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A power-assisted exercise intervention in people with profound intellectual and multiple disabilities living in a residential facility: a pilot randomised controlled trial

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Abstract

Objective: To assess the feasibility of conducting a randomised controlled trial to determine the effectiveness of a twenty-week power-assisted exercise intervention in people with profound intellectual and multiple disabilities and to evaluate the potential beneficial effects of this intervention.

Design: Pilot randomised controlled trial.

Setting: A large-scale twenty-four-hour residential facility in the Netherlands.

Subjects: Thirty-seven persons with profound intellectual and multiple disabilities.

Intervention: Participants in the intervention group received a power-assisted exercise intervention three times a week for thirty minutes over a twenty-week period. Participants in the control group received care as usual.

Main measures: Trial feasibility by recruitment process and outcomes completion rates; intervention feasibility by programme compliance rates; potential outcomes by functional abilities, alertness, body composition, muscle tone, oxygen saturation, cardiovascular fitness and quality of life.

Results: Thirty-seven participants were recruited (*M* age = 32.1, *SD* = 14.6) and were randomly allocated to intervention (*n* = 19) and control (*n* = 18) groups. Programme compliance rates ranged from 54.2% to 97.7% with a mean (SD) of 81.5% (13.4). Oxygen saturation significantly increased in the intervention group. Standardised effect sizes on the difference between groups in outcome varied between 0.02 and 0.62.

Conclusions: The power-assisted exercise intervention and the trial design were feasible and acceptable to people with profound intellectual and multiple disabilities living in a residential facility. This pilot study

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suggests that the intervention improves oxygen saturation, but further implementation with the aim of improving other outcomes should be considered with caution.

Keywords
Profound intellectual and multiple disabilities, power-assisted exercise, motor intervention, motor activation, randomised controlled trial

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Introduction

Motor activation of persons with profound intellectual and multiple disabilities in daily practice is rather limited.[1] On weekdays, more than half of the participants in this study engaged in less than one motor activity per day on average.[1] These results reflect the overall image of a passive environment for people with intellectual disabilities in general[2–5] and especially in people with profound intellectual and multiple disabilities.[6,7] The consequences of motor inactivity for people with profound intellectual and multiple disabilities affect nearly all the domains of human functioning (e.g. functional abilities, alertness and physical and mental health).[8–11]

Increasing motor activity in daily practice is difficult due to a lack of feasible and evidence-based interventions for people with profound intellectual and multiple disabilities.[12] Although studies in people with severe to profound intellectual disabilities have reported beneficial effects for several types of motor interventions, many questions still have to be answered, such as *when* and exactly *how* often we need to provide *which* intervention in order to improve functioning most effectively.[12] Furthermore, which interventions are sustainable and address the needs of direct support persons? To date, most interventions have been shown to be difficult for direct support persons to maintain and are therefore frequently short-lived.[13]

Recently, a power-assisted exercise intervention for people with profound intellectual and multiple disabilities has been adapted from the field of support of elderly people without intellectual disabilities, in which positive effects on bodily function and functional abilities were achieved.[14] As the name already suggests, this intervention uses powered machines to assist people with profound intellectual and multiple disabilities to perform exercises. However, the effects of this power-assisted exercise intervention on the functioning of people with profound intellectual and multiple disabilities have not yet been researched. A pilot study was performed to assess the feasibility of conducting a randomised controlled trial to determine the effectiveness of the power-assisted exercise intervention in people with profound intellectual and multiple disabilities, and to evaluate potential outcome measures.

Method

A single-centre randomised controlled trial was conducted with repeated measurements at five-week intervals. Randomisation was performed by an independent researcher with a computer minimisation programme to create two similar groups with respect to gender, age (<18, 19-37, 38-57 and >58) and Gross Motor Function Classification System level (IV or V).[15] The physical therapist and researchers involved received an allocation list by e-mail. Approval for this research was granted by the institutional review board of the residential facility. The study is registered in the ISRCTN registry (reference number: ISRCTN85363315).

Participants

The participants were recruited from a large-scale twenty-four-hour residential facility which planned to implement the power-assisted exercise intervention. Sample size was based on eligibility within the facility. Participants were selected based on the following criteria: profound intellectual disability

(estimated intelligence quotient below 20–25 points or a developmental age of up to 24 months);[16] profound or severe motor disabilities (classified as Gross Motor Function Classification System level IV or V).[17] A medical condition which could not be resolved in the short term excluded participation. The parents or legal representatives of the participants provided written informed consent.

Intervention

The intervention group undertook power-assisted exercise rather than passive activity (e.g. watching TV or listening to music). The intervention consisted of power-assisted exercises such as sit-ups, hip flexion, spreading and closing of arms and legs and moving arms and legs up and down. All the exercises were carried out using six different powered-exercise machines which supported the participants in performing the exercises. The intervention was an adaptation of a power-assisted exercise programme for the elderly,[14] with each participant in the intervention group participating three times a week for thirty minutes over a twenty-week period. A more detailed description can be found in Appendix A (Supplementary material).

Control

The control group participated in the regular programme (usual care) which is characterized by a considerable number of hours in which no activities take place.[7] Activities offered are represented by sedentariness; activation is a minor part of the support provided.[1,6]

Measurements for feasibility

Trial feasibility. Willingness to participate and the acceptance of randomisation was measured by the number of participants assessed for eligibility minus the number of parents or legal representatives of participants who declined to participate over the total number assessed for eligibility times 100.[18] The ability to participate was measured by the number of participants assessed for eligibility minus the number of participants who met the exclusion criterion over the total number assessed for eligibility times 100. The completion rates for outcomes were measured per measurement as the number of completed assessments divided by the total number of participants multiplied by 100.[18]

Intervention feasibility. Programme compliance was measured by the number of sessions attended divided by the total number of sessions (minus number of missing) multiplied by 100.

Measurements of potential outcomes

Functional abilities. Functional abilities were measured using the Behavioural Appraisal Scales.[19] These scales consist of 100 items divided into five independent scales.

Alertness. Alertness was measured using the Alertness Observation List.[20] Within this instrument, an individual alertness profile was described using information gathered by direct support persons.

Body composition. This variable was measured using the Body Mass Index.[21]

Muscle tone. Muscle tone was measured using the Modified Ashworth Scale.[22]

Assessment of oxygen saturation and cardiovascular fitness. For ethical reasons, heart rate and oxygen saturation were evaluated using a within-subjects design with weekly measurements in the intervention group. During the power-assisted exercises, the oxygen saturation level was measured using a finger pulse oximeter, while cardiovascular fitness was also measured by taking the heart rate using a finger pulse oximeter.

Quality of life. Quality of life was inventoried using the QOL-PMD, a questionnaire which maps the objective components of the quality of life of people to profound intellectual and multiple disabilities.[23]

The outcomes were assessed by blinded test assistants, separately from the assessments of body composition and quality of life (both completed by direct support persons) and the assessment of

oxygen saturation and cardiovascular fitness (completed by the test assistants).

Statistical analysis

The mean (SD) and range were used to describe the sample, completion rates and the feasibility parameter. Trial feasibility measurements were calculated and a diagram was used for participant flow. To evaluate potential beneficial effects, preliminary analyses were conducted to determine the type of missing data and the comparability of the groups at baseline. It was expected that the missing data was at the least Missing At Random. Little's Missing Completely At Random tests were conducted to obtain a more accurate indication of whether the data was Missing At Random or Missing Completely At Random.[24] When the test indicated that the data was Missing At Random, a chi-square test checked whether the missing data correlated with the allocated group. Baseline measurements were compared using a Mann-Whitney U test.

Mean (SD), median and range were used to describe measurement outcomes. Change scores (T4 minus baseline) were then calculated, separately from body composition. The results of body composition are expected to change into 'normal'. Therefore, descriptive statistics were added per subgroup (i.e. underweight, normal or overweight). The change mean (SD) and the 95% CI of the change mean were calculated for the rest of the potential outcomes. Independent-samples t-tests were performed to compare differences in the change between intervention and control group on functional abilities, alertness and muscle tone. Regarding quality of life, a MANOVA and separate independent-samples t-tests were conducted on the change scores of the subscales of the QOL-PMD. The significance level was set at .05. The standardised and raw mean differences were reported so as to understand the practical relevance of the results.[25–27] Standardised mean differences (d) between .00 and .19 were considered insignificant, between .20 and .49 small, between .50 and .70 medium and .80+ large.[28] Small, medium and large standardised mean difference were placed in a clinical context using the raw mean difference (D) and its 95% CI.[26,27] Analyses were performed using SPSS Statistics version 23.0.

The effect of the intervention on heart rate and oxygen saturation was analysed using multilevel analyses. Changes in heart rate and oxygen saturation over time were modelled using potential growth patterns.[29] A significant effect of the model parameters is determined if the regression coefficient is twice as large as the standard error, with the significance level set at .05.[29] Deviance tests were used for model comparison.[29] Analyses were performed using MLwiN version 2.35.

Results

A sample of 37 people with profound intellectual and multiple disabilities (25 males and 12 females) participated (M age = 32.1, SD = 14.6, range: 4–60 years). Figure 1 presents the recruitment process. The rate of willingness to participate and acceptance of randomisation was 95.2% and the ability to participate in the study was 92.9%. Completion rates of outcomes per measurement ranged from 50% (Heart rate, measurement week 3) to 100% (Heart rate and oxygen saturation level, measurement week 7) with a mean (SD) of 84.4% (11.2). The feasibility parameter of the intervention ranged from 54.2 to 97.7% with a mean (SD) of 81.5% (13.4). No adverse events were caused by the intervention.

Results for functional abilities, alertness and quality of life

Table 1 presents the results per measurement and group. No significant differences were found between the two groups at baseline measurement ($p > 0.05$). The missing data about functional abilities and alertness was assumed to be Missing At Random. None of these were significantly associated with group ($p > 0.05$). Analysis showed that the changes in functional abilities did not differ significantly between the two groups, see Table 2.

The standardised mean difference effect sizes show a negative small effect size on general communicative behaviour (d = -0.24) and a positive

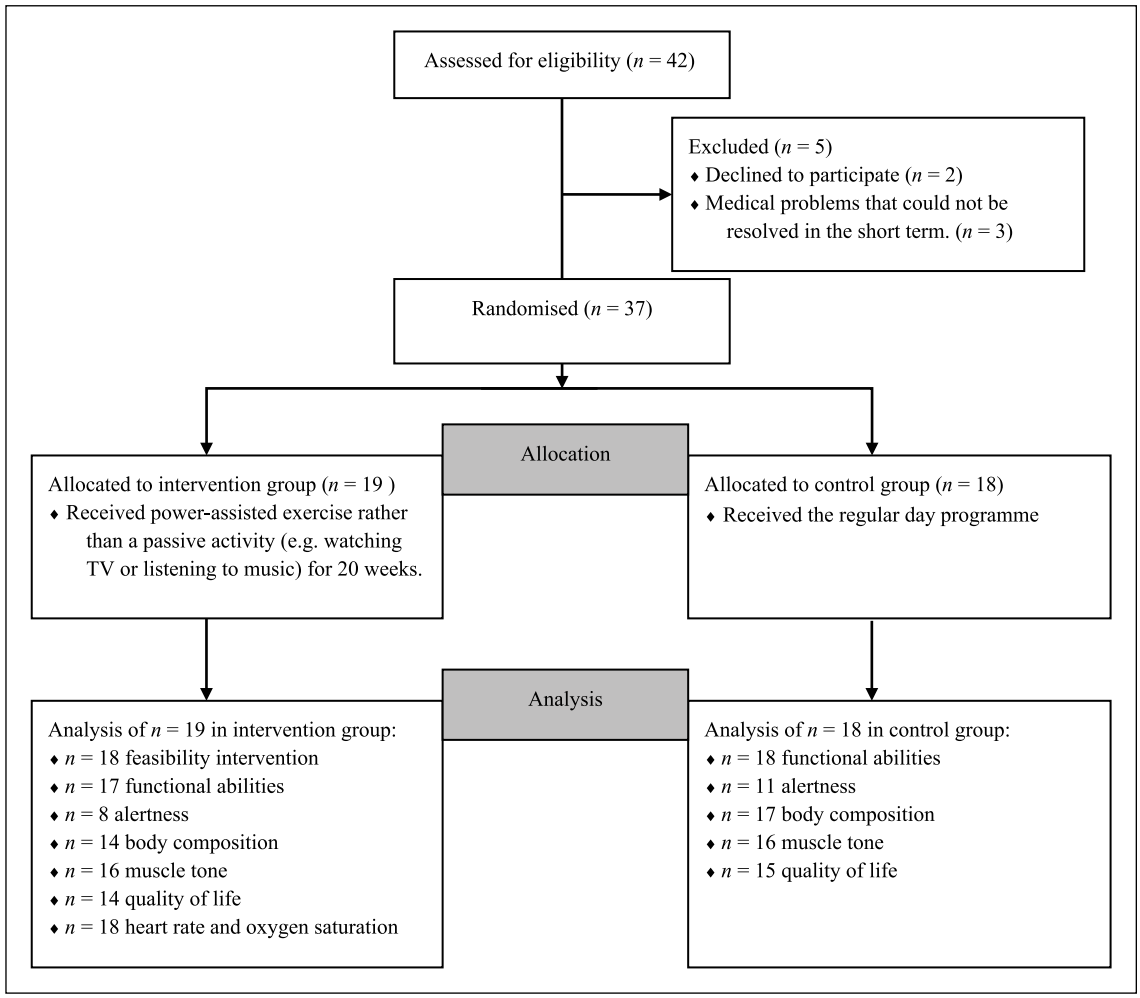

Figure 1. Participant flow chart.

medium effect size on receptive language behaviour ($d = 0.52$). The raw mean differences indicate, however, practically insignificant results as both general communicative behaviour and receptive language behaviour did not show a mean difference between intervention and control groups of more than one item change. Changes in alertness also did not differ significantly between intervention and control group, as no practically significant results were found. Finally, no significant differences were found between the intervention and control groups for quality of life, Pillai's trace = $F(6,22) = 0.92$, $p = 0.50$. The standardised mean difference effect sizes show a negative medium effect size on physical wellbeing ($d = -0.62$), a negative small effect size on communication and influence ($d = -0.22$) and a positive small effect size on social wellbeing ($d = 0.47$). The change in physical wellbeing, communication and influence and social wellbeing differ, on average, between the intervention and control groups with 8.374, 3.813, and 10.44% on an outcome scales, which ranged from zero to 100%. The results seem to indicate that physical wellbeing decreases and social wellbeing increases due to the intervention. The confidence intervals of the raw mean differences are broad, however.

Table 1. Outcome measures at baseline (T0), mid measures (T1, T2, T3) and after the intervention period (T4).

Outcome (scale)		Intervention group			Control group		
		n	Mean (SD)	Median (range)	*n*	Mean (SD)	Median (range)
BAS – Affective expressions (0-3)	T0	17	2.9 (0.2)	3 (2, 3)	18	3.0 (0.0)	3 (3, 3)
	T4	17	2.8 (0.7)	3 (0, 3)	18	2.8 (0.4)	3 (2, 3)
BAS – Receptive language behaviour (0-9)	T0	17	4.4 (2.6)	6 (0, 7)	18	5.4 (1.6)	5 (2, 9)
	T4	17	4.8 (2.7)	5 (0, 9)	18	5.1 (2.0)	5.5 (0, 8)
BAS – General communicative behaviour (0-15)	T0	17	5.1 (4.2)	4 (0, 11)	18	4.8 (3.1)	4 (1, 11)
	T4	17	5.5 (4.6)	3 (0, 14)	18	5.8 (4.5)	3 (1, 14)
BAS – Visual behaviour (0-36)	T0	17	10.8 (11.0)	7 (0, 33)	18	9.4 (11.2)	3.5 (0, 36)
	T4	17	9.7 (10.3)	5 (0, 34)	18	8.2 (10.8)	4 (0, 35)
BAS – Explorative behaviour (0-37)	T0	17	13.4 (9.2)	15 (0, 31)	18	13.7 (9.6)	13 (2, 32)
	T4	17	14.5 (9.7)	17 (0, 33)	18	15.1 (10.4)	13.5 (1, 33)
AOL – Alertness (0-100)	T0	14	61.6 (28.4)	64.5 (4, 100)	15	64.5 (26.4)	70.0 (10, 100
	T1	10	69.8 (27.6)	80.0 (20, 100)	10	62.8 (21.0)	65.5 (28, 100)
	T2	16	61.9 (32.9)	58.0 (12, 100)	11	62.1 (20.7)	63.0 (30, 96)
	T3	14	63.5 (32.4)	72.0 (0, 100)	13	59.6 (13.4)	57.0 (44, 89)
	T4	12	66.0 (33.1)	72.0 (0, 100)	14	71.1 (26.4)	74.0 (18, 100)
QOL-PMD – Physical wellbeing (0-100)	T0	17	62.6 (18.9)	64.3 (30.0, 93,8)	17	59.4 (17.3)	64.3 (25.0, 87.5)
	T4	15	54.1 (15.5)	56.3 (25.0, 78.6)	16	60.5 (17.0)	57.7 (25.0, 83.3)
QOL-PMD – Material wellbeing (0-100)	T0	17	74.4 (12.6)	75.0 (50.0, 100.0)	17	75.5 (10.3)	77.8 (50.0, 88.9)
	T4	15	74.7 (13.4)	77.8 (50.0, 93.8)	16	75.9 (13.3)	77.8 (50.0, 94.4)
QOL-PMD – Communication & influence (0-100)	T0	17	64.4 (25.7)	75.0 (14.3, 100.0)	17	65.6 (20.7)	64.3 (35.0, 100.0)
	T4	15	68.5 (31.9)	80.0 (0.0, 100.0)	16	70.1 (23.5)	75.0 (11.1, 100.0)
QOL- PMD – Social wellbeing (0-100)	T0	17	44.3 (21.5)	44.4 (0.0, 83.3)	17	50.7 (18.1)	44.4 (22.2, 85.7)
	T4	15	54.0 (25.5)	50.0 (11.1, 91.7)	16	51.8 (21.9)	52.8 (6.3, 100.0)
QOL-PMD – Development (0-100)	T0	17	64.4 (23.1)	68.8 (11.1, 94.4)	17	73.3 (19.5)	75.0 (38.9, 100.0)
	T4	15	73.2 (21.9)	78.6 (14.3, 100.0)	16	77.9 (22.1)	83.3 (27.8, 100.0)
QOL-PMD – Activities (0-100)	T0	17	68.3 (20.4)	70.0 (25.0, 95.0)	17	76.5 (17.3)	77.8 (30.0, 100.0)
	T4	15	77.7 (13.5)	85.0 (50.0, 95.0)	16	83.5 (13.5)	85.0 (60.0, 100.0)
MAS – Muscle tone (0, 1, 1.5, 2, 3, 4)	T0	17	1.2 (0.8)	1.0 (0, 2)	18	1.0 (1.2)	1.0 (0, 4)
	T1	18	1.6 (0.8)	1.5 (0, 3)	16	0.8 (0.9)	1.0 (0, 3)
	T2	18	1.8 (1.2)	1.5 (0, 4)	17	0.9 (0.9)	1.0 (0, 3)
	T3	16	1.0 (1.0)	1.0 (0, 4)	16	0.8 (0.9)	0.5 (0, 2)
	T4	18	1.4 (1.0)	1.3 (0, 4)	16	1.0 (1.2)	1.0 (0, 4)

Results on body composition and muscle tone

No significant differences were found between the two groups at baseline measurement ($p > 0.05$). The missing data on muscle tone was assumed to be Missing At Random, but was not significantly associated with group ($p > 0.05$). Table 3 presents the descriptive statistics for Body Mass Index by subgroup. Changes in muscle tone did not differ significantly between the intervention and control groups, and the standardised and raw mean differences show practically insignificant differences (Table 2).

Results on cardiovascular fitness and oxygen saturation

On average, heart rate decreased from a mean of 82.2 beats/min at baseline to a mean of 78.9 beats/

Table 2. Change in outcome measures after the intervention period.

Outcome (scale)		Intervention group			Control group			Independent-samples t-test					
		n	Δ Mean (SD)	95% CI for Δ Mean	*n*	Δ Mean (SD)	95% CI for Δ Mean	t	*df*	*p*	*d*	*D*	95% CI for *D*
BAS – Affective expressions (0-3)	T4 – T0	17	−0.1 (0.8)	−0.52, 0.28	18	−0.2 (0.4)	−0.36, 0.02	0.234[a]	23	0.817	0.08	0.049	−0.39, 0.48
BAS – Receptive language behaviour (0-9)	T4 – T0	17	0.5 (1.8)	−0.44, 1.38	18	−0.3 (1.3)	−0.97, 0.30	1.544	33	0.132	0.52	0.804	−0.26, 1.86
BAS – General communicative behaviour (0-15)	T4 – T0	17	0.4 (2.0)	−0.59, 1.35	18	1.0 (2.8)	−0.22, 2.28	−0.713	33	0.481	−0.24	−0.588	−2.27, 1.09
BAS – Visual behaviour (0-36)	T4 – T0	17	−1.1 (4.2)	−3.30, 1.06	18	−1.2 (6.1)	−4.25, 1.80	0.059	33	0.954	0.02	0.105	−3.52, 3.73
BAS – Explorative behaviour (0-37)	T4 – T0	17	1.1 (5.5)	−1.70, 3.94	18	1.4 (4.6)	−0.89, 3.67	−0.159	33	0.875	−0.06	−0.271	−3.74, 3.20
AOL – Alertness (0-100)	T4 – T0	8	1.6 (11.9)	−8.34, 11.59	11	4.6 (27.7)	−14.08, 23.17	−0.312[a]	14.4	0.760	−0.14	−2.920	−22.94, 17.10
QOL-PMD – Physical wellbeing (0-100)	T4 – T0	14	−6.2 (14.9)	−14.76, 2.45	15	2.2 (12.1)	−4.48, 8.92	−1.667	27	0.107	−0.62	−8.374	−18.68, 1.93
QOL-PMD – Material wellbeing (0-100)	T4 – T0	14	0.5 (14.5)	−7.82, 8.90	15	−0.2 (21.0)	−11.87, 11.43	0.112	27	0.911	0.04	0.758	−13.10, 14.62
QOL-PMD – Communication & influence (0-100)	T4 – T0	14	3.2 (18.2)	−7.29, 13.77	15	7.1 (17.1)	−2.39, 16.50	−0.582	27	0.566	−0.22	−3.813	−17.26, 9.63
QOL- PMD – Social wellbeing (0-100)	T4 – T0	14	13.3 (23.0)	0.05, 26.62	15	2.9 (21.1)	−8.77, 14.55	1.276	27	0.213	0.47	10.440	−6.35, 27.23
QOL-PMD – Development (0-100)	T4 – T0	14	7.9 (15.8)	−1.24, 17.06	15	5.2 (16.5)	−3.94, 14.36	0.447	27	0.658	0.19	2.699	−9.66, 15.05
QOL-PMD – Activities (0-100)	T4 – T0	14	8.3 (22.2)	−4.47, 21.10	15	6.4 (12.5)	−0.59, 13.31	0.295	27	0.770	0.11	1.954	−11.64, 15.55
MAS – Muscle tone (0, 1, 1.5, 2, 3, 4)	T4 – T0	16	0.06 (0.7)	−0.31, 0.44	16	−0.03 (1.2)	−0.68, 0.62	0.267	30	0.792	−0.09	0.094	−0.62, 0.81

[a]Equal variance not assumed.

Table 3. BMI by subgroup at baseline (T0), mid measures (T1, T2, T3) and after the intervention period (T4).

	Subgroup[a]		Intervention group			Control group		
			n	Mean (SD)	Median (range)	n	Mean (SD)	Median (range)
BMI (kg/m^2)	Underweight	T0	2	16.6 (1.5)	16.6 (15.5, 17.6)	6	17.3 (0.6)	17.2 (16.5, 18.2)
		T1	2	16.7 (1.6)	16.7 (15.5, 17.8)	6	17.2 (0.5)	17.2 (16.5, 17.8)
		T2	2	16.7 (1.6)	16.7 (15.5, 17.8)	6	17.3 (0.5)	17.2 (16.5, 17.9)
		T3	2	16.4 (1.4)	16.4 (15.4, 17.4)	6	17.1 (0.5)	17.0 (16.5, 18.0)
		T4	1	15.4 (-)	15.4 (-)	6	17.1 (1.1)	17.2 (15.5, 18.5)
	Normal	T0	13	21.3 (1.7)	21.3 (19.0, 24.0)	7	21.6 (1.9)	21.4 (19.0, 24.6)
		T1	13	21.2 (1.8)	21.3 (18.9, 24.4)	6	21.5 (2.8)	21.4 (17.0, 24.6)
		T2	13	21.3 (2.0)	21.3 (18.0, 24.2)	7	21.8 (2.2)	21.2 (18.0, 24.6)
		T3	13	21.2 (1.9)	21.3 (18.0, 24.2)	7	22.1 (2.5)	22.0 (18.0, 24.9)
		T4	10	21.5 (2.2)	21.7 (18.0, 24.2)	7	21.4 (1.8)	21.5 (18.0, 24.0)
	Overweight	T0	4	27.0 (1.4)	26.9 (25.8, 28.6)	4	27.3 (3.3)	25.8 (25.3, 32.1)
		T1	4	27.2 (1.9)	26.8 (25.4, 29.8)	4	27.2 (2.9)	26.1 (25.3, 31.4)
		T2	4	26.8 (2.1)	26.3 (24.9, 29.8)	4	27.8 (2.6)	26.8 (25.9, 31.6)
		T3	4	26.8 (2.2)	26.4 (24.6, 29.8)	4	27.5 (2.3)	26.6 (25.9, 30.8)
		T4	3	27.0 (2.6)	26.5 (24.6, 29.8)	4	27.0 (2.8)	26.6 (24.2, 30.8)

[a]Based on baseline measurement (T0).

min in the last week of the intervention. No significant growth pattern in heart rate could be predicted which improved the model fit significantly ($p > 0.05$). The oxygen saturation level increased on average from 90.9% at baseline to 96.3% in the last week of the intervention. The results of the growth model are presented in Table 4. A quadratic model including a significant quadratic term which varies from participant to participant turned out to yield the best statistical fit, $\chi^2 = 67.3$ (7), $p < .001$. This model presents a significant increase in oxygen saturation over the earlier weeks of intervention, which levelled off during the second half of the intervention period.

Table 4. Quadratic growth model for oxygen saturation (%) in the participants of the intervention group.

Fixed effect	Empty model	Final model
	Coefficient (SE)	Coefficient (SE)
Intercept	94.9 (0.33)	94.9 (0.32)
Week (linear)		5.15 (1.30)*
Week (quadratic)		–2.24 (1.05)*
Random effect	**Parameter (SE)**	**Parameter (SE)**
Level 2:		
Intercept variance	1.23 (0.66)	1.27 (0.62)
Slope variance (*week*)		17.6 (10.1)
Slope variance (*week*^{2})		7.53 (6.6)
Intercept-slope covariance (*week*)		–3.39 (1.95)
Intercept-slope covariance (*week*^{2})		2.88 (1.60)
Level 1:		
Residual variance	11.8 (1.02)	9.01 (0.83)
-2 Log likelihood	1540.3	1473.1

* Significant at alpha .05 (i.e., coefficient is larger that two times the standard error).

Discussion

The main finding is that the power-assisted exercise intervention and trial design were feasible and acceptable to people with profound intellectual and multiple disabilities living in a residential facility. The participants completed on average 81.5% of the intervention sessions. Nearly all the parents or legal representatives of the participants accepted the randomisation and almost all the people who met the inclusion criteria were able to participate. Test assistants and direct support persons were able to perform the majority of the measurements ($M = 84.4\%$).

The results showed no promising effects according to the effect sizes (i.e. standardised and raw mean differences and its 95% CI) on the outcome measurements, apart from a slight tendency towards a decrease in physical wellbeing in the intervention group. Furthermore, an increase in social wellbeing in the intervention group compared to the control group was observed. That these outcomes were measured by direct support persons who knew to which group the participant belonged should be taken into account. The lack of change in muscle tone and functional abilities was unexpected and in contrast to a study which reported on the benefits of the power-assisted exercise intervention in the elderly.[14] This might be explained by the differences between the target groups: the elderly were still able to perform physical exercise themselves and might have had more active input. In addition, the lack of change in functional abilities, alertness, cardiovascular fitness and quality of life was not in line with the evidence of the benefits of (motor) activation in people with intellectual disabilities found in earlier research.[8–11] However, a study into the effectiveness of interventions consisting of power-assisted exercises in people with intellectual disabilities has, as far as we know, not yet been done. Therefore, the differences in the results might still be explained by the specific characteristics of this intervention compared to the content of interventions evaluated in earlier research.

An additional finding in this study was a significant increase in oxygen saturation during the power-assisted exercise in the intervention group. What the findings on oxygen saturation exactly mean, as well as what is considered to be normal oxygen saturation for people with profound intellectual and multiple disabilities, are not yet known. The precise meaning of the significant improvement in oxygen saturation in the intervention group is open to discussion. Nevertheless, the low levels of oxygen saturation at the baseline measurement for various participants were striking.

A strength of this study was the use of a randomised controlled trial design. This study also seems to be one of the first to evaluate a motor intervention for adults with profound intellectual and multiple disabilities by means of an RCT.[12] However, this study has a number of limitations. The randomisation of the participants was done at the gender, age and Gross Motor Function Classification System levels. People with profound intellectual and multiple disabilities have additional problems which were not taken into account in the randomisation.[16] Although the baseline measurements for all the variable outcomes were checked and no significant differences between groups were found, a further study within this target group should take into account heterogeneity in relation to the research question. Some outcomes included in this study might be explained by heterogeneity or age of people with intellectual and multiple disabilities.

The lack of statistically significant results is influenced by the study's small sample size. However, the standardised effect sizes varied between 0.02 and 0.62 and eight of the thirteen effect sizes were lower than 0.20, which was considered insignificant.[28] A study with a larger sample size would therefore not be expected to show such large differences in outcome between the groups. The remaining five effect sizes were considered small (-0.22, -0.24, 0.47) and medium (0.52, -0.62). However, placing these effect sizes in a practical context did not suggest meaningful differences. Based on this, we did not calculate the number of participants needed for a fully powered RCT study. This study's results are presented so that they can be combined with other results in a future meta-analysis.

Examining the potential beneficial outcomes in this pilot study was worthwhile because the independent t-test alone provides useful and meaningful measures of the effect sizes. Furthermore, in our opinion, it was worthwhile looking into potential outcomes of the intervention within the target group without taking heterogeneity into account, because the current residential support for people with profound intellectual and multiple disabilities is mainly group focused, no matter what their additional impairments and/or their age might be.[6,30] Further research could focus on deeper analyses of the effects of the power-assisted exercise intervention on various outcomes, taking these factors into account. When dividing people with profound intellectual and multiple disabilities into subgroups based on their additional impairments, the number

of participants will be too small for a single-centre RCT and therefore a multi-centre study is required in future research into the effectiveness of the intervention in this target group.

We certainly do not want to discourage the trend in which practice itself is looking for suitable interventions, given that insufficient motor activation negatively affects a person's functioning. However, we advise that professionals in practice carefully consider the further implementation of the power-assisted exercise intervention for all people with profound intellectual and multiple disabilities with the aim of improving outcomes in several domains. Until evidence is obtained, professionals need to evaluate every individual effect of this intervention systematically, by using goal attainment scaling for example.[31,32]

Clinical messages

- The power-assisted exercise intervention is feasible and acceptable for people with profound intellectual and multiple disabilities.
- The power-assisted exercise intervention improves the oxygen saturation of people with profound intellectual and multiple disabilities during activity.
- Further implementation of the power-assisted exercise intervention with the aim of improving other outcomes should be considered with caution.

Conflict of interest

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References

1. Van der Putten AAJ, Bossink LWM, Frans N, et al. Motor activation in people with profound intellectual and multiple disabilities in daily practice. *J Intellect Dev Disabil* 2017; 42: 1–11. DOI: 10.3109/13668250.2016.1181259.
2. Draheim CC, Williams DP and McCubbin JA. Prevalence of Physical Inactivity and Recommended Physical Activity in Community-Based Adults With Mental Retardation. *Ment Retard* 2002; 40: 436–444.
3. Emerson E. Underweight, obesity and exercise among adults with intellectual disabilities in supported accommodation in Northern England. *J Intellect Disabil Res* 2005; 49: 134–143.
4. Hilgenkamp TIM, van Wijck R and Evenhuis HM. Low physical fitness levels in older adults with ID: results of the HA-ID study. *Res Dev Disabil* 2012; 33: 1048–1058.
5. Lahtinen U, Rintala P and Malin A. Physical Performance of Individuals With Intellectual Disability : A 30-Year Follow-Up. *Adapt Phys Act Q* 2007; 125–143.
6. Vlaskamp C, Hiemstra SJ, Wiersma LA, et al. Extent, Duration, and Content of Day Services' Activities for Persons With Profound Intellectual and Multiple Disabilities. *J Policy Pract Intellect Disabil* 2007; 4: 152–159.
7. Zijlstra HP and Vlaskamp C. Leisure provision for persons with profound intellectual and multiple disabilities: quality time or killing time? *J Intellect Disabil Res* 2005; 49: 434–448.
8. Van der Putten AAJ, Vlaskamp C, Reynders K and Nakken H. Children with profound intellectual and multiple disabilities: the effects of functional movement activities. *Clin Rehabil* 2005; 19: 613–620.
9. Carmeli E, Zinger-Vaknin T, Morad M, et al. Can physical training have an effect on well-being in adults with mild intellectual disability? *Mech Ageing Dev* 2005; 126: 299–304.
10. Munde V, Vlaskamp C, Post WJ, et al. Observing and Influencing Alertness in Individuals With Profound Intellectual and Multiple Disabilities in Multisensory Environments. *Journal of Cognitive Education and Psychology* 2012; 11: 5–19.
11. Jones MC, Walley RM, Leech A, et al. Behavioral and Psychosocial Outcomes of a 16-Week Rebound Therapy-Based Exercise Program for People With Profound Intellectual Disabilities. *J Policy Pract Intellect Disabil* 2007; 4: 111–119.
12. Houwen S, van der Putten A and Vlaskamp C. A systematic review of the effects of motor interventions to improve motor, cognitive, and/or social functioning in people with severe or profound intellectual disabilities. *Res Dev Disabil* 2014; 35: 2093–2116.
13. Bartlo P and Klein PJ. Physical activity benefits and needs in adults with intellectual disabilities: systematic review of the literature. *Am J Intellect Dev Disabil* 2011; 116: 220–232.
14. Jacobson BH, Smith D, Fronterhouse J, et al. Assessment of the benefit of powered exercises for muscular endurance and functional capacity in elderly participants. *J Phys Act Health* 2012; 9: 1030–1035.
15. Altman DG and Bland JM. Treatment allocation by minimisation. *BMJ* 2005; 330: 843.
16. Nakken H and Vlaskamp C. A Need for a Taxonomy for Profound Intellectual and Multiple Disabilities. *J Policy Pract Intellect Disabil* 2007; 4: 83–87.

17. Palisano RJ, Hanna SE, Peter L, et al. Validation of a Model of Gross Motor Function for Children With Cerebral Palsy. *Phys Ther J Am Phys Ther Assoc* 2000; 80: 974–985.
18. Leon AC, Davis LL and Kraemer HC. The role and interpretation of pilot studies in clinical research. *J Psychiatr Res* 2011; 45: 626–629.
19. Vlaskamp C, van der Meulen BF and Zijlstra HP. De intrumentele realisering van het Gedrags Taxatie Intrument. *Tijdschr voor Orthop* 2002; 41: 22–31.
20. Vlaskamp C, Fonteine H, Tadema AC, et al. *Manual for the 'Alertness in people with profound intellectual and multiple disabilities' checklist*. Groningen: Stichting Kinderstudies, 2010.
21. Waninge A, van der Weide W, Evenhuis IJ, et al. Feasibility and reliability of body composition measurements in adults with severe intellectual and sensory disabilities. *J Intellect Disabil Res* 2009; 53: 377–388.
22. Waninge A, Rook RA, Dijkhuizen A, et al. Feasibility, test-retest reliability, and interrater reliability of the Modified Ashworth Scale and Modified Tardieu Scale in persons with profound intellectual and multiple disabilities. *Res Dev Disabil* 2011; 32: 613–620.
23. Petry K, Maes B and Vlaskamp C. Psychometric evaluation of a questionnaire to measure the quality of life of people with profound multiple disabilities (QOL-PMD). *Res Dev Disabil* 2009; 30: 1326–1336.
24. Little RJA. A test of missing completely at random for generalised estimating equations with missing data. *J Am Stat Assoc* 1998; 1198–12002.
25. Dempsey I and Balandin S. Reporting the magnitude of study findings. *J Intellect Dev Disabil* 2012; 37: 87–88.
26. Snijders TAB. Hypothesis testing: Methodology and limitations. In: Smelser NJ and Baltes PB (eds) *International encyclopedia of the social & behavioral sciences*. Amsterdam: Elsevier, 2001, pp. 7121–7127.
27. Wilkinson L. Inference T force on statistical. Statistical methods in psychology journals: guidelines and explanations. 1999; 54: 594–604.
28. Dunst CJ and Hamby DW. Guide for calculating and interpreting effect sizes and confidence intervals in intellectual and developmental disability research studies. *J Intellect Dev Disabil* 2012; 37: 89–99.
29. Snijders TAB and Bosker R. *Multilevel Analysis: an introduction to basic and advanced multilevel modeling*. 2nd ed. London: SAGE Publications Ltd, 2011.
30. Van der Putten AAJ and Vlaskamp C. Day services for people with profound intellectual and multiple disabilities: An analysis of thematically organized activities. *J Policy Pract Intellect Disabil* 2011; 8: 10–17.
31. Vlaskamp C and van der Putten AAJ. Focus on interaction: The use of an Individualized Support Program for persons with profound intellectual and multiple disabilities. *Res Dev Disabil* 2009; 30: 873–883.
32. Jones MC, Walley RM, Leech A, et al. Using goal attainment scaling to evaluate a needs-led exercise programme for people with severe and profound intellectual disabilities. *J Intellect Disabil* 2006; 10: 317–335.