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Individualized music for people with dementia

Submission date	Recruitment status	[_] Prospectively registered
27/02/2018	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/04/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/11/2024	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
The increasing prevalence of dementia raises the question of how the quality of life and care for people with dementia can be maintained and enhanced. Previous research shows that listening to personally meaningful music can promote positive emotions and memories as well as a reduction of stress, agitation, and anxiety of people with dementia. Thus, individualized music can be regarded as a promising, non-drug intervention for people with dementia. This study investigates whether listening to individualized music improves quality of life, well-being, social participation and reduces problem behaviour and stress of people with dementia. It aims at evaluating the effectiveness, applicability, and acceptance of an individualized music intervention for people with dementia in institutional care.

Who can participate?
People with dementia living in one of the cooperating nursing homes

What does the study involve?
Participants are randomly allocated to an intervention group or a control group. Over a period of 6 weeks, participants in the intervention group listen to their individualized music playlist every other day for 20 minutes. The control group participants receive standard care. In this period of time, observation of behavior is conducted for both groups every other week for 60 minutes. During the first and the last observation of behavior saliva will be collected (please note that saliva will be only collected for a subsample). External assessments by the nursing staff are conducted at four assessment points regarding well-being, social participation, problem behavior, and daily behavior of the people with dementia.

What are the possible benefits and risks of participating?
The possible benefits of listening to individualized music include improvement of quality of life and a reduction of stress levels as well as a reduction of problem behaviour of people with dementia. The intervention is expected to enhance well-being, quality of sleep and social participation as well as reduce agitation and resistance to care. A possible risk of participating is that agitated behavior increases temporarily in response to the music selected for the individualized playlists. However, project staff or staff from the nursing home monitor the participants and intervene if a negative reaction is observable during the music intervention.

Where is the study run from?
The study is being run by the Department of Counseling and Clinical Intervention, Institute of Psychology, Friedrich-Schiller University Jena. It takes place in four to five nursing homes in Thuringia (Germany).

When is the study starting and how long is it expected to run for?
January 2018 to July 2020

Who is funding the study?
National Association of Statutory Health Insurance Funds (Germany)

Who is the main contact?
Prof. Dr. Gabriele Wilz, gabriele.wilz@uni-jena.de

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
DRKS00013793

Study information

Scientific Title
Individualized music for people with dementia - Improvement of quality of life and social participation for people with dementia in institutional care

Study objectives
Current hypothesis as of 22/01/2019:
The trialists expect an improvement of quality of life and a reduction of problem behavior (e.g. agitation, resistance to care) as well as a reduction of stress levels (measured via saliva analyses of cortisol and alpha-amylase) for the participating people with dementia in the intervention

group compared with the control group. Quality of life includes well-being, quality of sleep and social participation.
In addition, they expect to observe positive short-term effects during and after the music intervention: emotional and motor changes (facial expression, body movement and other positive reactions) and an enhancement of communication, attention and orientation.

Previous hypothesis:
The trialists expect an improvement of quality of life and a reduction of problem behavior (e.g. agitation, resistance to care) for the participating people with dementia in the intervention group compared with the control group. Quality of life includes well-being, quality of sleep and social participation.
In addition, they expect to observe positive short-term effects during and after the music intervention: emotional and motor changes (facial expression, body movement and other positive reactions) and an enhancement of communication, attention and orientation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethical Commission of the Faculty of Social and Behavioural Sciences, 20/02/2018, ref: FSV 18 /06
2. Ethical Commission of the Faculty of Social and Behavioural Sciences, 14/08/2018, ref: FSV 18 /39 (for ethical approval of biological measures [saliva analyses])

Study design
Multicenter randomized controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Dementia

Interventions
Current intervention as of 22/01/2019:
Participants are randomly allocated to an intervention or a control group.

Over a period of 6 weeks, the intervention group participants will listen to their individualized music playlist through headphones every other day for 20 minutes in the presence of employees of the nursing home or project staff. Observation of behavior will be conducted by the project staff every other week for 60 minutes before, during and after the music intervention. For a subsample, collection of saliva will be done during the first and the last observation of behavior sessions before and after music intervention as well as at the end of the 60 minutes' observation period.

The control group receives standard care. The observation of behavior and saliva collection will be conducted with the same frequency and duration as in the intervention group. Saliva will only be collected for a subsample.

External assessments by the nursing staff will be conducted at four assessment points regarding well-being, social participation, problem behavior, and daily behavior of the people with dementia. baseline (6 weeks before treatment), pretest, posttest, follow-up (6 weeks after the treatment)

Previous intervention:
Participants are randomly allocated to an intervention or a control group.

Over a period of 6 weeks, the intervention group participants will listen to their individualized music playlist through headphones every other day for 20 minutes in the presence of employees of the nursing home or project staff. Observation of behavior will be conducted by the project staff every other week for 60 minutes before, during and after the music intervention.

The control group receives standard care. The observation of behavior will be conducted with the same frequency and duration as in the intervention group.

External assessments by the nursing staff will be conducted at four assessment points regarding well-being, social participation, problem behavior, and daily behavior of the people with dementia. baseline (6 weeks before treatment), pretest, posttest, follow-up (6 weeks after the treatment)

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measures as of 22/01/2019:
1. Quality of life:
1.1. External assessment by the nursing staff at all four assessment points: mood, sleep quality, social participation (assessed with a visual analogue scale, based on Wilz & Soellner, 2015), depressive symptoms (assessed with the Cornell Scale for Depression in Dementia, CSDD)
1.2. Observation of behavior will be conducted three times during the intervention period using an adapted rating scale: emotional and motor changes (facial expression, body movement, other (positive) reactions), activation regarding social participation
2.Problem behavior:
2.1. External assessment by the nursing staff at all four assessment points: resistance to care (assessed with a visual analogue scale, based on Wilz & Soellner, 2015), problem behavior /behavioral syndromes (assessed with the Cohen-Mansfield Agitation Inventory (CMAI) and the Nurses Observation Scale for Geriatric Patients (NOSGER II)
2.2. Observation of behavior (see above): appearance of problem behavior or other negative reactions

Measured at baseline (6 weeks before treatment), pretest, posttest, follow-up (6 weeks after the treatment)
3. Stress:
3.1. Saliva analyses in regard of cortisol and alpha-amylase
3.2. Subjective ratings of stress levels (smiley face assessment scale).
Stress ratings/saliva will be measured three times each observation of behavior session.

Previous primary outcome measures:
1. Quality of life:
1.1. External assessment by the nursing staff at all four assessment points: mood, sleep quality, social participation (assessed with a visual analogue scale, based on Wilz & Soellner, 2015), depressive symptoms (assessed with the Cornell Scale for Depression in Dementia, CSDD)
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2.Problem behavior:
2.1. External assessment by the nursing staff at all four assessment points: resistance to care (assessed with a visual analogue scale, based on Wilz & Soellner, 2015), problem behavior /behavioral syndromes (assessed with the Cohen-Mansfield Agitation Inventory (CMAI) and the Nurses Observation Scale for Geriatric Patients (NOSGER II)
2.2. Observation of behavior (see above): appearance of problem behavior or other negative reactions
Measured at baseline (6 weeks before treatment), pretest, posttest, follow-up (6 weeks after the treatment)

Secondary outcome measures
Acceptance and applicability of the intervention measured using a self-developed questionnaire at posttest

Overall study start date
01/01/2018

Completion date
31/07/2020

Eligibility

Key inclusion criteria
1. Diagnosis of dementia
2. Living in institutional care
3. Informed consent provided by the participants themselves, their relatives or their conservator

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
130, to achieve 92 randomized, with saliva samples collected from 50

Key exclusion criteria
1. Severe hearing problems
2. No informed consent provided by the participants themselves, their relatives or their conservator

Date of first enrolment
15/01/2018

Date of final enrolment
31/12/2019

Locations

Countries of recruitment
Germany

Study participating centre
Friedrich-Schiller-Universität Jena, Abteilung Klinisch-psychologische Intervention
Humboldtstraße 11
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Sponsor information

Organisation
Friedrich-Schiller-Universität Jena

Sponsor details
Institut für Psychologie
Abteilung Klinisch-psychologische Intervention
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07743

Sponsor type
University/education

Website
http://www.uni-jena.de/Klinisch_Psychologische_Intervention.html

ROR
https://ror.org/05qpz1x62

Funder(s)

Funder type
Other

Funder Name
National Association of Statutory Health Insurance Funds

Results and Publications

Publication and dissemination plan
The study protocol will be submitted for publication on 15/04/2018. Planned publication of the results in high-impact peer-reviewed journals.

Intention to publish date
31/07/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Lisette Weise (lisette.weise@uni-jena.de).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	14/12/2018		Yes	No
Results article	Stress markers	25/02/2023	27/02/2023	Yes	No
Results article		12/09/2024	16/09/2024	Yes	No
Results article		24/11/2024	26/11/2024	Yes	No