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PAINT I: The effect of art therapy in preventing and managing delirium among hospitalized older adults in the PAINT I study: a randomized controlled trial

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Abstract:	Key Summary Points: Prevention of delirium in hospitalized older patients using art therapy The adapted art therapy intervention was effective in reducing duration of delirium among those who received the intervention. Art therapy expands patients' communication options to help them express their experiences during delirium The intervention is safe, with no adverse events in patients at risk of delirium Abstract: Background: Delirium is common among older hospitalized patients and is regarded as a negative outcome parameter. Non-pharmacological strategies have been shown to be effective in the prevention and management of delirium. This study aimed to determine the effectiveness of art therapy as part of a multicomponent intervention in preventing and managing delirium in hospitalized older patients. Methods: 138 patients at risk of developing delirium were randomized to receive an art therapy twice daily for 25 minutes using a mobile atelier. 107 participants were included in the final analysis (N=53 intervention, N=54 control). The primary outcome was the effectiveness of art therapy in preventing delirium. The secondary outcome was to determine its impact on duration of delirium in patients with existing delirium. Delirium was assessed using the Nursing delirium Screening Scale (Nu-DESC). Results: 8 patients (7.5%) developed new onset delirium during admission, equally distributed among control and intervention group. Therefore, no valid statistical analysis could be performed. There was a significant decrease in duration of delirium in the intervention group (4 days, IQR 2.25-9.75) compared to the control group (7 days, IQR 4-10) . A reduction of 67% (p=0.015) in days with delirium was seen in the intervention group. Whilst the intervention was beneficial for patients with dementia, higher benefit was found for participants with better cognitive abilities. Conclusion: Findings from this study showed that the integration of art therapy as part of a multicomponent intervention in delirium management is feasible, and can reduce duration of delirium among hospitalized older adults.
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Abstract:

Background: Delirium is common among older hospitalized patients and is regarded as a negative outcome parameter. Non-pharmacological strategies have been shown to be effective in the prevention and management of delirium. This study aimed to determine the effectiveness of art therapy as part of a multicomponent intervention in preventing and managing delirium in hospitalized older patients.

Methods: 138 patients at risk of developing delirium were randomized to receive an art therapy twice daily for 25 minutes using a mobile atelier. 107 participants were included in the final analysis (N=53 intervention, N=54 control). The primary outcome was the effectiveness of art therapy in preventing delirium. The secondary outcome was to determine its impact on duration of delirium in patients with existing delirium. Delirium was assessed using the Nursing delirium Screening Scale (Nu-DESC).

Results: 8 patients (7.5%) developed new onset delirium during admission, equally distributed among control and intervention group. Therefore, no valid statistical analysis could be performed. There was a significant decrease in duration of delirium in the intervention group (4 days, IQR 2.25-9.75) compared to the control group (7 days, IQR 4-10). A reduction of 67% (p=0.015) in days with delirium was seen in the intervention group. Whilst the intervention was beneficial for patients with dementia, higher benefit was found for participants with better cognitive abilities.

Conclusion: Findings from this study showed that the integration of art therapy as part of a multicomponent intervention in delirium management is feasible, and can reduce duration of delirium among hospitalized older adults.

Key words:

Non-pharmacological intervention – art therapy - delirium - prevention – – communication

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Introduction

Delirium is one of the most common complications in hospitalized older patients. Its consequences are far-reaching with an increased risk of long-term cognitive and functional decline, as well as a 1-year mortality of up to 30%. (1). Non-pharmacological and individually tailored approaches are widely accepted to be effective in delirium prevention (2). Contrary to pharmacological prevention strategies which currently lack robust evidence, there is strong research evidence to support the promotion and further evaluation of non-pharmacological interventions to prevent delirium in hospital (3, 4). In clinical practice, NICE guidance recommends the provision of multicomponent interventions tailored to the individual patient´s needs and care setting (5). Recommended interventions include careful evaluation of daily medication, provision of vision and hearing adaptations, hydration, nutrition, maintenance of a structured sleep rhythm, and stimulation, reorientation, and therapeutic activities.

Many of the studies evaluating non-pharmacological delirium interventions focus on the prevention of delirium and do not address patients with delirium on admission (6, 7). In addition, many of the proposed interventions require professional expertise and therefore increased staff resources. Therefore, the development of new innovative non-pharmacological delirium interventions is highly relevant to ensure age-friendly hospital care.

The WHO-report ”Health Evidence Synthesis report: what is the evidence for the role of the arts in improving health and well-being in the WHO European region“ emphasizes the role of arts including visual arts as effective, safe, and cost-effective in healthcare settings. (8). Nonetheless, the integration of this multifaceted therapy in European health systems is still lacking.

Currently, there is a lack of evidence regarding the effectiveness of art therapy, particularly in managing delirium(9,10). Art therapy can be tailored to the individual patient´s needs, applied by professional therapists, and has a low risk of adverse events. It offers a potential therapeutic option in the management of patients at high risk of delirium. This randomized controlled trial is part of the PAINT-study (Preventive Art Intervention Therapy), a large-scale research project evaluating the effectiveness of art therapy for older adults in different care settings.

The aim of this study was to determine the preventive effect of a newly developed concept of art therapy on the incidence of delirium among hospitalized older patients. The secondary goal was to evaluate its impact on the duration of delirium in patients with existing delirium.

Patients and Methods

Study design

This single centre randomized controlled trial was designed to determine the effectiveness of an adapted art therapy intervention in patients ≥70 years old admitted to an acute geriatric ward. The duration of the study was two years (09/2017 – 08/2019). Patients were randomized in an alternating three-months interval (three months recruitment of the intervention group, followed by three months recruitment of the control group). Allocation sequence was generated by KS. After obtaining informed consent, patients in the intervention group received twice-daily individually tailored art therapy intervention in addition to usual care (control group) during the weekdays. The intervention followed a newly developed therapy concept which comprises structure giving templates, theme-centred work, reduced choice of material, orientation on individual needs, and facilitation of non-verbal expression. All patients were screened daily for delirium using the Nu-DESC (Nursing delirium screening scale) (11).

The study was approved by the local Institutional Review Board and the ethical committee (Freiburger Ethikkomission International, Nr.017/1504) and registered in the German Clinical Trials Register (DRKS00012417).

Setting and Selection of participants

The study was conducted in a 60-bedded acute geriatric ward of a German urban university hospital. During a pilot-phase which included 10 patients, the assessments and intervention concept were tested for feasibility. All patients admitted during the given time periods were screened for eligibility. Inclusion criteria were age ≥70 years, given informed consent, and at least one of the following three conditions: pre-existing dementia, delirium in the past medical history, or any formal care or dependency in activities of daily living. An initial positive screening for delirium (4-AT, Nu-DESC) was not a contraindication for participation. Patients were excluded from the study if informed consent could not be sought, the patient did not speak German language, the patient was isolated for infection control reasons, the patient required end of life care, the patient was admitted from other hospital wards than A&E department, or if art therapy was not feasible.

Interventions

Following a comprehensive geriatric assessment conducted by a trained multidisciplinary team, participant baseline characteristics including sociodemographic data, chief complaints, comorbidities (CIRS-G), frailty (Clinical Frailty Score), mobility before admission (Parker mobility score), ability to perform basic activities of daily living (Barthel index) and cognitive status (Mini Mental State Examination (MMSE)) were recorded. Presence of delirium (4-AT, Nu-DESC) was assessed by a study nurse. All participants were screened daily for delirium by a study nurse using the Nu-Desc (Monday-Friday). On weekends, the Nu-Desc was conducted by trained ward staff and retrospectively verified by a geriatrician (KS) following a review of patients´ medical records. Both the control and the intervention groups received usual care which includes delirium preventive elements such as avoidance of dehydration, nutritional support, regular mobilization, and cognitive stimulation. These care aspects were delivered by nurses, physiotherapists, and occupational therapists.

In the intervention group, additional individual art therapy took place twice daily for 25 minutes using a mobile studio. The intervention followed a study-specific adapted concept of art therapy as described above. To facilitate orientation, enable creative work, and serve as a recognition factor, the patient chose from two templates (circle or square) at the beginning of each intervention. The therapeutic approach was tailored individually to patients´ medical condition and resources (stimulating, stabilizing, reducing anxiety and relaxing), but followed an underlying structure of 1. description of patients´ mood, 2. creative work, and 3. discussion of the picture including patients entitling their created work.

The intervention took place at the bedside using a mobile studio and a defined set of material (Fig.1). Art therapy intervention was suspended if the patient declined to participate, the present medical condition did not allow participation or if the patient required urgent medical intervention which could not be delayed. The art therapy intervention ended at time of patients´ discharge.

Outcomes and Data Analysis

The primary outcome measure was the incidence of delirium. The secondary outcome measure was the duration of delirium in patients who developed new delirium during hospitalization. Statistical analysis was conducted by statisticians who were not involved in the data collection process. Data were excluded from final analysis if the length of stay on

the ward was less than 4 days (statistical outliers, fig.2) as it was deemed that during short term stays, the art therapy interventions were too few to influence the outcome. Continuous variables are presented as means or medians and categorical variables as numbers and percentages. To determine the effect of art therapy on the numbers of days spent with delirium, we used a zero inflated Poisson model due to the large number of patients with zero days with delirium (12). To verify this rationale, we calculated the Akaike's Information Criterion (AIC, corrected for small samples) for four potential models: negative binomial model, Poisson model, zero inflated negative binomial model and zero inflated Poisson model (13). The zero inflated Poisson model yielded the lowest AICs.

Our model controlled for age, sex, cognitive abilities (MMSE), dementia diagnosis and the total duration of a patient's stay in the count part. The zero part contained all predictors except for age and duration of stay. Finally, we included two-way interaction terms between intervention and sex, intervention and MMSE, as well as intervention and dementia diagnosis.

We tested model stability by comparing estimates derived from the entire data with those derived from data excluding patients one at a time. We check for collinearity using Variance Inflation Factors (14). To test the overall effect of our predictors, we compared the full model's deviance with that of a null model containing all predictors except intervention and the related interaction terms, using a likelihood ratio test (15).

We fitted the model in R (version 4.0.2; R Core Team, 2020) using the function zeroinfl of the package pscl (version 1.5.5) (16). We determined Variance Inflation Factors using the function vif of the R package car (version 3.0-9) applied to a standard linear model (17) .

Results

During the study period, 906 patients aged ≥70 years presented to the acute geriatric ward and were screened for eligibility. 655 did not meet the inclusion criteria and 113 declined to participate in the study. 138 patients were randomized, with 72 participants in the intervention group, and 66 in the control group. 30 patients were lost to follow-up or due to adjustment of statistical outliers, 18 patients in the intervention and 12 patients in the control group. 53 patients in the intervention and 54 patients in the control group were included in the final analysis (fig.2).

The median age of the study cohort was 86 years (Interquartile range (IQR 81-90) years. 75 participants (70.1%) were female. During the initial comprehensive assessment, the median clinical frailty scale score was 6.0 (IQR 5.0-6.0), the median Barthel Index was 65 (IQR 45-75), the median MMSE-Score was 22 (IQR 17-25), and the median Parker Mobility Score was4.0 (IQR 3.0-6.0). Patients in the intervention group participated on average in 9.8 (SD 4.8) art therapy sessions. Participants' characteristics as displayed in Table 1 were well balanced between the intervention and the control group.

Incidence of delirium and length of delirium (days with delirium)

Of the 107 included in the final analysis, 19 participants (17.8%) had delirium during first screening. Of the 88 participants (82.2%) who did not have delirium on admission, 8 (7.5%) participants subsequently developed delirium during their hospital stay. Those were equally distributed between the intervention (n=4, 7.5%) and the control group (n=4, 7.4%). Most of our study population (N= 80, 75%) did not spend any days with delirium. Due to the very low incidence of delirium in both groups, statistical analysis for the incidence of delirium was not performed.

However, we were able to show statistically significant improvement in the number of days patients spent with delirium among the intervention group compared with the control group. Among patients with delirium, the median duration of delirium was 7 days (IQR 5-10) in the control group vs. 4 days (IQR 2.25-8.75) in the intervention group (Mann-Whitney-U-Test, p-value = 0.26). After adjusting to excess zero counts using the zero-inflated Poisson regression (full-null model comparison: $x2=26.075$, $df=8$, P=0.001) the number of days with delirium decreased by 67.2% for the intervention group (95% CI: 0.19% - 0.87%; P=0.015). Looking at the pre-defined interaction terms (sex, MMSE and diagnosis of dementia), we

found that the intervention had greater benefit for participants with better cognitive abilities (e.g. higher MMSE scores P=0. 025) (Fig.4). Those participants showed an increased probability of not spending any days with delirium (P=0.002). While the intervention was beneficial for patients with a diagnosis of dementia, it was more beneficial for those without. (P=0.038) (Tab.2). Although female participants spent 68% less days with delirium than men (P=<0.001), female participants in the intervention group had a decreased probability of not spending any days with delirium compared to men in the intervention group (P=0.035). No adverse events were observed.

Discussion

Delirium is a common neuropsychiatric syndrome among hospitalized older peoples and is associated with adverse outcomes including prolonged hospital admission, and increased risk of mortality (18).

Non-pharmacologic strategies, frequently implemented by nursing staff, have been proven to be effective in the primary prevention of delirium and typically comprised of multicomponent interventions (19). To our knowledge, no data exists on the effectiveness of art therapy as part of a tailored multicomponent intervention on delirium prevention. Our study addresses this research gap by determining the preventive effect of art therapy on the development of delirium among hospitalized older adults who are a high risk group, and on the incidence and duration of delirium.

. In our study, the addition of art therapy to usual care showed a significant positive effect on the duration of delirium. The intervention was able to decrease length of delirium (days with delirium) by 67%. Patients with better cognitive abilities received greater benefit from the intervention (P=0.002).

Multicomponent interventions have been proposed to be included in delirium management strategies and its implementation has been recommended in several practice guidelines (5, 20). Our study adhered to the NICE recommendations of assessing for risk of delirium within 24 hours of admission and administration of individually adapted multicomponent interventions. Both the control and the intervention group received comprehensive geriatric care which included delirium preventive elements. The additional intervention of art therapy as a psychotherapeutic treatment enabled an individually tailored intervention which focuses on stimulation, (re)focusing as well as relaxation and reducing anxiety. Art therapy is classified under the domain of arts therapy as well as music-, dance- drama and poetry therapy, but scientific research on art therapy among older people is scarce.

Although delirium research has exponentially increased over the last decade, RCTs on non-pharmacological delirium interventions are still lacking, with many of the studies showing moderate quality evidence. Several of the studies randomized less than 100 participants (3, 21). In our trial 907 patients were assessed for eligibility and only 107 complete data sets

were analyzed. This high drop-out rate can be explained by the applied exclusion criteria such as missing consent, prior hospital admission, secondary transfer to the geriatric ward, or an acute infectious disease that ruled out art therapy intervention due to infection control reasons. Nevertheless the overall occurrence rate of delirium among our study group was 25% (N=27), which corresponds with existing literature (3). As the incidence of delirium during the study period was observed in only 7.4% (N=8) of patients, we were not able to show a primary preventive effect of art therapy in this patient group. The finding of low new onset delirium in both groups (control group N=4 and intervention group N=4) can be explained by the comprehensive usual care which included other elements of delirium prevention measures received by participants in both groups. Our study was conducted in an acute geriatric ward with skilled nurses, doctors, and therapists. Usual care included multicomponent intervention such as hydration, regular mobilization, nutritional support, and basic cognitive stimulation). Art therapy was implemented as an additional intervention. Various of the interventions that reported a decrease in delirium incidence were conducted in orthopedic/orthogeriatric settings and only a few in general medical or geriatric medical hospital environment (19). Furthermore, most of the interventions were compared to usual care that did not include any evidence-based approach targeted to delirium risk factors. Among other variables such as comorbidities and severity of the underlying disease, the duration of delirium is associated with adverse consequences(22, 23). Morandi et al. described a 10% increase in in-hospital mortality among older SARS-CoV2 patients with each day with delirium (23). Therefore, non-pharmacological delirium interventions play a vital role in delirium management. Our study showed a reduction of days with delirium by 67% among those who received the intervention. Only few interventional studies in delirium focused on length of delirium, most of which were pharmacological interventions. Among studies investigating multicomponent non-pharmacological interventions, Jeffs et al. were not able to show a positive effect on incidence and length of delirium after implementing an enhanced exercise and cognitive program (24).

Another non-pharmacological intervention study on delirium which included the provision of clocks, calendars, glasses, hearing aids, familiar objects, and reorientation provided by family members in acute medical wards did not shorten duration of delirium (7).

In our study cognitive stimulation, reorientation and assistance in concentration were important elements of art therapy intervention. Art therapy focusses on the process and not

the end result of a finished art work. The underlying emotional experience during the intervention, influenced by the individual patients´ background is at the center of the therapeutic approach. Whilst the provision of therapeutic interventions such as art therapy among hospitalized older people is often logistically a challenge, we have shown that the provision of art therapy for older inpatients at the bedside is feasible. Art therapy enables patients to expand their communication options and express their experiences during delirium, which is essential for people with delirium (25).

Limitations of the study

There are several limitations to our study. The low number of patients that were included in the final analysis was described above. Nonetheless, findings from this study will help inform a future multicentre trial to determine the effectiveness of the intervention and increase the generalizability of the findings. Another limitation of the study was the exclusion of infectious patients due to infection control reasons. Infection is one of the major triggers of delirium. Excluding this patient group (N=79) may have impacted on the results for both incidence and duration of delirium. Only medical geriatric patients were included in the study. Postoperative older patients are also at a high risk of developing delirium and would benefit from the intervention. Furthermore art therapy is a resource that is not widely available and will be limited to places where interprofessional co-management is available.

Conclusion

Findings from this study showed that art therapy as part of a multicomponent intervention in delirium management can reduce duration of delirium among hospitalized older adults. The intervention is safe, with no adverse events, and it gives insight to delirium experiences and enables patients to communicate non-verbally. Future studies evaluating the effectiveness of art therapy in different clinical settings are needed (e.g. postoperatively).

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Table 1. Baseline characteristics

	Intervention (N=53)	Control (N=54)	P-value
Gender			
Female	36.0 (67.9%)	39.0 (72.2%)	0.784 [a]
Male	17.0 (32.1%)	15.0 (27.8%)	
Age			
Mean (SD)	85.4 (6.62)	85.0 (5.88)	0.733 [b]
Median [Q1, Q3]	87.0 [81, 90]	86.0 [80, 90]	
CIRS-G			
Mean (SD)	20.6 (4.72)	21.0 (5.11)	0.859 [c]
Median [Q1, Q3]	21 [17 , 24]	21 [17 , 24]	
LOS			
Mean (SD)	11.4 (4.79)	11.6 (4.94)	0.846 [c]
Median [Q1, Q3]	10.0 [7.0 , 16.0]	10.5 [7.0 , 16.8]	
Clinical Frailty Index			
Mean (SD)	5.79 (0.948)	5.49 (0.973)	0.143 [c]
Median [Q1, Q3]	6 [5 , 7]	5 [5, 6]	
Missing	0 (0%)	1.00 (1.9%)	
Barthel			
Mean (SD)	56.6 (22.0)	61.4 (23.2)	0.208 [c]
Median [Q1, Q3]	60.0 [45.0 , 70.0]	67.5 [46.3 , 80.0]	
MMSE			
Mean (SD)	19.7 (5.75)	21.3 (5.35)	0.118 [c]
Median [Q1, Q3]	19 [17 , 24]	22 [18 , 26]	
Parker Mobility			
Mean (SD)	4.12 (2.24)	4.41 (2.41)	0.4 [c]
Median [Q1, Q3]	4 [3 , 6]	4 [3 , 6]	
Missing	1.00 (1.9%)	0 (0%)	

Table 1: Characteristics of participants

[1] One participant was excluded for the calculation of each of these values due to missing value.

[a] chi square test, , [b] t test, [c] Man withney u test

SD= standard deviation, CIRS-G=Cumulative Illness Rating Scale – Geriatric, LOS= Length of stay, MMSE= Mini Mental Status Examination

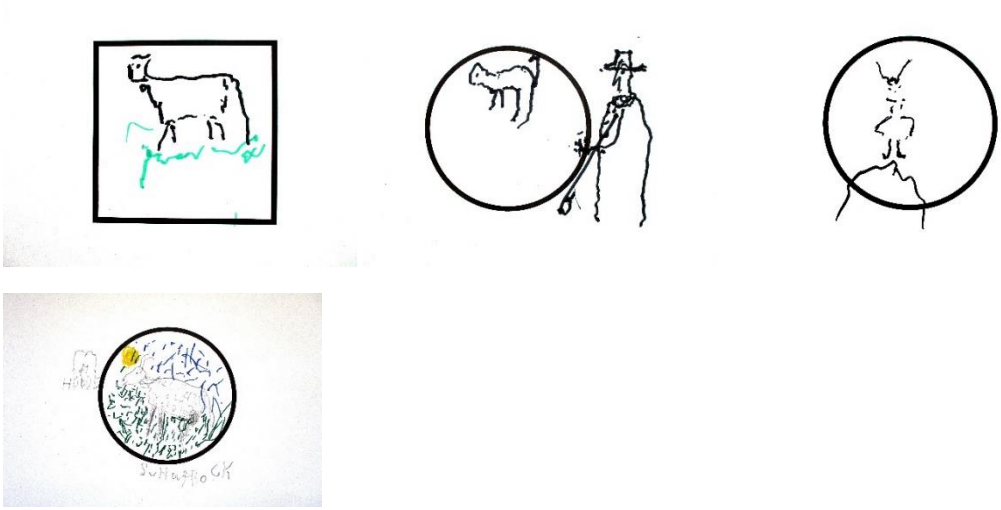

Figure 1 (a-d) shows an example of four pictures of a 90-years old patient, a former shepherd, with an intercurrent delirium

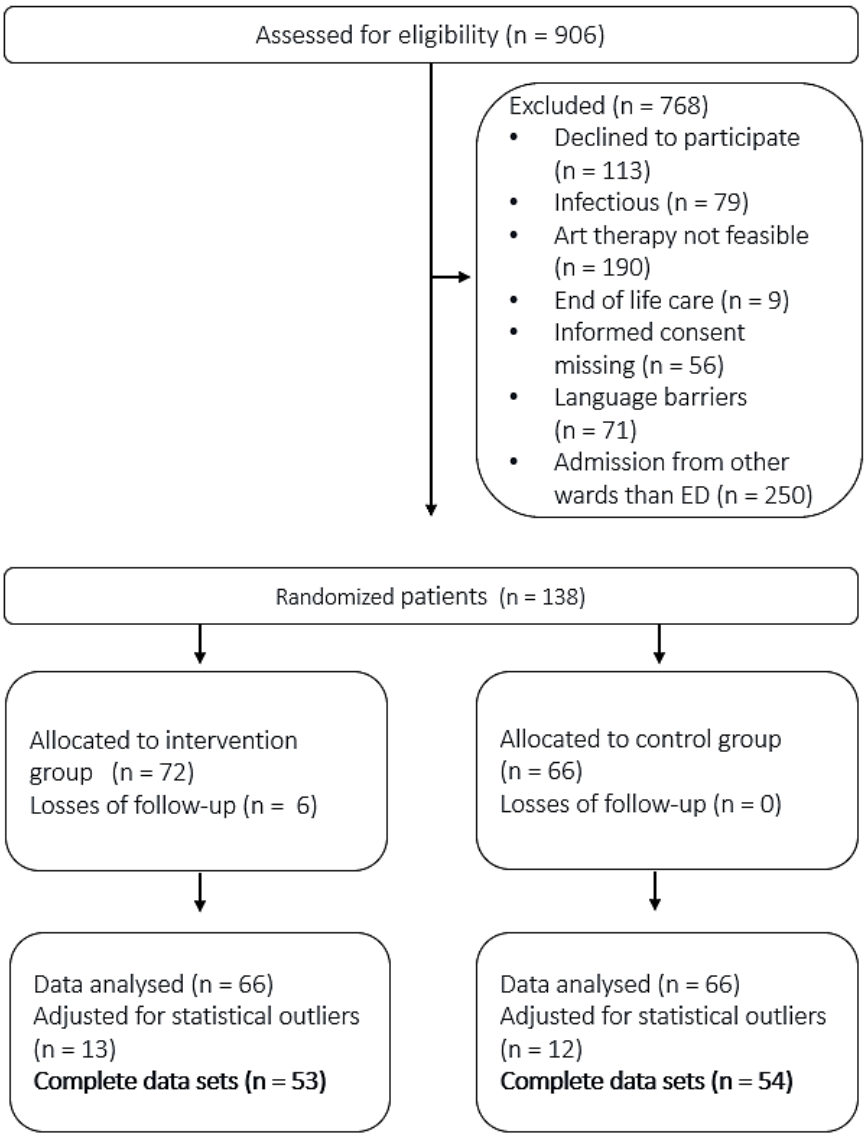

Fig. 2: PAINT I flow diagram

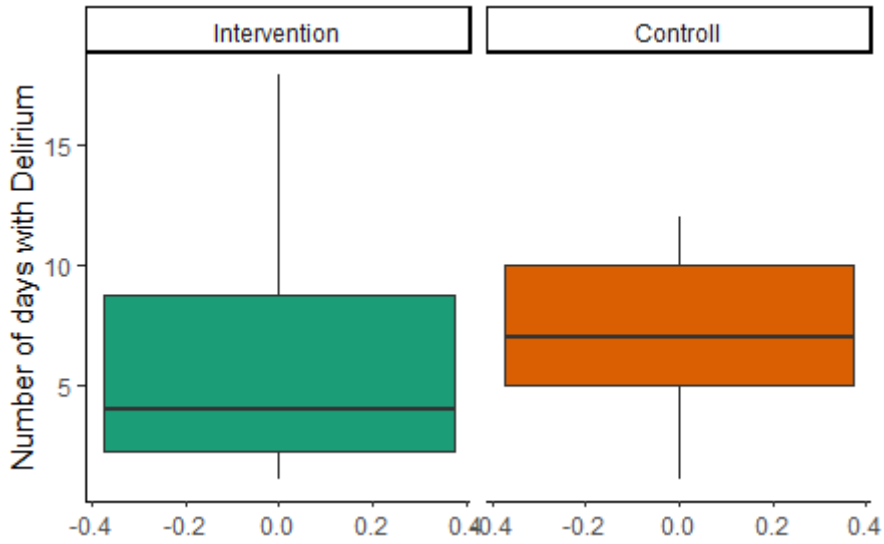

Fig. 3: Boxplot Days with Delirium, comparison of control and intervention study group

Figure 4 Click here to access/download;Figure;Singler EGM Fig.4.docx

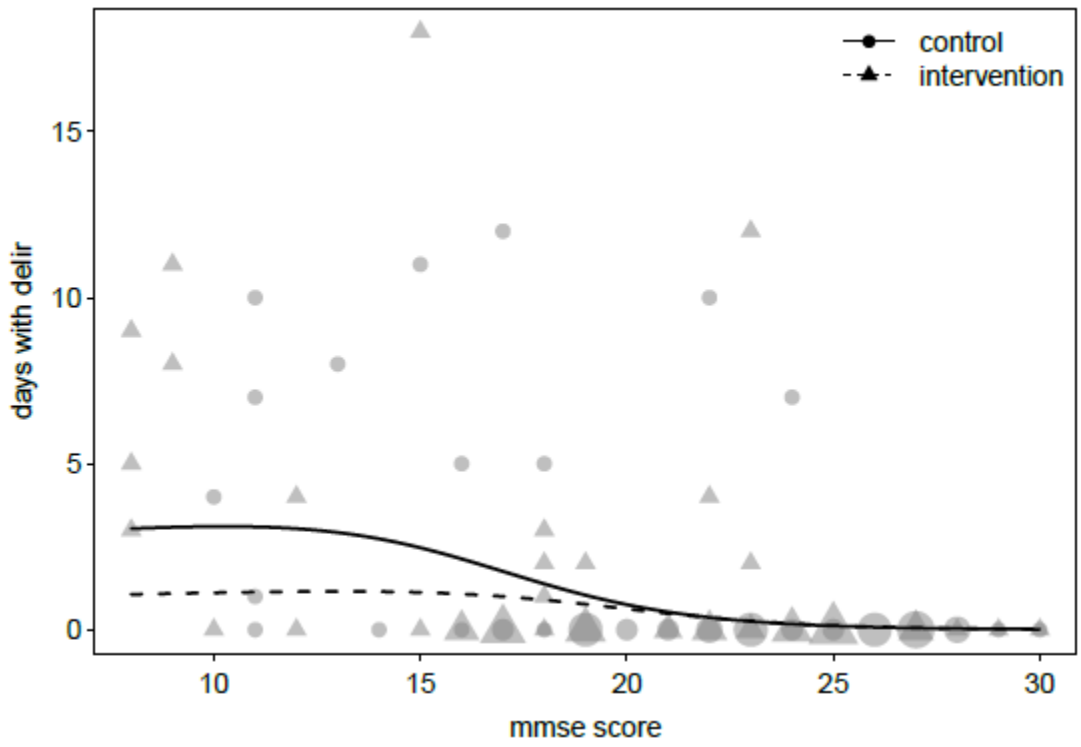

Fig. 4: Visualization of Relationship of the MMSE values with the days of delirium in the intervention and control arm. The plot is based on the full model specified above.