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Effects of Galileo® vibration exercise in addition to care-related exercise according to the Viv-Arte® nursing conception on motor control, motor function, motor action and muscular strength in patients with chemotherapy-related polyneuropathy [Auswirkungen des Galileo®-Vibrationstrainings als Zusatz zum pflegerischen Trainingskonzept des VivArte® Modells auf Bewegungssteuerung, Alltagsbewegungen, Alltagshandlungen und Muskelkraft bei Chemotherapie-Induzierter Polyneuropathie]

Submission date
25/08/2010

Recruitment status
No longer recruiting

Registration date
06/09/2010

Overall study status
Completed

Last Edited
15/02/2017

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PI-PNP-_01_10 (sponsor), DJCLS R 09/22 (funder)

Study information

Scientific Title
Effects of whole-body vibration exercise in addition to care-related exercise according to the Viv-Arte® nursing conception on motor control, motor function and muscular strength: a randomised controlled trial in chemotherapy-related polyneuropathy

Study objectives
Based on a further development of kinesthetic nursing, Viv-Arte® Training conception (VAT) includes
1. Manual therapy
2. Gymnastic exercise
3. Functional training
Whole-body vibration has proved to help persons who are bedridden or otherwise unable to exercise, maintaining muscular strength needed for activities of daily living. It is hypothised, that patients suffering from chemotherapy-related polyneuropathy could also benefit from whole-body vibration exercise, when added to VAT. Therefore, the trial at hand compares randomised groups treated with VAT versus VAT + whole-body vibration.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Ulm (Germany) Ethics Board, 25/05/2010, ref: 27/10 UBB/bal

Study design
Open-label single-centre randomised active controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Polyneuropathies, secondary to haematologic neoplasms and chemotherapy

Interventions
Control group and experimental group:
15 sessions (two per week) of 60 minutes each, containing VAT manual therapy and functional training. The latter will be skipped for patients who are not reliant upon personal assistance for mobility tasks (according to MOTPA, see secondary outcome measurements). Gymnastic exercise is instructed individually during the session, but should be conducted between sessions. Patients receive a diary and a pedometer for documentation of exercise including walking.

Experimental group only:
In each session, whole-body vibration exercise is integrated after manual therapy. Using a Galileo® training platform, a side-alternating motion similar to a seesaw movement is applied. Amplitude and frequency are variable and will be individually adjusted.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Chair Rising Test (5 times standing up from a chair) at baseline, 8th exercise session, 15th (last) exercise session, and 4 weeks after last exercise session

Secondary outcome measures
1. Bipedal jump test and balance test using a force plate (Leonardo® Mechanography) at baseline, 15th (last) exercise session, and 4 weeks after last exercise session
2. Functional mobility measured using motor tests including the Timed up and go test (TUG) and the Mobility test for patients in acute care (MOTPA) at baseline and 15th (last) exercise session
3. Quality of life, measured using the EORTC Quality of Life Core Questionnaire (QLQ-C30), Version 3.0, at baseline, 15th (last) exercise session, and 4 weeks after last exercise session
4. Neurotoxicity, measured using the FACT/GOG Ntx (Funktional Assessment of Cancer Therapy /Gynecologie Onkcology Group - Neurotoxity) at baseline, 8th exercise session, 15th (last) exercise session, and 4 weeks after last exercise session
5. Paresthesia, measured using the Visual Analogue Scale (VAS) at baseline, 15th (last) exercise session, and 4 weeks after last exercise session
6. Sensory function, measured at baseline and 15th (last) exercise session, using a standardized quantitative sensory testing (QST) battery:
6.1. Thermal detection threshold, using a computer controlled thermode
6.2. Tactile detection threshold, using von-Frey hairs
6.3. Mechanical pain threshold/sensitivity for pinprick and for light touch, including wind-up (series) sensitivity

6.4. Vibration detection threshold, using a tuning fork
6.5. Pressure pain threshold, using a pressure algometer
7. In order to estimate velocity of nerve conduction as well as sensory and motor evoked potentials (SNAP, MEP), additional electrophysiological measurements will be taken on the discretion of the neurologist

Overall study start date
01/07/2010

Completion date
30/06/2014

Eligibility

Key inclusion criteria
1. Aged between 18 and 70 years
2. Polyneuropathy diagnosed (MeSH D011115)
3. Ongoing or finished chemotherapy due to hematologic neoplasms (MeSH D019337)
4. Contiguity between polyneuropathy and chemotherapy supposable
5. Chair Rising Test with pathological score (> 10 s)
6. Informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
122

Key exclusion criteria
1. Blood coagulation disorder
2. Infection beyond control
3. Thrombosis within 6 months before the trial
4. Severe neurological or psychiatric disorder, which might impair the validity of informed consent or the compliance with trial interventions
5. Epilepsy
6. Pregnacy

Date of first enrolment
01/07/2010

Date of final enrolment

30/06/2014

Locations

Countries of recruitment
Germany

Study participating centre
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Sponsor type
University/education

Website
http://www.uniklinik-ulm.de/struktur/zentrale-einrichtungen/pflegedienst

ROR
https://ror.org/032000t02

Funder(s)

Funder type
Industry

Funder Name

German Jose Carrera Leukaemia Foundation (Deutsche José Carrera Leukämie Stiftung e.V.) (Germany) - (DJCLS R 09/22)

Funder Name
NOVOTEC Medical GmbH (Germany)

Funder Name
Viv-Arte® Bewegungsschule (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	07/02/2017		Yes	No