

SUMMARY

WEIGHTED BLANKETS AND VESTS: SAFETY, EFFICACY AND ISSUES RELATED TO THEIR USE IN DIFFERENT INTERVENTION SETTINGS

Introduction

Weighted blankets are part of a vast range of tools used for their calming effect in people with difficulties in adjusting to environmental stimuli.

The death of a young child with autism following the improper use of a weighted blanket during school time launched an investigation by the coroner who reported the potential dangers of these blankets and the basic rules that should be applied for their safe use. The Ministère de la Santé et des Services sociaux (MSSS) therefore asked AETMIS to synthesize the evidence on the use of weighted blankets for all potential clients, namely, those with pervasive developmental disorders, mental health disorders, or physical or intellectual disabilities, and frail elderly people. This report also examines the safety and efficacy of weighted vests, given that they appear to be widely used in Québec, especially with children. It aims to provide the MSSS with a synthesis of the evidence on the topic to allow it to subsequently formulate recommendations on the use of weighted blankets and vests. The approaches or applications underpinning the use of these tools are also examined.

Research methods

An exploratory literature search was conducted in April 2009 in different databases in the fields of health, education, occupational therapy, psychology, sociology and social work. Relevant documents were then identified through analysis of the bibliographic references cited in the selected articles. A second literature search was conducted in July 2009 to ensure that no relevant study had been omitted. Regular updates were made until the time the report went to publication. All the studies specifically addressing the assessment of the safety or efficacy of weighted blankets or vests were extracted and then analyzed. Furthermore, published legislation was examined for the purpose of describing the legislative framework governing the use of weighted blankets and vests in Québec.

Local experts were also consulted to validate contextual information especially on the use of weighted blankets and vests in different settings, on practitioners' and administrators' roles and responsibilities, and on the organization of services.

General framework for use of weighted blankets and vests

Weighted blankets are purported to have calming properties leading to a decrease in anxiety, whereas weighted vests are used to “normalize” behaviour and improve attention to task. Other uses for weighted blankets and vests were found but were not assessed. These devices may be used as a means of restraint or of punishment or as a relaxation tool. Regardless of their application, certain potential contraindications to the use of weighted blankets and, by extension, weighted vests, require a preliminary assessment of a potential wearer's health status by a qualified professional, as well as implementation of safety rules.

Scientific evidence

Therapeutic foundations

Overall, authors agree to recognize that the therapeutic foundations of weighted blankets and vests lie in the sensory integration approach. This approach emerged from a theory advancing that perceptual, sensory and motor difficulties may be partly due to the poor integration of sensory information and to the inability of the cortical system to modulate and regulate the sensorimotor functions of the limbic system. This approach has led to derived applications that are built on it but not aimed at correcting sensory processing disorders. Yet, this distinction between the sensory integration approach and its derived applications was not always explicit in the studies, which compromised their conceptual validity.

Efficacy of the sensory integration approach and its derived applications

The efficacy of the sensory integration approach is a controversial issue. A recent review of secondary studies on the topic presented the outcomes of four descriptive reviews and three meta-analyses. The descriptive reviews concluded that methodological weaknesses or inconsistencies in the outcomes of the studies did not make it possible to rigorously demonstrate the efficacy of the sensory integration approach or to support its use in a therapeutic context. The meta-analyses yielded more mitigated results. The first meta-analysis, which addressed eight studies, concluded that the sensory integration approach had positive effects, while the remaining two did not confirm these promising outcomes, while stating that the more rigorously designed studies achieved more modest results.

Evidence of the efficacy of derived applications proved just as weak. The fundamental problem lay in the weakness of their conceptual validity. Most of the studies generally failed to describe the intervention processes, which invalidated their compliance with the intervention's purported foundations. As a result, the efficacy of these derived applications has not been demonstrated and will not be demonstrable until their foundations are established.

Safety and efficacy of weighted blankets and vests

Without evidence-based therapeutic foundations, specifically assessing the therapeutic effects of weighted blankets and vests remains hazardous. A single experimental study of the safety and efficacy of **weighted blankets** conducted with apparently healthy university students was found. The results of this study showed that the use of weighted blankets did not generally cause physiological reactions exceeding safety limits. The authors therefore concluded that weighted blankets were safe. With regard to efficacy, results were mixed, the most promising being subject to social desirability bias. Finally, the conclusions of this study may in no way be generalized to children, and even less so to children with disabilities or to frail elderly people.

No study on the safety of weighted vests was found. Two surveys of occupational therapists revealed that some children may wear weighted vests for more than four hours, or for most of the school day. The weight of the vest, estimated to be 10% of a child's body weight, was set according to the ratio proposed by the American Pediatric Association for the safe use of backpacks. The appropriateness of this extrapolation to weighted vests raises some doubt.

Concerning the efficacy of **weighted vests** in children with disabilities, such as autism spectrum disorder, the results of the three most recent studies and of two literature reviews showed no significant effects on the targeted behaviours. The authors of the two literature reviews drew conclusions on the efficacy of weighted vests on the basis of the methodological quality of the studies included. One drew particular attention to the selection bias linked to the choice of subjects for whom weighted vests could—in theory—be appropriate, without mentioning their sensory disorders or the processes used to establish their diagnoses. The other proposed that research should be undertaken on larger samples, be based on a standardized protocol for using the vest and be conducted in different geographic areas. The authors of the two reviews concluded that the current state of evidence did not demonstrate the therapeutic effects of weighted vests and that their use should be subject to specific conditions or discontinued.¹

Contextual information

In Québec and Canada, several laws, regulations and policy directions govern the use of weighted blankets and vests, and the obligations of professionals, manufacturers and retailers.

Main target groups

According to the experts consulted, the use of weighted blankets and vests with frail elderly people is unusual. These tools are used especially with children who have pervasive developmental disorders, physical or intellectual disabilities, learning disorders, attention-deficit hyperactivity disorders, and communication disorders. In this report, these children are considered without regard

1. At the time of publication of this report, a doctoral thesis published in 2010 by Sandra Hodgetts was found. Reference is made to it at the end of Chapter 6 (Discussion) and its abstract is presented in an addendum (Appendix E). The conclusions that emerged from this thesis are consistent with those in the two reviews in that there is a lack of evidence supporting the efficacy of weighted vests.

for their diagnoses, each rather being viewed as a “handicapped person,” that is, “a person with a deficiency causing a significant and persistent disability, who is liable to encounter barriers in performing everyday activities.”²

Restraint

The coroner’s recommendations mentioned measures to be taken to prevent weighted blankets from being used for restraint purposes. In Québec, the Act to Amend the Professional Code and Other Legislative Provisions as Regards the Health Sector authorizes a greater number of professionals to make decisions as to the use of restraint measures. However, restraint is regulated by the Act Respecting Health Services and Social Services (section 118.1) and by MSSS policy directions aimed specifically at minimizing the use of restraint and other control measures. This law limits the use of restraint in institutions within the health and social services system but does not apply to other settings, such as schools, daycare centres and homes.

Corporal punishment

Judicial limitations brought to section 43 of the Criminal Code of Canada define the concepts of behaviour deemed reasonable and unreasonable. The use of objects to punish children is deemed unreasonable. The use of weighted blankets or vests as a means of punishing a child may therefore constitute behaviour deemed unreasonable under the Criminal Code of Canada.

Policy direction for services for children with disabilities

Three ministries are chiefly concerned in the services offered to children likely to use weighted blankets or vests: Ministère de l’Éducation, du Loisir et du Sport (MELS); Ministère de la Santé et des Services sociaux (MSSS); and Ministère de la Famille et des Aînés (MFA). All are obligated to direct their services in accordance with the laws governing them. These laws are all centred on the individual needs of children to promote their health, well-being and development and are applied through policies, directions, programs and action

plans, and by different stakeholders, including the Québec Ombudsman, who advises these government ministries in fulfilling their missions, especially with children who have special needs.

Stakeholders

Retailers and manufacturers of weighted blankets and vests

In Québec, at least two companies include weighted blankets and vests as part of their range of therapeutic products. However, their Web advertisements may lead people to believe that these blankets have proven efficacy, which has not been scientifically demonstrated. This may violate certain provisions of the Consumer Protection Act, which the Office de la protection du consommateur is responsible for enforcing.

Occupational therapists

In her report, the coroner asked the Ordre des ergothérapeutes du Québec (OEQ) to provide clear directives to its members concerning the use of weighted blankets. The OEQ issued a notice on the safety of weighted blankets, without mentioning the therapeutic efficacy of weighted blankets or the sensory integration approach. The notice therefore does not impose conditions on its members’ use of weighted blankets as part of individualized intervention plans.

Conclusion

The scientific evidence available does not allow the possibility of ruling either on the safety or on the efficacy of weighted blankets and vests, given that the existing studies have methodological flaws, especially in terms of conceptual validity and compliance with intervention processes and contexts. However, these tools are used for therapeutic purposes by occupational therapists applying the sensory integration approach or derived applications with some children with disabilities and in various settings such as homes, daycare centres, schools and health and social service institutions. Practice guidelines do not recommend their use. Moreover, no study has addressed their use with frail elderly people.

2. Act to secure handicapped persons in the exercise of their rights with a view to achieving social, school and workplace integration, R.S.Q. c. E-20.1, s. 1.

In the absence of evidence-based proof of the efficacy and safety of these tools, but given that they are already being used in Québec and that their inappropriate use pose risks, AETMIS concludes that, in terms of their safety, and regardless of their target objectives:

- Weighted blankets and vests should always be used with the informed consent of the wearers or their parents or guardians.
- Safety rules for their use should be established.
- These tools should always be used under supervision and following an assessment conducted by a qualified health professional to exclude all possible contraindications.
- In all publicly funded public and private institutions, these tools should always be used by duly trained educational or social interveners supervised by qualified professionals.

Furthermore, to ensure that this method of intervention meets the health and welfare needs of the people affected, the following measures should be taken:

- The use of weighted blankets or vests for non-therapeutic purposes should be clearly explained to all parties concerned, and the

underlying intentions should comply with the laws of Québec and Canada to exclude any unreasonable punitive behaviour and any unjustified restraint.

- The use of weighted blankets or vests for therapeutic purposes should be supported by clear and measurable objectives to be included in an individualized intervention plan or service plan.
- The individualized intervention plan or service plan should include periodic assessments to ascertain whether the target objectives have been achieved and should specify that the use of weighted blankets or vests will be terminated should it not yield the expected benefits.
- All practitioners who use weighted blankets or vests and all manufacturers should inform their clients (including parents and guardians) that their therapeutic efficacy has not been proven.
- The use of weighted blankets and vests should never be used in the place of proven, evidence-based interventions.