



School of Health, Care and Social Welfare

CAN INTERVENTIONS BASED ON SELF-DETERMINATION THEORY OPTIMIZE PARTICIPATION IN PHYSICAL ACTIVITIES IN CHILDREN AND YOUNG ADULTS WITH DISABILITIES?

A SYSTEMATIC LITERATURE REVIEW

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ABSTRACT:

Background: Participation in physical activities (PA) is vital for the well-being of children and young adults with disabilities, yet barriers hinder their engagement. With the United Nations reporting 150 million children with disabilities, understanding the self-determination theory (SDT) role in promoting PA participation is essential for improving their health and well-being.

It aimed to explore how intervention based on SDT facilitates the possible determinants for PA participation in children and young adults with disabilities (CAYAWD).

Methods: A systematic review approach was employed. Databases like PubMed, PsycINFO, and CINAHL were searched for studies published between 2006 and 2022. Inclusion and exclusion criteria were applied, and the quality of the selected studies was assessed using relevant checklists from SBU, 2018. Data synthesis included intervention, description, participant characteristics, and quality evaluation.

Results: This review analyzes seven studies on interventions for physical activity in CAYAWD based on SDT. Participants totaled 341 (mean age 12.6 years) with various conditions. Studies used motivational climates or basic psychological needs (BPN) in designing the interventions to enhance autonomous (intrinsic) motivation and improve needs satisfaction to increase PA. Significant effects included improved PA, need satisfaction and autonomous motivation. The measurement instruments had acceptable validity and internal consistency. Qualities of the included studies were moderate to high. The overall strength of the evidence was moderate.

Conclusion: It emphasized that intrinsic motivation and need-satisfaction act as possible determinants for participation in PA among CAYAWD. It provides valuable insights into the importance of motivational climates in PA settings. The limited number of studies urges the need for interventional studies based on SDT among CAYAWD.

ABBREVIATIONS:

SDT: Self-determination Theory

ICF: International Classification of Functioning, Disability and Health

fPRC: family of Participation Related Constructs

PLWD: People living with disabilities.

PA: Physical Activity

BPN: Basic Psychological Needs

BPNS: Basic psychological need satisfaction

CSAT: Competence Satisfaction

PE: Physical Education

MVPA: Moderate to Vigorous intensity physical activity

COPM: Canadian Occupational Performance Measure

CAYAWD: Children and young adults with disabilities

RCT: Randomized Controlled Trial

GRADE: Grading of Recommendations Assessment Development and Evaluation

ROB 2: Risk of Bias II

ROBINS I: Risk of Bias in Non-randomized Studies I

SBU: Statens beredning för medicinsk och social utvärdering (Swedish)

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1. BACKGROUND:

Participation in physical activities is essential for the mental and physical well-being of children and young adults. Children and young adults with disabilities meet restrictions to participate due to health inequalities compared to their typically developing peers (Carty et al., 2021). Interventions based on supporting participation in physical activity need to be developed to overcome barriers children and young adults face. Interventions based on elements from the self-determination theory (SDT) such as autonomy, relatedness and competence seem to be effective. Still, it is unclear what impact the constructs from SDT have on improving participation in physical activity among children with disabilities and in what way and how effective these interventions are.

According to the United Nations Children's Fund (UNICEF), the number of children with disabilities under 18 years is 150 million. The Global Burden of Disease indicated that 93 million children (5.1%) aged 0-14 years have moderate or severe disability, and further 13 million (0.7%) children are experiencing severe difficulties.

The Convention on the Rights of Persons with Disabilities (CRPD) defines children with disabilities as those who have long-term impairments, whether physical, mental, intellectual, or sensory, that interact with various barriers hindering their full participation in society. 'Disability' is defined as "impairment, activity, limitation and participation restriction" (WHO/ICF, 2001). Disability is not solely determined by health conditions but also influenced by environmental factors like availability of facilities or parental support. These disabilities can lead to restrictions in everyday activities and accessing healthcare services (UNICEF, 2021).

1.1 Importance of physical activity participation for children and young adults with disabilities:

Physical activity, which is defined as 'any bodily movement produced by skeletal muscles' (WHO, 2020), is essential for overall health in children with disabilities. Participation in regular physical activity improves their physical functioning, mental and emotional well-being (Carbone et al., 2021; Verschuren et al., 2016). It is reported that there are low levels of physical activity participation in children with intellectual disabilities (Frey et al., 2008) and in children with physical disabilities (Maher et al., 2007) and that they are engaged in a more sedentary lifestyle when compared to their peers without disabilities, which leads to a greater risk of overweight, obesity (Neter et al., 2011), decrease in their physical deconditioning, physical function and other non-communicable diseases (Ryan et al., 2015).

According to WHO's physical activity guidelines for PLWD (people living with disabilities), substantial health benefits can be achieved from physical activity, even below 150 minutes per week (Martin et al., 2021). According to the first Global Physical Activity and Sedentary Behavior Guidelines, children and adolescents with a disability should do at least an average of 60 minutes per day of moderate to vigorous physical activity in a week. Adults with disabilities are suggested to do at least 150-300 minutes of moderate-intensity aerobic physical activity, or an equivalent combination of moderate- and vigorous-intensity activity throughout the week for substantial health benefits (Carty et al., 2021).

To be able to participate in physical activities is one of the most important goals for children, their families, and therapists (Sebire et al., 2013). International Classification of Functioning, Disability and Health (ICF) defined 'participation' as "involvement in a life situation" in all areas of life. A further development of the ICF's definition of participation can be found in the 'family of Participation Related Constructs (fPRC) model by Imms et al., (2016). In the fPRC-model, participation can be explained to have two components: attendance and involvement. Attendance is a state of individuals 'being there' and can be measured as frequency and the diversity of activities the individual take's part in. Involvement is the 'experience of participation while attending, that may include elements of engagement, motivation, persistence, social connection and affect' (Imms et al., 2016). Physiotherapy aspect in children and young adults with disabilities.

Physiotherapy plays an important role in the treatment of children with various physical disabilities. The main goal for physiotherapists is to help children and young adults with disabilities in improving functional motor skills and facilitating participation in PA (Wentz et al., 2021). Interventions that physiotherapists use on a regular basis are aimed at the body structure and function predominantly such as strengthening, stretching, weight-bearing exercises, gait training. According to a systematic review of the participation interventions' effectiveness, treatment on body function level does not seem to be effective (Adair et al., 2015). Consequently, in the last decades, physiotherapy has started to broaden the assessment and treatment of individuals, besides the functional assessment and treatment, the behaviour approach also appeared (Hardig et al., 1998; Sandborgh et al., 2010; Fritz et al., 2019).

International Society of Behavioral Medicine defined behavioural medicine as "the interdisciplinary field concerned with the development and integration of psychosocial, behavioral and biomedical knowledge relevant to health and illness and application of this knowledge to prevention, etiology, diagnosis, treatment and rehabilitation". Johnston and Johnston, (2017) proposed that "the scope of behavioral medicine extends from the fundamental biobehavioral mechanisms to behavioral processes in clinical diagnosis and intervention and in public health". Reedman et al., (2017), in their review, explored those unconventional interventions like physical training, activity level training and a combination of physical training and behavioural change therapy have a positive effect on PA participation. To elaborate, physical training would include aerobic and anaerobic exercise training; activity level training like throwing and jumping. Physical training in combination with behavioural change therapy is done through an online-based program based on social

cognitive theory, self-reflection, goal setting, and positive remodeling (Maher et al., 2010). These programs also included interventions like motivational interviewing, home-based physiotherapy (Wely et al., 2014) in which the results showed potential increase in social participation and daily activities and context focused therapy resulted in positive outcomes of increased physical activity participation (Law et al., 2011).

A meta-analysis examining behavioural change techniques-based interventions to increase physical activity behaviour among people with physical disabilities are found to be even more effective when guided by behavioural medicine theories (Ma & Ginis, 2018). A scoping review conducted in 2017, stated that in the last decade only 18% of the intervention targeting physical activity and exercise for people with physical and cognitive disabilities used behavioural medicine theories. Social cognitive theory and the transtheoretical model were among the most commonly used ones (Lai et al., 2017) out of all the existing behavioural theories. This scoping review highlighted that interventional studies based on behavioural theories were scarce. It suggested future research should strongly emphasis on these type of interventions as they have promising activity outcomes (Lai et al., 2017). Recent research in Sport Science using behavioral theories, advocated the value of Self-Determination theory (SDT) in understanding exercise behavior and demonstrating the importance of autonomous motivation in facilitating PA (Teixeira et al., 2012). A study conducted to explore the applicability of SDT as possible determinants for PA concluded that behavioral regulators and intrinsic motivation were significantly powerful determinants for regular participation in PA (Craike, 2008).

1.2 Self-determination Theory

Self-Determination Theory (SDT) is a framework that explores human motivation. It emphasizes the significance of individuals' internal resources for personal growth and behavioural self-regulation. SDT identifies three fundamental basic psychological needs (BPN): autonomy, competence, and relatedness, which are crucial for psychological well-being and the development of intrinsic motivation. In the context of physical activity and exercise, interventions aimed at promoting health behaviour changes should focus on enhancing participant fulfilment of these basic needs (Ryan, Kuhl, & Deci, 1997; Fortier et al., 2007).

Self-determination theory (SDT; Ryan & Deci, 2000) includes the process of motivation in a continuum. The elaboration of self-determination continuum is shown in *Figure 1* (Hagger & Chatzisarantis (2007); Ryan & Deci, 2000). The continuum in SDT starts from amotivation, then continues in controlled extrinsic motivation (which can be external motivation or internal regulation), after that autonomous external motivation (identified regulation, integrated regulation) to intrinsic motivation (Ryan & Deci, 2017). In accordance with SDT people are amotivated when they are short of a sense of efficacy or have less sense of control towards the desired outcome. The behavior is controlled or non-self-determined to the extent when people feel pressured to do it. The consequences of actions can take many

forms and are grouped as internal or external. External consequences contain rewards and punishments, things which have an actual physical existence, social support, and rejection. Internal consequences can involve emotions experienced upon achievement or feelings reflected of fulfillment from maintenance of a valued consequence (Ryan et al., 2020). The external regulations are internalized through the process of introjection, identification, or integration. The process will result in different types of extrinsic motivation. Extrinsic motivation can be defined as behaviours that are done for any other reason than their own benefit. Extrinsic motivation can be separated based upon how controlled the behavior is (e.g., avoiding punishment) or can be influenced by different autonomous motivational levels (e.g. achievement of beneficial outcome). Even fully internalized, extrinsic motivation does not become intrinsic motivation as it is instrumental. Intrinsic motivation can be defined as activities done for one's own benefit. It can facilitate individual's engagement which can result in higher achievement. Intrinsic motivation and well-internalized extrinsic motivation are the basis of autonomous or self-determined behavior. In SDT it is claimed that intrinsically motivated behaviours are based in people's needs to feel competent and self-determined (Ryan & Deci, 2000). SDT proposes that the regulation of the individuals' motivation is driven by the satisfaction or frustration of basic psychological needs. The basic psychological needs are autonomy, competence, and relatedness (Ryan & Deci, 2000; Ryan and Deci, 2020).

1.3 Figure 1

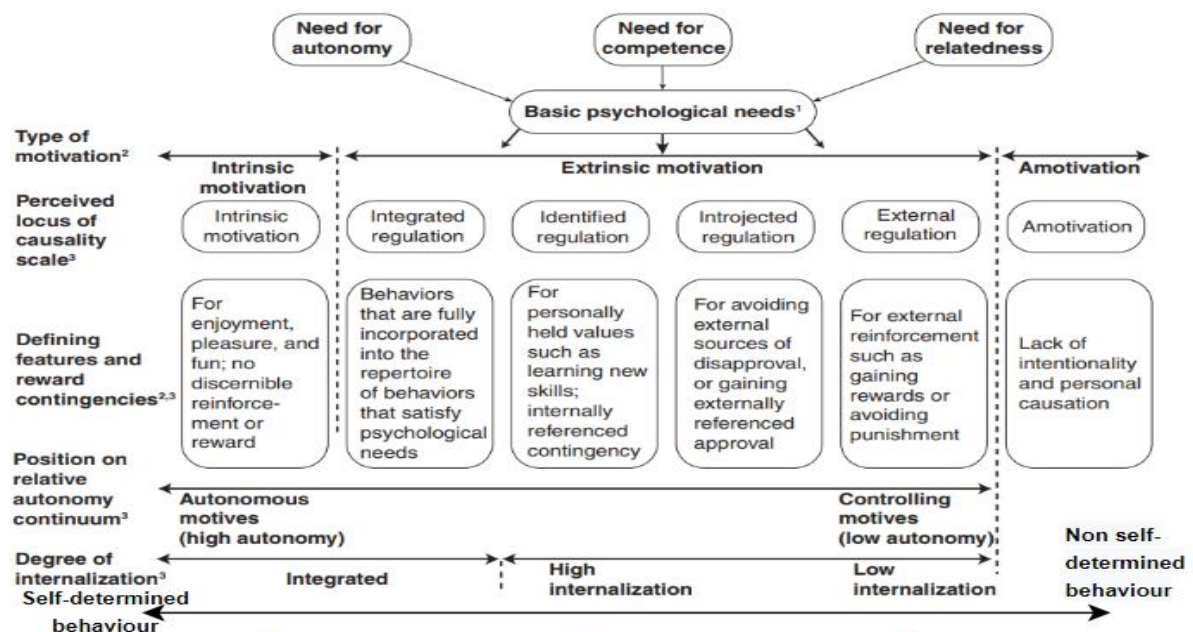


Figure 1: The self-determination continuum, displaying the motivational, self-regulatory of behaviors that vary to the extent they are self-determined (Hagger & Chatzisarantis (2007).

Note: External regulation: In this people's behavior is controlled by specific external contingencies. People behave to attain a desired outcome or to avoid punishment.; Introjected regulation: It represents a partial internalization in which regulations are in the person but have not been assimilated to the self, thus the resulting behaviors are not self-determined; Identified regulation: The process through which people recognize and accept the underlying value of a behavior; Integrated regulation: The most complete form of internalization of extrinsic motivation because it would identify the importance of behavior and integrate those identifications with other aspects of self.

Autonomy refers to the experience of free will and willingness. When satisfied, the child could experience a sense of integrity, when frustrated, the child could experience a sense of pressure and often conflict. For instance, when the child would experience that he or she has the opportunity and the freedom of choices among activities, the child would rather engage in that PA. Relatedness denotes the experience of bonding, and care, and is satisfied by feeling significant to others. When the child has buddies with to participate in PA, he or she would be more likely to engage in PA. Relatedness frustration can come with a sense of social alienation, exclusion, and loneliness, this way the child would have fewer friends or excluded by others from an activity. Competence concerns the experience of effectiveness. It becomes satisfied when the child successfully engages in activities and experiences, opportunities for using and extending skills. When frustrated, the child experiences a sense of failure and helplessness (Vansteenkiste & Ryan, 2013; Deci & Ryan, 2000; Vansteenkiste et al., 2020). In the scenario of physical education, autonomy means when the student experiences the freedom of choice and participate voluntarily; competence means the confidence in his or her ability to perform, while relatedness refers to creating the sense of belonging to a group (Abdulla et al., 2022).

Furthermore, according to SDT, climates that allow individuals to demonstrate autonomously motivated behaviors will promote interest and excitement, and thus lead to task engagement and persistence (Ryan and Deci, 2000). These climates are considered as motivational climates. Motivational climate can also be referred to as motivational conditions (Causgrove et al., 2000).

1.3.1 Self-determination theory and its relation to physical activity

The motivational climate allows individuals to choose what activity, when they want to do that activity and how the activity is performed (Deci et al., 2001). A positive motivational climate is an environment that involves task-oriented goals, satisfaction, enjoyment, and self-motivation (Abdulla et al., 2022). The satisfaction of the BPNs and motivational climates that promote the satisfaction of the needs can facilitate the internalization of motivation. A study carried out by Cid et al. (2019) emphasizes the significance of the environmental factors in which the activity is performed and makes it as a starting point for a model in which motivational regulation for predicting participation in Physical Education is displayed. The authors' interpretation of the results indicates that i) the satisfaction of BPN is influenced by motivational climate (i.e., learning climate), ii) the

individuals' motivation is influenced by the satisfaction of three basic psychological needs (i.e., particularly competence), and iii) the motivational regulations have direct and significant effects with intention to practice sports outside school in the future and PE grades (Cid et al., 2019). The facilitation of physical activity based on the SDT constructs is proved effective in promoting physical activity among children and young adults without disabilities (González-Cutre et al., 2018).

Recent studies have revealed that the satisfaction of basic psychological needs (BPN) can enhance the intrinsic motivation of children and adolescents to increase participation in physical activities (Sebire et al., (2013); Franco et al., (2017)). Furthermore, according to Ryan and Deci, (2017), the satisfaction of the three basic psychological needs (autonomy, competence and relatedness) plays a crucial role in nurturing motivation for PA among individuals with disabilities. Intervention strategies based on promoting autonomy, competence, and relatedness in PE increased the intrinsic motivation, satisfaction of psychological needs, intention to be physically active, and enjoyment in Physical Education. Although there was an increase in the perception of autonomy and competence support, no increase was observed in the need for relatedness, which could be attributed to pre-existing stable relationships that were difficult to modify (Franco et al., 2017). The effectiveness of the intervention aimed to satisfy the relatedness need is found to be more challenging as there are several factors which should be considered when designing the program such as: the educational stage, and the intention to be physically active. To modify relatedness longer intervention would be required (Franco et al., 2017). The relatedness would include the social support such as parental support what the children can get in order to increase their PA. Recent studies aimed to explore the effectiveness of social support via PE teachers applying SDT elements during PE (Katarzi et al., 2011).

Students who reported higher levels of satisfaction of psychological needs such as autonomy, competence, and relatedness in physical education showed greater self-determined motivation. This motivation was related to their enjoyment, interest, vitality, self-esteem, concentration, and effort levels in physical education. Moreover, it showed a correlation between self-determined motivation and greater effort, higher achievement in gymnastics tasks, future participation in optional PE classes, intention to participate in physical activity outside of school, effort in PE, and physical activity during leisure time (Katartzi et al., 2011). The satisfaction of psychological needs is a potential way to increase autonomous motivation among children and adolescents, thus it could be a foundation for autonomy supportive interventions (Sebire et al., 2013). The need fulfillment helps in increased autonomous motivation for engagement in a particular behaviour. However, a basic need satisfaction, namely competence satisfaction along with intrinsic motivation can be the key influencers to sustain physical activity level among adults (Teixeira et al., 2012). Research has shown that fostering this autonomous motivation through the satisfaction of these basic psychological needs is associated with greater engagement, persistence, and adherence to PA among children and young adults with disabilities (Bentzen & Malmquist, 2022). Additionally, students with higher levels of autonomous motivation reported being more active during their university years and also retrospectively reported being more active during their secondary school years (Katartzi et al., 2011). Moreover, a systematic review

indicated that autonomous forms of motivation, such as intrinsic motivation and identified regulation, were positively connected with physical activity, while controlled forms of motivation, such as introjection and external regulation, were negatively associated with physical activity (Owen et al., 2014). Thus, adherence to the health behaviour of exercising is enhanced by the facilitation of autonomous forms of motivation and the avoidance of controlled forms of motivation in children. Intentions to exercise in leisure time vs actual exercising in leisure time were consistent when the children experienced autonomous motivation and not controlled motivation (Chatzisarantis et al., 1997). Furthermore, a systematic review suggested that identified regulation form of motivation as an initiation for PA, while intrinsic motivation was a predictor for maintaining participation in physical activity (Teixeira et al., 2012).

To our knowledge a limited number of studies have been conducted to examine the impact of SDT interventions from physiotherapy perspective. The systematic review which tended to explore the connection between motivation and PA among children and young adults stated that PA evidence base regarding SDT studies are limited, as little research focused on children (Owen et al., 2014). A deeper understanding of children's pattern of PA is much needed to create useful future interventions for promoting PA. Furthermore, most of the SDT intervention studies have been conducted on children and adolescents without disabilities. More knowledge is required about the effectiveness of SDT interventions to enhance PA in children with disabilities. Researchers suggest that the understanding of intrinsic motivation could have theoretical and practical advantages for participants, designers, and organizers in creating intervention programs which could include physical activities, mentally prompting activities and sedentary leisure activities.

2 PROBLEM FORMULATION

Self-determination theory is a widely used concept in the last few decades among scientists to facilitate human motivation in engaging physical activity. Interventions based on concepts of SDT (such as competence, autonomy, relatedness, and motivation) have been found effective to promote physical activity (PA) among children and adults without disabilities. Unfortunately, children and young adults with disabilities often face barriers to participation in physical activities, which become more pronounced as they age. Consequently, increasing participation in physical activities is often a main goal for children and young adults with disabilities, their families, and physiotherapists. Unfortunately, there is a lack of evidence and consensus regarding the design and content of interventions increasing participation in physical activities for children and young adults with disabilities. Interventions with the goal to increase participation in physical activities have traditionally been based on the reasoning that training the child/young adults in performing skills will lead to increased participation. However, there is little empirical support for this assumption. Instead, interventions based on the constructs of SDT seem to be possible determinants for

physical activity participation such as autonomy and increasing intrinsic motivation. To our knowledge no systematic review has been made to summarize the existing interventions based on physiotherapy and the constructs of SDT in the aim of supporting/increasing participation in PA among children and young adults with disabilities.

3 AIM

The objective was to explore how interventions based on the constructs of SDT facilitate possible determinants for physical activity participation in children and young adults with disabilities.

3.1 Study questions

The four steps process has been utilized to narrow down a general topic into a research question. It started with the topic identification and selection, the second step was problem identification and selection. The process continued with the third step by theoretical framework selection and identification, and then the fourth step was the question identification and selection (Balthazar and Vendrely, 2022). The following research questions were formulated by using the PICO formula.

The study questions are as follows:

1. What constructs from SDT have been used and how was the self-determination continuum represented in the design of interventions as possible determinants for physical activity participation in children and young adults with disabilities?
2. What was the content (frequency, duration, activities etc) of the interventions included in the studies?
3. What were the primary outcomes of the interventions?
4. What were the psychometric properties of the primary outcome measures?
5. What were the effects of the interventions based on SDT?
6. What was the quality of the included studies?

4 METHODS

4.1 Study design

A systematic review design was chosen to understand an overview of existing research about how interventions based on the constructs of SDT facilitate possible determinants for physical activity participation in children and young adults with disabilities.

According to Cochrane Collaboration, it seeks to systematically search for, appraise and synthesize research evidence (Higgins et al., 2009). Balthazar & Vendrely, (2022), states that systematic review requires explicit inclusion, exclusion criteria and documented search strategies. The five-step program of conducting a systematic review by Khan et al. (2003) and the guidelines for PRISMA for systematic review (Liberti et al., 2009) were utilized to create a transparent and valuable review in which it is clearly stated why the review is done, how it is conducted and what is found. According to Khan et al. (2003), the first step: framing appropriate research question and structure the search (Miller et al., 2020). The second step; the identification of relevant studies from multiple scientific databases. It targeted to identify the primary outcomes as increased physical activity participation considering the inclusive and exclusive criteria. Third step; an in-depth quality assessment of included studies was carried out to check for risk of biases using design-specific quality checklists. This step helped to understand the strength of the review and its reliability. Fourth step; summarizing the evidence from the studies included. Fifth step; interpreting the findings from the studies is crucial and imposes an impression for future research. It also depends on the quality of the studies included and how cautiously one can interpret the results.

4.2 Study Sample

4.2.1 *Inclusive Criteria*

The inclusion criteria were the following: a study was included if it was published in English, if the primary outcome in the study was participation in physical activity or measured the possible determinants of PA from SDT perspective, if it included interventions based on the constructs of SDT, if the participants had a disability and a mean age between 1-25 years, if the study design was a randomized controlled trial, quasi-experimental study, non-randomized controlled trial, or a pre-and post-experimental study.

4.2.2 *Exclusive Criteria*

Studies were excluded from the review if the core intervention was based on other concepts than SDT, published before 2006, or if it was a systematic review and studies which were not available in full text.

4.3 Literature Search/Data Sources

The database search was done by the authors individually, with a first screening of the studies' titles and abstracts, followed by the screening of studies in full text. Beside database search, the authors also did a manual search through the reference list of the screened full text studies. The following databases were used for conducting the search: PubMed, PsycINFO, CINAHL. The combinations of search terms were based on PICO and adapted to the different databases. Keywords and the combinations were used combining the PICO and MeSH (Medical Subject Subheadings) terms during the search: P=population: children and adolescents with disability (" Disabled Children" [MeSH]; disabilit* AND "children" OR "adolescents" OR "youth" OR "child" OR " teenager"). I=Intervention: intervention based on SDT (" Personal Autonomy" [MeSH]; "self-determination" OR "autonomy" OR " competence" OR " relatedness" OR "motivation"). C=Comparison: non. O=outcome: participation in PA (" Exercise" [MeSH];" participation in physical activity"). PubMed was chosen for the first quick search, as it is possible to enter search terms without formatting, thus would give a wider search in the field of biomedical and life sciences literature. PsycINFO was utilized as it provides studies the field of behavioural medicine. CINAHL was used as it covers all the academic journals related to nursing with biomedicine and other allied health disciplines. The search was performed between April 2022 and April 2023. The final search strategies are presented as Appendix A. The researchers screened the title, abstract, full text of each founded study together and decided if the study fit the inclusion criteria. Furthermore, the supervisor also screened the included studies and if any disagreement was found, it was discussed together until consensus was reached.

Table 1: PICO formula utilised for research questions formulation.

P (Population)	Children and young adults with disabilities
I (Intervention)	Interventions deriving from the concepts of self-determination theory (autonomy, competence, relatedness, motivation)
C (Comparision)	Children and young adults without disabilities or no comparison
O (Outcome)	Quantitative outcomes measuring increased participation in PA or possible determinants of PA.

4.4 Study selection

4.4.1 Screening for titles and abstracts for relevance

The titles and abstracts were screened individually by the authors in accordance with the aim of the systematic review and research questions. Furthermore, abstracts and full texts of studies were screened to check if they meet the inclusion criteria. Studies that did not meet the inclusion criteria were excluded. Relevant titles and abstract, and full-text studies were identified. The reference list of the identified full text studies was also screened to identify any further relevant studies. The checklist of relevance from SBU was used in the process (SBU, 2018).

4.4.2 Assessment of full text publications

Full-text papers were assessed according to the inclusion and exclusion criteria. In the first step the studies were assessed according to inclusion and exclusion criteria and in the second step data were extracted from the studies according to the research questions. Assessment was done by both authors independently and compared until the agreement was achieved. Studies published in multiple journals were screened for the original publisher and utilized. The number of screened and included or excluded studies is presented in a flowchart. Reasons for exclusion were if the study was part of dissertation, not yet published, mixed methods or if it was only a protocol. See Flowchart (*Figure 2*).

4.5 Data extraction

Data was extracted individually, and cross-checking was performed. Relevant data required for the review process to answer the research questions was extracted from the included studies. A data extraction table (Appendix B) was used to synthesise the information which included the title of the study, published year of the study, authors of the study, design, sample size, participant characteristics, intervention content, primary outcomes, quality of the study. The constructs of SDT facilitate the possible determinants for physical activity participation in children and young adults with disabilities. As for the characteristics of participants, characteristics of the population control group (age, number, diagnoses) and characteristics of the population experimental group were described separately. Interventions (content, duration, frequency, design) used for the control and experimental groups were described separately.

4.6 Evaluation of the study quality and evidence

The evaluation of quality assessment of the articles was done individually, and cross-check was performed. Any disagreement found, were discussed together, until an agreement

was reached. As the systematic review contained different study designs, for each design its specific checklist was utilized to evaluate the quality. ROB-2 was used to assess risk of bias in randomized controlled trial. ROBINS-I was used to assess risk of bias in non-randomized controlled studies of interventions. Checklist from SBU for relevance was used in the process.

4.7 Data synthesis

Data was synthesised descriptively on how the interventions were designed using the constructs of self-determination theory, and how these interventions alter the participation levels of physical activity or the possible determinants of PA participation among children and young adults with disability and the potential outcome effects of the interventions. The SDT continuum was analysed in the intervention based on the definitions of the constructs (Hagger & Chatzisarantis (2007) and the context of the studies. Depending on whether the construct was a dependent or an independent variable, the two approaches were classified. For instance, enjoyment and interest (autonomous forms of motivation) were independent variables and goal-performance was a dependent variable (Reedman et al., 2021), it was classified as the approach of facilitating autonomous motivation to increase intrinsic motivation in participation in PA. The Cohen's D values were calculated to estimate the effect sizes of the outcome variables in interest. Cohen's D or standard mean difference is the most widely used measure for effect size. The effect size shows how large the effect is (Cohen, 1988). The effect sizes are defined to be small to large, $d = 0.2$ (small), 0.5 (medium), 0.8 (large) (Field, 2018). The quality of the included studies was assessed using checklists ROB-2 and ROBINS-I by SBU, 2018 and presented in the Table 5 & Table 6. Then the body of evidence was assessed using GRADE (Grading of Recommendations Assessment Development and Evaluation) by SBU's method book (Swedish: Statens beredning för medicinsk och social utvärdering [SBU] 2018) on a four-point scale: strong (+++), moderate (+++o), low (++oo) and very low (+ooo). These scales mean the level of reliability of the combined results. It was done to assess the strength of evidence using the five domains: Risk of bias, lack of consistency, lack of precision, lack of transferability and publication bias. The GRADE's risk of bias is not for the individual studies, but for the overall risk after the compilation of the risks across the included studies. The lack of consistency is defined as the lack of heterogeneity, meaning that the results of the included studies are different. The reliability of the results is low when the disagreement cannot be explained. Lack of precision is referred to the extent to which the study measures what it is intended to measure. GRADE assess the precision through the confidence interval of the combined result. The relative effects are focused and the width of confidence intervals. The lack of transferability refers to that the results of the included studies are different from the context to which the research questions refer to. Publication bias indicate that the studies are not published or with a time delay. There is a risk of unpublished studies are not included and thus, it is very difficult to determine if there is a publication bias.

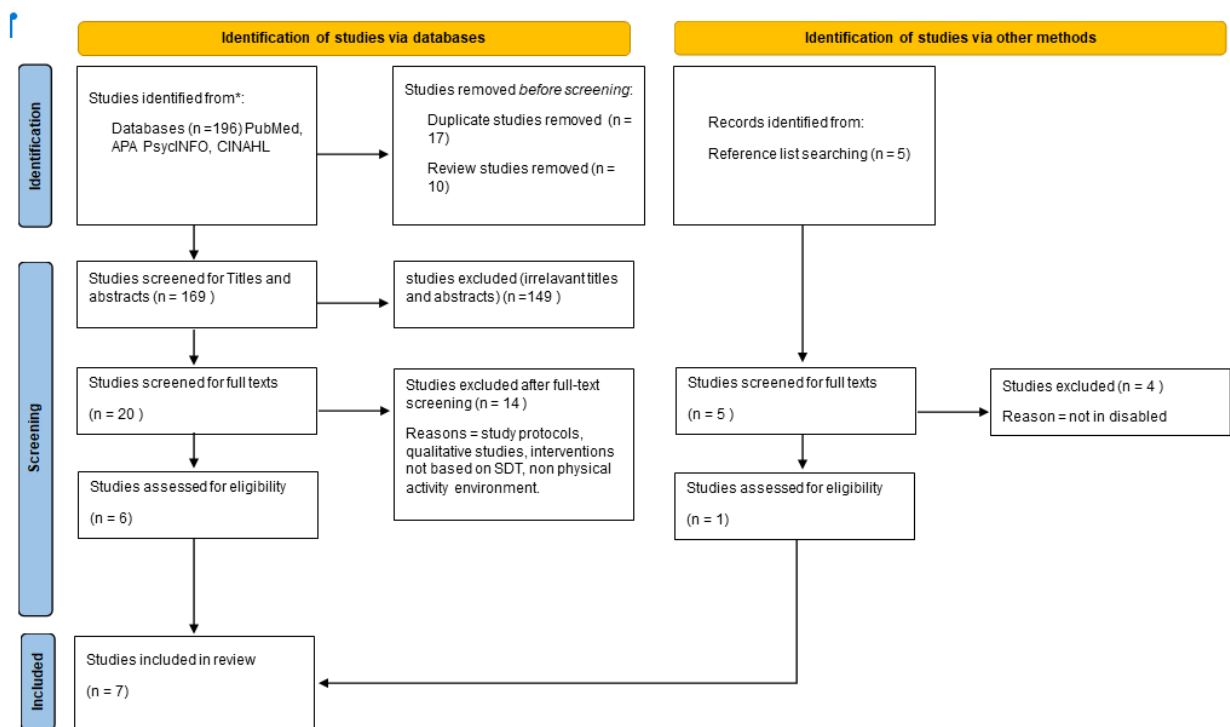
4.8 Ethical considerations

As for ethical considerations, studies were searched via databases which would have peer reviewed studies and already published in journals. For this reason, these studies must fulfil the requirements set up by the Helsinki Ethical Guidelines and obtain the approval of the Ethics committee (World Medical Association, 2022) for research on human subjects. The ethical principles include informed consent from the potential research participants, minimization of the risk of harm to participants, protection of confidentiality and anonymity of participants, ensuring the rights of participants to withdraw from the research.

5 RESULTS

The present review aimed to explore how interventions based on the constructs of SDT facilitate physical activity participation in children and young adults with disabilities. A total of seven studies published between 2006 and 2022 were included in the review. It includes two RCTs, three experimental studies, one quasi-experimental and one longitudinal experimental study. The total number of participants in the review were 341 participants. The mean age of the total number of participants were approximately 12.6 years. The most common diagnoses were Cerebral Palsy, Autism Spectrum disorder and physical disabilities. Furthermore, there were participants diagnosed with Down Syndrome, Motor Delay, Williams Syndrome, Intellectual Delay, DiGeorge Syndrome, Noonan Syndrome, Muscular Dystrophy, Rheumatoid Arthritis.

5.1 Figure 2



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. For more information, visit: <http://www.prisma-statement.org/>

Figure 2: PRISMA flowchart for inclusion of studies

5.2 SDT constructs in focus in the intervention to improve participation in PA

The SDT process shown in Figure 1 was utilised to document and present the results regarding how the included studies designed their interventions based on SDT.

As presented in Figure 1 the SDT continuum and its elements clearly justify how the behavioural regulation process for human motivation. In line with this each type of motivation and the process of continuum from amotivation to motivation poses to be the possible determinants for behaviour change in children and young adults with disabilities (CAYAWD). All these elements including the BPN become the possible determinants to promote physical activity participation in our review.

All the studies used the SDT continuum, motivational climate in the design of the interventions. The elements of the SDT were also considered as the possible determinants of physical activity as they play crucial role in motivational regulation towards physical activity participation in CAYAWD. This self-determination continuum, as possible determinants for physical activity participation, was displayed differently in each study. In this review the authors used 'motivational climate' for better transparency, although in the studies different

terms with the same meaning were used beside motivational climate, such as need-supportive climate and autonomy-supporting climate. As the dynamic of self-determination continuum varied in the studies, this paragraph attempts to describe the relationship between the constructs of SDT which leads to improved physical activity participation among CAYAWD.

There were two main SDT approaches used to increase the participants intrinsic motivation in physical activity. The first approach was that the intervention was based on facilitating the participant's BPN (autonomy, competence, and relatedness) to increase their autonomous motivation and second approach was that the intervention was based on facilitating participants autonomous motivation (intrinsic motivation or identified regulation) to satisfy their BPN to promote participation in PA.

Four out of seven studies (Huéscar et al., 2020; Behzadnia et al., 2022; Reedman et al., 2019; Saebu et al., 2013), used the first approach. Two studies (Reedman et al., 2021; Johnson et al., 2018) used the second approach. While Tsalavoutas & Reid (2006) used the participants satisfaction of competence through seeking the challenges that are optimal for the person's abilities and enhance practising those skills through activity. The Tsalavoutas & Reid (2006) study can also be considered as facilitating BPN approach (first approach), but rather focuses on competence alone. Further approaches to increase participants intrinsic motivation towards PA were found in two studies, Huéscar et al. (2020) used a diminishment in external regulation and Behzadnia et al., (2022) displayed a decrease in controlled motivation (introjected regulation and external regulation) in taking part in activities.

5.3 Intervention characteristics of the included studies

Out of seven studies, three studies (Huéscar et al., 2020; Tsalavoutas & Reid, 2006; Johnson et al., 2018) were designed as a comparative intervention between motivational or mastery climate and instructional or controlling climate/ conditions, while the other four studies used a design with a motivational climate. The content of the interventions (frequency, duration, activities etc.) of the included studies are presented in Appendix B.

Regarding the participants, five studies (Reedman et al., 2019; Reedman et al., 2021; Huéscar et al., 2020; Tsalavoutas & Reid, 2006; Johnson et al., 2018) included elementary school- aged individuals, Behzadnia et al. (2022) included child, teen, and adult age groups, while Saebu et al. (2013) included an adult age group. The participants in the interventions were only children and young adults with disabilities, except in two studies (Tsalavoutas & Reid, 2006; Johnson et al., 2013) in which children with and without disabilities were involved in the interventions. Most of the included studies (Huéscar et al., (2020); Behzadnia et al. (2022); Saebu et al. (2013); Johnson et al., (2018) formed their participants into small groups to perform activities together, while Reedman et al. (2019), Reedman et al. (2021) and Tsalavoutas & Reid (2006) utilized individual sessions. Along with the children or young adults with or without disabilities, the interventions involved PE teachers, physiotherapists, or parents either as a service delivery person or as a part of social support.

The following designs were used in accordance with the delivery of the included interventions. Two (Huéscar et al., 2020; Behzadnia et al., 2022) out of the seven studies designed the intervention for a semester-long program in PE classes performed by PE teachers, likewise, Tsalavoutas & Reid (2006) used PE setting for an approximately 2-week period. Further two studies used a 3-week physical activity program in an intense rehabilitation stay (Saebu et al., 2013) and in a summer camp (Johnson et al., 2018). While another two studies (Reedman et al., 2019; Reedman et al., 2021) designed the intervention in an 8-week program among clinical settings performed by physiotherapists. The various physical activities involved in the interventions in the studies were swimming, cross-country skiing, riding, aerobics, alpine skiing, kayaking, ball striking, dance activities, resistance and flexibility training, bicycle activities, swimming, and recreational activities in gym. The duration of these activities ranged from 20 mins per session to 3 hours per session and one session per week to six sessions per week (everyday) (Appendix B).

Six of the included studies (Saebu et al., 2013; Johnson et al., 2018; Reedman et al., 2019; Huéscar et al., 2020; Reedman et al., 2021; Behzadnia et al., 2022) used elements of BPN, *autonomy*, *competence*, and *relatedness* need-satisfaction in designing the intervention. The most common motivational strategies for *autonomy* were to provide the participants with the opportunity of choice in decision-making, usage of non-judgmental and non-controlling language and self-initiation for goal setting. The following strategies were used to increase the participants *competence*; explanatory behaviors to perform tasks, organizing programs according to the participants preference with activities suiting the individuals, providing positive feedback in a non-evaluative way. For optimize the participants' *relatedness*, the most common strategies were group settings, and encouragement of using emotionally appropriate language with peers. Additionally, in the study by Saebu et al., (2013), strategies for relatedness such as facilitating exchanging activity experiences and encouraging positive feedback to each other among participants were used. Moreover, in the study conducted by Behzadnia et al., (2022) motivational strategies for relatedness were used such as; displaying patience, understanding students' emotions, recognizing, and accepting their expressions, and encouraging students to ask questions regarding their process. Only Tsalavoutas & Reid (2006) used participants' competence satisfaction out of the BPN to design the intervention, which was done through a mastery climate, where the participants challenge their own previous scores rather than challenging their peers.

5.4 Primary outcome of the included studies

The interventions in the included studies aimed to facilitate physical activity (Huéscar et al., 2020) (Saebu et al., 2013) or increase MVPA level (Reedman et al., 2019; Reedman et al., 2021; Johnson et al., 2018) or increase participants intrinsic motivation in practicing PE activities via increased autonomous motivation (Behzadnia et al., 2022) or via participants competence satisfaction (Tsalavoutas & Reid, 2006).

Three main themes were identified from the primary outcomes of the included studies: 1) physical activity or participation in physical activity among CAYAWD, 2) basic psychological needs satisfaction or frustration in relation to physical activity or participation in PA among CAYAWD, and 3) motivational regulations in relation to PA or participation in PA among CAYAWD. Table 2 illustrates the instrumental tools used to measure the primary outcomes.

Three studies measured moderate to vigorous intensity physical activity as the outcome, using ActiGraph GT3X+ (Reedman et al., (2019); Reedman et al., (2021); Johnson et al., 2018). Reedman et al., (2019) also measured goal attainment regarding physical activity participation goals using the Canadian Occupational Performance Measure (COPM) and habitual physical activity (MVPA and sedentary time) through accelerometers. Physical activity levels were measured in two studies (Huéscar et al., 2020; Saebu et al., 2013). Huéscar et al., (2020), used Questionnaire for Measurement of a Person's Habitual Physical Activity, while Saebu et al. (2013) used International Physical Activity Questionnaire (IPAQ) to measure these PA levels.

In five studies basic psychological needs satisfaction and/or frustration were used as primary outcomes (Behzadnia et al., (2022); Saebu et al. (2013); Huéscar et al., (2020); Reedman et al., (2019); Reedman et al., (2021)), measured by using Basic Psychological Need Satisfaction and Need Frustration Scale (Behzadnia et al., 2022), Basic Psychological Needs in Exercise Scale (Saebu et al., 2013), Psychological Need Satisfaction in Exercise Scale (Huéscar et al., 2020), Exercise self-efficacy Scale (Saebu et al., 2013), Belief in Goal Self-competence Scale (Reedman et al., 2021; Reedman et al., 2019). Additionally, a study by Tsalavoutas and Reid, (2006), calculated the scores for risk-taking and achievement, which contributes to increased competence satisfaction towards physical activity participation.

The motivational regulations in relation to participation in PA were measured in four studies, using Self-regulation questionnaire (Behzadnia et al., 2022), Exercise Self-Regulation Questionnaire (SRQ-E (Saebu et al., 2013), Pictorial Scale of Sport Motivation. (Huéscar et al., 2020) and Motives for Physical Activities Measure-Revised (MPAM-R) (Reedman et al., 2021). Huéscar et al., (2020), examined intrinsic motivation, extrinsic motivation and amotivation using Pictorial Scale of Sport Motivation. While Saebu et al., (2013), measured the primary outcome as the relations in SDT process model related to physical activity through efficacy and autonomous motivation using Exercise Self-Regulation Questionnaire (SRQ-E). Behzadnia et al., (2022) measured motivational regulations, including autonomous motivation, controlled motivation and amotivation in relation to physical education programs using Self-regulation questionnaire.

Table 2: Categorizing the measurement tools utilized in the included studies.

Physical activity	Basic Psychological needs satisfaction or frustration	Motivational regulation
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Physical Activity Readiness Questionnaire (PAR-Q) (Behzadnia et al., 2022)	Basic Psychological Need Satisfaction and Need Frustration Scale (Behzadnia et al., 2022),	Self-regulation questionnaire (Behzadnia et al., 2022)
International Physical Activity Questionnaire (IPAQ) (Saebu et al., 2013)	Basic Psychological Needs in Exercise Scale (Saebu et al., 2013),	Exercise Self-Regulation Questionnaire (SRQ-E) (Saebu et al., 2013)
Questionnaire for Measurement of a Person's Habitual Physical Activity (Huéscar et al., 2020)	Psychological Need Satisfaction in Exercise Scale (Huéscar et al., 2020),	Pictorial Scale of Sport Motivation. (Huéscar et al., 2020)
Canadian Occupational Performance Measure (COPM) (Reedman et al., 2019; Reedman et al., 2021)	Exercise self-efficacy Scale (Saebu et al., 2013),	Motives for Physical Activities Measure-Revised (MPAM-R) (Reedman et al., 2021)
ActiGraph GT3X+ (Reedman et al., 2019; Reedman et al., 2021; Johnson et al., 2018)	Belief in Goal Self-competence Scale (Reedman et al., 2021; Reedman et al., 2019),	
	Health care climate Questionnaire (Saebu et al., 2013),	
	Scale Autonomy Support (Huéscar et al., 2020),	
	Physical activity Climate Questionnaire (Reedman et al., 2021),	
	Problems in School Questionnaire (Reedman et al., 2021),	
	Interpersonal Behavior Questionnaire (Behazadnia et al., 2022),	
	Participation and Environment measure for children and youth (Reedman et al., 2019)	

5.5 The psychometric properties of instruments measuring the outcomes.

The tools measuring the outcomes of the included studies were categorized into physical activity, need supportive or need thwarting climate, basic psychological needs, motivational regulation. The categorized instruments are illustrated in the following *Table 2*.

Further instruments which would not fit into the previous categories are listed as the following ones, Barriers to Participation in Physical Activity Questionnaire (Reedman et al., 2019), Stages of Change for Baseline Readiness for Behavior Change (Reedman et al., 2021) and Goal Attainment Scale (GAS) (Reedman et al., 2021). All the measures said to have adequate and acceptable validity and reliability, and are documented in detail in APPENDIX C.

5.6 The effects of the intervention based on SDT

The effects of the interventions in the included studies can be categorized into three subgroups based on how the following SDT elements were effective in influencing participants physical activity: 1) the relation of motivational climate and the participants physical activity level, 2) the relation of need satisfaction and participants physical activity and 3) the relation of autonomous motivation and participants physical activity. As mentioned earlier, all the elements of SDT are considered as possible determinants to promote physical activity participation among children and young adults with disabilities (CAYAWD). The SDT elements are the independent variables influencing the outcome variable of physical activity. The independent and dependent variables are presented in *Table 3*.

The effect of motivational climate showed statistical significance on participants physical activity level/ participation in PA/ time spent in physical activity after the intervention in Huéscar et al., (2020); Johnson et al., (2018); Saebu et al., (2013) and Reedman et al. (2021). The effect of participants need-satisfaction showed statistical significance on physical activity after intervention in Huéscar et al., (2020); Johnson et al., (2018) and Saebu et al., (2013), Reedman et al. (2019), Reedman et al. (2021), Tsalavoutas & Reid (2006). The effect of increase in participants autonomous motivation (intrinsic motivation and/or identified regulation) after intervention showed statistically significant changes on performance in Saebu et al., (2013), Reedman et al. (2021), Johnson et al. (2018). The findings of the included studies are analyzed in accordance with the categorized themes.

The Cohen's D values were calculated to estimate the effect sizes of the outcomes of the included studies. MVPA among children with disabilities between the motivational climate and instructional climate had a medium effect size in Johnson et al., (2018). Likewise, in Huéscar et al., (2020) had medium effect size in relation to physical activity between the participants in the motivational climate and control climate. Medium effect size was estimated for PA between baseline to post-intervention in Saebu et al., (2013). Further, in Reedman et al. (2019), large effect size was estimated for performance of the experimental group from baseline to post-intervention. The effect size estimates of Cohen's D for the significant outcome variables are documented as Appendix D. The statistical significances for effects sizes are documented in Table 4.

Table 3: Results of the studies based on their independent and dependent variables.

Study	Independent variable	Dependent variable
Behzadnia et al., (2022)	Need supportive climate or the need supportive teaching style and need thwarting teaching style	Need satisfaction, autonomous motivation, Amotivation, need frustration, controlled motivation
Huéscar et al., (2020)	Motivational climate and controlling style climate	Autonomy, competence, relatedness, intrinsic motivation, extrinsic motivation, amotivation and physical activity levels.
Johnson et al. (2018)	Autonomy supportive climate and instructional climate	Moderate to vigorous physical activity.
Reedman et al. (2019)	Motivational strategies	Habitual physical activity, perceived satisfaction, and confidence.
Reedman et al. (2021)	Interest or enjoyment, competence, appearance motivation and baseline MVPA	Performance, Satisfaction, and minutes per day MVPA.
Saebu et al., (2013)	Autonomy support, BPN satisfaction, autonomy need, competence need, relatedness need.	Autonomous motivation, Physical activity
Tsalavoutas & Reid (2006)	Mastery or performance climates	Performance, risk taking, Achievements and competence satisfaction.

Theme 1: Motivational Climate and Physical Activity:

In our case, all studies incorporated the SDT continuum into their interventions with varying terminologies like motivational climate, need supportive climate or autonomy supportive climate in their intervention design.

In Huéscar et al., (2020); Johnson et al., (2018); Saebu et al., (2013), a significant relationship between motivational climate and participants physical activity emerged following the interventions. Notably, in Reedman et al.'s (2019) randomized controlled trial, post-intervention outcomes demonstrated increased performance in participants leisure-time physical activity goals, with increased cycling, football, and swimming. Additionally, participants perceived satisfaction and confidence were observed. In another study (Reedman et al., 2021), 59% of the change in post-intervention moderate-to-vigorous physical activity (MVPA) was explained by the participants appearance motivation, controlling or need-supportive parenting style and goal attainment, expectations. In Huéscar et al., (2020), a motivational climate not only increased perceived autonomy but also decreased extrinsic motivation towards PA. Similarly, Johnson et al. (2018) reported

increased time spent in moderate to vigorous physical activity (MVPA) in response to a motivational climate. Participants need-frustration towards PA significantly decreased in motivational climate while it increased in a conventional setting (Behzadnia et al., 2022). Further amotivation was significantly lesser right after intervention and 12-week follow up among participants exposed to motivational climate based on SDT (Behzadnia et al., 2022).

Theme 2: Need Satisfaction and Physical Activity:

In majority of the studies (Huéscar et al., 2020; Johnson et al., 2018; Saebu et al., 2013; Tsalavoutas & Reid, 2006; Behzadnia et al., 2022) demonstrated that the satisfaction of participants basic psychological needs had a significant impact on their physical activity after interventions. The effect of the single basic psychological needs (autonomy, competence, or relatedness) on the participants autonomous motivation, which was significantly indirectly related to needs satisfaction towards PA and change in physical activity (Saebu et al., 2013). The single needs had different significance between the baseline to post-intervention and to follow up. The relatedness was positively related to the autonomous motivation towards PA from the baseline to completion of the intervention and negatively related from the completion to the follow up. While participants autonomy and efficacy were positively related to their autonomous motivation only between completion and follow up with statistical significance (Saebu et al., 2013). Additionally, Reedman et al., (2021) findings also show 24% of changes in goal self-competence scores were explained by competence motivation and appearance motivation. Competence motivation had a positive association with goal self-competence scores, while appearance motivation (extrinsic motivation) exhibited a negative correlation with competence motivation for physical activity. The effect of need-satisfaction on post-intervention PA performance was evident in how the need satisfaction increased participants autonomous motivation for physical activity in two studies (Saebu et al., 2013; Behzadnia et al., 2022).

Theme 3: Autonomous Motivation and Physical Activity:

Saebu et al., (2013) revealed that the path between participants need satisfaction and autonomous motivation was significantly related to their increased PA post-intervention. So, the change in autonomous motivation is said to have acted as a mediator for changes in physical activity. In Behzadnia et al. (2022), participants in a need-supportive environment experienced a slight increase in their autonomous motivation for PE activities from baseline to follow-up. The dynamics between basic psychological needs and autonomous motivation were illuminated in Saebu et al. (2013), where participants autonomy and efficacy were positively related to their autonomous motivation towards PE activities between completion and follow-up. Reedman et al. (2021) used a new approach to facilitate autonomous motivation, examining children's intrinsic and extrinsic forms of motivation. Findings showed that the intrinsic motivation, represented by interest/enjoyment in physical activities, positively associated with performance satisfaction and explained a 32% post-intervention change in performance with participant age also playing a role. The participant's age was negative, while intrinsic motivation was positively associated with performance satisfaction (Reedman et al., 2021). Further approaches to facilitate intrinsic motivation

through need-supportive environment showed statistically significant results, such as decreased participants need-frustration from baseline to 12-week follow-up and decreased amotivation from baseline to 12-week follow up in PE activities (Behzadnia et al., 2022).

Beyond these three overarching themes, the participants characteristics and the need-supportive environment also played significant roles in influencing physical activity outcomes. Reedman et al., (2021) observed that participant age had a negative association with performance-satisfaction. This negative association was reasoned in the study as after the transition period from childhood to adolescents, individuals face more contextual and environmental barrier, such as reduced parental control. Further having a comorbidity such as autism spectrum disorder (ASD) decreased children's performance (Reedman et al., 2021). In Tsalavoutas & Reid, (2006), the achievement was significantly related to participants competence satisfaction through risk taking only in people with disabilities (PWD) in mastery climate, as the risk taking was depended on whether they had to challenge their own scores (mastery climate) or their peers' (performance climate).

These themes were utilized in order to display the findings of the studies more clearly and cohesively, but the point of how the dynamics of the elements of the SDT makes these themes interconnected with one another must be remembered.

Table 4: Statistical values of results of included studies.

Study	Statistical values of intervention group	Control group
Behzadnia et al., (2022)	Need-satisfaction - Significant increase [Baseline (M=4.11) to 12 weeks follow-up (M=4.51) with $p<0.001$]. Need-frustration – significant decrease Autonomous Motivation – increased [(M=4.64 to M=4.72)] Amotivation – Decreased [(M=2.34) to (M=1.73)] with $p<0.001$.	Need satisfaction – No significant difference from baseline (M=4.03) to follow-up (M=3.81) Need-frustration - increased. Autonomous Motivation – No difference
Reedman et al., (2021)	Significant increase in performance post intervention ($p=0.017$). Strong correlations were observed between intrinsic motivation and PA (32% change, $p=0.02$), goal self-competence and competence motivation (24% with $p=0.02$), baseline PA, need-supportive parenting style and MVPA (59% with $p=0.04$).	
Huéscar et al., (2020)	Significant increase in PA (M=5.95, SD= 0.79, $p<0.01$) & Autonomy (M=5.18, SD= 0.69, $p<0.001$). Significant decrease in extrinsic motivation (M=1.60, SD= 0.46, $p<0.01$)	Controlling teaching style showed significant decrease in autonomy and relatedness, along with control group.
Reedman et al., (2019)	Baseline M(SD)–8weeks M(SD)–16weeks M(SD) Performance-M=2.8 (1.3) - M=7.5 (1.8) - M=6.96 (2.0) with $p<0.001$ Satisfaction-M=3.9 (1.9) - M=7.9 (1.4) - M=7.6 (1.8); $p=0.01$ Confidence-M=7.8 (1.8) - M=8.3 (1.1) - M=8.6 (1.4); $p=0.001$	Performance-M=2.7 (1.1) - M=3.8 (2.3) - M=3.8 (2.3) Satisfaction-M=3.9 (1.4) - M=6.1 (2.2) - M=5.8 (2.5) Confidence-M=7.2 (2.4) - M=6.0 (2.9) - M=6.3 (2.8)

Johnson et al., (2018)	Autonomy-supportive climate significant within subject effect on MVPA post intervention (M=52.6, SD=8.3) in children with disabilities	(M=45.4, SD=8.3) instructional climate for children with disabilities.
	Compared to typically developing children, the group & climate interaction did not reach significance (p=0.31).	
Saebu et al., (2013)	Significant correlation between need-satisfaction ($r = .38, p < .01$), autonomous motivation (T1–T2: $r = .47, p < .01$) & PA at T1 to T2. Relatedness significantly changes AM from T1 to T2 ($r = .52, p < .01$) and from T2 to T3 ($r = -.28, p < .05$).	-
Tsalavoutas & Reid (2006)	Performance significantly related with competence satisfaction in mastery climate for PWD through achievement ($p < 0.05$). Achievement in children with disabilities (M=3.05, SD = 14.35) in mastery climate compared to performance climate (M=-5.57, SD=19.37).	People without disabilities performed better in performance climate.

5.7 The quality of the studies

The quality of the included studies was assessed using checklists ROB-2 and ROBINS-I by SBU, 2018 and presented in the Table 5 & Table 6. The quality of the included studies was ranging from moderate to high quality assessed according to ROB-II and ROBINS-I (Appendix E). The criteria for deciding the overall quality of the study were discussed by the authors and the research supervisor and concluded. The criteria for a study to be of moderate quality is that out of the seven domains of assessment, four should be low risk of bias and three should be moderate risk of bias. While the criterion for high quality is to have no more than two domains of moderate risk of bias assessments out of seven. The two RCTs (Reedman et al., 2019; Reedman et al., 2021) were assessed to have high quality along with further three studies (Saebu et al., 2013; Huéscar et al., 2020; Behzadnia et al., 2022). Two studies (Tsalavoutas & Reid, 2006; Johnson et al., 2018) were assessed to have moderate quality. Tsalavoutas & Reid (2006) was assessed to be moderate quality due to it gained moderate scores for confounders, selection of bias for reported results and measurement of outcome bias. Furthermore, it had small effect and sample size and low generalizability as the population was from only one school. Johnson et al. (2018) was assessed to be of moderate quality as it gained moderate on confounding bias, measurement of outcome bias, selection bias of the reported result and bias missing data. The main reasons were the inclusiveness of participants with and without disabilities, the confounding effects of including wide variety of the different types of disabilities, the lack of appropriate analysis for confounders as the normality of the data was not checked.

The overall strength of evidence was evaluated by using GRADE by SBU, 2018 through the domains risk of bias, lack of consistency, lack of precision, lack of transferability and publication bias. The overall risk of bias for this review was assessed to be moderate reliability (+++o), as the included studies had moderate to high quality studies and no

serious risk of bias. The consistency was assessed to be high reliability (++++), as the results of the studies show similarities to great extent, and the partial differences existed could be explained by the different study designs. The evidence of precision was assessed to be moderate (+++o) as the confidence interval of the studies varied in a wide range. The evidence of transferability was found to be high (+++++) due to that the context and the research question explains the results appropriately. The evidence of publication was found to be of high reliability (++++), as the results of unpublished studies (part of dissertation) which were found were in line with the results of the included studies (Todd, 2008).

Table 5: It displays the individual risk of bias by ROB-II.

	Randomization bias	Deviations bias from the intended intervention (effect of adhering to intervention)	Deviations bias from the intended intervention (effect of assignment to intervention)	Missing outcome data bias	Measurement of the outcome bias	Selection of reported result bias
Reedman et al. (2019)	+	+	O	+	O	+
Reedman et al. (2021)	+	+	+	+	O	+

Table 6: It displays the assessed individual risk of bias by ROBINS-I

	Confounding bias	Selection bias of participants	Classification bias of interventions	Deviation bias from intended interventions	Missing data bias	Measurement of outcomes bias	Selection bias of the reported result
Tsalavoutas & Reid (2006)	O	+	+	+	+	O	O
Saebu et al. (2013)	+	+	+	+	O	+	+
Johnson et al. (2018)	O	+	+	+	O	O	O

Huéscar et al. (2020)	O	+	+	+	+	O	+
Behzadnia et al. (2022)	+	+	+	+	+	+	+

Note: O stands for moderate risk of bias, + stands for low risk of bias.

6 DISCUSSION

The present review aimed to explore how interventions based on the constructs of self-determination theory facilitate possible determinants for physical activity participation in children and young adults with disabilities (CAYAWD). The review analysed seven studies including two RTC's, three experimental, one longitudinal experimental and one quasi-experimental studies published between 2006 to 2022. Various elements of SDT were used in the interventions, with focus on motivational climate and basic psychological needs (autonomy, competence, or relatedness). Results showed significant improvements in participant's physical activity, need satisfaction and autonomous motivation. The studies exhibited moderate to high quality, reliable evidence. The psychometric properties of outcome measures were considered adequate with acceptable validity and reliability.

The focus of the interventions in all the studies was to promote physical activity participation among CAYAWD directly or indirectly through increased intrinsic motivation or autonomous motivation via basic psychological need (BPN) satisfaction. All the studies used motivational climate or autonomy- supportive climate as strategies to facilitate the satisfaction of BPN which led to increased intrinsic motivation for physical activity participation or time spent in PA. The approach followed was either by designing the intervention to increase autonomous motivation towards PA through basic psychological needs facilitation (Huéscar et al., 2020; Behzadnia et al., 2022; Reedman et al., 2019; Reedman et al., 2021) or to satisfy basic psychological needs for PA through autonomous motivation which led to physical activity participation (Saebu et al., 2013; Johnson et al., 2018) or single need satisfaction (competence) resulting in improved scores in PA (Tsalavoutas & Reed, 2006).

Interventions based on the motivational climate showed a statistically significant effect regarding the participants PA levels or participation or time spent in PA which increased significantly post-intervention along with their need-satisfaction in Huéscar et al., (2020); Johnson et al., (2018) and Saebu et al., (2013), Reedman et al. (2021) Behzadnia et al., (2022). While the results in Reedman et al., (2019), and Tsalavoutas & Reid (2006) showed a significant effect on PA through need-satisfaction. Furthermore, Saebu et al., (2013);

Johnson et al. (2018); Behzadnia et al., (2022) also showed that an increase in participants autonomous motivation has a significant effect on their PA participation through their intrinsic motivation.

6.1 Results discussion

6.1.1 *Self-determination continuum as a tool for behavioral regulation and the characteristics of interventions*

The SDT emphasizes the significance of individuals behavioral regulation. The theory was used in previous studies with success to promote participation in PA among children and adolescents without disabilities (Sebire et al., 2013) (Franco et al., 2017). It is important to highlight the point that each element of the SDT continuum regulates physical activity behaviour through the motivational process and facilitates PA participation. Thus, all the constructs of SDT act as possible determinants to promote participation in physical activity among children and young adults with disabilities (CAYAWD). Furthermore, it is suggested that self-determined motivation has an essential role in improving participation in PA among individuals with disabilities (Ryan and Deci, 2017). Our results are in line with the previous limited findings, that SDT based interventions can be a potential way to promote physical activity among CAYAWD.

The SDT continuum played a pivotal role in regulating motivation for physical activity participation among CAYAWD, though their dynamics varied in studies. The SDT continuum was displayed differently in the intervention strategies to promote participation in PA (Deci and Ryan, 2000) (Deci and Ryan, 2020). Our results suggest a dynamic process based on the included studies' SDT continuum: the climate in which the individuals perform physical activity affects the satisfaction or frustration of BPNs, which in turn influences the individuals' motivation toward PA and thus the motivational behavioral regulations have direct effect on the intention to exercise and to participate in PA. This result ties well with previous evidence wherein the authors described a model which is based on SDT in a PE setting. According to which, learning climate supports BPN which facilitates individuals' autonomous motivation, which has direct impact on intentions/PE grade (Cid et al., 2019).

Theme 1: Motivational Climate and Physical Activity

The context and environment can influence participation (Imms et al., 2016), likewise, SDT (self-determination theory) describes motivational climate as an environment which involves task-oriented goals, enjoyment, and self-motivation (Abdulla et al., 2022), all of which could influence participation in PA. All the studies included in this review utilized motivational or mastery climate which are in line with SDT. It is important to highlight that in most of the studies the motivational climate significantly increased the time being physically active or the physical activity level after the SDT based interventions (Huéscar et al., 2020) (Johnson et al., 2018) (Saebu et al., 2013) (Reedman et al., 2019). The basis of the

discussion of the next two themes: Need-satisfaction and Physical Activity and Autonomous Motivation and Physical Activity are based on the pattern found among the included studies, that participant's intrinsic motivation for physical activity can be achieved by satisfaction of BPN and facilitating autonomous motivation. Previous research suggests that an enhanced intrinsic motivation of children and adolescents' increases participation in PA (Sebire et al., 2013; Franco et al., 2017). It was supported by the findings of our review in six studies (Johnson et al., 2018; Saebu et al., 2013; Reedman et al., 2019; Reedman et al., 2021; Huéscar et al., 2020; Behzadnia et al., 2022). Evidence states that an increase in participants' intrinsic motivation can be achieved by the satisfaction of BPNs, or reduction of frustration of BPNs and facilitating their autonomous motivation (Deci and Ryan, 2020).

Theme 2: Need-satisfaction and Physical Activity

Evidence proposes that satisfaction of basic psychological needs results in more efforts in PE, higher achievements in gymnastics, higher intention to participate outside schools' PE classes and increased participation in PA during leisure time (Katarzi et al., 2011). Findings reported by existing evidence (Katarzi et al., 2011; Franco et al., 2017; Sebire et al. 2013) are in accordance with the findings of our review which showed that the post-intervention change in performance in physical activity among CAYAWD was due to the effect of participants need-satisfaction (Huéscar et al., 2020; Johnson et al., 2018; Saebu et al., 2013; Reedman et al., 2019; Reedman et al., 2021; Tsalavoutas and Reid, 2006). Moreover, research justifies the usefulness of intervention based on SDT that involves strategies supporting BPN satisfaction (Franco et al., 2017). Previous studies carried out among typically developing children and young adults, also supports that satisfaction of BPNs increases participants intrinsic motivation in taking part in physical activity. The findings suggested different patterns of the individual effects of single needs (autonomy, relatedness, or competence). Our findings showed that the participants' sense of competence satisfaction can be itself enough to improve achievement scores in PA (Tsalavoutas and Reid, 2006). Further, competence in a motivational climate including "just the right challenge" is said to facilitate competence satisfaction towards PA as it boosts a positive experience in balancing goal setting and achievement (Reedman et al., 2021; Tsalavoutas and Reid, 2006). A similar pattern of results was obtained in the study carried out by Cid et al. (2019) in which participants competence had a more outstanding impact on improving intrinsic motivation in participation of PA. It is argued that satisfaction of relatedness in intervention programs are rather challenging tasks (Franco et al., 2017; Katarzi et al., 2011). Our findings and previous research pointed out the importance of keeping consistent contact with social support during intervention programs can be essential for maintaining participation in PA. Contrary to the findings and previous studies suggestions that longer interventions are required to modify relatedness, we found that during a short three-week intense physical activity program (Saebu et al., 2013), relatedness showed significantly positive relation to participation in PA between the baseline and the end of the program. Furthermore, follow-up checks revealed that the influence of relatedness-satisfaction gradually reduced after the end of the rehabilitation stay, which was explained by the fact that participants lost contact with their peers and support staff after the intervention finished (Saebu et al., 2013). These basic findings demonstrate similarities with research showing that there was no increase observed

in relatedness during an intervention program where pre-existing stable relationships were difficult to modify (Franco et al., 2017).

Theme 3: Autonomous Motivation and Physical Activity

Our review showed a pattern that increased participant autonomous motivation can lead to their satisfaction of BPNs which can result in improved PA participation among children and young adults with disabilities (Saebu et al., 2013; Johnson et al., 2018). The motivational strategy of satisfying BPN to increase autonomous motivation in participation in PA had statistically significant effects in most included studies which used this approach (Saebu et al., 2013; Reedman et al., 2021; Johnson et al., 2018). This is supported by the study carried out by Sebire et al. (2013), in which they suggested that participants satisfaction of BPN is a potential way to increase their autonomous motivation towards PA and can be the foundation of need-supportive interventions. This is also in line with a systematic review executed by Owen et al. (2014) which states that facilitating individual's autonomous forms of motivation (intrinsic motivation and identified regulation) have a positive relation to physical activity among children and young adults without disabilities (CAYAWD).

Evidence suggests that controlled forms of motivation have a negative effect on participation in PA (Owen et al., 2014). It is supported by our findings, that appearance motivation, which is categorized as an extrinsic motivation, was found to have a negative effect on participants competence for physical activity (Reedman et al., 2019). Furthermore, our systematic review suggests that diminishment of participants external regulation (Huéscar et al., 2020) can contribute to increased involvement in PA and decrease in controlled motivation towards PA (Behzadnia et al., 2022) has positive association with increase in participants autonomous motivation related to PE activities.

An unexpected pattern was found between the different age groups and the different forms of behavioral regulations related to PA participation. Although it was undeniable that intrinsic motivation and identified regulations are both essential in changing health behaviour in PA. Studies which included elementary school aged or younger children with disabilities were prone to explore more about intrinsic motivation such as enjoyment, pleasure of the activity (Reedman et al., 2019; Reedman et al., 2021; Huéscar et al., 2020; Johnson et al., 2018), while studies including teenagers or young adults likely to have impact of identified regulations on their PA behaviours (Behzadnia et al., 2022; Saebu et al., 2013). Our findings are in line with previous findings that assumes that different age groups require different forms of motivation strategies, while children's main motivator is intrinsic motivation (enjoyment of activities), adolescents show higher engagement by self-regulatory motivations (Leisterer et al., 2021; Cachón-Zagalaz et al., 2023).

The different follow-up timelines at 12 weeks (Behazadnia et al., 2022; Saebu et al., 2013) and at 16 weeks (Reedman et al., 2019) made the comparison of follow-up measures difficult and less comprehensive. Saebu et al. (2013) reported a significant positive correlation between autonomy and efficacy with physical activity participation at follow-up. Behzadnia et al. (2022) had significant decrease in amotivation and need-frustration and significant increase in need-satisfaction towards PE activities at follow-up. In Reedman et al.

(2019) the significant increase in performance and satisfaction was retrained at follow-up. It should be mentioned that the limited measures on long-term effects of the included studies interventions raise awareness of the need for more follow-up measures in future studies.

6.1.2 Primary outcomes and psychometric properties

The primary outcomes summarized were physical activity, basic psychological needs satisfaction or frustration with PA and motivational regulations for PA. All the outcomes were measured using different measurement tools. For example, physical activity was measured either as MVPA (Johnson et al., 2018; Reedman et al., 2019; Reedman et al., 2021) or physical activity levels (Huéscar et al., 2020; Saebu et al., 2013) or achievement scores (Tsalavoutas & Reed, 2006). Though physical activity was directly measured in six studies, all the studies utilized different measurement tools except for MVPA (Actigraph GT3X). This gives rise to highlighting the point of consistency of the measurement tools and comparability, which made it challenging to combine the results meaningfully. The existence or use of consistent measurement tools across the included studies is essential for ensuring that the outcomes are comparable. There is a possibility of potentially significant implications on the results due to this. The inconsistency in measurement tools made it difficult to identify patterns, draw conclusive findings and decrease the generalizability of the findings. While Philips et al., (2021) argue that the key is to consider the validity, reliability and feasibility of the tools used in the studies, as it is difficult to use one single tool in all given contexts of the respective interventions of the included studies and cannot be generalized. The instruments used in the inclusive studies had acceptable internal validity and reliability and were examined in contexts (in children and young adults with disabilities) that are applicable along with reliable pretest-posttest scores. It must be noted that the included studies used few tools which are either the adapted versions or translated versions for their context and tested for their validity and reliability (Behzadnia et al., 2022; Huéscar et al., 2020; Saebu et al., 2013). The process of adaptations, translations and validations were described appropriately for the specific context ensuring their applicability and accuracy in capturing the intended constructs. This process enhanced the quality and comparability of the results of this review through contextual applicability, acceptable internal validity, and reliability, yet it is recommended that future studies in this area should strive to adopt standardized measurement tools, enabling more accurate cross-study comparisons.

6.1.3 Quality of the studies

The authors found that the comprehensive guidance and instructions provided by SBU on the utilization of the tools significantly facilitated their proficiency in employing these assessment tools during the research process. The quality of the studies included ranged from moderate to high quality, assessed by ROB-2 and ROBINS-1 (SBU, 2018). These tools were used to understand the strengths and limitations of the studies. Authors thrived to be transparent and bias-free during the assessment according to their competence. The overall strength of evidence of this review was considered moderate quality using GRADE from SBU, (2018). The reason for assessing the quality to be moderate is due to the individual

studies' drawbacks as below. The assessment of the quality of the studies is less comprehensive due to the inclusion of RCTs as well as experimental studies in this review, leading to the compromise of the overall strength of evidence of this review. The limitations of the included experimental studies were small sample size (Saebu et al., 2013; Tsalavoutas et al., 2006), uncontrolled possible confounders (Johnson et al., 2018), lack of generalizability due to the selection of participants from one institution (Huéscar et al., 2020), possible misinterpretation of the self-reported questionnaire in participants with intellectual disabilities (Behzadnia et al., 2022). Though the RCTs' (Reedman et al., 2019; Reedman et al., 2021) have a strong methodology, with a strong interventional base based on ParticiPate CP, that can be replicated, yet have limitations. For example, the intervention required a discussion about the goals of the participants, which may have introduced bias (unblinded assessor) (Reedman et al., 2019). The Reedman et al., (2019) results cannot be generalized, as it involved only ambulatory participants with cerebral palsy. So, it is difficult to generalize the results to individuals with other disabilities. While Reedman et al., (2021) had a small sample size, robust statistical approach, and no follow-up measurement of outcomes to assess the long-term effects of the intervention on physical activity. The potential reasons for these limitations include that the included studies were the first attempts of research in this area, and it is difficult to recruit a larger number of participants, especially in studies with specific population like those with disabilities. Controlling for every confounder is challenging, especially in non-randomized studies.

Choosing an appropriate measurement instrument for the population in a study is crucial. As it was showcased in Reedman et al., (2019), the children with ASD had tactile sensory sensitivity and refused to wear devices such as ActiGraph GT3X+. Moreover, wearing a waistband can underestimate activities such as cycling, which leads to missing data inducing potential measurement bias. Though the results of the studies had promising results, these limitations can restrict the generalizability of the findings and hence, there is a need to acknowledge these in further studies.

6.2 Methods discussion

The systematic review design was chosen in order to create a comprehensive overview of the available evidence on the intervention based on the motivational strategies of SDT to facilitate possible determinants of PA participation among children and young adults with disabilities. Conducting a systematic review was appropriate to answer the aim and the research questions (Munn et al., 2018) as systematic search makes it possible to find more relevant studies and to track back and replicate the search which reduces selection bias. Further, it involves assessing the quality of included studies which improves the strength of evidence in the problem area of the research (Khan et al., 2003).

It can be stated that the authors searched and found relevant studies within the problem area which answer the research question. The database search was performed in three databases systematically in line with PICO and manually documented in a search diary.

Although previous evidence does not state an optimum number of databases, it is suggested to use approximately three (Wright et al., 2015) (Lim et al., 2016). To improve the accuracy of the search terms and blocks were built with the help of several librarians in the process. Through this the authors attempted to minimize selection and publication biases. Our access to full-text articles was provided by Mälardalen University Library. The inclusion criteria for the systematic review got broadened gradually during the process, as even a smaller number of hits were found at the beginning of the search, after realizing that, the age group of participants extended from children to adults, as well as first attempts to include only RCTs extended too. The unavailability of RCTs in this problem area made us have experimental designs in our inclusive criteria. We broadened the age group due to the restricted number of available evidence, which revealed unexpected patterns of the SDT continuum in different age groups.

This review's main goal is to synthesize existing evidence from the studies included and draw comprehensive and reliable conclusions. It is important to address the applicability of the findings beyond the included studies through external validity, transferability, and generalizability. Considering the limitations of individual included studies, the point of the extent to which the findings of this review can be generalized to other populations is debatable, due to their small sample size. However, the diversity of the interventions, participants' characteristics (age, disabilities), different settings, time frames and that the studies are from different countries, broadens the scope of this review and enhances its external validity, generalizability, and transferability to different contexts. The findings of this review can be replicated using the search strategies, inclusion, and exclusion criteria. The process of presenting the results of this review attempted to be addressed without any personal biases.

The limitations of the present review include evidence selection bias and publication bias. The selection bias can be due to the database searches, as there is always a potential for using different search terms or blocks. Although the authors tried to reduce the bias by booking several times with librarians for choosing databases, building search blocks, carrying out systematic searches and documenting the searches systematically. As for publication bias, during database searches dissertations and study protocols of yet unpublished studies might include some statistically significant data which is not included in this present review. Due to the inclusion criteria to include only English language studies might have led to potential publication bias. A major source of limitation is due to the restricted number of studies and the inconsistency of study designs in the problem area. The limited number of hits and the variety of the included study designs made the analysis of the studies challenging. Despite the authors aiming to analyze the studies objectively, a further weakness can be that the authors' interpretations are included in the results part.

Furthermore, the authors strived to report the results as transparently as possible. However, the themes and patterns identified were purely the interpretations of the authors. It is noteworthy that it is the first attempt for the authors to conduct a systematic review and therefore it is subjective to their capabilities.

6.3 Ethical discussion

All the studies included in this systematic review were ethically approved by their respective ethical boards and standards, and thus met the ethical requirements. This implies that the studies are in accordance with the CODEX (n.d.), which is based on the Declaration of Helsinki, 1964, the ethical considerations include informed consent from the participants and guardians, right to privacy and confidentiality of the personal information. The researchers must follow local and national rules, instructions, and norms for academic and professional integrity. As the studies originate from different countries the ethical committees differ too, a university ethics committee in Canada (Tsalavoutas and Reid, 2006), provincial education office and school principals in Iran (Behzadnia et al., 2022), Regional Medical Committee for Research Ethics in Norway (Saebu et al., 2013), Project Evaluation Body of the Universidad Miguel Hernandez de Elche in Spain (Huéscar et al., 2020), Institutional Review Board for Human Subjects Research in US (Johnson et al., 2018), The Childrens Health Queensland Medical Research Ethics Committee, Australian New Zealand Clinical Trials Registry (Reedman et al., 2019) (Reedman et al., 2021). Furthermore, it is important to note that ethical standards evolve over time and may differ by location, as emphasized by Weingarten et al., (2004). This review included studies from diverse cultural backgrounds, which can induce possible discrepancies in ethical standards. So, the authors made sure that it is important to consider whether the ethical principles and individual rights have been balanced across the studies as per their ethical committees by ensuring that ethical standards are met.

7 CLINICAL IMPLICATIONS AND FUTURE RESEARCH

The systematic review suggests that health professionals should emphasize designing treatment plans based on self-determination theory for children and young adults with disabilities (CAYAWD). In order to support the intrinsic motivation, which is crucial for PA participation for CAYAWD, healthcare providers should focus on improving their competence to differentiate extrinsic and intrinsic motivation. As elements of SDT act as possible determinants for participation in PA, the findings suggest creating motivational climates through need-supportive parental style, need-supportive teaching style or need-supportive behavioral style of health professionals. PA programs should consider using motivational strategies such as setting meaningful goals and providing choices within activities. The evidence suggests that treatment plans should consider creating a long-term social support system to optimize the satisfaction of relatedness to sustain PA among CAYAWD.

For future research, the overall evidence highlights the need for more longitudinal studies exploring the dynamics between BNP and the behavioral regulations of self-determination theory to assess the sustainability of participation in PA. Future research should include more RCTs to establish causal relationships and to strengthen the evidence. It also highlights the vigorous need for interventional studies based on SDT to explore more about the role of single needs in designing motivational strategies. Researchers should work towards standardization of measurement tools to assess physical activity outcomes in this population, in order to facilitate more accurate cross-study comparisons. The study proposes the need for diverse population studies to increase the generalizability of effects of the interventions based on SDT. Future research should also aim for larger sample sizes to improve statistical power and enhance the representativeness of the findings through diverse population recruitment across different demographics.

8 CONCLUSION

In conclusion, this review underscores the potential of interventions based on self-determination theory as possible determinants to enhance physical activity participation among children and young adults with disabilities. It emphasized the significance and role of the motivational climate, basic psychological needs satisfaction, and various forms of autonomous motivation regulations across age groups in promoting physical activity participation. It highlights the importance of the self-determination continuum in influencing behavioural regulation related to physical activity among children and young adults. It points out that a need-supportive climate, aligned with SDT, tends to be more effective in promoting PA compared to the controlling or instructional climate. The outcomes in focus were physical activity or autonomous motivation for physical activity or need satisfaction for physical activity. These outcomes were measured using respective tools among studies with acceptable validity and reliability. Yet, inconsistency of measurement instruments was observed. The quality of the included studies was found to be strong to moderate strength of evidence. The overall strength of evidence was assessed to be moderate, due to the distinctive designs of the studies included. However, due to the limited evidence, the conclusions must be considered with caution. Additionally, the methodology used in this review may also limit its conclusion due to the exclusion of unpublished studies and non-English publications. Moreover, the way results from each study were classified may be subjective to criticism and various interpretations.

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APPENDIX A

Final Database search strategies

Date of search	Database	Search terms (Free text or subject terms)	Limits or Filters	Results (Number of documents retrieved & included studies)
2023-03-27	PubMed	("self determination theory"[Title/Abstract] OR "motivation"[Title/Abstract]) AND "physical activity"[Title/Abstract] AND "participation"[Title/Abstract] AND ("special education"[Title/Abstract] OR "leisure"[Title/Abstract])	Clinical trial, Randomized control trial (2009), English	6 (Reedman et al., (2021); Reedman et al. (2017) protocol)
2023-04-11	CINAHL	AB (students OR adolescent* OR "youth*" OR "child*" OR teenager* OR young*) AND AB ("self-determination" OR "motivation" OR "autonomous motivation" OR "basic psychological needs" OR "competence" OR "relatedness") AND AB (Exercise OR "physical activity" OR "physical education" OR "activity") AND AB ("physical disabilit*" OR "intellectual disabilit*" OR "developmental disabilit*")	Year: 2006-2023 English Academic journals	67 (Behzadnia et al.,2022; Tsalavoutas & Reid, 2006)
2023-04-28	APAPsychINFO	AB (students OR adolescent* OR "youth*" OR "child*" OR teenager* OR young*) AND AB ("self-determination" OR "competence" OR "autonomy") AND AB (Exercise OR "physical activity" OR "physical education" OR "activity") AND AB ("physical disabilit*" OR "intellectual disabilit*" OR "developmental disabilit*" OR "special needs")	Year: 2006-2023 English Academic journals	123 (Tsalavoutas & Reid, 2006; Saebu et al., 2013; Johnson et al., 2018; Huéscar et al.,2020)

APPENDIX B

Characteristics of the included studies

Selected study	Design of the study	Country	Participants of experimental group			Participants of the control group	Characteristics of interventions				Primary outcome/effect	Quality of the studies
			Mean Age	Number	Diagnosis		Duration	Frequency	Design	Content		
Reedman et al.,	RCT	Australia	10 yrs	37	Cerebral palsy		8-week + 8 weeks follow up.	8 sessions (one 60 minutes session per week)	SDT, autonomy, competence, and relatedness	ParticiPAte CP protocol based on Reedman et al., (2017) utilizing motivational strategies such as goal setting, BCT taxonomy, Motivational interviewing based on SDT.	Increased MVPA	Low risk of bias
Reedman et al.,	RCT	Australia	10 yrs	33	Cerebral palsy		8 weeks	1 hour sessions, once a week for 8 weeks	Autonomy, competence, and relatedness.	ParticiPAte CP protocol based on Reedman et al., (2017)	Increased MVPA	Low risk of bias

Huéscar et al., (2020)	Quasi-experimental	Spain	10-12 yrs/ Mean age = 10.75; SD = 0.80	63	Students from special education, characterized by their late incorporation into educational system, complex educational history, periodic educational dropouts		20 mins /sessions (5 mins warm-up, 15mins engagement in PA) for 5 months	3 sessions per week	Autonomy-supportive style	In a PE program autonomy-supportive strategies were utilised to increase PA involvement among students.	Increased sense of autonomy, increased PA level	Low risk of bias
Behzadnia et al., (2022)	Experimental study	Iran	11-25 yrs, Mage = 16.64, SD = 3.17	50	Students from special education were categorized based on Raven's Colored Matrices Test Either with mild or borderline intellectual disability	Control group: N=48 Students from special education were categorized as either with mild or borderline intellectual disability Mean age = 16.42, SD = 3.29	6 months	Before the beginning of semester 3-hour meeting for the teachers and at week 6th a 2-hour online meeting.	Competence-supportive, autonomy-supportive and relatedness supportive motivational strategies	The PE teachers were trained to use competence-supportive, autonomy-supportive, and relatedness-supportive teaching style to increase PA involvements for students	Increased need satisfaction, lesser need frustration, lesser amotivation	Low risk of bias
Saebu et al., (2013)	Longitudinal experimental	Norway	Mean age=24.7 yrs	44	Young adults with physical disabilities		3 weeks	3-5 hours of PA/day for 6 days/week	Autonomy-support in focus, and additional instructions to enhance Relatedness and Competence from SDT	The rehabilitation center had activities such as swimming, cross-country skiing, riding, aerobics, alpine skiing, kayaking to provide opportunity to choose the activities best suited to the individuals. The intervention provided choice of opportunity and self-initiation.	Increased PA through SDT motivational variables	Low risk of bias

Tsalavoutas et al., (2006)	Johnson et al., (2018)
Experimental	Experimental
Canada	USA
Mean age= 9.1 yrs	Mean age=6.89yrs
N=16	N= 32. (14 + 18)
Children with disabilities: cerebral palsy, muscular dystrophy, rheumatoid arthritis	Children with developmental disabilities (DD) (4) autism spectrum disorder, (4) Down Syndrome, (2) Motor Delay, (1) Williams Syndrome, (1) Intellectual Delay, (1) DiGeorge Syndrome, (1) Noonan Syndrome N=14 (children with developmental disabilities) & N=18 Children with typical development
Children without disabilities, n=18, Mage=9.1yrs	N=18 Children with typical development
NR (2 phases, the 2nd phase was performed the following week after Phase I.)	3 weeks
Phase I: 20 trials plus depending on individual preference exchange points for trials. Phase II: 20 trials plus depending on the individual preference exchange of the points for trials	6 sessions/ week, 60 mins / occasion Week 1 :6 randomly ASC or IC Week 2 & 3: ASC for 3 days & IC for other 3 days
Competence satisfaction based on SDT principles in mastery (motivational) climate	Autonomy-supportive climate (ASC): choice making opportunities and control over their actions
SDT based intervention on competence satisfaction in mastery climate in ball striking during PE in elementary school.	The intervention was carried out in a summer camp, recreational physical activity program for 6 sessions with 60-min MVPA. It was a comparison between autonomy-supportive climate and instructional (low-autonomy) climate (IC). Activities were bicycle activities, swimming, recreational activities in gym
Risk taking (RT), achievement (ACH) RTxACH= competence satisfaction /CSAT	Increased moderate-to-vigorous (MVPA)
Moderate risk of Bias	Moderate risk of bias

APPENDIX C

Psychometric properties of the instruments used in the included studies.

Instrument	Validity/ Reliability
<i>Interpersonal Behaviors Questionnaire (IBQ)</i> (Rocchi et al., 2017) (Behzadnia et al., 2022)	<p>Content: The questionnaire measured need-supportive and need-thwarting behaviors by 2 items. Items were rated from 1 (not at all true) to 5 (very true).</p> <p>Construct validity: Confirmatory Factor Analysis (CFA) with need support and need thwart fitted the data well. χ^2 (53) = 68.42, $p = .075$, CFI = 0.94, TLI = 0.92, RMSEA = 0.055 (0.000, 0.089), SRMR = 0.070.</p>
<i>Basic Psychological Need Satisfaction and Need Frustration Scale (BPNSNFS)</i> by Chen et al., 2015. (Behzadnia et al., 2022)	<p>Content It is a 12-item scale, in which each need was assessed by four items, of which two items assessed satisfaction and two items assessed frustration. The items were rated from 1 (not at all true) to 5 (very true).</p> <p>Construct validity: CFA with 2 s-order factors fitted to the data well. χ^2 (53) = 68.09, $p = .079$, CFI = 0.92, TLI = 0.90, RMSEA = 0.052 (0.000, 0.089), SRMR = 0.078. All item loadings were above 0.43, $p < .001$.</p> <p>Internal consistency: Behzadnia et al. (2022) referred to an acceptable internal consistency.</p> <p>Cross-cultural validity: The short 12-item version of the scale was translated and validated</p>
<i>Self-regulation questionnaire validated to PE program by Goudas et al (1994) and Ntoumanis (2001)</i> (Behzadnia et al., 2022)	<p>Content: 10-items scale was used for measuring autonomous motivation (intrinsic motivation and identified regulation), controlled motivation (introjected and external regulation) and amotivation</p> <p>Construct validity: CFI tested a 3-factor model in which 10 items loaded on their respective three latent factors fit the data well.</p> <p>χ^2 (31) = 34.15, $p = .32$, CFI = 0.99, TLI = 0.97, RMSEA = 0.032 (0.000, 0.085), SRMR = 0.071.</p>
<i>Positive and negative affects scale by Diener and Emmons (1984)</i> (Behzadnia et al., 2022)	<p>Content: 8-items of positive and negative affects scale were used; each effect was measured with 4 items.</p> <p>Construct validity: CFA tested the 2-factor model for positive and negative effects and the model fitted the data well. χ^2 (19) = 27.46, $p = .09$, CFI = 0.96, TLI = 0.94, RMSEA = 0.068 (0.000, 0.12), SRMR = 0.059. All item loadings were above 0.46, $p < .001$.</p>

<p><i>Physical Activity Readiness Questionnaire (PAR-Q)</i> by Thomas et al., (1992) (Behzadnia et al., 2022)</p>	<p>PAR-Q measured students' physical health and if they are at any risk with the increasing PA level. Students who filled it with yes were excluded from the study.</p>
<p><i>Health Care Climate Questionnaire (HCCQ)</i> by Williams et al., 1996)</p> <p>(Saebu et al., 2013)</p>	<p>Content: Used a short version of HCCQ with 6 items to assess the participants perception on how much they feel their health care providers to be autonomy supportive vs controlling in the intervention.</p> <p>Construct validity: Psychometric properties were established in a sample of 1,183 patients in various studies where the measure yielded a one-factor solution with all factor loadings above .74.</p> <p>Internal consistency: It represented good internal consistency ($\alpha = .80$), and correlated .91 with the full version</p>
<p><i>Basic Psychological Needs in Exercise Scale (BPNES)</i> by Vlachopoulos & Michailidou, (2006)</p> <p>(Saebu et al., 2013)</p>	<p>Content validity: It is suitable for structured exercise settings. This is a 12-item scale to measure perceptions of autonomy, competence, and relatedness of the participants in the domain of exercise.</p> <p>The psychometric properties were established by using a 1,012-sample size and the results showed an appropriate factor structure, internal consistency, generalizability of the factor dimensionality across the calibration and the validation samples, discriminant validity, and predictive validity.</p>
<p><i>Exercise Self-Regulation Questionnaire (SRQ-E)</i> by Ryan & Connell, (1989)</p> <p>(Saebu et al., 2013)</p>	<p>Content: SRQ-E was used to measure the autonomous motivation and controlled motivation which had items to measure participants identified regulation, intrinsic regulation, introjected regulation, and external regulation.</p> <p>Construct validity: Factor analysis revealed 2 factors representing intrinsic and identified regulation with factor loadings above 0.60.</p> <p>Internal consistency: SRQ-E had good reliability on intrinsic regulation ($\alpha = .80$) and identified regulation ($\alpha = .85$).</p>
<p><i>Exercise Self Efficacy Scale (ESES)</i> by Kroll et al., (2007)</p> <p>(Saebu et al., 2013)</p>	<p>Content: responses to the sample item are given on a 10-point Likert scale ranging from not all true (1) to always true (10).</p> <p>Content validity: It was measured to be satisfactory in terms of face and construct validity as well. Principal component analysis extracted only one factor, 62.3% variance.</p> <p>Internal consistency: The instrument was measured to have high internal consistency ($\alpha = .86$) and scale integrity.</p>

<i>International Physical Activity Questionnaire (IPAQ)</i> by Craig et al., (2003) (Saebu et al., 2013)	Content: Usually used to measure total time in vigorous-intensity PA, moderate intensity PA, total time in walking and time spent sitting during last 7 days. In Saebu et al., (2019), IPAQ was modified for wheelchair users. It showed adequate reliability (Spearman's ρ clustered r around 0.8) and criterion validity ($r = .30$).
<i>Scale of autonomy support (SAS)</i> by Moreno-Murcia et al., (2019) Huéscar et al. (2020)	Content: 11-item scale, which assesses perceived autonomy-support in classroom. Internal consistency: The Cronbach's alpha (pre-and post-test) value were 0.71 and 0.70.
<i>Controlling Teaching Style (CTS)</i> by Hernández et al., (2017) Huéscar et al. (2020)	Content: 9-item questionnaire to measure controlling teaching style perceived by students in PE. Internal consistency: The Cronbach's alpha (pre-and post) values were 0.70 and 0.74.
<i>Psychological Need Satisfaction in Exercise Scale (PNSE)</i> by Wilson et al., (2006) Huéscar et al. (2020)	Content: 18-item questionnaire with 6-item grouped into 3 three subscales (autonomy, competence, and relatedness). Internal consistency: Cronbach's alpha (pre and posttest): competence: .71 and .81, autonomy: .82 and .93, relatedness: .63 and .78.
<i>Pictorial Scale of Sport Motivation</i> by Moreno-Murcia et al., (in press) Huéscar et al. (2020)	Content: 9-item instrument with 3 subscales (intrinsic and extrinsic motivation and amotivation) Internal consistency: Cronbach internal consistency values on the pre- and post-test were 0.74 and 0.70 for intrinsic motivation; 0.67 and 0.66 for extrinsic motivation; and 0.74 and 0.79 for amotivation, respectively.
<i>Questionnaire for Measurement of a Person's Habitual Physical Activity</i> by Baecke et al., (1982) Huéscar et al. (2020)	Content: Leisure-time sport and physical activity involvement were assessed through four questions. Internal consistency: Cronbach's alpha values were 0.71.
<i>Canadian Occupational Performance Measure (COPM)</i> by Law et al., (2014)	Content: Modified version of COPM which has identification of goals in leisure, included parent-proxy rating, addition of BiGSS (Belief in Goal Self-competence Scale). BiGSS measures self-efficacy (level of confidence that a goal can be achieved).

(Reedman et al., 2019; Reedman et al., 2021)	<p>An increase of 2 points indicates a clinically significant change.</p> <p>Internal consistency: valid and reliable in cerebral palsy.</p>
<p>ActiGraph GT3X+</p> <p>(Reedman et al., 2019; Reedman et al., 2021; Johnson et al., 2018)</p>	<p>Content: Tri-axial accelerometer waistband to record the wear time, PA intensity and the data downloaded using ActiLife software.</p> <p>Construct validity: Measurements based on 15second-epochs with validated GMFCS-specific cut points to validate the wear time.</p> <p>Johnson et al., (2018) validated wear time using Troiana et al., (2008) algorithm and Freedson et al., (2013) for PA levels.</p>
<p>Barriers to participation in physical activity questionnaire (BPPA-Q) by Huijg et al., (2014)</p> <p>(Reedman et al., 2019)</p>	<p>Content: BPPA-Q is a 60-item questionnaire corresponding to different behavioural barriers to participation on a 7-point Likert scale that measures the presence and extent of parent-reported barriers to their child's PA participation. Higher scores mean fewer barriers.</p> <p>Construct validity: It is based on a valid and reliable instrument constructed on the Theoretical Domain Framework (TDF).</p>
<p>Participation and environment measure for children and youth (PEM-CY) by Coster et al., (2011)</p> <p>(Reedman et al., 2019)</p>	<p>Content: The community domain of (PEM-CY) measures the patient reported community participation frequency and involvement. It gives the scores for frequency (0-never to 7-daily), involvement (1-minimal to 5-very involved) and perceived environmental supportiveness (percentage).</p>
<p>Cerebral Palsy Quality of Life questionnaire for children (CPQOL-Child) by Waters et al., (2007)</p> <p>(Reedman et al., 2019)</p>	<p>Content: It is a 52-item child-report measure of the condition-specific quality of life. Scores range from 0-100. Scores for participation, physical health, emotional well-being, and self-esteem in response to ParticiPAtE CP. Higher scores in four of five domains mean better self-reported QOL.</p>
<p>Goal Attainment Scaling (GAS) by Kiresuk et al., (1994)</p>	<p>Content: It is used to quantify goal attainment. Used to set, increment, and rate goals in 5 possible scores [-2 (much less than expected) to +2 (much more than expected)]</p>

(Reedman et al., 2021)	<p>Construct validity: Very well suitable for pediatric population. Valid and excellent sensitivity to change.</p> <p>Internal consistency: good reliability (Cohen's kappa= 0.65 - 0.92)</p>
<p>Physical Activity Climate Questionnaire by Hagger et al., (2007)</p> <p>(Reedman et al., 2021)</p>	<p>Content: 15-item questionnaire with statements about the climate for physical activity ranging from 1 (controlling climate) to 7 (autonomy supportive climate).</p> <p>Construct validity: previously used in typically developing children with 6-item version and had demonstrated acceptable discriminant and cross-cultural validity.</p> <p>Internal consistency: $\alpha = 0.80 - 0.81$.</p>
<p><i>Problems in Schools Questionnaire (PISQ) by Deci et al., (1981)</i></p> <p>(Reedman et al., 2021)</p>	<p>Content: Series of vignettes about child's behaviour reported by caregivers. 4 responses for each behaviour from 1 (highly inappropriate) to 7 (highly appropriate). Average of the scores is considered. A score above zero mean autonomy-supportive parenting styles and below zero means more controlling style.</p> <p>Construct validity: PISQ has fair test-retest reliability with subscale coefficients = 0.77-0.82.</p> <p>Internal consistency: Good (Cronbach's $\alpha = 0.63 - 0.80$)</p>
<p><i>Motives for Physical Activities Measure-Revised (MPAM-R) by Ryan et al., (1997)</i></p> <p>(Reedman et al., 2021)</p>	<p>Content: Child-reported questionnaire with 30 questions on a 7point Likert scale (1=strongly disagree [not motivated by this], 7=strongly agree [very motivated by this]). The average scores correspond to child's motivation to participate in PA in 5 subscales: interest/enjoyment, competence, social motivation, appearance, and fitness. The first three are for intrinsic motivation and the last two for extrinsic motivation.</p> <p>Internal consistency: High internal consistency (Cronbach's $\alpha=0.78-0.92$) for exercise adherence and responsive for PA intervention in adolescents.</p>
<p><i>Stages of change for baseline readiness for behaviour change by Prochaska et al., (1997)</i></p> <p>(Reedman et al., 2021)</p>	<p>Content: this is in accordance with transtheoretical model to facilitate intervention tailoring. The 5 stages of readiness for health behaviour change: (1) pre-contemplation; (2) contemplation; (3) preparation; (4) action; or (5) maintenance. Parents rated their children's readiness to change their PA behaviour at one of the above five levels.</p>

APPENDIX D

Calculated Cohen's D effect size estimates of the significant outcome variables.

Studies	Comparison groups	Outcome variable	Mean (M), Standard Deviation (SD) & Number of participants(N)	Cohen's D (d)
Behzadnia et al. (2022)	Within group- Baseline to Post-intervention	Need satisfaction	M1 = 4.51, SD = 0.09, N = 50 M2 = 4.11, SD = 0.13; N = 50	3.63 Large effect
		Need frustration	M1=2.50, SD=0.11, N =50 M2=2.06, SD=0.10, N=50	4.19 Large effect
		Autonomous motivation	M1=5.91, SD = 0.94, N=44 M2=5.82, SD =0.94, N=44	1.06 Large effect
		Amotivation	M1 = 3.09, SD = 0.14, N = 50 M2 = 2.98, SD = 0.18; N = 50	0.69 Medium effect
Huéscar et al. (2020)	Between motivational climate and controlling climate	Physical activity	M1 = 5.95, SD = 0.79 N= 22 M2 = 5.18, SD = 1.75 N =22	0.54 Medium effect
		Autonomy	M1 = 5.18, SD = 0.69 N= 22 M2 = 1.89, SD = 0.62 N =22	0.72 Medium effect
Johnson et al. (2018)	Children with disabilities between the autonomy-supportive climate and instructional climate.	Moderate to vigorous intensity physical activity	M1= 52.6, SD=8.3, N = 14 M2= 45.4 SD=8.3, N = 14	0.75 Medium effect
Reedman et al. (2019)	With intervention group- baseline to post-intervention	Performance	M1 = 7.50, SD = 1.73, N = 18 M2 = 2.79, SD = 1.29, N = 18	2.76 Large effect

		Satisfaction	M1= 7.9 (SD1=1.4) N=18 M2= 3.9 (SD2=1.9) N=18	2.15 Large effect
Saebu et al. (2013)	Between baseline to post-intervention	Physical activity	M1 = 7251, SD = 4704, N = 44 M2 = 4672, SD = 4581 N = 44	0.532 Medium effect
		Autonomous motivation	M1=5.91, SD1= 0.94 N=44 M2=5.82, SD2=0.94 N=44	0.092 The effect is negligible
Tsalavoutas & Reid, (2006)	In children with disabilities between mastery climate and performance climate	Achievement	M1=3.05, SD=14.35, N=8 M2=-5.57, SD=19.37, N=8	0.45 Small effect

Note: The Cohen's D values for effect size in Reedman et al., (2021) was not estimated due to the absence of the mean and standard deviation values for the outcomes in the study.

Formulas used to calculate Cohen's d:

For pooled Standard Deviation in case of equal number of participants in the groups:

$$SD_{pooled} = \sqrt{\frac{(SD_1^2 + SD_2^2)}{2}}$$

For pooled Standard Deviation in case of unequal number of participants:

$$SD^*_{pooled} = \sqrt{\frac{(n_1 - 1)SD_1^2 + (n_2 - 1)SD_2^2}{n_1 + n_2 - 2}}$$

The calculation of Cohen's d value:

N=number of participants

ME= mean value for experimental group, Mc= mean value for control group

$$d = \frac{M_E - M_C}{\text{Sample } SD \text{ pooled}} \times \left(\frac{N-3}{N-2.25} \right) \times \sqrt{\frac{N-2}{N}}$$

correction factor for
small samples <50

Small effect = 0.2
 Medium Effect = 0.5
 Large Effect = 0.8

Reference from: Cohen, (1988); Glen, (2021); Glen, (2021).

APPENDIX E

The assessed quality tools of the included studies can be found as a supplementary document with the link below:

https://studentmdh-my.sharepoint.com/:w:/g/personal/saa21007_student_mdu_se/EXrpe4wNsoJCrNQc_-XjStYBo5D33cR_OwKC2g_iPsQUSg?e=qg3dPK

Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)

TEMPLATE FOR COMPLETION

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne
on behalf of the RoB2 Development Group

Version of 22 August 2019

The development of the RoB 2 tool was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/2- N61), with the support of the host MRC ConDuCT-II Hub (Collaboration and innovation for Difficult and Complex randomised controlled Trials In Invasive procedures - MR/K025643/1), by MRC research grant MR/M025209/1, and by a grant from The Cochrane Collaboration.



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Study details

Reference

Study design

- ☒ Individually-randomized parallel-group trial
- ☐ Cluster-randomized parallel-group trial
- ☐ Individually randomized cross-over (or other matched) trial

For the purposes of this assessment, the interventions being compared are defined as

Experimental:

Comparator:

Specify which outcome is being assessed for risk of bias

Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure, or paragraph) that uniquely defines the result being assessed.

Is the review team's aim for this result...?

- ☐ to assess the effect of *assignment to intervention* (the ‘intention-to-treat’ effect)
- ☐ to assess the effect of *adhering to intervention* (the ‘per-protocol’ effect)

If the aim is to assess the effect of *adhering to intervention*, select the deviations from intended intervention that should be addressed (at least one must be checked):

- ☐ occurrence of non-protocol interventions
- ☐ failures in implementing the intervention that could have affected the outcome
- ☐ non-adherence to their assigned intervention by trial participants

Which of the following sources were obtained to help inform the risk-of-bias assessment? (tick as many as apply)

- ☐ Journal article(s) with results of the trial
- ☐ Trial protocol
- ☐ Statistical analysis plan (SAP)
- ☐ Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
- ☐ Company-owned trial registry record (e.g. GSK Clinical Study Register record)
- ☐ “Grey literature” (e.g. unpublished thesis)
- ☐ Conference abstract(s) about the trial
- ☐ Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
- ☐ Research ethics application
- ☐ Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
- ☐ Personal communication with trialist
- ☐ Personal communication with the sponsor

8.1 Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in **red** are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

DOMAIN 1: RISK OF BIAS ARISING FROM THE RANDOMIZATION PROCESS

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?		<u>Y</u> / <u>PY</u> / PN / N / NI
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		<u>Y</u> / <u>PY</u> / PN / N / NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?		Y / PY / <u>PN</u> / <u>N</u> / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias arising from the randomization process?		NA / Favours experimental / Favours comparator / Towards null / Away from null / Unpredictable

DOMAIN 2: RISK OF BIAS DUE TO DEVIATIONS FROM THE INTENDED INTERVENTIONS (*EFFECT OF ASSIGNMENT TO INTERVENTION*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?		Y / PY / <u>PN</u> / <u>N</u> / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / <u>PN</u> / <u>N</u> / NI
2.3. If <u>Y/PY</u> /NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?		NA / Y / PY / <u>PN</u> / <u>N</u> / NI
2.4 If <u>Y/PY</u> to 2.3: Were these deviations likely to have affected the outcome?		NA / Y / PY / <u>PN</u> / <u>N</u> / NI
2.5. If <u>Y/PY</u> /NI to 2.4: Were these deviations from intended intervention balanced between groups?		NA / <u>Y</u> / <u>PY</u> / <u>PN</u> / <u>N</u> / NI
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?		<u>Y</u> / <u>PY</u> / <u>PN</u> / <u>N</u> / NI
2.7 If <u>N/PN</u> /NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA / Y / PY / <u>PN</u> / <u>N</u> / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null / Away from null / Unpredictable

DOMAIN 2: RISK OF BIAS DUE TO DEVIATIONS FROM THE INTENDED INTERVENTIONS (*EFFECT OF ADHERING TO INTERVENTION*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?		Y / PY / <u>PN</u> / <u>N</u> / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / <u>PN</u> / <u>N</u> / NI
2.3. [If applicable:] If Y/PY/NI to 2.1 or 2.2: Were important non-protocol interventions balanced across intervention groups?		NA / <u>Y</u> / <u>PY</u> / <u>PN</u> / <u>N</u> / NI
2.4. [If applicable:] Were there failures in implementing the intervention that could have affected the outcome?		NA / Y / PY / <u>PN</u> / <u>N</u> / NI
2.5. [If applicable:] Was there non-adherence to the assigned intervention regimen that could have affected participants' outcomes?		NA / Y / PY / <u>PN</u> / <u>N</u> / NI
2.6. If N/PN/NI to 2.3, or Y/PY/NI to 2.4 or 2.5: Was an appropriate analysis used to estimate the effect of adhering to the intervention?		NA / <u>Y</u> / <u>PY</u> / <u>PN</u> / <u>N</u> / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null / Away from null / Unpredictable

DOMAIN 3: MISSING OUTCOME DATA

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?		<u>Y</u> / <u>PY</u> / <u>PN</u> / <u>N</u> / NI
3.2 If <u>N</u> / <u>PN</u> / <u>NI</u> to 3.1: Is there evidence that the result was not biased by missing outcome data?		NA / <u>Y</u> / <u>PY</u> / <u>PN</u> / <u>N</u>
3.3 If <u>N</u> / <u>PN</u> to 3.2: Could missingness in the outcome depend on its true value?		NA / <u>Y</u> / <u>PY</u> / <u>PN</u> / <u>N</u> / NI
3.4 If <u>Y</u> / <u>PY</u> / <u>NI</u> to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA / <u>Y</u> / <u>PY</u> / <u>PN</u> / <u>N</u> / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to missing outcome data?		NA / Favours experimental / Favours comparator / Towards null / Away from null / Unpredictable

DOMAIN 4: RISK OF BIAS IN MEASUREMENT OF THE OUTCOME

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?		Y / PY / <u>PN</u> / <u>N</u> / NI
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?		Y / PY / <u>PN</u> / <u>N</u> / NI
4.3 If <u>N/PN/NI</u> to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?		NA / Y / PY / <u>PN</u> / <u>N</u> / NI
4.4 If <u>Y/PY/NI</u> to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?		NA / Y / PY / <u>PN</u> / <u>N</u> / NI
4.5 If <u>Y/PY/NI</u> to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NA / Y / PY / <u>PN</u> / <u>N</u> / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias in measurement of the outcome?		NA / Favours experimental / Favours comparator / Towards null / Away from null / Unpredictable

DOMAIN 5: RISK OF BIAS IN SELECTION OF THE REPORTED RESULT

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?		<u>Y</u> / <u>PY</u> / <u>PN</u> / <u>N</u> / NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?		<u>Y</u> / <u>PY</u> / <u>PN</u> / <u>N</u> / NI
5.3 ... multiple eligible analyses of the data?		<u>Y</u> / <u>PY</u> / <u>PN</u> / <u>N</u> / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?		NA / Favours experimental / Favours comparator / Towards null / Away from null / Unpredictable

OVERALL RISK OF BIAS

Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the overall predicted direction of bias for this outcome?		NA / Favours experimental / Favours comparator / Towards null / Away from null / Unpredictable



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THE RISK OF BIAS IN NON-RANDOMIZED STUDIES – OF INTERVENTIONS (ROBINS-I) ASSESSMENT TOOL

(version for cohort-type studies)

Developed by: Jonathan AC Sterne, Miguel A Hernán, Barnaby C Reeves, Jelena Savović, Nancy D Berkman, Meera Viswanathan, David Henry, Douglas G Altman, Mohammed T Ansari, Isabelle Boutron, James Carpenter, An-Wen Chan, Rachel Churchill, Asbjørn Hróbjartsson, Jamie Kirkham, Peter Jüni, Yoon Loke, Terri Pigott, Craig Ramsay, Deborah Regidor, Hannah Rothstein, Lakhbir Sandhu, Pasqualina Santaguida, Holger J Schünemann, Beverly Shea, Ian Shrier, Peter Tugwell, Lucy Turner, Jeffrey C Valentine, Hugh Waddington, Elizabeth Waters, Penny Whiting and Julian PT Higgins

Version 1 August 2016

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ROBINS-I tool (Stage I): At protocol stage

9 SPECIFY THE REVIEW QUESTION

Participants

Experimental intervention

Comparator

Outcomes

10 LIST THE CONFOUNDING DOMAINS RELEVANT TO ALL OR MOST STUDIES

--

List co-interventions that could be different between intervention groups and that could impact on outcomes

--

ROBINS-I tool (Stage II): For each study

11 SPECIFY A TARGET RANDOMIZED TRIAL SPECIFIC TO THE STUDY

Design Individually randomized / Cluster randomized / Matched (e.g. cross-over)

Participants

Experimental intervention

Comparator

12 IS YOUR AIM FOR THIS STUDY...?

- ☐ to assess the effect of *assignment to* intervention
- ☐ to assess the effect of *starting and adhering to* intervention

13 SPECIFY THE OUTCOME

Specify which outcome is being assessed for risk of bias (typically from among those earmarked for the Summary of Findings table). Specify whether this is a proposed benefit or harm of intervention.

--

14 SPECIFY THE NUMERICAL RESULT BEING ASSESSED

In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure, or paragraph) that uniquely defines the result being assessed.

--

15 PRELIMINARY CONSIDERATION OF CONFOUNDERS

Complete a row for each important confounding domain (i) listed in the review protocol; and (ii) relevant to the setting of this particular study, or which the study authors identified as potentially important.

“Important” confounding domains are those for which, in the context of this study, adjustment is expected to lead to a clinically important change in the estimated effect of the intervention. “Validity” refers to whether the confounding variable or variables fully measure the domain, while “reliability” refers to the precision of the measurement (more measurement error means less reliability).

(i) Confounding domains listed in the review protocol				
Confounding domain	Measured variable(s)	Is there evidence that controlling for this variable was unnecessary?*	Is the confounding domain measured validly and reliably by this variable (or these variables)?	OPTIONAL: Is failure to adjust for this variable (alone) expected to favour the experimental intervention or the comparator?
			Yes / No / No information	Favour experimental / Favour comparator / No information

(ii) Additional confounding domains relevant to the setting of this particular study, or which the study authors identified as important				
Confounding domain	Measured variable(s)	Is there evidence that controlling for this variable was unnecessary?*	Is the confounding domain measured validly and reliably by this variable (or these variables)?	OPTIONAL: Is failure to adjust for this variable (alone) expected to favour the experimental intervention or the comparator?
			Yes / No / No information	Favour experimental / Favour comparator / No information

* In the context of a particular study, variables can be demonstrated not to be confounders and so not included in the analysis: (a) if they are not predictive of the outcome; (b) if they are not predictive of intervention; or (c) because adjustment makes no or minimal difference to the estimated effect of the primary parameter. Note that “no statistically significant association” is not the same as “not predictive”.

PRELIMINARY CONSIDERATION OF CO-INTERVENTIONS

Complete a row for each important co-intervention (i) listed in the review protocol; and (ii) relevant to the setting of this particular study, or which the study authors identified as important.

“Important” co-interventions are those for which, in the context of this study, adjustment is expected to lead to a clinically important change in the estimated effect of the intervention.

(i) Co-interventions listed in the review protocol		
Co-intervention	Is there evidence that controlling for this co-intervention was unnecessary (e.g. because it was not administered)?	Is presence of this co-intervention likely to favour outcomes in the experimental intervention or the comparator
		Favour experimental / Favour comparator / No information
		Favour experimental / Favour comparator / No information
		Favour experimental / Favour comparator / No information

(ii) Additional co-interventions relevant to the setting of this particular study, or which the study authors identified as important		
Co-intervention	Is there evidence that controlling for this co-intervention was unnecessary (e.g. because it was not administered)?	Is presence of this co-intervention likely to favour outcomes in the experimental intervention or the comparator
		Favour experimental / Favour comparator / No information
		Favour experimental / Favour comparator / No information
		Favour experimental / Favour comparator / No information

16 RISK OF BIAS ASSESSMENT (COHORT-TYPE STUDIES)

Responses underlined in green are potential markers for low risk of bias, and responses in **red** are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Bias domain	Signalling questions	Elaboration	Response options
Bias due to confounding	1.1 Is there potential for confounding of the effect of intervention in this study? If <u>N/PN</u> to 1.1: the study can be considered to be at low risk of bias due to confounding and no further signalling questions need be considered	In rare situations, such as when studying harms that are very unlikely to be related to factors that influence treatment decisions, no confounding is expected and the study can be considered to be at low risk of bias due to confounding, equivalent to a fully randomized trial. There is no NI (No information) option for this signalling question.	Y / PY / <u>PN</u> / N
	If Y/PY to 1.1: determine whether there is a need to assess time-varying confounding:		
	1.2. Was the analysis based on splitting participants' follow up time according to intervention received? If N/PN, answer questions relating to baseline confounding (1.4 to 1.6) If Y/PY, proceed to question 1.3.	If participants could switch between intervention groups then associations between intervention and outcome may be biased by time-varying confounding. This occurs when prognostic factors influence switches between intended interventions.	NA / Y / PY / PN / N / NI
	1.3. Were intervention discontinuations or switches likely to be related to factors that are prognostic for the outcome? If N/PN, answer questions relating to baseline confounding (1.4 to 1.6) If Y/PY, answer questions relating to both baseline and time-varying confounding (1.7 and 1.8)	If intervention switches are unrelated to the outcome, for example when the outcome is an unexpected harm, then time-varying confounding will not be present and only control for baseline confounding is required.	NA / Y / PY / PN / N / NI
	Questions relating to baseline confounding only		
	1.4. Did the authors use an appropriate analysis method that controlled for all the important confounding domains?	Appropriate methods to control for measured confounders include stratification, regression, matching, standardization, and inverse probability weighting. They may control for individual variables or for the estimated propensity score. Inverse probability weighting is based on a function of the propensity score. Each method depends on the assumption that there is no unmeasured or residual confounding.	NA / <u>Y / PY</u> / PN / N / NI

	1.5. If Y/PY to 1.4: Were confounding domains that were controlled for measured validly and reliably by the variables available in this study?	Appropriate control of confounding requires that the variables adjusted for are valid and reliable measures of the confounding domains. For some topics, a list of valid and reliable measures of confounding domains will be specified in the review protocol but for others such a list may not be available. Study authors may cite references to support the use of a particular measure. If authors control for confounding variables with no indication of their validity or reliability pay attention to the subjectivity of the measure. Subjective measures (e.g. based on self-report) may have lower validity and reliability than objective measures such as lab findings.	NA / Y / PY / PN / N / NI
	1.6. Did the authors control for any post-intervention variables that could have been affected by the intervention?	Controlling for post-intervention variables that are affected by intervention is not appropriate. Controlling for mediating variables estimates the direct effect of intervention and may introduce bias. Controlling for common effects of intervention and outcome introduces bias.	NA / Y / PY / PN / N / NI
	Questions relating to baseline and time-varying confounding		
	1.7. Did the authors use an appropriate analysis method that adjusted for all the important confounding domains and for time- varying confounding?	Adjustment for time-varying confounding is necessary to estimate the effect of starting and adhering to intervention, in both randomized trials and NRSI. Appropriate methods include those based on inverse probability weighting. Standard regression models that include time-updated confounders may be problematic if time-varying confounding is present.	NA / Y / PY / PN / N / NI
	1.8. If Y/PY to 1.7: Were confounding domains that were adjusted for measured validly and reliably by the variables available in this study?	See 1.5 above.	NA / Y / PY / PN / N / NI
	Risk of bias judgement	See Table 1.	Low / Moderate / Serious / Critical / NI

	Optional: What is the predicted direction of bias due to confounding?	Can the true effect estimate be predicted to be greater or less than the estimated effect in the study because one or more of the important confounding domains was not controlled for? Answering this question will be based on expert knowledge and results in other studies and therefore can only be completed after all of the studies in the body of evidence have been reviewed. Consider the potential effect of each of the unmeasured domains and whether all important confounding domains not controlled for in the analysis would be likely to change the estimate in the same direction, or if one important confounding domain that was not controlled for in the analysis is likely to have a dominant impact.	Favours experimental / Favours comparator / Unpredictable
Bias in selection of participants into the study	<p>2.1. Was selection of participants into the study (or into the analysis) based on participant characteristics observed after the start of intervention?</p> <p>If N/PN to 2.1: go to 2.4</p> <p>2.2. If Y/PY to 2.1: Were the post- intervention variables that influenced selection likely to be associated with intervention?</p> <p>2.3 If Y/PY to 2.2: Were the post- intervention variables that influenced selection likely to be influenced by the outcome or a cause of the outcome?</p>	<p>This domain is concerned only with selection into the study based on participant characteristics observed <i>after</i> the start of intervention. Selection based on characteristics observed <i>before</i> the start of intervention can be addressed by controlling for imbalances between experimental intervention and comparator groups in baseline characteristics that are prognostic for the outcome (baseline confounding). Selection bias occurs when selection is related to an effect of either intervention or a cause of intervention and an effect of either the outcome or a cause of the outcome. Therefore, the result is at risk of selection bias if selection into the study is related to both the intervention and the outcome.</p>	<p>Y / PY / PN / N / NI</p> <p>NA / Y / PY / PN / N / NI</p> <p>NA / Y / PY / PN / N / NI</p>
	2.4. Do start of follow-up and start of intervention coincide for most participants?	If participants are not followed from the start of the intervention then a period of follow up has been excluded, and individuals who experienced the outcome soon after intervention will be missing from analyses. This problem may occur when prevalent, rather than new (incident), users of the intervention are included in analyses.	Y / PY / PN / N / NI

	2.5. If Y/PY to 2.2 and 2.3, or N/PN to 2.4: Were adjustment techniques used that are likely to correct for the presence of selection biases?	It is in principle possible to correct for selection biases, for example by using inverse probability weights to create a pseudo-population in which the selection bias has been removed, or by modelling the distributions of the missing participants or follow up times and outcome events and including them using missing data methodology. However such methods are rarely used and the answer to this question will usually be “No.”	NA / Y / PY / PN / N / NI
	Risk of bias judgement	See Table 1.	Low / Moderate / Serious / Critical / NI
	Optional: What is the predicted direction of bias due to selection of participants into the study?	If the likely direction of bias can be predicted, it is helpful to state this. The direction might be characterized either as being towards (or away from) the null, or as being in favour of one of the interventions.	Favours experimental / Favours comparator / Towards null / Away from null / Unpredictable
Bias in classification of interventions	3.1 Were intervention groups clearly defined?	A pre-requisite for an appropriate comparison of interventions is that the interventions are well defined. Ambiguity in the definition may lead to bias in the classification of participants. For individual-level interventions, criteria for considering individuals to have received each intervention should be clear and explicit, covering issues such as type, setting, dose, frequency, intensity and/or timing of intervention. For population-level interventions (e.g. measures to control air pollution), the question relates to whether the population is clearly defined, and the answer is likely to be ‘Yes.’	Y / PY / PN / N / NI
	3.2 Was the information used to define intervention groups recorded at the start of the intervention?	In general, if information about interventions received is available from sources that could not have been affected by subsequent outcomes, then differential misclassification of intervention status is unlikely. Collection of the information at the time of the intervention makes it easier to avoid such misclassification. For population-level interventions (e.g. measures to control air pollution), the answer to this question	Y / PY / PN / N / NI

		is likely to be 'Yes.'	
	3.3 Could classification of intervention status have been affected by knowledge of the outcome or risk of the outcome?	Collection of the information at the time of the intervention may not be sufficient to avoid bias. The way in which the data are collected for the purposes of the NRSI should also avoid misclassification.	Y / PY / <u>PN</u> / <u>N</u> / NI
	Risk of bias judgement	See Table 1.	Low / Moderate / Serious / Critical / NI
	Optional: What is the predicted direction of bias due to measurement of outcomes or interventions?	If the likely direction of bias can be predicted, it is helpful to state this. The direction might be characterized either as being towards (or away from) the null, or as being in favour of one of the interventions.	Favours experimental / Favours comparator / Towards null / Away from null / Unpredictable
	If your aim for this study is to assess the effect of assignment to intervention, answer questions 4.1 and 4.2		

Bias due to deviations from intended interventions	4.1. Were there deviations from the intended intervention beyond what would be expected in usual practice?	<p>Deviations that happen in usual practice following the intervention (for example, cessation of a drug intervention because of acute toxicity) are part of the intended intervention and therefore do not lead to bias in the effect of assignment to intervention.</p> <p>Deviations may arise due to expectations of a difference between intervention and comparator (for example because participants feel unlucky to have been assigned to the comparator group and therefore seek the active intervention, or components of it, or other interventions). Such deviations are not part of usual practice, so may lead to biased effect estimates. However these are not expected in observational studies of individuals in routine care.</p>	Y / PY / <u>PN</u> / <u>N</u> / NI
	4.2. If Y/PY to 4.1: Were these deviations from intended intervention unbalanced between groups <i>and</i> likely to have affected the outcome?	Deviations from intended interventions that do not reflect usual practice will be important if they affect the outcome, but not otherwise. Furthermore, bias will arise only if there is imbalance in the deviations across the two groups.	NA / Y / PY / <u>PN</u> / <u>N</u> / NI
	If your aim for this study is to assess the effect of starting and adhering to intervention, answer questions 4.3 to 4.6		
	4.3. Were important co-interventions balanced across intervention groups?	Risk of bias will be higher if unplanned co-interventions were implemented in a way that would bias the estimated effect of intervention. Co- interventions will be important if they affect the outcome, but not otherwise. Bias will arise only if there is imbalance in such co-interventions between the intervention groups. Consider the co-interventions, including any pre-specified co-interventions, that are likely to affect the outcome and to have been administered in this study. Consider whether these co- interventions are balanced between intervention groups.	<u>Y</u> / PY / PN / N / NI
	4.4. Was the intervention implemented successfully for most participants?	Risk of bias will be higher if the intervention was not implemented as intended by, for example, the health care professionals delivering care during the trial. Consider whether implementation of the intervention was successful for most participants.	<u>Y</u> / PY / PN / N / NI

	4.5. Did study participants adhere to the assigned intervention regimen?	Risk of bias will be higher if participants did not adhere to the intervention as intended. Lack of adherence includes imperfect compliance, cessation of intervention, crossovers to the comparator intervention and switches to another active intervention. Consider available information on the proportion of study participants who continued with their assigned	Y / PY / PN / N / NI
		intervention throughout follow up, and answer 'No' or 'Probably No' if this proportion is high enough to raise concerns. Answer 'Yes' for studies of interventions that are administered once, so that imperfect adherence is not possible. We distinguish between analyses where follow-up time after interventions switches (including cessation of intervention) is assigned to (1) the new intervention or (2) the original intervention. (1) is addressed under time- varying confounding, and should not be considered further here.	
	4.6. If N/PN to 4.3, 4.4 or 4.5: Was an appropriate analysis used to estimate the effect of starting and adhering to the intervention?	It is possible to conduct an analysis that corrects for some types of deviation from the intended intervention. Examples of appropriate analysis strategies include inverse probability weighting or instrumental variable estimation. It is possible that a paper reports such an analysis without reporting information on the deviations from intended intervention, but it would be hard to judge such an analysis to be appropriate in the absence of such information. Specialist advice may be needed to assess studies that used these approaches. If everyone in one group received a co-intervention, adjustments cannot be made to overcome this.	NA / Y / PY / PN / N / NI
	Risk of bias judgement	See Table 2	

	Optional: What is the predicted direction of bias due to deviations from the intended interventions?	If the likely direction of bias can be predicted, it is helpful to state this. The direction might be characterized either as being towards (or away from) the null, or as being in favour of one of the interventions.	
Bias due to missing data	5.1 Were outcome data available for all, or nearly all, participants?	“Nearly all” should be interpreted as “enough to be confident of the findings,” and a suitable proportion depends on the context. In some situations, availability of data from 95% (or possibly 90%) of the participants may be sufficient, providing that events of interest are reasonably common in both intervention groups. One aspect of this is that review authors would ideally try and locate an analysis plan for the study.	<u>Y / PY</u> / <u>PN / N</u> / NI
	5.2 Were participants excluded due to missing data on intervention status?	Missing intervention status may be a problem. This requires that the <i>intended</i> study sample is clear, which it may not be in practice.	Y / PY / <u>PN / N</u> / NI
	5.3 Were participants excluded due to missing data on other variables needed for the analysis?	This question relates particularly to participants excluded from the analysis because of missing information on confounders that were controlled for in the analysis.	Y / PY / <u>PN / N</u> / NI
	5.4 If PN/N to 5.1, or Y/PY to 5.2 or 5.3 : Are the proportion of participants and reasons for missing data similar across interventions?	This aims to elicit whether either (i) differential proportion of missing observations or (ii) differences in reasons for missing observations could substantially impact on our ability to answer the question being addressed. “Similar” includes some minor degree of discrepancy across intervention groups as expected by chance.	NA / <u>Y / PY</u> / PN / N / NI

	5.5 If PN/N to 5.1, or Y/PY to 5.2 or 5.3: Is there evidence that results were robust to the presence of missing data?	Evidence for robustness may come from how missing data were handled in the analysis and whether sensitivity analyses were performed by the investigators, or occasionally from additional analyses performed by the systematic reviewers. It is important to assess whether assumptions employed in analyses are clear and plausible. Both content knowledge and statistical expertise will often be required for this. For instance, use of a statistical method such as multiple imputation does not guarantee an appropriate answer. Review authors should seek naïve (complete-case) analyses for comparison, and clear differences between complete-case and multiple imputation-based findings should lead to careful assessment of the validity of the methods used.	NA / Y / PY / PN / N / NI
	Risk of bias judgement	See Table 2	Low / Moderate / Serious / Critical / NI
	Optional: What is the predicted direction of bias due to missing data?	If the likely direction of bias can be predicted, it is helpful to state this. The direction might be characterized either as being towards (or away from) the null, or as being in favour of one of the interventions.	Favours experimental / Favours comparator / Towards null / Away from null / Unpredictable
Bias in measurement of outcomes	6.1 Could the outcome measure have been influenced by knowledge of the intervention received?	Some outcome measures involve negligible assessor judgment, e.g. all-cause mortality or non-repeatable automated laboratory assessments. Risk of bias due to measurement of these outcomes would be expected to be low.	Y / PY / PN / N / NI

	6.2 Were outcome assessors aware of the intervention received by study participants?	If outcome assessors were blinded to intervention status, the answer to this question would be 'No'. In other situations, outcome assessors may be unaware of the interventions being received by participants despite there being no active blinding by the study investigators; the answer this question would then also be 'No'. In studies where participants report their outcomes themselves, for example in a questionnaire, the outcome assessor is the study participant. In an observational study, the answer to this question will usually be 'Yes' when the participants report their outcomes themselves.	Y / PY / <u>PN</u> / <u>N</u> / NI
	6.3 Were the methods of outcome assessment comparable across intervention groups?	Comparable assessment methods (i.e. data collection) would involve the same outcome detection methods and thresholds, same time point, same definition, and same measurements.	<u>Y</u> / <u>PY</u> / <u>PN</u> / <u>N</u> / NI
	6.4 Were any systematic errors in measurement of the outcome related to intervention received?	This question refers to differential misclassification of outcomes. Systematic errors in measuring the outcome, if present, could cause bias if they are related to intervention or to a confounder of the intervention-outcome relationship. This will usually be due either to outcome assessors being aware of the intervention received or to non-comparability of outcome assessment methods, but there are examples of differential misclassification arising despite these controls being in place.	Y / PY / <u>PN</u> / <u>N</u> / NI
	Risk of bias judgement	See Table 2	Low / Moderate / Serious / Critical / NI
	Optional: What is the predicted direction of bias due to measurement of outcomes?	If the likely direction of bias can be predicted, it is helpful to state this. The direction might be characterized either as being towards (or away from) the null, or as being in favour of one of the interventions.	Favours experimental / Favours comparator / Towards null / Away from null / Unpredictable

Bias in selection of the reported result	Is the reported effect estimate likely to be selected, on the basis of the results, from...		
	7.1.....multiple outcome <i>measurements</i> within the outcome domain?	For a specified outcome domain, it is possible to generate multiple effect estimates for different measurements. If multiple measurements were made, but only one or a subset is reported, there is a risk of selective reporting on the basis of results.	Y / PY / <u>PN</u> / <u>N</u> / NI
	7.2 ... multiple <i>analyses</i> of the intervention- outcome relationship?	Because of the limitations of using data from non-randomized studies for analyses of effectiveness (need to control confounding, substantial missing data, etc), analysts may implement different analytic methods to address these limitations. Examples include unadjusted and adjusted models; use of final value vs change from baseline vs analysis of covariance; different transformations of variables; a continuously scaled outcome converted to categorical data with different cut-points; different sets of covariates used for adjustment; and different analytic strategies for dealing with missing data. Application of such methods generates multiple estimates of the effect of the intervention versus the comparator on the outcome. If the analyst does not pre-specify the methods to be applied, and multiple estimates are generated but only one or a subset is reported, there is a risk of selective reporting on the basis of results.	Y / PY / <u>PN</u> / <u>N</u> / NI
	7.3 ... different <i>subgroups</i> ?	Particularly with large cohorts often available from routine data sources, it is possible to generate multiple effect estimates for different subgroups or simply to omit varying proportions of the original cohort. If multiple estimates are generated but only one or a subset is reported, there is a risk of selective reporting on the basis of results.	Y / PY / <u>PN</u> / <u>N</u> / NI
	Risk of bias judgement	See Table 2	Low / Moderate / Serious / Critical / NI

	Optional: What is the predicted direction of bias due to selection of the reported result?	If the likely direction of bias can be predicted, it is helpful to state this. The direction might be characterized either as being towards (or away from) the null, or as being in favour of one of the interventions.	Favours experimental / Favours comparator / Towards null / Away from null / Unpredictable
Overall bias	Risk of bias judgement	See Table 3.	Low / Moderate / Serious / Critical / NI
	Optional: What is the overall predicted direction of bias for this outcome?		Favours experimental / Favours comparator / Towards null / Away from null / Unpredictable



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SELF-REPORT OF WORKING IN PAIRS

	My contribution in percentage of 100%	
I have contributed with:	Student 1	Student 2
Planning of the degree project, including background literature, theoretical/conceptual framework, problem formulation, aim and possible study questions and methods.	50%	50%
Implementation of sampling, data collection, data analysis, and interpretation of data.	50%	50%
Ethical considerations and ethical discussion.	50%	50%
Reporting in the form of a thesis, including a critical discussion between the authors about the scientific content in the thesis	50%	50%
Agreement to be accountable for all parts of the degree project (yes/no question)	yes	yes



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