

The Effectsof Backpack Load and Placement on Postural Deviation in Healthy Students: A Systematic Review

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ABSTRACT

Background

Knowledge about the appropriate load and placement of a backpack for children is thought to be important in reducing both immediate and future musculoskeletal problems in students. The purpose of this systematic review is to investigate the evidence related to effects of backpack load and placement on postural deviation in healthy students.

Methods

Six electronic databases were systematically searched to identify studies that reported the effects of backpack load and placement on postural deviation in healthy students in June 2012. All study designs and years of publication were included. Search results were selected based on relevance to the topic; participants should be healthy, aged between 6 and 12 years, and the full text available in English. Level of evidence for each article was determined based on NHMRC Evidence Hierarchy (2009), while the quality of each article was assessed using a modified PEDro and modified Downs & Black scales (1998).

Results

Seventy relevant articles were identified, of which eleven articles met inclusion and exclusion criteria and six were deemed appropriate for review. Only one article was categorized as Level II hierarchy of evidence. One randomised control article was classified as high-quality using the modified PEDro scale and five non-randomised control articles were classified as intermediate quality using modified Downs & Black checklist. Results on appropriate load limit seemed to meet the consensus but the appropriate load placement was inconsistent between articles. Further investigation is urgently required to identify appropriate load and placement of backpacks for school students.

Conclusions

Most articles have shown that the appropriate load limit for students is between

10%-15% BW. However, lack of articles, the low hierarchy of evidence, inconsistent results, and small sample size are the limitations for recommending the appropriate load placement of backpacks in students.

Keywords: children, backpack, load limit, placement, postural deviation.

Introduction

Normal posture is difficult to define as everyone has a unique anthropometric and biomechanical profile (Trew & Everett, 2001). The ideal standing posture in the sagittal plane includes consideration of a straight line passes through the ear lobe, the seventh cervical vertebra, the acromion, the greater trochanter, just anterior to the midline of the knee and slightly anterior knee and lateral malleolus (Kendall, McCreary, Provance, Rodgers, & Romani, 2005). Postural deviation refers to any deviation from this ideal posture. Placing an excessive load on the back, as occurs when carrying a backpack, commonly causes postural deviations (Grimmer, Dansie, Milanese, Pirunsan, & Trott, 2002), musculoskeletal pain (Iyer, 2001, 2002; Koroivessis, Koureas, Zacharatos, & Papazisis, 2005) and may contribute to deformities such as scoliosis, kyphosis and lordosis (Koroivessis et al., 2005; Lai & Jones, 2001). Some studies have reported that low back pain in childhood is a strong predictor of persistent low back pain in adulthood (Brattberg, 2004; Hestbaek, Leboeuf-Yde, Kyvik, & Manniche, 2006).

Over the last 15 years, efforts have been made to set a safe load limit for students, but universal safe limits remain elusive, due to inconsistent results from scientific articles (Lindstrom-Hazel, 2009). Most studies have found that an acceptable load limit for school children is between 10% to 15% of their body weight (BW) (Bauer & Freivalds, 2009; Brackley & Stevenson, 2004; Kistner, Fiebert, & Roach, 2012), though some studies have suggested it should not exceed 10% BW (Hong & Brueggemann, 2000; Mohan, Singh, & Quddus, 2007). Despite this, students often have to carry more than 15% of their BW (Negrini

& Carabalona, 2002; Pascoe, Pascoe, Wang, Shim, & Kim, 1997) as there is no legislation to protect them such as that applied to adults in occupational or workplace settings. This is particularly alarming for students, who are yet to develop mature musculoskeletal systems and are therefore vulnerable to injury.

In addition to the weight of a heavy backpack, backpack placement may also contribute to postural deviation. Literature indicates that carrying a backpack at different locations affects the spinal muscles and therefore affects posture in both children and adults (Devroey, Jonkers, de Becker, Lenaerts, & Spaepen, 2007; Fiolkowski, Horodski, Bishop, Williams, & Stylianou, 2006; Grimmer et al., 2002). It is crucial to investigate where best to position the backpack on the spine because at present there is no clear guideline regarding this matter (Brackley, Stevenson, & Selinger, 2009; Chow, Ou, Wang, & Lai, 2010). Although numerous studies have been carried out to identify the effects of backpack carriage on posture, there are no studies that identify and appraise the research evidence, in order to recommend the most appropriate position for the backpack on the back, particularly in school-aged students. The primary purpose of this systematic review is to investigate the effects of backpack load and placement on postural deviation in healthy students.

Methods

2.1 Search strategy

A 'Problem, Intervention, Comparison and Outcomes' (PICO) search strategy (Sayers, 2007) was used to identify articles published until June 2012. Searches of eight databases related to this area were performed i.e. Medline, Cochrane Database, Allied and Complementary Medicine (AMED), CINAHL, Scopus, PubMed and Google Scholar. The search strategy employed was as follows:

Keywords: (child* OR "school child*" OR adolescen* OR student*) AND (backpack* OR "school bag*" OR "school backpack*" AND ("load place*" OR "centre of mass") AND (posture* OR deviation OR "postural deviation*"))

- Inclusion criteria: studies on static standing posture in healthy participants aged between 6 and 25 years.
- Exclusion criteria: Studies that include participants with spinal abnormalities (scoliosis, kyphosis or lordosis).
- Included study design: All study designs included.
- Outcomes measures: Measuring the effect of load and placement on postural deviation.
- Publications: Published in English.

2.2 Hierarchy of evidence and quality appraisal

Articles were filtered based on the appropriateness of the title and whether the set criteria were met. Level of evidence of each article was determined based on National Health and Medical Research Council Evidence Hierarchy (NHMRC, 2009) as illustrated in Table 1. Since articles in this area were extremely limited, we decided to accept all levels of evidence as long as the articles met the criteria.

Table 1: Hierarchy of evidence (NHMRC, 2009)

Level I	Systematic review.
Level II-1	Randomised control trial.
Level III-1	Pseudo randomised controlled trial (i.e. alternate allocation or some other method).
Level III-2	A comparative study with concurrent controls: <ul style="list-style-type: none"> • Non-randomised, experimental trial⁹. • Cohort study. • Case-control study. • Interrupted time series with a control group.
Level III-3	A comparative study without concurrent controls: <ul style="list-style-type: none"> • Historical control study. • Two or more single arm study¹⁰. • Interrupted time series without a parallel control group.
Level IV	Case series with either post-test or pre-test/post-test outcomes.

The quality of each article was appraised using a PEDro scale as this is the premier scale in this field to appraise articles ("PEDro scale," 1999). Since five articles reviewed were non-RCT, the scale was modified by removing three blinding criteria from the original scale (Appendix 1). Precedents for modification of the PEDro scale have previously been reported by Slade and Keating in their systematic review paper (Slade & Keating, 2007) because it was not possible to blind therapists while they were administering exercise. In this case, it is very difficult to blind students to wearing and not wearing a backpack. We followed the Slade and Keating (2007) criteria and removed three criteria, leaving seven criteria because no score was given for eligibility criteria, as these were clear. Answers were scored 0 or 1 for each criterion. The final scale consists of 7 items with a maximum score of 7. Higher scores indicate a higher quality.

To further strengthen our assumption, quality of non-randomised articles were also appraised using D&B scale (Downs & Black, 1998). This checklist has been used to examine the quality of randomised and non-randomised control articles (Cappuccio, D'elia, Strazzullo, & Miller,

2010; Gorber, Tremblay, Moher, & Gorber, 2007; McMillan & Payne, 2008). There are 27 items to be answered in this checklist, reporting (10 items), external validity (3 items), bias (7 items), confounding (6 items), and power (1 item) as depicted in Appendix 2. Answers were scored 0 or 1, except for one item in the reporting subscale, which scored 0 to 2 and the single item on power, which was scored 0 to 5. However, we have been using a modified checklist as recommended by (Gorber et al., 2007) because not all items in the original checklist related to this review. The modified version does not include the following items: items 5 and 8 in the reporting scale, items 11, 15 and 19 in the section on bias, 21-26 relating to

confounding and item 27 addressing power. Answers were scored 0 or 1 for each item. The final checklist consists of 15 items with a maximum score of 15 points (Appendix 3). Higher points indicate higher quality. Any dispute was resolved by discussion to obtain consensus.

Results

3.1 Literature search

Initially, seventy articles were identified by using all combinations of keywords; sixty-two from databases and eight from Google scholar (Table 2).

Table 2: Results of literature search.

#	Searches	Results from databases						
		PubMed	Medline	AMED	Cochrane (RCT)	Cochrane Systematic Review	Scopus	CHINAHL
1	Child*.mp.	1625995	649064	15874	52246	2943	3030723	288940
2	"School child*".mp.	355	6055	229	1725	123	229113	1988
3	Adolescen*.mp.	1361238	601568	3333	68702	719	1836761	175802
4	Students.mp	153675	83318	5443	8719	302	586857	82689
5	1 OR 2 OR 3 OR 4	2413079	1013060	22349	105186	3148	4135389	441607
6	Backpack*.mp.	464	353	71	30	3	2493	274
7	"School bag*".mp	18	18	6	0	0	152	11
8	"School backpack*".mp	13	9	4	1	0	66	15
9	6 OR 7 OR 8	477	366	76	30	3	2552	280
10	"Load place*".mp.	1118	48	14	13	0	437	12
11	"Centre of mass".mp.	433	348	85	8	2	5276	49
12	10 Or 11	1551	385	97	21	2	5712	60
13	Posture.mp	61379	24346	4481	3176	124	115927	6324
14	"Postural deviation".mp.	39	26	6	3	0	118	7
15	14 OR 15	61394	24354	4483	3177	124	115972	6327
16	5 AND 9 AND 12 AND 15	2	1	1	0	0	39	19

After screening the titles, only eleven articles were considered relevant to the topic. Chow et al. (2006) has been excluded from this review as participants had idiopathic scoliosis while Frank et al. (2003) was removed as this was an abstract of a conference presentation and therefore not fully published.

Articles by (Abe, Yanagawa, & Niihata, 2004; Chow, Ting, Pope, & Lai, 2009; Zultowski & Aruin, 2008) were excluded as their studies were not related to postural deviation (Figure 1). From the remaining, only six articles (Brackley et al., 2009; Chow et al., 2010; Devroey et al., 2007; Grimmer et al., 2002; Singh & Koh, 2009; Talbott, 2005) were considered appropriate for inclusion.

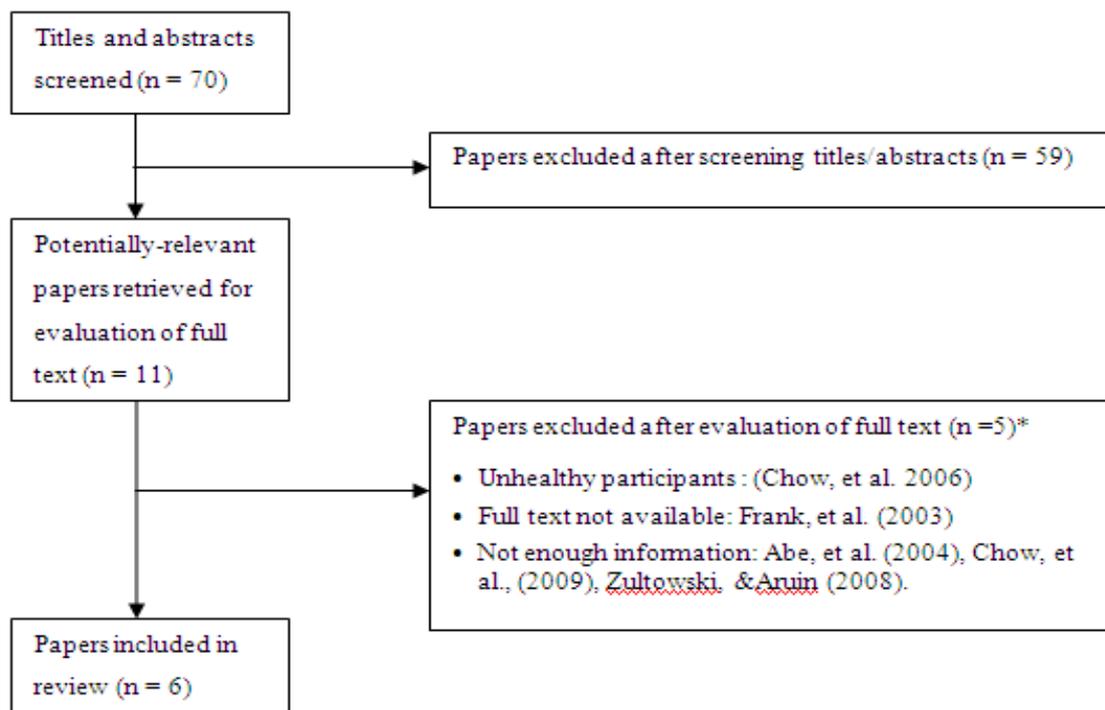


Figure 1: Flow of screening the literatures. * Papers may have been excluded for failing to meet more than one inclusion criteria.

3.2 Hierarchy of evidence and quality appraisal

Search results show scarcity of articles from the Level I and II NHMRC levels (2009) regarding the effects of backpack load and placement on postural deviation in healthy students. Only one article was found when criteria were limited to these levels.

However, as there is such a limited amount of research information on this topic, we decided to include all levels of evidence. By using a modified PEDro scale, the randomised control article has been classified as high-quality and non-randomised classified as medium and low as shown in Table 3.

Table 3: Scores for quality appraisal using the modified PEDro scale

Articles	Eligibility criteria	Randomly allocated	Allocation was concealed	Similar at baseline	More than 85% of the subjects	Intention to treat	Between group statistics comparisons	Point measures and measures of variability	PEDro Score (Modified)	Quality
Brackley et al. (2009)	1	0	0	1	1	0	1	1	4/7	Intermediate
Chow et al. (2010)	1	0	0	0	1	0	1	1	3/7	Low
Devroey et al. (2007)	1	0	0	0	1	0	1	1	3/7	Low
Grimmer et al. (2002)	1	1	0	1	1	0	1	1	6/7	High
Singh et al. (2009)	0	0	0	0	1	0	1	1	3/7	Low
Talbott (2005)	1	0	0	1	1	0	1	1	4/7	Intermediate

* No score was given for eligibility criteria

When the non-randomised control articles were reappraised using the Downs & Black checklist, all were classified as intermediate as shown in Table 4.

Table 4: Scores for quality appraisal using the modified Downs & Black checklist.

#	Article	Scores (value)				Quality
		Reporting (8)	External validity (3)	Internal validity (4)	Total (15)	
1	Brackley et al. (2009)	6	0	4	10	Intermediate
2	Chow et al. (2010)	6	0	4	10	Intermediate
3	Devroey et al. (2007)	7	0	4	11	Intermediate

4	Singh & Koh (2009)	6	0	4	10	Intermediate
5	Talbott (2005)	7	0	4	10	Intermediate

Due to the parameters used varies between studies, meta-analysis using forest plots to assess the clinical importance of the evidence is irrelevant.

3.3 The effects of load on postural deviation

The purpose of investigating the effect of load on posture was to determine how heavy the load lifted can cause significant postural deviation. Despite the various outcome measures used, all were still related to postural measurement. As illustrated in Table 5, most articles reported that the increase in backpack load may lead to postural deviation compared to unloaded condition (baseline posture).

Table 5: Summary of reviewed literature.

Author/ Date/ Study location	Mean Age ± SD	N	Study Type	Purpose/Hypotheses	Baseline	Intervention
Brackley, H. M., Stevenson, J. M., Selinger, J. C. (2009) Canada	10	5 M 10 F	Self-controlled Repeated Measures.	To examine the effect of load placement (higher, middle, and lower) on posture, specifically trunk forward lean (TFL) posture, head on neck (CVA) postures and lordosis angle (LA) for standing and walking in pre-pubescent children.	Weight: 0% BW. Placement: Not stated in article but personal communication High (± 26.3 cm above L5) Middle (between higher and lower) Low (± 10.3 cm above L5).	Weight: 15% BW. Placement: High Middle Low
Chow, D. H. K., Ou, Z. Y., Wang, X. G., & Lai, A. (2010) Hong Kong	11.4±0.5	11M 8F	Repeated Measures.	To investigate the effects of different backpack placements on spinal deformation and repositioning error in schoolchildren.	Weight: 0% BW. Placement: High (T7) Middle (T12) Low (L3).	Weight: 15% BW Placement: High Middle Low.
Devroey, C., Jonkers, I., Becker, A.D., Lenaerts, G., Spaepen, A. (2007) Belgium.	23.9±2.59	12 M 8 F	Repeated Measures.	H1: Increased backpack load causes significant changes in the strain variables. H2: Physical strain differs between carrying loads at the thoracic level compared to the lumbar level.	Weight: 0% BW Placement: High (thoracic region) Low (lumbar region).	Weight: 5%, 10%, and 15% BW. Placement: High Low

Author/ Date/ Study location	Mean Age ± SD	N	Study Type	Purpose/Hypotheses	Baseline	Intervention
Grimmer et al.(2002) Australia	12.9±0.5 12.8±0.5 13.8±0.4 13.8±0.5 14.9±0.6 14.8±0.5 15.8±0.6 15.8±0.5 16.7±0.5 16.8±0.5	25 M 25 F 25 M 25 F 25 M 25 F 25 M 25 F 25 M 25 F	Randomised Controlled.	To describe the effect on adolescent sagittal plane standing posture of different loads and positions of a common design of school backpack. The underlying study aim was to test the appropriateness of two adult 'rules-of-thumb'-that for postural efficiency, backpacks should be worn high on the spine, and loads should be limited to 10% of body weight.	Weight: 0% BW. Placement: High (T7) Middle (T12) Low (L3).	Weight: 3%, 5% BW and 10% BW. Placement: High Middle Low.
Singh &Koh (2009) Singapore	9.65±1.58	17 M	Repeated Measures.	To analyze how different load weights and the vertical positioning of these loads on the back affect trunk forward lean and spatiotemporal parameters and also how these variables in turn possibly affect balance during gait.	Weight: 0% BW. Placement: High (superior to T8-T9) Low (inferior to T8-T9).	Weight: 10%, 15% and 20% BW. Placement: High Low.
Talbott (2005) (USA)	12.5 12.3	11 M 29 F	Repeated Measures.	To identify differences in the postural balance and posture of adolescents during static and dynamic activities with and without backpacks.	Weight: 0% BW. Placement: High (C7) Low (inferior angle of the scapula).	Weight: 10% and 20% BW. Placement: High Low.

M - Male; F - Female; C7 - 7thcervical;
T7 - 7ththoracic; T12 - 12ththoracic;
L3 - 3rdlumbar, L5 - 5thlumbar;

Table 5:Summary of reviewed literature (cont.).

Article	Main outcome measures	Posture response to load	Posture response to placement	Conclusion
Brackley et al. (2009)	Trunk forward lean (TFL) angle Cranio-vetebral angle (CVA) Lordosis angle (LA)	0% BW vs. 15% BW (***). 0% BW vs. 15% BW (**). No significant differences between loads.	No significant differences between placements.	<ul style="list-style-type: none"> Using backpack with 15% BW cause significant changes of TFL and CVA. Backpacks should place lower on the spine.
Chow et al. (2010)	Cervical, higher and lower thoracic, higher and lower lumbar, pelvic tilt angles	0% BW vs. 15% BW (*)	Significant differences between placements (*) except pelvic tilt.	<ul style="list-style-type: none"> No conclusion for load limit. Higher position may cause more deviation compared to middle and lower.
Devroey et al. (2007)	Head and spine angles Neck angle Thorax angle Pelvis angle Hip	No significant differences between loads. 0% BW vs. 10% BW (**) 0% BW vs. 10%, 15% BW (***). 5% BW vs. 10%, 15% BW (**). 0% BW vs.10% (*), 15% BW (**). 0% BW vs.10% BW (*), 15% BW (**).	Most postural deviation occurred in higher position.	<ul style="list-style-type: none"> Load 10% BW and above should be avoided. Could not recommend the best placement based on the findings.

The uses of different loads between studies make it difficult to get consensus on the appropriate load limit for students. Grimmer et al. (2002) have

reported that carrying a backpack at 3% BW had caused postural deviation in all measured parts; i.e. tragus of ear, spinous process C7, mid acromion shoulder, lateral superior iliac crest, greater trochanter and mid joint knee. However, no significant deviation found while carrying 10% BW load compared with less weight. Thus they could not support the recommendation that suggest the load should be limited to 10% BW for adolescents.

In contrast, Singh & Koh (2009) found significant differences in TFL while carrying 10% BW compared with postural without backpack whilst Talbott (2005) had reported, out of ten locations measured, only three (right shoulders and both temporals) had shown significant postural deviation while carrying 10% BW. Devroey et al. (2007) have also detected significant postural deviation at all assessed locations (head, spine, neck, thorax, pelvic and hip) while carrying 10% BW but using older participants, i.e. college/university aged students. Brackley et al. (2009) and Singh & Koh (2009) used TFL to measure postural deviation, but failed to get consensus due to the use of different loads (10%, 15%, and 20% BW). Results from Brackley et al. (2009) and Chow et al. (2010) strengthen the studies that lifting 15% BW caused postural deviation. In addition, Talbott's (2005) recommendation to avoid carrying 20% BW supported the likelihood that appropriate load limits for children are below 15% BW.

3.4 The effects of load placement on postural deviation

The purpose of investigating the effect of placing the centre of the backpack on various positions on the back was to propose the best location to place backpack for students in order to reduce the students' postural deviation. Comparisons were made based on whether significant postural deviation was detected when the backpack was placed in three different locations on the back; high, middle and low. The effect of load placement on the postural deviation was inconsistent across the articles, as shown in Table 5.

Although there were no significant differences reported by Brackley et al. (2009), placing the backpack at a lower location appears better than higher and middle positions in terms of reducing postural deviation at TFL and CVA. In addition, Grimmer et al. (2002) reported that regardless of location, the weight of backpack caused significant postural deviation except the greater trochanter and mid joint knee. Chow et al. (2010) also reported

significant postural deviation in all parts measured except pelvic tilt.

Another study by Talbott (2005) reported that postural deviations, especially in the right shoulder and head, were detected when placing the backpack in different locations. Even though Singh & Koh (2009) studied the effect of placement on TFL in static and dynamic conditions but, less explanation was given in static posture. In summary, all articles reported that placement on the lower back reduced postural deviation compared to higher and middle positions. The best location to place the backpack involves less postural deviation because there are studies reporting that even small deviations from the normal posture may result in adverse mechanical tension in the central nervous system (Garde, 1992; Harisson, 1992).

Discussion

This systematic review shows that there is a lack of quality information on what maximum load should be carried by students and where the backpack should be placed on their backs. The load limit for students seems to meet the consensus that loads should be limited to 10% - 15% of BW (Brackley & Stevenson, 2004). The studies that have been performed relating to safe backpack load were not only related to the changes in posture but also to direct effects of the load in the backpack on children such as oxygen consumption, blood pressure, energy consumption (Hong, Li, Wong, & Robinson, 2000), heart rate (Bauer & Freivalds, 2009; Hong & Brueggemann, 2000; Hong et al., 2000), cardiorespiratory (Daneshmandi, Rahmani-Nia, & Hosseini, 2008), pulmonary function (Danial et al., 2005) and gait pattern (Hong & Brueggemann, 2000).

According to Talbott (2005), legislation of load limits is difficult to establish because of the lack of studies on the acute and chronic effects of backpack use. Furthermore, to establish a policy on universal load limit, both static and dynamic conditions must be analysed in order to understand the whole picture related to posture (Brackley, et al., 2009). There remain inconsistent results between scientific articles as to the maximum amount, and the influence of backpack load. For example, does a load of 10% of body weight for a 6 year old weighing 20 kg have the same effect on the posture as 10% body weight of a 12 year old weighing 45 kg? Is there a difference between children who have lower and higher Body Mass Index (BMI)? (Bauer & Freivalds, 2009). These questions should also be considered in order to propose appropriate load limit for healthy school age students.

The issue of best backpack placement requires further investigation. There is no consensus of information concerning whether to carry it high on the back, in the middle of the back or lower. This is further hampered by the inconsistency of definition of positions (high, middle and low) on the back. Some authors (Grimmer et al., 2002; Chow, et al., 2010) are very specific about their terminology and placement, whereas others are less precise (Brackley et al., 2009; Devroey et al., 2007) specifying only a region of the back. However, it is impossible to analyse all six studies together, as the classifications of higher, middle and lower are inconsistent, and, in some cases, the lower placement in one study is the higher placement in another.

Unfortunately, the inconsistency of results is of concern. Furthermore, it may be that backpack placement is related to the individual - where the child's centre of gravity is situated, or related to age or body structure (endomorph vs. ectomorph body types for example). Current evidences recommend that children should carry backpacks that are less than 10% BW, but absolutely below 15% BW. It is difficult to recommend best location to place the backpack on the back, but the best evidence suggests that the backpack should be positioned with the centre of backpack at waist or hip level (closer to the centre of body mass). However, more high quality studies are required to support the current evidence in order to establish universal guidelines or legislation. This means that further work is required, but that lower limits should be adhered to as best practice.

At present, in term of articles on load limit and posture, only one study (Grimmer et al., 2002) is considered the highest in quality by a long way, despite the age of the article. The evidence on the effect of load placement on postural deviation in students is limited, with the majority of articles categorized as intermediate hierarchy of evidence. The results between articles were also inconsistent because some articles found statistical significant differences but some did not find significance between placements. This may be due to different outcome measures and different definitions between articles of position (high, middle, and low) where the backpack was placed on the back (Table 5). As the load limit, the locations of load on the back also need consistent results on both standstill and dynamic posture before a universal guideline can be established, we would support the recommendations that further study on larger populations and stratified age ranges are performed (Brackley et al. 2009, Talbott, 2005)

Limitation

Our review is limited to the articles published in English. Since there is no standard approach for measuring posture (McEvoy & Grimmer, 2005), the use of different measures between articles may have also contributed to inconsistent findings.

Conclusions

In conclusion, the findings on the determination of the load limit in children associated with postural deviation are still not consistent. The literature shows that placing a backpack of less than 15% BW on the back may cause postural deviation, and even high-quality articles also reported that postural deviation occurred at as little as 3% BW. Based on the most current literature (Bauer & Freivalds, 2009; Ramprasad, Alias, & Raghuvver, 2010), students should not carry more than 15% BW. To date, there is no consensus as to the best position on the back to carry a backpack. This is mainly due to inconsistency of definition of backpack position. However, based on the best available evidence it appears that carrying a backpack with the weight centred between the third and fifth lumbar (L3-L5) is recommended.

Suggestion for future research

Both load limit and load placement are still open issues to be debated. Although several studies attempted to identify the appropriate load limit by studying the load and posture, most of them are classified under low quality of evidence. Studies on load placement seem more complicated due to an inconsistency in definition of position of the load on the back. More rigorous studies are required to protect backpack users from immediate and future musculoskeletal problems. Priority should be given to school-aged children because they are at risk of musculoskeletal-related problems and their risk remains uncertain in terms of the long-term implications of these problems (Jones & Macfarlane, 2005).

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Appendix 1

PEDroscale: Rating scale for RCT's, non-RCTs, and Case Series

For each item, please justify scoring (for both YES and NO responses), by at least mentioning page and paragraph numbers	Rater 1	Rater 2	Rater 3	Consensus
	_____	_____	_____	_____

Eligibility score (not included in score)

1. Eligibility criteria were specified	yes <input type="checkbox"/>	yes <input type="checkbox"/>	yes <input type="checkbox"/>	yes <input type="checkbox"/>
	no <input type="checkbox"/>	no <input type="checkbox"/>	no <input type="checkbox"/>	no <input type="checkbox"/>
	where: _____	where: _____	where: _____	where: _____

Internal validity criteria (2-9)

2. Subjects were randomly allocated to interventions (in a crossover study, subjects were randomly allocated an order in which treatments were received)	yes <input type="checkbox"/>	yes <input type="checkbox"/>	yes <input type="checkbox"/>	yes <input type="checkbox"/>
	no <input type="checkbox"/>	no <input type="checkbox"/>	no <input type="checkbox"/>	no <input type="checkbox"/>
	where: _____	where: _____	where: _____	where: _____
3. Allocation was concealed	yes <input type="checkbox"/>	yes <input type="checkbox"/>	yes <input type="checkbox"/>	yes <input type="checkbox"/>
	no <input type="checkbox"/>	no <input type="checkbox"/>	no <input type="checkbox"/>	no <input type="checkbox"/>
	where: _____	where: _____	where: _____	where: _____
4. The intervention groups were similar at baseline regarding the most important prognostic indicators	yes <input type="checkbox"/>	yes <input type="checkbox"/>	yes <input type="checkbox"/>	yes <input type="checkbox"/>
	no <input type="checkbox"/>	no <input type="checkbox"/>	no <input type="checkbox"/>	no <input type="checkbox"/>
	where: _____	where: _____	where: _____	where: _____
5. There was blinding of all subjects	yes <input type="checkbox"/>	yes <input type="checkbox"/>	yes <input type="checkbox"/>	yes <input type="checkbox"/>
	no <input type="checkbox"/>	no <input type="checkbox"/>	no <input type="checkbox"/>	no <input type="checkbox"/>

7. Does the study provide estimates of the random variability in the data for the main outcomes?
 In non-normally distributed data the inter-quartile range of results should be reported. In normally distributed data the standard error, standard deviation or confidence intervals should be reported. If the distribution of the data is not described, it must be assumed that the estimates used were appropriate and the question should be answered yes.

Yes	1
No	0

8. Have all important adverse events that may be a consequence of the intervention been reported?
 This should be answered yes if the study demonstrates that there was a comprehensive attempt to measure adverse events. (A list of possible adverse events is provided).

Yes	1
No	0

9. Have the characteristics of patients lost to follow-up been described?
 This should be answered yes where there were no losses to follow-up or where losses to follow-up were so small that findings would be unaffected by their inclusion. This should be answered no where a study does not report the number of patients lost to follow-up.

Yes	1
No	0

10. Have actual probability values been reported (e.g. 0.035 rather than <0.05) for the main outcomes except where the probability value is less than 0.001?

Yes	1
No	0

External validity

All the following criteria attempt to address the representativeness of the findings of the study and whether they may be generalised to the population from which the study subjects were derived.

11. Were the subjects asked to participate in the study representative of the entire population from which they were recruited?
 The study must identify the source population for patients and describe how the patients were selected. Patients would be representative if they comprised the entire source population, an unselected sample of consecutive patients, or a random sample. Random sampling is only

feasible where a list of all members of the relevant population exists. Where a study does not report the proportion of the source population from which the patients are derived, the question should be answered as unable to determine.

Yes	1
No	0
Unable to determine	0

12. Were those subjects who were prepared to participate representative of the entire population from which they were recruited?
 The proportion of those asked who agreed should be stated. Validation that the sample was representative would include demonstrating that the distribution of the main confounding factors was the same in the study sample and the source population.

Yes	1
No	0
Unable to determine	0

13. Were the staff, places, and facilities where the patients were treated, representative of the treatment the majority of patients receive?
 For the question to be answered yes the study should demonstrate that the intervention was representative of that in use in the source population. The question should be answered no if, for example, the intervention was undertaken in a specialist centre unrepresentative of the hospitals most of the source population would attend.

Yes	1
No	0
Unable to determine	0

Internal validity - bias

14. Was an attempt made to blind study subjects to the intervention they have received?
 For studies where the patients would have no way of knowing which intervention they received, this should be answered yes.

Yes	1
No	0
Unable to determine	0

15. Was an attempt made to blind those measuring the main outcomes of the intervention?

Yes	1
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No	0
Unable to determine	0

16. If any of the results of the study were based on “data dredging”, was this made clear?

Any analyses that had not been planned at the outset of the study should be clearly indicated. If no retrospective unplanned subgroup analyses were reported, then answer yes.

Yes	1
No	0
Unable to determine	0

17. In trials and cohort studies, do the analyses adjust for different lengths of follow-up of patients, or in case-control studies, is the time period between the intervention and outcome the same for cases and controls?

Where follow-up was the same for all study patients the answer should yes. If different lengths of follow-up were adjusted for by, for example, survival analysis the answer should be yes. Studies where differences in follow-up are ignored should be answered no.

Yes	1
No	0
Unable to determine	0

18. Were the statistical tests used to assess the main outcomes appropriate?

The statistical techniques used must be appropriate to the data. For example nonparametric methods should be used for small sample sizes. Where little statistical analysis has been undertaken but where there is no evidence of bias, the question should be answered yes. If the distribution of the data (normal or not) is not described it must be assumed that the estimates used were appropriate and the question should be answered yes.

Yes	1
No	0
Unable to determine	0

19. Was compliance with the intervention/s reliable?

Where there was noncompliance with the allocated treatment or where there was contamination of one group, the question should be answered no. For studies where the effect of any misclassification was likely to bias any association to the null, the question should be answered yes.

Yes	1
No	0
Unable to determine	0

20. Were the main outcome measures used accurate (valid and reliable)?

For studies where the outcome measures are clearly described, the question should be answered yes. For studies which refer to other work or that demonstrates the outcome measures are accurate, the question should be answered as yes.

Yes	1
No	0
Unable to determine	0

Internal validity - confounding (selection bias)

21. Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited from the same population?

For example, patients for all comparison groups should be selected from the same hospital. The question should be answered unable to determine for cohort and case-control studies where there is no information concerning the source of patients included in the study.

Yes	1
No	0
Unable to determine	0

22. Were study subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited over the same period of time?

For a study which does not specify the time period over which patients were recruited, the question should be answered as unable to determine.

Yes	1
No	0
Unable to determine	0

23. Were study subjects randomised to intervention groups?

Studies which state that subjects were randomised should be answered yes except where method of randomisation would not ensure random allocation. For example alternate allocation would score no because it is predictable.

Yes	1
No	0
Unable to determine	0

24. Was the randomised intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable?

All non-randomised studies should be answered no. If assignment was concealed from patients but not from staff, it should be answered no.

Yes	1
No	0
Unable to determine	0

25. Was there adequate adjustment for confounding in the analyses from which the main findings were drawn?

This question should be answered no for trials if: the main conclusions of the study were based on analyses of treatment rather than intention to treat; the distribution of known confounders in the different treatment groups was not described; or the distribution of known confounders differed between the treatment groups but was not taken into account in the analyses. In nonrandomised studies if the effect of the main confounders was not investigated or confounding was demonstrated but no adjustment was made in the final analyses the question should be answered as no.

Yes	1
No	0
Unable to determine	0

26. Were losses of patients to follow-up taken into account?

If the numbers of patients lost to follow-up are not reported, the question should be answered as unable to determine. If the proportion lost to follow-up was too small to affect the main findings, the question should be answered yes.

Yes	1
No	0
Unable to determine	0

Power

27. Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance is less than 5%?

Sample sizes have been calculated to detect a difference of x% and y%.

	Size of smallest intervention group	
A	< n ₁	0
B	n ₁ - n ₂	1
C	n ₃ - n ₄	2
D	n ₅ - n ₆	3
E	n ₇ - n ₈	4
F	n ₈ +	5

Appendix 3

Quality appraisal score using modified Downs and Black checklist

Items	Brackley et al. (2009)	Chow et al. (2010)	Devroey et al. (2007)	Singh et al. (2009)	Talbot (2005)
Is the hypothesis/ aim/ objective of the study clearly described?	1	1	1	1	1
Are the main outcomes to be measured clearly described in the Introduction or Methods section?	1	1	1	1	1
Are the characteristics of the patients included in the study clearly described?	0	1	1	0	1
Are the interventions of interest clearly described?	0	0	0	0	0
Are the main findings of the study clearly described?	1	1	1	1	1
Does the study provide estimates of the random variability in the data for the main outcomes?	1	1	1	1	1
Have the characteristics of patients lost to follow-up been described?	1	1	1	1	1
Have actual probability values been reported (e.g. 0.035 rather than <0.05) for the main outcomes except where the probability value is less than 0.001?	1	0	1	1	1
Were those subjects who were prepared to participate representative of the entire population from which they were recruited?	0	0	0	0	0
Were the staff, places, and facilities where the patients were treated, representative of the treatment the majority of patients receive?	0	0	0	0	0
Was an attempt made to blind study subjects to the intervention	0	0	0	0	0

they have received?

If any of the results of the study were based on “data dredging”, was this made clear? 1 1 1 1 1

In trials and cohort studies, do the analyses adjust for different lengths of follow-up of patients, or in case control studies, is the time period between the intervention and outcome the same for cases and controls? 1 1 1 1 1

Were the statistical tests used to assess the main outcomes appropriate? 1 1 1 1 1

Were the main outcome measures used accurate (valid and reliable)? 1 1 1 1 1

Total score 10 10 11 10 10

