Study protocol for virtual leisure investigating the effect of virtual reality-delivered stress reduction, entertainment and distraction on the use of coercion and need-based medication and patient satisfaction at a closed psychiatric intensive care unit - a mixed-methods pilot clinical trial

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ABSTRACT

Introduction The environment at a psychiatric inpatient ward can lead to emotional distress and behavioural deviations in vulnerable individuals potentially resulting in conflicts, increased use of need-based medication and coercive actions, along with low satisfaction with treatment. To accommodate these challenges, recreational and entertaining interventions are recommended. The tested interventions have, however, shown varying effects and demand a high degree of planning and staff involvement while being difficult to adapt to individual needs. Virtual reality (VR) may help overcome these challenges.

Methods and analysis The study is a mixed-methods clinical trial with a target sample of 124 patients hospitalised at a closed psychiatric ward in the capital region of Denmark. Outcomes (eg, coercion, need-based medication and perceived stress) for a 12-month period where all patients are offered VR-based recreational experiences during their hospitalisation will be compared with outcomes for a 12-month period where VR is not offered. Feasibility and acceptability will be explored with qualitative interviews supplemented with non-participant observations and focus groups. The study began on 1 January 2023, and we expect to complete data collection by 31 December 2024.

Ethics and dissemination The study is registered at Danish Data Protection Agency (j.no P-2022-466) and is approved by the Committee on Health Research Ethics of the capital region of Denmark (j.no 22013313). All patients will be required to provide informed consent. Results from this study will be disseminated via peer-reviewed journals and congress/consortium presentations.

Trial registration number NCT05654740.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The integration of qualitative and quantitative data enables comprehensive assessment of virtual reality (VR) in the context of psychiatric inpatient care.
⇒ The broad selection of VR experiences limits the opportunity to disentangle the active component of VR experiences.

INTRODUCTION

Background

Everyday life in psychiatric inpatient care is characterised by waiting, both alone and together with other patients suffering from various mental disorders, with patients suffering from various disorders such as personality disorders and psychotic illness.1 Patients may be distressed by interaction with other inpatients, by the rules and routines of life on the ward, the amount of leave granted or by the restrictions of involuntary admission, by feeling lonely, being isolated from others and by a lack of stimulation.2 Such an environment can lead to emotional distress and behavioural disturbances, such as acting out, in vulnerable individuals, which may be a cause of conflicts, use of need-based medication, (ie, medication, such as benzodiazepines, antipsychotic medication and sedative hypnotics, that is not taken regularly, but as needed), coercive actions (ie, comprise physical retention, mechanical restraint (belt
fixation) and forced sedation (injecting the patient with sedating medication without their consent) and a low overall satisfaction with staying at the ward.\(^3\) To reduce the use of coercion, recreational and entertaining interventions (ie, more gamified and enjoyable interventions) are generally recommended.\(^4\) Unfortunately, such interventions have shown varying effects on levels of coercion, and the strength of evidence on the effectiveness of such tested interventions is limited.\(^5\) Furthermore, most of the activities demand a high degree of planning and staff involvement and may be difficult to adapt to individual needs.

There is a significant interest in finding alternative non-invasive interventions that may have minimal side-effects and with the potential to reduce the use of need-based medication and coercive actions in mental health services.\(^7\)\(^8\) Research in mental health has shown great potential for the use of virtual reality (VR), which has been found to be an effective tool for the treatment of many psychiatric diagnoses, with minimal side-effects.\(^6\)\(^9\)\(^10\)

However, there is a need to establish evidence on the feasibility and acceptability of VR-based interventions in psychiatric treatment settings, such as hospital inpatient, residential or outpatient settings. VR creates artificial real-time experiences, making the user feel immersed and able to act as if it was the real world and mask outside stimuli. A major advantage of VR is the fact that the mind and body of the users of VR behave as if it is real, even though they know it is not.\(^11\) This may aid in alleviating feelings of confinement in the wards and provide distractions from uncomfortable thoughts that may be stressful to the patient. The availability of VR experiences at a closed psychiatric intensive care unit (PICU) may alleviate patients’ subjectively experienced distress (eg, ruminations, aggressive impulses) by either offering distraction to symptoms or by offering a tool that may aid in stress management (eg, relaxation or mindfulness). This could potentially de-escalate situations that may otherwise result in the use of need-based medication and coercive actions.

Over the past decade, several studies have investigated the effect of VR-based relaxation (ie, relaxation conducted in VR) on stress levels in people with psychiatric problems.\(^11\) Mindfulness is often applied in VR experience to induce relaxation and reduce stress, and appears to be broadly applicable.\(^12\)\(^13\) Learning mindfulness is a skill that can be transferred to many situations, and a recent review found mindfulness carried out in VR to reduce anxiety and depression and improve sleep quality, emotion regulation and mood across a broad range of diagnoses.\(^14\) VR relaxation appears to have a positive effect not only on stress, but also on affective states. For instance, a recent study with outpatients (anxiety, psychotic, depressive or bipolar disorder) found VR-delivered mindfulness to result in immediate improvement on both negative and positive affective states.\(^15\)

Additionally, another study found it to be a promising approach for managing behavioural and psychological symptoms in patients with dementia during acute care.\(^16\) Another interesting application of VR, distraction by playing games, has also proven its efficacy in health settings as a meta-analysis found VR to be an effective distraction-based intervention to reduce pain and anxiety in children undergoing medical procedures.\(^17\)

VR simulations are often enjoyable\(^18\) and are generally considered fun by patients even when painful stimuli are experienced at the same time.\(^19\)\(^20\) Thus, VR can potentially provide the opportunity of an enjoyable experience (be that relaxing or entertaining) during an otherwise stressful period.

Applying VR for recreational use in the form of stress reduction, entertainment and distraction could provide an alternative to regular practice that can be planned more flexibly and demand a reduced number of resources compared with in vivo. This notion is supported by preliminary findings from a study investigating the feasibility and tolerability of VR in a PICU, which demonstrated that VR can be used and tolerated within the high-stress environment.\(^21\) However, the application of a broad selection of recreational VR experiences (comprising both stress reduction, entertainment and distraction) with the aim to decrease coercive actions and need-based medication, and improve overall satisfaction at a closed PICU has not been thoroughly explored.

**Aim and hypotheses**

The aim of the current study is to identify whether the availability of a broad selection of diverse VR experiences comprising stress reduction, entertainment and distraction is feasible and acceptable and can reduce number of coercion, use of need-based medication and increase patient satisfaction at closed PICUs. We hypothesise that (1) VR-based experiences will be feasible and acceptable for patients at a PICU; (2) the availability of VR-based experiences will decrease the number of coercive interventions, use of need-based medication and increase overall patient satisfaction at the PICU in a 12-month period with VR experiences available compared with a 12-month period when these are not available.

**METHODS AND MATERIALS**

**Study design**

The study is a clinical trial, employing a mixed-methods design, enrolling patients hospitalised at a closed PICU in the capital region of Denmark. Qualitative interviews will be conducted with a subsample of patients and staff to elucidate the subjective experiences of VR from both a patient and health professional perspective and to evaluate feasibility and acceptability. This comprises situations in which the VR-based experiences are indicated and potentially contraindicated. To further assess patients’ behaviour and patient–staff interaction and communication in relation to the use of VR, repeated non-participant observations will be performed. Quantitative measures will be used to compare outcomes for a 12-month period where all patients are offered VR experiences at least daily.
(and repeatedly, with similar amounts of time between one time and the next) with outcomes for a 12-month period with no availability of VR experiences.

Comparing outcomes for the same ward with and without VR available makes us able to control for variables that potentially affect the outcome. It also entails a low selection bias, as there is no reason to expect any systematic difference in the participating patients in the two periods. The study began on 1 January 2023, and we expect to complete data collection on 31 December 2024.

**Participants**

The study will enrol all patients referred for inpatient admission at a specified closed PICU in the capital region of Denmark. The ward treats a broad selection of patients with different psychiatric disorders such as schizophrenia spectrum disorders, affective disorders (such as depression and anxiety) and personality disorders (such as borderline personality disorder). The ward is scaled to accommodate 13 inpatients and has an average hospitalisation period of 8 weeks per patient. All inpatients will be approached about participating in this clinical trial, and will be offered VR-based stress reduction, entertainment and distraction regularly during their hospitalisation.

**Inclusion criterion**

1. Ability to give informed consent.

**Exclusion criteria**

1. Significantly impaired vision hindering engagement in VR experiences.
2. Head injury.

We have kept the criteria at a minimum to have the participants be as representative of the PICU as possible.

**Sample size**

The ward is scaled to accommodate 13 inpatients and has an average hospitalisation of 8 weeks for each patient. Thus, the expected number of patients during the two periods is approximately 156 in total. Based on previous studies in our research group, and on high patient interest conveyed through conversations with both patients and staff, we expect to enrol 80% (N=62) of patients in each 12-month study period, resulting in a total N=124. Thus, the study will have approximately 62 patients in the experimental VR condition and 62 patients in the control condition without VR. Based on data from similar wards, we estimate approximately 77 occurrences of coercion for a group of 62 patients over a period of 12 months. With the expected N, we will then have 80% power to detect, at alpha=0.05, an incidence rate ratio of 0.688, corresponding to a reduction to 53 or fewer occurrences of coercion for a group of 62 patients exposed to VR experience. This corresponds to a reduction rate of 31%. This is in line with what previous studies have considered relevant. For instance, an evaluation of a Safewards trial found reduced seclusion rates by 36% which the authors considered significant and high enough to recommend implementation. A similar study analysing data from cluster randomised controlled trial reported an estimated 15% decrease in conflict and 26.4% decrease in containment, which the authors considered being a demonstrable impact on conflict and containment rates.

**Analyses**

**Qualitative analyses**

Using a semistructured, theme-driven interview guide, qualitative interviews will be conducted in a subsample of up to 20 patients to evaluate feasibility and acceptability of the VR experiences. The interviews will be carried out in line with the theoretical framework of acceptability. In this framework, acceptability is conceived as a multifaceted construct that reflects the extent to which people delivering or receiving a healthcare intervention consider it to be appropriate, based on anticipated or experienced cognitive and emotional responses to the intervention. The interview guide also explores if the use of VR has prevented compulsive situation or avoided the need of more need-based medication. Furthermore, the interview guide seeks to cover how the patients relate to the practical feasibility of VR: self-reported (sequence of) consumption, case of use and why they have or have not used. We will also carry out focus group interviews with up to 10 health professionals for the ward on the use of VR in a PICU exploring their experiences with and views on safety, immersion, realism in the virtual environment, general issues with the technology and their views on VR as an alternative to standard practice. All interviews are to be audio-recorded and transcribed. The interviews will be analysed by means of qualitative content analysis, which will be performed by two coders, meaning that two researchers will assign codes independently.

To access patients’ behaviour and patient–staff interaction and communication in relation to the use of VR, allowing a more comprehensive description and understanding of the VR-induced change processes, non-participant observations will be performed four to six times. Each observation will be 2–6 hours and preferably cover both day and night-time, as well as both weekend and workday. Short, informal conversations will be held with patients and/or staff in relation to the observations if possible. Observations will be carried out on the basis of semistructured observational guidelines and include field notes.

**Quantitative analyses**

Independent t-tests and interrupted time series analyses will be used to evaluate differences regarding effect outcomes. Interrupted time series analyses employ Poisson regression to estimate the development of incidence rates of various outcomes before, during and after the study period, and can thus test if there is a slope change (does the development over time change speed)
and/or a level change (does the introduction of the intervention immediately affect outcome). Under the assumption that no other substantial societal changes occur at the exact same time with an effect on the outcomes in question, a slope or level change at the time of introduction of the intervention will imply an effect of the intervention.25 Interrupted time series are powerful tools for analysing the effects of natural experiments. In essence, they test whether the development of coercion prior to the intervention differs from the development after the intervention, in terms of either a change in level or slope (or both).

Virtual Reality experiences

The VR experiences will be delivered through a head-mounted display and are user-friendly and self-automated. They are developed by Khora VR and use a setup with a Lenovo tablet M10 Lite with Pico G24K enterprise and Oculus Quest 2 VR headsets. The software consists of the Khora Exposure platform software, which is hosted at AWS (Amazon Web Service) with AWS CDN (Cloudfront), securing optimal performance worldwide. All AWS services are ‘General Data Protection Regulation’ (GDPR) compliant (referring to EU-rules of exchange-regulations). We use RSA-1024 to sign or encrypt parts of the API communication, which is not a proprietary method (non-standard). The VR system has an inbuilt feature logging the use of the equipment, hence providing estimates of how often the VR programmes are used in clinical practice. The VR headsets do not contain any personal data by default. It is only the date of using the system and the content of the VR experience being displayed that is logged. These logs will be evaluated by the researchers involved in the study at a weekly basis. If periods (2 days or more) are encountered without use of the VR programmes, the PICU will be contacted to ensure a regular use of the system.

There are a wide number of VR experiences of varying duration covering stress reduction, entertainment and distraction. These include both active (experiences with an element of interaction including games, drawing and walking around) and passive (non-interactive experiences, such as mindfulness) experiences. The active experiences have the possibility of being cast to a screen (on the patient’s request) so others can watch. The active experiences aim for the user to interact with the VR programme and provide distraction and entertainment. These include Lightsaber game (hitting flying objects with lightsabers out in space), Nature treks and Tiltbrush. The passive experiences provide distraction and stress reduction (including mindfulness with both a focus on internal state and a focus on ‘external’ stimuli in the VR experience) and comprise the following experiences: beach with either breathing exercises, or calming music and waves; northern light with guide; a quiet forest with calming music or with trickling stream and birdsong; desert with music; mindfulness in the woods with guide; a visit to the city of Copenhagen or Copenhagen Zoo or the North Sea; history walk in the city of Helsingor; Tour de France Denmark, dive at coral reefs and skydiving.

All clinical staff will be trained in applying the VR equipment and assisting patients in the use of it. They will be educated in being attentive to indications for when it is recommendable to propose it to patients. Patients will be offered the VR experiences in situations prompting the use of distraction, stress reduction/mindfulness or merely needing entertainment. The indications for using VR mindfulness and distraction can be patients feeling distress caused by their psychiatric symptoms such as anxiety, restlessness, depressive ruminations/suicidal ideations or if they have a need to ‘burn off’ energy. VR experiences can also potentially de-escalate situations where the patient for instance shows subtle aggressive tendencies that can result in serious harmful behaviour from the patient towards him/herself or others and prompt the use of need-based medications or coercive actions. However, if the patient is severely agitated (e.g., show aggressive behaviour), it is not considered advisable or feasible to use VR experiences. If the patients are too agitated for the VR experiences to be recommended, the staff will propose suitable interventions according to standard practice at the ward, for example, need-based medication. The VR experiences could be instigated when patients are restless and long for activities or are hospitalised for a longer period (weeks) and possibly start feeling isolated possibly with a need to maintain a sense of connection with the outside society.

Ethics and dissemination

The study is registered at Danish Data Protection Agency (j.no P-2022-466) and is registered at ClinicalTrials.gov (NCT05654740) and is approved by the Committee on Health Research Ethics of the capital region of Denmark (j.no 22013313). VR therapy is generally well tolerated and with minimal or no side-effects or adverse events.26 There are, though, few reports on cyber sickness caused by the VR therapy.27 Side-effects and adverse events will be monitored and recorded throughout the study period. Any adverse events will be reported to the Committee on Health Research Ethics of the capital region of Denmark. All participants will be asked to sign informed consent. It will be emphasised that the participants are free to leave the study at any time without it having any consequences for their further psychiatric treatment. The study will be carried out in accordance with guidelines from the Danish Committee on Health Research Ethics.

Dissemination

Our dissemination plans include presentations at international scientific meetings and publications in peer-reviewed journals.

Patient and public involvement

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research.
STUDY PROCEDURES: ASSESSMENTS

Primary outcomes
Feasibility and acceptability of the VR experiences.
1. Acceptability
   a. ≥80% of the inpatients’ consent to participating in the study.
   b. Acceptability will be further assessed by qualitative interviews with patients and staff.
2. Feasibility
   a. Feasibility will be assessed by qualitative interviews with patients and staff.

Secondary outcomes
3. Assessment of the effect of the intervention
   a. Use of coercions that comprise physical retention, mechanical restraint (belt fixation) and forced sedation (injecting the patient with sedating medication without their consent).
   b. Use of need-based medication (benzodiazepines, antipsychotic medication and sedative hypnotics).
   c. Patients’ satisfaction is assessed at discharge from hospital with the 8-item Client Satisfaction Questionnaire.28

Exploratory outcomes
4. Assessment of the effect of the intervention
   a. Global perceived level of stress over the past week is assessed at discharged from hospital with the Perceived Stress Scale, assessing the degree to which situations are appraised as stressful. It includes 10 items that are designed to tap how unpredictable, uncontrollable and overloaded respondents find their lives.29
   b. Distress before and after using the VR experiences as measured by the Subjective Units of Distress Scale rating intensity of feelings and other internal experiences, such as anxiety, anger, agitation, stress or other painful feelings.30
   c. Number of days hospitalised. Registered as part of standard procedure at discharge.
   d. Risk of violence within the next 24 hours. Measured three times a day with the Brøset Violence Checklist (BVC) as part of standard procedure. The BVC assesses the patient’s behaviour on: irritability, noisy behaviour, physical threats, verbal threats, attacks on things or objects.31

DISCUSSION
The current study will provide important information on the use of VR experiences for psychiatric inpatients and may expand the intervention options for this patient group. The integration of qualitative and quantitative data enables/secures comprehensive assessment of (the use of) VR in the context of psychiatric inpatient treatment/care. We do, however, acknowledge that the study does employ a broad selection of VR experiences limiting the opportunity to disentangle the active component of VR experiences, if found effective. To conclude, if the VR intervention is found effective in a psychiatric inpatient setting, it may provide an important incentive for its use in psychiatric treatment facilities more broadly. Thus, if VR experiences are found to be an effective, non-invasive intervention that can be adapted to individual needs with no or minimal side-effects, it may benefit a large group of patients.

Future studies may explore the impact of factors such as diagnoses and symptoms as well as the potential differential impact of the different types of VR experiences.

REFERENCES


