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MULTIDIMENSIONAL APPROACH INCLUDING PHYSICAL ACTIVITY IN REDUCING OBESITY IN CHILDREN AND TEENAGERS

A Systematic Literature Review

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Sammanfattning

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Bakgrund Barn som växer upp med fetma har ökad risk att få ett antal fetmarelaterade hälsoproblem som diabetes, hjärt-kärlsjukdomar, funktionsnedsättningar och för tidig död. Fetma beror på ett antal faktorer. Och det finns olika interventioner med en kombination av multidiciplinära insatser för barn och ungdomar med fetma. En studie behövs gällande hur multidimensionell intervention som inkluderar fysiskt aktivitet effektivt kan genomföras för att behandla fetma risk hos unga.

Syfte Att genomföra en systematisk litteraturöversikt med syfte att undersöka om multidimensionell intervention, inklusive fysiska aktiviteter är effektiv för att minska fetma och påverka aktivitetsmönstret hos barn och ungdomar.

Metod Systematisk litteraturöversikt av randomiserade kontrollade studier som undersöker olika multidimensionella interventioner och tillämpningar av fysisk aktivitet hos barn och ungdomar 2-18 år med övervikt eller fetma. För att kontrollera kvaliteten på de tio utvalda studierna användes kvalitetsgranskningsformulär som rekommenderas av Cochrane Collaboration.

Resultat Positivt förändringar i livsstil och dagliga aktiviteter hos överviktiga barn noterades efter multidimensionell intervention som inkluderade miljöförändringar och motivationsstöd. Två studier rapporterade minskning av stillasittande tid, förbättring av familjeaktiviteter, matvanor och självreglerande färdigheter. Tre studier rapporterade minskning i BMI eller BMI z-poäng för barn i interventionsgrupperna. Fyra studier rapporterade minskning av kroppsfett och midjaomkrets, men ingen förändring i BMI.

Slutsats Effekten av fysisk aktivitet för att förhindra fetma hos barn är svag, den mest effekten noterades i multidimensionella interventioner som använde övervakad träning och verktyg för att främja fysisk aktivitet, beteendehantering som innebär förändrade attityder till fysisk aktivitet, informationsstöd, näringsråd, social stöd från lärare och föräldrar och förbättringar av miljö- och institutionella förhållanden för att främja fysisk aktivitet.

Abstract

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Background: Children growing up with obesity are at a higher risk for a number of obesity-related health issues, such as diabetes, cardiovascular disease, disability, and premature death. Obesity is a result of multiple factors; thus, the aim of reducing childhood obesity can only be accomplished through a combination of multidisciplinary efforts. An evaluation of how multidimensional interventions, including physical activity, can be effectively implemented for management of overweight risk in children needs to be performed.

Aim: To perform a systematic literature review and to assess if the application of multidimensional interventions, including physical activities, was effective in reducing obesity and affecting the activity patterns in children and teenagers.

Method: A systematic literature review of randomized control trials that discuss different approaches of multidimensional interventions and applications of physical activity in children and adolescents 2–18 years old who were overweight or obese has been chosen as the study design. To check the quality of the ten selected studies, the risk-of-bias assessment tool, recommended by the Cochrane Collaboration, was used.

Result: Significant changes in lifestyle and daily activities in overweight children were noticed after multidimensional interventions that included environmental changes and motivational support. Two studies reported decreases in sedentary times and improvements in family activities, feeding habits, and self-regulatory skills. Three studies reported reductions in the BMIs or BMI z-scores of children in the intervention groups; however, four studies reported reductions of body fat and waist circumferences but no changes in BMIs.

Conclusion: The impact of physical activity for preventing obesity in children is weak; the largest impact was noticed in multidimensional interventions that used supervised exercise and tools for promoting physical activities, behavioral management that involved changing attitudes toward physical activity, informational support and nutrition advice, social support from teachers and parents, and improvements in environmental and institutional conditions to promote physical activity.

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1. Background

Obesity and being overweight can be defined as an excess of body fat. It can usually be the result of an imbalance between energy intake and expenditure, which is associated with lifestyle and dietary intake preferences (1). The excess weight can increase the risk of disability, defined as an impairment in activities of daily living (ADL), which is a term referring to a person's daily activities. (2) Risk factors for child obesity include dietary intake, physical activity, and sedentary behavior (3). Also, activity level, environmental factors, sociocultural factors, family factors, and psychological factors are important in the development of obesity and being overweight (3).

In recent decades, obesity became a significant public health concern worldwide. According to data from the Health Behavior in School-aged Children (HBSC) survey (2009/2010) in Sweden, the prevalence of adolescents who are overweight or obese is up to 24% of boys and 16% of girls among 11-year-olds (4). Estimates from the first round (2007/2008) of the WHO European Childhood Obesity Surveillance Initiative (COSI) in Sweden showed that among 7-year-olds, 23.5% of boys and 22.0% of girls were overweight and 6.8% and 5.1%, respectively, were obese (5).

Children who grow up with obesity are at a higher risk for a number of obesity-related health issues, such as diabetes, cardiovascular disease, disability, and premature death (6). Usually, obesity is a result of multiple factors, thus, the aim of reducing childhood obesity can only be accomplished through a combination of multidisciplinary efforts. That's why public health needs to address childhood obesity. Whole population approaches can be applied with interventions for high risk obesity groups and intensive interventions for those who are overweight (7). Physical activity, defined as bodily movement produced by skeletal muscles that requires energy expenditure, and fitness are reported to have a positive effect on the cognitive development and academic achievement in children and adolescents (8, 9).
Because of recent changes in the lifestyles that modern children experience (increased times spent interacting with electronic devices), they spend less time outdoors. Increased sedentary time results in a rise of the risk of developing obesity (3).

In cases where a child's obesity or a co-morbid disorder limits his or her participation in the occupations of self-care and daily activities, occupational therapy can be a tool for the assessment, intervention, and prevention of obesity. This allows a child to participate in his or her meaningful occupations, which may include play, physical activity, participation in school, and mealtimes (10). Through the use of meaningful occupations, the child will participate in activities that add meaning, value, and purpose to his or her life and at the same time improve his or her health (11).

A child's involvement in daily activities is a very important subject for occupational therapy (OT) because the interventions in daily activities include the complex reorganization of habits, performance, capacity, and environmental conditions (12). Involvement in activities is giving the person a feeling of well-being by enriching positive feelings, which consequently makes the activity meaningful for the person, and allows the creation of new activity patterns (12). Those patterns are formed by the individual's self-perception, interests, and goals (12). Through adaptation to those patterns, children can develop positive feelings toward new daily activities. Specifically children's involvement in play is crucial for their development (14), which provides kids with opportunities to develop competency and experience mastery for the further

development of advanced skills (15). According to the model of human occupation (MOHO) (12), the environment includes not only physical space but also social parts, such as people or animals.

The goal of using OT to work with obese or overweight children should be to develop a comfortable environment to get the children more involved in the activities that will, in turn, make them feel better about themselves (12). "Interaction" with the other children through play is important for the development of children, not only physically but also mentally, because a large portion of mental identity and development occurs during early childhood (15). It is important to focus on the dynamics of occupational engagement and consider the patient's efforts as a contribution for the change (13).

Professional organizations, such as primary care and medical organizations specifically working with obesity management, confirm the need for a multidimensional approach. This should include education and training for health care professionals to deal with this growing health problem (16). Collaborative approaches to chronic disease management, including OT, between the patient and care provider are emphasized to bring individualized, self-managed care (16).

OT practitioners can provide services in various settings, such as school-based primary care and community-based programming, by using tools and frameworks to implement a healthy lifestyle, including physical activities, healthy meal preparations, and strategies to prevent bullying (17).

The importance of education and availability of resources and tools should also be considered. This will help health care professionals provide comprehensive, individualized obesity treatments (16). The family and people in the school environment (e.g. teachers, classmates) can have serious implications for a child's physical health and eating habits. For example, food choices can be influenced by family members and friends, as well as attitudes toward physical activities. A family-centered perspective, where there is involvement of parents and other family members in the planning or evaluation of interventions, is very important because children from age 7–11 spend the vast majorities of their time at home with relatives (18). Family members can be very helpful in adapting new activity patterns for overweight children.

MOHO has a client-centered approach, in which the patient is not the passive target of an intervention but an active part in his or her care and the decision-making process (19). The environmental impact is also discussed in MOHO, indicating that environment choice can be a useful tool for motivation in the formation of activity patterns (12).

On OT overview, the volitional development is very important for self-determination and independence (12,14). Volition is different, because it is comprised of a person's values, interests, and senses of personal causation, meaning a child's sense of effectiveness or competence in his or her abilities. According to Danielsen et al., overweight children have lower self-esteem scores than normal-weight children. Athletic competence and physical appearance were the most impaired in overweight children (20).

Children's activity choices and the decisions they make are shaping their futures; thus, selecting activities, what to do and how to do them, is crucial for therapy. Also, the

long-term change in therapy occurs if there is a commitment to accomplish the goal. Studying previous experiences is helpful for making the right decisions in therapy and helpful in setting children into certain routines and activities, thus enhancing the effectiveness of the applied therapies.

It is important for occupation therapists to learn the concerns, daily routines, and the relationships of the child and parents to build an occupational profile to include environmental factors, such as the average time spent with devices, potential influences, and recourses of the family.

However, there is still no unified opinion if the application of physical activity has an impact on reducing obesity in children, which is why the goal was to study this subject. However, there are just a few randomized controlled trials available that estimate the effectiveness of interventions promoting physical activity for improving activity patterns and cognitive skills in children and adolescents (21,22). In these few trials, it was concluded that physical activity based on interventions with playground games and short-term, high-intensity interval training were useful for improving academic achievement and health issues and controlling obesity in the short-term; however, the effects diminished with time (21,22).

As a basis for further development of the subject area, there is a need to study how multidimensional interventions, including physical activity, can be effectively implemented for forming new activity patterns in the management of obesity risk in children. This study intends to perform a comprehensive literature study to assess recent findings on this subject.

2. Purpose

To perform a systematic literature review, to assess if the application of multidimensional interventions, including physical activities, was effective in reducing obesity and affecting the activity patterns in children and teenagers.

3. Methods

3.1 Study design

A systematic literature review with a quantitative prospective (23), which includes randomized control trials that discuss different approaches of interventions and applications of physical activity in children and adolescents from 2–18-years-old with obesity or are overweight, was chosen as the study design. A systematic literature study included systematically and critically seeking and reviewing scientific articles on the chosen topic. To check the quality of the selected studies, the risk-of-bias assessment tool, recommended by the Cochrane Collaboration, was used (24).

3.2 Selection

The literature review study consisted of reviewing all available data that met the inclusion criteria: (1) randomized control trials that compared two or more exercise interventions or were compared with a control group; (2) trials with multidimensional

approaches, including physical activity; (3) studies had a follow-up period of 1 month or more, (4) participants of the study were children and adolescents from 2–18-years-old, (5) the children were overweight or obese (data specified by BMI (body mass index) in kg/m2, fat mass or percent body fat), and (6) the articles were published after January 1, 2013, in peer-reviewed journals that were written in English.

3.3 Procedure

To assess needed information, an extensive literature review using PubMed, Web of Science, Scopus, and individual journals was performed within a 5-year time frame. In collaboration with a librarian from Gothenburg University, relevant search words and combinations were developed. The generated search words were set up according to search standards used in common databases: (exercise OR physical activity OR physical fitness OR strength training OR weight training) AND (children OR boys OR girls OR 2-18 years old) AND (overweight OR obesity) AND (BMI OR body mass index OR fat OR body composition OR adipos*) AND random*). The generated search was performed January 24 2018, and resulted in 1,438 entries; from those articles, 685 were published in the last 5 years, and 324 of these were randomized control trials. The results of the database search are presented in Table 1.

Table 1. Database number of papers for the keywords.

Database	Keywords	Result
PubMed	(exercise OR physical activity OR physical fitness OR strength training OR weight training) AND (children OR boys OR girls OR 2–18 years old) AND (overweight OR obesity) AND (BMI OR body mass index OR fat OR body composition OR adipos*) AND (random*)	Standard: 1,438 Articles from last 5 years: 685 Randomized control trials: 324
Scopus	(exercise OR physical activity OR physical fitness OR strength training OR weight training) AND (children OR boys OR girls OR 2–18 years old) AND (overweight OR obesity) AND (bmi OR body mass index OR fat OR body composition OR adipos*) AND (random*)	Standard: 5 Articles from last 5 years: 5 Randomized control trials: 4
Web of Science	(exercise OR physical activity OR physical fitness OR strength training OR weight training) AND (children OR boys OR girls OR 2-18 years old) AND (overweight OR obesity) AND (bmi OR body mass index OR fat OR body composition OR adipos*) AND random*)	Standard: 22,345 Articles from last 5 years: 1,230 Randomized control trials: 384

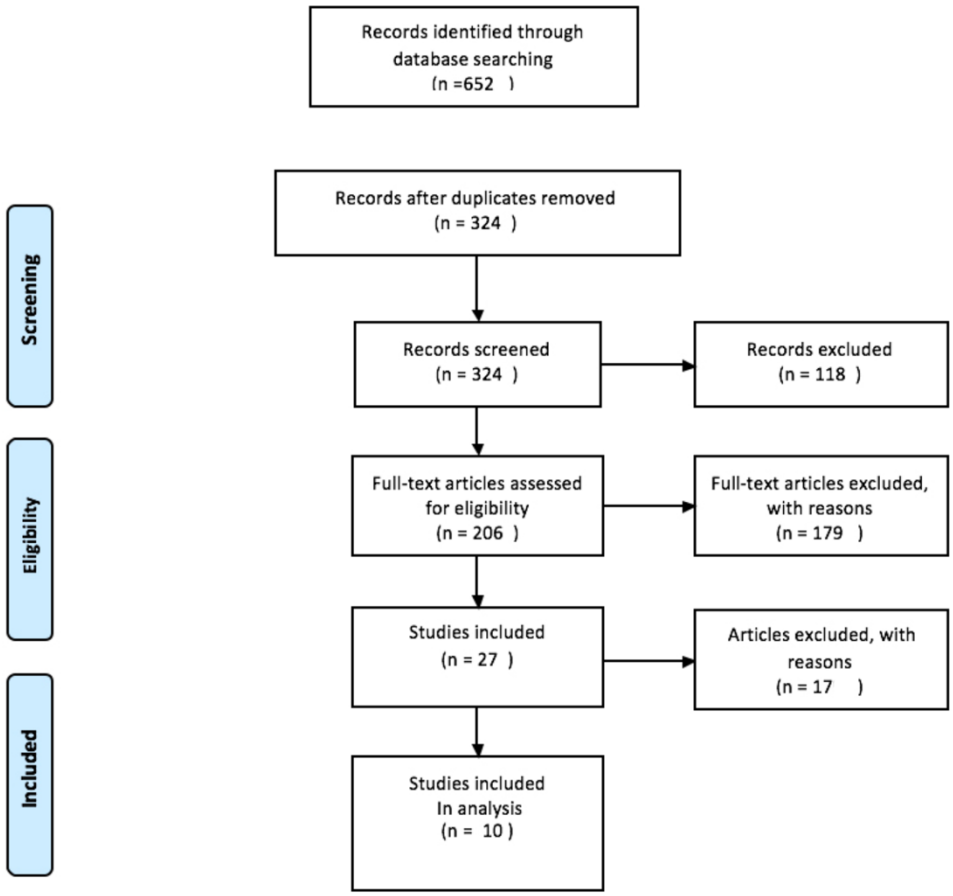

Figure 1. PRISMA flow diagram

3.4 Selection process

Based on the 324 search results from the database search, the first selection of studies was done, excluding duplicates in the title or abstract. This was done by adding all 324 search results in the Endnote Reference Manager and using the “Find duplicates” feature. If there was uncertainty in the title, the abstract was read to find out whether the study would proceed in the selection process. If uncertainty remained after reading the abstract, the study was included for further review in the full text. In this step, 118 of the search results were excluded, and there were 206 studies continued for further review. After extensive checking of the papers to meet the inclusion criteria, 179 papers were excluded (e.g., not RCT, not full text, participants were not children, foreign language, overweight was not the focus, follow-up period was less than 4 weeks, BMI was not measured as an outcome), and 27 were continued for the review.

The remaining 27 studies were checked for completion of peer review before publication. All had undergone this process and, thus, proceeded for relevance assessment according to the SBU’s template (Statens beredning för medicinsk och social utvärdering) (25). During the relevance assessment, there were some studies that were not relevant and were excluded. Henrikson et al. (28) was excluded due to the

nature of the study, which was investigating the environment of obese children but not the impact of physical activity on obese children. Some studies were excluded due to not having clear descriptions of RTC methods or for not having proper control groups (29,31,35,36,53–55). Several studies were excluded for not having relevant outcomes (40–42,48,50–53). Jago et al. (49) and Saunders et al. (56) were excluded because physical activity application was studied in terms of how vigorous exercise changes the level of certain merits in the blood in the short-term, immediately after exercise. In total, 17 studies were excluded, and 10 studies proceeded for further analysis.

The selection process is shown on the PRISMA flow diagram in Figure 1.

3.5 Quality of methodology assessment

To check the quality of the selected studies, the risk-of-bias assessment tool, recommended by the Cochrane Collaboration, was used to evaluate the following six domains: sequence generation, allocation concealment, blinding, incomplete data, selective outcome reporting, and other sources of bias (24). Results of the methodology assessment are presented in Table 2.

3.6 Analysis

A combined assessment of the included studies was made on the basis of the questions in the GRADE system as described in the SBU's template(25). During this step, all included studies were estimated based on study quality, consistency between studies, generalization, and data accuracy. The qualifications that were checked included the study quality, the randomization procedure, blinding, and/or if the loss of primary outcomes were present in the study. Additionally, conflict of interest was also considered as a tool for impacting the comprehension of the study. The consistency between the studies was assessed according to the similarity of the studies' results. Credibility increased if the studies were conducted by different researchers with different populations groups and the results converged.

4. Results

4.1 Scientific quality of studies

According to the assessment based on the Cochrane Collaboration system, these studies were considered as low risk (26,39,44) or medium risk (27,37,45,46,47), and the rest were a high risk for bias (38,57). Studies with a high risk for bias had problems with descriptions of randomization and blinding the participants or personnel and had no appropriate control group and no potential conflicts of interest (Table 2)

Table 2. Risk of bias in the studies (+, low risk of bias; ?, unclear risk of bias; −, high risk of bias)

	Selection bias		Performance bias	Detection bias	Attrition bias	Reporting bias	Other bias
	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	
Larsen KT et al., 2016 (44)	+	+	+	+	+	+	-
Oreskovich et al., 2016 (45)	+	+	-	-	+	+	-
Bogart et al., 2016 (47)	+	+	-	-	+	-	-
Davis et al., 2016 (46)	+	+	-	?	+	+	-
Jones et al., 2015 (27)	+	?	-	-	+	+	-
Kokkvol et al., 2015 (39)	+	+	+	+	+	-	-
Nina Majlund Harder-Lauridsen et al., 2014 (37)	?	?	-	-	+	+	+
McCormack et al., 2014 (38)	?	?	-	-	-	-	-
Neiderer et al., 2013 (26)	+	+	+	-	?	+	+
Orban et al., 2014 (57)	+	-	-	-	+	-	-

The sequence-generation process for randomization were clearly described in most studies (26,27,38,42) For some studies, the methods of randomization were not clear, however, it was mentioned that randomization had been done (37,38,57).

The blinding for intervention (for participants and personnel) was performed in several studies (26,39,44), but in the majority, it was not possible to establish due to the nature of intervention.

4.2 Intervention description

Studies selected for the review were broad in geography and had been done in the USA (38,45,47); Australia (27); Europe, including Denmark (37,44), Norway (39), Sweden (57), and Switzerland (26); and Mexico (46). Publication timing varied from 2013–2017. The ages of the participants varied from 3–18 years. Populations in the study were ethnically diverse, and sample sizes ranged from 21–166.

The settings varied between studies (Table 3). The interventions investigated in five studies were conducted in a hospital or clinical setting (37,39,45), at school (26,27,38,47), camp (44), an academic outpatient community health center (45), and at home through data collection online (38). Davis et al.(46) reported data from group randomized control trials based in preschools, community and health centers, and (one) in homes (46). For recruiting to the intervention, researchers used physician referrals (38,57), flyers posted in the city public transportation systems, local advertisements (27,38), posters placed on the campus of a university hospital (43), postal letters (38,47), media coverage (27,39), volunteer website and newsletter (36), or a preset randomly selected school (26). The way of recruitment was not clarified in one study (45).

As for the theoretical basis for intervention, researchers used different theories (27,46, Table 3), such as social cognitive theory (27), socio-ecological theory (30,46), and social cognitive and self-efficacy theories and motivational interviewing (46). In the selected studies, a specific occupation-focused theoretical framework (57), social cognitive theory (27), and the psychosocial model of planned behavior change and the trans-theoretical model at the individual level through systematic use of group processes (44) were used. Davis et al.(46) had a complex theoretical basis because the setting of this study included a group of randomized control trials (46). The other studies did not record any theoretical basis for the intervention. Material and informational support was used for the interventions (26,37,38,44–47).

The duration of the series of interventions from study to study ranged from 1–5 years (Table 3). The intervention components can be categorized as follows: physical activity or exercise promotion, which included behavioral management (26,27,38,45,48); education and informational support (26,27,37-39,44–47, 57); social support (26,27,37, 44–47) and nutritional advisory and/or restriction (26,37,38,44–47,57).

Even though studies didn’t aim to make changes of patterns in daily activities, the interventions in those studies (Table 4) included activities that resulted in changes in daily activity patterns, such as supervised exercise that included additional hours of physical activity classes added to the usual school schedule (27), for example, biweekly physical activity sessions. Also, the physical activity programs included a home and parental component. In addition, activities included camping (44,39), a weekly group

training session (37), play-based activities in the summer camp (26), cycling exercises (38), and counseling on how to increase daily activities (37,57).

In Oreskovic's(45) study, researchers tested the daily activities of children in order to increase adolescent physical activity. They used the children's specific surroundings and ready-built environments, including geocoded physical activity data displayed on color maps and color charts. The charts classified their ready-built environment use as a means for daily moderate-to-vigorous physical activity and sedentary time spent in specific land-use categories, including parks, playgrounds, home, school, streets, and sidewalks (45). The behavioral management included goal setting, problem solving, behavior monitoring, preplanning, self-rewarding, coping strategies, motivation, and provision of feedback on performance (44). The importance of applying lifestyle changes, such as increasing daily activities, and promoting family-based changes were discussed in several studies (37–39,47,57).

Education and informational support were provided with reprints, booklets, newsletters; two of the studies used games as material support to enhance physical activity (26), individualized counseling on how to increase daily physical activity with weekly text messages and/or phone call reminders (45), and messages designed to encourage healthful habits (38). Social support was conducted through including the families in the interventions, providing lifestyle educational sessions for the parents (26,44), providing meetings and interviews during the interventions (45), and performing group activities (44).

The importance of parental support and collaboration is vital in attempting to achieve changes in a child's pattern of daily occupations was discussed in a study by Orban et al. (57) where they demonstrated the effect of occupation, in which parents spent time with their children simultaneously in daily routines, such as having meals, playing, and self-care (57).

Dietary restriction was applied to some studies, prepared meals in the camp were used in the study by Larsen et al. in 2016 (44), while other studies used dietary recommendations or nutrition education as a part of the behavioral management skills (26,27,37,44,57,39), as well as proposing improvements in the school canteen (39,47). In a study by Davis et al.(46), which presents the group data collected from 16 centers where intervention had been applied to 3-year-old children, interventions included a local grocery store component with the goal of increasing availability and visibility of healthier food options (46).

For most of the studies, the inclusion criteria "overweight" or "obese" were based on a BMI (body mass index). The BMI is defined as the body mass divided by the square of the body height and is universally expressed in units of kg/m2, and it is an accurate reflection of body fat percentage in the majority of the population (32).
The overweight and obesity classifications can be based on a screening BMI and are usually classified as overweight (25.0–29.9), obese (30.0–35.0), and morbidly obese (BMI > 35.0) in the adult population. In children, overweight is defined as a BMI at or above the 85th percentile and below the 95th percentile for children and teens of the same age and sex, while obesity is defined as a BMI at or above the 95th percentile for children and teens of the same age and sex (33).
To assess the BMI in children, body mass index *z*-scores (or BMI standard deviation) can be used; body mass index *z*-scores correspond to growth chart percentiles and can

be converted into their equivalent BMI-for-age percentiles (33). However, there were some differences in definitions of “overweight” between studies. Some studies used a threshold greater than the 75th percentile (27), a threshold greater than the 85th percentile of the population (35), some of them used a threshold above the 90% percentile (35–37), a BMI equal to or greater than the 95th percentile (28,31,39,40), BMI cut-off values (boys > 20.20 kg·m−2 and girls > 20.29 kg·m−2 (41,42), overweight as a BMI of Z between +1 and +2, and obese as a BMI considered Z > +2 (43).

Table 3. Description of participants and interventions (+ available, - not available)

Author & year of publication	Participants	Mean age	Settings	Mean BMI	Duration	Supervised exercise	Behavioral management skills	Activity of daily living	Material and informational support	Motivational interviewing	Social support	Dietary regimen or restriction
Larsen KT, et al., 2016 (44)	115	11–13-year-old	Camp	24.3	52 weeks	+	+	+	+	-	+	+
Oreskovich et al., 2016 (45)	60	10–16 years	Outpatient community health center	BMI percentile 94	4 months	+	+	+	+	+	+	+
Bogart et al., 2016 (47)	1368	12–15	School	93.22	2 years	+	+	+	+	-	+	+
Davis et al., 2016 (46)	1898	3-year-old	Schools, research centers, home	BMI-z mean = 0.63	5 years	?	+	+	+	?	+	+
Jones et al., 2015 (27)	20 boys 17 girls	8–11	Elementary school	BMI > 25 (kg/m^2), parent assessed	7 months	+	+	+	+	+	+	?
Kokkvol et al., 2015 (39)	97	6–12	Hospital	BMI kg/m^2 26.9 ± 4.2	2 years	+	+	+	+	+	+	+
Nina Majlund Harder-Lauridsen et al., 2014 (37)	37	7–10	Hospital	BMI of 21.8 ± 3.7 kg/m2	20 weeks	+	+	+	+	+	+	+
McCormack et al., 2014 (38)	21	10–17	Home	BMI ≥ 95%ile)	8week	-	+	+	+	+	-	+
Neiderer et al., 2013 (26)	652	preschool	Preschool	18 ± 1,3	1 year	+	+	+	+	+	+	+
Orban et al., 2014 (57)	30	4–6	Home	BMI z-score 3.35 (1.3–4.5)	1 year	-	+	+	+	+	+	-

Table 4. Detailed description of physical activity including the interventions and results

Study	Study Design	Patients	Intervention	Measurement	Results	Quality of study
Neiderer et al., 2013(26) Switzerland	RCT 2 groups with 2 subgroups	OW* (n = 130) NW*(n. 519) LF* (n. 154) HF* (n. 462) Age = 5.2 BMI OW = 18.0 NW = 15.1 LF = 16.1 HF = 15.6	- Physical activity (PA) program consisting of four 45 min sessions of PA per week, 22 lessons on healthy nutrition, media use, and sleep. -Healthy snacks, activity cards were used (cards with different themes and nutritional recommendations and specific exercises to be done at home). Card had three different activities that corresponded to different levels of difficulties. The control group did not receive any intervention and continued the regular school curriculum.	BMI, Waist circumference,	BMI (P = 0.5) and sum of four SF (P = 0.08). The intervention effects on aerobic fitness were significant in the normal weight group and marginally non-significant in the OW group (with a smaller sample size), with effect sizes of 15.4% for the OW and of 10.0% for the normal weight children, respectively.	High
Jones et al., 2015 (27) Australia	RCT 2 groups	17 girls (mean age = 9.6 ± 0.9 years) and 20 boys (mean age = 9.9 ± 0.8 years). (BMI ≥ 75th percentile	-PA programs (treatment group) comprised 30 min of homework plus 90 min of structured physical activity. -Facilitators optimized time spent in moderate-to-vigorous PA by: (i) implementing activities—often with modifications (e.g., to rules, equipment, and play space)—designed to encourage participation and maximize 'movement time,' (ii) minimized or eliminated 'wait time' within and between activities, and (iii) provided regular verbal positive reinforcement and feedback. -Participants were provided with a health passport containing weekly challenges to be completed at home with parents. -Participants were also encouraged to participate in a 4-week pedometer challenge, designed to motivate children to maintain PA participation during the 2-week winter school holiday break. -Participants were encouraged to record their daily steps online and track the group progress as they completed a virtual walk across Australia from the beach to the outback The healthy lifestyle (HL) education program (active comparison group/control) consisted of 30 min of homework, 45 min of healthy lifestyle education and 45 min of PA.	Percentage body fat and BMI z-score	Large intervention effects were reported for waist circumference and waist circumference z-score, with the latter difference between groups being statistically significant. At 12 months, all effect sizes were small to medium, with the majority in favor of the boys' PA program. At 7 months and 12 months, all effect At 12 months, all effects sizes for physical activity outcomes were small to medium with the majority being in favor of the boys' HL group. Physical activity outcomes at 7 months, small to medium effect sizes in favor of the girls' PA program. At 12 months, large effects in favor of the girls' PA group were shown for percent time in sedentary behavior and light PA.	Average
Majlund Harder-Lauridsen1, 2014 (37) Denmark	RCT 2 groups	37 children aged 8.7 ± 0.9 years with a BMI of 21.8 ±	The intervention consisted of (a) a 60 min weekly group training session of the children at schools close to the children's residences, (b) a 90 min weekly group training session of the children, their parents, and	Primary outcome (BMI)	BMI (the intervention effect is the difference in change between the groups adjusted for the respective baseline values (DELTA) = − 2.0 kg/m2 , 95% CI: − 2.5; − 1.5, P < 0.001), total body mass (DELTA = − 4.0 kg, 95% CI: − 4.9; − 3.0, P < 0.001), and	Average

		3.7 kg/m2 (mean ± SD), and 36 children completed the study	siblings at a municipal fitness club, (c) individual nutritional guidance and coaching of the children and their families (twice during the program), and (d) common cooking and dining with the children and their families (twice during the program). The weekly training session for the children alone began with a 15-min talk about the past week and the well-being of the children, followed by 45 min of continual exercise, games, and dancing. The weekly training session for the families began with 30 min of instruction on health topics (e.g. a healthy diet and the consequences of being overweight and physical inactivity). The control group did not receive any intervention.		fat mass (DELTA = − 3.3 kg, 95% CI: − 4.2; − 2.7, P < 0.001) compared to the control group after the intervention. Mean number of steps per day, as well as the mean number of minimum steps taken per day, was increased in the intervention group. All children (n = 36) improved cardiorespiratory fitness (within group; control group with 8.2% and intervention group with 18.5%) and leg strength (within group; control group with 9.4% and intervention group with 15.4%), and there was no significant improvement in the intervention group compared to the control group at follow-up.	
Orescovic et al., 2016(45) USA	RCT 2 groups	30 interventions and 30 control overweight and obese adolescents ages 10–16 years	-Prior to interventions, the level of daily physical activity was tested. Individualized counseling based on data to increase their daily physical activities by using the specific surrounding environments were suggested. -The participant and pediatrician also decided on a physical activity goal, which the subject agreed to achieve two to three times per week and involved a new use of the surrounding environment. -Intervention participants received weekly text messages and/or phone call reminders about their agreed upon goals after their team meetings. -Adolescents in the intervention group also received a physical activity promotion gift valued under $5 at T2, along with financial incentives ($5 to the subject and $10 to the family) for meeting their agreed upon environment goals. For the control group, there was only testing of the level of daily physical activity.	The primary outcome, MVPA, was measured by accelerometer to obtain a valid, objective measure of physical activity. Secondary outcome – BMI	The mean change in the mean daily MVPA from T1 to T2 was +13.9 min for adolescents in the intervention group (median, +10.7; interquartile range [IQR], −14.7 to +21.4) and −0.6 min for the controls (median, −1.9; IQR, −14.1 to +3.7) (p = 0.0001). The mean change in the mean daily sedentary time was +5.8 (±86.3) min for adolescents in the intervention group and +11.1(±73.9) min for controls (p = 1.0) from T1 to T2, and −4.4 (±91.3) and −22.9 (±75.6) min from T1 to T3 (p = 0.5), respectively. There were no significant differences between the study groups in BMI (T1 – baseline, T2 – 1 month after intervention, T3 – 3-4 months after T2).	High
Kokkvol et al., 2015(39) Norway	RCT 2 groups	6–12 years with body mass index (BMI) corresponding to ≥ 27.5 kg/m2	-Multiple-family interventions was comprised of a 3-day inpatient program at the hospital with other families and a multidisciplinary team; individual and group-based follow-up visits in their hometowns; weekly group-based physical activities; and a 4-day family camp. -Single-family intervention was comprised of a clinical examination and individual counselling by a pediatric nurse, a pediatric consultant and a nutritionist at the	Anthropometric measurements, blood samples, bioelectrical impedance analysis, and clinical examinations. Height, weight, waist circumference,	BMI increased by 1.29 kg/m2 in the multiple-family intervention compared with 2.02 kg/m2 in the single-family intervention (p = 0.075). BMI SD score decreased by 0.20 units in the multiple-family group and 0.08 units in the single-family intervention group (p = 0.046). A between-group difference of 2.4 cm in waist circumference (p = 0.038) was detected. The parent-reported and self-reported quality of life data showed no difference between the intervention groups at any time point.	High

			hospital and follow-up by a local public health nurse.	skin fold thickness and body composition were measured as described previously.		
McCormak et al., 2014 (38) USA	RCT 2 groups	21 obese (BMI ≥ 95%) subjects, ages 10–17 years.	-Participants received standardized weekly lifestyle modification messages designed to encourage healthful habits. -The exercise training group received three training sessions per week for 8 weeks. Subjects performed 20 min of aerobic training on a stationary bicycle with exer-gaming capacity (GB300S/L, GameBike Fitness, Dallas TX) at 60–80% of heart rate reserve as determined by initial exercise testing for up to 35 min per session. -To determine adherence to the prescribed exercise regimen, heart rate was recorded at the end of each minute during each exercise training session. In addition, subjects chose combinations of stretching and resistance training exercises from those available on the Wii Fit for up to 25 min per session. The control group did not receive any intervention.	Peak VO2	*Cardiovascular fitness*—effect of intervention group (time Â~ group effect), such that peak VO2, adjusted for lean body mass (5 [95% CI, −11 – 20] versus −18 [−33 – −3] ml/kg3/4 lean body mass/minute, p=0.03), as well as maximal power generated during exercise testing (32 [−3 – 67] versus −20 [−−30 – −10] Watts, p = 0.01) improved in the exercise group relative to the control. *Adherence to in-home exercise regimen*—subjects remained in or above the prescribed target heart range for an average of 81% of the minutes (95% CI, 65–97%) of supervised training. *Energy intake and expenditure*—here was a trend (p = 0.05) toward decreased self-reported daily caloric intake over both groups.	Low

Bogart et al., 2016 (47) USA	RCT, 2 groups	1,368 participants, (829 intervention, 539 control) ages 12–15 years, BMI ≥ 85th percentile	-School-wide food environmental changes with a seventh-grade peer leader club that incorporated social marketing (offering a greater variety of sliced/bite-sized food and freely available chilled, filtered water at lunch; posters promoting physical activity, cafeteria food, and healthy eating; and nutritional postings about cafeteria food). -The environmental changes included offering a greater variety of sliced/bite-sized food and freely available chilled, filtered water at lunch; posters promoting physical activity, cafeteria food, and healthy eating; and nutritional postings about cafeteria food. -Using role-play, seventh-grade student peer leaders were taught skills for approaching other students during lunchtime activities, as well as family members at home, to promote messages (regarding cafeteria food, water, sugar-sweetened beverages, fruits/vegetables, and physical activity/inactivity) with a motivational interviewing (nonconfrontational and encouraging) style. -Each peer leader was asked to recruit a partner (another student) to assist with lunchtime activities, which directly exposed more students to intervention messages. The social marketing aspect also included taste tests of cafeteria foods, delivered by peer leaders, and a short film shown to the entire seventh-grade class that encouraged physical activity (e.g. through a dance video) and healthy eating. -Students were given take-home activities to do with their parents during each week of the program (e.g. a worksheet to indicate parents' and adolescents' likes and dislikes for fruits and vegetables, and the types of fruits and vegetables kept at home). The control group did not receive any intervention.	BMI	The significance and magnitude of the intervention effect for the overall study sample, as well as the student BMI percentile subgroups, were similar in the sensitivity analysis, omitting the control school that received the intervention one year later. In this analysis, the point estimates for the significant effect among obese seventh-graders were slightly stronger than what was observed in the overall analysis (b [SE], –2.47 [0.87]; P = .005). Positive changes in physical activity and diet were sustained from middle school to high school, leading to reductions in BMI.	Average
Larsen et al., 2016 (44) Denmark	Parallel-group RCT	115 of 11–13-year-old Children	-Intervention group had a 6-week day-camp intervention arm focusing on increased physical activity and healthy diet, followed by a subsequent 1-year family-based intervention. -Control group had one weekly exercise session for six weeks.	BMI	After 52 weeks, the day-camp intervention arm had a lower BMI (-1.2 kg/m^2 (95% CI -1.8 to -0.5, P = 0.001)), BMI z-score (-0.20 (95% CI -0.35 to -0.05, P = 0.008)), and clustered cardiovascular risk z-score (-0.23 (95% CI -0.37 to -0.08, P = 0.002)) compared to the standard intervention arm. No group differences were detected in body composition after 52 weeks.	High
Davis et al.,2016 (46)	Group RCT	1,898 children 3-year-old	-Repeated opportunities to taste a new fruit or vegetable and to add 30 min of physical activity to daily class	BMI	Change in BMI-z per 6 months of study time for the primary age 3 cohort was similar for the comparison and intervention centers	High

Mexico		children in 16 Head Start (HS) centers	activities. -Quarterly professional development training for HS teachers and food service staff to provide assistance in implementing the interventions and information about physical activity and nutrition. -A component focused on integrating policy and behavior change in food purchasing, preparation, and serving by HS food service staff. -A family component consisting of take-home materials about nutrition and physical activity and family events reinforcing these messages twice during the school year. -A local grocery store component with the goal of increasing availability and visibility of healthier food options and providing recipes and nutrition-related information to families while shopping. -A component that asked local health care providers to emphasize healthy eating and physical activity during routine patient visits and invited health professionals to attend CHILE family events to show support for the intervention. The control had no intervention.		(*p* = 0.54; comparison slope = 0.038 [95% CI, 0.014 to 0.063]; intervention slope = 0.039 [95% CI, 0.014 to 0.063]; difference = 0.011 [95% CI −0.024 to 0.046]). Change for children in the intervention group with baseline BMI percentile < 85% was −0.01 (SE = 0.049, *p* = 0.83) lower than in the comparison group.	
Orban K, 2013, (57) Sweden	Two arms of RCT	Aged 4–6 years; 30 (n = 30) parents of 17 (n = 17) children (11 girls and 6 boys).	-Intervention was divided into two arms, one occupation-focused family intervention (LiLi) and one behavior-focused family intervention. -After randomization, all parents were given individual instructions how to access a website (with a unique password) containing general information about nutrition and exercise and were invited to attend a 2-hr lecture in which health professionals gave information about obesity.	BMI z-scores	A change was shown in the children's BMI z-scores from 2.93 (SD 0.97) at inclusion to 2.82 (SD 1.08), −0.11 units (SD 0.61), ranging from −0.20 to 0.42 at the end of the intervention, although it was not significant. Parents' perceptions of value in daily occupations demonstrated statistically significant changes during the intervention (p = .013).	Low

- OW–overweight, NW–normal weight, LF–low fit, HF–high fit, RCT–randomized control trial, BMI–body mass index, PA–physical activity, HL–healthy lifestyle, ADL–activity of daily living

4.3. Summary of results

The studies presented in Table 4 had multidimensional approaches that included physical activities as supervised exercises and tools for promoting physical activities. Those tools were behavioral management that involved changing attitudes toward physical activity, informational support, nutritional advice, social support from teachers and parents, and improvements in environmental and institutional conditions to promote physical activity. The results of the overall assessment of the studies demonstrated that only a multidimensional approach resulted in a positive change in activity patterns for the management of obesity in children; however, physical activity alone didn't show statistical significant data.
Also, family involvement where parents changed their lifestyles and implemented new activity patterns in their daily activities was vital for keeping the achieved results long term. Such activities as spending more time with their children in preparing and having meals and participation in physically activities.
According to Table 5, interventions of Neiderer et al. (26), Kokkvol et al. (39), and Larsen et al. (44) were more effective in the management of obesity in children, by multidimensional approach, however there is no significant difference in results between those studies

Table 5. Statistically significant improvements between the intervention group (IG) and control group (CG)

	BMI		
Study	Difference between IG and CG	Improvement within groups	Quality of study
Neiderer et al.,2013 (26) Switzerland	no	no	High
Jones et al., 2015 (44) Australia	no	no	Average
Majlund Harder-Lauridsen, 2014 (37) Denmark	*	no	Average
Oreskovic et al.,2016 (45) USA	no	no	High
Kokkvol et al.,2015 (39) Norway	no	*	High
McCormak et al.,2014 (38) USA	no	no	Low
Bogart et al., 2016 (47) USA	*	no	Average
MeLarsen et al., 2016 (44) Denmark	*	*	High
Davis et al.,		*	High

2016(45) Mexico	no		
Orban, 2013 (57) Sweden	no	*	Low

* = Statistical significant difference, no = no statistical significant difference

Effect of multidimensional intervention on daily activity patterns. The positive effect of physical activity for psychological changes is mentioned in the study by Kokkvol et al. (39). An increase in children's activity levels, may support favorable changes in their mental health and well-being. The self-reported improvement in athletic competence could provide such a change (39); motor agility was reported as improved in a study by Neiderer et al. (26).

Some studies reported improvement in the BMI or BMI z-scores of children in the intervention groups (37,44,47); however, several studies reported reductions of body fat and waist circumferences but no changes in BMI (26,39,46,57).

Significant changes were found in the lifestyles and daily activities in overweight children after multidimensional interventions that included environmental changes and motivational support (47,55). Positive changes in sedentary times (45), family activities, feeding habits (53), self-regulatory skill usages, mood and self-efficacies (50), and occupational patterns in family routines (57) were reported in the studies.

The role of physical activity application for preventing obesity in children is contradictory. Multidimensional interventions that used supervised exercise and tools for promoting physical activities were most effective. Tools for promoting physical activities included behavioral management that involved changing attitudes toward physical activity, informational support, nutrition advice, and social support from teachers and parents. Additionally, improvements in the environmental and institutional conditions to promote physical activity were used.

5. Discussion

5.1 Methods discussion

The study was performed in order to assess if a multidimensional approach, including the application of physical activities, is effective in reducing obesity in children and teenagers through improvement of their performances in daily activities. A systematic literature review with quantitative prospective was decided (23), as a systematic review can provide aggregated knowledge in a particular topic with a large population. The results of such a review may later affect and develop the application of clinical work (23). Systematic studies assess the studies' credibility and assures that relevant studies were included in the assessment.

The inclusion criteria were chosen to include a wide spread of the population (23) and also to cover the purpose with relevant research. Randomized control trials were chosen because they provide the most evidence-based scientific data. The English language was chosen as an inclusion criterion, and studies published within the last 5 years in peer-reviewed journals were considered.

The keywords were developed in collaboration with the librarian from Gothenburg University to ensure that relevant studies would be found. The keyword 'multidimensional' had not been applied to the search due to the possible limitation it can bring in search results because no study mentioned the term 'multidimensional'. PubMed, Scopus, and Web of Science were used as databases; it may weaken the study by not considering other databases, such as CINAHL or Cochrane Library, which could have provided other relevant articles. Those databases were not considered for the current study because CINAHL is mainly a database for nursing journals, and Cochrane Library is limited for public access.

The literature search resulted in a huge number of studies; however, a limited number of relevant studies were continued for the review. In the case of different keywords, other studies could probably be included in the review, or the changes in the inclusion criteria could also result in an increased number of relevant studies, with those factors increasing the selection bias.

Articles related to the application of physical activities in overweight or obese children were included and, according to the SBU's template (25), were assessed for relevance, and, later, the quality assessments of the studies' methodologies were done using the Cochrane risk-of-bias assessment tool. The overall assessment of this category for the risk-of-bias was assessed, as medium or high, based on the fact that the answers were unclear and whether primary and secondary measurements were stated. It was difficult to access high quality studies because from study to study there were some unclear points; some studies were not clearly describing the methods of randomization, or the allocation concealment was not clear. However, the outcomes from complex interventions were similar and strengthened the study.

A comprehensive assessment of the scientific basis was made based on the questionnaire quality, consistency, generalizability, and accuracy of data as part of the GRADE assessment tool (24). The fact that the evidence was assessed by one author makes the high-quality assessment of the scientific evidence difficult (24), which may weaken the result of the study.

This study has several limitations: (1) the choice of keywords and databases to find relevant articles, (2) the selection process was done by one person, which may result in selection bias, (3) the review itself was done by one person, which may put a limitation on the interpretation of the results, qualification of the studies, and methodology assessment. A language restriction was applied; thus, studies in other languages than English were excluded. The assessment criteria for the methodological quality of the studies, according to the Cochrane collaboration risk-of-bias assessment, was used to check the quality of studies, which may increase the selection bias.

The strength of the study is that the investigation was performed on relevant RCT studies that included large populations with high participation rates.

This review included studies that studied physical activity interventions with multidimensional approaches in overweight or obese children. Those studies were used to estimate the effects of physical activities on the BMI of overweight children. The interventions analyzed in this study were complex, which is why it was quite challenging to summarize what was the most important for the positive change in children.

Forsberg et al. (23) mentions that ethical considerations should be considered during the selection process. This was not incorporated into the inclusion criteria; however, it does not mean that ethical reviews had not been performed in the studies.

All studies involved minors; thus, it was necessary for the study to be approved by ethical committees, and a parent or legal representative of each child provided written informed consent. All included studies had performed necessary ethical considerations. During the systematic review, ethical consideration was applied for the results interpretation and discussions.

5.2 Results discussion

A multidimensional approach is important in achieving the goal of reducing obesity rates in children, implementing changes in daily occupations, providing environmental changes, and increasing physical activity and education in nutrition. Social support and family involvement are also crucial for lifestyle changes.

The change of BMI was greater in the interventions with supervised exercise (e.g. 70 min of sessions of moderate-to-vigorous physical activity) (45) or in interventions with longer durations (e.g. 20 weeks or more) (36); however, it was reported that the impacts diminished with time (44), which is why the tools for sustaining healthy behaviors for a lifetime are necessary. Therefore, the concept of a client-centered approach of OT could be a useful tool in keeping the achieved results in the long-term, as suggested by MOHO (12). This approach includes daily activities by reorganizing habits (e.g. implementing physical activities into the daily routines of overweight children) and providing help for improving performance and environmental conditions (8). Effective tools for OT in the management of overweight children could be advising the development of feelings of well-being, which requires the involvement of children in play to develop competence (9–19).

Several studies reported no change in BMI. However, Neiderer et al. (26) demonstrated that in preschoolers the multidimensional lifestyle intervention was able to reduce body fat and waist circumference; but, no significant change in BMI was observed, which could be explained with the body rearrangement and growth of children (26).
The variety of OT techniques, including health and life coaching, play and therapeutic activity integration, and counseling and group therapies, could be the key to achieving the multidimensional approach for positive effects of physical activity application in obese and overweight children (59).

Orban et al.(57) reported results of an occupation-focused family intervention (LiLi) and a behavior-focused family intervention, which was a part of the Lund Overweight and Obesity Preschool study (LOOPS). Based on the results, parents who changed their lifestyles to include more time with their children in preparing and having meals and

being involved in daily active occupations (the togetherness-focused family and the child-focused family) positively affected the children's weights (57). The occupation-focused family intervention (LiLi) is based on the organization of daily occupations, which motivate and provide the parents with the knowledge they need to be able to suggest strategies and set meaningful goals for the family (57).
Harder-Lauridsen et al.(37) noted that reported low-cost, twice-a-week training session interventions that included the families were able to reduce not only the children's BMIs but also the fat distributions; and, by increasing their minimum steps per day, the intervention improved their physical activity (37). The importance of parent-involved treatments for achieving better results is the primary key of change, which may result in greater self-efficacy for parents in the treatment of their overweight children (43).

Behavioral and social supports were used in some studies (45,47). Teaching self-regulation as part of behavioral support can facilitate health behavior changes, which can result in healthier weights (50). As previously discussed in the background, a child's sense of competence and effectiveness in his or her abilities is usually built from a child's values and interests. Thus, encouragement of a child's progress with consideration of his or her values and interests is a helpful tool for keeping the results long-term.

In the study of Bogart et al.(47), the implications of environmental changes were suggested: offering a greater variety of sliced/bite-sized food and freely available chilled, filtered water at lunch; posters promoting physical activity, cafeteria food, and healthy eating; and nutritional postings about cafeteria food. Motivational, non-confrontational, and encouraging style interviews were made during interventions, and students were provided with pedometers to track their activity levels (47). In 2016, Oreskovic et al.(45) noted the importance of feasibility in implementing personalized, ready-built environment counselling for overweight children, where the motivational support and education were very important for achieving long-term results for promoting and sustaining daily activities (45).

In 2014, Orban et al. (57) demonstrated that parents maintain the key role in preventing child obesity. During their interventions, it was observed that the children's weight was affected mostly in families where parents changed their lifestyles and implemented daily activities: spending more time with their children in preparing and having meals and participating in physically active occupations (the togetherness-focused family and the child-focused family), thus concluding that taking the whole family context into consideration when designing occupation-focused family interventions is very important (57).

As a result of our systematic review, multidimensional approach, including physical activity, demonstrated better effective in reducing obesity and affecting the activity patterns in children and teenagers. Considering the role of OT in this multidimensional approach, MOHO provides a framework that is used effectively to design interventions in children, with an understanding of dynamic influences on occupational performances (12). In the MOHO-based process of therapeutic reasoning, the goal of the OT practitioner in the management of overweight and obese children is effectively to find out the strengths and weaknesses and productively guide the applied interventions (12,59) (MOHO). The application of OT activities in the management of obesity would be beneficial for the complex reorganization of children's habits, performances, capacities, and environmental conditions, which are necessary, according to the MOHO

concept, for providing children with feelings of well-being and making activities meaningful for them (12). The development of children depends on feelings of being involved in playing (12) for the further mastery of advanced skills (14). According to MOHO (14), providing the right environments (including social) is very important for achieving results in the long-term.

Occupational therapists may positively influence the change of environmental factors, for example, the average time spent with devices. By building an occupational profile, OT therapists may help implement healthy daily routines and help encourage parents in the reorganization of children's habits and promote motivation for outdoor activities.

By using a client-centered approach, in which the patient takes an active part in his or her care and the decision-making process (19), OT can be very effective in the motivation for healthy environment choices during formation of new daily activity patterns, as discussed in MOHO.

5.3 Clinical application

The family-oriented daily occupations can be established during the care of overweight and obese children. Education on lifestyle changes and environmental improvements at home and schools are recommended. Participation in supervised exercises and improvement of daily physical activities would be helpful in the management of weight in children.

6. Conclusion

The effect of physical activity for preventing obesity in children is contradictory. The greatest impact was noticed in complex multidimensional interventions that used supervised exercise and tools for promoting physical activities. Those tools included behavioral management that involved changing attitudes toward physical activity, informational support, nutrition advice, social support from teachers and parents, and improvements in environmental and institutional conditions to promote physical activity. The participation of occupational therapists in the implementation of supervised exercise and activities in promoting physical activities and motivation for lifestyle changes is very important. Participation in the improvement of environmental and institutional conditions through a client-centered individual approach with whole family involvement, as referenced in the MOHO study (12), may have a positive influence in multidimensional obesity prevention programs at school and within households.

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8 Supplemental material: The Cochrane Risk of Bias Tool

RANDOM SEQUENCE GENERATION **Selection bias (biased allocation to interventions) due to inadequate generation of a randomized sequence.**	
Criteria for a judgment of 'Low risk' of bias.	The investigators describe a random component in the sequence generation process, such as: • Referring to a random number table; • Using a computer random number generator; • Coin tossing; • Shuffling cards or envelopes; • Throwing dice; • Drawing of lots; or • Minimization*. *Minimization may be implemented without a random element, and this is considered to be equivalent to being random.
Criteria for the judgment of 'High risk' of bias.	The investigators describe a non-random component in the sequence generation process. Usually, the description would involve some systematic, non-random approach, for example: • Sequence generated by odd or even date of birth; • Sequence generated by some rule based on date (or day) of admission; or • Sequence generated by some rule based on hospital or clinic record number. Other non-random approaches happen much less frequently than the systematic approaches mentioned above and tend to be obvious. They usually involve judgement or some method of non-random categorization of participants, for example: • Allocation by judgement of the clinician; • Allocation by preference of the participant; • Allocation based on the results of a laboratory test or a series of tests; or • Allocation by availability of the intervention.
Criteria for the judgment of 'Unclear risk' of bias.	Insufficient information about the sequence generation process to permit judgement of 'Low risk' or 'High risk'.
ALLOCATION CONCEALMENT **Selection bias (biased allocation to interventions) due to inadequate concealment of allocations prior to assignment.**	

Criteria for a judgment of 'Low risk' of bias.	Participants and investigators enrolling participants could not foresee assignment because one of the following, or an equivalent method, was used to conceal allocation: • Central allocation (including telephone, web-based and pharmacy-controlled randomization); • Sequentially numbered drug containers of identical appearance; or • Sequentially numbered, opaque, sealed envelopes.
Criteria for the judgment of 'High risk' of bias.	Participants or investigators enrolling participants could possibly foresee assignments and, thus, introduce selection bias, such as allocation based on: • Using an open random allocation schedule (e.g. a list of random numbers); • Assignment envelopes were used without appropriate safeguards (e.g. if envelopes were unsealed or non-opaque or not sequentially numbered); • Alternation or rotation; • Date of birth; • Case record number; or • Any other explicitly unconcealed procedure.
Criteria for the judgment of 'Unclear risk' of bias.	Insufficient information to permit judgement of 'Low risk' or 'High risk'. This is usually the case if the method of concealment is not described or not described in sufficient detail to allow a definite judgement—for example, if the use of assignment envelopes is described, but it remains unclear whether envelopes were sequentially numbered, opaque, and sealed.
SELECTIVE REPORTING **Reporting bias due to selective outcome reporting.**	
Criteria for a judgment of 'Low risk' of bias.	Any of the following: • The study protocol is available and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way; or • The study protocol is not available, but it is clear that the published reports include all expected outcomes, including those that were pre-specified (convincing text of this nature may be uncommon).
Criteria for the judgment of 'High risk' of bias.	Any one of the following: • Not all of the study's pre-specified primary outcomes have been reported; • One or more primary outcomes is reported using measurements, analysis methods, or subsets of the data (e.g. subscales) that were not pre-specified; or • One or more reported primary outcomes were not pre-specified

	(unless clear justification for their reporting is provided, such as an unexpected adverse effect); • One or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis; or • The study report fails to include results for a key outcome that would be expected to have been reported for such a study.
Criteria for the judgment of 'Unclear risk' of bias.	Insufficient information to permit judgement of 'Low risk' or 'High risk'. It is likely that the majority of studies will fall into this category.
OTHER BIAS **Bias due to problems not covered elsewhere in the table.**	
Criteria for a judgment of 'Low risk' of bias.	The study appears to be free of other sources of bias.
Criteria for the judgment of 'High risk' of bias.	There is at least one important risk of bias. For example, the study: • Had a potential source of bias related to the specific study design used; • Has been claimed to have been fraudulent; or • Had some other problem.
Criteria for the judgment of 'Unclear risk' of bias.	There may be a risk of bias, but there is either: • Insufficient information to assess whether an important risk of bias exists; or • Insufficient rationale or evidence that an identified problem will introduce bias.
BLINDING OF PARTICIPANTS AND PERSONNEL **Performance bias due to knowledge of the allocated interventions by participants and personnel during the study.**	
Criteria for a judgment of 'Low risk' of bias.	Any one of the following: • No blinding or incomplete blinding, but the review authors judge that the outcome is not likely to be influenced by lack of blinding; or • Blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken.
Criteria for the judgment of 'High risk' of bias.	Any one of the following: • No blinding or incomplete blinding, and the outcome is likely to be influenced by lack of blinding; or • Blinding of key study participants and personnel attempted but likely that the blinding could have been broken, and the outcome is likely to be influenced by lack of blinding.

Criteria for the judgment of 'Unclear risk' of bias.	Any one of the following: • Insufficient information to permit judgment of 'Low risk' or 'High risk'; or • The study did not address this outcome.
BLINDING OF OUTCOME ASSESSMENT **Detection bias due to knowledge of the allocated interventions by outcome assessors.**	
Criteria for a judgment of 'Low risk' of bias.	Any one of the following: • No blinding of outcome assessment, but the review authors judge that the outcome measurement is not likely to be influenced by lack of blinding; or • Blinding of outcome assessment ensured, and unlikely that the blinding could have been broken.
Criteria for the judgment of 'High risk' of bias.	Any one of the following: • No blinding of outcome assessment, and the outcome measurement is likely to be influenced by lack of blinding; or • Blinding of outcome assessment but likely that the blinding could have been broken, and the outcome measurement is likely to be influenced by lack of blinding.
Criteria for the judgment of 'Unclear risk' of bias.	Any one of the following: • Insufficient information to permit judgment of 'Low risk' or 'High risk'; or • The study did not address this outcome.
INCOMPLETE OUTCOME DATA **Attrition bias due to amount, nature, or handling of incomplete outcome data.**	
Criteria for a judgment of 'Low risk' of bias.	Any one of the following: • No missing outcome data; • Reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias); • Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups; • For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk not enough to have a clinically relevant impact on the intervention effect estimate; • For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes not enough to have a clinically relevant impact on observed effect size; or • Missing data have been imputed using appropriate methods.

Criteria for the judgment of 'High risk' of bias.	Any one of the following: • Reason for missing outcome data likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups; or • For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk enough to induce clinically relevant bias in intervention effect estimate.

Thresholds for Converting the Cochrane Risk-of-Bias Tool to AHRQ Standards (Good, Fair, and Poor)

Good quality: All criteria met (i.e. low for each domain)

Using the Cochrane ROB tool, it is possible for a criterion to be met even when the element was technically not part of the method. For instance, a judgment that knowledge of the allocated interventions was adequately prevented can be made even if the study was not blinded, if EPC team members judge that the outcome and the outcome measurement are not likely to be influenced by a lack of blinding.

Fair quality: One criterion not met (i.e. high risk of bias for one domain) or two criteria unclear, and the assessment that this was unlikely to have biased the outcome, and there is no known important limitation that could invalidate the results

Poor quality: One criterion not met (i.e. high risk of bias for one domain) or two criteria unclear, and the assessment that this was likely to have biased the outcome, and there are important limitations that could invalidate the results.

Poor quality: Two or more criteria listed as high or unclear risk of bias.