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Virtual Reality Experience In Long Term Care Resident Older Adults With Dementia: A Case Series

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Abstract

BACKGROUND: Behavioural and psychological symptoms of dementia (BPSD) worsens as dementia progresses, intensifies caregiver distress and consequent institutionalization. We wanted to evaluate feasibility of Virtual Reality (VR) as non-pharmacologic intervention for BPSD in a Long-Term Care (LTC) home.

METHODS: A single site (Henley Place at London, Ontario) case series with a convenience sample (24 older adult residents with moderate to severe dementia). Intervention was 30 minutes of VR experience with Broomx©, five days a week for two weeks. BPSD was measured with Cornell Scale for Depression in Dementia (CSDD), Cohen-Mansfield Agitation Inventory (CMAI) scale, Dementia Observation System (DOS) scale, and proportion of night-time sleep. We validated selected tools with Global Rating of Change (GRC) scale.

RESULTS: Implementing VR experience was possible at Henley Place (recruitment rate=40%, the adherence rate=21%, and the attrition=0%) and participants could tolerate it. No emergency transfers or one-to-one staff use were recorded during the intervention period. BPSD measuring instruments also were sensitive to change.

CONCLUSION: VR experience can be implemented in a LTC home.

TRIAL REGISTRATION: The study was not registered as clinical trial. We obtained ethics approval from ADVARRA Canada Ethics Board before recruiting participants for the study.

Background

Dementia is a progressive neurocognitive condition, predominantly affecting older adults that evolves to disability and, eventually, mortality [1]. There is no cure for dementia [1]. According to the Alzheimer's Association [2], over 747,000 Canadians are living with dementia. The annual dementia incidence rate in Canada was 360 per 100,000 people in 2011 [3]. In 2016, dementia ranked the fifth leading cause of death worldwide [4]. Dementia accounted for 6.3% (95% confidence interval [CI] 5.4% to7.5%) of disability-adjusted life in years for the people aged 70 years and over [5].

Behavioural and psychological symptoms of dementia (BPSD) is common in people with dementia that may include but are not limited to symptoms such as apathy, depression, agitation, aggression, sleep disorders, and psychosis [6, 7]. The most frequent disturbances reported were anxiety/agitation/aggression (52%; 95% CI 47% to 57%), apathy (36%; 95% CI 31% to 41%), depression (32%; 95% CI 28% to 37%), sleep disturbance (27%; 95% CI 23% to 32%) and irritability (27%; 95% CI 23% to 32%) [7]. Lyketsos and colleagues [7] reported 75% (95% CI 70% to 79%) of participants with dementia exhibited at least one BPSD from the onset of their cognitive symptoms. Depression and apathy are common in vascular dementia [8]. Frontotemporal dementia typically presents with gross decline in behaviours (BPSD) and speech/language [9] with disinhibition and eating disturbances being common [8]. In Alzheimer's dementia, delusion is common [8]. Family members of individuals with dementia reported that their loved ones' BPSD are the reason for their decision in placing them in a Long-Term Care (LTC) home [10, 11].

Apathy is characterized by a lack of emotional responsiveness [12]. On the other hand, depression symptoms include loss of energy/interest, change in appetite, impaired concentration, insomnia, sadness, anhedonia, suicidal ideation, self-blame, weight change, sexual disinterest, and hypersomnia [13]. Apathy and depression in individuals with dementia are associated with other behavioural symptoms [14]. For instance, apathy is associated with disinhibition and abnormal motor behaviour, whereas depression is associated with anxiety, agitation, irritability, and hallucinations [14].

Typically, agitation is referred to as inappropriate verbal, vocal, or motor activity that cannot be otherwise explained [15]. Agitation may include rejection of care, noncompliance, uncooperative behaviour, resistance to care, and aggression [16]. Aggression can be explained as deliberate, overt, and harmful acts toward another person, object, organism or one's self

[17]. Possible causes of agitation/aggression in individuals with dementia include pain, medical illness, loneliness, boredom, medication side effects, environmental changes, and fatigue [18].

Sleep disorder in individuals with dementia includes difficulty falling asleep or staying asleep, sleep fragmentation, wandering, and excessive daytime sleepiness [19]. The causes of sleep disorder in individuals with dementia may include disturbances of their circadian rhythm, pain or discomfort, medications, anxiety, and depression [20]. Disturbances in circadian rhythm refer to early sleep onset and offset, late sleep initiation and rise time, and irregular sleep–wake rhythm [21]. The neurodegenerative changes in dementia (deposition of amyloid and tau) can impair melatonin production and release from brain that consequently may affect the circadian rhythm [22]. A five-year retrospective survey on institutionalized individuals with dementia (n=2447) reported sleep disorder as a common complaint (> 50% of cases) in later stages of the condition irrespective of types of dementia [23]. Inadequate or poor-quality night-time sleep can impact a person's daytime functioning and quality of life [24].

According to the *Diagnostic and Statistical Manual of Mental Disorders* (5th ed.) and the World Health Organization, the central concept of psychosis is impaired reality [25. 26]. Hallucinations (without insight into their pathologic nature), delusions, or both are present in psychosis [25, 26]. Psychotic symptoms are less common than depression, agitation, and sleep disorders in individuals with dementia [27]. However, psychosis can be a source of distress for both individuals with dementia and their caregivers [27].

Managing BPSD is often challenging as the causal relationship of the symptoms and pathophysiology is complex [28]. For example, an individual with dementia may exhibit BPSD due to pain necessitating pain management instead of psychotherapy [29]. However, available pharmacotherapies for BPSD has limited effectiveness in terms of possible serious side-effects resulting from multi-morbidity or polypharmacy or age-related altered metabolism [30]. Consequently, BPSD management is increasingly focusing on maintaining an optimal quality of life with non- pharmacotherapies [31]. The Registered Nurses' Association of Ontario best practice guideline on dementia management recommends non-pharmacologic interventions to manage BPSD for individuals with dementia, irrespective of drug treatments received [32]. Various activities (e.g. listening to music, singing, dancing, reading, painting, drawing, cooking, knitting, talking, listening to others, playing with a pet, playing video games, and virtual reality [VR] experience) engaging individuals with mental stimulation, reminiscence, and orientation had been used as non-pharmacologic interventions in clinical setting [33-35].

VR experience is considered a computer-generated non-pharmacologic intervention focusing on sensory stimulation using a virtual environment [35, 36]. An individual using VR can look around or move around in an artificial environment [36]. This technology requires the user to either use a headset or a projector (e.g. BroomX©) to generate realistic images, sounds and other sensations that simulate an user's physical presence in a virtual or imaginary environment [36]. The technology does not need a specialist/technical person to setup the machine, to use the VR program [35] and is cost effective for people with psychotic disorders [37]. A randomized control study in hospitalized patients (n=116) with psychotic disorders found that six months' VR experience improved participants' Quality-Adjusted Life Years (QALY) (effect size [ES]=0.01, 95% CI 0.03-0.07) [37]. The average cost of gained QALY was Euro 42,030 [37].

BroomX© provides an immersive experience with images and sound through a projection device having automatic control to conform the visuals to a 360^0 experience no matter the size of the room, or what furniture is in the room [38]. Unlike other types of VR technology, users of BroomX© can control the distance of images (bringing the image closer for better look) to get an interactive experience and can incorporate customized music with customized images [38].

Individuals with dementia enjoy virtual experiences [35, 39] but its effect can be negligible on emotion (ES=0.1, 95% CI -0.07 to 0.36) and execution of daily activities (ES=0.1, 95% CI -0.3 to 0.49) when provided with a headset without music [40]. To date there is no published research about the use of VR experience with BroomX© as a non-pharmacologic intervention in LTC residents with moderate to severe dementia and BPSD. Therefore, we considered the technology worth exploring and decided to conduct a feasibility pilot in a LTC home.

Our primary objective was to explore the feasibility of VR experience. We evaluated 1) the rate of recruitment, adherence and attrition; 2) participants' tolerance for VR; 3) facilitators and barriers to implementation of VR to achieve that objective. Our secondary objective was to understand whether the instruments used to detect BPSD in the pilot study could detect change when even a small change has occurred. Therefore, we evaluated 1) the sensitivity to change of selected BPSD measuring tools; and 2) the association of those selected tools with a generic (disease non-specific) health scale.

Methods

Study design

A single site case series.

Participants

Older adults (aged ≥ 65 years) residing in a LTC home at London ON Canada with a Cognitive Performance Scale (CPS) score between 3 to 5 and exhibiting at least one BPSD were eligible to participate in this study. Ontario LTC homes regularly evaluate their residents' cognition with CPS score [41]. The CPS includes four areas: memory, decision-making skills, communication and eating [42]. Residents experiencing no difficulties in these four areas score 0, whereas residents having severe memory problems and are unable to make daily decisions or feed themselves or are comatose score 6 on the CPS scale [42]. A CPS score 0 indicates no dementia, whereas a score of 1-2 indicates mild, score of 3 indicates moderate, and score of 4-6 indicates severe dementia [42]. We excluded those diagnosed with epilepsy, those who were blind, at end of life, and unable to communicate in English. We also excluded those having Substitute Decision-Maker (SDM) appointed as Public Guardian and Trustee.

One LTC home staff member identified the possible participants using their CPS score. Once identified, the LTC home staff spoke with participants' SDM face-to-face or by phone to learn if the SDM would agree to be contacted for a possible study participation. Once agreed, we (KC, Research Assistant [RA]) contacted the SDM from November 26, 2018 to January 04, 2019 to recruit participants.

Intervention

The intervention was VR experience using BroomX© technology, introduced in 2017 [43]. The technology uses a MK Player360© hardware and a software [43]. A MK Player360© is a projection device with light and sound control that can provide an immersive experience covering the user's field of vision (180° horizontal view x 120° vertical view) with full high definition resolution [43]. The software provides customized interactive visual and auditory experience accessed by a smartphone app (See Figure 1: Technical information on Broomx©) [43]. The family members informed us about participants' leisure activities, objects of attention, preferences for musical instruments, genres of music, images of nature, and urban scenes. One of us (ASG from Crosswater Digital Media [https://crosswater.net/]) customized the multimedia content of BroomX© smartphone app accordingly and created a multimedia library with pleasing images of nature, set to music (72 beats/minute) for this study.

The maximum duration and frequency of the VR experience (intervention) was 30 minutes, five days a week (Monday to Friday) for two weeks. The timing of the intervention was customized for each participant to avoid their usual lunch time, visiting hours, and nap time. However, the two-week intervention schedule was fixed for the convenience of the project. If a participant missed the intervention for the day for any reason, there was no makeup session on a different day. RA selected the library items for each. If a participant preferred a particular library item, the RA selected that item several times. There was no limit to the frequency or variety of the played library items.

For safety concern, we stopped the intervention if a participant became agitated with a specific VR library item. RA was present inside the intervention area during the VR sessions in case the participant needed assistance with postural balance

and thus reduced the risk of falls. The LTC home staff also were on call during the VR sessions in case of any unforeseen adverse events.

We provided the intervention at the LTC home from November 2018-January 2019.The VR experience was provided using a headset at the beginning of the intervention (November 5-9, 2018) to five participants. We noticed that all five participants felt uncomfortable using the headset as it limited their vision, was too loud, and was heavy. The pilot study was conducted during Ontario flu season. We were obliged to disinfect the headset after each use with a disinfecting liquid, challenging our time management. We did not use headset from then on.

During the second week of the intervention period (November 12-16, 2018), we carried the MK Player360© projector to the participants' own rooms. We plugged the electrical cord from the projector into a working electrical outlet, kept the projector in a vertical position, and used LTC home's Wi-Fi connection to pair the devise with study smartphone. We covered TV with bed sheet, brought down any wall hangings, closed windows and door curtains for a clearer visualization of VR images when setting up MK Player360© projector inside a participant's room. Two participants got agitated when setting up the hardware and software in their own rooms. Our time management also was challenged when assembling/disassembling VR hardware at participant's own room. From that time forward, we assembled MK Player360© projector in a pre-determined area inside the LTC home before starting the VR sessions to accommodate participants' discomfort and practicality of time management.

Outcome Measures and Statistical Methods

Feasibility of VR experience. 1) The rate of recruitment (the proportion of consenting participants to eligible participants over the 6-week recruitment period), adherence (the proportion of participants attending 10 intervention sessions to the number of participants allocated to the intervention) and attrition (the proportion of participants completing the study to the number of participants allocated to intervention).

2) Participants' tolerance for the VR with measures such as the proportion of participants who were able to tolerate at least 80% of the planned sessions, the mean length of participants' VR experience in minutes per session, number of times each type of negative behaviour observed and the proportion of participants who experienced each negative behaviour, number of times each type of positive behaviour was observed and the proportion of participants who experienced each positive behaviour, number of Adverse Events (AE) during the intervention period, health care resources used (i.e. the number of participants requiring transfers to emergency, number of participants requiring one-to-one staff use, psychotropic drug prescription), and change in Euro-Qol 5-Dimention [EQ-5D]) to indirectly indicate their tolerance to VR experience.

According to the Need Driven Behaviour Model [44], an individual with dementia expresses his/her physical/emotional needs or exhibits his/her dementia symptoms through physical/verbal expressions/gestures. Following this model, we labelled the following behaviours as "negative" for this pilot study: agitation, wandering, hitting (including self), kicking, grabbing onto people, pushing, throwing objects, biting, scratching, spitting, hurting self or others, tearing objects or destroying property, making physical/verbal sexual advances, inappropriate dressing or disrobing, intentional falling, eating/drinking inappropriate substance, handling objects inappropriately, hiding objects, hoarding objects, performing repetitive mannerisms, screaming, cursing or verbal aggression, repetitive sentences or questions, strange noises (weird laughter or crying), complaining, constant unwarranted request for attention or help, pulling away/walking away, perseveration of word/repetitive talking, raising tone of voice, resisting, and not eating. We labeled the following behaviours as "positive" based on staff members' experience with the participating LTC home residents for this pilot study: being seated still, being focused, sleeping better than usual during nigh time, being calm, smiling, and communicating verbally/non-verbally.

We defined AE as any event due to being in a VR session leading to emergency transfer, hospitalization, death, a persistent or significant incapacity or substantial disruption of the participants' ability to conduct the activities of daily living following

Code of Federal Regulations [45].

In our judgement, transfers to emergency and one-to-one staff usage indicated acute decline or worsening of a participant's health. For instance, the LTC home may provide a participant one-to-one staffing if he/she causes another individual a physical incident or a sexual incident; becomes physically aggressive (non-manageable) with drug and other therapy; has history of a similar behaviour that ended up on having one-to-one staff usage in the recent past; is in risk of potential self-harm; exhibits an agitated aggressive behaviour or a wandering behaviour; and is at risk of being victimized by another individual. Psychotropic drugs refer to any drug affecting mental processes and behaviour [46]. Psychotropic drugs include, but are not limited to, antipsychotics, antidepressants, antianxiety drugs, mood stabilizers, anticonvulsants, and hypnotics [46]. The EQ-5D scale is a generic quality of life tool, insightful in identifying which dimensions of health are most affected by a given condition or treatment [47]. The tool has five domains: mobility, self-care, usual activities (e.g. work, study, housework, family or leisure activities), pain/discomfort, and anxiety/depression with five possible answers for each domain (1=no problem, 2=slight problem, 3=moderate problem, 4=severe problem, 5=unable to do/extreme problem) [47].

3) Facilitators and barriers to implementation of VR included data on the number of times a library item was selected, whether the SDM was present during the VR sessions, and factors that were observed to be enabling or disabling during the VR experience.

Change in participants' BPSD. 1) We collected the pre-to post (before any VR intervention took place [baseline] and at the end of second week of intervention) change of BPSD and reported the BPSD measuring instruments' sensitivity to change with ES. Sensitivity to change of a tool is its ability to detect change (signal over noise) regardless of whether the change is meaningful to the clinician or decision maker [48]. The most appropriate statistic for sensitivity to change remains a matter of debate [49]. Usually, for a single group index, sensitivity to change is reported using effect size (ES) [50]. ES analysis is based on the assumption that the participants are homogenous at the baseline and may exhibit a change by approximately the same amount over the study period [51]. ES is expressed using a ratio of mean change scores (δx=x2- x1) to the Standard Deviation (SD) of the baseline scores [52].If change has occurred, ES value greater than 1 indicates that the instrument is sensitive to change [52]. As ES can determine the sample size [52] and can facilitate comparison between studies in meta-analyses [53], we selected ES to report the sensitivity to change for this study.

BPSD are usually measured with subjective psychometric tools, originally developed to rate feelings or opinions or attitudes [54]. A systematic review located 83 BPSD tools focusing either on depression (n=46) or irritability (n=37) or non-aggressive agitation (n=26) or anxiety (n=22) or hallucination (n=21) or delusion (n=20) or wandering (n=22) or apathy (n=17) or sleep problems (n=14) [54]. According to Linde and colleagues [54], the frequently used BPSD tools for older adults in clinical settings are the Cambridge Mental Disorders of the Elderly Examination (CAMDEX) [55], the Geriatric Mental State Schedule (GMS)/Automated Geriatric Examination for Computer Assisted Taxonomy (AGECAT) [56], the Apathy Evaluation Scale (AES) [57], the Geriatric Depression Screening scale (GDS) [58], the Neuro Psychiatric Inventory (NPI) [59], Cornell Scale for Depression in Dementia (CSDD) [60], and Cohen-Mansfield Agitation Inventory (CMAI)[61].

For this study, we used CSDD, CMAI, proportion of night-time sleep, and Dementia Observation System (DOS) scale [62] to measure participants' BPSD. Our null hypothesis was that VR experience had no effect on participants' BPSD. We selected CSDD as it is feasible for those with advanced dementia [60] and CMAI as it is applicable for LTC residents [54]. Since Henley Place routinely records residents' night-time sleep as a proportion of the total expected asleep time (8 hours, from 10:00 pm to 6:00 am each night), we opted to measure sleep using methods already in place. We selected DOS as it is designed to be completed by LTC staff members [62].

The 19-item CSDD detects depression in dementia, and includes five domains: mood, behaviour, physical signs, cyclic function, and ideation, from interviews with a caregiver [60]. Each item is rated for severity based on symptoms occurring during the week before the interview on a scale of 0-2 where 0 indicates no symptoms and 2 indicates severe symptoms [60].The interrater reliability (k=0.67) and internal consistency (α=0.84) of the instrument is high [60]. The association

between CSDD and Research Diagnostic Criteria Depression [63] (a scale measuring similar construct) also is strong (r=0.83, p < 0.001) [48].

The 29-item CMAI tool assesses the agitated behaviours within four components: 1) Physical Aggressive (PA), 2) Physical Non-Aggressive (PNA), 3) Verbal Aggressive (VA), and 4) Verbal Non-Aggressive (VNA) [61]. Each behaviour is rated on a 7-point scale of frequency, ranging from the resident never manifesting the behaviour (1) to manifesting the behaviour several times an hour (7)[64]. The scale is reliable (test-retest reliability coefficient=0.830; p<0.001) [65] in individuals with dementia and has demonstrated construct validity (i.e. strong association with Agitated Behaviour in Dementia, r=0.62; p<0.001) [66].

Sleep disturbance (e.g. difficulty falling asleep, repetitive sleep awakenings, and waking up early) is a risk factor for developing depressive symptoms [67], apathy [68], and aggressiveness [19] in dementia. Individuals with sleep problems had a higher risk of Alzheimer's disease (Risk ratio [RR]=1.55, 95% CI 1.25 to1.93), cognitive impairment (RR=1.65, 95% CI, 1.45 to1.86), and preclinical Alzheimer's disease (RR=3.78, 95% CI: 2.27–6.30 than individuals without sleep problems [69]. The association between sleep disturbance with Pittsburgh Sleep Quality Index [70] and NPI-Apathy domain is moderate (r=0.38; p<0.01) [71]. Thus, proportion of night-time sleep indirectly predicts BPSD [71].

DOS evaluates objective and accurate data about an individual's behaviour throughout each 24-hour cycle over a period of five consecutive days to identify patterns, trends, contributing factors and modifiable variables associated with BPSD [62]. The rater records a maximum of five observed behaviours (sleeping, awake/calm, positively engaged, repetitive vocal and motor expressions, and sexual/ verbal/physical expression of risk) based on his/her judgement every half an hour for five days and colour codes the observed behaviours [62].

We did not select CAMDEX and GMS/AGECAT for our pilot as they are predominantly diagnostic tools, irrelevant to our objective. We also did not select AES and GDS as they are self-reported, which is not suitable for our participants. Even though the NPI is a validated clinical tool designed explicitly to provide a comprehensive evaluation of BPSD [72], raters' tight work schedule can deviate the original NPI protocol (e.g., an arbitrary evaluation of symptoms is made based on the general domains instead of using sub-questions) [73] or can lead to a possible recall bias (e.g. rating is based on retrospective information [one month]) [74, 75]. Considering tight work schedule of LTC staff members and possible recall bias, we did not select NPI.

2) We measured the association of pre-to post change BPSD scores between week 1 and pre-intervention and again between week 2 and week 1 for the CSDD and CMAI with the Global Rating of Change (GRC) scale [76] and reported the association with Pearson's r (rho) or coefficient r.

The GRC scale captures an individual's perspective (in this case, participants' caregivers) regarding their change in health condition (in this case, depression and agitation) [76]. The scale quantifies the change (from a small, unimportant change to a very great deal of change) using scores 0 to 7 (0=no change, +1 to +7= a perceived improvement in condition, and -1 to -7= a perceived deterioration in condition) [76]. We classified GRC as a lot worse (GRC=-7,-6), moderately worse (GRC=-4, -5), minimally worse (GRC=-1, -2, -3), stable (GRC=0), minimally better (GRC=1, 2, 3), moderately better (GRC=4, 5), and a lot better (GRC=6, 7).

To demonstrate the association, we expected that a GRC rating of 0 would be associated with little to no change in the CSDD/CMAI (i.e. a change score of 0). Considering the short period of intervention (two weeks), we did not expect many participants to experience very large changes, thereby reducing the breadth of the scale and reducing the magnitude of the association. Thus, our *a priori* hypothesis for the correlation between CSDD/CMAI and GRC was weak to moderate. The categorization of the strength of correlation using coefficient r was strong when $r \geq 0.6$, moderate when r=0.3 to 0.6, and weak when $r \leq 0.3$ [52].

Data collection. KC and RA used electronic data capture forms to record the number of participants contacted, consented, completed VR sessions; labelled participants' behaviours during the VR sessions based on direct observation; completed AE

forms, archived the number of emergency transfers, one-to-one staff usage, proportion of night-time sleep, and psychotropic drug prescription at baseline, at the end of first week, and at the end of second week of intervention from the participant's medical chart.

We invited the SDM to complete the CSDD, CMAI, and DOS scale. However, the SDM felt that the LTC staff could more accurately complete these tools since they provide care for the residents 24/7. One of us (KC) trained the LTC staff caregivers to complete the above-mentioned tools. LTC staff caregivers completed CSDD, CMAI, DOS, and EQ-5D at baseline, at the end of first week, and at the end of second week of intervention.

Sample Size

We felt that approximately 40% of participants would be eligible and have an SDM willing to provide consent to participate in the trial from the LTC home (192 bed capacity). The reason for our low estimate was that attempts to contact the SDM were to take place during Holiday season (Christmas and New Year), which did not optimize access. To maximize the recruitment, RA contacted SDM on weekdays from 9 to 5 and kept the study phone open on evenings and weekends for them to call back. The RA also went into the LTC home after hours to meet SDM in the evenings and weekends. Given this estimate, to be 95% confident we needed 18-27 eligible participants (and their SDM) in the population to provide consent [77].

Results

We presented the number of eligible participants who were approached, screened, signed/withdrew informed consent, received/not received the intervention, lost to follow up/discontinued, and analyzed, describing the reasons for each one in Figure 2 (The flow chart for participant enrollment, allocation, follow-up, and analysis).

Six participants failed the screening due to a change of their health condition (CPS score >5 [n=2], epilepsy [n=1], palliative care [n=1], blind [n=1], unable to communicate in English language [n=1]). One participant withdrew consent before the intervention started due to a conflicting family visit schedule. The demographic and clinical characteristics of the participants are shown in Table 1.

Primary objective 1. The recruitment rate was (31/77) 40% (95% CI, 29% to 52%), the adherence rate was (5/24) 21% (95% CI, 7% to 42%), and the attrition was (0/24) 0% (95% CI, 0% to 14%).

Primary objective 2. 75% of participants were able to complete at least 80% of the sessions. The maximum number of sessions attended by any participant was 10 and the minimum number of sessions attended by any participant was 2. The average length of participants' VR experience was 22.2 (95% CI, 23.5 to 20.9) minutes per session. The shortest length of a session was 1 minute; this participant was agitated when session started and left the intervention area.

The observed negative behaviours were complaining (n=6), restlessness (n=5), agitation (n=2), calling out for help (n=2), and crying (n=1). Sixteen (66%; 95% CI, 45% to 84%) of the 24 participants experienced at least one negative behaviour and 5/24 (21%; 95% CI, 7% to 42%) participants experienced more than one negative behaviour. The observed positive behaviours were sleeping (n=24), interacting with VR images/attendant (n=19), smiling (n=12), singing/humming (n=5), dancing/ tapping feet in rhythm (n=4), and kissing RA's/PI's hand (n=2). All (100%) participants experienced at least one positive behaviour and 23/24 (96%; 95% CI, 79% to 100%) participants experienced more than one positive behaviour.

All AE were observed outside the VR sessions and were not related to the intervention. We noted five AE during the two-week intervention period; falls (n=2), respiratory tract infection (n=1), loose stool (n=1), and urinary tract infection (n=1). Overall, the pilot participants were relatively stable since none of them were transferred to emergency four weeks before, during, and after the intervention period. None of them used one-to-one staff four weeks before and during the intervention period. However, three participants used one-to-one staff service after the intervention (3/24, 13%; 95% CI, 3% to 32%). The dosage

of psychotropic drugs remained either unchanged (14/24, 58%; 95% CI, 37% to 78%) or reduced (8/24, 33%; 95% CI, 16% to 55%) after the intervention. The frequencies and proportions by EQ-5D dimensions and level indicate no detectable change in participants' health condition from baseline to end of second week of intervention (Table 2). The EQ-5D index value using Crosswalk value set for North America (https://euroqol.org/eq-5d-instruments/eq-5d-5l-about/valuation-standard-value-sets/crosswalk-index-value-calculator/) based on van Hout and colleagues' [78] work also indicates no detectable change in their health condition (index value mean for EQ-5D ±SD at baseline=0.4±0.2; at week-1=0.4±0.3; and at week-2=0.4±0.3).

Primary objective 3. The order of instances a library item was selected, from most selected to least selected were Cherry Blossom (an afternoon stroll in the park with blooming cherry flowers set to soft classical music) (127 times), Farm (morning walk in a farmyard with cows and chicken set to animal and bird sound) (61 times), Truck driving (day time simulated driving in the country roads) (34 times), Symphony (a concert playing classical music) (32 times), London, UK (aerial view of city streets and iconic building in London, UK set to soft classical music) (30 times), Bavarian Alps (a morning stroll in the alpine meadow set to bird sound) (15 times), Fishing (simulated fishing in the river set to water sound) (13 times), Dolphin Swim club (simulated under water diving set to water sound) (8 times), Ireland (aerial view of city streets and iconic building in Ireland set to soft classical music) (4 times).

SDM were present in 2 out of 192 sessions (0.0104%, 95% CI, 0.0013 to 0.0371). The factors enabling participants' VR experience included: 1) use of Broomx© projector instead of headset, 2) the physical proximity of a familiar individual during VR sessions (researchers sitting beside the participant, holding his/her hand), 3) a sound proof room with no visual distractions (e.g. windows, furniture, wall decorations), 4) having the VR set up and running prior to introducing the resident into the intervention area, and 5) knowledge of participants' preferences/dislikes on VR library items. For instance, the library item, Bavarian Alps, brought back traumatic World War 2 memories in a participant; the water themed library items (Dolphin Swim club, Fishing, and Boat ride) frightened a participant; and the Sun and Clouds library item reminded a participant of her departed husband. Avoiding these themes improved their attendance at VR sessions. Library items such as Farm and Truck Driving improved five participants' attendance as they felt a personal connection (used to be farmers/ grew up on a farm or used to drive Harley Davidson motorcycle).

The factors that negatively affected the participants' VR experience included: 1) interrupted internet (Wi-Fi) connection, 2) VR volume too high, 3) auditory distractions like the sound of closing doors and conversations among the staffs and other residents in the hallway, 4) participants' conflicting schedule, and 5) a negative emotional state of the participant (a participant missed five sessions as his ex-wife accompanied him to the intervention area against his will. Once, the ex-wife stopped accompanying him, he continued VR sessions).

Secondary objective 1. Table 3 and 4 illustrate the mean scores with SD, score difference, and sensitivity to change of CSDD, CMAI, and proportion of night-time sleep to VR intervention. Overall, the selected tools were sensitive to change in BPSD. A small clinically meaningful change was observed in CMAI score. We also observed small to moderate clinically meaningful negative change in proportion of night-time sleep. Reporting of the DOS was inconsistent with a large proportion of missing data. We, therefore, chose not to report the results.

Secondary objective 2. We observed a weak association between GRC and CSDD/CMAI score confirming our *a priori* hypothesis. The domain specific association revealed a moderate association in certain domains (the behavioural disturbance domain of CSDD and the verbal aggressive/non-aggressive domain of CMAI). However, the mean change per domain did not equal zero when the GRC indicated no change as per our expected pattern of association (Table 5 and 6). We had two outliers for GRC-depression (GRC=-4 [n=1] at the end of the first week and GRC=7 [n=1] at the end of the second week). On the same note, we had one outlier for GRC-agitation (GRC=-4 [n=1] at the end of first week and second week).

Discussion

Overall, this pilot shows feasibility and tolerability of VR experience with BroomX© in a LTC home. Our selected tools were sensitive to change, even given the small intervention time. Particular domains of CSDD and CMAI had moderate association with GRC; demonstrating longitudinal construct validity. The study recruited typical Ontario LTC population and the researchers did not require specialization for setting up and conducting VR sessions. Therefore, this study was pragmatic in nature and likely to be applicable in Ontario LTC homes.

The intervention period was only two weeks (10 sessions). Five participants missed VR sessions during the first week due to their conflicting schedule and health condition. A longer (four weeks) and flexible (seven days a week) intervention period might have improved the adherence rate. Furthermore, use of headset, intermittent Wi-Fi network and absence of a suitable intervention area also affected the adherence rate. As the length of our intervention was short, we did not expect to observe a large change in BPSD among individuals. In fact, when we apply the thresholds described by other authors [79, 80] as clinically meaningful, we observed a small clinically meaningful change in CMAI score and in proportion of night-time sleep.

Individuals with a visual impairment and non-English speakers were not eligible for this pilot. However, after observing our pilot participants, we felt that individuals with a visual impairment might also appreciate the advantages of VR experience through auditory sensation. Further, having music/image-based VR experience, participants need not be capable of communicating in English to appreciate the effects.

A literature review on potential benefits of VR experience concluded that such experience may provide an opportunity to enjoy leisurely activities that may promote quality of life, psychological well-being, and social interaction in people with dementia without leaving their home [35]. They located nine studies of varying study designs and durations [35]. The common barriers in VR use across the studies were confusion (n=3), discomfort associated with headset (n=2), sadness (n=1), tiredness (n=1), and difficulty with the technology (n=1). We encountered similar barriers in our pilot study, however we were able to propose and test solutions including using projector instead of a headset, consulting with SDM to help identify content most likely to be appealing, paying particular attention to immediate reaction to VR content and making changes as necessary, setting up the VR machine early, and using a dedicated intervention area.

A recent pilot randomized control trial in older adults (71.8 ±6.6) without dementia (n=24) used VR games with headset (30 min/day, two days/week for three months) to explore its feasibility [81]. Similar to us, they declared that VR experience is feasible for older adults (adherence rate was 91.55% ±6.41%) in the VR group [81]. Unlike us, they reported AE such as dizziness and fatigue during the intervention in the VR group [81]. They also measured participants' depression symptoms with 15-item Korean version of GDS [82] and reported an improvement (week 12 score-baseline score=1.1, 95% CI, -0.87 to 3.07) [81].

Another recent feasibility study in older adults (80.5±10.5) attending hospitals/day care centers (4 centers) used one session (maximum duration was 20 minutes) of 360^0 VR video footage with headset [39]. Similar to us, the participants (n=66) were diagnosed with dementia [39]. They declared VR intervention is safe (no AE) and feasible (adherence rate was 100%, attrition rate was 0%) [39]. They measured participants' anxiety status with a modified version of the State-Trait Anxiety Inventory (STAI) [83] pre-and post-intervention [39]. Overall, the STAI questionnaire revealed lesser anxiety in 12 out of 16 domains (calm, relaxed, content, adventurous, energetic, happy, sad, tense, upset/angry, worried, stressed, and anxious) [39] confirming our findings.

A mixed-method pilot study (n=10) evaluated the effects of VR experience on the level of engagement, apathy, and mood states of people with dementia from two LTC homes [84]. The VR session was 15 minutes in length and was experienced once [84]. The sensitivity to change of Person–Environment Apathy Rating (apathy) was trivial [84]. The study reported environmental distractions (noise, cluttered space) as a potential barrier in implementing VR intervention [84] confirming our findings.

A feasibility study on VR intervention for people with dementia (n=57) visiting a memory clinic asked the participants rate their VR experience [85]. The participants reported that they felt secure, comfortable, less anxious, and less fatigued in VR environment [85], which is similar to our experience.

Limitations

The participant recruitment depended on communication with their SDM. The recruitment phase was short (around six weeks) during holiday season and required us to reach the SDM during their occasional visit to the Henley Place or over the phone only during weekdays from 9 to 5pm. In a fully funded study, with greater resources to allocate to recruitment efforts, we expect recruitments rates to improve.

The clinical utility of the CSDD is highly questionable in identifying depression when administered by LTC staff because of the complexity of the scale, the time and skills required for collecting data, and knowledge of assessing depression [86]. Further, the creators of the CSDD recommend standardized training [60], which reduces its utility in a practice setting.

We found a low rate of completion for DOS scale, likely because it was not part of regular required reporting and is conceptually difficult to complete. Therefore, we do not recommend using this tool in a larger trial. We acknowledge that LTC homes collect residents' health related data using Resident Assessment Instrument-Minimum Data Set (RAI-MDS) 2.0 as part of their usual reporting to guide their care planning and monitoring [87]. The RAI-MDS 2.0 collects residents' data on accidents, behavioural and emotional patterns, clinical management, cognitive patterns, elimination and continence, infection control, nutrition and eating, physical functioning, psychotropic drug use, quality of life, and skin care [87]. The RAI-MDS 2.0 components for evaluating BPSD are 1) the Depression Rating Scale (DRS) and 2) the Aggressive Behaviour Scale (ABS) [88]. The DRS evaluates depression using seven items (negative statements, persistent anger with self or others, verbal/non-verbal expressions of unrealistic fear, repetitive health/ non-health complaints, sad/pained/worried facial expression, and crying/tearfulness) scoring 0 to 2 (0=no symptoms in last 30 days, 1=symptoms present five days a week, 2= symptoms present six/seven days a week) [89]. The scale adds all seven items to provide a final score where 0 indicates no symptoms, 3 indicates mild depression, and , 14 indicates major depression [89]. The DRS is reliable (α=0.69) and valid (correlation with CSDD [r=0.69, $p<0.01$] and Hamilton Depression Rating Scale [90] [r=0.70, $p<0.0$] is strong) [89]. The ABS has four components (verbal abuse, physical abuse, socially disruptive behaviour, and resistance of care) with a score range from 0-12 (higher scores indicates greater frequency and diversity of aggressive behaviour) [91]. The scoring of ABS is based on seven days' observation of residents where each item is scored from 0 to 3 (0=no symptoms, 1=symptoms observed 1-3 days in the past 7 days, 2=symptoms observed 4-36 days in the past 7 days) [91]. The tool is reliable (α=0.8) and valid (correlation with CMAI is strong, r=0.72, $P<0.01$) [92]. The Ministry of Health and Long-Term Care recommends using RAI-MDS 2.0 in Canadian LTC homes [41]. We suggest using RAI-MDS 2.0 in future studies to measure BPSD to avoid redundancy.

Overall, our study was biased inherent to the study design. For example, absence of a control group impaired our ability to report whether changes in outcome reflected the intervention or simply the ups and downs associated with dementia progression. However, a systematic review on 118 studies targeting psychosocial treatments of behavior symptoms in dementia suggested that interventions tailored to individuals' preferences reporting small to moderate change in a short duration of action might work best in specific, time-limited situations [93].

Conclusion

VR intervention was feasible in an Ontario LTC home and the residents of that home with moderate to severe dementia tolerated such experience. The sensitivity to change of our selected tools (CSDD and CMAI) indicated that VR intervention might have a role in reducing BPSD in the population of interest. The study recruited typical Ontario LTC population and the researchers did not require specialization for setting up and conducting VR intervention. Therefore, we can conclude that VR intervention is likely to be applicable in Ontario LTC homes. However, we are not confident of the precision of these

estimates from this small pilot study. Considering the burden of BPSD on older adults with dementia and their caregivers, VR experience is a possible non-pharmacologic intervention in managing BPSD in LTC homes.

List Of Abbreviations

ABS=Aggressive Behaviour Scale

AE=Adverse Events

AES=Apathy Evaluation Scale

AGECAT=Automated Geriatric Examination for Computer Assisted Taxonomy

BPSD=Behavioural and Psychological Symptoms of Dementia

BSO=Behavioural Supports Ontario

CAMDEX=Cambridge Mental Disorders of the Elderly Examination

CI=Confidence Interval

CMAI=Cohen-Mansfield Agitation Inventory

CPS=Cognitive Performance Scale

CSDD=Cornell Scale for Depression in Dementia

DOS=Dementia Observation System

DRS=Depression Rating Scale

EQ-5D=Euro-Qol 5-Dimention

ES=Effect Size

GDS=Geriatric Depression Screening scale

GMS=Geriatric Mental State Schedule

GRC=Global Rating of Change

LTC=Long-Term Care

NPI=Neuro Psychiatric Inventory

QALY=Quality-Adjusted Life Years

RA=Research Assistant

RAI-MDS=Resident Assessment Instrument-Minimum Data Set

RR=Risk Ratio

SD=Standard Deviation

SDM=Substitute Decision-Maker

VR=Virtual Reality

Declarations

Ethics approval and consent to participate: The study was ethically approved by ADVARRA Canada Ethics board. The protocol number of this study is Pro00030688. The protocol can be accessed on https://www.cirbi.net with permission from the sponsor (primacare Living Solutions Inc. TM).

Consent for publication: All authors consent for publication and declare no conflict of interest.

Availability of data and material: Data and materials can be accessed on http://www.empowerhealthresearch.ca/ with permission from the sponsor (primacare Living Solutions Inc. TM) but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are however available from the authors upon reasonable request and with permission of primacare Living Solutions Inc. TM.

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Authors' contributions: MS analyzed and interpreted data, written the manuscript, and revised it critically for important intellectual content; KC designed and conducted the pilot study, and contributed in revising the manuscript; MJ contributed in analysis, interpretation of data, and critical revision for the work. MMO and JBO contributed in interpretation of data and revision of the manuscript; JK contributed in conception, design, and critical revision for the work; ASG created VR library for this project; and DB contributed in design, analysis, interpretation, and critical revision for important intellectual content. All authors are in agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Tables

Table 1

The demographic and clinical characteristics of the participants

Characteristics of participants	
Age (mean, standard deviation [SD])	85.8 ±8.6
Sex (n, %)	Female (18, 75%)
CPS score (mean, SD)	3.4 ± 0.6
Dementia types:	
Alzheimer's disease (n, %)	3, 12.5%
Unspecified dementia (n, %)	21, 87.5%
Comorbidities:	
Depression (n, %)	21, 87.5%
Diabetes mellitus (n, %)	3, 12.5%
Stroke (n, %)	2, 8.3%
Concussion (n, %)	1, 4.2%

Table 2

Distribution of EQ-5D dimension responses at baseline, week 1 and week 2 with index value

EQ-5D Baseline profile	EQ-5D Baseline index value	EQ-5D Week-1 profile	EQ-5D Week-1 index value	EQ-5D Week-2 profile	EQ-5D Week-2 index value
22432	0.6	12332	0.7	12232	0.7
55355	-0.1	55555	-0.1	54334	0.2
55435	0.1	55511	0.2	55532	0.1
35322	0.4	53453	0.1	53432	0.3
35543	0.3	44542	0.3	44453	0.3
15411	0.5	23333	0.6	13222	0.7
11121	0.7	11211	0.9	11112	0.9
44532	0.4	45533	0.3	54221	0.3
23423	0.6	22121	0.8	22322	0.7
55511	0.2	55521	0.2	55522	0.1
55513	0.2	55524	0.1	55332	0.2
15521	0.4	15534	0.3	15121	0.5
14411	0.7	35531	0.4	25421	0.4
55543	0.1	55523	0.1	55544	0.0
24532	0.4	23321	0.7	24332	0.6
34433	0.5	15523	0.4	24423	0.5
12421	0.7	12312	0.7	12121	0.8
25534	0.3	34332	0.6	24433	0.5
45523	0.3	45454	0.1	55544	0.0
54333	0.2	55544	0.0	55432	0.2
23311	0.8	12321	0.8	12124	0.6
23244	0.4	13355	0.2	24332	0.6
24222	0.6	13232	0.7	14322	0.7
25431	0.4	13221	0.8	23332	0.6

Table 3

Mean scores with standard deviation and pre-post score difference of the outcome measures

Scales	Baseline (mean, SD)	Week 1 (mean, SD)	Week 2 (mean, SD)	Change (Week 1-Baseline) (mean, SD)	Change (Week 2-Baseline) (mean, SD)
CSDD	9.7 ± 5.3	7.5 ± 4.6	7.5 ±4.1	2.2±6.1	2.1±4.9
Mood	3.0 ± 1.8	2.4 ± 1.9	2.5 ± 1.8	0.5±2.1	0.5±1.8
Behaviour	2.4 ± 1.6	1.8 ± 1.5	1.7 ± 1.2	0.6±2.1	0.7±1.9
Physical signs	1.8 ± 1.3	1.4 ± 1.0	1.4 ± 1.2	0.4±1.3	0.5±1.4
Cyclic function	1.8 ± 1.7	1.5 ± 1.6	1.3 ± 1.3	0.4±2.2	0.5±1.7
Ideation	0.6 ± 0.8	0.3 ± 0.9	0.7 ± 1.0	0.3±1.1	0.1±1.1
CMAI	53.3 ±19.1	51.3 ±21.7	48.8 ±17.2	2.3±13.4	4.8±15.2
Physical aggressive	18.8 ± 10.7	17.8 ± 9.2	16.4 ± 6.7	1.0±4.3	2.3±7.7
Physical non-aggressive	18.3 ± 6.3	16.5 ± 6.5	16 ± 5.8	1.8±7.1	2.3±6.5
Verbal aggressive	6.4 ± 4.3	6.5 ± 4.6	5.9 ± 3.1	0.1±2.8	0.5±3.2
Verbal non-aggressive	10.2 ± 6.3	10. 6 ± 8.2	10.7 ± 7.1	0.4±5.9	0.5±5.7
Sleep	94.3 ± 9.1	88.3 ± 17.5	89.3 ± 16	5.9±13.3	5.1±10.2

CSDD= Cornell Scale for Depression in Dementia, CMAI= Cohen-Mansfield Agitation Inventory, SD=Standard Deviation

Table 4

Pre-post sensitivity to change of the outcome measures size of response, and clinical importance

Scales	ES (Week 1-Baseline)	ES (Week 2-Baseline)	Clinically meaningful (at 2 weeks only)
CSDD	0.4	0.4	Yes (small)
Mood	0.3	0.3	Yes (small)
Behaviour	0.4	0.4	Yes (small)
Physical signs	0.3	0.4	Yes (small)
Cyclic function	0.2	0.3	Yes (small)
Ideation	0.3	0.1	Yes (trivial)
CMAI	0.1	0.2	Yes (small), Clinically meaningful
Physical aggressive	0.1	0.2	Yes (small)
Physical non-aggressive	0.3	0.4	Yes (small)
Verbal aggressive	0.02	0.1	Yes (trivial)
Verbal non-aggressive	0.01	0.1	Yes (trivial)
Sleep	0.7	0.6	Yes (small to moderate), Clinically meaningful

CSDD= Cornell Scale for Depression in Dementia, CMAI= Cohen-Mansfield Agitation Inventory, ES=Effect Size.

According to Cohen an ES is trivial if it is less than 0.20, small if it is between 0.21 – 0.49, moderate if it is between 0.51-0.79, and large if it is greater than 0.80 (Cohen, 1988). We considered the change to be clinically meaningful when ES of CMAI score was ≥ 0.2 (Rapp et al., 2013), and ES of sleep percentage was ≥ 0.4 (Perlis et al., 2000).

Table 5

Longitudinal validity of Cornell Scale for Depression in Dementia domains at the end of week 1 and week 2

CSDD domain	GRC-depression			
N=24	Week 1			
	Pearson correlation	Moderately better (4, 5) (n=5) (mean ±SD)	Minimally better (1, 2, 3) (n=2) (mean ±SD)	Stable (0) (n=16) (mean ±SD)
Total score	-0.23	6.6 ±5.5	6 ±1.4	7.5 ±4.6
Mood-related signs	-0.15	2.4 ±2	2 ±1.4	2.3 ±1.9
Behavioural disturbance	-0.28	1.2 ±1.1	1 ±1	2 ±1.6
Physical signs	-0.05	4.2 ±0.5	2.5 ±0.7	1.4 ±1
Cyclic functions	-0.22	1.2 ±1.1	1 ±0.0	1.4 ±1.8
Ideational disturbance	0.02	0.4 ±0.9	0.0 ±0.0	0.4 ±1.0
	Week 2			
	Pearson correlation	Moderately better (4, 5) (n=5) (mean ±SD)	Minimally better (1, 2, 3) (n=4) (mean ±SD)	Stable (0) (n=14) (mean ±SD)
Total score	-0.16	5.2 ±3.3	9 ±3.6	7.9 ±4.5
Mood-related signs	-0.09	1.8 ±1.6	2.8 ±1.7	2.6 ±2
Behavioural disturbance	-0.25	1 ±0.7	1.5 ±1.3	2 ±1.4
Physical signs	-0.08	1 ±1	2 ±1.2	1.4 ±1.3
Cyclic functions	0.07	1 ±1	2 ±1.2	1.2 ±1.4
Ideational disturbance	-0.18	0.4 ±0.9	0.8 ±1	0.8 ±1.1

CSDD= Cornell Scale for Depression in Dementia, GRC= Global Rating of Change, SD=Standard Deviation

Table 6

Longitudinal validity of Cohen-Mansfield Agitation Inventory domains at the end of week 1 and week 2

CMAI domain		GRC-agitation			
N=24	Week 1				
	Pearson correlation	Moderately better (4, 5) (n=2) (mean ±SD)	Minimally better (1, 2, 3) (n=8) (mean ±SD)	Stable (0) (n=10) (mean ±SD)	Minimally worse (-1, -2, -3) (n=3) (mean ±SD)
Total score	-0.16	53.5 ±7.8	48.9 ±19.6	42.5 ±19.4	80 ±13.5
Physical aggressive	-0.15	16 ±7.1	17.5 ±10.0	16.7 ±10.4	24.3 ±4.3
Physical non-aggressive	0.05	21 ±4.2	17 ±7.1	14.2 ±6.6	20 ±6.3
Verbal aggressive	-0.43*	5 ±2.8	5.8 ±3.4	4.7 ±3.5	13 ±5.3
Verbal non-aggressive	-0.43*	11.5 ±6.4	8.6 ±7.9	6.9 ±2.4	22.7 ±9.1
	Week 2				
	Pearson correlation	Moderately better (4, 5) (n=3) (mean ±SD)	Minimally better (1, 2, 3) (n=9) (mean ±SD)	Stable (0) (n=8) (mean ±SD)	Minimally worse (-1, -2, -3) (n=3) (mean ±SD)
Total score	0.06	38 ±8.5	56.8 ±13.9	41.3 ±15.4	58.7 ±29.6
Physical aggressive	0.08	14 ±2.7	18.7 ±8.0	14 ±5.9	18.3 ±8.1
Physical non-aggressive	0.21	12 ±2	20.1 ±5.2	12.8 ±5.2	17.3 ±5.0
Verbal aggressive	0.06	6 ±3.6	6.1 ±2.6	5.5 ±4.1	6 ±3.6
Verbal non-aggressive	-0.22	7.3 ±4.0	10.8 ±5.1	9.3 ±7.1	19 ±12.1

CMAI=Cohen-Mansfield Agitation Inventory, GRC=Global Rating of Change, SD=Standard Deviation

*$p<0.05$

Figures

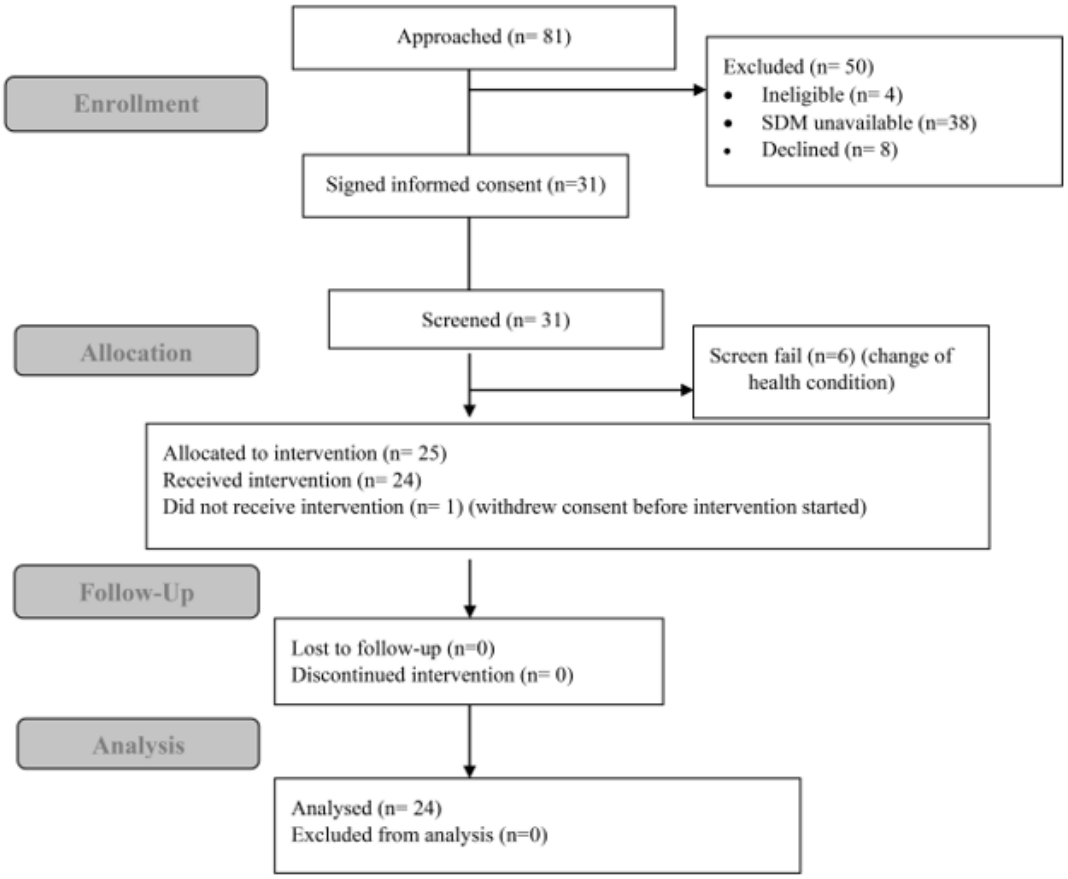

Figure 1

The flow chart for participant enrollment, allocation, follow-up, and analysis.

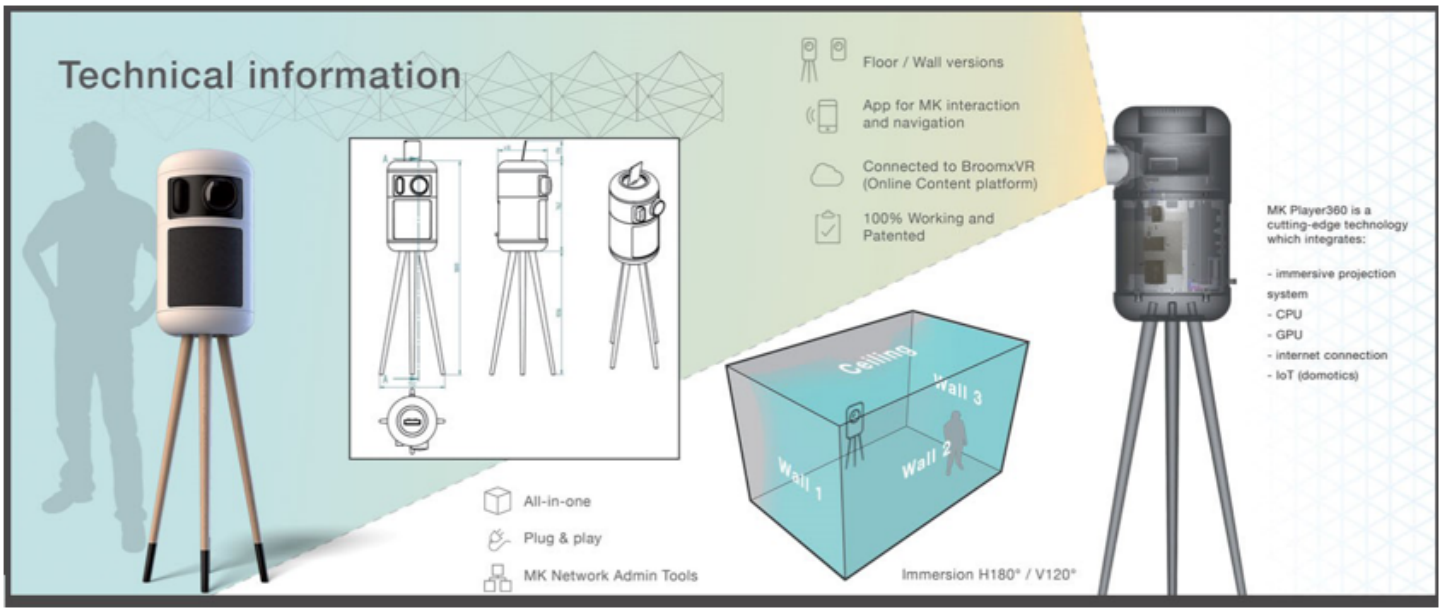

Figure 2

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