ISRCTN68084105 https://doi.org/10.1186/ISRCTN68084105

Individualized music for people with dementia in home care

Submission date	Recruitment status	[X] Prospectively registered
24/03/2022	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/04/2022	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
04/07/2025	Mental and Behavioural Disorders	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Dementia is a syndrome (a group of related symptoms) associated with an ongoing decline in brain functioning. There are many different causes of dementia, and many different types. The rate of dementia is increasing. As the disease progresses, people with dementia experience psychological and behavioral symptoms that decrease their quality of life. In addition, family caregivers are also burdened by caregiving and nursing. Research shows that listening to favorite music that has a personal connection to the biography of people with dementia before the disease can improve quality of life and promote positive emotions, memories, and social interaction. There is a high need for cost-effective and non-drug treatments that improve the quality of life of people with dementia and provide relief for family caregivers such as reducing behavioral agitation. To date, there is a lack of studies in Germany investigating the experience of people with dementia while listening to individualized music in-home care. The aim of this study is to investigate the acceptance, effectiveness, and applicability of app-based individualized music listening in-home care.

Who can participate?

People with dementia who live at home, and their family caregivers.

What does the study involve?

After a detailed explanation about study participation and receipt of the consent forms, all family caregivers formulate six weeks before the start of the intervention an individual goal to be achieved during the 6-week intervention phase and establish target criteria. Then all dyads are randomly assigned to an intervention group or a control group. For the intervention group, family caregivers complete a questionnaire about individualized music preferences of the people with dementia on the tablet. To supplement this, a telephone interview is conducted and if possible, the people with dementia themselves are asked about their music preferences. Then the playlists are created by the project team.

Over a period of 6 weeks, people with dementia in the intervention group listen to their individualized music via headphones for 20 minutes every other day. The music is provided via an app and played from a tablet. They are accompanied by their family caregivers. The participants in the control group do not listen to any music and go about their daily lives as usual and will get 200 Euros after participation. Both groups will receive information brochures on dementia.

During the 6-week intervention phase, three home visits with behavioral observations and video recordings are planned by the project team in both groups. At the first home visit, the severity of dementia and the person with dementia's ability to provide information about his/her own well-being is assessed. Family caregivers receive technical instruction on how to use the tablets. In addition, hair samples are collected from the dyads of both groups at the first and third home visit with the consent of the participants. Family caregivers assess the intervention, feasibility, and acceptability with a semi-structured interview at the third home visit. Meta-data about the intervention (frequency, duration, and stopping of music listening) are stored automatically and directly via the app.
During the study period, family caregivers complete more detailed paper-pencil questionnaires about the well-being and quality of life as well as the behavior problems of the person with dementia, the experienced care burden, and dyadic interaction 6 weeks before, directly before the intervention phase, directly after the intervention phase, as well as 6 weeks after the intervention phase. They also complete short questionnaires daily on their own well-being, the well-being of the person with dementia, and dyadic interaction, as well as before and after listening to music (only intervention group). If possible, people with dementia assess their own well-being.
After the successful completion of the study, all study participants will be informed about the study results if they are interested.

What are the possible benefits and risks of participating?
Possibe benefits are improvement of quality of life and reduction of psychobiological stress of people with dementia and family caregivers, an increase of caregiver burden and an improvement of dyadic interaction.
It is possible that listening to individualized music can trigger negative or unpleasant memories. This could be indicated, for example, by restlessness, irritation, or negative affect. Moreover, these possible negative effects could also occur due to inappropriately selected music. Accompanying music listening by family caregivers makes it possible to respond individually to the situation.

The emergence of the stresses for the participating people with dementia could also have an impact on the accompanying family caregivers. Likewise, the daily completion of the questionnaires could be a burden for the family caregivers, too. In addition, using technology (tablet) could be challenging for older family caregivers. Family caregivers will be supported by the music project team during study participation.

Where is the study run from?
The study is run from Friedrich-Schiller University Jena, Germany, Institute of Psychology, Department of Counseling and Clinical Intervention

When is the study starting and how long is it expected to run for?
June 2021 to May 2025

Who is funding the study?
The study is funded by the National Association of Statutory Health Insurance Funds (GKV Spitzenverband der Pflege- und Krankenkassen) (Germany)

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Individualized music for people with dementia in home care - acceptance and effectiveness of an app-based music intervention

Acronym
IMuD-App

Study objectives
The main aim of this study is to investigate the acceptance, effectiveness, and applicability of an app-based individualized music listening intervention for people with dementia in-home care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/03/2022, Ethical Commission of the Faculty of Social and Behavioral Sciences, Friedrich-Schiller Universität Jena (Carl-Zeiss-Platz 16, 07743 Jena, Germany; +49 3641/945805; martin.omalley@uni-jena.de), ref: FSV 22/013

Study design
Multicenter randomized controlled study

Primary study design
Interventional

Study type(s)
Quality of life

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

Interventions
Six weeks before the start of the intervention (Baseline) and before randomization, an individual goal for people with dementia that aim to achieve through the 6-week music intervention will formulate by family caregivers (Goal Attainment Scaling) during a telephone interview with a project member. Criteria will also be defined to measure goal attainment. Then participating dyads (people with dementia and family caregiver) are randomly assigned to an intervention group or a control group by an external person.

Over a six-week intervention phase, people with dementia in the intervention group will listen to their individualized music via headphones for 20 minutes every other day (3-4 times a week). The music will be provided via a self-developed app and played from a tablet. Family caregivers will accompany the music intervention. In addition, three home visits are planned where participants

will be observed for 60 minutes immediately before listening, during listening, and immediately after listening to the individualized music.
During the six-week intervention phase, the control group will receive standard care and be observed during three home visits with the same frequency and duration as the intervention group. For participating in the study, the control group will receive 200 Euros.
At the first home visit, both study groups will be assessed for dementia severity using the Mini-Mental-State-Examination (MMSE; Folstein et al., 1975). If MMSE >10, then the Subjective Quality of Life Inventory (CapQOL; Wong et al., 2005) is used to assess the ability of people with dementia to make statements about their own well-being. Family caregivers will receive a detailed technical briefing and an introduction to the daily assessments.
During the first and third home visits, hair samples of the people with dementia and their family caregivers will be taken in both groups with consent. At the third home visit, family caregivers' acceptance, the applicability of the music intervention (only intervention group), and experience with the tablet, app, and measurements will be assessed using a semi-structured interview.

In both groups, external and self-report assessments by family caregivers will be conducted at four assessment points (6 weeks before (T0), directly before the intervention phase (T1), directly after the intervention phase (T2), as well as 6 weeks after the intervention phase (follow-up)). They will answer detailed paper-pencil questionnaires about their own well-being and quality of life, the well-being and quality of life as well as the behavior problems of the person with dementia, the experienced care burden, and dyadic interaction.
In addition, family caregivers will use the tablet to complete daily assessments of their own well-being and the well-being of people with dementia, family caregivers of the intervention group will complete assessments before and after listening to music, and if possible, people with dementia will assess their own well-being (Ecological Momentary Assessment; EMA).
Both groups will receive information brochures on dementia.

Intervention Type
Behavioural

Primary outcome(s)
Before randomization, an individual goal that participants aim to achieve through the 6-week music intervention, will be formulated by family caregivers using Goal Attainment Scaling (GAS) during a telephone interview with a project member. Criteria will also be defined to measure goal attainment. The assessment of goal attainment will take place at T2 (after intervention) by family caregivers.

Key secondary outcome(s))
At four-measurement time points (6 weeks before the start of the intervention (T0), the start of the intervention (T1), after the intervention (T2), and follow-up measurement 6 weeks after the end of the intervention (T3)), family caregivers will assess themselves as well as the persons with dementia.
If possible, people with dementia will complete self-assessments during three home visits, and before and after listening to their music (EMA).
Family caregivers will answer daily assessments (EMA).
Family caregivers of the intervention group will answer coupled with the music intervention assessments (EMA).
In addition, the music project team will conduct behavioral observations and collect psychobiological stress markers during three home visits.

1. Outcomes related to people with dementia:
1.1. Well-being measured using Visual Analog Scales regarding emotional well-being (Wilz & Söllner, 2016) and arousal (adapted by Wilz & Söllner, 2016) by external assessment by family caregivers at T0, T1, T2, T3, and EMA, as well as by the music project team using a self-constructed coding guide during the behavioral observation.
If possible, people with dementia will assess their own emotional well-being with the self-report-tool Dementia Mood Picture Test (DMPT; Tappen & Berry, 1995) and Smiley Assessment Scale (SAS), based on three faces with different emotional expressions (adapted from Mittelman & Epstein, 2009; Rosenberg, 2009; Perez-Saez et al., 2020; Lee et al., 2008) at three home visits. In addition, the Smiley Assessment Scale will be used before and after listening to individualized music (EMA).
1.2. Quality of life: If possible, measured using by self-assessment of people with dementia via a single item, which has already been used successfully in one major German study (H.I.L.D.E - Heidelberg Instrument for the Quality of Life of Dementia Patients, Becker & Kaspar, 2006), during three home visits.
1.3. Resistance to care measured using a Visual Analog Scale (Weise et al., 2019) by external assessment by family caregivers at T0, T1, T2, T3, as well as by the music project team using a self-constructed coding guide during the behavioral observation.
1.4. Depressive Symptoms measured using the Cornell Scale for Depression in Dementia (CSDD; Alexopoulos et al., 1988) by external assessment by family caregivers at T0, T1, T2, T3, as well as by the music project team using a self-constructed coding guide during the behavioral observation.
1.5. Immediate and short-term responses to individualized music measured before and after listening to the music by family caregivers (EMA), as well as by the music project team using a self-constructed coding guide during the behavioral observation.

2. Outcomes related to family caregiver:
2.1. Self-efficacy measured using a subscale (satisfaction with one's own performance as a caregiver) of Abbreviated Sence of Competence Questionnaire (SCQ- Short; Pendergrass et al., 2015) at T0, T1, T2, and T3.
2.2. Well-being measured using visual analog scales of emotional well-being (Wilz & Söllner, 2016) and arousal (adapted by Wilz & Söllner, 2016) at T0, T1, T2, T3, and EMA.
2.3. Burden of and coping with behavioral problems measured using a German version of the Behavioral Pathology in Alzheimer´s Disease Rating Scale (Behave-AD; Sittler et al., 2020) at T0, T1, T2, and T3.
2.4. Positive aspects of care measured using a subscale of the Positive Aspects of Care questionnaire (PAC; Tarlow et al., 2004) at T0, T1, T2, and T3.
2.5. Care burden measured using the German short version of the Home Care Scale (HPS; Gräßel, 2001) at T0, T1, T2, and T3.

3. Outcomes related to family caregiver and people with dementia:
3.1. Dyadic interaction between family caregivers and people with dementia measured using a self-constructed questionnaire with eight items by family caregivers at T0, T1, T2, T3, and EMA, as well as by the music project team using a self-constructed coding guide during the behavioral observation, and via video analysis.
3.2. Psychobiological stress of people with dementia and family caregivers will be assessed via hair sample analysis (cortisol/ DHEA) at T1 and T2, and heart rate variability using FaceReader via video analysis. Video recordings will be made during three home visits, during the intervention phase.

Completion date
31/05/2025

Eligibility

Key inclusion criteria
1. People with dementia with medically diagnosed dementia
2. Lives at home
3. No serious hearing problems
4. Participation as a dyad with family caregivers

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
All

Total final enrolment
102

Key exclusion criteria
For people with dementia:
1. Planned move to a nursing home within the next 3 months

For family caregivers:
2. Serious unstable or progressive illness
3. Lack of German language skills
4. Serious psychiatric diagnoses
5. Obvious cognitive impairments
6. Participation in another study for family caregivers

Date of first enrolment
16/05/2022

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
Germany

Study participating centre

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Sponsor information

Organisation
Friedrich Schiller University Jena

ROR
https://ror.org/05qpz1x62

Funder(s)

Funder type
Government

Funder Name
Kassenärztliche Bundesvereinigung (The National Association of Statutory Health Insurance Funds)

Results and Publications

Individual participant data (IPD) sharing plan
All personal information will be treated as strictly confidential and stored in accordance with data protection regulations. Participants will receive consent forms for data processing and publication. Upon return of the consent, they will receive an identification number with which all subsequent questionnaires will be pseudonymized.
The analysis of the collected data from the questionnaires and behavioral observations will be pseudonymized. Only anonymized data will be used in publications of the research results.
The fully anonymized data of this study will be made available as open data on the Internet in a data archive no later than five years after completion of the study. Thus, this study follows the recommendations of the German Research Foundation (DFG) and the German Psychological Society (DGPs) for quality assurance in research.

The study protocol will be available.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		26/03/2024	27/03/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes