Randomized clinical trial in soundscape research

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ABSTRACT

The mechanism that connects the sonic environment to how it is perceived and understood by persons are becoming more evident, and there are standardized methodologies for assessing the soundscape. The importance of the sonic environment on the health and well-being of people is well known. Therefore, using the Soundscape approach to design an atmosphere that improves people's quality of life is essential. This approach is more challenging for people with cognitive difficulties; in this study, people with dementia. This project uses a personalized algorithm; based on questionnaires and evaluations to play sounds at prescheduled moments through a day in patients' rooms in a research hospital specializing in dementia care for six weeks for each study group. A single-blind repeated measure randomized clinical trial is designed to estimate the overall or average effects of the customized soundscape on people with dementia. The outcome measure will assess the intervention's impact on agitation, distress, night sleep, stress, and quality of life. The results will have a significant impact on designing soundscape for people with dementia by improving the quality of life and reducing the behavioural and psychological symptoms of dementia.

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1. INTRODUCTION

In the last few decades, insights into the impact of the sonic environment on persons have grown to include not only the adverse effects of extensive mechanical noise but also the beneficial effects of a well-designed sonic environment [1].

Besides disturbance of cognitive functions, behavioural and psychological symptoms of dementia (BPSD) occur very often in persons with dementia, with reported rates up to 80% and more [2]. BPSD is considered as a characteristic of dementia, but indirect factors also contribute to the etiopathogenesis of BPSD. Tible et al. [3] distinguish biological, psychosocial and social or environmental factors. One of the environmental factors is the infrastructure of care facilities. Various modifications can support a dementia-friendly environment that can also contribute to the prevention or reduction of BPSD [4]. Research also stresses the influence of noise on BPSD, influencing sleep, agitation and anxiety [5].

The mechanism that connects the sonic environment to how it is perceived and understood by persons is becoming more evident, and now it is clear that soundscape influences mood [6]. The methodologies for assessing the soundscape has been standardized [7]. A soundscape is defined as the acoustic environment as perceived or experienced and understood by a person or people, in context. This perception is also the case for persons with dementia; however, they perceive and understand the sonic environment differently [8]. The most obvious difference is the deviant meaning they may give to the sounds they notice due to changing mental associations.

In previous research, AcustiCare [9], the use of soundscapes was tested in Flanders' nursing homes in Belgium. After using a co-creation process with stakeholders and adding acoustic stimuli to an existing environment, it was observed that the soundscapes had a supportive effect on persons with dementia [10]. This study demonstrated that the interaction between personal and acoustical environmental factors was significant in influencing BPSD [11].

The team tested the soundscapes in an iterative process, with 15 residents with dementia. The testing phase itself was based on an ethnographic design employing 24/7 participatory observations in the five nursing homes through an iterative process, and constant comparison characterized Data-analysis [12].

This research shows that designing a personalized soundscape can improve the quality of life for people with dementia.

2. RATIONALE

In this study, we are using AcustiCare sound system that uses a personalized algorithm to play sounds at prescheduled moments throughout the day. As people with dementia may have difficulty in interpretation of time and space, this system provides sonic elements that help with understanding the day or the place. In a previous observational study [11], the AcustiCare system was used to implement a soundscape into the existing sonic environment to improve the well-being of persons with dementia.

The personalization of the sonic environment is essential because every person has his/her preferences when it comes to sound, and different manifestations of dementia have different effects on sound perception.

This study aims to evaluate the effect of soundscape on the well-being and behaviour of persons with dementia. Most of the existing studies in the field of the acoustic environment in health care are descriptive [13], and there is a need for a more rigorous evaluation of interventions. Using a pilot Randomized Control Trial (RCT) design, we will be able to establish the effect size of soundscape on outcomes of interest in this population of people with dementia. These results will support evidence-based practices by healthcare providers, architects, engineers and designers in

implementing environmental health factors and designing better care facilities for people with dementia.

3. STUDY OBJECTIVES

The study objective is to determine the effect size of a carefully tuned personalized sonic environment on agitation and distress, night sleep and stress, and quality of life. 1) To determine the effect size of a designed soundscape on BPSD, as measured by the Neuropsychiatric Inventory Questionnaire (NPI) (primary outcome), and the Pittsburgh Agitation Scale (PAS) [14] "resistance to care" item (secondary outcome), also the Distress-related affect and behaviours observed by staff through a real-time evaluation system (secondary outcome).

2) Examine the effects of a designed soundscape on physiological measures of sleep and stress by evaluating nocturnal activity levels and heart rate variability through a wearable device.

3) Examine the impact of designed soundscape on quality of life.

4. METHOD

4.1. Study Design

We have developed a pilot single-blind Repeated-Measures RCT to estimate the overall or average treatment effect over the evaluation period (one year). We propose a 2:4:1 design, with the assessment of baseline measures at two weekly time points, followed by randomization to soundscape or Treatment As Usual (TAU), four weekly outcome measurements, and a 1-week post-intervention assessment. We will then use generalized linear mixed-effects models to analyse our primary and secondary outcomes, which provide a flexible and powerful tool to deal with longitudinal data with heterogeneity or variability among subject-specific response profiles and missing data.

4.2. Study Setting

This study takes place in the Specialized Dementia Unit at the Toronto Rehabilitation Institute (TRI-SDU), unit is a 17-bed unit that admits people with moderate-severe dementia from nursing homes for the treatment of BPSD. The unit is an academic one with experience in clinical research. They have implemented a Centralized Recruitment Process, which will be in place for this study. There are also several standardized outcome measures in place that collects data as part of usual care into a clinical database (DADOS system). This database also collects other clinical information about weekly medications and adverse events such as falls and restraint use.

There are 12 private rooms on the unit in which will be used for this study.

4.3. Study Participants and Recruitment

Participant recruitment will take place through the Centralized Recruitment process. All Substitute Decision Makers (SDM) have an opportunity to indicate their interest in learning about the research at the time of admission. The vast majority (>98%) of patients on this unit are incapable of consenting to research. Centralized recruitment will confirm this through an assessment of capacity, and if incapable of consenting to research, their SDM will ask to provide consent.

Individual participation is entirely voluntary. Participants or their SDM may refuse to participate, withdraw at any time, decline to participate in some aspect of the research, and refuse to give any reason. There will be no consequences for participants if they choose to withdraw. Participants and their SDM will be able to select at the time of withdrawal whether they wish for their data to be retained or deleted.

4.3.1. Inclusion and Exclusion

Inclusion Criteria: all participants should be 65 years or older, have diagnosis of dementia, show symptoms of BPSD at baseline, speak English, and assigned to a private room with soundscape installed.

Exclusion Criteria: patients with severe hearing impairment (as evaluated through a simple hearing test— the examiner stands arm's length (0.6m) behind the seated patient and says the patient's name, and it is noted if they turn towards the sound) [15] and those receiving end-of-life care.

4.4. RANDOMIZATION AND INTERVENTION

4.4.1 Randomization and blinding

Participants will be randomized using block randomization after the two-week baseline period to either TAU or Soundscape. The study is a single-blind study, where the assessor and responsible physician will be blinded to treatment assignment, while the staff, patient and family will not be blinded, as they will expose to the soundscape intervention. Staff will be instructed not to document in the medical chart about the study group assignment unless it is material to the documentation of a clinically relevant event. They will also be asked not to unblind the assessor or the responsible physicians involved in proposing treatment decisions. The timing of the soundscape intervention is such that it will be delivered in the morning and evening, outside of the usual physician and research assistant hours on the unit, to prevent inadvertent unblinding.

4.4.2 Treatment as usual

As part of routine care, patients on the Specialized Dementia Unit receive a comprehensive assessment of their health and symptoms of dementia involving consultation by a geriatric psychiatrist, geriatrician, physical therapist, occupational therapist, and recreation therapist, and pharmacological and nonpharmacological treatment plans are developed and executed. All participants in the study will receive this standard of care.

4.4.3 Soundscape System

The study intervention consists of the delivery of a soundscape in the private rooms of the participant, through AcustiCare. The delivered soundscape includes a composition of different long duration sounds played at specific times throughout the day. These sounds are selected from a custom sound database consisting of natural sounds, environmental sounds, music, etc. This soundscape is composed in accordance with the daily schedule of activities of the participant and is delivered in the participant's room using a soundscape player system. The soundscape system consists of a sound playing device and feedback buttons connected to the web interface. This web interface gives access to the overall soundscape control. It allows in the initial composition of the soundscape and the daily schedule of the different soundscape player systems of all rooms. The interface allows the activation and deactivation of the players. The software programs deliver the soundscape and use the feedback from the button panel to personalize the soundscape.

Each device will be labelled in the server by an ID. The research assistant will note in a participant log which device has been assigned to which study participant by participant ID. The research assistant will have the ability to activate or deactivate devices based on study week and group assignment.

5. DATA COLLECTION

5.1. Study Outline

As shown in Figure 1, all participants will undergo a baseline assessment at study entry and will have a one-week further evaluation before randomization and treatment group assignment. Those randomized to the soundscape intervention will have a one-week personalization period before delivering the personalized soundscape for the next three weeks. At the beginning of week six, the soundscape system will turn off, and an exit assessment will take place one week later. Outcome measures will be assessed weekly over this period, for a total of 2 pre-intervention and four intervention and one post-intervention measure (2:4:1).

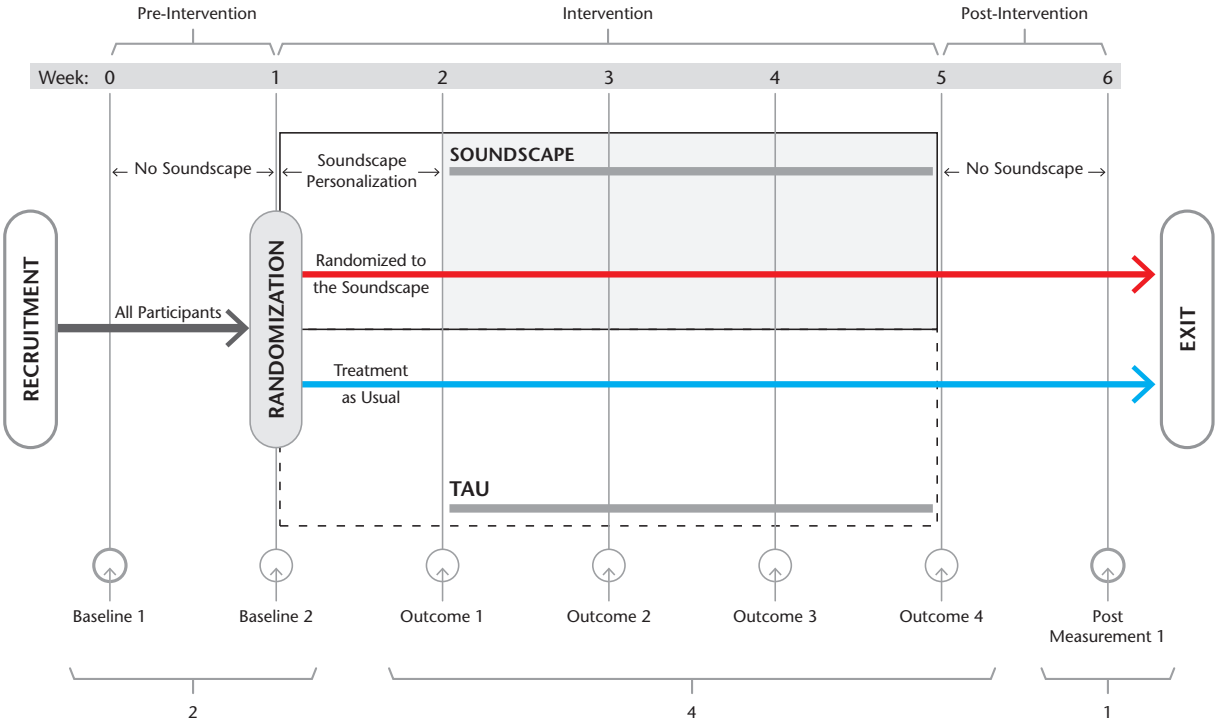

Figure 1: Study Design

5.2. Baseline measures

The study sample will be characterized at baseline timepoint 1 (see Figure 1) using demographic measures (age, sex) and several study-specific assessments:

Assessment of cognition via Mini-Mental State Examination; MMSE, an 11-item measure that tests five areas of cognitive function: orientation, registration, attention and calculation, recall, and language [16]

Severe Impairment Rating Scale; SIRS, a brief assessment of cognitive function in people with advanced dementia [17]

Assessment of self-care, Resident Assessment Instrument – Minimum Data Set; RAI-MDS, self-sufficiency in self-care performance in various activities of daily living over the past seven days [18]

Mobility, Performance Oriented Mobility Assessment; POMA, a task-oriented outcome measure that assesses gait and balance ability [19]

Dementia staging, Quick Dementia Rating System; QDRS, a brief informant-based dementia staging tool that validly and reliably differentiates individuals with and without dementia and provides accurate staging of individuals [20]

Assessment of frailty; Clinical Frailty Scale, CFS, a judgment-based summary of clinical information to assess frailty, and broadly stratify degrees of fitness and frailty [21]

The Qualidem, a dementia-specific Quality of Life (Qol) instrument that allows a proxy-based Qol rating in all stages of dementia [22]

Simple Hearing Test [15]

The research assistant will complete an NPI and Pittsburgh agitation scale at the timepoints baseline 1 and 2 (see Figure 1) using behaviours exhibited in the previous week, through a chart review and discussion with staff.

5.3. Delivery of Intervention

After recruitment, participants' specific information is collected through soundscape questionnaires from SDM and participants at the time of consent. After group assignment, the device ID in the rooms of those assigned to the treatment group will be noted, and those devices programmed through the web interface with information from the soundscape questionnaire will deliver a personalized soundscape.

During the intervention period, the soundscape player system is switched on. In this way, the soundscape group will hear from the player additional sounds intended to contribute to the background during specific periods of the day. This intervention starts after week one by instruction in the web interface. Staff is asked to evaluate the general behaviour of a resident as an assessment during the care moment. The evaluation is done by pressing one of the five feedback buttons of the feedback button panel (from very content to very distressed) when leaving the room. In this way, the remote server obtains information on the appropriateness of the soundscape and adjusts what is delivered. The feedback will lead to a personalized soundscape, which will be delivered from week two onwards. As it is essential to have sufficient feedback, staff will be asked to continue to press the button panel to provide feedback about the effects of the soundscape on the individual with dementia. They also will be asked to give feedback through the button panel in the TAU rooms for behavioural assessment. After week five, the soundscape is switched off by instruction in the web interface.

The reference group, with treatment, as usual, will not hear such sounds as the speakers will not be activated in their rooms.

5.4. Outcome Measure

Outcome measures will be assessed at five weekly time points. Outcome 1 to 4 and Post-Intervention 1; (see Figure 1).

The NPI will be completed at each time point by the research assistant in the review of the totality of weekly behaviours by the participant, including a review of the written chart and interview with staff.

The Neuro-psychiatric inventory gives an idea on the presence and number of BPSD, the severity and emotional distress the BPSD causes the care-professionals. The total NPI score will be a primary outcome, with the subscale scores being secondary outcome measures.

As a secondary outcome, the Pittsburgh Agitation Scale (PAS) is completed by nurses once per shift (day, evening, night) and documents the severity of 4 different behaviours (resisting care, aggression, motor agitation, and aberrant vocalization) on a scale from 0-4. The research assistant will review the nurses' scores and the written chart and will provide a final score for each shift based on this information.

There will thus be a total of 21 ratings of each item per week (3 per day). The daily scores of each item will be summed, and these daily scores for the "Resistance to care" item will be the second primary outcome for the study. We will also examine the total weekly PAS score.

Finally, for Aim 3, Qualidem will be re-assessed by the research assistant at outcome timepoint 4.

5.5. Physiological Measures

As part of an exploratory aim to develop some evidence for the effects of a personalized soundscape on physiological measures, we will use the Empatica wearable device to acquire real-time physiological data for 24 hours at four different time points during the study. The study team has used these wristbands successfully in a previous study on the TRI-SDU and have demonstrated their feasibility and reliability as a research tool for tracking behaviours.

The Empatica wearable has four sensors collecting information about movement (accelerometer), temperature, heart rate (PDG) and sweat conductance (EDA). Participants will wear the wristband for one 24-hour period (from 10 am to 10 am) in the second (baseline), fourth, fifth, and sixth weeks of the study.

5.6. Data Analysis

Participant characteristics will be summarized using descriptive statistics, and any baseline differences between the TAU and soundscape groups identified.

Aim 1: We will use generalized linear mixed-effects models to determine the overall effect of assignment to the soundscape intervention on 1) the change in NPI score over time and 2) on the PAS Resistance to Care score over time. We will explore the effect of a designed soundscape on real-time ratings of distress behaviours by nursing staff by examining linear regression models of reported scores over time and developing mixed-effects models to examine the group x time interaction.

Aim 2: We will use generalized linear mixed-effects models to examine the effects of a designed soundscape on nocturnal motor activity and on heart rate variability.

Aim 3: ANOVA (Analysis of variance) will be used to compare the Qualidem scores recorded at baseline and at outcome point 4.

6. CONCLUSION

This research is a pilot single-blind Repeated-Measures RCT to estimate the overall or average treatment effect of the soundscape approach on people with dementia in the hospital setting over the evaluation period of one year. This project will be among the first to use a randomized control trial to precisely evaluate the soundscape intervention.

This pilot study expected to impact the design of soundscape in healthcare facilities for people with dementia from three different views:

From a research perspective, soundscape in healthcare settings is still not investigated in-depth and only through exploratory research in nursing homes. This research will be the primary step to test soundscape in the hospital setting.

From a design aspect, this study will further support the evidence-based approach in healthcare design by bringing clinical data into the design process.

From a soundscape view, this research helps to expand the study of soundscape in healthcare settings by introducing the RCT data collection method, which can be used in other environments.

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