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Design of the Virtual Leisure pilot Study - Virtual reality delivered stress reduction, entertainment, and distraction at a closed psychiatric intensive care unit

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The Virtual Leisure Study

Design of the Virtual Leisure pilot Study - Virtual reality delivered stress reduction, entertainment, and distraction at a closed psychiatric intensive care unit

Lars Clemmensen1*, Gry Jørgensen1, Kristina Ballestad Gundersen1, Lisa Charlotte Smith1, Julie Midtgaard Klausen2, Stéphane Bouchard3, Christina Plambøck Thomsen4, Louise Turgut4, Louise Birkedal Glenthøj1,5.

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* corresponding author

ABSTRACT

Background: The environment at a psychiatric in-patient ward can lead to emotional distress and behavioral 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: The study is a clinical trial, employing a mixed-methods design, enrolling 124 patients hospitalized at two closed psychiatric wards in the capital region of Denmark. All patients will be
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offered VR-based recreational experiences during their hospitalization. Feasibility and acceptability will be explored with qualitative interviews supplemented with non-participants observations and focus groups. The effect of the intervention will be assessed by comparing quantitative outcomes (e.g., coercion, need-based medication, and perceived stress) for a six-month period with VR-experiences available to a six-month period without. The periods will be in reversed order in the wards.

Discussion: It is of significant interest to find non-intrusive interventions with minimal side-effects that may provide an alternative to pharmacological interventions and coercive actions in mental health services. If the VR-intervention is found to be feasible and acceptable a larger study can be initiated and if found to be effective in an in-patient setting, it can be scaled for use in psychiatric treatment facilities in general where it may benefit a large group of patients.

Trial registration: NCT05654740

1. INTRODUCTION

1.1. Background

Everyday life in psychiatric inpatient care can be described as an environment where routines and rules are inconsistent meanwhile also offering safety. Time spent is characterized by waiting, both “in loneliness” and “in togetherness” with patients suffering from various mental disorders. Such an environment can lead to emotional distress and behavioral disturbances, such as acting out, in vulnerable individuals, which may be a cause of conflicts, use of need-based medication, coercive actions, and a low overall satisfaction with treatment. To reduce the use of coercion, recreational and entertaining interventions are generally recommended. Unfortunately, such interventions have
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shown varying effects on levels of coercion, and the strength of evidence is limited. 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-intrusive interventions in mental health
services that may have minimal side-effects and may reduce the use of need-based medication and
coercive actions. The use of Virtual Reality (VR) in mental health treatment has shown promising
results from studies in diverse psychiatric populations such as schizophrenia, eating disorders,
personality disorders, and anxiety disorders. However, there is a need to establish evidence on the
feasibility, and acceptability of VR based interventions in different psychiatric populations and
treatment settings. The potential for using VR in mental health research, and treatment is great, and
has been found to be an effective tool for the treatment of many psychiatric diagnoses, with minimal
side effects. VR creates artificial real-time experiences, making the user feel immersed and able
to act as if it was the real world and “block out” outside stimuli. A major advantage of VR is the fact
that the mind and body of the user of VR behave as if it is real, even though they know it is not. 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 easy availability of VR experiences
at a closed ward is hypothesized to alleviate patients subjectively experienced distress (e.g.,
ruminations, aggressive impulses) by either offering distraction to symptoms or by helping the
individual become calmer and more mindful. This may 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 on stress
levels in people with psychiatric problems specifically. Stress is a transdiagnostic factor that has
be related to both onset, course, and recurrence of mood, anxiety, and psychotic disorders, and hence an important area of focus. Mindfulness is among the most commonly applied types of VR relaxation and appears to be broadly applicable. Learning mindfulness is a skill that can be transferred to many situations, and a recent review found VR mindfulness to reduce anxiety and depression and improve sleep quality, emotion regulation, and mood. VR relaxation appears to have a positive effect not only on stress, but also on affective states. For instance, a recent randomized crossover trial with out-patients (anxiety, psychotic, depressive, or bipolar disorder) found immediate improvement on both negative and positive affective states. Additionally, another study found it to be a feasible approach for managing behavioral and psychological symptoms in patients with dementia during acute care. VR distraction has also proven its efficacy in health settings as a meta-analysis found VR to be an effective distraction intervention to reduce pain and anxiety in children undergoing medical procedures.

Finding non-invasive, non-pharmacological interventions that can effectively improve individual satisfaction with treatment and reduce the use of need-based medication and coercion is of the utmost importance. The enjoyable properties of VR as well as its ability to “block out” outside stimuli can assist in diverting attention from uncomfortable sensations or thoughts that could otherwise escalate and result in coercion or need for medication. 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 for lesser costs. VR simulations are often enjoyable, and are generally considered fun by patients even when painful stimuli are experienced at the same time. Thus, VR can potentially provide the opportunity of an enjoyable experience (be that relaxing or entertaining) during an otherwise stressful period. The fun and entertaining aspects of VR may also increase engagement and thereby the probability that the patients in fact uses the scenarios.
The findings on VR in mental health are generally positive and a pilot study on the feasibility and
tolerability of VR in a closed Psychiatric Intensive Care Unit (PICU) demonstrated that VR can be
used and tolerated within the high-stress environment. 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, need-based medication and improve overall
satisfaction at a closed PICU has not been satisfactorily explored.

1.2 Aim and hypotheses

The aim of the current study is to identify whether multiple VR experiences comprising stress
reduction, entertainment, and distraction are feasible and acceptable and can reduce number of
coercions, use of need-based medication, and increase treatment satisfaction at closed PICUs. We
hypothesize that 1) VR-based experiences will be feasible and acceptable for patients at a PICU. 2)
VR-based experiences will decrease coercions, use of need-based medication, and increase overall
satisfaction with treatment at a PICU.

2. METHODS AND MATERIALS

2.1 Study design

The study is a clinical trial, employing a mixed-methods design, enrolling patients hospitalized at two
closed PICUs 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. To further assess
patients’ behavior 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
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compare outcomes for a six-month period where all patients are offered VR experiences regularly to
outcomes for a six-month period with no availability of VR experiences. The order of the two periods
will be opposite in the two wards. Comparing outcomes for the same wards 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.

2.2 Participants

The study will enroll all patients allocated to treatment at two specified closed PICUs in the capital
region of Denmark. These wards treat a broad selection of patients with different psychiatric disorders
such as schizophrenia spectrum disorders, affective disorders, and personality disorders. The wards
are both scaled to accommodate 13 in-patients and has an average hospitalization of 8 weeks for each
patient. All in-patients will be approached about participating in this clinical trial, and will be offered
VR based stress reduction, entertainment, and distraction regularly during their hospitalization.

Inclusion criteria

1. Ability to give informed consent

Exclusion criteria

1. Significantly impaired vision hindering engagement in VR experiences

2.3 Sample size and qualitative and statistical analyses

The two wards are scaled to each accommodate 13 in-patients, and both have an average
hospitalization of 8 weeks for each patient. Thus, the expected number of patients during the two
periods are approximately 156 in total. We expect to enroll 80% (N=62) of patients in each six
months study period, resulting in a total N=124. Thus, the study will have 62 subjects in the
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1 experimental VR condition and 62 subjects in the control condition without VR. Based on data from
2 two similar wards we estimate approximately 77 cases of coercions for a group of 62 patients over a
3 period of 6 months. With the expected N we will then have 80% power to detect, at alpha=0.05, an
4 incidence rate ratio of 0.688, corresponding to a reduction to 53 or fewer cases of coercion for a group
5 of 62 patients exposed to VR-experience, which could be considered a clinically relevant reduction.
6 The study will use a mixed-methods design. Qualitative analyses with patients and staff at the PICUs
7 will be conducted to elucidate on the feasibility and acceptability of the VR-based experiences. This
8 comprises situations in which the VR-based experiences are indication and potentially contra-
9 indicated.
10
11 Using a semi-structured, theme-driven interview-guide qualitative interviews will be conducted in a
12 subsample of 20 patients to evaluate feasibility and acceptability of the VR experiences. The
13 interviews will be carried out in line with the theoretical framework of acceptability. In this
14 framework acceptability is conceived as a multi-faceted construct that reflects the extent to which
15 people delivering or receiving a healthcare intervention consider it to be appropriate, based on
16 anticipated or experienced cognitive and emotional responses to the intervention 25. Furthermore, the
17 interview guide seeks to cover how the patients relate to the practical feasibility of VR: self-reported
18 (sequence of) consumption, ease of use and why they have or have not used it. We will also carry out
19 focus group interviews with 10 health professionals for the two wards on the use of VR in a PICU
20 exploring their experiences with and views on safety, immersion, realism in the virtual environment,
21 general issues with the technology, and their views on VR as an alternative to standard practice. All
22 interviews are to be audio-recorded and transcribed. The interviews will be analyzed by means of
23 qualitative content analysis, which will be performed by two coders, meaning that two researchers
24 will assign codes independently.
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To access patients’ behavior 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 4-6 times. Each observation will be 2-6 hours and preferably cover both day and nighttime, 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 semi-structured observational guidelines and include field notes.

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.

2.4. 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 uses a setup with a Lenovo tablet M10 Lte 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 GDPR compliant. We use RSA-
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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 programs 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 (two days or more) are encountered without use of the VR
programs, the PICU will be contacted to ensure a regular use of the system.

The applied VR environments include both active and passive experiences. The active experiences
aim for the user to interact with the VR program 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 mindfulness (including both with a focus
on internal state and a focus on “external” stimuli in the VR experience) and include the following
experiences in nature and cities: 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 behavior 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 behavior) it is not considered advisable or feasible to use VR experiences. The VR entertainment could be instigated when patients experience lack of activities or are hospitalized for a longer period (weeks) and need to maintain a sense of connection with the outside society.

3. STUDY PROCEDURES

3.1. Assessments

Primary outcomes:

1. Feasibility and acceptability of the VR experiences

   1. Acceptability
      a. ≥80% of the in-patients’ 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, i.e., comprise physical retention, mechanical restraint (belt fixation) and forced sedation (injecting the patient with sedating medication without their consent). Ward level data will be extracted weekly.
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b. Use of need-based medication (benzodiazepines, antipsychotic medication, and sedative hypnotics). Ward level data will be extracted weekly.

c. Patients satisfaction with treatment (The Client Satisfaction Questionnaire) filled out at discharge

4. Exploratory outcomes

Assessment of the effect of the intervention

a. Global perceived level of stress over the past week as measured by the Perceived Stress Scale, assessing the degree to which situations are appraised as stressful.

b. Distress before and after using the VR experiences as measured by the Subjective Units of Distress Scale (SUDS) rating intensity of feelings and other internal experiences, such as anxiety, anger, agitation, stress or other painful feelings.

c. Number of days hospitalized. 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 behavior on: irritability, noisy behavior, physical threats, verbal threats, attacks on things or objects.

4. DISCUSSION

The current study will provide important information on the use of VR experiences for psychiatric in-patients 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
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effective in a psychiatric in-patient setting, it may provide an important incentive for its use in psychiatric treatment facilities more broadly. Thus, VR experiences may benefit a large group of patients if it is found to be an effective, non-intrusive intervention that can be adapted to individual needs with no or minimal side-effects.

5.1 Ethics approval and consent to participate

The study is registered at Danish Data Protection Agency (j.no P-2022-466) and is registered at clinicaltrial.gov (MHSCRDenmark record 1000; 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. There are, though, few reports on cyber sickness caused by the VR therapy. 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 Denmark. All participants will be asked to sign informed consent. It will be emphasized 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 on accordance with guidelines from the Danish Committee on Health Research Ethics.

5.2 Consent for publication

Not applicable

5.3 Acknowledgements

Not applicable

5.4 Availability of Data and Material (ADM)

The datasets used and/or analysed during the current study will be available from the corresponding author on reasonable request.

5.5 Competing Interests
The Virtual Leisure Study

1 Stéphane Bouchard is president and part owner of In Virtuo, a company that distributes virtual environments (although not those used in the current study), and conflict of interests are managed under UQO’s conflict of interest policy. No other authors declare competing interests.

5.6 Funding

5 The study received no funding.

5.7 Authors' contributions

7 LC wrote the main manuscript text. GJ wrote the section on qualitative aspects of the study. LC, LBG, CPT and LT developed the idea for the study. All authors reviewed the manuscript.

5.8 Patient and Public Involvement

10 Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research.

References


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1 2017;17(1):88. doi:10.1186/s12913-017-2031-8
6 2002;106(SUPPL.S412):103-105. doi:10.1034/j.1600-0447.106.s412.22.x
SPIRIT 2013 Checklist

Title 1 Design of the Virtual Leisure pilot Study - Virtual reality delivered stress reduction, entertainment, and distraction at a closed psychiatric intensive care unit

Trial registration 2 The study is registered at clinicaltrial.gov (MHSCRDenmark record 1000)

Protocol version 3 November 25th 2022 vers 1.0

Funding 4 The study received no funding. Virtual Reality equipment is provided by KhoraVR

Roles and Responsibilities 5a Names, affiliations, and roles of protocol contributors: Lars Clemmensen1, Gry Jørgensen1, Kristina Ballestad Gundersen1, Lisa Charlotte Smith1, Julie Midtgaard Klausen2, Stéphane Bouchard3, Christina Plambock Thomsen4, Louise Turgut4, Louise Birkedal Glenthøj1,5.

1VIRTU research Group, Copenhagen Research Center on Mental Health, Copenhagen University Hospital, Denmark. 2Center for applied research in mental health care (CARMEN), Mental Health Center Glostrup, Denmark. 3Département de psychoéducation et de psychologie, Université du Québec en Outaouais, Gatineau, Canada 4Mental Health Center Glostrup, Denmark 5Department of Psychology, University of Copenhagen, Copenhagen, Denmark

LC wrote the main manuscript text. GJ wrote the section on qualitative aspects of the study. LC, LBG, CPT and LT developed the idea for the study. All authors reviewed the manuscript.

Background and rationale 6a In the background section of the ms

6b In the background section of the ms

Objectives 7 The aim of the current study is to identify whether multiple Virtual Reality (VR) experiences comprising stress reduction, entertainment, and distraction are feasible and acceptable and can reduce number of coercions, use of need-based medication, and increase treatment satisfaction at closed psychiatric intensive care units (PICU)

Trial design 8 The study is a clinical trial, employing a mixed-methods design, enrolling patients hospitalized at two closed PICUs 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. To further assess patients’ behavior 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 six-month period where all patients are offered VR experiences regularly to outcomes for a six-month period with no availability of VR experiences.

Study setting 9 The study will be set at two specified closed PICUs in the capital region of Denmark. These wards treat a broad selection of patients with different psychiatric disorders such as schizophrenia spectrum disorders, affective disorders, and personality disorders.
Eligibility criteria

Patients admitted at one of the two specified wards at meeting the following criteria will be eligible for participation. Inclusion criteria: Ability to give informed consent. Exclusion criteria: Significantly impaired vision hindering engagement in VR experiences.

Interventions

Interventions for each group with sufficient detail to allow replication, including how and when they will be administered: Patients will be offered VR experiences in situations prompting the use of distraction, stress reduction, 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 behavior 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 behavior) it is not considered advisable or feasible to use VR experiences. The VR entertainment could be instigated when patients experience lack of activities or are hospitalized for a longer period (weeks) and need to maintain a sense of connection with the outside society.

Criteria for discontinuing or modifying allocated interventions for a given trial participant: N/A

Outcomes

See assessment section of the ms

Participant timeline

Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants: All patients will be invited to participate at admission and ask to sign informed consent. Participating patients will be offered VR regularly during their stay and will be asked to answer the SUD questionnaire before and after each use of VR. Once a week they will be asked to fill out the PSS, and the CSQ at discharge.

The two wards are scaled to each accommodate 13 in-patients, and both have an average hospitalization of 8 weeks for each patient. Thus, the expected number of patients during the two periods are approximately 156 in total. We expect to enroll 80% (N=62) of patients in each six months study period, resulting in a total N=124. Thus, the study will have 62 subjects in the experimental VR condition and 62 subjects in the control condition without VR. Based on data from two similar wards we estimate approximately 77 cases of coercions for a group of 62 patients over a period of 6 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 cases of coercion for a group of 62 patients exposed to VR-experience, which could be considered a clinically relevant reduction.

Recruitment

All in-patients will be approached at admission by the staff members at the ward about participating in this clinical trial.

Data collection methods

See assessment section in ms

No outcome data will be collected for participants who discontinue or deviate from intervention protocols.
## Data management

19. Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol:

Assessments (interviews and questionnaires) will be carried out at the wards. Data on paper notes is stored locally and secured, and subsequently entered electronically in the Research Electronic Data Capture (REDCap). All study data will be collected and managed using REDCap tools hosted at the mental health services in the Capital Region of Denmark. REDCap is a secure, state-of-the-art web-based application designed to support data capture for research studies and is in accordance with the Danish legislation for the storage of personal data (Datatilsynet). Trial managers and research assistants are the only ones who can access data in REDCap. Research data will be exported without personal identification markers to all well-known software packages (SPSS, SAS, Stata, R) and stored in logged folders on a network drive under the control of the Capital Region, CIMT. A data manager will ensure that all variables are properly defined with variable and value labels. All derived variables and algorithms will be kept in separate files. Data will be examined for errors in data entry.

## Statistical methods

20a. 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

20b. Methods for any additional analyses: N/A

20c. Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation): Missing data will be handled by multiple imputations.

## Data monitoring

21a. Composition of data monitoring committee (DMC); summary of its role and reporting structure: As the trial has minimal risks, there will be no Data Monitoring Committee (DMC).

21b. N/A

## Harms

22. 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 Denmark.

## Auditing

23. N/A

## Research ethics approval

24. The study is approved by the committee on health research ethics of the capital region of Denmark (j.no 22013313).

## Protocol amendments

25. N/A
Consent or assent 26a All in-patients will be approached by the staff members at the ward about participating in this clinical trial, and will be asked to sign informed consent. It will be emphasized that the participants are free to leave the study at any time without it having any consequences for their further psychiatric treatment.

Confidentiality 27 Outcome variables will not be linked to specific participants.

Declaration of interests 28 Stéphane Bouchard is president and part owner of In Virtuo, a company that distributes virtual environments (although not those used in the current study), and conflict of interests are managed under UQO’s conflict of interest policy. No other authors declare competing interests.

Access to data 29 The datasets used and/or analyzed during the current study will be available from the corresponding author on reasonable request.

Ancillary and post-trial care 30 The study is covered by The Patient Compensation Association.

Dissemination policy 31a A trial protocol has been published at www.clinicaltrials.gov. This will ensure that the project is conducted and analysed as planned. Possible deviations and reasons for those will be described in publications. All data published will be verified for authenticity by controlling for internal inconsistency. All results, positive, negative as well as inconclusive, will be published as quickly as possible and still in concordance with Danish law on the protection of confidentiality and personal information. Results will be presented at national and international scientific conferences.

31b Authorship in accordance with standard guidelines

31c No plans for granting public access to the full protocol, participant-level dataset, and statistical code
Study protocol for Virtual Leisure - a mixed methods pilot clinical trial 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

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<td>clemmensen, lars; Copenhagen Research Centre for Mental Health Jørgensen, Gry; Copenhagen Psychiatric Center Gundersen, Kristina; Copenhagen Research Centre for Mental Health Smith, Lisa Charlotte; Copenhagen Research Centre for Mental Health Midtgaard, Julie; Mental Health Services CPH, Mental Health Centre Glostrup; University of Copenhagen Faculty of Health and Medical Sciences, Department of Clinical Medicine Bouchard, Stephane; University of Quebec Thomsen, Christina Plamböck; mental health center glostrup Turgut, Louise; mental health center glostrup Glenthøj, Louise Birkedal; Mental Hlth Ctr Copenhagen</td>
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<td>Secondary Subject Heading:</td>
<td>Mental health</td>
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<td>Keywords:</td>
<td>PSYCHIATRY, Adult psychiatry &lt; PSYCHIATRY, Schizophrenia &amp; psychotic disorders &lt; PSYCHIATRY, Anxiety disorders &lt; PSYCHIATRY</td>
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The Virtual Leisure Study

Study protocol for Virtual Leisure - a mixed methods pilot clinical trial 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

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ABSTRACT

Introduction: The environment at a psychiatric in-patient ward can lead to emotional distress and behavioral 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-method clinical trial with a target sample of 124 patients
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1 hospitalized at a closed psychiatric ward in the capital region of Denmark. Outcomes (e.g., coercion, need-based medication, and perceived stress) for a 12-month period where all patients are offered VR-based recreational experiences during their hospitalization will be compared to 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 January 1st, 2023, and we expect to complete data collection by December 31st, 2024.

Ethics and dissemination: The study is registered at Danish Data Protection Agency (j.no P-2022-466) and is registered at clinicaltrial.gov (NCT05654740) 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.

Strengths and limitations:

- The integration of qualitative and quantitative data enables comprehensive assessment of 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.

1. INTRODUCTION
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1.1. Background

Everyday life in psychiatric inpatient care is characterized 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 in-patients, 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 behavioral disturbances, such as acting out, in vulnerable individuals, which may be a cause of conflicts, use of need-based medication, (i.e. medication such as benzodiazepines, antipsychotic medication, and sedative hypnotics, that is not taken regularly, but as needed), coercive actions (i.e. 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 (i.e. more gamified and enjoyable interventions) are generally recommended(4,5). 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 (6). 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
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diagnoses, with minimal side effects(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(9). 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 (e.g., ruminations, aggressive impulses) by either offering
distraction to symptoms or by offering a tool that may aid in stress management (e.g. 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 (i.e
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 out-patients (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 behavioral and
psychological symptoms in patients with dementia during acute care(16). Another interesting
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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 to in vivo. This notion is supported by preliminary findings from a
study investigating the feasibility and tolerability of VR in a PICU, that 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, need-based medication and improve overall
satisfaction at a closed PICU has not been thoroughly explored.

### 1.2 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 are feasible and acceptable
and can reduce number of coercions, use of need-based medication, and increase patient satisfaction
at closed PICUs. We hypothesize 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
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1 a 12-month period with VR experiences available compared to a 12-month period when these are not
2 available.

3

4 2. METHODS AND MATERIALS

5 2.1 Study design

6 The study is a clinical trial, employing a mixed-methods design, enrolling patients hospitalized at a
7 closed PICUs in the capital region of Denmark. Qualitative interviews will be conducted with a
8 subsample of patients and staff to elucidate the subjective experiences of VR from both a patient and
9 health professional perspective and to evaluate feasibility and acceptability. This comprises situations
10 in which the VR-based experiences are indicated and potentially contra-indicated. To further assess
11 patients’ behavior and patient-staff interaction and communication in relation to the use of VR
12 repeated non-participant observations will be performed. Quantitative measures will be used to
13 compare outcomes for a twelve-month period where all patients are offered VR experiences at least
14 daily (and repeatedly, with similar amounts of time between one time and the next) to outcomes for
15 a twelve-month period with no availability of VR experiences.
16 Comparing outcomes for the same ward with and without VR available makes us able to control for
17 variables that potentially affect the outcome. It also entails a low selection bias, as there is no reason
18 to expect any systematic difference in the participating patients in the two periods. The study began
19 January 1st, 2023, and we expect to complete data collection December 31st, 2024.

20 2.2 Participants

21 The study will enroll all patients referred for inpatient admission at a specified closed PICU in the
22 capital region of Denmark. The ward treats a broad selection of patients with different psychiatric
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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 in-patients and has an average hospitalization period of 8 weeks per patient. All in-patients will be approached about participating in this clinical trial, and will be offered VR based stress reduction, entertainment, and distraction regularly during their hospitalization.

Inclusion criteria

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.

2.3 Sample size

The ward is scaled to accommodate 13 in-patients and has an average hospitalization of 8 weeks for each patient. Thus, the expected number of patients during the two periods are approximately 156 in total. Based on a previous study assessing the feasibility and tolerability of using a VR headset in a PICU that found that 81% of the patients meeting eligibility criteria took part(21), on previous and ongoing VR studies in our research group, and on high patient interest conveyed through conversations with both patients and staff, we expect to enroll 80% (N=62) of patients in each 12-month study period, resulting in a total N=124. Thus, the study will have approximately 62 subjects in the experimental VR condition and 62 subjects in the control condition without VR. Based on data from similar wards we estimate approximately 77 occurrences of coercions for a group of 62 patients
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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(22). A similar study analyzing data from cluster randomized 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(23).

2.4 Analyses

2.4.1 Qualitative analyses

Using a semi-structured, theme-driven interview-guide qualitative interviews will be conducted in a subsample of 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 multi-faceted 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(24). The interview guide also explores if the use of VR has prevented compulsive situation or avoided the needing 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, ease of use and why they have or have not used. We will also carry out focus group interviews with 10 health professionals for the two wards 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
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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 analyzed by means of qualitative content analysis, which will be performed by two coders, meaning that two researchers will assign codes independently.

To access patients’ behavior 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 two to six hours and preferably cover both day and nighttime, 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 semi-structured observational guidelines and include field notes.

2.4.2 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. Interrupted time series are powerful tools for analyzing the effects of natural experiments. In essence, they test whether the development of coercions prior to the intervention...
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differs from the development after the intervention, in terms of either a change in level or slope (or both).

2.5 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 uses a setup with a Lenovo tablet M10 Lte 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 GDPR compliant. 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 programs 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 (two days or more) are encountered without use of the VR programs, 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 patients request) so others can watch. The active experiences aim for the user to interact with the VR program 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
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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 Helsingør; 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 behavior 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 behavior) 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 e.g., need-based medication. The VR experiences could be instigated when patients are restless and long for activities or are hospitalized for a longer period (weeks) and possibly start feeling isolated possibly with a need to maintain a sense of connection with the outside society.
2.6 Ethics and dissemination

The study is registered at Danish Data Protection Agency (j.no P-2022-466) and is registered at clinicaltrial.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 Denmark. All participants will be asked to sign informed consent. It will be emphasized 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.

2.7 Patient and Public Involvement

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

3. STUDY PROCEDURES: ASSESSMENTS

Primary outcomes:

Feasibility and acceptability of the VR experiences

1. Acceptability

a. ≥80% of the in-patients’ consent to participating in the study.

b. Acceptability will be further assessed by qualitative interviews with patients and staff.
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2. Feasibility

a. Feasibility will be assessed by qualitative interviews with patients and staff.

3. Secondary outcomes:

3. Assessment of the effect of the intervention

a. Use of coercions, i.e., 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 discharged 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 (SUDS) rating intensity of feelings and other internal experiences, such as anxiety, anger, agitation, stress or other painful feelings(30).

c. Number of days hospitalized. 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
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patient’s behavior on: irritability, noisy behavior, physical threats, verbal threats, attacks on things or objects(31).

4. DISCUSSION

The current study will provide important information on the use of VR experiences for psychiatric in-patients 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 in-patient 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.

5.2 Consent for publication

Not applicable

5.3 Acknowledgements

Not applicable

5.4 Availability of Data and Material (ADM)
5.5 Competing Interests

Stéphane Bouchard is president and part owner of In Virtuo, a company that distributes virtual environments (although not those used in the current study), and conflict of interests are managed under UQO’s conflict of interest policy. No other authors declare competing interests.

5.6 Funding

The study received no funding.

5.7 Authors’ contributions

LC wrote the main manuscript text. GJ and JMK wrote the section on qualitative aspects of the study. LC, LBG, CPT and LT were responsible for the study concept, design and ethics applications. SB, KBG and LCS made critical inputs. All authors read and approved the final manuscript.

References

8. Bak J, Aggernæs H. Coercion within Danish psychiatry compared with 10 other European


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**SPIRIT 2013 Checklist**

<table>
<thead>
<tr>
<th>Title</th>
<th>1</th>
<th>Design of the Virtual Leisure pilot Study - Virtual reality delivered stress reduction, entertainment, and distraction at a closed psychiatric intensive care unit</th>
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<tr>
<td>Trial registration</td>
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<td>November 25th 2022 vers 1.0</td>
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<tr>
<td>Funding</td>
<td>4</td>
<td>The study received no funding. Virtual Reality equipment is provided by KhoraVR</td>
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<tr>
<td>Roles and Responsibilities 5a</td>
<td></td>
<td>Names, affiliations, and roles of protocol contributors: Lars Clemmensen¹, Gry Jørgensen¹, Kristina Ballestad Gundersen¹, Lisa Charlotte Smith¹, Julie Midtgaard Klausen², Stéphane Bouchard³, Christina Plamboeck Thomsen⁴, Louise Turgut⁴, Louise Birkedal Glenthøj², ⁵. ¹VIRTU research Group, Copenhagen Research Center on Mental Health, Copenhagen University Hospital, Denmark. ²Center for applied research in mental health care (CARMEN), Mental Health Center Glostrup, Denmark, ³Département de psychoéducation et de psychologie, Université du Québec en Outaouais, Gatineau, Canada ⁴Mental Health Center Glostrup, Denmark ⁵Department of Psychology, University of Copenhagen, Copenhagen, Denmark</td>
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<td>Background and rationale</td>
<td>6a</td>
<td>In the background section of the ms</td>
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<td>6b</td>
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<td>Objectives</td>
<td>7</td>
<td>The aim of the current study is to identify whether multiple Virtual Reality (VR) experiences comprising stress reduction, entertainment, and distraction are feasible and acceptable and can reduce number of coercions, use of need-based medication, and increase treatment satisfaction at closed psychiatric intensive care units (PICU)</td>
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<tr>
<td>Trial design</td>
<td>8</td>
<td>The study is a clinical trial, employing a mixed-methods design, enrolling patients hospitalized at two closed PICUs 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. To further assess patients’ behavior 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 six-month period where all patients are offered VR experiences regularly to outcomes for a six-month period with no availability of VR experiences.</td>
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<tr>
<td>Study setting</td>
<td>9</td>
<td>The study will be set at two specified closed PICUs in the capital region of Denmark. These wards treat a broad selection of patients with different psychiatric disorders such as schizophrenia spectrum disorders, affective disorders, and personality disorders.</td>
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Eligibility criteria 10 Patients admitted at one of the two specified wards at meeting the following criteria will be eligible for participation. Inclusion criteria: Ability to give informed consent. Exclusion criteria: Significantly impaired vision hindering engagement in VR experiences.

Interventions 11a Interventions for each group with sufficient detail to allow replication, including how and when they will be administered: Patients will be offered VR experiences in situations prompting the use of distraction, stress reduction, 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 behavior 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 behavior) it is not considered advisable or feasible to use VR experiences. The VR entertainment could be instigated when patients experience lack of activities or are hospitalized for a longer period (weeks) and need to maintain a sense of connection with the outside society.

11b Criteria for discontinuing or modifying allocated interventions for a given trial participant: N/A

Outcomes 12 See assessment section of the ms

Participant timeline 13 Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants: All patients will be invited to participate at admission and asked to sign informed consent. Participating patients will be offered VR regularly during their stay and will be asked to answer the SUD questionnaire before and after each use of VR. Once a week they will be asked to fill out the PSS, and the CSQ at discharge.

14 The two wards are scaled to each accommodate 13 in-patients, and both have an average hospitalization of 8 weeks for each patient. Thus, the expected number of patients during the two periods are approximately 156 in total. We expect to enroll 80% (N=62) of patients in each six months study period, resulting in a total N=124. Thus, the study will have 62 subjects in the experimental VR condition and 62 subjects in the control condition without VR. Based on data from two similar wards we estimate approximately 77 cases of coercions for a group of 62 patients over a period of 6 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 cases of coercion for a group of 62 patients exposed to VR-experience, which could be considered a clinically relevant reduction.

Recruitment 15 All in-patients will be approached at admission by the staff members at the ward about participating in this clinical trial.

Data collection methods 18a See assessment section in ms

18b No outcome data will be collected for participants who discontinue or deviate from intervention protocols.
Data management 19

Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol:

Assessments (interviews and questionnaires) will be carried out at the wards. Data on paper notes is stored locally and secured, and subsequently entered electronically in the Research Electronic Data Capture (REDCap). All study data will be collected and managed using REDCap tools hosted at the mental health services in the Capital Region of Denmark. REDCap is a secure, state-of-the-art web-based application designed to support data capture for research studies and is in accordance with the Danish legislation for the storage of personal data (Datatilsynet). Trial managers and research assistants are the only ones who can access data in REDCap. Research data will be exported without personal identification markers to all well-known software packages (SPSS, SAS, Stata, R) and stored in logged folders on a network drive under the control of the Capital Region, CIMT. A data manager will ensure that all variables are properly defined with variable and value labels. All derived variables and algorithms will be kept in separate files. Data will be examined for errors in data entry.

Statistical methods 20a

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

20b Methods for any additional analyses: N/A

20c Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation): Missing data will be handled by multiple imputations.

Data monitoring 21a

Composition of data monitoring committee (DMC); summary of its role and reporting structure: As the trial has minimal risks, there will be no Data Monitoring Committee (DMC).

21b N/A

Harms 22

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 Denmark.

Auditing 23

N/A

Research ethics approval 24

The study is approved by the committee on health research ethics of the capital region of Denmark (j.no 22013313).

Protocol amendments 25

N/A
Consent or assent

All in-patients will be approached by the staff members at the ward about participating in this clinical trial, and will be asked to sign informed consent. It will be emphasized that the participants are free to leave the study at any time without it having any consequences for their further psychiatric treatment.

Confidentiality

Outcome variables will not be linked to specific participants.

Declaration of interests

Stéphane Bouchard is president and part owner of In Virtuo, a company that distributes virtual environments (although not those used in the current study), and conflict of interests are managed under UQO’s conflict of interest policy. No other authors declare competing interests.

Access to data

The datasets used and/or analyzed during the current study will be available from the corresponding author on reasonable request.

Ancillary and post-trial care

The study is covered by The Patient Compensation Association.

Dissemination policy

A trial protocol has been published at www.clinicaltrials.gov. This will ensure that the project is conducted and analysed as planned. Possible deviations and reasons for those will be described in publications. All data published will be verified for authenticity by controlling for internal inconsistency. All results, positive, negative as well as inconclusive, will be published as quickly as possible and still in concordance with Danish law on the protection of confidentially and personal information. Results will be presented at national and international scientific conferences.

Authorship in accordance with standard guidelines

No plans for granting public access to the full protocol, participant-level dataset, and statistical code.