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Impact of dance therapy on the psychophysical well-being of wheelchair-bound cancer patients in palliative care

Submission date 10/12/2024	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 10/12/2024	**Overall study status** Ongoing	
Last Edited 10/12/2024	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims

For most cancer patients, oncological treatment is traumatic (involving organ/body part removal, pain, nausea, hair loss, fatigue, etc). Many patients experience a loss of control over their bodies and of life's meaning. Considering the holistic impact of dance on the physical, psychological, and spiritual spheres, it is widely used in the treatment of people with psychological and emotional issues. In cancer patients, dance interventions are associated with positive physical, functional, and psychosocial outcomes improving mental well-being and overall quality of life. A literature review indicates that dance as a form of therapy has never been assessed in palliative patients with advanced cancer. The planned study aims to gain knowledge about the impact of dance therapy on selected psychophysical aspects of patients with advanced cancer who are wheelchair-bound and under palliative care. It is hypothesized that dance therapy will improve their quality of life, reduce symptoms of depression, and alleviate pain and fatigue. If the hypothesis is confirmed, it would be worthwhile to recommend and promote dance therapy in palliative physiotherapy to improve the quality of life for the patients.

Who can participate?

Hospice palliative care patients with advanced cancer who are wheelchair-bound.

What does the study involve?

Before the intervention begins, patients will undergo a medical consultation and a physiotherapy consultation to prepare them for the experiment. The final inclusion of patients in the study will depend on the results of the assessment of their independence in daily activities and cognitive function. Patients included in the study will be randomly assigned to two groups: an experimental group (EG) and a control group (CG). Both groups will receive routine medical, nursing, physiotherapy, and psychological care following the best clinical practice guidelines recommended in palliative care. In both groups, patients will continue their daily activities. Patients in the EG will additionally participate in individual dance exercise sessions twice a week for 30 minutes over 8 weeks (16 dance sessions). The dance therapy will be provided by a physiotherapist with 13 years of experience in palliative physiotherapy and who is

also a certified ballroom dance teacher. Patients in the CG will not engage in regular, organized dance exercises. Before the intervention, after 4 and 8 weeks, and 4 weeks after its completion, all participants will be assessed by questionnaires for quality of life, depression, pain, and fatigue. Assessment of independence in daily activities and cognitive function will be repeated after 8 weeks of intervention.

What are the possible benefits and risks of participating?
The results of the study will provide knowledge about the effectiveness of dance therapy in patients with advanced cancer, who are under palliative care. It can be expected that dance therapy will effectively contribute to alleviating symptoms of depression and reducing fatigue and pain, which may improve the quality of life of the participants. If dance therapy proves to be effective, it may encourage therapists to incorporate this form of therapy into rehabilitation programs at palliative care facilities. No invasive assessment methods will be used in the study; the planned assessment methods are commonly used in clinical practice, particularly for older individuals. Therefore, the likelihood of adverse effects during the study is minimal. However, there may be some fatigue due to the exercises and a slight risk of injury. This risk will be minimized since participants will be qualified by a physician and the dance exercises sessions will be conducted by an experienced physiotherapist.

Where is the study run from?
1. Social Society Cordis Hospice in Katowice (Poland)
2. Academy of Physical Education in Katowice (Poland)

When is the study starting and how long is it expected to run for?
June 2024 to December 2027

Who is funding the study?
Academy of Physical Education in Katowice (Poland)

Who is the main contact?
Agnieszka Opala-Berdzik, a.opala-berdzik@awf.katowice.pl

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Evaluation of the effects of dance therapy on psychophysical aspects of wheelchair-bound cancer patients in advanced stages undergoing palliative care: a randomized controlled trial

Acronym
Dancetherapyeffectsoncancerpatientsinpalliativecare

Study objectives
1. Dance therapy will reduce symptoms of anxiety and depression in wheelchair-bound cancer patients in advanced stages undergoing palliative care
2. Dance therapy will reduce pain perception in wheelchair-bound cancer patients in advanced stages undergoing palliative care
3. Dance therapy will reduce fatigue perception in wheelchair-bound cancer patients in advanced stages undergoing palliative care
4. Dance therapy will improve the quality of life for wheelchair-bound cancer patients in advanced stages undergoing palliative care

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 07/11/2024, The University Bioethics Committee for Scientific Research at the Jerzy Kukuczka Academy of Physical Education in Katowice (ul. Mikołowska 72A, Katowice, 40-065, Poland; +48 (0)32 2075352; komisjabioetyczna@awf.katowice.pl), ref: 3-XI/2024

Study design
Single-centre interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)

Hospice

Study type(s)
Quality of life, Treatment

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

Health condition(s) or problem(s) studied
Wheelchair-bound cancer patients in advanced stages undergoing palliative care

Interventions
For dance therapy intervention, patients included in the study will be randomly assigned to two groups by drawing one of two cards with the inscriptions "experimental group" (EG) and "control group" (CG). Both groups will receive routine medical, nursing, physiotherapy, and psychological care following the best clinical practice guidelines recommended in palliative care. In both groups, patients will continue their daily activities.

In the EG, dance therapy sessions will be conducted individually (with a physiotherapist with 13 years of experience in palliative physiotherapy and ballroom dance teaching certification and patient) twice weekly for two months. Each session will consist of dance exercises to the music rhythm lasting 30 minutes (5-10 minute warm-up, 20-minute main part, and 5-minute cool-down). The main part of the session will include exercises with elements of dance. Patients will imitate the movements of the physiotherapist to the rhythm of the music. The exercises will be simple, repeated several times, and designed for individuals without dance experience, with limited physical abilities, and potentially facing self-acceptance issues. The movements will particularly engage the upper body, including the cervical and thoracic spine, shoulder girdle, upper limbs, chest, and trunk. Stretch bands and plastic poles will be used during the sessions to help patients focus on the movement and reduce anxiety (i.e., to have something to hold onto). A total of 16 dance therapy sessions will be conducted in the experimental group. In the control group, patients will not participate in regular, supervised dance exercises.

During the study, a physician will exclude the patient if their health condition prevents further participation.

Intervention Type
Other

Primary outcome measure
1. Level of anxiety and depression will be measured using the Hospital Anxiety and Depression Scale (HADS), Polish version, at baseline, after 4 and 8 weeks of the intervention, and 4 weeks after its completion.
2. Pain intensity will be measured using the Visual Analogue Scale (VAS) at baseline, after 4 and 8 weeks of the intervention, and 4 weeks after its completion.
3. Fatigue will be measured using the Fatigue Assessment Scale (FAS), Polish version, at baseline, after 4 and 8 weeks of the intervention, and 4 weeks after its completion.
4. Quality of life will be measured using the Edmonton Symptom Assessment System (ESAS-r), Polish version, at baseline, after 4 and 8 weeks of the intervention, and 4 weeks after its completion.

Secondary outcome measures

1. Independence in daily activities will be measured using a 100-point Barthel Scale at the stage of qualifying patients for the study and after 8 weeks of the intervention.
2. Cognitive function will be measured using the Mini-Mental State Examination (MMSE), Polish version, at the stage of qualifying patients for the study and after 8 weeks of the intervention.

Overall study start date
10/06/2024

Completion date
14/12/2027

Eligibility

Key inclusion criteria
1. Social Society Cordis Hospice patient
2. Diagnosis of advanced cancer
3. Completed causal treatment
4. Wheelchair-bound patient
5. Provided informed consent to participate in the study
6. Scoring above 20 points on the 100-point Barthel Index assessing independence in daily activities
7. Scoring above 23 points on the Mini-Mental State Examination (MMSE) assessing cognitive functions

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
90 Years

Sex
Both

Target number of participants
60 (experimental group: 30, control group: 30)

Key exclusion criteria
1. Central nervous system tumors
2. Internal and external bleeding
3. Dangerous heart arrhythmia
4. Unstable hypertension
5. Acute phlebitis or deep vein thrombosis
6. Acute respiratory failure
7. Intestinal obstruction

8. Vomiting, diarrhea (within the last 24-36 hours)
9. Inflammatory processes in the abdominal cavity, during and after radiotherapy (up to 6 weeks after abdominal radiation)
10. Infection requiring antibiotic therapy
11. Age <18 years
12. Inability to understand the Polish language, both spoken and written

Date of first enrolment
14/01/2025

Date of final enrolment
14/10/2027

Locations

Countries of recruitment
Poland

Study participating centre
Social Society Cordis Hospice in Katowice, Poland
Społeczne Towarzystwo Hospicjum Cordis
ul. Teofila Ociepki 2
Katowice
Poland
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Study participating centre
Academy of Physical Education in Katowice
Akademia Wychowania Fizycznego im. Jerzego Kukuczki w Katowicach, ul. Mikołowska 72
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Sponsor information

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Sponsor type
University/education

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ROR
https://ror.org/05wtrdx73

Funder(s)

Funder type
University/education

Funder Name
Akademia Wychowania Fizycznego im. Jerzego Kukuczki w Katowicach

Alternative Name(s)
The Jerzy Kukuczka Academy of Physical Education in Katowice, AWF Katowice

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Poland

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal and a doctoral dissertation.

Intention to publish date
14/12/2028

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed during the study will be available upon request from Agnieszka Opala-Berdzik (a.opala-berdzik@awf.katowice.pl)

IPD sharing plan summary

Available on request