Arts and Dementia

Using Participatory Music Making to Improve Acute Dementia Care in Hospital Environments: An Exploratory Study

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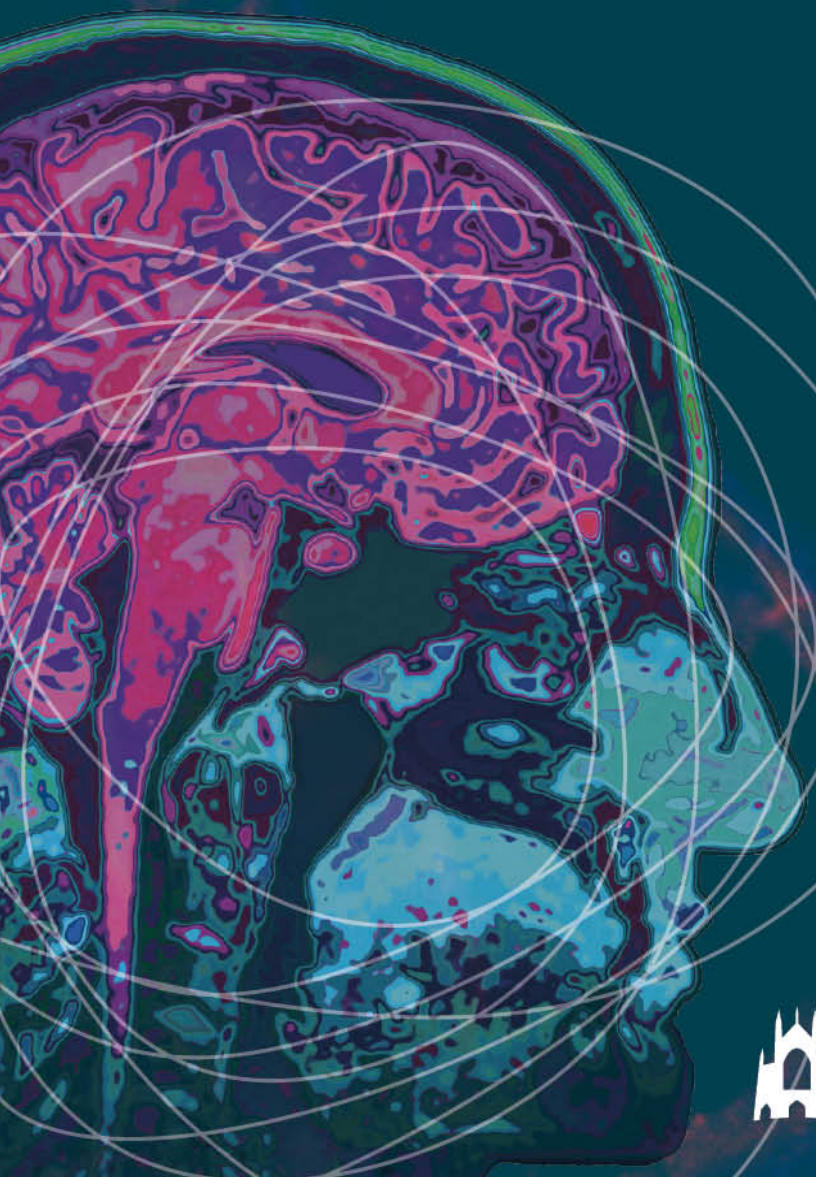

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Using Participatory Music Making to Improve Acute Dementia Care in Hospital Environments: Findings from Evaluation Research.

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Background

Music making and music therapy have been shown to be beneficial for older people (Skingley & Vella-Burrows, 2010) and for people with dementia (PWD) and their carers (Raglio et al. 2008; 2012). Music is often viewed as a medium that can reach individuals, accessing their personalities, histories and memories, and enable them to connect with family, friends and carers. Research has examined the effects of music participation on cognitive functioning of PWD as well as its impact on wellbeing. Evidence from a recent Finnish randomised control study found that compared with usual care, singing and music listening improved mood, orientation, attention, memory and quality of life in people with mild to moderate dementia (Särkämö et al. 2013). Evaluation of a UK based community singing activity for PWD showed high levels of engagement in the activity, with participants and carers strongly supportive of the group and reporting positive impacts on wellbeing (Camic et al. 2011).

Much of the existing research concentrates on people with mild to moderate dementia in community settings. Few studies have examined music making with PWD in acute hospital settings. This may be because these settings are challenging environments where staff are extremely busy and where research, with this particular patient group, may seem

impractical. However, there is an extensive body of evidence that links music with psychological and physiological outcomes across adult and children's services. Clift and Staricoff (2011) reviewed one hundred and thirty three studies showing reduced stress, anxiety and depression, improved behavioural outcomes, pain management and changes in blood pressure, heart rate and respiratory function. None of these studies focused explicitly on dementia, although some of these outcomes may be relevant to the care of PWD in hospital. Evidence from programme evaluation suggests that music interventions in acute hospitals can benefit dementia patients by reducing anxiety and agitation as well as improving sleep and nutrition (Naidoo 2014). There is a need for further research to investigate the effects of music as a hospital based intervention for PWD, including its impacts on the wellbeing of patients and carers, its impact on behaviour and consequently its impact on staff workloads.

Study aims and objectives

The setting for this pilot study was an acute elderly care service for older patients, a total of 54 beds, in a UK hospital. This pilot study sought to examine the effects of a 10 week period of weekly music sessions on the health and wellbeing of patients with dementia. It did so by exploring the responses of participants (patients, carers and staff) to the music programme, and by comparing the ward environment during the music intervention period with an equivalent usual care period of 10 weeks in the previous year.

The music project

The origins of this study stem from an initial interest expressed by the Chief Executive of the NHS Trust to establish an innovative research niche. Putting evidence at the heart of service improvements for a growing elderly population, it was suggested that the creative arts be explored within a clinical setting as a means of facilitating transition from the acute setting to the community for, in particular, elderly health service users locally. The pilot study would identify who, within the NHS trust and the university, would need to be approached as stakeholders for the development of a sustaining arts initiative.

Arts and Dementia Care is a programme aimed at supporting patients with dementia and staff in an acute hospital setting. Music activities including group music sessions and bedside performances are provided by professional musicians employed by a local orchestra through its outreach programme. The orchestra provides training for musicians to work with vulnerable people, including people with dementia, in health and social care settings.

From June 15th 2015 a male musician, a professional viola player, visited the hospital most Tuesday afternoons until 26th January 2016. During these visits he ran group music sessions for patients, carers and staff in a patient activity room used by the acute elderly care service. For up to two hours, participants listened, sang, played percussion instruments and occasionally composed new songs. They also took part in social activities, chatting to the musician, staff and each other over tea and biscuits. After each session, the musician went on to the wards to perform at the bedsides of patients who requested it.

Research design

The study used mixed methods including quantitative and qualitative data collection and analysis. Quantitative ward level data were collected during two equivalent ten week time periods: 1st September to the 3rd November 2014 (time frame A – usual care) and the 1st September to the 3rd November 2015 (time frame B – music project). During time period A there was no music on the ward while during time period B there were weekly two hour music sessions. Data were collected for all in-patients with dementia during one of the two time periods. Patient record data were available for 85 patients with a dementia diagnosis who had stayed on the wards during the study periods. During time period A, data were available for 38 out of 59 dementia patients (64.41%), while during time period B, data were available from 47 out of 84 dementia patients (55.95%).

Although the two time periods were equivalent in terms of time of year, it is recognised that the many factors could have contributed to differences in the ward environment between the two time periods. For example, the average age of patients during time period A was 80 years old and 91 years old for time period B.

Qualitative methods included participant observation, semi-structured interviews and focus groups with patients, visitors, the musician and staff. The research included an action research component in which care staff worked together in a small group to reflect on learning from the project.

Study population, sampling and recruitment

The study population included 38 patients and 12 staff members who supported the music project. Participation in interviews was open to all patients with a diagnosis of dementia admitted to the wards over the 10 week period where music was present (time period B). All 12 staff members were invited to an end of project focus group. In addition, a core group of four staff members formed, along with the researcher, an action research group with the aim of capturing learning and best practice from the project.

Ethics and consent

The research was approved by the NHS NRES (South Central Hampshire A) Committee and by the University of Winchester Research Ethics Committee. All members of the research team completed Good Clinical Practice Training in research ethics, including modules on ethical and scientific quality standards in clinical research and informed consent with adults lacking capacity. The Principal Investigator and the field researchers worked under honorary contract with Hampshire Hospitals NHS Foundation Trust. Members of the research team were accompanied by clinical staff at all times and did not accompany patients or the musician into ward or private areas of the hospital.

The dementia care clinical nurse specialist (CNS) initially and invited potential participants to take part. Written information about the study was provided in the form of a participant information leaflet for patients, carers and staff. Where a patient lacked the capacity to consent, consultee agreement was btained. It was made clear that participation was voluntary and that if an individual declined to take part in the research they would still be able to take part in the music activity and that their refusal would not affect their care in any way. Consent /assent was taken by the CNS.

Data collection

Quantitative ward level data

Quantitative data were collated from two sources: from the NHS Trust Business Intelligence Team (BIT) and from routine care data collected at ward level. The BIT data include:

- The number of falls recorded during the time frames
- The number of falls recorded on an average Tuesday during the time frames
- The average length of stay during each of the time frames.
- Staff absences during the time frames.

The ward level data include:

- The number of prescriptions of anti-psychotic drugs during stay
- The number of prescription of anti-psychotic drugs on an average Tuesday
- The number of in-patients recorded as requiring one-to-one attention on a Tuesday.

Ward data were extracted and collated by clinical care staff under supervision of the CNS as Principal Investigator for the study and provided as anonymised data to researchers for analysis. A case report form (CRF) was completed for each available electronic patient record or medical record during time periods A and B using NHS number only as an initial patient identifier. This identifier was only used to check the completeness of CRF data

where information was missing prior to this identifier being removed from the forms and the anonymised CRFs being made available for data collation and analysis.

Participant observation

Participant observation was undertaken unobtrusively by one of two researchers, supervised by the Chief Investigator who is an experienced qualitative researcher. Researchers between them attended ten music sessions between November 2015 and January 2016. Each week the researcher arrived twenty minutes early to observe the preparations, and stayed behind for up to an hour after the session: to undertake interviews or discuss the project with the musician and staff action research group. Where feasible, the researcher completed the Arts Observational Scale (ArtsObs), This is a structured assessment tool designed by Chelsea and Westminster Hospital NHS Foundation Trust to allow researchers and staff members to observe the effects that arts activities are having on participants' mood, relaxation and other criteria such as agitation (http://www.cwplus.org.uk/research/arts-research/artsobservational/). The researcher also took detailed notes after each session.

Semi-structured interviews

A total of 11 interviews were undertaken with participants (patients, carers and staff). These followed a topic guide and explored participants' accounts of the music project. Interviews were one to one or in small groups, where the CNS identified patients with capacity to participate, or in pairs or small groups of participants. They were held in the activity room, off the ward, and took the form of brief, relaxed conversations. It was sometimes challenging to interview patients one to one as they often struggled to remember what they had done during the session. Other difficulties, such as hearing impairments, meant that interviews were difficult. Participants tended to give short, fragmented answers and needed frequent prompts. Sometimes they seemed keen to get

back to the ward in case they missed visitors. The researcher did not delay them, the main concern being for the wellbeing of patients. Some also declined to be interviewed, for example if they were feeling anxious/agitated or needed to be seen by a doctor/ visitors etc. This meant that some consented patients were not in fact interviewed. The environment was on occasion rather hectic, with staff bringing patients to and from the clinical areas. Another challenge during interviews was the presence of staff who sometimes joined in to try to offer support. Occasionally patients and staff would be talking at the same time, which made it difficult to focus on the study participant and also made the transcription task difficult.

Shared Learning Group

An action research process sought to evaluate staff experiences and perceptions of the project using tools such as reflective diaries to identify the impacts of the intervention on patients and to attempt to define the components of a successful music intervention for patients with dementia. Despite gentle reminders, it was not apparent that the staff used the reflective diaries. They were told that they were for their own use, so they were not shared with the researchers and staff did not generally bring them to the shared learning group (although they were reminded that they could do so if they wished). Four members of staff who were involved in supporting the music sessions met several times with a researcher as a group. At the beginning of the project they discussed their expectations and agreed the number and timings of subsequent meetings. After sessions they met to review what had gone well, what had not gone so well and to prepare for the next session.

A total of 6 staff members took part in a final focus group to discuss the impact of the project on patients and on themselves, the working environment and work organisation. This was facilitated by two researchers and followed a topic guide. The data from the action research process was drawn together to identify key components of a successful music programme.

Data analysis

Quantitative data were analysed using descriptive statistics to illustrate the frequencies of ward characteristics before and after the intervention. No participant identifiers were used in the transfer of data for analysis. This analysis was used to identify any potential differences that might indicate project impacts and cost savings. The BIT data are presented in Table 1 while the routine care data are presented in Table 2. Limitations of the data are discussed at the end of the report.

Interview and focus group data were audio recorded and transcribed in full, while observational data were collected using detailed written notes. Any identifying details were removed from the data prior to thematic analysis (Braun & Clarke, 2006), assisted by NVivo software. Qualitative analysis followed principles of analytic induction (Silverman, 2011), treating data comprehensively, employing the constant comparative approach and searching for disconfirming cases in regard to emerging themes and interpretation.

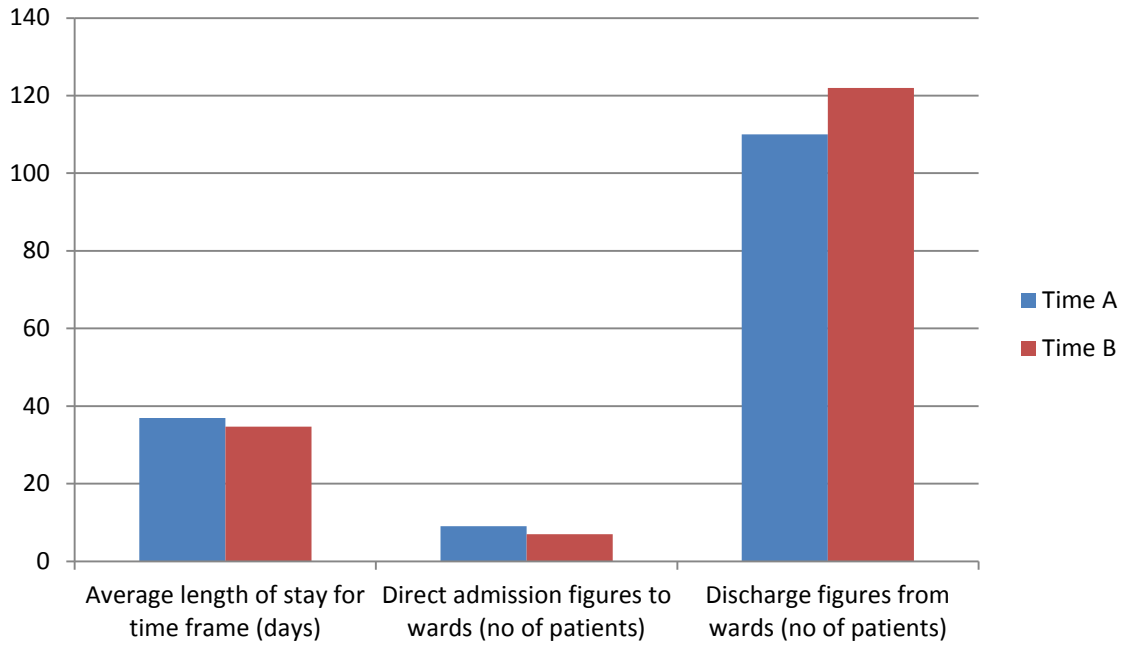
Data analysis was led by the Chief Investigator with researcher validation provided by a second researcher. This was an inductive process that emerged from the data and not from a priori assumption. Each researcher coded segments of data, keeping in mind not just what happened and what was said but also drawing on sensory awareness (what was seen, heard, how did it feel, what did it sound like) as well as understanding of the context and social relations which shaped the project. After an initial coding exercise, the CI and the researcher met to compare notes and agree a framework for secondary coding and categorisation. This process was repeated until data saturation was reached.

Findings

Quantitative Results

The BIT data provided information on admissions, length of stay and discharge rates. The average length of stay during time period A was 36.90 days compared to 34.68 days in time period B. This equates to a 6.2% decrease in length of stay between the two time periods. The discharge figure from the two wards was 110 in time period A, compared to 122 in time period B; this is a 9.84% increase in the number of discharges. Chart 1 illustrates these differences.

Chart 1: Length of stay, direct admissions and discharge figures



Number of falls recorded

BIT data also show that during time period A there were 47 falls recorded compared to 31 in time period B (Table 1).

Staff absences

Data from BIT show a reduction on staff absences overall, with 22 absences recorded during time period A and 16 recorded during time period B. The number of staff absences on a Tuesday in time period A was 6 compared to 8 in time period B.

Markers of patient behaviour

The ward level data includes the recording indicators of patient behaviour including agitation (Chart 2). During time period A, one patient (2.63%) required one to one attention compared two patients (4.26%) in time period B. Chart 2 illustrates the time period comparisons of the number of patients prescribed anti-psychotic drugs. Time period B showed a 4.26% decrease in the number of patients prescribed anti-psychotic drugs compared with time period A. Further, there was a 27.72% decrease in the number of prescribed anti-psychotic drugs on a Tuesday (the day of the music activity) in time period B, compared to time period A. The number of patients who took anti-psychotic drugs during their stay but not on a Tuesday was one (2.63%) in time period A and 15 (31.91%) in time period B.

Chart 2: Markers of behaviour

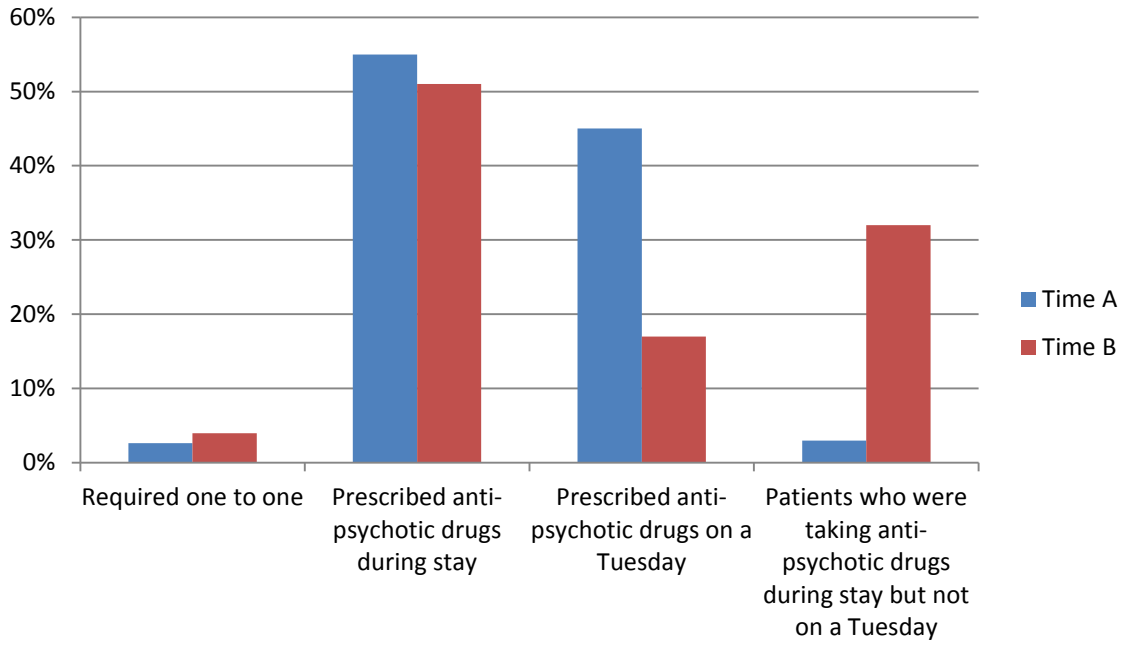


Table 1: BIT data

Metrics	Time A	Time B	Time A to Time B comparison
Average number of falls recorded on a Tuesday during time frame	6	7	increase
Total number of falls recorded during time frame	47	31	decrease
Average length of stay for time frame	36.90	34.68	6.2% decrease
Staff absences during period	22	16	Decrease
Staff absences on a Tuesday	6	9	Increase

Table 2. Routine care data

Metrics	Time A	Time B	Time A to Time B comparison
Required one to one	1 (2.63%)	2 (4.26%)	1.63% increase
Prescribed anti-psychotic drugs during stay	21 (55.26%)	24 (51.06%)	4.26% decrease
Prescribed anti-psychotic drugs on a Tuesday	17 (44.74%)	8 (17.02%)	27.72% decrease
Patients who were taking anti-psychotic drugs during stay	1 (2.63%)	15 (31.91%)	29.28% increase

Arts Obs Findings

ArtsObs data are available for 20 patients (13 female and 7 male), observed over the final five sessions (weeks 5 to 10). A total of 41 patients took part in the sessions, but the ArtsObs tool was only used to record responses of patients with dementia who had consented to be part of the pilot study. Over the five weeks, the numbers of staff involved in the project

were recorded. The ArtsObs data encompass the effects of the activity on participants' moods, engagement and behaviour as well as the overall impact of the activity on the ward environment.

Effects of the project on mood.

Table 3 presents participant mood scores recorded at the start and after the activity using ArtsObs. These range from 0 to 7, with 0 indicating an angry response, 1 indicating a frustrated response, moving through descriptors of sad, calm, satisfied, happy and excited, which receives the highest score of 7. The data show that participants at the start of sessions showed a range of moods, from angry through to calm and satisfied, that all the scores increased by between 1 and 3 points (average 1.6), with no decreases recorded, and that several participants at the end of the session appeared happy and excited.

Table 3. Happiness Scores Recorded

	Week 6				Week 7				Week 8			Week 9				Week 10				
	F1	F2	F3	M1	M2	F4	F5	M3	F6	M4	F7	M5	M6	F8	F9	F10	F11	F12	M7	F13
Score at start	5	1	2	5	4	4	4	4	1	4	3	4	4	1	4	3	3	4	5	5
Score after (/7)	6	3	3	7	5	5	5	6	2	7	4	7	6	2	6	6	4	6	7	6
Change in happiness score.	+1	+2	+1	+2	+1	+1	+1	+2	+1	+3	+1	+3	+2	+1	+2	+3	+1	+2	+2	+1

Effects of the project on relaxation, distraction, engagement and agitation.

The ArtsObs tool includes pre-set questions about the activity including, 'did it help to relax patients?' and, 'did it help distract from hospital?' We also included two additional questions pertinent to our study, 'did it increase engagement?', and 'did it help to reduce agitation?'. The observer answers on a scale of 1 – 3, depending on what signs of relaxation etc. participants are exhibiting. The lowest score of 1 indicates that no change is evident, while a score of 2 indicates some changes and a score of 3 indicates a strong degree of change. The results are presented in Table 4. The data show that the observed effects on

relaxation, distraction, engagement and agitation were consistently positive, often very much so.

Table 4. Impacts on relaxation, distraction, engagement and agitation.

	Week 6				Week 7				Week 8			Week 9				Week 10				
	F1	F2	F3	M1	M2	F4	F5	M3	F6	M4	F7	M5	M6	F8	F9	F10	F11	F12	M7	F13
Relaxation	3	2	2	3	2	2	3	3	2	3	3	3	3	2	3	3	3	3	3	3
Distraction	3	2	2	3	2	2	2	3	2	3	3	3	3	2	3	3	3	3	3	3
Engagement	3	2	2	3	2	2	2	3	2	3	3	3	3	2	3	3	2	3	3	3
Reduced agitation	3	2	2	3	3	3	3	3	1	3	3	3	3	2	3	3	2	3	3	3

Overall impact of the music activity on the ward environment.

The ArtsObs tool invites the observer to score the overall effect of the activity on participants. This is scored on a scale of 1 to 3, with the lowest score of 1 indicating that the activity brought no benefit or even had negative effects to the ward, such as causing complaints, missing its target audience or getting in the way of staff. A score of 2 indicates that moderate effects were observed, for example, the activity helped lift the mood of the ward, bring a sense of calm or have a small beneficial effect on patients, relatives or staff. The highest score of 3 indicates that the observed effects were very positive, that the activity was almost universally liked, or made a significant difference to the feel of the ward. Taking into account staff feedback on the effects of the project on participants once they had returned to the ward, the observer rated the overall effect of the project consistently as being very positive, with a score of 3 for each week that data were recorded.

Positive and negative feedback reported

The ArtsObs tool allows the observer to record free text feedback from patients, relatives and staff on the wards. Free text reporting indicate that participants were often observed to be in high spirits during the sessions, singing, smiling and laughing. They often seemed to be fully engaged with the music and the instruments, frequently requesting particular songs from the musician. Participants often commented that they enjoyed the music, the singing and playing as well as the social element of the project and the opportunity to get away

from their beds. Some participants reacted strongly to certain pieces of music, for example closing their eyes, leaning back and appearing absorbed in a favourite piece. There were sometimes poignant instances when participants reminisced about their younger years.

The ArtsObs tool also invites the observer to record negative feedback if this is given. These records show that at times participants were confused and distracted and therefore unable to fully participate or enjoy the session. The ArtsObs tool does not include information about factors such as medication that may have affected participants' concentration and mood.

Aspects of the hospital environment

Other factors recorded using ArtsObs indicate issues that affected the programme. Occasionally the room seemed a little crowded, for example when hospital staff, visitors and observers outnumbered patients. Generally, there were a mixture of patients with and without dementia on the wards and this may have affected participants' experience of the project. Having this mixture was a positive effect as it allowed patients with dementia to interact with patients without dementia. However, it may have been a little frustrating for those without dementia when some patients struggled to follow instructions from the musician or were on occasion agitated.

Observation findings

These findings are confirmed in the open-ended observation data, which generated a rich description of the project activities. Patients were escorted individually to and from the wards by staff. This was a labour intensive task that often took between 20 and 30 minutes. Patients arrived in various states, sometimes positive and upbeat, but sometimes patients arrived in low moods, on occasion not knowing where they were.

Each session followed a similar structure, beginning with a brief viola performance by the musician of a piece of music, usually an extract of a classical piece, played as patients arrived and tea and biscuits were being distributed. This was followed by a 'Hello' song that incorporated participants' names, sung by the musician to each participant in turn. The same theme would be repeated at the end of the session, with 'hello' replaced by, 'goodbye.' During most sessions participants were also involved in playing light hand percussion instruments, guided by the musician. Sessions also included singing, usually commencing with familiar, popular songs. Typed song sheets were also used to encourage patients to read along (if possible) if they didn't know the words to a song. Another creative technique employed by the musician was the use of a baton to create music. Participants would be given the baton to handle and as they moved it, he would respond with corresponding pitches, tempo and changing dynamics on the viola.

Study participants initially responded by listening quietly, and field notes record pleasurable responses to the music performance. Emotional responses were nuanced, with even apparently 'sad' music welcomed by some participants. On occasions where they indicated sad responses, the musician responded by shifting gear and performing a livelier piece, in response to which most participants smiled, sometimes humming or singing along or tapping their fingers.

The 'Hello' song encouraged patients to respond to their name and to use the names of others in the group. It also allowed for reciprocal engagement as participants in the music group usually said 'thank you' in the 'good bye' version of the song. Some of the participants also said 'thank you' in response to the 'hello', indicating that they were perhaps uncertain about what response was expected. Not all of them introduced themselves, but they did generally respond when the musician used their names.

Most participants were able to understand the process of improvising with percussion instruments and joined in with the playing. Participants often responded enthusiastically to the singing part of the session, with instances of high spirits as well as poignant moments of

reminiscence. During the sessions, many participants were fully focused on the tasks and were able to interact effectively, for example making appropriate eye contact with others in the group and showing concern for each other. However, some seemed disconnected and less able to engage. In some sessions the musician invited participants to come up with their own lyrics and music for songs. The baton allowed participants to take control of the music, for example directing tempo and pitch. It was exciting to see the change in expression on participants' faces as they realised that they were conducting; there was a sense of power and exhilaration as they moved the baton to create ever more interesting sounds and music.

In general, the patients who attended the music group often told staff that they enjoyed hearing the music, singing songs, having tea and biscuits & cake. Some participants were already aware of the potential of music to positively affect mood. Staff also frequently commented on the positive effects of the sessions on participants' moods.

The success of the session depended on a number of factors, the main one being the skills and qualities of the musician. Without a lead musician, it was likely that the music sessions would be replaced by passive listening, for example, if listening to CDs or watching something on the TV were substituted. As well as musical knowledge and skill, the qualities that were observed as being particularly important are: regard and awareness for others, for example using preferred individual names to address participants; sensitivity towards the requirements of the setting; ability to respond musically in the moment, remaining calm and using a warm, friendly and gentle communication style.

Variations in group size and composition also affected the delivery of the music session and its impact. Some activities worked better in smaller groups and it took time to develop rapport. Some patients attended a number of sessions and others only attended one or two, attendance being linked with their length of stay in the hospital. Participants' responses to the sessions were strongly affected by underlying health conditions, which included hearing, sight and mobility impairments as well as dementia. Staff generally agreed that the project was effective in meeting particular needs, reducing aggression, wandering and agitation.

Staff were very positive about the group and were keen to support it. The project could not have been delivered without staff facilitating the sessions and escorting participants to and from the wards. Occasionally hospital routines got in the way of the project. The music activity sometimes clashed with other programmed activities, such as physiotherapy. The music project was subject to regular interruptions, for example, on one occasion a medical practitioner entered the room mid-session to undertake a procedure on a patient who was taking part.

Themes from the semi structured interviews

Interviews were brief conversations: participants often found it difficult to participate in interviews because of memory problems and confusion as well as other difficulties such as hearing problems. Nevertheless, the themes suggested by the interview data confirm he observation findings.

Participants reported that they enjoyed the music and singing:

I enjoyed the music (male)

I like to sing (female)

The singing was good for me (male)

They also reported enjoying the project as a social activity:

Oh I enjoy it, it's like going to the pub (male)

For some, enthusiasm for the sessions continued once back on the ward. When asked, 'how do you feel once you are back on the ward?', one male participant said:

I get them all to sing.

Participants reported positive emotions triggered by the project:

It perks me up (male)

They also reported difficulties. When asked, 'what sort of music cheers you up?' one female participant responded:

> *I don't know, because I'm never really happy.*

For some, the project triggered positive memories:

> *It's got to be sea music or things connected with the sea. I had a husband who was a sailor and he was a lovely lad, man (female).*
>
> *Ride of the Valkyries – makes me think of riding horses, I used to ride horses (female).*

Responses were nuanced:

> *Different pieces, different things from different pieces I suppose (F)*

Not all aspects of the project were enjoyed by everyone:

> *I enjoyed the music (listening) rather than the playing (male).*
>
> *I didn't enjoy so much the playing (male)*

Conclusions

Results from this analysis show some interesting trends, especially given that the sample in 2015 were on average eleven years older than the patient sample in 2014. Data from markers of behaviour show a trend for a decrease in the number of patients requiring anti-psychotic drugs on an average Tuesday following the musical intervention. A trend was identified with fewer falls recorded as occurring on a Tuesday when the musical intervention was taking place. The results suggest that the length of stay was reduced during the 2015 time period compared to 2014. However, without more specific data on patients it is not possible to know whether this was related to the reason for admission rather than a response to the music sessions.

Given the limitations discussed above, these trends should be taken with care. However the results do warrant further exploration into the possible impact that the musical intervention may be having on patients with dementia. At the end of the report there are recommendations in order to optimise the research for a more rigorous quantitative analysis in the future.

The ArtsObs data show that the observed impacts of the project were consistently positive. Impacts included improved moods and happiness as well as strongly positive effects on relaxation, distraction, engagement and agitation. The overall effect of the project was consistently observed as being very positive.

The qualitative data confirm these findings and provide a rich description of the project activities and participants' responses. Participants were generally attentive and engaged during musical performances, which sometimes triggered happy, sad and nuanced emotions. It is likely that participants' responses were affected by underlying health conditions and possibly prescribed medication, however, the activity was also a helpful distraction from these concerns. Most patients appeared to understand the purpose of the participatory activities and many were fully focused on the tasks and able to interact effectively with each other. There were instances of high spirits during singing sessions and enjoyable reminiscence, with a positive and energised atmosphere in many sessions.

Staff played an essential role in facilitating the music project as well as the research. Most staff were very enthusiastic about the project. The success of the session in part depended on the skills and qualities of the musician. It is unlikely that session run by volunteers or care staff would engage participants as effectively. Other factors affected delivery and need to be considered in the planning of a larger study. These include group size and composition and their impact on group dynamics, facilities (and whether the sessions can be run without interruptions), resources (including the location of the music sessions in relation to ward, funding to support effective research within a busy clinical setting), and consideration of day-to-day hospital routines when novel interventions are implemented.

Limitations of the study

The quantitative research took place over two different time periods, these time periods were one year apart. There is not detailed data available about each time period and as such possible differences in the environment, besides the intervention, are hard to identify. This makes it more challenging to infer whether differences identified between the two time periods were due to the musical intervention or other confounding variables.

Collection of ward level data at these two time periods was done to explore how feasible it was to access such data for a more rigorous study design in the future. Clearly Time A and Time B differ in more ways than the music intervention. For example, data show that there was on average an 11 year age difference between the 2014 and 2015 samples. There was no matching or control group and it would be useful to study the effect of the intervention on the same patients, measuring before and after the intervention. This will minimise variation in the sample due to individual characteristics.

The data used in this study was taken retrospectively from medical records available. This required considerable time commitment by the clinical nurse specialists who manually screened medical notes and records. There was a significant amount of missing data in the research; data was not available for 35.59% of the 2014 sample and 44.05% of the 2015 sample. In this pilot study, the pragmatic sample size of n=50 was not achieved. Recruitment to the study required considerable CNS time and this was not always protected for research activities. CNS expertise was frequently required for acute care activities and therefore time to recruit participants in the pilot study became a secondary activity. The quantitative data were collected to explore potential relevance as outcome measures in a future (larger) study.

The ArtsObs data provide a perspective on the project impacts from the point of view of an observer. The ArtsObs findings are confirmed in detailed field notes and in interviews with participants. Focus groups were designed to promote critical reflection, and researchers stressed that the study aims were not simply to generate positive examples of benefit, rather to explore the impact of the music project more broadly, addressing what works and what does not work. Staff were very open to this and engaged fully in group discussion.

Learning from the research process

The research process was supported by a research advisor employed by the NHS Trust who assisted with preparation of the protocol, obtaining ethics approval and liaising with staff to ensure that the music sessions could be observed. Nevertheless, the research was at times challenging. Staff members with recognised roles in the research team were generally supportive of the pilot study but, in reality, their clinical workloads took priority. This was despite managerial support and funding to allow some dedicated time to participate in the research process. It took time to make sure that the conditions on the ward made it possible to implement the protocol, for example, finding a secure storage facility for study documents, including signed consent forms. Research governance approval was delayed and this, together with delays in obtaining consent, delayed the start of the data collection. The process of obtaining consent was onerous and time consuming for the CNS and would, with hindsight, have been better to have been explicit in the protocol that this could be a shared responsibility between designated GCP trained researchers in the study team.

The study made use of the ArtsObs tool, backed up by participant observation, to document the impacts of the music programme. Given the difficulties of interviewing people with dementia, this combination of approaches proved to be valuable, if time consuming as a methodology for this project.

The methodology included use of reflective diaries by staff members. We have not directly reported on these as they were confidential: staff were not required to share them with

other staff or researchers, rather they were used for personal reflection and to inform discussions. It was made clear that the diaries should not contain any patient information. Their use was the subject of discussion during shared learning group meetings and while they were not used by everyone those who did use them found them of value.

Recommendations

Due to the nature of the data collected, it has not been appropriate to run an inferential analysis. As discussed above the descriptive analysis does suggest some interesting trends. For future research it will be important to build on this and collect data that will be amenable to an inferential analysis. Recruitment of a representative and sufficiently large sample of participants in an appropriately powered study, would enable the identification of any significant differences or relationships in the data which may then be generalised to a wider population, for example dementia patients across a clinical commissioning group, or within the NHS.

In order to run this analysis it will be important to consider the following recommendation at the planning stage of future research:

- *Collecting data from a representative sample*. The results from analyses can then be generalised to a wider population. In order to increase representation it will be important to increase the number of patients in the study, and the number of wards involved. Calculating the sample size for a future larger study would ensure the number of patients recruited was sufficient to be representative.
- *Collect more detailed data on ward characteristics before and after the intervention*. Data on key characteristics can then be assessed for possible impact on the results, and any confounding variables identified can be controlled for in the inferential analysis.
- *Collect detailed patient data on factors which may affect the results,* for example age, gender, stage of dementia, other health conditions or impairments, medication. As above any confounding variables identified can then be controlled for in the

analysis. This will provide a clearer picture of associations between variables, including the intervention and the outcomes.

- *Design and implement a within subjects research study.* By using the same patients and assessing the impact of the intervention (i.e a before and after comparison) the measurement error produced from population variation will be minimised. Whilst this would be preferable from a research perspective it will be important to consider the impact this design might have on resources at ward level, especially given the transient nature of a busy ward.
- *Plan the study methodology to include an economic analysis to allow a valid interpretation of factors such as the ward level data to consider cost changes from the intervention.*
- *Reduce the time points of measurement from the intervention.* By collecting data closer to the intervention, we can be more confident that we are assessing the impact of the intervention.
- *Ensure validity in measurement indicators*. As part of the next stage of research it would be useful to ensure the indicators that are included as part of the research are valid indicators of patient improvement, as well as considering any additional indicators that could be added in to increase the validity of the research and minimise any possible measurement error.
- *Ensure 'buy in' from senior staff who can influence day to day implementation* The research process could not have been undertaken without the support of the NHS research advisor. Additionally, care staff need to be engaged in research planning and fully informed in advance about the potential impact of research on their work, more so if the project funding means that the study is not compliant with NIHR portfolio status and therefore does not allow research nurse time to be allocated to facilitate study recruitment. Pilot studies do not qualify for portfolio adoption.
- *Clarify the responsibility for obtaining consent.* While support and guidance from clinical staff is essential, the responsibility for obtaining consent from patients to take part in a research study should be held by the senior researcher who is more

likely to be based in an environment where suitable conditions for the management of research data are a given.

- *Use mixed methods to document project impacts and outcomes*. This study has shown the value of using mixed methods to evaluate the impacts of a music project on patients with dementia in an acute care environment. Whilst the project shows that it is possible to interview patients with relatively advanced dementia, interviews with this group may not generate as rich data as they would for other groups and needs to be supplemented with other methods, particularly observational methods. Where it is not possible to undertake extensive qualitative methods the study has shown that the ArtsObs tool offers a relatively quick and efficient way of recording some impacts as well as documenting process issues. Longitudinal research would be needed to establish any longer term project impacts.
- *Include ward based observations.* In this study the researchers did not observe ward level interactions as it would not have been possible, given the timescale and project resources, to gain informed consent from every individual, including professional staff and ad hoc visitors, who might enter the ward and therefore be included in research observations. In future research it would be useful to undertake direct observation of ward based activity as well as project based activity that takes place in a separate space.
- *Ensure sufficient funding*. The undertaking of such a pilot study should always be planned with an early discussion of the funding required for the study to be undertaken with sufficient expertise and methodological rigour. The funding secured allowed an opportunity to begin such a process but soon relied upon the enthusiasm and commitment of the research team to "see it through" in the absence of cost reimbursement from a study grant. This reflects an admirable array of qualities both from NHS and academic members of the research team to sieze upon this opportunity, recognising its considerable potential to inform innovative health and wellbeing initiatives within healthcare settings that can meaningfully address the needs of an aging population.

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Appendices

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04 September 2015

Mr David Walters
Head - Centre for Arts as Wellbeing
University of Winchester
Sparkford Road
Winchester
SO22 4NR

Dear Mr Walters

Study title:	**Dementia Care and the Arts -- understanding the impact of a music intervention on patients with dementia in an acute hospital setting.**
REC reference:	**15/SC/0420**
IRAS project ID:	**131976**

Thank you for your letter responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager, Mrs Maxine Knight, nrescommittee.southcentral-hampshirea@nhs.net. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation

as revised, subject to the conditions specified below.

Mental Capacity Act 2005

I confirm that the committee has approved this research project for the purposes of the Mental Capacity Act 2005. The committee is satisfied that the requirements of section 31 of the Act will be met in relation to research carried out as part of this project on, or in relation to, a person who lacks capacity to consent to taking part in the project.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will

be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

The Committee has not yet completed any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon as an SSA application(s) has been reviewed. In the meantime no study procedures should be initiated at non-NHS sites.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		08 July 2015
GP/consultant information sheets or letters [Information Letter_GP]	1.0	27 August 2015
Interview schedules or topic guides for participants [Methodology_BronwynPlatten]		09 June 2015
Interview schedules or topic guides for participants [Methodology_BronwynPlatten_090615_v1.0]	1.0	09 June 2015
Interview schedules or topic guides for participants [Interview Schedule_Patients and Carers]	1.0	27 August 2015
Interview schedules or topic guides for participants [Topic Guide_staff]	1.0	27 August 2015
IRAS Checklist XML [Checklist_16072015]		16 July 2015
IRAS Checklist XML [Checklist_01092015]		01 September 2015
Letter from funder [WAHSNAgreement_Arts and Dementia Care_final]		
Other [ArtsObs Tool (2015)]		
Other [ArtsObs Manual (2015)]		
Other [ArtsObs Tool (2015)]	1.0	
Other [ArtsObs Manual (2015)]	1.0	
Other [REC response letter]		27 August 2015

Participant consent form [Consent Form_patient]	1.1	27 August 2015
Participant consent form [Consent form_carer]	1.0	27 August 2015
Participant consent form [Consultee Agreement Form]	1.1	27 August 2015
Participant consent form [Consent_Form Staff v1.0]	1.0	27 August 2015
Participant information sheet (PIS) [Participant Information Sheet]	1.1	27 August 2015
Participant information sheet (PIS) [Participant Information Sheet_consultee]	1.1	27 August 2015
Participant information sheet (PIS) [Participant information sheet_staff]	1.0	27 August 2015
REC Application Form [REC_Form_29062015]		29 June 2015
Research protocol or project proposal [Dementia Care and the Arts_RHCHprotocol]	1.1	27 August 2015
Summary CV for Chief Investigator (CI) [Norma Daykin]		
Summary CV for Chief Investigator (CI) [Norma Daykin_2page_CV]		09 June 2015

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

15/SC/0420	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

pp

Dr Simon Kolstoe
Chair

Email:nrescommittee.southcentral-hampshirea@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: *Mr David Walters, University of Winchester*
Mrs Christine Poile, Hampshire Hospitals NHS Foundation Trust

Hampshire Hospitals NHS
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30th October 2015

Rachel Hayden
Royal Hampshire County Hospital
Romsey Road
Winchester
SO22 5DG

Dear Mrs Hayden

Re: **Final HHFT Research Department Approval Confirmation**

Title: **Dementia Care and the Arts -- understanding the impact of a music intervention on patients with dementia in an acute hospital setting.**

R & D Ref. No: **2015-MED-19** Ethics Ref. No: **15/SC/0420**

Thank you for completing the R&D Approval procedure for the above study. This letter confirms that this research proposal has approval to commence at Hampshire Hospitals NHS Foundation Trust.

The conditions of this trust approval require you as Principal Investigator to ensure the following:

- You have returned a signed '**Principal Investigator Agreement**' outlining your responsibilities in the conduct of this research study before you commence.
- You and your research staff are required to be aware of and adhere to responsibilities, as detailed in the protocol and Clinical Trial Agreement, as well as comply in full with ICH / Good Clinical Practice, UK Law, DH Research Governance Framework (2005), Data Protection Act (1998), Freedom of Information Act (2000) and current EU Legislation – please see the references listed below.
- All serious adverse events should be reported to the Sponsor in accordance with the protocol and copied to R&D within 7 days of becoming aware of the event. The Trust Incident Reporting System should also be used if applicable.
- All recruitment to this study must be recorded on E-DGE, a web-based Clinical Research Management System. Please contact R&D for registration details.
- All research team members involved in the study have attended Good Clinical Practice (GCP) training within the last 2 years.

Please note that this Trust approval only applies to the versions of documents listed below. Any changes to the protocol can only be initiated following further approval from the Ethics Committee via a protocol amendment. The Research Department must also be notified of any changes to the study or the documents below.

Document Versions at Approval		
Document	**Version**	**Date**
REC Approval Letter		04 Sept 2015
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		08 Jul 2015
GP/consultant information sheets or letters [Information Letter_GP]	1.0	27 Aug 2015
Interview schedules or topic guides for participants [Methodology_BronwynPlatten]		09 Jun 2015
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Participant information sheet (PIS) [Participant information sheet_staff]	1.0	27 Aug 2015
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Summary CV for Chief Investigator (CI) [Norma Daykin]		
Summary CV for Chief Investigator (CI) [Norma Daykin_2page_CV]		09 Jun 2015
mNCA		30 Oct 2015
SSI	131976/868803/6/185/205418/334530	

I am enclosing two Principal Investigator Agreements which detail your responsibilities and would be grateful if you would return one signed Principal Investigator Agreement to the research office at the above address as soon as possible and before commencing the study. The 2nd copy should be kept with your Trust Approval letter in your Investigator Site File.

This approval is subject to full ethical and MHRA approval for the study to commence within Hampshire Hospitals NHS Foundation Trust.

Please contact the research team at the address above if you require further information.

On behalf of the Trust I wish you every success with the study.

Yours sincerely,

Dr John K Ramage
Director of Research and Development

cc.

References

Research governance framework for health and social care 2nd edition 2005
www.dh.gov.uk/assetRoot/04/12/24/27/04122427.pdf

For Clinical Trial Regulations:-
Medicines & Healthcare products Regulatory Authority – www.mhra.gov.uk/index.htm

Data Protection Act - www.opsi.gov.uk/Acts/Acts1998/ukpga_19980029_en_1

Freedom of Information Act - http://www.opsi.gov.uk/Acts/acts2000/ukpga_20000036_en_1

Mental Capacity Act - www.opsi.gov.uk/acts/acts2005/ukpga_20050009_en_1

Human Tissue Act:- www.hta.gov.uk/

DEMENTIA CARE AND THE ARTS

-- Royal Hampshire County Hospital --

Can weekly music sessions provided during a hospital stay for people with dementia (and their carers) benefit health and wellbeing?

A research project to inform the development of dementia-friendly ward environments.

STUDY INFORMATION: PATIENTS

This is information about a study that is happening on the ward during your hospital stay. We'd like to invite you to be part of it. We'd like to know if having the chance to attend a weekly music session during your hospital stay is something which benefits your health and wellbeing.

- How do you feel about having the opportunity to attend music sessions during your stay with us?
- Are you less anxious during your stay as a result of the music sessions?
- Does it make the ward a place you feel happy to be?
- Does music have any effect on medicine prescription, sleeping patterns, food intake, length of hospital stay, falls risk and mood and conversations between people on the ward?

WHY IS THIS IMPORTANT TO KNOW?

The hospital has not offered regular music sessions for people with dementia in the past. Other studies have shown that music sessions are beneficial for people in hospital. They can help to improve mood, mobility, confidence and concentration; reduce anxiety and agitation; improve sleep patterns and food intake; encourage conversations; and improve the experience of people when in hospital.

The researchers running this study would like to know if there is evidence that taking part in music sessions benefits people with dementia and whether it is a cost-effective approach to improving patient care. Some hospitals already run a fully integrated Arts programme for people who are in hospital. This is a new and interesting area of work for the Royal Hampshire County Hospital and the research will help us to plan service improvements in the future.

The Dementia care nurse will provide you with information about the study.

WHAT IS INVOLVED?

You will only be asked to attend the music sessions which run during your hospital stay.

The music sessions will be run every Tuesday afternoon for up to an hour. If for any reason you are too unwell to go to the lounge area where the sessions will run, the musician will offer you the chance to have a music session at your bedside.

You are welcome to attend as much or as little of each music session as you wish. You are welcome to attend with someone who cares for you when you are not in hospital, if they are visiting you at the time.

You may be one of twelve people invited to meet with the arts researcher to talk about what it was like being part of each music session. If so, you will meet the researcher for a brief discussion, with a nurse or your carer present if you prefer. No information will be used to identify you specifically in any study information. It is possible that, the discussion may be recorded, with your permission, to be sure your thoughts are accurately noted. You will not be identified at all when the study information is written up as a report but you may be quoted anonymously to give an example of the type of reactions there were to the music sessions.

The arts researcher will observe each of the group music sessions and the ward activities before and after the music sessions to see if there are any differences in how much people talk together on the ward. She will complete the Arts Observational Scale (ArtsObs) to make a note of how people are reacting to the music during each group session.

ArtsObs has been specially designed to show the effects of arts activities on participants, relatives and carers. It documents the effects that arts activities are having on mood, relaxation and other responses such as agitation. It also allows the researcher to write brief notes to include responses by patients, carers, the musician and staff and significant moments during the music activity. This information is collected discreetly by the arts researcher who will be taking an active part of in the music activity.

The Dementia care nurse will ask you to sign a consent form if you'd like to be part of the study during your hospital stay.

WHAT IF I'M NOT WELL ENOUGH TO SIGN THE CONSENT FORM?

It would be helpful to understand the response of people from the perspective of carers as well as from the people with dementia themselves. Hence, others who care for you are also invited to participate in the music sessions.

Should you be so unwell that you are unable to give consent yourself to be part of the study, a person who is a family member or friend can act as personal consultee and give agreement on your behalf, in compliance with section 32 of the Mental Capacity Act (2005).

ARE THERE ANY RISKS TO BEING PART OF THIS STUDY?

Attending the music sessions is completely voluntary and they will be run alongside the usual ward activities. They will not be run instead of any care provided during your stay but they will be offered in addition to your usual care. The research team predicts no adverse effects of being part of the music sessions and the specialist nurses on the ward will continue to oversee your care.

WILL ANY OTHER INFORMATION BE COLLECTED AS PART OF THE STUDY?

Yes, staff members will be interviewed to find out their views about the music project. We will also collect general information which describes the ward during the ten week period of the study and a similar period during 2014. This will not include personal information about you. It will include: staffing levels, general in-patient population characteristics (for example: the age range of in-patients, number of patients with dementia, average length of hospital stay, and other routinely collected ward-specific descriptive information). This will allow us to compare the two time periods in order to see whether there are any differences and whether the music session may have contributed to improvements in ward conditions. We hope this routinely collected information might indicate how a more detailed study in the future could be developed.

THE STUDY TEAM MEMBERS ARE:

Professor Norma Daykin, Centre for Arts as Wellbeing, University of Winchester.

Mrs Rachel Hayden, Dementia Care Nurse Specialist, Royal Hampshire County Hospital.

Dr Bronwyn Platten, Arts Researcher, Centre for Arts as Wellbeing, University of Winchester.
Dr Anne Henry, Arts Researcher, Centre for Arts as Wellbeing, University of Winchester.

Mr Neil Valentine, Musician, Centre for Arts as Wellbeing, University of Winchester and Bournemouth Symphony Orchestra – BOOST programme musician.

Additionally, approval for this study to be undertaken has been given by the Hampshire Hospitals NHS Foundation Trust Research Department (2015-MED-19), the information governance team and the South Central - Hampshire A Research Ethics Committee (15/SC/0420).

CAN I SPEAK TO ANYONE OUTSIDE THE RESEARCH TEAM ABOUT THIS STUDY IF I HAVE ANY CONCERNS?

Yes, you can speak with the Hampshire Hospitals NHS Foundation Trust Patient Advisory and Liaison Service (PALS) Manager, Lisa Denton, on (01962 825965).

THIS PROJECT IS FUNDED BY:

Wessex Academic Health Science Network Innovation and Wealth Creation Accelerator Fund 2014/15

with matched funding from

Arts and Health South West via an Awards for All (Lottery) grant

DEMENTIA CARE AND THE ARTS

-- Royal Hampshire County Hospital --

Can weekly music sessions provided during a hospital stay for people with dementia (and their carers) benefit health and wellbeing?

A research project to inform the development of dementia-friendly ward environments.

STUDY INFORMATION: PATIENT'S CONSULTEE

YOU HAVE BEEN ASKED TO READ THIS INFORMATION IN THE ROLE OF CONSULTEE AND ADVISE ON WHETHER ANOTHER PERSON WHO LACKS THE CAPACITY TO CONSENT FOR THEMSELVES CAN BE PART OF THIS STUDY.

Where people cannot take decisions for themselves, for example the decisions to consent to be involved in a research project, a consultee is appointed to advise on that person's wishes or feelings. This could be a friend, family member, court appointee for a patient recently admitted to hospital or seen in clinic with dementia. This patient is invited to participate in a research project in which we are collecting information from patients with dementia during their hospital stay. We are asking you to advise on whether the patient should take part in the project and if you feel that he/she would be content to take part. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives or other people providing healthcare if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you think it is appropriate for the patient to take part. Remember that your decision must be in the patient's best interests and should not reflect your personal views on the project.

Please read this information from the perspective of the person for whom you are consultee.

This is information about a study that is happening on the ward during your hospital stay. We'd like to invite you to be part of it. We'd like to know if having the chance to attend a weekly music session during your hospital stay is something which benefits your health and wellbeing.

- How do you feel about having the opportunity to attend music sessions during your stay with us?
- Are you less anxious during your stay as a result of the music sessions?
- Does it make the ward a place you feel happy to be?
- Does music have any effect on medicine prescription, sleeping patterns, food intake, length of hospital stay, falls risk and mood and conversations between people on the ward?

WHY IS THIS IMPORTANT TO KNOW?

The hospital has not offered regular music sessions for people with dementia in the past. Other studies have shown that music sessions are beneficial for people in hospital. They can help to improve mood, mobility, confidence and concentration; reduce anxiety and agitation; improve sleep patterns and food intake; encourage conversations; and improve the experience of people when in hospital.

The researchers running this study would like to know if there is evidence that taking part in music sessions benefits people with dementia and whether it is a cost-effective approach to improving patient care. Some hospitals already run a fully integrated Arts programme for people who are in hospital. This is a new and interesting area of work for the Royal Hampshire County Hospital and the research will help us to plan service improvements in the future.

The Dementia care nurse will provide you with information about the study.

WHAT IS INVOLVED?

You will only be asked to attend the music sessions which run during your hospital stay.

The music sessions will be run every Tuesday afternoon for up to an hour. If for any reason you are too unwell to go to the lounge area where the sessions will run, the musician will offer you the chance to have a music session at your bedside.

You are welcome to attend as much or as little of each music session as you wish. You are welcome to attend with someone who cares for you when you are not in hospital, if they are visiting you at the time.

You may be one of twelve people invited to meet with the arts researcher to talk about what it was like being part of each music session. If so, you will meet the researcher for a brief discussion, with a nurse or your carer present if you prefer. No information will be used to identify you specifically in any study information. It is possible that, the discussion may be recorded, with your permission, to be sure your thoughts are accurately noted. You will not be identified at all when the study information is written up as a report but you may be quoted anonymously to give an example of the type of reactions there were to the music sessions.

The arts researcher will observe each of the group music sessions and the ward activities before and after the music sessions to see if there are any differences in how much people talk together on the ward. She will complete the Arts Observational Scale (ArtsObs) to make a note of how people are reacting to the music during each group session.

ArtsObs has been specially designed to show the effects of arts activities on participants, relatives and carers. It documents the effects that arts activities are having on mood, relaxation and other responses such as agitation. It also allows the researcher to write brief notes to include responses by patients, carers, the musician and staff and significant moments during the music activity. This information is collected discreetly by the arts researcher who will be taking an active part of in the music activity.

The Dementia care nurse will ask you to sign a consent form if you'd like to be part of the study during your hospital stay.

WHAT IF I'M NOT WELL ENOUGH TO SIGN THE CONSENT FORM?

It would be helpful to understand the response of people from the perspective of carers as well as from the people with dementia themselves. Hence, others who care for you are also invited to participate in the music sessions.

Should you be so unwell that you are unable to give consent yourself to be part of the study, a person who is a family member or friend can act as personal consultee and advise on your behalf, in compliance with section 32 of the Mental Capacity Act (2005).

ARE THERE ANY RISKS TO BEING PART OF THIS STUDY?

Attending the music sessions is completely voluntary and they will be run alongside the usual ward activities. They will not be run instead of any care provided during your stay but they will be offered in addition to your usual care. The research team predicts no adverse effects of being part of the music sessions and the specialist nurses on the ward will continue to oversee your care.

WILL ANY OTHER INFORMATION BE COLLECTED AS PART OF THE STUDY?

Yes, staff members will be interviewed to find out their views about the music project. We will also collect general information which describes the ward during the ten week period of the study and a similar period during 2014. This will not include personal information about you. It will include: staffing levels, general in-patient population characteristics (for example: the age range of in-patients, number of patients with dementia, average length of hospital stay, and other routinely collected ward-specific descriptive information). This will allow us to compare the two time periods in order to see whether there are any differences and whether the music session may have contributed to improvements in ward conditions. We hope this routinely collected information might indicate how a more detailed study in the future could be developed.

A REMINDER OF THE RESPONSIBILITIES OF A CONSULTEE:

You have been chosen as a consultee because the person with dementia who could be part of this study has been assessed by the clinical team as having lost the capacity to consent. You are not obliged to undertake the role of consultee if you do not wish to do so. You are asked to advise on whether the person who lacks capacity should take part in the project. For example, they should consider whether the person who lacks capacity would be content to take part or whether doing so might upset them.

You should also give your opinion on what the past and present wishes and feelings the person who lacks capacity would have been about taking part in the study. For example, this may consider whether the person had previously expressed specific or general support for research of this nature when they had capacity, or temporarily regained some capacity or are otherwise able to indicate their views.

If you advise that the person would not have wanted to take part, the researchers will abide by this. However, you are also bound by the normal duty of care to act responsibly and in good faith when advising on the past and present wishes and feelings.

You are not being asked for advice on your personal views on participation in the specific project, or research in general.

You are not being asked to consent on behalf of the person who lacks capacity.

You should consider the broad aims of the research, the risks and benefits and the practicalities of what taking part will mean for the person who lacks capacity.

You should also consider their present views and wishes. For example, the study might involve activities in the afternoon when the person who lacks capacity is most tired so would find it a strain, or conversely it might involve an activity that the person who lacks capacity particularly enjoys.

At any stage, you can advise the researchers that the person who lacks capacity would not want to remain in the project, and your advice will be respected by the researchers.

THE STUDY TEAM MEMBERS ARE:

Professor Norma Daykin, Centre for Arts as Wellbeing, University of Winchester.

Mrs Rachel Hayden, Dementia Care Nurse Specialist, Royal Hampshire County Hospital.

Dr Bronwyn Platten, Arts Researcher, Centre for Arts as Wellbeing, University of Winchester.
Dr Anne Henry, Arts Researcher, Centre for Arts as Wellbeing, University of Winchester.

Mr Neil Valentine, Musician, Centre for Arts as Wellbeing, University of Winchester and Bournemouth Symphony Orchestra – BOOST programme musician.

Additionally, approval for this study to be undertaken has been given by the Hampshire Hospitals NHS Foundation Trust Research Department (ref: 2015-MED-19), the information governance team and the South Central - Hampshire A Research Ethics Committee (15/SC/0420).

CAN I SPEAK TO ANYONE OUTSIDE THE RESEARCH TEAM ABOUT THIS STUDY IF I HAVE ANY CONCERNS?

Yes, you can speak with the Hampshire Hospitals NHS Foundation Trust Patient Advisory and Liaison Service (PALS) Manager, Lisa Denton, on (01962 825965).

THIS PROJECT IS FUNDED BY:

Wessex Academic Health Science Network Innovation and Wealth Creation Accelerator Fund 2014/15 with matched funding from Arts and Health South West via an Awards for All (Lottery) grant

DEMENTIA CARE AND THE ARTS

-- Royal Hampshire County Hospital --

Can weekly music sessions provided during a hospital stay for people with dementia (and their carers) benefit health and wellbeing?

A research project to inform the development of dementia-friendly ward environments.

STUDY INFORMATION: STAFF

This is information about a study that is happening on the ward. We'd like to invite you to be part of it. We'd like to know if attending a weekly music session during their hospital stay can benefit patients' health and wellbeing, for example, by reducing anxiety, providing an enjoyable, interactive experience and encouraging positive interaction with other patients and staff. We would also like to know whether the project enhances staff experiences of the workplace, and find out what staff think about the project and the way it is run. Finally, we would also like to assess the impact of the intervention on ward level data including medicine prescription, sleeping patterns, food intake, length of hospital stay and falls risk.

WHY IS THIS IMPORTANT TO KNOW?

The hospital has not offered regular music sessions for people with dementia in the past. Other studies have shown that music sessions are beneficial for people in hospital. They can help to improve mood, mobility, confidence and concentration; reduce anxiety and agitation; improve sleep patterns and food intake; encourage conversations; and improve the experience of people when in hospital.

The researchers running this study would like to know if there is evidence that taking part in music sessions benefits people with dementia and whether it is a cost-effective approach to improving patient care. Some hospitals already run a fully integrated Arts programme for people who are in hospital. This is a new and interesting area of work for the Royal Hampshire County Hospital and the research will help us to plan service improvements in the future.

WHAT IS INVOLVED?

The arts researcher will observe each of the weekly group music sessions and ward activities before and after the music sessions to see if there are any differences in patient mood or in ward activities before and after. She will complete the Arts Observational Scale (ArtsObs) to make a note of how people are reacting to the music during each session. This will include staff responses, however, the researcher will not record names or other identifying details of anyone involved, including staff. You will be invited to give feedback to the researcher after each session, including what went well and what didn't go so well. The researcher will not record your name or details but will use the feedback generally to advise the musician and inform delivery of future sessions.

You may be invited to join an action learning group, made up of four staff members who are closely involved in supporting patients who take part in the weekly music sessions. This group will meet three times: once at the beginning of the project, once half way through and again at the end to review the project. Discussions will be confidential and the researcher will record general views and feedback. You may be asked to keep a reflective diary to record your observations and experiences of the sessions. This will be treated as confidential and you will not be asked to submit the diary as part of the research project, however, you may wish to draw on it during discussions to help you reflect and remember important details.

You may be invited to join an end of project focus group. This will include up to 8 staff members who have been involved in supporting the project. It will discuss what went well, what didn't go so well in order to draw out the learning from the project. It will discuss your views about the impact of the project on patients as well as any impacts on yourself, including whether the project enhanced the work environment or created difficulties.

No information will be used to identify you specifically in any study information. The focus group discussion may be audio recorded, with your permission, to be sure your thoughts are accurately noted. You will not be identified at all when the study information is written up as a report but you may be quoted anonymously to give an example of the type of reactions there were to the music sessions.

ARE THERE ANY RISKS TO BEING PART OF THIS STUDY?

Participation in the research is completely voluntary. You will be asked to discuss your views about the music project and its effects on patients, carers and ward activity. The information is confidential and you will only be invited to disclose information that you deem relevant to the study. The research team predicts no adverse effects of being part of the study and it is expected that you may enjoy the opportunity to reflect and give your views. However, if you do have concerns, the researcher will be able to identify appropriate, established, confidential referral services and resources.

WILL ANY OTHER INFORMATION BE COLLECTED AS PART OF THE STUDY?

Yes, patients with dementia (with or without their carers) are the main participants in the study and twelve people will be invited to meet with the arts researcher to talk about what it was like being part of each music session. Further details of patient participation can be found in the "study information: patients" document (v1.1, 27 August 2015).

THE STUDY TEAM MEMBERS ARE:

Professor Norma Daykin, Centre for Arts as Wellbeing, University of Winchester.

Mrs Rachel Hayden, Dementia Care Nurse Specialist, Royal Hampshire County Hospital.

Dr Bronwyn Platten, Arts Researcher, Centre for Arts as Wellbeing, University of Winchester.
Dr Anne Henry, Arts Researcher, Centre for Arts as Wellbeing, University of Winchester.

Mr Neil Valentine, Musician, Centre for Arts as Wellbeing, University of Winchester and Bournemouth Symphony Orchestra – BOOST programme musician.

Additionally, approval for this study to be undertaken has been given by the Hampshire Hospitals NHS Foundation Trust Research Department (2015-MED-19), the information governance team and the South Central - Hampshire A Research Ethics Committee (15/SC/0420).

CAN I SPEAK TO ANYONE OUTSIDE THE RESEARCH TEAM ABOUT THIS STUDY IF I HAVE ANY CONCERNS?

Yes, you can speak with the Hampshire Hospitals NHS Foundation Trust Research Department who will ensure the study is compliant with research governance and good clinical practice guidance.

Contact Mrs Christine Poile, Research Manager on 01256 314557.

THIS PROJECT IS FUNDED BY:

Wessex Academic Health Science Network Innovation and Wealth Creation Accelerator Fund 2014/15

with matched funding from

Arts and Health South West via an Awards for All (Lottery) grant

DEMENTIA CARE AND THE ARTS

-- Royal Hampshire County Hospital --

Can weekly music sessions provided during a hospital stay for people with dementia (and their carers) benefit health and wellbeing?

PARTICIPANT IDENTIFICATION NUMBER: **DCA/RHCH/_____**
eg: DCA/RHCH/001

CONSENT FORM: PATIENTS

NAME OF RESEARCHERS: Professor Norma Daykin, Dr Bronwyn Platten, Dr Anne Henry

		Please initial box
1.	I confirm that I have read the information sheet dated 27 August 2015 (version 1.1) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2.	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	
3.	I understand that I may be interviewed and the interview may be digitally recorded in order to ensure my views are accurately transcribed. Any quotations used in the study reporting will be anonymised and no personal data will form part of the study report.	
4.	I understand that my participation in each of the music sessions will be observed by the arts researcher and information will be documented about each session for the purposes of the study. Again there will be nothing recorded that will identify me personally.	
5.	I agree to take part in the above study.	

_____ _____ _____

Name of participant: **Date:** **Signature:**

_____ _____ _____

Name of person taking consent: **Date:** **Signature:**

DEMENTIA CARE AND THE ARTS

-- Royal Hampshire County Hospital --

Can weekly music sessions provided during a hospital stay for people with dementia (and their carers) benefit health and wellbeing?

PARTICIPANT IDENTIFICATION NUMBER: **DCA/RHCH/_____**
eg: DCA/RHCH/001

CONSENT FORM: CARERS

NAME OF RESEARCHERS: Professor Norma Daykin, Dr Bronwyn Platten, Dr Anne Henry

		Please initial box
1.	I confirm that I have read the information sheet dated 27 August 2015 (version 1.1) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2.	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	
3.	I understand that I may be interviewed and the interview may be digitally recorded in order to ensure my views are accurately transcribed. Any quotations used in the study reporting will be anonymised and no personal data will form part of the study report.	
4.	I understand that my participation in each of the music sessions will be observed by the arts researcher and information will be documented about each session for the purposes of the study. Again there will be nothing recorded that will identify me personally.	
5.	I agree to take part in the above study.	

_____ _____ _____

Name of participant: **Date:** **Signature:**

_____ _____ _____

Name of person taking consent: **Date:** **Signature:**

DEMENTIA CARE AND THE ARTS

-- Royal Hampshire County Hospital --

Can weekly music sessions provided during a hospital stay for people with dementia (and their carers) benefit health and wellbeing?

PARTICIPANT IDENTIFICATION NUMBER: **DCA/RHCH/_____**
eg: DCA/RHCH/001

CONSENT FORM: STAFF

NAME OF RESEARCHERS: Professor Norma Daykin, Dr Bronwyn Platten, Anne Henry

		Please initial box
1.	I confirm that I have read the information sheet dated 27 August 2015 (version 1.0) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2.	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	
3.	I understand that I may be invited to take part in a focus group and that this may be digitally recorded in order to ensure my views are accurately recorded. Any quotations used in the study reporting will be anonymised and no personal data will form part of the study report.	
4.	I understand that my participation in each of the music sessions will be observed by the arts researcher and information will be documented about each session for the purposes of the study. Again there will be nothing recorded that will identify me personally.	
5.	I agree to take part in the above study.	

_____ _____ _____

Name of participant: **Date:** **Signature:**

_____ _____ _____

Name of person taking consent: **Date:** **Signature:**

DEMENTIA CARE AND THE ARTS

-- Royal Hampshire County Hospital --

Can weekly music sessions provided during a hospital stay for people with dementia (and their carers) benefit health and wellbeing?

PARTICIPANT IDENTIFICATION NUMBER: **DCA/RHCH/_____**
eg: DCA/RHCH/001

CONSULTEE AGREEMENT FORM

[in accordance with section 32, Mental Capacity Act (2005)]

NAME OF RESEARCHERS: Professor Norma Daykin, Dr Bronwyn Platten, Dr Anne Henry

		Please initial box
1.	I confirm that I have read the information sheet dated 27 August 2015 (version 1.1) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2.	I understand that this person's participation is voluntary and that I am free to advise of their withdrawal from the study at any time without giving any reason, without my medical care or legal rights being affected.	
3.	I understand that I may be interviewed with this person and the interview may be digitally recorded in order to ensure my views are accurately transcribed. Any quotations used in the study reporting will be anonymised and no personal data will form part of the study report.	
4.	I understand that this person's participation in each of the music sessions will be observed by the arts researcher and information will be documented about each session for the purposes of the study. Again there will be nothing recorded that will identify them personally.	
5.	I agree for this person to take part in the above study.	

_____
Name of participant:

_____ _____ _____
Name of consultee: **Date:** **Consultee Signature:**

_____ _____ _____
Name of person taking consent: **Date:** **Signature:**

DATE:

Dear Dr

Re. (name of patient)

I am writing to notify you that whilst staying as an inpatient at Royal Hampshire County Hospital your patient has been recruited to a research project, 'Dementia Care and the Arts'. The aim of this pilot study is to understand the impact of a music intervention with older people in an acute hospital setting. The project is funded by The Wessex Academic Health Science Network (WAHSN), Hampshire Hospitals Foundation Trust and The University of Winchester. The music intervention is funded by Arts Council England through Arts and Health South West.

The intervention being assessed is a 10 week period of weekly music sessions for patients on the acute ward. A classically trained musician who is also trained in delivering participatory arts activities for vulnerable people leads a group music making session on a side room on the ward. Participants are invited to listen, play, sing and improvise using simple techniques led by the musician. The repertoire includes a mixture of familiar songs and improvised music created by the group. An arts researcher from Winchester University undertakes participant observation to document responses to the group music session using a nonintrusive measure (ArtsObs) specifically designed for evaluating arts interventions.

The research team recognises the potential vulnerability of patients with dementia and the possibilities of them becoming distressed or anxious when invited to participate in what is a change to the ward environment. The musician leading the sessions and the researcher are sensitive to this and will be conducting the project with the full support of experienced ward staff, including the dementia care clinical nurse specialist. No patient is coerced into consenting or attending and refusal to participate in the music or the research will not influence the high quality care which the ward is committed to providing to all in-patients. Patients and their carers are free to attend the sessions for as long as they wish even if this is only for part of a session.

The evaluation involves confidential, semi structured interviews with a sub sample of up to 12 patients, carers, consultees and staff. The purpose of these is to explore their perceptions of the music intervention. Potential participants are approached on the acute ward by the clinical nurse specialist (dementia care) who provides information and consents patients/carers into the study.

Participation is voluntary and participants are free to withdraw at any time without giving any reason, without medical care or legal rights being affected.

Qualitative data from interviews and observations are anonymised prior to analysis. No individuals are to be named or otherwise identified in study reports.

The time frame for data collection of consented patients and carers is September to December 2015. If a participant, who has given informed consent, loses capacity to consent during the study, the research team will consider the views of the participant's personal consultee and review their participation in the study. As the study focuses on patients with dementia, the research team contends that any further loss of capacity during the study would not necessarily preclude participation.

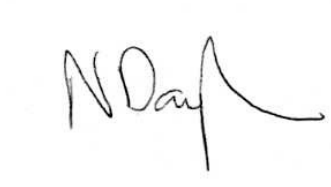
Participants finish their involvement in the study at discharge from the acute ward.

The study design includes assessment of ward level data at two time points, prior to and during the music intervention, including length of stay, prescribing costs, food intake/plate waste, staff absence, mood assessment, patient anxiety, sleep patterns, falls and challenging behaviour incidents. The purpose of this exercise is to establish whether there are any noticeable ward level differences between the two time points. This part of the study does not use individual patient records or any other form of data from individuals.

The study has been reviewed by the South Central - Hampshire Research Ethics Committee (REC reference: 15/SC/0420; IRAS project ID: 131976)

If you have any questions or concerns please address them to the Chief Investigator, Professor Norma Daykin, at the address below.

Yours sincerely



Professor Norma Daykin,
Chief Investigator, Dementia Care and the Arts.
University of Winchester,
Sparkford Road Winchester.
SO22 4NR, Tel: 01962 824897,
Mob: 07786 063634,
Email: Norma.Daykin@winchester.ac.uk

DEMENTIA CARE AND THE ARTS

-- Royal Hampshire County Hospital --

Can weekly music sessions provided during a hospital stay for people with dementia (and their carers) benefit health and wellbeing?

INTERVIEW SCHEDULE: PATIENTS AND CARERS

The schedule is intended as a general guide that can be tailored to individual respondents. Do not pursue topics where there is an indication that the participant does not wish to discuss things further. Add further prompts where appropriate and allow space for the participant to volunteer responses.

1. Introductions and thanks.
2. Confirmation of the study details, aims and purpose of the interview.
3. General information
    a. What kinds of music do you enjoy?
    b. Have you ever been involved in singing or playing music in the past?
4. Responses to the music project
    a. How many sessions did you take part in?
    b. What happened during the sessions?
    c. What did you enjoy most about the sessions?
    d. Was there anything you did not like about the sessions?
5. Responses to the musician/session organisation
    a. What did you think about the way the session were organised?
    b. What did you like about the things that the musician did?
    c. Was there anything you did not like about the way the music sessions were organised?
    d. Was there anything that you would have done differently?
6. Repertoire and musical experience
    a. Did you enjoy the songs and music that were used during the session?
    b. Was there any music that you did not think should be included?
    c. Did you enjoy the traditional songs used by the musician?
    d. Were these songs familiar to you?
    e. What did you think about the improvisation activity?
7. Health and wellbeing
    a. Did the music project help you to feel relaxed?
    b. Did the music project help you to feel less anxious or stressed?
    c. Did the music project help you to interact with other patients?
    d. Did the music project help you to interact with staff?
    e. Were there any other effects of the music project on you?
    f. Did the music project have any negative effects on you?
8. Closing:
    a. Is there anything else that you would like to say about the project?
    b. Would you recommend the project to other patients in the future?
    c. Thanks and further information including researcher contact details for further questions and information.

DEMENTIA CARE AND THE ARTS

-- Royal Hampshire County Hospital --

Can weekly music sessions provided during a hospital stay for people with dementia (and their carers) benefit health and wellbeing?

REFLECTIVE DIARY: STAFF

This template is intended as a general guide. Use the prompts to write notes after the music session. Add further topics if you wish. The information you note here is confidential and you are not required to show this diary to anyone. You may wish to consult it before meeting with colleagues and the researcher to review progress.

Name_____

Session Date _____

What happened during today's music session?

How did participants respond to the session?

What went well during today's session?

What did not go so well?

In what way did you yourself participate (eg singing, playing)?

How did you feel about participating in the session?

What effect did the session have on the atmosphere on the ward?

Did the session create any challenges or difficulties for you or for the ward staff?

Any other comments

DEMENTIA CARE AND THE ARTS -- Royal Hampshire County Hospital --

Can weekly music sessions provided during a hospital stay for people with dementia (and their carers) benefit health and wellbeing?

TOPIC GUIDE: STAFF

The schedule is intended as a general guide. Do not pursue topics where there is an indication that participants do not wish to discuss things further. Add further prompts where appropriate and allow space for participants to volunteer responses.

1. Introductions and thanks.
2. Confirmation of the study details, aims and purpose of the focus group.
3. General information
    a. What kinds of music do you enjoy?
    b. Have you ever been involved in music projects for patients in the past?
4. Responses to the music project
    a. How many sessions did you support?
    b. What happened during the sessions?
    c. What do you think was effective about sessions?
    d. Was there anything you thought was ineffective?
5. Responses to the musician/session organisation
    a. What did you think about the way the session were organised?
    b. What did you like about the things that the musician did?
    c. Was there anything you did not like about the way the music sessions were organised?
    d. Was there anything that you would have done differently?
6. Repertoire and musical experience
    a. Did you think that the songs and music used during the sessions were appropriate?
    b. Was there any music that you did not think should be included?
    c. Did you think the use of traditional songs was effective?
    d. Were these songs familiar to you?
    e. Did you join in with the improvisation activity?
    f. How did you feel about taking part in the improvisation activity?
7. Patients' health and wellbeing
    a. Would you say that the music project helped patients to feel more relaxed and/or less anxious?
    b. Would you say that the music project helped patients to interact with each other?
    c. Would you say that the music project helped you to interact with patients?
8. Effects on staff
    a. What effects did the music project have on you?
    b. Did the music project have any negative effects on you?
9. Closing:
    a. Is there anything else that you would like to say about the project?
    b. Challenges?
    c. Would you recommend the project to similar wards in the future?
    d. Thanks and further information including researcher contact details for further questions and information.