SolCos model-based individual reminiscence for older adults with mild to moderate dementia in nursing homes

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Relevance statement

To improve care practice of nursing home residents with dementia scientific studies are essential. The present study was focussed on the effect of individual standardized reminiscence therapy, developed and tested in a previous study, and performed by trained nursing home volunteers. Based on the insight of this study, in a next study staff will perform the reminiscence therapy to learn systematically more about each participant's aspects of his or her life, personality and preferences and these insights can be used to deliver individualized care for each resident.

Accessible summary

What is known on the subject?

- To stimulate reminiscence of older adults with dementia performed individually or through group sessions is a well-known practice in nursing homes resulting in effects on behaviour and well-being as an alternative for medication.
- Robust scientific proof of the effectiveness of individual reminiscence therapy performed in nursing homes is sparse.

What this paper adds to existing knowledge?

- We have provided individual standardized reminiscence therapy to residents with dementia. The therapy was developed and tested in a previous study and performed in this study by trained nursing home volunteers.

- In comparison with a control group who received usual care, residents who received the reminiscence therapy showed significant less depressive symptoms. Moreover, residents were in general attentive, open and collaborative during the sessions and volunteers experienced the sessions as useful and pleasant.

What are the implications for practice?

- Individual reminiscence therapy can be learned and used by nursing home volunteers to improve care in nursing homes.

Abstract

Aim

To investigate the effect of a standardized individualised intervention based on the SolCos transformational reminiscence model on depressive symptoms (primary outcome), cognition and behaviour (secondary outcomes) for older people with mild to moderate dementia, performed by trained nursing home volunteers as facilitators.

Background

Because of limited pharmacological treatment options for older adults with dementia relevant physical, sensory, psychological or social interventions offer alternative opportunities.

Method

Randomized controlled trial (ISRCTN74355073) was set up in two nursing homes with 29

and 31 residents in the intervention and the control group, respectively. Eighteen nursing home volunteers were trained to perform the reminiscence therapy. Various assessment scales were measured pre- and post-sessions.

Results

Linear regression analysis showed an impact on depressive symptoms. However, no impact was identified on cognition and behaviour. Facilitators experienced the sessions as useful and pleasant and study participants were in general attentive, open and collaborative.

Discussion

Study results showed that organizing standardized individual reminiscence therapy with nursing home volunteers was feasible and study participants' attention and participation was overall good. Further study initiatives to explore the potential of individual reminiscence therapy within a person-centred framework are recommended in order to improve care in nursing homes.

Key words: Dementia, Alzheimer disease, reminiscence therapy, non-pharmacological interventions, long term facilities, older adults

Background

Dementia is an acquired brain disorder that impairs cognition and functional capacity and leads to behavioural changes and reduces quality of life. Difficulties in communication, emotions, sense of well-being and social relationships often have an impact on feelings of loneliness, and depressive symptoms. In the absence of curative treatments, our attention must turn to alternative strategies to manage dementia related symptomology and optimise quality of life (Tolson et al. 2011). Pharmacological interventions offer short-term benefit and clinical guidelines discourage inappropriate or long-term prescribing of antipsychotics (Lundvisk et al. 2014).

The bio-psychosocial model of dementia care embraces both psychosocial and biological domains and identifies factors that are fixed and not amenable to change as well as tractable factors, which can be influenced by efficacious interventions (Spector & Orrell 2010). The majority of people at some point in the disease trajectory will exhibit behavioural and psychological symptoms of dementia (BPSD) and non-pharmacological approaches should be used as first choice treatments (Volicer 2012). Moreover, recommendations and clinical guidelines promote non-pharmacological approaches such as structured social interaction (Scottish Intercollegiate Guidelines Network, 2006; National Institute for Health and Clinical Excellence 2006). However, many studies have investigated the clinical effectiveness of non-pharmacological treatments with physical, sensory, psychological or social interventions (e.g. individual or group interventions) without robust conclusions (Woods et al. 2005, 2012, Yamaguchi et al. 2010). A randomised study in ten Danish nursing homes (Gudex et al. 2012) evaluated the introduction of reminiscence into daily routines. Reminiscence focuses on early memories, which are often relatively intact

for people with dementia, and bring into the foreground the person's preserved abilities rather than their impairments. The study found that resident outcomes significantly improved at 6 months, but did not persist till 12 months. These findings, however are difficult to interpret because of the intervention involved training nursing home staff three forms of reminiscence: general group based reminiscence, personalised individual reminiscence and spontaneous reminiscence. The authors did not report information on the balance nor on the frequency of using the different approaches over time per resident. In addition, the disappointing findings can be explained by the partial, rather than full, implementation of the structured reminiscence intervention within their intervention sites. In the Danish study two main drawbacks were mentioned: the context of sites (e.g. lack of time to plan, insufficient management support, lack of interest in learning and using) and insufficient tailored facilitators' training programs. In addition, the authors discussed the challenging shift in long-term facilities from a routine task-oriented daily practice to more holistic and flexible care centred on residents and their quality of life. A recently published systematic review (Livingston et al. 2014) investigating the clinical effectiveness and cost-effectiveness of sensory, psychological and behavioral interventions for managing agitation in older adults with dementia. The authors concluded that future interventions should change care home culture through staff training and permanently implement evidence-based treatments and evaluate health economics. Another systematic review (Terstadt et al. 2014) focusing on personalized interventions to address behavioral and psychological symptoms in nursing home residents with dementia revealed increasing evidence of benefits arising from personalized interventions such as reminiscence and person-centered care training and practice development.

In order to address some of the methodological shortcomings described in the literature we undertook a randomized controlled intervention study in nursing homes in the Dutch speaking part of Belgium (Van Bogaert et al. 2013). The aim of this study was to investigate the effect of a standardized individualised intervention based on the SolCos transformational reminiscence model on cognition, behaviour and depressive symptoms for older people with mild to moderate dementia, performed by trained nursing home volunteer facilitators.

The Study

Aims

To investigate the effect of a standardized individualised intervention based on the SolCos transformational reminiscence model on depressive symptoms (primary outcome), cognition and behaviour (secondary outcomes) on older people with mild to moderate dementia in nursing homes.

We hypothesized that depressive symptoms, cognition and behaviour of older people with mild to moderate dementia resided in nursing homes can be significantly positively influenced by specific developed individual structured reminiscence therapy.

Design

Study population

The study was a randomized controlled intervention study conducted in two nursing homes in Belgium and compliant with the CONSORT requirements. A two-phase study was

registered (ISRCTN registered http://www.isrctn.com/ISRCTN74355073) and this study was the first phase, conducted between January '15 and March '15 (10 weeks) though registered retrospectively. The study protocol was executed as approved by the ethics committee. All study participants were aged ≥ 60 and residents of a study nursing home, diagnosed with major neurocognitive disorder according to DSM-V criteria (American Psychiatric Association 2013) and had a Mini-Mental State Examination (MMSE) between <24 and < 10. We consider older adults with mild and moderate dementia based on a MMSE between <24 and >18 and between ≤ 18 and >10), respectively (Van Bogaert et al. 2013). In addition, based on the opinion of the nursing home physician / nursing staff, residents with unstable medical conditions and/or limited in their capacity to communicate verbally were not eligible to participate in the study. Eligible individuals and their legal representatives were provide with study information and both signed a written consent before the start of the trial in accordance with ethical procedures as approved by the ethical committee.

Participants were randomly selected into the intervention group or control group by using sequentially numbered, opaque sealed envelope for each resident (n=72), establishing two equal study groups before the trial started (Doigs & Simpson 2005). A person not involved with the study divided the envelopes in two blinded boxes manually and randomly. No participants were added after the randomization and/or during the trial.

Based on our previous study (Van Bogaert et la. 2013), 43 study participants per group were needed for a difference of 2.1 on CSDD delta scores with a standard deviation of 3.4 using an independent t-test on difference in change scores (power 80% and p< .05). Ninety-three residents of the two nursing homes in the Dutch speaking part of Belgium were potential eligible for the study, 72 residents have met the inclusion criteria and agreed to

participate in the study (see Figure 1).

Intervention protocol

The standardized individual reminiscence intervention was based on the SolCos model (Soltys and Coats, 1994) delivered for each study participant by one facilitator. The intervention protocol contained the three elements of the SolCos model, namely process, items and outcomes. The process component describe the standard approach for facilitator(s) to use to interview participants with a raising awareness of their own characteristics and perspectives as well as the personalised context of the participants (e.g. family, home, community, and life role). The items component has two subcomponents: stimuli and responses. During structured sessions interviewed items evoke recollections used by the facilitator to focus and stimulate the reminiscence process. Intense verbalization and/or sensory stimulation can focus on family, home, community, or life role. The outcome components focus on the participants' and the facilitators' outcomes aiming to impact participants' cognition, well-being and behaviour as well as to increase facilitators' supportive role and experiences as a change agent in the reminiscence process.

The reminiscence sessions were strictly structured, starting with an introduction interview to prepare the sessions (e.g. characteristics and particular life events and experiences of participants). The sessions were administered two times per week during 8 weeks (week 1 until week 8 of the study). Each session lasted 45 minutes. Each week, one of four standardized topics (e.g. family, profession, holiday, games) was explored. The standardised topics were based on a review of the literature (Schweitzer & Bruce 2008), experiences of a previous study (Van Bogaert et al. 2013) as well as through involvement of nursing home

residents and family. The purpose of the preliminary interview was to determine individual interests, establish access to various personal items, goods and images which family and friends were asked to provide to supplement the contents of 4 personalized memory boxes, one for each theme. Each session was structured with an introduction and round off phase of 15 minutes and a reminiscence phase of 30 minutes. The sessions took place in the resident's room or a small private lounge in the nursing home. These places were familiar places to the participants and had a homely décor. We selected and trained 18 nursing home volunteers as facilitators. The majority of the facilitators were female (n=16) who were involved in residents' social activities. Their mean age was 43 years (range 20 – 67). Eight had received higher education (e.g. bachelor degree or higher), six facilitators received secondary education and four facilitators received basic education. One researcher responsible for the intervention performed the training program. Moreover, the researcher has provided support and advice to the facilitators. Each resident of the intervention group received the reminiscence sessions by one of the trained nursing home volunteer facilitators uniquely.

Measures

Descriptive data collection included study participants' age, gender, facility, length of stay, social and other activities (e.g. reading, memory games), chronic disease, number of chronic medications and antidepressant use.

Outcome Measures

All participants, intervention group as well as control group, were tested pre and post

intervention (week 0 and week 9 respectively) with various validated assessment scales to evaluate depressive symptoms, cognition, behaviour and (see Table 1). Pre and post intervention outcome measures were recorded using a battery of validated assessment scales:

Scale for Depression in Dementia (CSDD) (Kørner et al. 2006) is a valid screening tool to evaluate depression in older adults and equally valid in populations of demented and non-demented. The CSDD contains 19-items with a 3-point score of absent, mild, or intermittent and severe. Scores of >7 suggest the presence of depressive symptoms.

The *Mini-Mental State Examination* (MMSE) (Folstein et al. 1975) is a standard screening tool for cognitive assessment in the clinical setting and facilitates the detection of mental status changes, with scores ranging from 0 to 30 and allows comparison of performance across time and among older adults. Low scores can be associated with cognitive impairment. The *Frontal Assessment Battery* (FAB) (Dubois et al. 2000) evaluated frontal lobe function exploring the following functions: conceptualization, mental flexibility, motor programming, sensitivity to interference, inhibitory control, and environmental autonomy.

The *Neuropsychiatric Inventory* (NPI) (Cummings et al. 1994) assesses behavioural disturbances occurring in dementia patients: delusions, hallucinations, agitation, dysphoria, anxiety, apathy, irritability, euphoria, disinhibition, aberrant motor behaviour, night-time behaviour disturbances, and appetite and eating abnormalities. The severity and frequency of each neuropsychiatric symptom are rated on the basis of scripted questions. The *Cornell*

A second researcher, who was not involved with any aspect of the intervention program,

has collected the study participants' assessments scales and other data (week 0 and 10 before and after the trial, respectively). Therefore, this researcher was blinded to the assignment of the participants to the intervention or to the control group.

After each session facilitators filled in a 10-item survey – *residents' attention and participation* - on a 4-point Likert type answering scale (*strongly disagree, disagree, agree, strongly agree*). The survey indicated the extent that the participant was attentive, open, cooperative and concentrated; if the participant started the session immediately; took the memory box spontaneously; talked spontaneously further when facilitator offered an item; recollected spontaneously; talked a lot and took out the memory box an item spontaneously. Furthermore, the duration of each session was noted. In addition, after the session each facilitator filled in an 11-item survey - *session conditions and facilitators' experiences* - on a 4-point Likert answering scale (*strongly disagree, disagree, agree, strongly agree*). The survey indicates how facilitators experienced the conditions to guide the sessions (e.g. were sessions schedule appropriate; in an appropriate environment; with sufficient amount of residents' personal items in the memory boxes), whether they experienced the sessions as pleasant and useful.

Ethicalconsiderations

The study was performed based on the study protocol approved by the ethics committee of the Antwerp University Hospital. Eligible individuals and their family signed a written consent form before the start of the study.

Data analysis

Continuous variables were reported as mean (SD) when normally distributed and median (interquartile range) otherwise. Categorical variables were presented as numbers and percentages. Comparison of baseline characteristics between control and intervention group were performed by means of a chi-square test (for categorical variables), independent T-test (for normally distributed variable) or Mann-Whitney U test (for non-normally distributed continuous variables). The differences between post and pre intervention scores (delta scores) of the baseline and outcome scores were calculated for each assessment scale. To compare delta scores within and between control and intervention group Wilcoxon Signed Ranked test and Mann-Whitney U test were used, respectively. Linear regression analysis correcting for the possible confounders described in Table 1 was performed to evaluate the effect of reminiscence therapy on CSDD delta scores (continuous outcome). A two-sided statistical significance level of $p < .05$ was set. SPSS 22.0 (IBM Statistics Inc, Chicago, IL, USA) was used for data analysis.

Results

Seventy-two residents gave consent to participate in the study. Twelve participants dropped out of the study (16%) because of sudden illness leading to admission to hospital (n =1) or palliative care (n =1) and death (n =6), disruptive or aggressive behavior during the sessions (n=2) and withdrawal of consent after baseline (n =2). Finally, 60 residents completed the study, 29 in the intervention group and 31 in the control group. Table 1 shows the study participants' characteristics. Mean age of the study participants was 84 years, 80% was female and stayed on average 2.5 years in the facility. The majority was involved in social activities and 40% read and played memory games regularly. Two out of

three suffered from one or more chronic diseases and more than half were treated with antidepressants. Both intervention and control group showed no differences, except for memory games and antidepressant use. In the intervention group 69% of the residents was treated with antidepressants in comparison with 42% in the control group ($p < .037$). In the latter group 55% of the residents played memory games in comparison with 28% in the intervention group ($p < .034$)

The majority of the study participants of the intervention group received all 16 sessions, 9 residents missed 1 to 2 sessions, 4 residents missed 4 to 7 sessions. The reason of the missed session(s) was primarily caused because residents were not available on planned times. On average, the session's duration was 30 minutes (*SD* = 10.6) and the mean *residents' attention and participation* score (range 10 – 40) was 28 (*SD* = 6.8). Although we observed no significant differences of these scores between sessions, the first session, session 12 and session 13 presented the lowest *residents' attention and participation* scores.

In general, residents were attentive, open, concentrated and collaborative. Facilitators, however, scored less favorable on following items: participant started with the memory box spontaneously; talked spontaneously further when facilitator offered an artefact; recollected spontaneously and took out items spontaneously. The mean *session conditions and facilitators' experiences* score (range 11 – 44) was 29 (*SD* = 2.75). Facilitators experienced the sessions as useful, pleasant and performed in sufficient conditions (e.g. were sessions schedule appropriate; in an appropriate environment). To gather enough study participants' personal items supporting the reminiscence session (e.g. memory boxes) was rated as less favorable.

We observed no differences in the scores on the pre-session assessment scales between

treatment and control group (see Table 2). After the intervention, the intervention group showed decreased scores on the NPI (p = .065), the NPI subscale appetite (p = .056) and night-time disturbance (p = .024) in comparison with pre-session scores. Although not significantly different from the control group, the intervention group MMSE delta score was increased post-session (.86, p = .238).

For the intervention group the post-session CSDD score was significantly lower as compared to the pre-session score (-2.48, p = .005). The post-session CSDD score of the control group, however, was slightly increased (+0.19 – p = .847). Comparing the delta scores between both groups, the intervention group delta score was significantly lower than the control group score (p = 0.02). Percentage of participants with depressive symptoms (CSDD > 7) changed from 19.4% and 24.1% pre-session in the control group and intervention group respectively to 16.1% and 6.9% post session, respectively. However these post session percentages were not significantly different between the groups. Using linear regression analysis correcting for the variables described in Table 1 (e.g. treated with antidepressant) we interpreted the adjusted intervention effect in the model including intervention (p =0.056), length of stay (p = 0.042), memory games (p = 0.562) and antidepressant (p = 0.757). This model showed only a trend of reminiscence therapy on CSDD delta score; b = -2.37, t(55)= -1.953, 95% CI [-4.81,0.06].

Discussions

This study identified the potential capacity of the standardized individualised intervention based on the SolCos transformational reminiscence model applied to randomly selected older people with mild to moderate dementia of two nursing homes. Two randomized study

groups – intervention and control – were selected with largely comparable characteristics (except for use of antidepressants and memory games) and pre-session assessment scale scores. In the execution of the study two researchers were involved. In this study we selected and trained 18 facilitators who performed for each participants 16 sessions during 8 weeks. Facilitators experienced the session as pleasant and meaningful, but to prepare the memory boxes by gathering various personalized items, goods and images was rated less favourable. The effect of the reminiscence therapy was confirmed based on significant better CSDD delta scores in the intervention group. However, linear regression analysis with correction for confounders (see Table 1) showed no significant effect of reminiscence therapy on the Cornell Scale for Depression in Dementia delta scores ($p = 0.056$). The study was underpowered so possibly with more participants significance was reached.

Limitations

Some study limitations should be mentioned. Firstly, the present study established a method for individual reminiscence therapy with a convenient sample to detect some differences between study groups though a larger study sample is necessary as calculated (see method section). Unfortunately, we had a significant drop out of our study sample (see Figure 1). Secondly, the sessions were guided with trained nursing home facilitators and a potential bias because of varied performed sessions by each facilitator, although a standardized training could have influenced results. Thirdly, we double the intervention period and the number of performed sessions (e.g. 8 weeks and 16 sessions) in comparison with a previous pilot study (Van Bogaert et al. 2013). The study design though, did not allow identifying neither long-term benefits nor the effect on the pharmacological status.

Fourthly, we have avoided bias by using two independent researchers, but it was impossible to blind completely the intervention group as the intervention was organized and integrated in the nursing homes daily practice. Finally, we identified some lower residents' attention and participation scores during sessions 12 and 13, which suggests perhaps the limitation of our approach performing two sessions during a certain number of weeks and the necessity to switch over a maintenance dose of one session per week or less.

Most published randomly controlled trials performed in long-term facilities and nursing homes used group reminiscence therapy and showed effects on depressive symptoms, behavioural symptoms, and cognitive and affective functioning (Hsieh et al. 2010, O'Shea et al. 2014, Wang 2007). These studies concluded that group reminiscence might, in certain circumstances, be an effective care option for people with dementia in long-care facilities with a potential impact positively on the quality of life of residents. Woods et al. (2012) performed one of the largest trials of any reminiscence-based intervention for people with dementia, a study sample of 487 people with dementia/family caregiver pairs. Study results showed no benefit from being allocated to receive the reminiscence intervention for either people with dementia or their caregivers, in terms of quality of life, for the person with dementia, or psychological distress, for the family caregiver. The authors concluded that although some beneficial effects for people with dementia, this must be viewed in the context of raised anxiety and stress in their family caregivers. The reasons for these discrepant outcomes need to be explored further, and may necessitate reappraisal of the movement towards joint interventions.

Person-centred care is increasingly being regarded as synonymous with excellent quality of

aged care and previous work has studied the content described by people with dementia, family members and staff in residential aged care (NICE SCIE Guideline 2006, 2012, Røsvik et al. 2011). To promote continuation of self and normality of older people with dementia Edvardsson and colleagues (2010) described the person– centred care approach based on 5 tangible aspects; (1) knowing the person; (2) welcoming family; (3) providing meaningful activities; (4) being in a personalised environment and (5) experiencing flexibility and continuity. In addition, within the person-centred framework the focus on staff nurses and caregivers' communication skills to better meet residents' needs, reduce residents' resistiveness to care and BPSD will be essential (Moyele et al. 2013). We suggest to combine described standardized individualised intervention based on the SolCos transformational reminiscence model with a broader person centred framework that underpins the nursing home culture as suggested in previous studies (Livingston et al. 2014). Through the reminiscence therapy staff will learn systematically more about each participant's aspects of his or her life, personality and preferences and these insights can be used within the person-centred framework to deliver more a supportive and individualized care plan for each resident with a strong involvement of family members. In turn, the person-centred framework and staff' communication skills are necessary to optimize the reminiscence therapy achieving better and sustained outcomes.

Conclusion

Study results identified the effect of the reminiscence therapy based on significant better CSDD delta scores in the intervention group. The effect on cognition was not confirmed in this study. Study results showed that organizing standardized individual reminiscence

therapy with nursing home volunteers was feasible and study participants' attention and participation was overall good. Further study initiatives to explore the potential of individual reminiscence therapy within a person-centred care framework are recommended in order to improve care in nursing homes.

Conflict of interest

None declared.

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Figure 1. Study population flow diagram

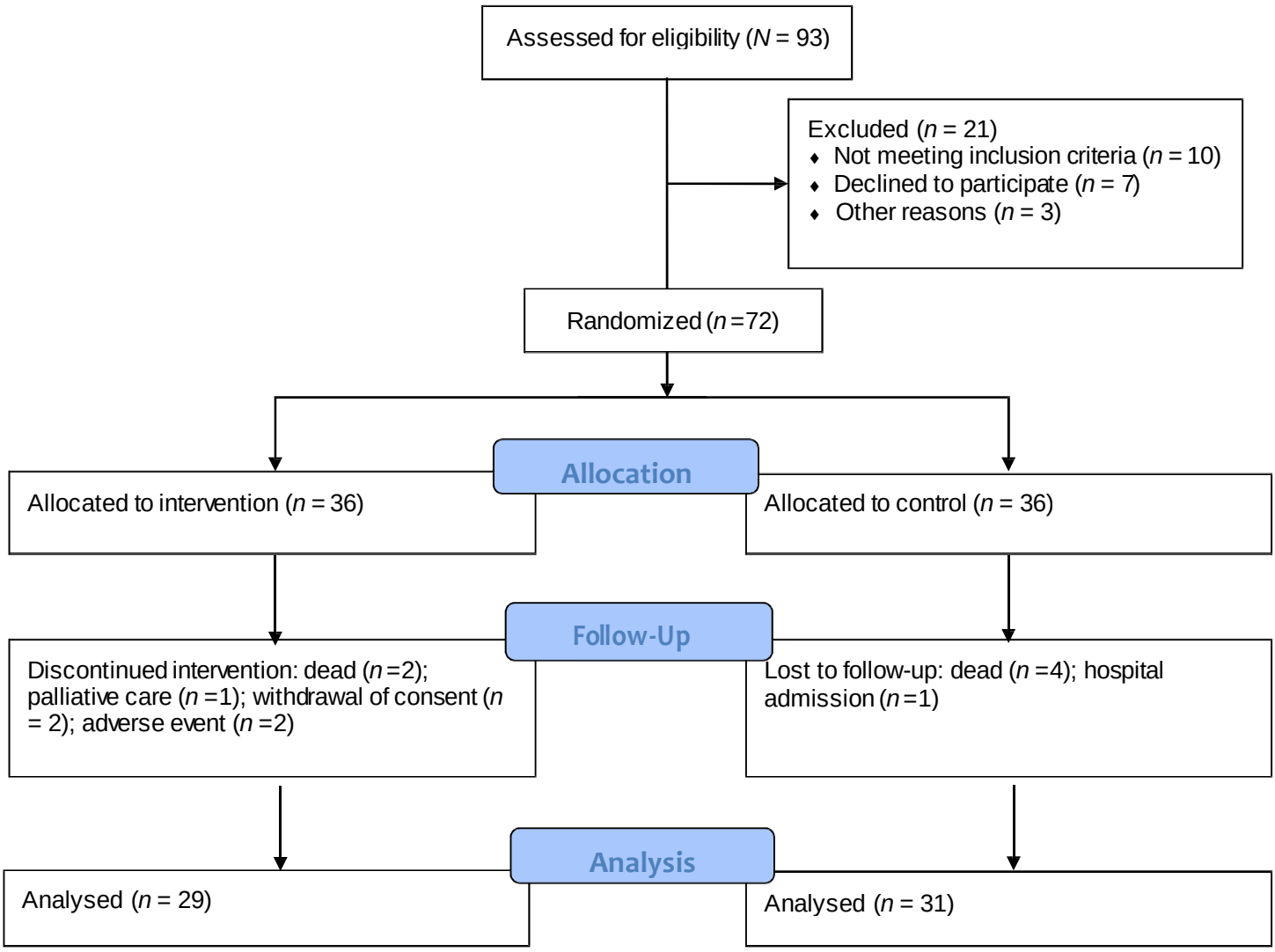

Table 1. Characteristics of study participants at baseline.

	Total	Intervention group	Control group	*P-value*
N	60	29	31	
Age in years *median (IQR)*	84 (78-90)	84 (79.5 - 90,5)	84 (76 - 89)	.482§
Female *(%)*	80	82.8	77.4	.608$
Facility 1 *(%)*	65	65.5	64.5	.936$
Length of stay (months) *median (IQR)*	31.5 (14.5 - 49.9)	34.6 (15.4 - 59.6)	27.4 (14.2 - 49.0)	.506§
Social activities *(% ≥ 1 time / week)#*	86.7	86.2	87.1	.920$
Memory games *(% ≥ 1 time / week)#*	41.7	27.6	54.8	.034$
Reading *(% ≥ 1 time / week)#*	41.7	51.7	32.3	.130$
Chronic disease *(%)*	63.3	69.0	58.1	.385$
Chronic Medications *median (IQR)*	2.0 (1 - 3)	2 (1 - 3)	2.0 (1 - 2)	.312§
Treated with antidepressant *(%)*	55	69.0	41.9	.037$

§ Mann-Whitney U test $ Chi Square test

The extent that residents (≥ 1 time per week) joined social activities such as music, knitting, walking, games other the memory games etc …; read such a journal, newspaper, …; played memory games.

Table 2. Pre and post session scores assessment scales *median (IQR*) and delta scores as calculated difference between post and pre session scores.

All study participants	Control group $N = 31$			Intervention group $N = 29$		
	Pre-session	*Post-session*	*Delta score*	*Pre-session*	*Post-session*	*Delta score*
MMSE	18 (15 - 22)	18 (15 - 22)	0 (-2 - 2)	15 (12.5 - 20)	17 (14.5-21)	2 (-2 - 3.5)
FAB	9 (6 - 13)	11 (9 - 14)	1 (0 - 4)	8 (6 - 12)	9 (6.5 -15)	2 (0 - 3.5)
NPI	3 (1 - 10)	4 (0 - 12)	0 (-5 - 2)	5 (1.5 - 22-5)	4 (0 - 10)	-1 (-11.5 - 1)
CSDD	3 (1 - 5)	3 (1 - 6)	0 (-2 - 2)	5 (2 - 8)	2 (0.5 - 3)	-4 (-5.5 - 0.5)*
Depression	19.4	16.1	- 3.3	24.1	6.9	-17.2

Mini-Mental State Examination (MMSE); Frontal Assessment Battery (FAB); Cornell Scale for Depression in Dementia (CSDD); Depression CSDD % score > 7; Neuropsychiatric Inventory (NPI); * p-value <.05, ** p-value <.01 and *** p-value <.001; Mann-Whitney U test.

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	Page 1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Page 2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	Page 4-6
	2b	Specific objectives or hypotheses	Page 6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Page 6 - 7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Page 6 - 7
Participants	4a	Eligibility criteria for participants	Page 6 - 7
	4b	Settings and locations where the data were collected	Page 6 - 7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Page 7 – 8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Page 9 - 10
	6b	Any changes to trial outcomes after the trial commenced, with reasons	-
Sample size	7a	How sample size was determined	Page 7
	7b	When applicable, explanation of any interim analyses and stopping guidelines	-
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	Page 7
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Page 7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Page 7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Page 7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	Page 7

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	-
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	Page 11 - 12
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Page 23
	13b	For each group, losses and exclusions after randomisation, together with reasons	Page 23
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Page 6
	14b	Why the trial ended or was stopped	Page 9
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Page 24
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Page 24
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Page 25
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	-
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Page 13 - 14
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Page 12
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Page 15-16
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Page 15-16
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Page 16
Other information			
Registration	23	Registration number and name of trial registry	Page 6
Protocol	24	Where the full trial protocol can be accessed, if available	Page 6
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Page 18

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials.

Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.