentary, no sports.</p>	<p><b>Outcomes</b> Perceived competence and self-worth measured by SPP [27].</p>	No significant effects on the specific domains of perceived competence and general self-worth.
Jacques (1998) [28]	Effects of the participation of non-disabled children in a cooperative learning programme on their social acceptance of classmates with mild intellectual disability.	<p><b>Intervention agent:</b> teachers for instructions, typical developing peers as co-participants in group learning.</p> <p><b>Dosage:</b> 30-min daily sessions for 4 days each week, 6 weeks in total.</p>	<p><b>Intervention group:</b> cooperative learning programme, identical procedure across classrooms/schools, small groups learning (four to six members, one or two are children with mild ID, others are non-disabled aged 9 to 11 children), study one social studies material (written by the author) and complete the relevant test weekly for 6 weeks, during the learning process, children with mild ID are given the easiest section, mutual supports are encouraged, context (specific rules posted at all times).</p> <p><b>Control group:</b> usual classroom program.</p>	<p><b>Outcomes</b> Social acceptance (standard sociometric procedure) [29]. Self-esteem measured by Coopersmith Self Esteem Inventory [30] Tacher ratings of social adjustment (a series of IH Likert-scale items). All measured immediately following the program and 5 weeks later.</p>	Significant between group effects on social acceptance both immediately following the programme ( $p < .001$ ) and 5 weeks later ( $p < .01$ ) for both the former special class pupils and the children with mild ID who had never attended special classes. No significant effects on self-esteem and teacher ratings of social adjustment.

Balthazar (1971) [31]	Effectiveness of a program which combines nurturant nursing and conditioning principles on behaviour mediation for severely mental retarded children.	<b>Intervention agent:</b> Nurses and other caring staff. <b>Dosage:</b> not reported.	<b>Intervention group:</b> environment (home-like living unit converted from a regular ward, w/ living, playing, dining, and nursing area), individualised nursing care plan for each child (reviewed & modified weekly), small groups nursing (3 children w/ 1 staff for care & supervision), tantrum management (remove physical basis; isolate from others; guide to instructive play; reinforce desirable bhvrs), methods to reduce insecurity (simple explanations for routine, prepare children for unusual events). <b>Control group:</b> usual care.	<b>Outcomes</b> Social behaviour seven factors measured by Central Wisconsin Colony Scales of Adaptive Behaviours [32].	Significant improvements on unskilled verbalization, failure to respond to contact by others ( $p < .05$ ). No significant differences on passive response to contact, resistive response, posturing & stereopathy or inapt responses to others.
<b>Activities of Daily Living: personal independence at home/in the community (x7)</b>					
Lee (2020) [33]	Compare the effects of the simplified 5-step and the conventional 7-Step hand hygiene program for students with ID.	<b>Intervention agent:</b> trained school nurses or schoolteachers (5-step & 7-step groups). <b>Delivery / dosage:</b> month 1-3: 3 days/week month 4-6: 3 days every 2 weeks.	<b>5-step group:</b> video, poster and magnetic sticker. intensive training for the research assistants, school nurses and schoolteachers, learning (watching 5-step teaching video, practising), supervision (school nurses or schoolteachers), rating (research assistants), context (posters and magnetic stickers with hand-washing steps). <b>7-step group(control):</b> video, poster and magnetic sticker. intensive training for the research assistants, school nurses and schoolteachers, learning (watch 7-step teaching video, practising), supervision (school nurses or schoolteachers), rating (research assistants), context (posters and magnetic stickers with hand-washing steps).	<b>Primary outcomes</b> Hand-washing technique (validated checklist), hand cleanliness (percentage of squares in which gel stain remained in photographs). <b>Secondary outcomes</b> Monthly sick leave days (respiratory and gastroenteric diseases, fever, influenza-like illness symptoms).	Significant between group effect on hand-washing technique scores ( $p < .05$ ) and hand cleanliness scores ( $p < .05$ ) at 6th month post-intervention. Significant within group effect on hand-washing technique scores ( $p < .05$ ) and hand cleanliness scores ( $p < .05$ ). All effect sizes small to medium; Hedges $g$ . No significant between and within group effect on sick leave days.
Bagattoni (2020) [34]	Effect of audio-visual distraction on dental chairside bhvr of children w/ DS & its influence on operator stress & appt duration.	<b>Intervention agent:</b> 3 dentists – trained in SN dentistry; familiar with research protocol from previous study. <b>Delivery / dosage:</b> 1 dental visit per participant	<b>Study group:</b> choose movies and adjust volumes before dental treatment, wearing video eyeglasses and watching movies during treatment. <b>Control group:</b> conventional behaviour management during dental treatment (voice control, nonverbal communication, tell-show-do and positive reinforcement). <b>Both groups:</b> parents present; dental exam consistent.	<b>Primary outcomes</b> Pain-related behaviour (r-FLACC scale [35]), behaviour (Frankl scale [36]). <b>Secondary outcomes</b> Operator stress (VAS [37]). Duration of appointment (start point the topical anaesthesia application to end point of the occlusal adjustment).	Significant effects favouring control group on pain-related behaviours ( $p = .015$ ) and negative behaviours between two groups ( $p = .011$ ). No significant effects on duration and operators' stress.



Janeslätt (2019) [38]	Evaluation of the intervention 'My Time' on improving time-processing ability for children with ID aged 10–17 years	<b>Intervention agent:</b> teachers and/or teacher assistants for both groups <b>Dosage:</b> 8 weeks	<b>Intervention group:</b> assessed at baseline, training for teachers and teacher assistants during 8-week implementation, intervention integrated into the learning process for all pupils in the class by a single teacher (no time-assisted devices used), documentation (recorded in a log book by teachers). <b>Control group:</b> assessed at baseline, education as usual by teachers.	<b>Primary outcomes</b> Time processing ability (KaTid-Child, [39]) <b>Secondary outcomes</b> Occupational performance perceived by children (Autonomy scale, [40]); Occupational performance rated by parents (Time-Parent scale, [41])	Both groups improved on the ability of time processing (KaTid-Child), the Autonomy scale and the Time-Parent scale. Significant between group effect on time processing (KaTid-Child, $p = .021$ , $d = 0.64$ ). No significant between group effects on the Autonomy scale and the Time-Parent scale.
Lee (2017) [42]	Compare efficacy of 6 month School-Based Weight Management Program (SBWMP) extended from school to home setting by involving parents via mHealth tools to control group.	<b>Intervention agent:</b> School nurses, teachers, peers, parents. <b>Delivery / dosage:</b> 24 sessions over 6 months. Initially weekly, they fortnightly, then monthly.	<b>Intervention group</b> – Structured weight management (WM) program promoting healthy eating and regular exercise via training sessions at school and extended to home via mHealth. Training sessions for parents (8 sessions), 16 training sessions for both parents and children, all sessions delivered in age/developmentally appropriate way with interactive games and activities promoting healthy lifestyle. <b>Control group</b> – Usual WM activities, including: posters to promote healthy lifestyle behaviours; routine P.E. lessons 2/week; scheduled talks on dietary habits. Parents not involved. Measures taken at baseline and post-intervention, 6months for both groups.	<b>Outcomes</b> Lifestyle health knowledge scores (food pyramid tests, sports pyramid tests, snack choice tests), self-efficacy (nutritional self-efficacy, self-efficacy in peer interaction), psycho-social well-being measured by quality of Life (QoL, PedsQLTM 4.0 [43]), self-esteem (Rosenberg's Self-esteem Scale, C-SES [44,45]), perceived body shape scale [46]; perceived body image questionnaire [47] and Stunkard self-figure rating scale [48]. Social relationships and preferred cooking method measured with unclear instruments.	Scores in intervention group significantly higher than control group on sports pyramid tests ( $p < .001$ ) of lifestyle health knowledge scores, QoL ( $p < 0.001$ ) and self-esteem ( $p < 0.001$ ). Scores in the intervention group significantly lower than control group on snack choice tests ( $p = .04$ ) of lifestyle health knowledge scores, self-figure rating scale ( $p < 0.001$ ) and perceived body image questionnaire ( $p = 0.008$ ). No significant between group effects on social relationships and preferred cooking methods.
McPherson (2017) [49]	Evaluation of a health intervention package designed to improve health advocacy for adolescents with ID.	<b>Intervention agent:</b> teachers for both groups. <b>Dosage:</b> the first two terms of a year.	<b>Intervention group:</b> materials (Ask Project Curriculum Strategy Booklet, The Ask Health Diary), incorporated into curriculum teaching in schools. <b>Control group:</b> usual care.	<b>Outcomes</b> Questionnaires used for assessing health advocacy skills, household demographic and social characteristics, usage of the diary and the intervention program.	Treatment groups significantly more likely to go to doctor alone ( $p = .04$ ), and ask questions ( $p = .05$ ). Carers of treatment groups significantly more likely to record health problems ( $p = .04$ ).

Wuang (2013) [50]	Effectiveness of a proposed occupational therapy home program for children with ID.	<b>Intervention agent:</b> parents taught and supported by therapists. <b>Dosage:</b> 15-min sessions for 20 weeks.	<b>OTHP group:</b> before intervention (parent-therapist collaboration building, five meetings, two home visits, and one school visit), COPM goals setting (general goals identified first by parents, specific goals set by researchers), appropriate therapeutic activities selected, therapeutic activities performed by parents, outcome and feedback (parents' diaries for documentation). <b>Non-OTHP group:</b> no intervention provided.	<b>Outcomes</b> Occupational performance measured by COPM [51], participation and enjoyment measured by CAPE [52], motor proficiency (BOT-2).	Significant between group effects on activity participation ( $p < .05$ , medium effect size), occupational performance ( $p = .01$ , large effect size). No significant between group effects on enjoyment, bilateral coordination, strength and agility.
Drysdale (2008) [53]	Is community living skills training effective in the functional ability of children with moderate learning disability?	<b>Intervention agent:</b> Program delivery – researcher, blinded to baseline (t1) assessment score Assessment – 2x OT research assistants, blinded to group allocations. <b>Delivery / dosage:</b> 2 x 30 minute sessions per week for 8 weeks.	<b>Class-based only intervention</b> – groups of 6 children. Training techniques included: instruction; demonstration; role play; group exercises; games & discussion. Range of functional skills covered: road safety; money concepts; shopping; preparing snacks; telephone use; finding information. <b>Classroom &amp; community-based intervention</b> – school-based program + 2 visits to a local shop to practice skills in real situation. Different shop than 1 used in assessment to avoid rehearsal setting. <b>Control group</b> – no intervention/TAU.	<b>Outcomes</b> Task Analysis of shopping task, 13 steps. Task Analysis of telephone task. 10 steps from 1. Picks up receiver to 10. Replaces receiver. One therapist completed pre-/posts tests for shopping task; another completed for phone task to ensure reliability of task results.	Shopping task: statistical improvement between intervention and control groups, $p = .007$ , effect size 0.178 (described as “large” (p.252) but not reported how calculated). No significant difference between treatment groups. Telephone task: no statistical difference between groups.
<b>School &amp; Work Functioning (x1)</b>					
Baran (2013) [54]	Examine the effect of participation in a United Sport (UNS) soccer program on fitness and skilled performance compared to the fitness and skilled performance of a control group in soccer for youth with and without ID.	<b>Intervention agent:</b> 2 coaches/team, certified: experienced & qualified to teach children with ID. + 1 head coach Investigator & project assistants. <b>Delivery / dosage:</b> 3 x 90minute sessions/week, for 8weeks. 2-week tournament following the training.	<b>Training group (TRG program)</b> —structured sessions (general Soccer Skill Instructional Program, encompassed skill training, soccer rules, sportsmanship and various team tactics), each session: warm up exercises without the ball, then tactical warm up exercises with and without the ball. Participants: ID-TRG & WoID-TRG <b>Control group</b> – treatment as usual, 2 x 45-minute P.E. classes/week. Participants: ID-CG & WoID-CG. <b>Both groups:</b> parental consent received; assessments taken pre-test and post-test (after 8-week program). Physical fitness (30 minutes) and football skill tests (40 minutes) administered on different days by the investigator, project assistants and football coaches.	<b>Outcomes</b> Soccer skills (Football Athletes Skills Assessment (FASA) x6 domains: Individual skills (IS): dribbling; shooting; run & kick. Team skills (TS): dribbling slalom; control & pass; shooting. Total soccer score.	No significant differences observed between the 4 groups in run & kick. Significant improvements ( $p < .01$ ) in ID-TRG, WoID-TRG & ID-CG, compared to WoID-CG in: control pass; dribble; shoot; total soccer score. Between group effect sizes not reported. ID-TRG significantly improved ( $p < .01$ , large effect size) compared to WoID-CG in: shooting; slalom.

<b>Comprehensive: multiple domains addressed (x3)</b>					
Tanet (2020) [55]	Feasibility, acceptability and efficacy of the two-year DS1-EI intervention for children with ASD and ID.	<b>Intervention agent:</b> DS1-EI- a specialized teacher (French public school system) aided by assistants (specialized educators or nurses) to reach one-to-one ratio. TAU- Specialized teachers. <b>Delivery / dosage:</b> 4 mornings/week (2 h and 30 min per session).	<b>DS1-EI group:</b> one week training for teachers and assistants, structured classroom setting, structured context (agenda, activity or teacher changes), teachers aided by assistants. Supervisions (daily peer supervision, weekly supervision by a psychologist, main investigator and an external audit). <b>Treatment as usual group (TAU):</b> usual care of institutions from psychologist, therapists and teachers.	<b>Primary outcomes</b> Autism severity (CARS [56]), DQ(PEP-3 [57]), school assessment (French national abilities testing for pre-schoolers). <b>Secondary outcomes</b> Abilities for personal and social autonomy (VABS-II [58]), anomalies of interaction, communication and behaviour (ADI-R), intelligence (KABC-II [59]), global symptom severity (CGI [60], CGAS [61]).	0-to-18-month outcomes: no significant effect on group and group*time interaction, significant improvement over time of both groups on CARS, ADI-R(interaction), PEP (communication, motricity, maladaptive) ( $p < .02$ ). 12-to-24-month outcomes: no significant effect on group and group*time interaction, significant improvement over time of both groups on CGAS and VABS. ( $p < .001$ ).
Saint-Georges (2020) [62]	Effects of DS1-EI intervention on verbal communication, non-verbal communication, social skills and educational achievements at 36 months.	<b>Intervention agent:</b> DS1-EI- a specialized teacher (French public school system) aided by assistants (specialized educators or nurses) to reach 1:1 ratio. TAU- Specialized teachers. <b>Delivery / dosage:</b> 4 mornings/week (2.5 h per session)	<b>DS1-EI group:</b> one week training for teachers and assistants, structured classroom setting, structured context (agenda, activity or teacher changes), teachers aided by assistants. Supervision1 (daily peer supervision, weekly supervision by a psychologist, main investigator and an external audit) <b>Treatment as usual group (TAU):</b> usual care of institutions from psychologist, therapists and teachers.	<b>Primary outcomes</b> DQ and social communicative skills (PEP-3 [56]). <b>Secondary outcomes</b> Autism severity (CARS [57]), abilities for personal and social autonomy (VABS-II [58]), anomalies of interaction, communication and behaviour (ADI-R), intelligence (KABC-II [59]), global symptom severity (CGAS [61]), school assessment (French national abilities testing for pre-schoolers).	36-month outcomes: no significant effect in the group*time interaction, three composite PEP-3 scores (communication motor, maladaptive behaviours), secondary clinical measures, significant improvement over time of both groups on CARS, ADI-interaction, PEP-3, VABS, CGAS, school assessments- language, mathematic, autonomy ( $p < .001$ ).
Agbaria (2020) [63]	Efficacy of acquiring social and cognitive skills in an intervention for Arab parents of children with IDD accompanied by behavioural conditions.	<b>Intervention agent:</b> experimental group- parents led by two social workers with 10 years of experience Control group- Parents led by two accredited art therapists. <b>Delivery / dosage:</b> 15, 2.5-hr meetings.	<b>Experimental group:</b> attend intervention sessions (contents: a review of homework, learning using modelling, film viewing, role playing, relaxation exercises, and group work, and assignment of homework to be completed before next meeting). <b>Control group:</b> art and painting intervention.	<b>Outcomes</b> 7/10 domains within Bloomquist questionnaire, pertain to child: familial interaction; compliance with rules; social behavioural skills; problem solving; anger management; independent learning; self-assessment; + overall "general score" - all 10 domains (3 of which relate to parents).	Significant effects ( $p < .05$ ) within & between groups on familial interaction, compliance, social bhvral skills, anger management, independent learning & general score; effect size not reported. No significant effects on problem-solving and self-assessment for both within and between groups.

**Table 5 Notes.** ABA= Applied Behavioural Analysis; ADI-R=Autism Diagnostic Interview-Revised; A.P.A.= adapted physical activity; avg= average; AWMA= Automated Working Memory Assessment; B.B. Alt.= basketball in Alternated sport competition; bhvr/al (mod)=behaviour/al (modification); BASIC-MR= \*\*\* ; BLOC-C= Bateria de Lenguaje Objetiva Criterial; BOT-2= Bruininks–Oseretsky Test of Motor Proficiency–Second Edition; BRIEF= Behaviour Rating of Executive Function; BRIEF-P= Behaviour Rating of Executive Function – (preschool version); BTSR=Broad Target Speech Recasts; b/w= between; CA-MT=Calculation Abilities, MT group; CAPE= Children’s Assessment of Participation and Enjoyment; CARS=Childhood Autism Rating scale; CBCL= Child Behaviour Checklist; CCTT-2= Children’s Colours Traits Test, substest 2; CFA= Correspondence and Function Assessment; CG= Control group; CGAS= Clinical Global Assessment Scale; CGI=Clinical Global Impression; Conners 3= Conners Third Edition; comp= competition; COPM= Canadian occupational performance measure; CPT= Continuous Performance Task; cpu/’ed= computer/ised; C-SES= Chinese version of Self-Esteem Scale; CVLT= California Verbal Learning Test; CWMT= Cogmed Working Memory Training; DAVI= dynamic assessment procedure of verbal-imitation ability; DDSI= Denver Developmental Screening Inventory; DfES= Department for Education and Skills, UK; DQ= developmental quotient; DS=down syndrome; EDI=Easy Does It; EF=executive function; envmt= environment; EWR= Early Word Recognition; expmt/al /er= experiment/al /er; FU=Follow Up; FXS= fragile X syndrome; I(D)D=Intellectual (developmental) disabilities; (in)apt=(in)appropriate; info=information; int= intervention; KABC-II= Kaufman Assessment Battery for Children, second edition; KiTAP= Kiddie Test of Attentional Performance; Leiter-R= Leiter-Revised; LO= Logical Operations test; m’ments= measurements; NES= Nutritional Self-Efficacy Scale; OTHP= occupational therapy home program; PedsQLTM 4.0= Pediatric Quality of Life Scale – Chinese Version; PEP-3=Psychoeducational Profile, third edition; PICAC= Porch Index of Communicative Ability in Children; PPVT= Peabody Picture Vocabulary Test; pt/s/’s= participant/s/’s; req’ed=required; r/ship= relationship; Run Alt.= running in Alternated sport competition; Pt/’s/s= participant/’s/s; SALT= Systematic Analysis of Language Transcripts; SCWT= Stroop Colour & Word Test; SENCo= special educational needs coordinator; SLP=speech-language pathologist; SN=Special Needs; SO= Special Olympics; SPP= Self-Perception Profile; STM=short-term memory; TA= teaching assistant; TAU= treatment as usual; TIDieR= Template for intervention description and replication; TRG= training/treatment group; u/stand= understand; VABS-II= Vineland Adaptive Behaviour Scale II; VAS=Visual Analog Scale; w/= with; WISC-IV= Wechsler Intelligence Scale for Children, 4<sup>th</sup> ed; WL CG= waiting list control group; WM= working memory; WoID= without ID; YARC= York Assessment of Reading;

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  63. Agbaria Q. Acquiring social and cognitive skills in an intervention for Arab parents of children with intellectual developmental disability accompanied by behavioral conditions. *Child & Family Social Work*. 2020;25:73-82.

**Table 6.** Study Risk of Bias assessments

Study ID	D1	D2	D3	D4	D5	Overall	
Lee et al 2017	!	+	+	+	+	+	+
McDuffie et al. 2018	+	+	+	+	+	+	!
Lanfranchi et al. 201	-	+	+	+	+	-	-
Baran et al. 2013	+	+	+	+	+	+	
Bennett et al. 2013	!	+	+	+	+	!	D1 Randomisation process
Sepúlveda et al. (201	!	+	+	+	+	!	D2 Deviations from the intended interventions
Wuang et al. (2013)	+	+	+	+	+	+	D3 Missing outcome data
Burgoyne et al. (2012	!	+	+	+	+	!	D4 Measurement of the outcome
Hong & Lee (2012)	!	+	+	+	+	!	D5 Selection of the reported result
Drysdale et al. (2008	+	+	+	+	+	+	
Maïano et al. (2001)	!	+	+	+	+	!	
Jacques et al. (1998)	-	!	+	-	+	-	
Agbaria (2020)	!	+	+	-	+	-	
Bagattoni (2020)	+	+	+	+	+	+	
Balthazar et al. (197	!	-	+	!	+	-	
Boyce & Clinton (1976	!	+	+	-	+	-	
Hessl et al. (2019)	+	+	+	+	+	+	
Janeslätt et al. (201	!	+	+	+	+	!	
Kantner et al. (1982)	!	+	+	+	!	!	
Lee et al. (2017)	+	+	+	+	+	+	
Litrownick et al. (1	!	+	+	+	!	!	
McPherson et al. (201	+	+	+	+	+	+	
Tanet et al. (2020)	!	+	+	+	+	!	
St-Georges et al. (20	!	+	+	+	+	!	

Generated from RoB2.0 tool: Higgins JP, Savović J, Page MJ, et al. Assessing risk of bias in a randomized trial. Cochrane handbook for systematic reviews of interventions. 2019:205-228



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## Article



### **A systematic review of non-pharmacological interventions for children and adolescents with intellectual disabilities**

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## Article Summary

### A systematic review of non-pharmacological interventions for children and adolescents with intellectual disabilities

#### ABSTRACT

**Purpose:** A systematic review was conducted to identify non-pharmacological interventions using RCT designs for children with intellectual disability (ID); measure the methodological quality of identified studies; identify intervention categories.

**Materials & methods:** The study was registered in PROSPERO (CRD42021239599); followed PRISMA reporting guidelines. RoB2.0 was used to evaluate study methodological quality. Five databases were searched.

**Inclusion criteria:** Randomized controlled trials (RCTs); children, 5-18 years, with ID; non-pharmacological interventions; original, peer-reviewed English-language articles.

**Results:** 878 records identified; 24 studies included. Data extracted using pre-specified forms. Meta-analysis could not be performed due to heterogeneity. Studies categorized into groups relating to cognitive or adaptive functioning according to intervention focus.

**Conclusions:** Further research suggested in the areas of social skills and communication, and in relation to adolescents. Developing procedures to measure outcomes appropriate for individuals with ID across ages and abilities may support/promote the inclusion of people with more severe ID within RCTs.

#### ➤ IMPLICATIONS FOR REHABILITATION

- A small number of non-pharmacological interventions using RCT designs were found, and they focused on different aspects of intellectual and adaptive functioning for individuals with ID. Interventions used in studies that found significant differences between treatment and control groups of high quality and reasonably sized samples were noted to involve good communication between professionals working with children and their families.
- More high-quality RCT design research on non-pharmacological interventions across different settings for ID is needed
- Rehabilitation research areas that require particular attention include participant groups with more adolescents, and with more children and young people with more severe ID.

*Keywords:* intellectual disabilities; RCTs; children; adolescents; PRISMA; systematic review; non-pharmacological intervention.

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*Declarations of interest:* the authors report no conflicts of interest.

# Article Manuscript

## Introduction

Intellectual Disability (ID) is a complex condition, with various definitions, and diagnostic manuals used in assessment and treatment processes [1]. ID is characterized by substantial impairments of both cognitive functioning and adaptive behaviors, with onset during the developmental period, as defined by the three diagnostic manuals used in relation to ID (DSM-5; ICD11; AAIDD [2-4]). Cognitive functioning relates to areas such as executive functioning, abstract thinking, and learning academic skills [4]. Adaptive behaviors are considered within three domains: conceptual skills, social skills, and practical skills [4].

The assessments of cognitive and adaptive functioning require reliable and valid standard tools. Wechsler scales (WISC) and Vineland Adaptive Behavior scales (VABs) are most frequently used to measure cognitive functioning and adaptive abilities respectively [3,5-7]. ID is generally diagnosed over the age of five years when the WISC and VABs tools increase in diagnostic validity and reliability [8]. While the definitions of ID state that the condition must occur during the developmental period [1], neither the DSM-5 nor the ICD-10 specify upper age limits for the developmental period [2,4] while the AAIDD defines it as being prior to the age of 22 [3]. Historically, the severity of ID was determined on the basis of intelligence quotient (IQ) scores, differentiating between mild (IQ 50-69), moderate (IQ 36-51), severe (IQ 20-35), and profound (IQ < 20) [9]. However, all three diagnostic manuals now take into consideration adaptive functioning, or intensity of support required, [2-4]: IQ tests alone do not determine diagnosis [7,10].

As people with ID have different levels of need within diverse cognitive and adaptive functioning areas due to the heterogeneity within the population [1], a range of knowledge and understanding in how best to support these needs is required. Increasing emphasis has been placed on the importance of evidence-based practice across multiple disciplinary practices in supporting people with ID [11]. A diverse, high-quality evidence base, taking into consideration

interventions to support both cognitive functioning and adaptive behaviors, has been recognized as beneficial in order to support people with ID [11]. There are ongoing issues that negatively impact people with ID's quality of life, i.e. persistent negative attitudes within society, including healthcare professionals' attitudes [12-14]; lower incomes [15-17]; increased social exclusion and discrimination in schools and workplaces [17-19], with research finding that students with ID had fewer friends, fewer participation opportunities, and experienced increased loneliness and bullying [18-20].

Randomized controlled trials (RCTs) are generally accepted as the “gold standard” of evidence [21-23]. They are designed to assess intervention efficacy, by randomly allocating participants representative of their wider population group, to treatment or no-treatment control groups, and making comparisons of post-intervention outcomes between the groups [22,24]. In practice, RCTs can be used to determine funding of intervention programs [21,25], however, it has been observed that there is less evidence produced from RCTs in relation to people with ID than for those without ID [26,27]. Systematic reviews utilize scientific approaches to identify, analyze and synthesize related studies to address a particular research question [28,29], providing comprehensive overviews of up-to-date evidence, and are fundamental in informing practice for practitioners and policymakers [29]. Furthermore, a systematic review of RCT study designs is deemed the highest level of evidence [23].

From previous systematic reviews, it was noted that few RCTs were used in interventions for people with ID. In a recent systematic review of self-regulation interventions, from 36 studies identified, all reporting significant improvements, only eight studies were RCTs; most were case studies and contained small sample sizes [35]. A further systematic review, assessing the effectiveness of psychotherapeutic interventions for ID, found only one-third of identified studies were RCTs; the authors concluded that this limited the evidence, and suggested more well-designed RCTs were required to consolidate current evidence [30]. Another systematic review assessing the effectiveness of non-specialist psychosocial interventions found similar results, with only half of the included studies following RCT designs [31].

Although previous systematic reviews focused on non-pharmacological interventions for ID, they were limited to: the effectiveness of a specific intervention approach, i.e. mindfulness-based [32], psychotherapeutic [30] and cognitive behavioral [33]; a particular aspect of daily living skills, such as self-management [34], oral hygiene [35] and lifestyle change [36]; a particular age group or ID severity [30,37,38]. Reviews with a broad focus on non-pharmacological intervention, and across all ages and ID severity levels could not be identified.

This systematic review, therefore, aims to synthesize non-pharmacological interventions employing RCTs for children aged 5-18 years, with ID without limiting to one perspective, to provide potential directions for future research and practice. The age range 5-18 years was selected as ID is not diagnosed prior to 5 years, and the UN's Convention on the Rights of the Child defines children as being under 18 years [39].

#### *Research aims*

- 1) Identify existing non-pharmacological interventions using RCT experimental designs for children with ID.
- 2) Measure the methodological quality of included studies.
- 3) Identify intervention categories, reported outcomes, and effectiveness of studies.

## **Methods**

### ***Protocol and registration***

This systematic review utilized the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Checklist as reporting guidelines [40,41] ([see table 1](#)), and was registered on PROSPERO, international prospective register of systematic reviews, with the registration number: CRD42021239599.

### ***Information sources and search strategy***

The electronic databases Cinahl, Embase, Eric (Proquest), APA PsycINFO, and PubMed were searched on 29<sup>th</sup> January 2021. Combinations of two categories of subject headings or free texts were used for searching: (1) condition (intellectual disability, ID); (2) randomized controlled trials. Specific search strategies per database are presented in [table 2](#). A manual



reference list search of the included studies was conducted to find potentially missing articles.

### ***Eligibility criteria***

Included articles should meet the following criteria: (1) participants were children aged 5-18 years with a diagnosis of ID [4], including children with conditions known to have co-occurring ID, such as DS and FXS; (2) studies utilized RCTs as research designs; (3) interventions designed to improve social-behavioral functioning of children with ID; at least one outcome measure focusing on non-physiological areas including behavioral, cognitive abilities, social abilities and communication; (4) original articles published in English language, peer-reviewed journals.

Exclusion criteria consisted of: (1) pharmaceutical interventions; (2) outcomes focusing only on peers or caregivers; (3) interventions focusing only on physiological outcomes, i.e. blood pressure, heart rate, oxygen saturation, respiratory rate and temperature, blood sugar rate, BMI, weight change, posture, gait, and balance. No restrictions were placed on comparison groups; intervention settings or delivery agents; country; or publication year.

### ***Selection process, data collection process, data items***

Titles and abstracts of included articles were screened by two reviewers independently to identify articles meeting the inclusion criteria. Reviewers conferred after screening to agree on articles to be retrieved in full. Selected articles were retrieved and read in full by two reviewers to determine inclusion criteria. When there was a disagreement, both reviewers discussed and came to a consensus. When an agreement could not be reached, a third reviewer was contacted to determine whether the article met inclusion criteria. The process is presented in [figure 1](#), by the PRISMA flow diagram [41].

After studies were identified, data were extracted from the studies using pre-specified data extraction forms. The following data on study characteristics were extracted: (1) study (country, study design, and intervention category); (2) Methodological quality; (3) ID (definition, diagnosis criteria); (4) inclusion/exclusion criteria of the study population; (5) sample size (intervention and control group); (5) group descriptives (age, gender ratio, relevant medical

diagnosis). Data on intervention characteristics were extracted by: (1) intervention goal; (2) intervention agent, delivery, and dosage; (3) materials and procedures; (4) outcome measures; (5) treatment outcomes. One reviewer extracted data relating to study characteristics and the other extracted data relating to intervention characteristics. Reviewers exchanged extraction results on completion and checked for accuracy. Disagreements were discussed to reach a consensus. Meta-analysis was planned to be conducted dependent on the suitability of selected studies.

### ***Study risk of bias assessment***

To assess methodological quality, the Cochrane Collaboration “Risk of bias tool” for randomized controlled trials (RoB 2.0) [42] was used. RoB 2.0 contains five key specific domains: (1) bias resulting from the randomization process; (2) bias as a result of changes from planned interventions; (3) bias due to omitted outcome data; (4) bias caused by measurement of outcome; (5) bias in selective reporting of results. Two reviewers independently assessed five domains of each article and resolved disagreements by discussion until consensus was reached. The overall risk of bias judgment was determined by the guidelines of RoB 2.0 [42] and assessments of both reviewers. The likelihood of bias within this review was also reduced by the two reviewers having no affiliations or interests with the included articles.

## **Results**

A total of 878 records were identified from the database searches, 130 were removed due to duplication. The titles and abstracts of the remaining 748 records were screened by two reviewers. Following consensus discussions, 656 records were excluded; 92 original articles were sought for retrieval. Ten of the 92 articles could not be retrieved following searches with access provided from two university libraries and contact made to the authors. A further 66 records were excluded following the agreement between two reviewers (all excluded articles, including reasons for exclusion, presented in [table 3](#)). A further eight records were identified and assessed as eligible following manual reference list checks. [Figure 1](#) (PRISMA flow diagram) [43], provides information relating to the screening, retrieval, and inclusion process.

This resulted in a total of 24 included studies; see [table 4](#) for details relating to participant characteristics (age, gender), and [table 5](#) for details relating to study characteristics (intervention details, outcomes), with citations. Meta-analysis could not be undertaken for a variety of reasons. There was a diverse range of participants involved within the studies, both in terms of ID severity, and in terms of additional diagnoses such as DS and FXS. Further to this, both intervention strategies, methods, and outcomes measured ranged across the 24 studies. Finally, the statistical analyses used and reported were heterogeneous across the studies, with effect sizes reported inconsistently throughout.

### ***Risk of bias***

The outcome of assessments of the included studies using RoB 2.0 [42] is presented in [table 6](#). Of the 24 included studies, nine were rated “low risk,” five as “high risk” and ten as having “some concerns.” Within studies considered “high risk” and “some concerns,” the majority (11/15) were rated as such as they did not clearly state the randomization or concealment of the allocation sequence [44-54]. Another study was considered “high risk” due to baseline differences between the sample size in the intervention and control group, and a lack of description regarding allocation sequences [55]. Three studies were assessed as having “some concerns” because of baseline differences in diagnosis [56] and the total number of education hours participants received prior to intervention [57,58]. Two of the studies assessed as having “some concerns” did not contain pre-specified statistical analysis plans [52,53]. Among studies assessed as “high risk,” two assessed outcomes without blinding assessors from the allocation result of intervention [50,51]. The assessment outcomes of one study [54] were likely influenced by the non-blinding of assessors. Two studies were regarded as “high risk” because of utilizing measurement without established validity and reliability [49,51]. One “high risk” study had no appropriate analysis for estimating the effect of intervention assignment [50].

## ***Study & participant characteristics***

### *Publication year & country*

The included studies were published from 1971 – 2020. The sample size of the studies ranged from 17 [50] to 445 [59]. Over half of the studies (16/24) were conducted in the US (7/24) [45,50-53,60,61] and Europe (9/24) [44,46,48,55-58,62,63]. Five studies were conducted in Asia [47,49,59,64,65], one in New Zealand [54], one in Australia [66] and one in Turkey [67].

### *Sample size & age*

Over half of the studies (13/24) included only primary/elementary-school-aged participants from 5-12 years [44,46,47,49,51-54,57,58,62,63,65]. Few studies (2/24) included only adolescent participants aged 12-18 years [48,67]. A single study described participants as “children” but did not report their age range [50], while the remaining (8/24) studies included children of various age ranges across the 5-18 years inclusion criteria.

### *Gender & diagnoses*

Most studies (17/24) reported the ratio of male and female participants, with just under half (10/24) consisting of reasonably balanced gender proportions across both treatment and control groups (50-65% male) [44-46,53,55,56,60,63,65,66]. Within the remaining (14/24) studies the proportion was not balanced, involved only one gender, or did not report the gender [47-51,54,57,58,61,62,64,65,67].

In relation to diagnostic manuals, of the 24 studies, one referred to the ICD-10 [63], two referred to the DSM [49,65], and one referred to the AAIDD [47]. Less than half of the studies (9/24) did not specify how diagnostics were determined, but highlighted the use of intelligence tests to determine IQ <70, including: WISC [45,48,52,54]; alternative intelligence tests to measure IQ [51,53,61]; VABS-II to measure participant’s Developmental Quotient (DQ; the two studies based on the same cohort of participants, [57,58]). Few (4/24) studies specified how diagnostics were determined but reported: the presence of DS [44,46,55] or FXS [60]. The remaining (6/24) studies did not specify how diagnoses were made [50,56,59,64,66,67].

Most studies (17/24) reported ID severity explicitly or with the inclusion of participant IQ scores. The majority (14/24) included participants with mild-moderate ID [47-49,52,54,56,59-65,67]. The two studies published from the same cohort of participants at different time points recorded an average DQ of 30 [57,58]. The VABS-II takes into consideration adaptive behaviors, and provides a composite DQ score from 20-160 [68]; an average DQ of 30 could therefore be considered as low. While DQ does not correlate directly to an ID severity level, it has been found to be an acceptable approximation of intellectual capacity [69].

### ***Intervention sub-groupings***

The categorization of study interventions was based on the ID diagnostic criteria of the DSM-5[4]: intellectual and adaptive functioning. Where interventions focused on intellectual functioning, they were categorized as “cognitive abilities”, and included studies with a focus on executive functioning, problem-solving, and learning academic skills such as literacy and mathematics. Adaptive functioning can be described as competencies required for daily living, operationalized into the categories: “communication,” “social skills,” “activities of daily living,” (ADLs) “school or work functioning,” or “comprehensive.” Communication was defined as the ability to understand and be understood [1]; social skills as the ability to relate with others in a culturally and contextually appropriate manner [70]; this included sense of self and self-esteem, in consideration of the dialogical perspective, whereby identity is thought to be developed through social interactions with others [71]; ADLs as self-care abilities [1]; school or work functioning as the ability to conform to school or vocational standards [1]. “Comprehensive” was used for those studies which met multiple categories, resulting in the 24 studies being placed into one of:

- Intellectual functioning
  - Cognitive abilities
- Adaptive functioning
  - Activities of daily living
  - Communication skills & abilities

- Social skills
- School/work functioning
- Comprehensive (intervention could fulfill two or more categories).

The reported efficacy of interventions will be discussed under these categories: where the effect size is referred to, unless otherwise stated, Cohen's *d* was used. Of 24 included studies, eight were grouped into the category of cognitive abilities, seven into activities of daily living, two studies into communication, three into social skills, one into school or work functioning. Three studies were grouped as comprehensive interventions.

### *Cognitive abilities*

Most (7/8) of the studies were conducted within education settings by education staff, except for one conducted at home by parents [60]. Most interventions were high in frequency and duration, with 3-5 sessions per week over 6 to 12 weeks. Intervention aims of three of the included articles on cognitive abilities aimed to improve executive functions including memory [44,60] and attention [47]. The two studies aiming to improve memory made use of Cogmed [72], a paid-for downloadable computer program: one consisted of a large number of participants (N=100), however, the differences between treatment groups were not statistically significant [60]. The other study [44] did find significant differences between the treatment group and control group (CG) [44]. These two studies also use the same measurements [44,60]. The study focusing on attention [47] also found significant statistical differences between the TG and CG outcomes.

A further three studies targeted academic areas, all with children with DS, and all reported significant differences between TG and CGs. One study focused on developing math skills [55], with medium effect sizes. The other studies focused on language skills relating to reading [46], with small effect sizes reported, and grammar [45], with no reported effect sizes.

The two remaining studies were associated with experiential learning processes [51,53]. One study found no between-group differences [53], while the other [51], reported a significant difference in how children with or without ID responded to informative or affective social

reinforcement. Children with ID responded preferably to affective social reinforcement; effect sizes were not reported.

### *Activities of daily living*

Following cognitive abilities, activities of daily living (ADLs) were the next highest category (7/24). They were most frequently conducted within education settings with education staff implementing interventions (5/7). Overall, this category consisted of the largest sample sizes compared to the other groups (N = 40-445). Of these studies, approximately half (4/7) concentrated on health, over a 4-7 month period, all of which reported significant results: handwashing techniques [59]; behavioral management during dental restorations [63]; healthy lifestyle knowledge [64]; health advocacy skills [66]. The study conducted during the dental appointment [63] found statistically significant results in favor of the control group in relation to high pain-related behaviors displayed during the appointment. Small effect sizes (Hedges'  $g < 0.5$ ) were reported in [59], but no effect sizes were reported in [63,64,66].

The other (3/7) studies focused on independent living skills: time management [56], occupational performance [65], and community living skills [62]. The study with a focus on time management reported statistically significant between-group differences on time processing with a medium effect size [56]. In relation to occupational performance, significant differences were found in activity participation, and occupational performance [65]; effect sizes were not reported. The community living skills were measured by shopping skills and a telephone task [62]. Statistically significant differences were reported between treatment and control groups for the shopping skills, with a small effect size.

### *Communication*

Of the two communication-focused interventions, one intended only to improve spoken language [61], while the other aimed to enhance multiple communicative abilities [52]. The study with multiple language foci reported significant differences relating to intervention strategies and engagement time, with large effect sizes, however, no significant differences on language variables were found [61], possibly due to the relatively small sample size (N=20).

The study focusing on spoken language found no significant between-group differences [52]; no effect size was reported.

### *Social skills*

The three social skills interventions focused on behavior support [50] within a residential setting, and self-identity [48,54]. The study focusing on behavior support set in a residential home-school environment reported significant between-group differences but did not report effect size [50]. The two studies that related to self-identity focused on: children with ID's perceived competence and self-worth [48]; and increasing the social acceptance of children with ID [54]. No significant results were reported in relation to competence and self-worth [48]; the study had a moderate number of participants (N=32). The study that aimed to increase the social acceptance of children with ID reported significant between-group effects both post-intervention and at a 5-week follow-up [54]. Neither study reported effect sizes.

### *School or work functioning*

The only study included within this category aimed at soccer skills development [67], as developing specific skills can be considered necessary for functioning within school/work environments. The overall sample size was reasonable (N=76) and the intervention duration was 8 weeks. Significant statistical differences on total soccer skills scores were found in TGs for participants with ID compared with their CGs, with large effect sizes.

### *Comprehensive interventions*

Of the three interventions that could not be included within one category, one focused on both social skills and cognitive abilities [49] by supporting parents in a group work setting facilitated by social workers. They reported significant improvements in the outcome measures in the TG, although no effect size was reported. The other two consisted of one adapted instruction curricular intervention, published over two papers at different time points, aiming to improve cognitive abilities, communication, social skills, and school or work functioning [57,58]. Nonsignificant differences were reported, while significant improvements over time were found in the TG at 18 and 24 months Tanet [58]. This outcome was replicated at the 36-



month follow-ups Saint-Georges [57]. The effect sizes ranged from medium to large at months 18 and 24 [58], while they were mostly large (except for two components regarding communication and behaviors with small effect sizes) at month 36 [57].

## **Discussion**

### ***Interventions***

Following systematic searches to identify non-pharmacological interventions using RCT study design with children with ID, a broad range of research, addressing a variety of cognitive and adaptive functioning domains were identified. The research was conducted globally, across multiple decades and settings. The 24 included studies were categorized on the basis of intervention focus into cognitive abilities, and areas of adaptive functioning including ADLs, social skills, communication skills, school or work functioning, or comprehensive.

The initial finding was that most studies focused on either cognitive abilities or ADLs within adaptive functioning, with less evidence produced in relation to the other adaptive functioning areas of social skills, communication, school/work functioning, or comprehensive studies. The interest in cognitive abilities may relate to the previous emphasis placed on cognitive abilities within the assessment and diagnostic process [73]. The increased interest in ADLs compared to other areas of adaptive functioning may relate to an ongoing drive toward increasing independent living skills within ID populations, as has been the trend since the 1980s following deinstitutionalization [74]. Enhancing such abilities may help to reduce the intensity of support someone with ID requires on a daily or weekly basis [75].

It was of concern that more high-quality RCT design research had not been conducted in relation to social skills, communication abilities, and school/work functioning given the significant impact these skills have on health, activity participation, and quality of life. Deficits in these areas can increase social isolation, loneliness, and mental health difficulties [17,19,20]. It has also been noted that people with ID with enhanced social skills were less likely to display

psychiatric comorbidity [76]. Furthermore, given that limited communication abilities have been identified as a predictor for increased challenging behaviors [77], the presence of which results in poorer outcomes, that are less cost-effective, for people with ID, their caregivers, and communities [78], it was equally concerning that limited studies were found in this area. Future high-quality research would therefore be beneficial in the adaptive functioning areas of social skill development, communication, and skills for school and work functioning.

As reported in a recent systematic review, there is a trend of introducing digital devices into interventions [79]. It may be of interest to explore the use of technology such as applications available on smartphones, to increase the involvement of parents and other caregivers within the education and support of their children with ID. One study used this approach to involve participants' families in supporting the intervention and may be a cost-effective way to increase collaboration between the school and home settings [64].

### *Effectiveness*

Most of the included studies reported statistically significant improvements. Among studies reporting effect sizes, most reported small to medium effect sizes. There is some evidence that increased frequency and duration of interventions may increase their efficacy [80]. In considering the results of this review, the risk of bias and sample sizes were also taken into consideration. It was observed that studies with lower risk of bias, larger sample sizes, and increased frequency and duration had more effective outcomes [59,61,64-67]. However, few studies included follow-up measures to evaluate whether the effects of interventions were maintained. The inclusion of more follow-up measures is therefore recommended, as RCT evidence is often used to provide information on best practice and funding directions, and knowledge of long-term benefits could further support where best to use resources.

### *Methodological quality*

There were several issues in the generalizability of the results found. Most studies were completed in economically developed countries, predominantly in the US or Europe. The sample size was often limited, with about a third of studies consisting of fewer than 30 participants. There was also more research conducted with children under 12 years, but few studies involved only adolescents. The lack of studies focusing on adolescents with ID may have a significant impact during this crucial transition period, where it is necessary to support the development of skills to live independently in later adulthood [81]. Therefore, more RCT evidence exploring how best to effectively support people during this time would be beneficial particularly within low-income countries and with reasonable sample sizes.

There were also more studies set within school environments, with a smaller number utilizing home or community settings. The scarcity of studies set within local communities, and the limited number of studies exploring how effectively skills can be transferred between settings, limits the generalizability of the findings. Additionally, there was a significant imbalance of studies in terms of ID severity, with over half of the studies-focusing on children with mild ID. It has remained unclear whether intervention focuses and approaches for individuals with mild-moderate ID are appropriate or transferable for individuals with more severe ID [82,83], further supporting the need for RCTs that explore how best to support people with more severe ID.

Outcomes and outcome measures, varied significantly between all studies, reflecting the diverse range of needs within the ID population, and the broad topics considered within intellectual and adaptive functioning. This resulted in difficulties in drawing comparisons and performing a meta-analysis. Furthermore, few measures target the two core deficits of ID directly, i.e., intellectual function and adaptive function. As supported in a recent article, this may be due to a lack of measurements appropriate for all ID severities and of measurements sufficiently sensitive to detect small, incremental changes during interventions [84]. Overall,

these findings call for further development of appropriate measurements for ID across ages and abilities.

### ***Limitations***

One main limitation of this review was that only English studies were included. This was likely a barrier to potentially relevant and useful findings and further dissemination of information between cultures [85]. Another limitation was related to the age range; while this was selected at 5-18 years, arguments have been made for increasing the upper age limit of childhood to 21, or 25 years, as supported by social and cultural shifts in some countries, and from neuropsychological research [86]. Furthermore, different diagnostic manuals contain conflicting information as they either do not state the upper age limit of the “development period” in which symptoms must appear [2,4], or have placed the upper age limit at 22 years [3]. Finally, a common theme among all literature reviews is the limitation of publication bias. It has been well documented that issues persist in this area, with studies that report no significant findings often not being published [87].

### ***Conclusion***

This systematic review identified 24 studies that met the inclusion criteria. Most of these studies were in the areas of cognitive abilities and ADLs, with far less focus placed on social skills, communication, and school/work functioning. Most studies reported statistically significant improvements and targeted children with mild ID in school settings, with less focus placed on adolescents. Therefore, there is a need for more RCTs conducted in different settings involving adolescents in areas including social skills, communication, and school/work functioning. As a result of the heterogeneity of participant characteristics, interventions used, outcomes measured and outcome measures, a meta-analysis was not possible. Some evidence from high-level, low risk of bias research, indicates effective non-pharmacological interventions. However, further exploration of how to develop procedures to measure outcomes

explicitly related to changes in intellectual and adaptive functioning, particularly for people with severe-profound ID, would benefit future RCT research designs. This may support the increased involvement of people with more severe ID within RCTs, an area that is in critical need of high-level evidence to support best practice.

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