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Whole-body vibration training for inpatient children and adolescents receiving chemotherapy for first cancer diagnosis: an exploratory feasibility study

Introduction

Whole-body vibration (WBV) is described as a neuromuscular training method in which mechanical stimuli are transmitted to participants through a vibrating platform. A trigger mechanism for several physical responses during WBV is the "tonic vibration reflex" (TVR), a stimulation of the muscle spindles and alpha-motoneurons which induces reflexive muscle contractions (Chanou, Gerodimos, Karatrantou, & Jamurtas, 2012). Compared to voluntary exercises, WBV stimulates muscles more and efficiently and is, thus, assumed to increase training efficiency and to result in a faster gain of muscle function (Rauch, 2009). Current literature demonstrates WBV-related improvements in, for example, muscle mass and strength, balance and functional abilities like walking/gait in different populations also including pediatric patients (Rustler, Däggelmann, Streckmann, Bloch, & Baumann, 2019; Rittweger, 2010). The number of stimulations delivered per second thereby depends on the selected vibration frequency (e.g., frequency of 25 Hz is equivalent to 25 impulses/s). However, if the vibration frequency is selected too low, no reflexive muscle contraction can be triggered at all and if the frequency is very high permanent muscle tension develops. For optimal neuronal stimulation, a vibration frequency of above 18 Hz should be selected in the beginning (Streckmann, Rittweger, Bloch, & Baumann, 2014). Besides the TVR, several other mechanisms, such as metabolic or neuronal mechanisms, can also have an impact on the diverse physical responses observed in WBV training. As such, WBV is known to improve neuromuscular function and bone health (Oliveira, Oliveira, & Pires-Oliveira, 2016; Rittweger, 2010) which is why WBV is more and more often used in the rehabilitation of people with various diseases, including children with disabilities (Matute-Llorente, González-Agüero, Gómez-Cabello, Vicente-Rodríguez, & Mallén, 2014) and adult cancer patients. In adult oncology, WBV has already been applied to patients during medical treatment in order to prevent the onset of chemotherapy-induced peripheral neuropathy (Streckmann et al., 2018) or to maintain physical capacity in patients receiving allogeneic hematopoietic cell transplantation (Pahl, Wehrle, Kneis, Gollhofer, & Bertz, 2020).

In pediatric oncology, patients and survivors suffer from several neuromuscular limitations such as decreased lower extremity strength/flexibility, impaired balance, and inefficient gait patterns (Beulertz et al., 2015; Ness et al., 2012; Wright, Halton, & Barr, 1999; Wright, Galea, & Barr, 2005) as well as from poor bone health (Kang & Lim, 2013). Improving these limitations through, e.g., WBV training is of great benefit, as they may, among others, be important contributors for physical inactivity. Research has shown that survivors of pediatric cancer often do not meet physical activity guidelines (Florin et al., 2007; Ness et al., 2009). Adequate levels of physical activity, however, are imperative regarding children's overall health and well-being (Eime, Young, Harvey, Charity, & Payne, 2013; Strong et al., 2005).

Previous studies in pediatric oncology have evaluated WBV in survivors (Daeggelmann et al., 2021; Mogil et al., 2016; Rustler et al., 2018), demonstrating feasibility (Daeggelmann et al., 2021; Rustler et al., 2018) and preliminary beneficial effects on functionality (Daeggelmann et al., 2021; Rustler et al., 2018) as well as bone health (Mogil et al., 2016). However, there is no intervention investigating WBV in children and adolescents receiving active cancer treatment, although it is generally recommended to start rehabilitation from diagnosis onwards to preserve physical function in the pediatric cancer population (Thorsteinsson et al., 2017) and although general exercise programs, comprising endurance, strength and mobility elements, have been demonstrated to be feasible during hospitalization, with growing evidence for potential health benefits (Rustler et al., 2017). Compared to pediatric cancer survivors, patients receiving active treatment are exposed to increased burdens including depressed immune systems or severe infections that exercise-based interventions must be adapted to. Therefore, this study adds relevant information to previous findings in pediatric cancer survivors as it investigates the feasibility of a WBV training for inpatient children and adolescents actively receiving chemotherapy for first cancer diagnosis.

Materials and methods

Study design

This explorative pilot study was approved by the ethics committee of the German Sport University Cologne. The study was carried out in accordance with the Declaration of Helsinki and is registered at the German Clinical Trials Register (DRKS00008578).

Recruitment and participants

Childhood cancer patients were recruited from May 2015 to April 2017 at the Children's Hospital Amsterdamer Straße, Cologne; Clinic for Children and Youth Medicine; Department for Pediatric Hematology/Oncology. Inclusion criteria were the following: first diagnosis of pediatric cancer disease; age between 6 and 17 years; medical therapy comprising inpatient treatment and an indication of chemotherapy; signed informed consent from the legal guardian; medical clearance of the treating physician. Exclusion criteria were as follows: a former pediatric cancer disease; palliative treatment; WBV-specific contraindications (instable osteolysis, proven osteonecrosis or artificial implants in the lower extremities, a fracture in the lower extremity within the past 6 months, osteosynthesis, acute prolapse, epilepsy, pregnancy); central nervous system (CNS) metastases; inadequate knowledge of the German language; and specific psychosocial impairments that would prevent them from study participation.

WBV intervention

The WBV intervention was conducted concomitant to acute cancer treatment, which involved chemotherapy. The supervised training was implemented as part of a general exercise program and generally offered to patients 3 days a week during hospitalization by qualified and experienced exercise physiologists/physiotherapists. It was performed on a vibrating platform (Galileo Med®, Novotec Medical GmbH, Pforzheim, Germany) placed in the corridor of the ward. Besides WBV, the exercise program comprised individual combination training including aerobic, strength, stretching and coordination training with adaptability to meet fluctuating patient abilities.

The WBV protocol was developed based on a former WBV study performed in pediatric cancer survivors (Rustler et al., 2018) and contained five sets of vibration, including a warm-up (60 s, 18 Hz, 2 mm peak-to-peak displacement) and four progressive training exercises (60–120 s, 21–27 Hz, 2 mm peak-to-peak displacement) with 60 s rest in between resulting in 9–13 min of session duration and 5–9 min of overall vibration time. The vibration load sought to be gradually increased by adjusting vibration frequency and time using the following protocol: for every frequency (21, 24, and 27 Hz), set duration was increased in 3 stages (60, 90, and 120 s). Reaching 120 s, vibration frequency was increased, set duration was reset to the shortest duration and, subsequently, increased again. The aim was to reach the maximum vibration frequency (27 Hz), as muscle activity during WBV increases with rising frequency (Ritzmann, Gollhofer, & Kramer, 2013). Due to fluctuating patient abilities during acute pediatric cancer treatment, speed of progression was individualized to the patient's ability to tolerate the vibration and was controlled by the exercise physiologists (decision criteria beside daily patient ability: completed sessions without serious adverse event or perceived exertion/discomfort). Detailed information on the WBV training, e.g., training positions, has been described previously (Rustler et al., 2018).

Training was interrupted when patients had thrombocytopenia (thrombocyte count < 10,000/μL; thrombocytes between 10,000/μL and 20,000/μL in case of bleeding tendency or bleeding signs), experienced acute thrombosis, nausea, vomiting, dizziness, fever (> 38 °C) or severe infections; and for up to 7 days after minor and for at least 14 days after major surgeries (including port implantation). These relative contraindications were defined following published contraindications to exercise in children and adolescents with cancer (Beulertz et al., 2016).

Outcome measures

Feasibility of the WBV training was primarily assessed. Similar to a previous study evaluating WBV in pediatric cancer survivors (Rustler et al., 2018), feasibility was defined as the ability to participate in WBV without occurrence of WBV-related serious adverse events leading to health deterioration (e.g., bone fractures or severe pain) necessitating study dropout. In addition, WBV-related adverse events and side effects leading to training stops were recorded and are listed in the order of highest frequency.

Moreover, the following parameters were documented and analyzed: (i) attendance to training and reasons for not participating; (ii) compliance to the vibration protocol (number of patients reaching the highest vibration frequency; number of sessions with constant/increased but not reduced vibration load, meaning vibration frequency or time); (iii) necessary modifications to the vibration protocol by therapists and its reasons. The stated reasons in (i) and (iii) are categorized and listed in the order of highest frequency.

Anthropometric data and medical information of all study participants were collected from medical records to describe the sample.

Results

Study sample and intervention period

Twelve childhood cancer patients were eligible according to the criteria of inclusion. One child denied study participation. Thus, data from 11 patients who participated in the study until (i) participation in any sporting activity was banned due to cardiac issues unrelated to our intervention ($n = 1$), (ii) the transfer to another hospital for further treatment ($n = 2$), or (iii) the end of inpatient medical treatment ($n = 8$) was analyzed. Participant demographics and clinical characteristics are listed in **Table 1**.

The intervention period varied from 7 to 52 weeks. During this period, exercise physiologists/physiotherapists offered 690 WBV sessions. However, on 289 training days, the patients were not hospitalized and did, thus, not have the opportunity to exploit the training. Considering only the days of hospitalization, a total of 401 WBV sessions were offered to patients during the intervention period. Individual and total sample information on the intervention period for each study participant is summarized in **Table 2**.

Feasibility

No serious adverse event and consequently no study dropout occurred. However, 2 patients suffered from one adverse event (a one time bleeding event), each. One participant (#1) developed hematomas, distributed on the whole body, on the day of training (90 s, 21 Hz) and one (#4) suffered from a nosebleed directly after participating in WBV (60 s, 21 Hz). Both incidents occurred in patients with thrombocytes < 30,000/µL. Having detected the bleeding tendency in these 2 patients, a potential association between the bleedings and WBV training was discussed with the treating physician. Following medical advice, no further WBV trainings were performed in patients with platelet counts below 30,000/µL. After adjusting the platelet count threshold to 30,000/µL, no further incidents occurred. Both patients were able to continue the intervention.

Due to WBV-related side effects, a total of 21 training sessions (11% of all attended sessions, $n = 193$) had to be stopped. Of these 21 sessions, 6 sessions (28%) were stopped early because patients experienced WBV training as being too exhausting. Four of 21 sessions (19%) were stopped because WBV increased the feeling of treatment-related fatigue, another 4 of 21 sessions (19%) due to lack of personal motivation and 2 of 21 sessions (10%) due to lack of concentration. The remaining sessions could not be completed as the patients started to feel unwell (2/21, 10%), experienced pain (2/21, 10%), or too strong itching (1/21, 4%) in the lower limbs.

Attendance

Study participants attended 193 out of 401 possible sessions, resulting in a mean attendance rate of 48%. Of these, 49 sessions (25%) were performed respecting

Abstract

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Whole-body vibration training for inpatient children and adolescents receiving chemotherapy for first cancer diagnosis: an exploratory feasibility study

Abstract

Whole-body vibration (WBV) is a feasible and potentially beneficial exercise strategy for managing neuromuscular impairments like decreased strength or flexibility, mobility limitations and bone health in pediatric cancer survivors. However, as starting rehabilitation as early as possible is recommended to preserve physical function, this study investigated the feasibility of WBV for patients receiving cancer treatment for first cancer diagnosis. Eleven patients (various types of cancer, ages 7–17) participated in the supervised WBV intervention concomitant to acute cancer treatment, which involved chemotherapy. Training was implemented as part of a general exercise program and offered 3 days per week during hospitalization (warm-up, four progressive training exercises comprising 60–120 s, 21–27 Hz, 2 mm peak-to-peak-displacement). Feasibility, which was defined as the absence of WBV-related serious adverse events leading to study dropout, was primarily evaluated. Training documentation was additionally analyzed. As a main result, no serious adverse events leading to study dropout were reported. However, two incidents of bleeding (adverse events) were observed in patients with bleeding tendencies and low platelets (thrombocytes < 30,000/µL). After adjusting the platelet count threshold for WBV participation to 30,000/µL, no further incidents occurred. Moreover, due to WBV-related side effects like physical exhaustion, 11% of all training sessions had to be stopped and another 11% required reductions in the vibration load. Patients participated in 48% of the planned sessions. While main reasons for non-attendance were medical issues (35%), only few WBV sessions were missed, not completed or needed modifications due to motivational issues. Consequently, WBV seems to be feasible for inpatient pediatric patients receiving chemotherapy for first cancer diagnosis, given a sufficiently high platelet count of at least 30,000/µL. Although WBV tolerance and training motivation appear high, patient's reduced medical condition during hospitalization can negatively impact training progression and attendance. Future research is required to confirm our findings on feasibility and to assess efficiency of WBV training for pediatric cancer patients receiving cancer treatment.

Keywords

Pediatric oncology · Physical exercise · Muscle stimulation · Neuromuscular training · Vibration therapy

Table 1 Clinical characteristics of study participants

Patient	Gender	Age at diagnosis (years)	Duration of acute cancer treatment (months)[a]	Diagnoses	Treatment
1	f	12	4.9	Germ cell tumor	C, S
2	m	17	12.5	Ewing sarcoma	C, S, R
3	m	16	2.7	Lymphoma	C, R
4	m	16	4.0	Lymphoma	C, S
5	m	11	3.4	Lymphoma	C, S
6	m	7	10.1	Leukemia[b]	C
7	m	10	9.6	Germ cell tumor	C, S, R
8	m	9	7.8	Rhabdomyosarcoma	C, S
9	f	13	8.8	Leukemia[b]	C
10	f	13	4.4	Lymphoma	C
11	m	12	8.4	Leukemia[b]	C

C chemotherapy, *f* female, *m* masculine, *R* radiotherapy, *S* surgery
[a]This period represents the acute cancer treatment phase performed at Children's Hospital Amsterdamer Straße, Cologne; two patients received further medical treatment in another hospital
[b]Patient suffered from acute lymphoblastic leukemia

Table 2 Attendance rates for whole-body vibration training

Patient	Study period (weeks)	Offered WBV sessions (*N*)	Missed WBV sessions (due to absences from hospital, *N*)	Possible WBV-sessions (*N*)	Attended WBV sessions (*N*)	Attendance rate (%)[a]
1	15	45	1	44	27	61
2	52	134	61	73	21	29
3	11	32	2	30	10	33
4	6	18	1	17	15	88
5	7	27	18	9	9	100
6	52	113	34	79	33	42
7	16	41	13	28	14	50
8	27	64	46	18	13	72
9	38	96	43	53	32	60
10	20	48	32	16	6	38
11	31	72	38	34	13	38
Min/Max; Total; Mean	7/52	690	289	401	193	48

WBV whole-body vibration, *N* number, *Min/Max* minimum/maximum
[a]Number of attended WBV sessions divided by the number of possible WBV sessions (when patients were admitted)

the original platelet count threshold defined prior to the beginning of the study and 144 (75%) respecting the adjusted platelet count threshold of < 30,000/µL. The individual attendance rates for each participant are listed in **Table 2**.

Reasons why study participants missed 208 sessions were (i) medical issues including poor health condition or medical procedures such as acute administration of chemotherapeutic agents or blood/thrombocyte transfusions (73/208, 35%); (ii) relative contraindications for WBV including fever or low thrombocytes (66/208, 32%); (iii) procedures that clashed with WBV sessions including therapeutic offers, hospital school or medical appointments such as lumbar puncture (24/208, 12%); (iv) lack of personal motivation (18/208, 9%); (v) side effects of cancer treatment leading to non-exercise, such as fatigue or being unwell (17/208, 8%); (vi) personal reasons such as private visits (9/208, 4%). Finally, in one session, the patient denied participation, as he experienced pain in the previous training session.

Compliance to the vibration protocol

Five patients achieved the highest possible vibration frequency of 27 Hz, with a vibration time of 120 s (#5, #7), 90 s (#10), or 60 s (#1, #8) per exercise. The remaining patients progressed up to a vibration frequency of either 24 Hz (vibration time 90 s: #9; 60 s: #2, #11) or 21 Hz (vibration time 120 s: #4, #6; 90 s: #12), respectively. Overall, 171 out of 193 attended WBV sessions (89%) could be performed in accordance with the WBV protocol, meaning that no reductions in the vibration load were necessary.

Modifications in the vibration protocol by therapists

Vibration frequency and/or time had to be reduced 22 times in 9 patients either during or following a training session (22/193, 11%; frequency: $n = 12$; time: $n = 10$). Reasons stated were side effects of cancer treatment including fatigue, polyneuropathic pain or poor physical condition (27%); WBV-related issues such as strong itching or training being too exhausting (27%), long absences from the hospital (23%); motivational issues (14%); not specified (9%).

Discussion

The results of this exploratory study indicate that WBV training might be feasible for children and adolescents undergoing chemotherapy for first cancer diagnosis, given a sufficiently high number of blood platelets. Individual cancer- and treatment-related obstacles need to be taken into consideration.

In our study, the WBV training was a safe training method for all participating patients with platelet levels above 30,000/µL. Patients with bleeding ten-

Table 3 Framework conditions for inpatient whole-body vibration training offered during pediatric chemotherapeutic treatment

To ensure adequate safety:
1. Supervision of training should be offered by exercise physiologists or physiotherapists. Additional home-based training might be suitable
2. Whole-body vibration (WBV) training should only be performed in patients with a sufficiently high number of blood platelets. We recommend platelet levels of at least 30,000/µL
3. Special attention should be given to patients with bleeding tendencies
To respect patients' fluctuating health and physical condition:
4. Medical clearance before starting the training and continuous support by the medical and/or nursing staff are advised
5. Platelet levels should be checked each time before starting training
6. A standardized but at the same time flexible WBV protocol should be applied to individualize the training[a]

WBV whole-body vibration
[a]Preliminary recommendations that can provide guidance for an individualized WBV training have been published previously (Rustler et al., 2019)

dencies who had lower platelet counts were not recommended to take part in WBV training due to the two reported one-time bleeding events. Although it cannot be assumed with certainty that these two adverse events were caused by the vibration stimulus, it cannot be ruled out. After adjusting the platelet count threshold to 30,000/µL, no further incidents occurred in the subsequent 144 sessions. This platelet threshold of 30,000/µL might therefore be appropriate for the WBV training during acute cancer treatment. The changed blood pressure behavior and flow during WBV (Rittweger, Beller, & Felsenberg, 2000), as well as the increased shear stress at the wall of the vessel (Yue & Mester, 2007) can be reasons why higher platelet levels seem necessary for WBV.

Regarding all *attended* training sessions ($n=193$), only few sessions had to be stopped early due to WBV-related side-effects, indicating that pediatric cancer patients during chemotherapeutic treatment are able to tolerate the vibration stimulus. Regarding all *offered* training sessions ($n=401$) by contrast, the mean attendance rate of 48% is relatively low. Although knowing that age-dependent physiological and biological conditions of WBV participants (e.g., bone structure or muscle mass) or additional training (e.g., strength or endurance training) performed prior/concomitant to the WBV intervention might impact the individual training tolerance, this low attendance rates generally indicates that the increased burdens during treatment might prevent the patients from taking part in the intervention as the main reasons for non-participation were medical ones. Previous studies in pediatric cancer survivors demonstrated an attendance to WBV training of over 80% (Daeggelmann et al., 2021; Rustler et al., 2018). A recent review regarding exercise interventions for pediatric cancer patients during inpatient care shows an attendance to general exercise of 59–85% (Rustler et al., 2017). The comparably high rate of non-attendance in our intervention indicates that it seems useful to supplement WBV with varied training content such as playful strength and endurance training to increase the physical activity level during the inpatient stay. Another fitting approach in addition to WBV might be sensorimotor or balance training, as already been conducted by Streckmann et al. (2019) in adult cancer patients. Compared to WBV, general exercise in pediatric oncology does also cover mild intensity exercises like mobilization which can even be performed in bed (Götte, Kesting, Taraks, & Boos, 2015), if, for example, low levels of blood platelets do not allow for WBV. This is important, of course, to meet the fluctuating physical abilities of the patients, but not suitable for WBV and might explain the comparatively low attendance demonstrated in this study. The low attendance rates, in addition, raise another important question: Is hospitalization the optimal time for WBV training in pediatric oncology?

Hospitalization periods are a good opportunity for offering supervised training as they generally obtain the best benefits (Huang & Ness, 2011). Within this study, supervision of training was important to ensure correct performance of WBV, guarantee safety and allow for prompt modifications of the study protocol. To increase attendance, supervised WBV training could also be offered during appointments in the outpatient clinic. Moreover, a combined intervention of supervised training in hospital and additional training at home might be conceivable for WBV interventions during acute care. During the home periods, adequate levels of blood platelet counts can be ensured through the high-frequent blood tests generally applied during pediatric cancer treatment (if not indicated, additional tests would be necessary). Supervision might be possible via online consultation. Following a sufficient familiarization period, additional nonsupervised WBV training at home might also be conceivable, as already conducted in children with other chronic diseases (Vry et al., 2014) and in children after inpatient oncological treatment (Daeggelmann et al., 2021).

To further improve compliance, applying a standardized and at the same time flexible WBV protocol may be suitable to meet the populations' needs more accurately. Although most sessions could be performed in accordance with our WBV protocol, with no necessary reductions in the vibration load, 6 of 11 participating patients did not achieve the highest vibration frequency of 27 Hz. We recommend striving for higher vibration frequencies in WBV training, as muscle activity increases with rising frequencies (Ritzmann et al., 2013). Besides, through offering a more flexible and individualized vibration protocol, side effects like itching—which is a common side effect of WBV training (Rittweger et al., 2000)—and pain might be reduced. Previously published recommendations for WBV training in pediatric oncology might provide guidance in this context (Rustler et al., 2019). **Table 3** contributes to these recommendations and lists the main findings that need to be considered when offering WBV training *during* chemotherapeutic treatment for pediatric cancer.

In considering whether future research on WBV in pediatric oncology is warranted, not only objective feasibility parameters primarily investigated in this explanatory study should play a role, but also personal issues like training motivation and pleasure. Our results support previous findings that children with cancer generally like the vibration stimulus and that they have fun participating in WBV training (Daeggelmann et al., 2021; Rustler et al., 2018), as motivation was rarely the reason for not attending, stopping or modifying WBV sessions. We therefore support investigating WBV in future pediatric exercise oncology research.

It is necessary to confirm the preliminary results indicating WBV feasibility for hospitalized pediatric cancer patients undergoing chemotherapeutic treatment and to extend the scientific knowledge about WBV training for children and adolescents receiving acute cancer treatment. As such, future research might focus on ways to best implement this new exercise strategy (e.g., achieving greater attendance, assessing modified WBV protocols). In addition, future intervention studies should also include a comparison of WBV to other exercise modes to identify the most beneficial interventions, also assessing how general exercises performed concomitant to WBV influences the ability to participate in WBV or how general exercises and WBV may depend on each other. Regarding benefits of WBV, there is a high need for evaluating the effects of WBV on parameters such as nerve and physical function, treatment-related side effects and quality of life. In this context, we encourage scientists to also take patients sports and training experience into account when evaluating WBV benefits to consider, for example, learning effects or muscle memory. Defining criteria for WBV-specific contraindications and WBV progression should be considered. As hematological parameters seem relevant when applying WBV in pediatric cancer patients, measuring blood pressure while exercising WBV might hereby be a suitable mechanism in future studies to decide whether a training session should be conducted. It is also necessary to identify the optimal mode for WBV.

Considering the potential of WBV training to improve physical and neuromuscular limitations that pediatric cancer patients and survivors often suffer from, the effort to closer investigate WBV in pediatric oncology is important, as even small improvements in physical and neuromuscular performance are vital and may allow the children and adolescents to regain a normal, independent and active life after overcoming cancer.

Limitations

First, as the research field is only in its beginning stage, we chose an exploratory study design with a pilot nature. Objective and perceived benefits of WBV were not assessed. Second, the study sample included only a small number of patients with heterogeneous characteristics including different ages, both sexes and mixed cancer diagnoses/treatment regimen. This heterogeneity led to great differences in the duration of medical treatment and thus duration of the training intervention (**Table 2**) and impacts the transferability of results. In addition, the results of this study apply only to patients with an initial diagnosis and need to be re-evaluated for patients with a relapse, under palliative treatment or for bone tumor patients. Bone tumor patients did not receive medical clearance for participation from the treating physician (inclusion criteria), as malignant bone tumors mainly occur in the lower limbs (Dirksen, Poremba, & Schuck, 2005), and thus in the trained body region. Moreover, we cannot assure that all eligible patients were asked for study participation due to incomplete documentation. Third, WBV was performed irrespective of patients' age and, thus, without considering the children's motor development.

Conclusions

WBV training seems to be feasible for children and adolescents receiving chemotherapeutic treatment for cancer, given that the patients have a sufficiently high number of blood platelets (we recommend a platelet threshold of at least 30,000/µL) on the day of training. Although patients seem to generally like and tolerate the vibration stimulus, their reduced medical conditions can impact training progression and attendance. Future research is required to confirm our findings on feasibility and to assess efficiency of WBV training for pediatric cancer patients during treatment.

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Declarations

Conflict of interest. V. Oschwald, A. Prokop, V. Maas, F. Streckmann, W. Bloch, F.T. Baumann and J. Daeggelmann declare that they have no competing interests.

All studies mentioned were in accordance with the ethical standards indicated in each case.

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