EFFECTIVENESS OF MUSIC-BASED THERAPY AS A POSSIBLE INTERVENTION FOR DEMENTIA IN SOCIAL RESTRICTIVE SITUATIONS: A SYSTEMATIC REVIEW OF RCTS

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ABSTRACT

Introduction: Patients with dementia experience painful, confusing, frustrating, and amnesia-like emotional distress and instability because of their brain's inability to correlate their emotions with the memory that causes the emotion. Moreover, the dependency of dementia patients also results in an additional emotional, physical, and financial burden to their families and caregivers. In addition, the COVID-19 pandemic forces drastic self-isolation, which are hard to comprehend for dementia patients, increasing their feeling of anxiety, loneliness, and frustration. Music therapy has gained popularity amongst other therapy alternatives for dementia for its easy accessibility, previously proven effectiveness to reduce dementia symptoms and its positive impact on the caregivers.

Method: A systematic review was performed, searching for randomized controlled trials, according to the PRISMA statement, throughout five international databases with published studies up to 18 April 2021. Critical appraisal was further conducted utilizing the Cochrane Risk of Bias Tool 2.0.

Results: The search yielded eight randomized controlled trials with a total of 534 subjects. The intervention conducted was in individual or group music therapy. The outcomes were measured using various indicators, and significant improvements found in agitated behaviour, behavioural and psychological symptoms, and general mood of the patient.

Conclusion: Music therapy is a highly potential alternative therapy for elderly patients with dementia, showing significant and effective improvements to reduce dementia-related symptoms. Further studies in coherence with implementations of the therapy are urgently needed to aid the increasing prevalence of dementia worldwide, especially in Indonesia.

Keywords: dementia, music therapy, self-isolation, geriatric

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INTRODUCTION

Every three seconds, one person in the world suffers from dementia. (Alzheimer Indonesia, 2019) The prevalence of dementia worldwide continues to increase exponentially, with an estimation of almost 50 million people worldwide diagnosed with dementia. In addition, the World Health Organization also emphasizes nearly 60% of people with dementia live in low and middle-income countries. An estimation of almost 10 million new dementia cases emerges each year. The proportion of people suffering from dementia in 2030 is estimated to reach 82 million in 2030 and 152 million in 2050. (World Health Organization, 2015)

Suffering from dementia is painful yet confusing as the person cannot remember the reason causing their pain and suffering. Studies by Guzman-Velez et al. concluded that patients suffering from dementia could experience prolonged states of emotion that persist beyond the patient's memory of the event. The reason behind this is a phenomenon which Guzman-Velez et al. called "feelings without memory." (Guzmán-Vélez, Feinstein and Tranel, 2014) Patients with dementia suffer from emotional distress caused by loss of memory, confusion, and incompleteness— like a part of them has been taken away. Still, they can neither begin to articulate nor explain the feeling.

Moreover, dementia's impact of emotional distress and instability also affects their caregivers and family. Taking care of someone you love without them remembering who you are or even sometimes lashing out at you can be very frustrating. In addition, dementia is one of the significant causes of disability and dependency among older people worldwide, especially in low and middle-income countries where awareness and understanding of dementia are still lacking. Inadequate awareness of dementia results in stigmatization, barriers to diagnosis and care—making it a burden for caregivers and families. (World Health Organization, 2015). The stressor experienced by caregivers of dementia patients extends beyond physical and emotional stress, which also includes economic stress. According to WHO, in 2015, the total global economic burden of dementia was estimated to be around US$ 818 billion or equals to 1.1% of the global gross domestic product (GDP). (World Health Organization, 2015)

The loneliness and self-isolation patients with dementia experience inside their heads may worsen in reality during the COVID-19 pandemic. Social and physical contact are minimized during the

pandemic, restricting dementia patients from their much-needed socialization to reduce feelings of loneliness. This increases the burden and challenges for caregivers and families to take care of their loved ones with dementia. First, patients with dementia may experience difficulty understanding the pandemic situation and the importance of managing infection by isolation or why their caregivers are wearing personal protective equipment (PPE). Patients with dementia may not understand the changes in their routine, which usually offers comfort in predictability. (Tousi, 2020) Studies by Keng A et al. have shown that COVID-19 related lifestyle changes, social isolation, loneliness, and quarantine measures significantly impact the behavioural and psychological symptoms of dementia (BPSD). (Keng A, 2020; Di Santo SG, 2020) Second, communication challenges may occur when full PPE is being used.

Patients with dementia may find it even more difficult to recognize the voice of their caregivers underneath the PPE. (NHS, no date) Lastly, during times of uncertainty in this pandemic, there may be an increase of scams and people wanting to take advantage of vulnerable people, especially the elderly and those with dementia. (Tousi, 2020) In addition to the emotional impact of the COVID-19 pandemic on dementia patients, the possibility of SARS-CoV-2 infection also worsens the prognosis of dementia. It has been postulated that the inflammatory cascade of SARS-CoV-2 infection may worsen neuro-inflammatory and degenerative disorders, including dementia. (D'Cruz and Banerjee, 2020)

Music therapy is an emerging alternative therapy to calm anxiety, ease pain, and provide a pleasant experience for its listeners. Within the last two decades, researchers have shed light on the growing body of evidence that utilizes music as therapy to treat depression, including in patients with dementia. (Leubner and Hinterberger, 2017) Särkämö et al., in his research about the beneficial effects of music therapy for dementia, concluded significant cognitive and emotional benefits when dementia patients sing. (Särkämö et al., 2014). Dementia patients suffer from frustration as they are unable to articulate their emotions. The utilization of music therapy is an actual manifestation of a quote by Hans Christian Anderson, who says, "Where words fail, music speaks." Dementia patients might not traditionally express their feelings, but music allows them to articulate their unexpressed emotions through language far beyond human linguistics. Music-based intervention can open doors of possibilities to improve behavioural and psychological symptoms of dementia, thus improving the

quality of life. Regarding the positive impacts of music therapy mentioned above, this systematic review aims to analyze the effectiveness of music therapy as a possible intervention for patients suffering from dementia. In addition, the aim of this systematic review also walks coherently. It embodies the Sustainable Development Goals (SDGs) in the aspect of good health and well-being, specifically to reduce the premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being (SDGs Number 3.4), especially in Indonesia, where stigmatization, lack of understanding, and minimal dementia nursing facilities challenges the quality of life improvements of patients with dementia.

METHOD

Search Strategy

The literature search for this systematic review was conducted in accordance with the Preferred Reporting Items for Systematic Review and Meta-analysis (PRISMA). To obtain the relevant studies, the following keywords were used: ("Dementia" OR "Familial Dementia" OR "Senile" OR "Senile Paranoid") AND ("Music" OR "Song" OR "Music Therapy" OR "Song Therapy") AND ("Elderly" OR "Older adults" OR "Geriatric"), while also

using synonyms and Medical Subject Headings (MeSH) where possible. Searching was conducted in 5 international databases, being: Pubmed/MEDLINE, Wiley Online Library, Science Direct, ProQuest, and CENTRAL/Cochrane, for peer-reviewed articles up until 18 April 2021.

Inclusion & exclusion criteria

In the makings of this paper, the inclusion criteria used were as follows:

1. Randomized Controlled Trials (RCTs).
2. The sample population being elderlies (> 65 years) diagnosed with dementia.
3. The intervention given falls under the category of musical therapy.
4. The use of a control group or another intervention type (different from music therapy) was implemented for follow-up comparison.
5. Outcome measurement in the form of indicators or scales for agitation, mood, and behavioral or psychological symptoms.

On the contrary, the exclusion criteria applied were:

1. Articles with irretrievable full text.
2. Non-original research articles which include reviews, conference abstract or proceedings, advertorials, magazine articles, and letters to the editors.

3. Studies in languages other than Bahasa Indonesia and English.

Data extraction and Study Outcomes

Two independent reviewers (MMAZA & KGP) conducted data extraction with any differences or discrepancies identified to be mediated with consensus with the third investigator (APC). From the included studies, the information extracted includes:

1. Author and year of publication.
2. Study characteristics such as the study design and location.
3. Study population, which includes: sample size, sample characteristics, and means with standard deviation.
4. Type of intervention initiated or given.
5. Duration of study and follow-up.

Risk of Bias Assessment

Risk of bias (ROB) assessment was conducted using the Cochrane risk-of-bias tool for randomized controlled studies 2.0 to evaluate the methodological quality (Cochrane, 2020). This ROB assessment tool is made up of 5 domains, which attempt to address bias from: the randomization process, deviations from intended, measurement of outcome, any missing outcome data, and selection of the reported results. For each domain, possible response options include: Yes, Probably Yes, Probably No, No, and Not Included to depict the low, moderate, or high risk of bias according to the Agency for Healthcare Research and Quality (AHRQ). This assessment was performed by all three reviewers (MMAZA, KGP, APC), with any disputes resolved by consensus.

RESULTS

Search results

Literature searching carried out on the five databases using the stated keywords yielded 20 896 studies before screening was conducted. Initial evaluation on the relevancy of the title and abstract was conducted first, with 50 successfully screened after exclusion. Six studies were first excluded before full-text screening was performed. From full-text screening, 36 studies were excluded, with 22 studies having incompatible study design, six studies with relevant outcomes based on the inclusion criteria of the review, five studies having irretrievable full text, two pilot studies, and 1 study being a protocol article on how to conduct an RCT with a relevant topic to this review.
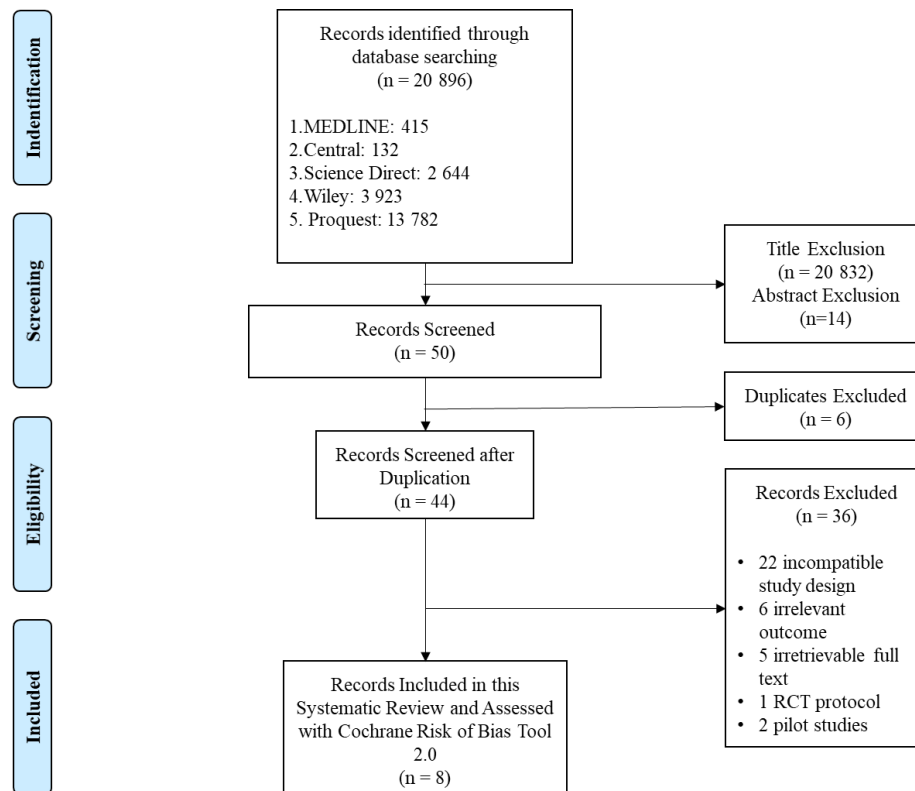
Figure 1. PRISMA Flow Chart of Search Strategies

Characteristics of Included studies

Deliberate screening according to the set inclusion and exclusion criteria resulted in 8 RCTs conducted in Asian (Taiwan & Hong Kong) and European (Spain, Italy, France) countries (Chu et al., 2014; Maseda et al., 2018; Sanchez et al., 2016; Sung et al., 2011; Lin et al., 2010; Ho et al., 2018; Raglio et al., 2015; Guetin et al., 2009). Six of the included studies employed a control for comparative follow-up. In contrast, studies conducted by Maseda *et al.* (2018) and Sanchez *et al.* (2016) compared music-based therapy with another intervention called Multisensory Stimulation Environment (MMSE). A total of 534 patients with dementia > 65 years old were tested with two types of music therapy: group and individualized, with follow-up periods ranging from 6 - 16 weeks. Outcome measurements within individual studies were conducted with various and different comparative indicators. The comparative indicators could be categorized into subgroups to analyze the effectiveness of music-based therapy on agitation, depression, anxiety and overall mood of the patient during the study **(Appendix 1)**. The 8 RCTs were assessed using the Cochrane Risk-of-Bias tool 2.0 with four studies achieving good quality (Maseda et al., 2018; Sanchez et al., 2016; Raglio et al., 2015; Guetin et al., 2009), three studies

having fair quality (Chu et al., Sung et al., Ho et al., 2018), and 1 study, Lin et al. (2010), having poor quality according to the AHRQ standards **(Appendix 2)**. All the eight studies achieved moderately concerning Domain 2: Bias due to deviations from intended interventions. Bias arising from the domain was due to none of the studies being blinded as blinding is virtually impossible as the type

of intervention in the included studies (Music therapy versus control, Music therapy versus Multisensory Stimulation Environment (MSSE)) are easily, visually, and procedurally different from one another. The complete summary table of study characteristics is shown in Table 1, while the full study table with the intended outcomes is attached as Appendix 1.

	Bias arising from the randomization process	Bias due to deviations from intended interventions	Bias due to missing outcome data	Bias in measurement of the outcome	Bias in selection of the reported results	Overall bias
Chu et al, 2014	🟢	🟡	🟢	🟡	🟢	🟡
Maseda et al, 2018	🟢	🟡	🟢	🟢	🟢	🟢
Sanchez et al, 2016	🟢	🟢	🟡	🟢	🟢	🟢
Sung et al, 2011	🟢	🟡	🟢	🟡	🟢	🟡
Lin et al, 2010	🟢	🟡	🟡	🟡	🟢	🔴
Ho et al, 2018	🟢	🟡	🟢	🟡	🟢	🟡
Raglio et al, 2015	🟢	🟡	🟢	🟢	🟢	🟢
Guetin et al, 2009	🟢	🟡	🟢	🟢	🟢	🟢

🟢	Low risk of bias
🟡	Some concerns
🔴	High risk of bias

Figure 2. Summary of Bias Assessment using Cochrane ROB 2

DISCUSSIONS

Dementia among geriatrics

According to WHO (2020), Dementia is defined as a progressive syndrome where one's cognitive function, which refers to one's memory, thought process and management capabilities, orientation, language, the capacity of

comprehending, calculating, judging, learning, and other various cognitive capabilities, declines way beyond the normal aging process. This deterioration inevitably often results in emotional disorders and dependency on daily life activities (Emmady, 2021). The most

common type of dementia is Alzheimer's Dementia (AD), responsible for approximately 70% of all cases and accounts for the 5th leading cause of death worldwide. Other common types of dementia include vascular dementia, dementia of Lewy Bodies, Parkinson's disease Dementia, and frontotemporal dementia. there are around 47 million individuals with dementia all over the world. Hence, it is safe to say that dementia may be considered a huge burden of disease universally. Treatment costs are considerably high, ranging from around 200 thousand dollars per patient. (WHO, 2020; Emmady, 2021)

As dementia is more prevalent as one age, it has a significant prevalence within geriatric individuals ranging between 5-8% of the entire population. It is also projected that cases will reach 82 million by 2030 and 152 million by 2050, with the second and third world countries as the most significant contributors to the percentage. However, 9% of all dementia cases also happen before someone reaches 65 years old due to accumulated exposure towards risk factors, such as sedentary lifestyle, smoking, alcohol, diet, and other comorbidities such as hypertension and depression. (WHO, 2020). There are various challenges when it comes to identifying and approaching the elderly with dementia. They are often at high risk

of being underdiagnosed due to inaccuracies in history taking, being isolated from the general community, or being neglected by their family, which is one of the most significant sources of support for the said group. (Larson, 1986)

Moreover, the dependency rate of dementia patients is considerably high. Research has proven that the rate of dependence in patients with dementia is as high as 77%. For example, as individuals with dementia are also prone to acute diseases, they would need further assistance, such as communication and decision-making, to achieve adequate healthcare. Dementia is also correlated with significant diseases such as cerebrovascular diseases and hip fractures, which are also related to age. (Agüero-Torres et al.,1998; Borbasi, 2006)

Furthermore, the elderly with dementia are at a higher risk of contracting COVID-19 than the general public. For example, individuals with Dementia may often forget to wash their hands, physically distance themselves, or use a mask when coming in contact with another individual. Moreover, it would also be harder for COVID-19 patients with dementia to self-isolate or quarantine by themselves due to their nature of being highly dependent on a caregiver. In addition, unlike the general population, elderlies with dementia also suffer from difficulties with technological

literacy. Hence, facilities such as video conferences and calls that ensure society is socially connected throughout the pandemic are hampered in this group. (Brown et al., 2020)

In addition, elderly with dementia are often seen living in a group and assisted setting, which brings its' own harms and benefits, especially with the current pandemic situation. a supportive living environment surrounded by caregivers and many other individuals with similar conditions are beneficial and has been proven to reduce dependency with activities of daily living, however, comes with a price of higher COVID-19 risks and transmission rates due to crowding, sharing rooms and restrooms, along with their inherent personal disabilities to perform in accordance to the recommended guidelines to reduce transmissions, such as personal hygiene. (te Boekhorst et al., 2020; Brown et al., 2020)

The concept of music therapy and why it works

Music therapy involves an enormous scope of music, including but not limited to singing, listening, creating, and playing a musical instrument, which may or may not be performed by a licensed therapist. Along with the definition established by the World Federation of Music Therapy, music therapy aims to improve one's quality of life by enhancing their "physical, social, communicative, emotional, intellectual, and spiritual health and well-being". Generally, there are two types of music therapy: passive, in which the individual listen to music that the therapists have provided or selected, and active, in which the patients are encouraged to participate in the selection or provision of music, for example, through singing or playing musical instruments. Music therapists should be able to cater to the needs of the patients through envisioning a therapeutic goal and a parameter on what to and what not to do. (van der Steen et al., 2018; Dewing, 2003)

The set of reasons why music therapy works have yet to be established clearly. However, theoretically speaking, music and singing stimulate the brain, especially in the left hemisphere, in which lesions often show speech deterioration. Therefore, through therapy, especially active therapy, patients are encouraged to follow along and gradually develop their articulation, breathing pattern, and rhythmic composition. In addition, with dementia, music may help them recall their memories that conjuncts with the particular song that is played or sung, thus assisting them with memory issues. On the other hand, language centers are often stimulated through singing, and coordination skills may be reestablished through musical

instruments. (van der Steen et al., 2018; Dewing, 2003)

Music therapy may be beneficial for dementia which has already elicited emotional disorders as subsequent progress. Music is found to decrease stress hormones and induce relaxation and communication holistically. The sense of familiarity that music brings goes beyond the need to recognize and understand words, which many patients with dementia experience. This is also supported by the nature of groups living in dementia patients, where residence can communicate with each other in a positive mood and socialize with their peers. (van der Steen et al., 2018; Dewing, 2003) It is unclear whether music therapy is used extensively in the clinical setting. However, it is found that in the UK, 250 out of 900 music therapists cater to dementia patients. Along with its inexpensive nature and adequate supply and demand growth, music therapy could be considered a non-pharmacological approach to dementia.

Effectiveness of music-based therapy on patients with dementia

The studies included in this review used a few different comparative indicators for outcome measurement. Generally speaking, all the included studies show relevant and positive changes in favor of music therapy compared to control. Studies conducted by Sanchez et al. (2016), Sung et al. (2011), and Lin et al. (2010) evaluated and even specifically analyzed agitated behavior among dementia patients sing the translated versions of CMAI (Cohen-Mansfield Agitation Inventory); due to it being the most troubling and primary source of pressure for caregivers and family members of the patient. Reductions of the CMAI scale was identified with larger reductions found in the experimental group (Baseline: 43.12, Follow-up: 35.78) compared to the control arm, with some control arms achieving an increase in CMAI scale (Baseline: 35.78, Follow-up: 37.75) (Lin et al., 2011). This outcome is also supported by findings of Ho et al. (2018), which used the Neuropsychiatric Inventory (NPI) to measure agitated behavior, which also favors the music therapy group (Baseline: 3.4, Follow-up: 1.4).

Other than agitating behavior, the severity of behavioral and psychological symptoms was measured by studies conducted by Chu et al. (2014), Sanchez et al. (2016), Sung et al. (2011), Raglio et al. (2015), and Guetin et al. (2009) with several indicators. Most of the studies used Mini-Mental State Examination (MMSE) to evaluate the patient's cognitive functioning before the intervention and is also used for outcome measurement. A patient with an MMSE score of >24 is

deemed cognitively functional, with scores ranging from 20 - 24 suggests mild dementia, 13 - 20 suggesting moderate dementia, and <12 indicating severe dementia. A reduction in MMSE scale was found in studies conducted by Chu et al. (2014) (p= 0.42) and by Sanchez et al. (2016) in favor of the music therapy group and suggesting the potential of the said therapy to improve the cognitive function of the dementia patients. Other than using MMSE, indicators such as the Rating Anxiety in Dementia (RAID) scale and Geriatric Depression Scale (GDS) or Cornell Scale for Depression in Dementia (CSDD) were used to evaluate other classical symptoms that are often seen in severe and moderate types of dementia such as anxiety and depression. Studies by Sanchez et al. (2016) and Sung et al. (2011) both show improvement in anxiety symptoms, with the latter showing significant results (Baseline: 36.26, Follow-up: 32.7) (p=0.004). For depression, similar results in favor of the music therapy found with significant results shown in studies by Raglio et al. (2015) (p=0.001) and Guetin et al. (2009) (p=0.002). Results obtained from this subgroup are also supported by a meta-analysis conducted by Zhang et al. (2017) on the improvement of behavioral function after music therapy with a standardized mean difference of -0.42 (-0.74, -0.11),

indicating prominent impact on dementia patients.

Publication and promotion plan in the Indonesian context

Indonesia's Ministry of Health established a National-scale Dementia Care Plan back in 2017, with seven main vital points:

1. Awareness and risk reduction
2. Advocacy for dementia patients
3. Easing access to information and services
4. Early diagnosis and management
5. Reinforcement of resources
6. The cycle of life approach mechanism
7. Increasing research on the said topic

With 1.2 million dementia patients, Indonesia is taking the issue to another level. However, with the pandemic striking in, dementia care facilities' progress is hampered. As caregivers are required to fully equip themselves with personal protective equipment fully, patients struggle to visually recognize these individuals, which is worsened by their memory impairment. (NHS, no date; Alzint, 2016)

Therefore, Music Therapy may come in place to cater to the gap that prevails in this pandemic. With this systematic review, we propose recommendations to the ministry of health,

along with their dementia care plan, to include music therapy as a mechanism to the cycle of life and resource reinforcement. By providing links and connections to dementia care facilities, the government may employ music therapists all over Indonesia to help with the patients' memory, especially towards their caregivers. Music, a form of non-verbal and non-visual communication, can help the patients and the caregivers connect and reduce anxiety through music. Music can aid patients in recalling their caregivers, and music can also reduce burnout within caregivers. This is where the music therapists come to play.

During this pandemic, where the government's focus is shifted majorly towards alleviating the pandemic, the implementation of Music Therapy could put the case on hold without hampering the outcome or progress of patients with dementia. Moreover, in music therapy, the burden put upon caregivers of dementia patients may be reduced, and patients can progress towards a better memory. At the same time, the government focuses on another urgent issue. As positive outcomes are measured through these studies, there is a high possibility that this measure would yield positive results in Indonesia.

Strength and limitation of study

The strengths of this systematic review lie in the eight included studies, which were all RCTs and often referred to as the gold standard for evidence-based medicine. The included studies also implemented sample follow-up time for significant outcome measurement and comparison between the experimental and control arms immediately after the intervention ended and after cessation. After the study ended, values after cessation signify the effectiveness of the intervention even after the treatment has stopped, adding to the strength and effectiveness of music therapy in non-adherence situations. However, several limitations may pose a risk to this review which is forefronted by some of the studies achieving moderate and high risk of bias. Despite that, this risk of bias is inevitable as the experimental and control groups are easily and visually distinguishable.

Moreover, another limitation also lies in participants' small collective sample size, with only 534 subjects included in this review. The small scope of the studies is further limited with the lack of variety in study locations, is only conducted in a few European and Asian Countries. Lastly, another possible limitation and error may arise from the different comparative indicators for outcomes used within each study. Although, despite the parameters

being different, some measurement outcomes are heavily similar and thus being able to be grouped in small categories for comparison.

Conclusion and recommendations

Dementia is a progressive syndrome whose numbers are progressively rising as well. In addition to the increasing prevalence, the provision of care towards individuals with dementia in the pandemic is significantly hampered as dementia patients are highly dependent on another individual, which contradicts the physical distancing requirements, and the usage of PPEs for caregivers even worsens the ability of dementia patients to recall the individual. This issue is an urgent matter: significant prevalence and hampered the progress of treatment; therefore, music therapy, as viewed on the data provided, may be a possible alternative approach method of dementia care in this pandemic, as it is capable of reducing agitated behavior, anxiety and depression, as well as to improve the holistic mood of the patient. Music therapy may also be considered equally as effective to current treatments such as multisensory stimulation environments. Along with the fact that minimal contact is required to implement this approach, and everyone can conduct this matter under certain jurisdictions, the requirements work hand in hand with the COVID-19 precautions.

There is a high possibility that dementia care issues in the pandemic may be mitigated through the implementation of Music Therapy.

We recommend conducting more randomized controlled trials that comprise a larger sample size and more variant subjects for future studies. Moreover, with a more significant burden of dementia affecting low to middle-income countries, we recommend conducting music-based intervention on these countries with supporting reasons such as low cost, high-effectivity, and easily accessible anywhere without any need for complicated logistics. In addition, after already concluding the effectiveness of music-based therapy, further studies to differentiate varieties of music genres and their effects on reducing behavioral and psychological symptoms of dementia (BPSD). Lastly, we recommend the Indonesian government utilize this music-based therapy widely and effectively through primary health care and specified dementia care facilities and collaborate with non-governmental organizations to create a wider scope of awareness. Hopefully, these recommendations could help further intervention to fulfill our support towards the SDGs 2030.

Authors' contributions

According to the Contributor Roles Taxonomy (CRediT) author statement: Firstly, **MMAZA** was responsible for Conceptualization, Methodology, Writing - Original Draft, Visualization, Project administration; Secondly, **KGP** was responsible for Writing-Original Draft, Investigation, Visualization; Thirdly, **APC** was responsible for: Writing - Original Draft, Investigation and Resources

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Appendix 1. Full Summary Table of Included Studies

No.	Author; Year	Study Design	Location	Study population			Type of intervention	Duration (weeks)	Outcome		
				Sample size	Characterisitc	Mean (SD)			Comparative indicator	Value*	P
1	Chu; 2014	prospective, randomized, parallel-group design	Taiwan	104	Diagnosis of dementia	82 (6.8)	Group music therapy (experimental) vs Control	6	CSDD	**Experimental** Baseline : 17.39 (9.56) Follow-up : 11.23 (8.64) **Control** Baseline : 15.70 (10.16) Follow-up : 11.43 (9.72)	0.352
									MMSE	**Experimental** Baseline : 12.80 (6.15) Follow-up : 14.24 (6.39) **Control** Baseline : 13.76 (5.36) Follow-up : 13.50 (4.60)	0.42
2	Maseda; 2018	randomized longitudinal	Spain	21	Diagnosis of dementia and the presence of severe or very	88.90 (6.69)	Individualized music therapy (experimental)	12	INTERACT SHORT - Mood	**Experimental** Baseline : 2.65 (0.55) Follow-up : 2.85 (0.46)	<0.005

									Experimental / MSSE	p
									(0.70)	
								INTERACT SHORT - Stimulation (Agitation)	**Experimental** Baseline : 1.08 (0.10) Follow-up : 1.09 (0.22) **MSSE** Baseline : 1.23 (0.53) Follow-up : 1.15 (0.27)	0.8
								INTERACT SHORT - Relating to people	**Experimental** Baseline : 1.98 (0.75) Follow-up : 2.13 (0.79) **MSSE** Baseline : 2.16 (0.66) Follow-up : 2.45 (0.83)	<0.005
3	Sanchez; 2016	Comparative RCT	Spain	22	Diagnosis of severe or very severe dementia	88.41 (6.93)	Individualized music therapy (experimental) vs MSSE	16	CMAI (mean range)	**Experimental** Baseline : 45-50 Follow-up : 35- 40 **MSSE** Baseline : 55-60 Follow-up : 35-40	0.032
									CSDD	**Experimental** Baseline : 3-4 Follow-up : 3-4 **MSSE** Baseline : 6-7 Follow-up : 2-3	0.006

								RAID	**Experimental** Baseline : 1-2 Follow-up : 0-1 **MSSE** Baseline : 6-7 Follow-up : 1-2	0.021
								MMSE	**Experimental** Baseline : 10-11 Follow-up : 6-7 **MSSE** Baseline : 10-11 Follow-up : 6-7	NA
4	Sung; 2011	Comparative RCT	Taiwan	60	Diagnosis of dementia	Experimental: 81.37 (9.14) Control: 79.5 (8.76)	Group music therapy (experimental) vs Control	6	CMAI	**Experimental** Baseline : 10.04 (10.48) Follow-up : 3.89 (4.02) **Control** Baseline : 12.14 (10.73) Follow-up : 5.36 (4.34)	0.95
									RAID	**Experimental** Baseline : 36.26 (13.28) Follow-up : 32.7 (4.98) **Control** Baseline : 35.79 (6.61) Follow-up : 31 (2.96)	0.004
5	Lin; 2010	RCT	Taiwan	104	Diagnosis of	Experimental:	Group music	6	CMAI	**Experimental**	0.124

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#	Author; Year	Study type	Country	N	Diagnosis	Age	Intervention	Duration	Outcome measure	Results	p-value
					dementia	81.46 Control: 82.15	therapy (experimental) vs Control			Baseline : 43.12 (16.32) Follow-up : 35.69 (9.99) **Control** Baseline : 35.78 (11.04) Follow-up : 37.75 (9.70)	
6	Ho; 2018	Cluster RCT	Hong Kong	73	Diagnosis of moderate dementia	Experimental: 85.0 (7.1) Control: 85.7 (7.0)	Group music therapy (experimental) vs Control	8	NPI (Agitation)	**Experimental** Baseline : 3.4 (3.6) Follow-up : 1.4 (2.0) **Control** Baseline : 2.1 (3.2) Follow-up : 1.8 (2.6)	<0.01
									VAMS	**Experimental** Baseline : 42.8 (16.4) Follow-up : 40.0 (18.1) **Control** Baseline : 36.6 (11.5) Follow-up : 39.3 (15.0)	<0.01
7	Raglio; 2015	RCT	Italy	120	Diagnosis of moderate and severe dementia	Individualized: 81.7 (7.8) Therapy: 81.0 (7.6) Control: 82.4 (6.8)	Individualized listening vs Music Therapy vs Control	10	NPI	**Individualized** Baseline : 33.0 (14.2) Follow-up : 28.4 (17.2) **Therapy** Baseline : 33.1	<0.001

											(16.2) Follow-up : 22.4 (11.9) **Control** Baseline : 36.7 (19.2) Follow-up : 26.8 (14.9)	
											CSDD (median, range)	**Individualized** Baseline : 10 (3-23) Follow-up : 9 (0-18) **Therapy** Baseline : 9 (3-20) Follow-up : 7 (0-25) **Control** Baseline : 8 (1-29) Follow-up : 7 (0-26)	0.001
											CBS-QoL	**Individualized** Baseline: 6.5 (9.3) Follow-up : 6.2 (8.5) **Therapy** Baseline : 5.9 (7.1) Follow-up : 5.5 (6.3) **Control** Baseline : 6.9 (9.1) Follow-up : 4.3 (9.1)	0.01

8	Guetin; 2009	Single centre, comparative RCT	France	30	Diagnosis of Alzheimer's Type dementia	Experimental: 85.2 (6) Control: 86.9 (5.2)	Individualized listening (experimental) vs Control	8	Hamilton Scale	**Experimental** Baseline: 22 (5.3) Follow-up : 8.4 (3.7) **Control** Baseline : 21.1 (5.6) Follow-up : 20.8 (6.2)	<0.001
									GDS	**Experimental** Baseline: 16.7 (6.2) Follow-up : 8.9 (3.3) **Control** Baseline : 11.8 (7.4) Follow-up : 11.2 (6.1)	0.002

Legend: Legend: CSDD (Cornell Scale for Depression in Dementia), MMSE (Mini-Mental State Examination), MSSE (Multisensory Stimulation Environment), CMAI (Cohen-Mansfield Agitation Iventory), RAID (Rating Anxiety in Dementia), CBS-QoL (Cornell Brown Scale for Quality of Life), GDS (Geriatric Depression Scale)

Bias domain	Signalling questions	Response options	Description/Support for judgement							
			Chu; 2014	Maseda; 2018	Sanchez; 2016	Sung; 2011	Lin; 2010	Ho; 2018	Raglio; 2015	Guetin; 2009
Bias arising from the randomization process	1.1 Was the allocation sequence random?	Y / PY / PN / N / NI	Y	Y	Y	Y	Y	Y	Y	
	1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	Y / PY / PN / N / NI	Y	Y	Y	Y	Y	Y	Y	Y
	1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	Y / PY / PN / N / NI	N	N	N	N	N	N	N	N
	Risk of bias judgement	- / + / ?	- (low risk)	- (low risk)	- (low risk)	- (low risk)	- (low risk)	- (low risk)	- (low risk)	- (low risk)
Domain 2: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	2.1. Were participants aware of their assigned intervention during the trial?	Y / PY / PN / N / NI	Y	Y	Y	Y	Y	Y	Y	Y
	2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?	Y / PY / PN / N / NI	Y	Y	Y	Y	Y	Y	Y	Y
	2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the experimental context?	NA / Y / PY / PN / N / NI	PN	PN	PN	PN	PN	PN	PN	PN
	2.4. If Y/PY to 2.3: Were these deviations from intended intervention balanced between groups?	NA / Y / PY / PN / N / NI	NA	NA	NA	NA	NA	NA	NA	NA
	2.5 If N/PN/NI to 2.4: Were these deviations likely to have affected the outcome?	NA / Y / PY / PN / N / NI	NA	NA	NA	NA	NA	NA	NA	NA
	2.6 Was an appropriate	Y / PY /	Y	Y	Y	Y	Y	Y	Y	Y

	analysis used to estimate the effect of assignment to intervention?	PN / N / NI								
	2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?	NA / Y / PY / PN / N / NI	NA	NA	NA	NA	NA	NA	NA	NA
	Risk of bias judgement	**- / + / ?**	**? (some concerns)**	**? (some concerns)**	**? (some concerns)**	**? (some concerns)**	**? (some concerns)**	**? (some concerns)**	**? (some concerns)**	**? (some concerns)**
Domain 2: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	2.1. Were participants aware of their assigned intervention during the trial?	Y / PY / PN / N / NI	Y	Y	Y	Y	Y	Y	Y	Y
	2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?	Y / PY / PN / N / NI	Y	Y	Y	Y	Y	Y	Y	Y
	2.3. If Y/PY/NI to 2.1 or 2.2: Were important co-interventions balanced across intervention groups?	NA / Y / PY / PN / N / NI	PY	PY	PY	PY	PY	PY	PY	PY
	2.4. Were there failures in implementing the intervention that could have affected the outcome?	Y / PY / PN / N / NI	N	N	N	N	N	N	N	N
	2.5. Was there non-adherence to the assigned intervention regimen that could have affected participants' outcomes?	Y / PY / PN / N / NI	N	N	N	N	N	N	N	N
	2.6. If N/PN/NI to 2.3 or 2.5 or Y/PY/NI to 2.4: Was an appropriate analysis used to estimate the effect of adhering to the intervention?	NA / Y / PY / PN / N / NI	NA	NA	NA	NA	NA	NA	NA	NA
	Risk of bias judgement	**- / + / ?**	**? (some concerns)**	**? (some concerns)**	**? (some concerns)**	**? (some concerns)**	**? (some concerns)**	**? (some concerns)**	**? (some concerns)**	**? (some concerns)**

Bias due to missing outcome data	3.1 Were data for this outcome available for all, or nearly all, participants randomized?	Y / PY / PN / N / NI	Y	Y	Y	Y	N	Y	Y	Y
	3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?	NA / Y / PY / PN / N	NA	NA	NA	NA	Y	NA	NA	NA
	3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?	NA / Y / PY / PN / N / NI	NA	NA	NA	NA	NA	NA	NA	NA
	3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?	NA / Y / PY / PN / N / NI	NA	NA	NA	NA	NA	NA	NA	NA
	Risk of bias judgement	**- / + / ?**	- (low risk)	- (low risk)	- (low risk)	- (low risk)	? (some concerns)	- (low risk)	- (low risk)	- (low risk)
Bias in measurement of the outcome	4.1 Was the method of measuring the outcome inappropriate?	Y / PY / PN / N / NI	N	N	N	N	N	N	N	N
	4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	Y / PY / PN / N / NI	PN	PN	PN	N	N	N	N	N
	4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	Y / PY / PN / N / NI	NI	NI	NI	NI	NI	NI	N	N
	4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	NA / Y / PY / PN / N / NI	PY	N	N	PY	PY	PY	NA	NA
	4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?	NA / Y / PY / PN / N / NI	PY	NA	NA	PY	PY	PY	NA	NA

	Risk of bias judgement	- / + / ?	? (some concerns)	- (low risk)	- (low risk)	? (some concerns)	? (some concerns)	? (some concerns)	- (low risk)	- (low risk)
Bias in selection of the reported result	5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	Y / PY / PN / N / NI	Y	PY	Y	PY	PY	PY	PY	PY
	Is the numerical result being assessed likely to have been selected, on the basis of the results, from...									
	5.2. ... multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	Y / PY / PN / N / NI	PN	PN	PN	PN	PN	PN	PN	PN
	5.3 ... multiple analyses of the data?	Y / PY / PN / N / NI	PN	PN	PN	PN	PN	PN	PN	PN
	Risk of bias judgement	- / + / ?	- (low risk)	- (low risk)	- (low risk)	- (low risk)	- (low risk)	- (low risk)	- (low risk)	- (low risk)
Overall bias	Risk of bias judgement	- / + / ?	? (some concerns)	- (low risk)	- (low risk)	? (some concerns)	(High Risk)	? (some concerns)	- (low risk)	- (low risk)

Thresholds for Converting the Cochrane Risk of Bias Tool to AHRQ Standards (Good, Fair, and Poor)

Good quality: All criteria met (i.e. low for each domain)

Using the Cochrane ROB tool, it is possible for a criterion to be met even when the element was technically not part of the method. For instance, a judgment that knowledge of the allocated interventions was adequately prevented can be made even if the study was not blinded, if EPC team members judge that the outcome and the outcome measurement are not likely to be influenced by lack of blinding.

Fair quality: One criterion not met (i.e. high risk of bias for one domain) or two criteria unclear, and the assessment that this was **unlikely** to have biased the outcome, and there is no known important limitation that could invalidate the results

Poor quality: One criterion not met (i.e. high risk of bias for one domain) or two criteria unclear, and the assessment that this was **likely** to have biased the outcome, and there are important limitations that could invalidate the results

Poor quality: Two or more criteria listed as high or unclear risk of bias