

STAM Protocol in Dementia: A Multicenter, Single-Blind, Randomized, and Controlled Trial

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Abstract

Background: The Sound Training for Attention and Memory in Dementia (STAM-Dem) is a manualized music-based protocol designed to be used in the rehabilitation of cognitive functions in elderly patients with dementia (PWD). **Method:** This was a multicenter, single-blind, randomized, and controlled trial that involved 51 PWD. The objective was to test the STAM-Dem efficacy. Patients in the experimental group followed the STAM-Dem for 2 weekly sessions of 45 minutes for 12 weeks (in addition to standard care). Those in the control group continued with the normal “standard care” provided. **Results:** In the experimental group, the instruments immediate prose memory test (MPI), deferred prose memory test (MPD), attentional matrices, activities of daily living, Music Therapy Activity Scale (SVAM) and Geriatric Music Therapy Profile (GMP) increase significantly from pre to post-test ($P < .05$). **Conclusion:** The protocol is feasible and data suggest that there was an effect on attention (matrices) and prose memory skills (MPI and MPD). The effect size reveals a general improvement in the results of the experimental group.

Keywords

dementia, STAM protocol, cognitive rehabilitation, music therapy, STAM-Dem protocol, evidence-based, Alzheimer's

Introduction

The *Diagnostic and Statistical Manual of Mental Disorders (DSM)*¹ indicates that the essential feature of dementia is the development of multiple cognitive deficits including memory impairment (criterion A1) and at least one of the following cognitive impairments (criterion A2): aphasia, apraxia, agnosia, or a change in executive functioning.

The cognitive deficits must be severe enough to cause impairment in social or occupational functioning and must represent a deterioration (criterion B) compared to a previous level of functioning.

Dementia is a condition found in 1% to 5% of the population older than 65 years, with a prevalence which will double every 4 years thereafter, reaching a rate of approximately 30% at 80 years of age.

The latest data regarding the prevalence of dementia in Italy² reported that 9% of those older than 60 years are affected. Alzheimer's dementia (AD) accounts for 50% to 60% of all

dementias. In Italy, it is estimated that 430 000 to 450 000 people will be affected.²

No effective treatment modality has yet been found for the various forms of dementia.

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In general, persons with dementia (PWD) have a shorter life expectancy, estimated at approximately 8 years from the time of diagnosis (for AD the period extends to up to 20 years), although death usually occurs owing to other health complications.

In recent years, the importance of the role played by psychiatric disorders and behavior in the development of the dementias has also been recognized. States of depression, anxiety, personality changes, and irritability are the disorders that accompany the progress of dementia, presenting in 90% of patients.³

The most important consequence of the disease, as indicated by the World Health Organization, lies in a serious alteration of the quality of life on the part of both patients and their families. In particular, although memory deficits are one of the earliest and important symptoms, PWD mainly present difficulties in the encoding of new information, while most of the implicit memory appears to remain intact.

Studies relating to encoding, storage, and retrieval processes have allowed for clarification of the stage of elaboration of information at which the AD deficit is placed.

In PWD, memory disorders seem to be mainly caused by difficulties at the level of encoding and, therefore, in the acquisition of new information, while the phases of storage and retrieval appear to be relatively intact.⁴

Recently, techniques deriving from research concerning the cognitive processes have been introduced in support of dementia rehabilitation interventions.

Unfortunately, a recent Cochrane Review,⁵ in which 6 studies of cognitive rehabilitation in the initial phases of AD and of the vascular dementia were analyzed, concludes that, to date, there is an absence of clear scientific evidence of the effectiveness of these personalized techniques applied in the initial phases of dementia.

Above all, the absence of controlled randomized studies relating to individual cognitive rehabilitation interventions in patients having milder forms of the disorder does not allow for the advancement of any kind of conclusion with respect to the effectiveness of this type of intervention.

Given the increase in the number of older people affected by serious forms of dementia in residential care homes (elderly people who are no longer self-sufficient), various interventions have been introduced, which include activities aimed at promoting the highest possible degree of self-sufficiency and services aimed at the reduction of the consequences of impairment.

Among the standard therapeutic activities, we find pharmacotherapy, psychological skills, cognitive stimulation and reactivation, reorientation toward reality, support for families, occupational therapy, and music therapy (MT).

Music Therapy and Dementia

Despite being a relatively young discipline, MT adopted in the context of nonpharmacological treatment in dementia is very common in daily clinical practice with PWD. In literature, many authors emphasize the positive effects of music,⁶ referring especially—rather than to receptive MT

techniques—to active MT interventions and their effect on mood and socialization skills,^{7,8} the short-term memory (STM) and autobiographical memory,⁹ and also the reduction of behavioral disorders.¹⁰

In 2 reviews of the literature, Koger and Brotons describe the success of MT in reducing the severity of many dementia symptoms.^{11,12}

In a first publication,¹³ these authors point out that PWD respond positively to MT interventions and emphasize how the literature reports a strengthening of communication skills and the capacity to access deep memories which would be difficult to recover by means of a verbal approach.

They also notice a significant reduction in agitation during and after MT sessions and a greater awareness of the relationship between behavior and musical sounds.

Again, in the other review,¹¹ the same authors observe that application of MT improves memory and language skills, reduces anxiety and depression, reduces agitation and dangerous behavior, and improves social relationships with family members, friends, and caregivers.

Nevertheless, attention should be drawn to various issues.

The MT does not have an empirically recognized effect; the available evidence is in fact insufficient from the scientific point of view owing to the very small number of scientific studies and methodologically well-conducted randomized controlled trials (RCTs).

Koger and Brotons,¹² moreover, state: “the review was unable to identify reliable empirical evidence on the basis of which the use of MT as a treatment for dementia might be justified. However, available evidence suggests that MT may be beneficial in managing or treating dementia symptoms, and the predominant conclusion of this review is the highlighting of the need for better designed studies of the intervention.”

In a recent contribution¹⁴ published by the Cochrane Review, in which only 5 studies were included, we note as a principle result: “the methodological quality of these studies was generally poor and results could not be validated or pooled for further analysis.”

And, as a consequence, the author concludes by stating that the “methodological quality and the reporting of the studies that were included were too poor to draw any useful conclusions.”

In view of this, more and more important data are emerging concerning the effects of MT and also—for example—as a result of methodologically well-conducted studies carried out in Italy^{15,16} highlighting the effectiveness of MT in reducing psychiatric and behavioral symptoms in patients with moderate-to-severe dementia (delusions, agitation, anxiety, apathy, irritability, aberrant motor activity, etc).

Using the Clair and Bernstein¹⁷ protocol, Lin and collaborators¹⁸ demonstrated the effectiveness of MT in reducing agitation in PWD. Svandottir and Snaedal,¹⁹ Ledger and Baker,²⁰ and Wall and Duffy in a review²¹ have also reported similar results. Individual sessions of receptive MT seem to produce valuable effects on anxiety and depression.²²

Live music also improves self-esteem, enhances a sense of belonging, and reduces depression in some PWD.²³

It would appear, however, that there are no research studies that specifically investigate the effects of MT on the cognitive functions—and on attention and the memory in particular—in PWD. Only 1 study suggests the effectiveness of a particular type of MT intervention, which seems to facilitate and maintain learning abilities in PWD.²⁴

Some studies have, however, focused on the effects of listening to music.

Hayden²⁵ described moments of exceptional lucidity in patients with serious AD (PWAD), and this is often referred to as a “reawakening” in response to listening to pieces of music that are significant from the autobiographical point of view.

Moreover, studies have been conducted which highlight how listening to music procures a benefit in relation to autobiographical memory^{9,26} and to performance in cognitive functioning tests.²⁷

In one particular study, Prickett and Moore²⁸ found that PWD remember the words of songs much better than words that have been spoken.

Long-term memory (LTM) and STM can also be influenced by music.²⁹⁻³¹

There are in fact few research studies that investigate the cognitive skills and functions in relation to exposure to music in PWAD.

Many anecdotal reports suggest that the ability to play, remember, learn, or obtain a benefit from listening to a song are often preserved, also when the overall functioning of an individual has been seriously compromised.

For example, some PWAD (with moderate-to-severe AD) whose cognitive functioning is generally found to be significantly compromised are capable of learning to play songs^{32,33} or recognize, reproduce, and remember songs that they know.^{34,35}

However, numerous studies document deficits in dementia in relation to the musical sphere.³⁶⁻⁴⁰

Finally, we note that 2 music-based assessments about music cognition among PWD were developed in the 90s: as Lipe et al reported⁴¹ that “the Residual Music Skills Test (RMST) was developed to identify residual music skills which have been acquired over one’s lifetime without the benefit of formal music training” and “the Music-Based Evaluation of Cognitive Functioning (MBECF) was developed to assess the degree to which active music making could reveal important information about general cognitive ability in PWD.”

Method

Research Design

This was a multicenter, single-blind, RCT with elderly PWD.

The research includes standardized instruments for evaluation and observation, of both the qualitative and quantitative type, which are used to evaluate cognitive, behavioral, and mood responses to interventions.

The study was characterized by collaboration occurring within a network setup between the F.S. Zerbato Center at Tregnago (VR; lead unit), the recently founded department of

Music Therapy at the Musical Conservatory of Verona, the Tuscan Music Therapy Center (*Centro Toscano di Musicoterapia*) and the following units:

1. Support Center at Cologna Veneta (province of Verona);
2. Support Center at Pescantina (province of Verona);
3. Support Center at Castiglione of the Stiviere (province of Mantua);
4. Support Center in Florence (province of Florence);
5. Support Center at Poggibonsi (province of Siena).

The adaptation of the protocol, identification and assignment of the centers, the training of music therapists, recruitment of patients, and the implementation of the project took 18 months.

Aims

The study has the objective of evaluating the efficacy of the application of the Sound Training for Attention and Memory (STAM-Dem) on the symptomatic, cognitive, behavioral, and emotional manifestations present in PWD.

In particular, the evaluation aims at studying effects on

1. maintenance of cognitive capacities (attention, memory, executive functions—primary outcome);
2. prevention and management of depressive states (secondary outcome);
3. prevention and management of aggressive behavior (secondary outcome).

Sound Training for Attention and Memory Protocol

The STAM-Dem is a manualized music-based protocol designed to be used in the rehabilitation of cognitive functions in elderly PWD. The STAM Protocol was initially constructed, thinking specifically of patients affected by schizophrenia and it has indeed demonstrated its efficacy with this pathology.^{42,43} In the study presented here, a specific adaptation of the STAM protocol for PWD (STAM-Dem) was used.

The adaptation makes the exercises easier and, as in the original protocol, consists of a progressive series of music sessions and sound tracks (some recorded on a CD) that can be used in a sequence of step-by-step exercises aimed at stimulating and checking both attention and memory. As we specified in another publication,⁴³ the focus is on “selective attention,” that is, the capacity to select internal or external sources of stimulation in the presence of competing information input (and hence, the capacity to concentrate one’s attention on what is interesting) and to elaborate important information in a privileged way for a pursued aim⁴⁴; “sustained attention,” that is, the capacity to focus on an event for a prolonged time; and “alternate attention,” that is, the mental flexibility required to shift from one task to another. With regard to memory, we focused on the “STM,” that is, the working memory which handles and retains information.⁴⁵

The STAM-Dem protocol is divided into 4 phases, one for each specific function. Each phase of the STAM-Dem is

organized into exercises, ranging from the simplest to the most difficult, both for groups and individuals.

Phase 1: stimulus–movement association. The music therapist instructs the participants to link particular sound stimuli with specific body movements. Participants freely listen to recorded music. When a particular sound stimulus appears over recorded music, the music stops for a while and the movement connected to the stimulus is performed.

Phase 2: reaction to acoustic stimuli. This task consists in reacting to previously heard acoustic stimuli. The sound stimuli of the previous exercise are used. Reacting means recognizing the type of stimulus and counting how many times it is present in a recording with noises in the background.

Phase 3: shifting attention (1). This task consists of reacting to a target stimulus—a drum—by clapping one's hands after having heard it, but not clapping when the drum is preceded by a second target stimulus, a cymbal. When the therapist gives a signal, participants must react by clapping their hands only when the drum is preceded by the cymbal. The task is then made more difficult with the therapist giving this signal more frequently.

Phase 3: shifting attention (2). The participants listen to a rhythmic sequence: a regular, alternating sequence of bass drum and snare drum beats. The task is to follow the bass drum beat and snare drum beat by alternately clapping hands and tapping the table with one's hand.

Phase 4: orderly and inverted repetition. This task consists of listening, recognizing, and repeating in an orderly or inverted way sequences of previously recorded sounds. The stimuli are previously sampled from instruments selected for the exercise. The exercise will range from various simple repetitions, for example, 2 sounds, to more and more difficult ones.

Beyond the music (deliberately chosen from within the classical and modern Western repertoire by the author), the core aim of the protocol is to exercise cognitive functions, without considering sociodemographic characteristics or the ethnicity of the PWD.

Although the STAM-Dem is highly structured, the therapists were nevertheless also instructed to pay attention to the relational atmosphere. The therapists were instructed to pay close attention to the motivational aspect of the intervention, providing many reinforcements whenever participants were successful in carrying out the exercises. The therapists also have to bear in mind that what matters is that the participants engage in the tasks, making an effort at the cognitive level above and beyond the results that are obtained. Moreover, the achievement of results and consequent gratification may be considerably important from the motivational point of view. The effort of the music therapist is, therefore, to try to maintain the level of motivation as high as possible—even though the patient may not succeed in the execution of the exercises—

by supporting the patients in the performance of the tasks and in any case trying to generate a sense of gratification. The STAM-Dem can be adopted by professionally trained music therapists, clinical psychologists, physicians, and psychosocial rehabilitation technicians.

Procedures

The participants at each center were randomly assigned to the experimental group or to the control group, and they continued with the activities they would normally perform (standard care). They were divided up using an online randomization program⁴⁶ by personnel not involved in the study, thereby ensuring totally “blind” conditions.

Pre- and postintervention testing was also administered by professionals who had no other role in the project; blind conditions were thus obtained for assignment treatment.

The STAM-Dem intervention was intended as an add-on to the treatment a PWD would usually receive and making sure that patients are not deprived of any usual treatment.

No follow-up was conducted after the intervention because of a lack of funding.

Two weekly sessions of 45 minutes were provided for the experimental group for 12 weeks and for a total of 24 meetings. The number of participants in the experimental group ranged from a minimum of 4 to a maximum of 5 patients. All groups were conducted by professional music therapists trained to administer the STAM-Dem protocol. Supervision was provided throughout the course of the intervention by the author of protocol.

The psychometric instruments were applied during the week prior to commencement of the study (“prestudy”) and in the week following the last session of therapy (“poststudy”).

Follow-up was planned but not carried out.

Participants

The group of potential users included 80 PWD, 51 of whom were actually enrolled in the study. Only 1 patient involved in the experimental condition abandoned the study due to a worsening of his medical condition after the pretests (at the end of the study, a total of 50 patients were involved in pre–post tests; Figure 1). For each patient enrolled, a medical/geriatric evaluation was sought in order to verify the diagnosis of dementia (the *DSM* [Fourth Edition] was used¹) and to assess the cognitive state of each patient and any comorbid conditions.

The operators involved in the research were informed about the state of health of the participants. The clinical evolution of the disease and pharmacological treatment were monitored throughout the entire research period.

The use of any medicines and participation in the intervention on the part of the patients in question occurred in compliance with procedures approved by the medical supervisory staff at the support centers.

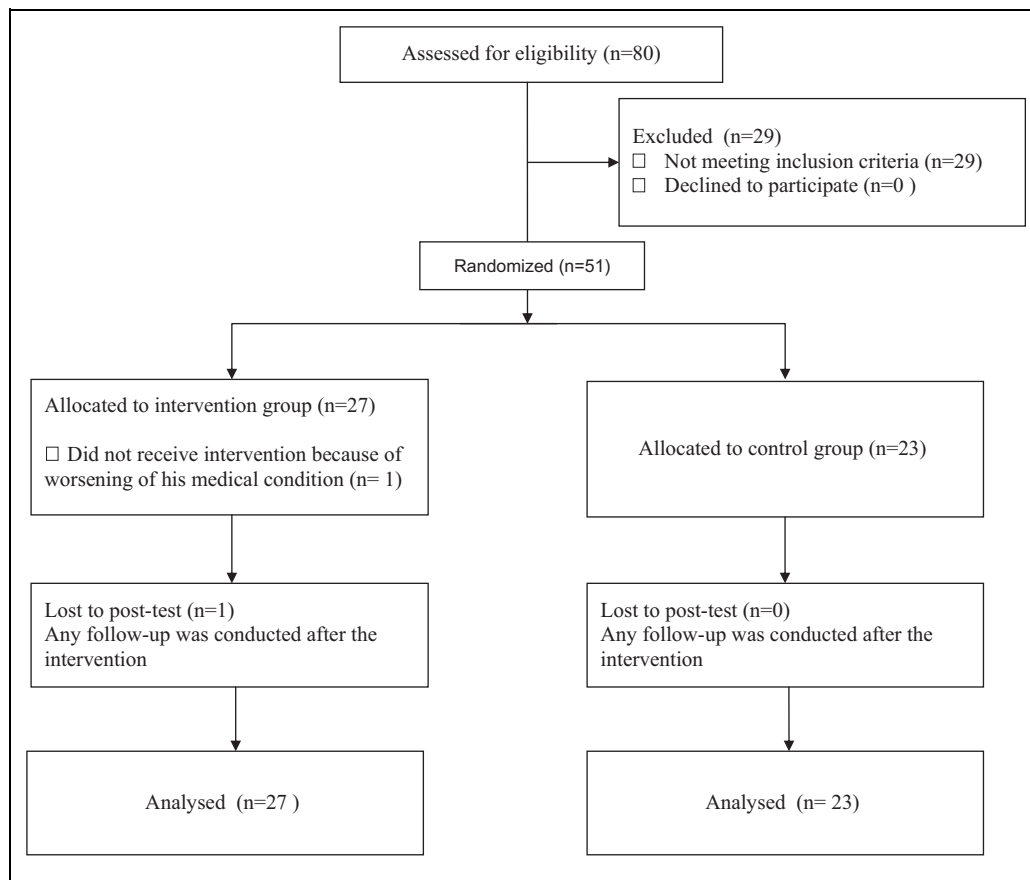


Figure 1. Research flow diagram.

Given the nature of the pathological condition of the participants in the research, a signature for informed consent was not requested.

Family members were informed and their consent was obtained.

At each center, participants were identified in accordance with the following inclusion criteria:

Clinical diagnosis within the dementia spectrum, from light to moderate/serious and currently in the subacute phase, and undergoing treatment in the above support centers;

- Mini-Mental State Examination (MMSE) score from mild (MMSE 18-24) to moderate (MMSE 12-18);
- Clinical condition established at least 15 days prior to identification;
- Age older than 65 years;
- Sensitive to sound/musical stimuli;
- The desire and capacity to remain in the setting;
- Acceptance (also at a minimum level) of sound/musical interaction;
- Presence of sufficient (also residual) hearing and perceptive-communicative and relational skills.

The exclusion criteria were

- Current delirium or psychosis;

- Presence of acute medical conditions (eg, pneumonia and cardiac insufficiency);
- Serious hypoacusis.

Instruments

The psychometric battery comprises standardized instruments. Cognitive functioning was measured by:

*Mini-Mental State Examination.*⁴⁷ This test consists of a battery of screening tests designed to verify cognitive functioning, with particular attention placed on such abilities as spatial and temporal orientation, verbal memory, calculation, drawing, and writing.

*Attentional matrices.*⁴⁸ This test assesses selective attention in a visual scanning task. It consists of 3 matrices of increasing difficulty, with 1, 2, or 3 target stimuli. Each matrix contains 13 rows, each of which contains 10 digits (0-9). The maximum time allowed for each matrix is 45 seconds. Scoring: total number of correct answers within 45 seconds in each of the 3 matrices.

*Forward and reverse digit-span exercise.*⁴⁹ The examiner verbally presents sequences of numbers of increasing length: the patient must correctly reproduce (following the order in which they were heard) at least 2 sequences of the same length (=verbal span). In the “reverse”

exercise, the patient is asked to repeat the sequence of numbers heard, from the last number to the first.

*Immediate and Deferred Prose Memory test (MPI and MPD).*⁵⁰ The examiner reads a short piece of prose. The patient is then instructed to immediately repeat everything that he or she can remember (MPI). The examiner then reads the text again and after 10 minutes (during which time the patient is occupied with nonverbal tasks), again asks the patient to repeat what he or she can remember (MPD).

Mood was measured by:

*Geriatric Depression Scale (GDS).*⁵¹ The GDS is a 30-item self-report assessment used to identify depression in the elderly individuals; the test excludes detection of somatic and psychotic symptoms. The GDS questions require a “yes” or “no” answer instead of the 5-categories response set. One point is assigned to each answer and the cumulative score is rated on a scoring grid. The grid establishes the range of 0 to 9 as “normal,” 10 to 19 as “mildly depressed,” and 20 to 30 as “severely depressed.”

Aggressive behavior was measured with:

Cohen Mansfield Agitation Inventory (CMAI).^{52,53} The CMAI is a 29-item caregiver rating questionnaire for the assessment of agitation in elderly persons. It includes descriptions of 29 agitated behaviors, each rated on a 7-point scale of frequency (from “never” to “several times an hour”). The behaviors are divided into 3 factors: (1) aggressive behavior (hurting, striking, and shoving); (2) physical nonaggressive behavior (pacing, repetitive mannerisms, and attempts to move away); (3) verbally agitated behavior (complaining, screaming, and demanding constant attention).

Nurses completed the:

*Index of Independence in Activities of Daily Living (ADL).*⁵⁴ The ADL is used to assess functional status as a measurement of the client's ability to perform ADL independently. The instrument is used to detect problems in performing ADL and to plan care accordingly. The index ranks adequacy of performance in the 6 functions of bathing, dressing, toileting, transferring, continence, and feeding. Clients are scored yes or no for independence in each of the 6 functions. A score of 6 indicates full function, 4 indicates moderate impairment, and 2 or less indicates severe functional impairment.

The music therapists completed the following:

Geriatric Music Therapy Profile (GMP). The GMP evaluates competences of the patient within the musical field and can be used to draw up a profile of the same in this sense. It is useful in defining and evaluating a—also customized—course of MT rehabilitation treatment (Pignatale D, personal communication, March 2009).

Scala di Valutazione dell' Attività Musicoterapeutica (JSVA-M]or Music Therapy Activity Scale). The SVAM comprises a set of 50 items that explore various aspects of the musical relationship. The relationship can be determined between a patient and another patient and between a music therapist and a patient. Attributed scores will increase proportionately as the positive nature of the relationship increases (optimal = 50; Pignatale D, personal communication).

The entire test takes approximately 1 hour and 15 minutes to administer, excluding the GMP, SVAM, and ADL.

Results

Statistical Analyses

Two questions were asked:

Question 1: At the prestudy stage, are the 2 groups (cases and controls) homogeneous and thus comparable?

The Fisher exact test was used for the sex of all participants involved and the *t* test for independent samples (Table 1).

Results: There are no statistically significant differences between the study cases and the controls as far as socio-demographic characteristics (sex and age) are concerned and the results of the prestudy tests. The groups at the prestudy stage are thus homogeneous with respect to the instruments administered.

Question 2: Do any differences exist within the groups between the pre- and poststudy phases? Changes (differences pre–post) in each individual were calculated and between-group differences of these scores were evaluated by *t* test for independent samples (Table 2).

Results: Between-group differences of change scores (pre–post) reveal a significant increase in the cases with respect to controls for the instruments MPI, MPD, MATRICES, ADL, SVAM, and GMP; the remaining instruments were not subjected to significant modification.

An analysis of “effect size” (Figure 2), a statistical measurement of the size of an effect which may relate to the difference between groups or an association between variables (for an overview in MT, see Gold⁵⁵), shows us in any case that there is a generalized improvement of the results of the experimental group and, in particular, in the MPI test, the MPD test, attentive matrices, and with the MT instruments.

Effect size (experimental group): MMSE + 0.29, MPI + 0.76, MPD + 0.73, REVERSE SPAN + 0.23, FORWARD SPAN + 0.19, MATRICES + 0.76, GDS + 0.25, CMAI –0.18, ADL + 0.52, SVAM + 1.01, and GMP + 0.83.

Table 1. Descriptive Sample Prestudy (N = 50) and Comparison Between Cases and Controls at the Prestudy Stage (Between Groups: Prestudy Phase)^a

Features PRE	Control group (n = 23)	Experimental group (n = 27)	P value ^b	Test
Sex				
Male	4 (17.4%)	6 (22.2%)	.736	Fisher's exact
Female	19 (82.6%)	21 (77.8%)		
Age	87.2 (7.1), 77-98 (13 missing)	85.5 (5.9), 77-94 (14 missing)	.528	t Test independent sample
MMSE	16.39 (3.90), 12-26	16.93 (3.66), 10-28	.620	t Test independent sample
MPI	1.83 (1.80), 0-6	2.37 (1.96), 0-7	.312	t Test independent sample
MPD	1.48 (2.31), 0-7	1.59 (2.26), 0-7	.861	t Test independent sample
SPAN forward	4.17 (0.89), 3-6	4.04 (0.90), 3-6	.591	t Test independent sample
SPAN reverse	2.30 (1.15), 0-4	1.81 (1.18), 0-3	.145	t Test independent sample
Attentional matrices	17.48 (11.16), 0-40	16.22 (6.51), 0-27	.623	t Test independent sample
GDS	9.91 (6.80), 0-25 (1 missing)	10.52 (6.17), 1-22	.744	t Test independent sample
CMAI	21.33 (12.73), 7-47 (8 missing)	23.47 (15.88), 7-62 (8 missing)	.674	t Test independent sample
ADL	1.93 (1.28), 0-4 (8 missing)	2.21 (1.13), 1-5 (8 missing)	.508	t Test independent sample
SVAM	34.35 (9.70), 17-54	33.59 (12.11), 5-62	.811	t Test independent sample
GMP	28.26 (9.63), 8-41	27.93 (7.12), 15-39	.888	t Test independent sample

Abbreviations: MMSE, Mini-Mental State Examination; SPAN forward and SPAN reverse, forward and reverse digit-span exercise; MPI, Immediate Prose Memory Test; MPD, Deferred Prose Memory test; GDS, Geriatric Depression Scale; CMAI, Cohen Mansfield Agitation Inventory; ADL, Index of Independence in Activities of Daily Living; GMP, Geriatric Music Therapy Profile; SVAM, Music Therapy Evaluation Scale; SD, standard deviation.

^aEach cell contains average, (SD), and min-max.

^bSignificance: *P* < .05.

Table 2. Descriptive Sample Changes (Pre-Post) in the 2 Groups (Controls and Cases; N = 50) and Between-Group Differences (Between Groups: Changes Comparison)

Features	Control group (n = 23), changes pre-post	Exp. group (n = 27), changes pre-post	P value between-groups differences	Test
MMSE	0.00 (3.40)	-0.67 (2.27)	.413	t test for independent samples
MPI	0.35 (1.50)	-1.07 (1.41)	.001 ^b	t test for independent samples
MPD	0.22 (1.17)	-1.23 (1.67)	.001 ^b	t test for independent samples
SPAN forward	0.13 (0.46)	-0.18 (0.79)	.085	t test for independent samples
SPAN reverse	0.09 (1.00)	-0.18 (0.96)	.332	t test for independent samples
Attentional matrices	2.09 (7.50) (2 missing)	-4.52 (5.98)	.001 ^b	t test for independent samples
GDS	-0.95 (4.94)	-0.86 (3.34)	.931	t test for independent samples
CMAI	1.47 (11.65) (8 missing)	2.16 (11.89) 8 missing	.866	t test for independent samples
ADL	0.20 (0.68) (8 missing)	-0.47 (0.90) 8 missing	.022 ^b	t test for independent samples
SVAM	3.00 (8.08)	-8.31 (8.19) 1 missing	.000 ^b	t test for independent samples
GMP	3.30 (6.50)	-4.31 (5.21) 1 missing	.000 ^b	t test for independent samples

Abbreviations: MMSE, Mini-Mental State Examination; SPAN forward and SPAN reverse, forward and reverse digit-span exercise; MPI, Immediate Prose Memory Test; MPD, Deferred Prose Memory test; GDS, Geriatric Depression Scale; CMAI, Cohen Mansfield Agitation Inventory; ADL, index of independence in activities of daily living; GMP, Geriatric Music Therapy Profile; SVAM, Music Therapy Evaluation Scale; SD, standard deviation.

^aEach cell contains: average of change (pre-post), (SD).

^bSignificance: *P* < .05.

Conclusion

To conclude, we may sustain that the protocol is indeed viable. There was, moreover, a very low number of dropouts (just 1 patient).

As far as the primary outcome is concerned, the quantitative data support the evidence that there was incisive action on attentive skills (matrices) and on the episodic-verbal LTM capacity, in both immediate and deferred components (MPI and MPD) in the patients who took part in the STAM-Dem.

With regard to the secondary outcome, no results were obtained. There was in fact no significant modification in the

perception of agitated behavior on the part of caregivers (CMAI). Also, with respect to the depressive dimension, there was no significant modification (GDS).

For us, this result is quite difficult to explain and is in contrast with what had been presumed by the music therapists involved in the study. In fact, all the music therapists sustained the importance of the motivational dimension and relations on the part of participants in the activity as a backdrop against which one might compare the positive evolution of the interventions.

As can be seen from the results of the SVAM, which explores various aspects of the musical relationship, scores in fact increase considerably (thereby demonstrating an increase

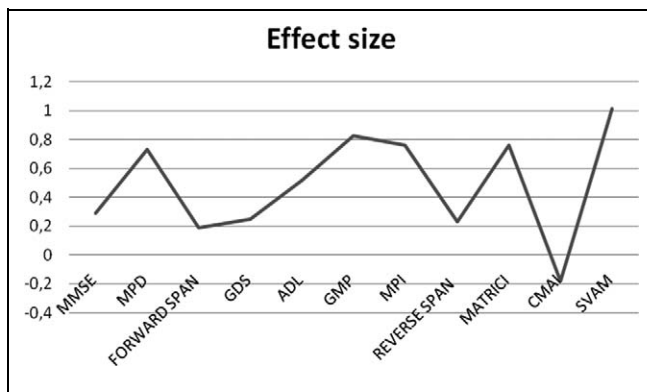


Figure 2. Effect size of all instruments. Effect size = (average post – average pre)/pooled SD. Referral value: <0.2 low effect size; >0.5 moderate; >0.8 high. MMSE indicates Mini-Mental State Examination; MATRICI, Attentional Matrices; SPAN AVANTI, forward span exercise; SPAN INDIETRO, reverse span exercise; MPI, Immediate Prose Memory Test; MPD, Deferred Prose Memory test; GDS, Geriatric Depression Scale; CMAI, Cohen Mansfield Agitation Inventory; ADL, Index of Independence in Activities of Daily Living; GMP, Geriatric Music Therapy Profile; SVAM, Music Therapy Evaluation Scale; SD, standard deviation.

in the positive nature of the relationship) between the beginning and the end of the intervention.

This may certainly derive from the impossibility of comparing the scales used (SVAM and GDS) or may be the result of the protocol used, which substantially—and in particular—acts on the cognitive functions. On the other hand, the GDS is a questionnaire administered directly to PWD, who do not all reliably report their mood and feelings. The psychologists responsible for assessment were in fact often faced with the situation of having to explain the meaning of the items to a patient, who, on account of his or her deterioration or low level of schooling did not understand the questions. In other cases, patients might answer in accordance with their mood, which in all probability was compromised by situational factors deriving from their daily routines and living. All these elements may have created discordant results in the answers in tests and retests.

However, from a strictly clinical point of view, an improvement in the relationship with the patients should also underlie an improvement in the depressive dimension of the patients.

This result could be interpreted as a possible distance between the personal and “subjective” observations of the music therapists and the results of the “objective” instruments.

One might suggest that the evaluations concern only the period of intervention of the MT and are insufficient to provide an overall picture of the patient.

Furthermore, the STAM-Dem protocol is found to be particularly useful and effective in reactivating the cognitive functions investigated with the above-mentioned tests and one should not overlook the fact that it is designed and structured for this particular purpose. Nor was any work conducted, specifically focusing on the aspects of an affective nature or concerning the management of stress deriving from admission to the

nursing homes or health care facilities. It is thus possible that the variations of mood and improvements of the state of agitation occur within the time period of the session but that such variations cannot be generalized to every other life context.

In any case, we think it may be very useful to investigate which personal elements are used by music therapists to evaluate the effectiveness of their work.⁵⁶ For professional operators, discovering which elements are relevant in the evaluation of work which is carried out and comparing them with those of the patients can contribute toward increasing the effectiveness of therapeutic activities.

A further interesting result, and one which was quite unexpected, derives from the nurses’ evaluations of the patients’ capacity to carry out ADL in an independent manner. The increase in ADL from pre- to postassessment is substantially in line with the observations of the music therapists concerning the general improvement of the patient. The nurses would certainly develop a more “general” opinion and evaluation of the patients but it is very difficult to believe that the STAM-Dem protocol can be so effective also with respect to ADL: first of all on account of the very specific features of the protocol itself and secondarily because it seems to be too short to have such important consequences on the patients’ daily living activities. Probably, the fact that the patients participate in rehabilitation interventions and are thus more active during the week produces in itself a feeling that there has been an improvement in their capacity to perform ADL in an independent manner, but this cannot be the final answer and more research is needed.

In any case, these observations would encourage us to always systematically perform qualitative assessments to support quantitative evaluations.

In conclusion, the STAM-Dem protocol appears to be a useful instrument within a more general sphere of rehabilitation, which contemplates the importance of the relational dimension and the motivational involvement of patients. The difficulties of an organizational nature which we had to contend with, given the high number of structures involved and the heterogeneity of the personnel involved, were addressed with attention constantly focusing on the issues of teamwork and collaboration. Finally, it may be said that the enthusiasm found at each unit or structure and also of the individual participants made the work much more simple than we had originally envisaged.

Limitations

In this work, we did not report in a privileged manner the evaluations of the music therapists involved in relation to evaluations of a qualitative type nor did we prepare a detailed analysis of the cost-effectiveness ratio.

We evidently need to carry out further experimentation to sustain that the protocol can be useful, and in this regard, we definitely remain at the disposal of any researchers or clinical group that may wish to contribute toward research on the application of the instrument.

We hope that the STAM-Dem will become a useful instrument which may be adopted in the rehabilitation of memory and attention in elderly participants having dementia.

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Declaration of Conflicting Interests

Enrico Ceccato, Paolo Pizziolo, Susanna Crociani, Emanuele Zanfretta, Lorenza Pollini, Paolo Alberto Caneva, and Lorella Baldin are professional music therapists.

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