BMC Digital Health

RESEARCH

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Unravelling the possibilities: a cross-over randomised controlled feasibility trial on immersive virtual reality in haemodialysis

Wendy Smyth[1*], Joleen McArdle[2], Gwenn Heinrich[2], Valli Manickam[2], Ickjai Lee[3], Jason Holdsworth[3], Olumuyiwa Omonaiye[4] and Cate Nagle[5]

Abstract

Background Research pertaining to the use of Virtual Reality (VR) in various healthcare settings is emerging. The aim of this study was to assess the feasibility of immersive VR in a haemodialysis setting and its effects on patients' adherence to dialysis regimens and quality of life in an Australian renal service.

Trial design A crossover Randomised Controlled Trial (RCT) was conducted in regional Queensland, Australia. The CONSORT reporting guidelines were used.

Methods The intervention was the use of immersive VR headsets to view three scenarios designed to represent the country of northern Queensland. Intervention and control periods were each four weeks' duration, with a one-week washout period. The primary objective was to compare participants' attendance at scheduled haemodialysis sessions between intervention and control periods. Secondary objectives included comparing adherence to fluid allowances, and changes in quality-of-life measures. Adult patients attending haemodialysis treatments three times per week were eligible. Data were gathered from medical records, the self-reported AQoL 6D scale, the K-5 scale and participant feedback. A survey was used to obtain clinicians' feedback on the feasibility of immersive VR reality in this setting.

Results Data were obtained for the 34 patients who completed the trial (one participant was withdrawn from the study) and 49 staff who completed the clinicians' survey. No harm or adverse events occurred. There were no statistically significant differences in attendance or adherence to fluid allowances between the intervention and control periods. Improvements in quality of life and mental wellbeing for participants who had lower self-reported measures at the commencement of the trial. Feedback from patients and clinicians was positive overall. Patients suggested modifications to the scenarios for enhanced engagement with VR.

Conclusions Results suggest haemodialysis patients can benefit from VR while on treatment. Further trials with larger sample sizes are needed to determine relationships between VR usage and patient outcomes.

Trial registration The trial was registered with the Australian New Zealand Clinical Trials Registry (ANZCTR). Registration number: ACTRN12621000732886. Registration date 01/06/2021.

*Correspondence:
Wendy Smyth
wendy.smyth@health.qld.gov.au
Full list of author information is available at the end of the article

Keywords Haemodialysis, Renal, Immersive virtual reality, Crossover randomised controlled trial

Introduction

Haemodialysis, a life sustaining treatment for individuals with end-stage kidney disease, imposes significant burden and challenges for patients and their families. Haemodialysis treatment affects patients physically, psychologically and socially [1]. Whilst some patients can have their dialysis treatment at home, most haemodialysis is provided in a clinical setting, in hospitals or satellite dialysis units, where patients attend two or three times a week, for four to five hours at a time. Consequently, many patients have had to relocate from their rural or remote communities to more densely populated cities to access dialysis treatment. Geographical access to haemodialysis has been shown to affect attendance at scheduled dialysis sessions, [2] particularly for First Nations Australians [3]. First Nations Australians comprise 9.04% of the total population within the Townsville Hospital and Health Service. [4] the site of this trial, yet comprise approximately 60% of the haemodialysis patients. Dialysis units in Australian hospitals are somewhat impersonal clinical areas. Patients' haemodialysis chairs/beds are surrounded by multiple advanced machinery required to safely administer the treatment (refer to Fig. 1). Other than ceiling-mounted televisions, it is rarely possible to offer any other entertainment without adding to the clutter and impeding emergency access if required (refer to Fig. 2).

Background

Virtual reality (VR) is a multi-dimensional audio-visual entertainment system that has caught the attention of many in the medical research community. With the advancement of technology and involvement of multi-billion dollar companies such as Meta and Sony in its development, VR has an ability to propel the user into

Fig. 1 The clinical area in the in-hospital dialysis unit

Fig. 2 The patient's view in the in-hospital dialysis unit

more realistic virtual environments [5]. With the ever-growing quality and quantity of content, the potential to bring new immersive audio-visual entertainment experiences to patients undergoing haemodialysis is promising [6]. From a healthcare perspective, VR has been shown to provide significant benefits to patients, including reducing pain and anxiety, and improving short-term function in orthopaedic patients, [7] reducing fear of needles in children [8], and reducing pain in wound care [9]. Furthermore, research also suggests that VR improves the effectiveness of mindfulness exercises, thereby having a positive effect on participants' mental health outcomes [10]. Research in a paediatric oncology setting has shown greater positive shifts in mood state and reductions of negative symptoms in children using immersive VR compared to using an iPad [11]. Virtual reality has also been shown to increase participants' motivation and adherence to rehabilitation exercises for stroke victims [12].

Attendance at haemodialysis sessions and adherence to fluid allowances between sessions is vital to patients with end-stage kidney disease [13]. Research shows that First Nations Australians were more likely to miss two or more treatments per month, leading to double the rate of hospital admissions and triple the rate of emergency department presentations compared to their non-Indigenous counterparts [3]. Facilitators of adherence to treatment regimen have been identified as perceived health benefits, self-efficacy and purpose in life [14]. Whilst data on the impact of VR on haemodialysis patients is limited, a pilot study showed that VR can be a medium to escape the harshness of dialysis [15]. A systematic review of VR in haemodialysis found that it is safe and can increase patients' engagement with care [16]. However, that systematic review only found three studies examining the impact of immersive VR on haemodialysis patients, with other studies using non-immersive VR [16].

Given the dearth of research about the impact of immersive VR on the adherence to treatment regimens by patients undergoing haemodialysis, it was considered timely to conduct a Randomised Controlled Trial (RCT) to add to the evidence on this issue. Wireless immersive VR was selected because it would not be intrusive in the clinical care environment and would not require attachment to additional equipment in an already cluttered area. Also, wireless immersive VR enabled the intervention to take place while haemodialysis was underway, thus not imposing additional burdens on the patients. The study aimed to explore the feasibility of immersive VR for patients undergoing haemodialysis, with a view to informing a multi-centred RCT about the effects of immersive VR for patients undergoing haemodialysis [6].

Objectives

The primary objective was to compare participants' adherence to haemodialysis regimens (with respect to attendance at scheduled dialysis sessions) between the intervention and control phases.

The secondary objectives were to:

- Compare participants' adherence to haemodialysis regimens (with respect to adherence to fluid allowances) between the intervention and control phases;
- Measure change in ratings of quality of life, engagement with self-care and other psychological measures reported by participants between the intervention and control phases;
- Measure usage and usability of VR by participants; and
- Assess the acceptability and appropriateness of using VR during haemodialysis from the perspectives of clinical staff [6].

Methods

Study design

A crossover RCT was undertaken as this design afforded all participants the experience of VR, required fewer participants as individuals act as their own control, and is suited to studies undertaken with participants with chronic or stable health conditions [17]. The CONSORT reporting guidelines for randomised crossover trials was used [17].

The intervention (immersive VR headsets available during haemodialysis) and control (usual activities) periods were both four weeks in duration, with a one-week washout period. Although short, the one-week washout period was deemed appropriate because carry-over effects were anticipated to be negligible [17]. During this washout period, usage data were downloaded from the used VR headsets, before thoroughly cleaning them prior to allocation to the next participant. Mid-assessments were also completed during the washout period. Recruitment and pre-trial assessments took place over a two-week period, and final post-trial assessments were undertaken in the week following conclusion of participation. Four dyads of participants were initially created based on days of dialysis, whether dialysis was undertaken in the morning or afternoon, location of dialysis unit and availability of headsets. After the first two dyads were completed, the last two dyads were merged into one to provide flexibility in recruitment and maximise use of headsets.

Settings and locations

The trial was conducted within a Renal Service in North Queensland, Australia. The Health Service involved in this trial covers an area of 148,000 square kilometres, almost 2% of the entire continent of Australia, with an approximate population of 250,000. The two facilities for this trial were situated in the regional city, to which many patients need to relocate for easier access to healthcare. Participants underwent haemodialysis at either the main dialysis unit located within the tertiary hospital, or the standalone satellite dialysis unit located 13 kms away near the centre of the regional city. The main unit has 30 dialysis chairs and provides haemodialysis for 113 patients. The satellite unit has 11 chairs and provides dialysis for 44 patients. Both units operate two shifts of patients daily from Monday to Saturday, with each haemodialysis session between four and five hours in duration.

Fig. 3 shows a typical patient area in the in-hospital dialysis unit. Patients are usually in a dialysis chair, although beds may be used at times at the in-hospital unit, as shown in the photo. Patients attending dialysis at this unit are allocated to one of three areas for patient treatment and are rarely allocated to the same chair/bed location every day. Whilst the two smaller areas have windows at one end, the area with the greater number of patients has no windows. The main unit is very busy with a lot of foot traffic at any one time.

Patients attending the satellite unit are more medically stable than those attending the main unit, although patients sometimes move between both units. Patients attending the smaller satellite unit are expected to take a greater responsibility with their self-care and are encouraged to independently connect themselves to the haemodialysis machines. Despite the outside of the building looking less clinical, the treatment area remains very clinical. Whilst there are windows along all sides, the blinds are drawn and patients' chairs face away from the windows. Each patient area has a ceiling-mounted television, and the unit can be very noisy as patients choose to watch different television programs. Patients could, and do, talk to each other but they must speak loudly to be heard over the other noises in the room.

Participants

There were two groups of participants. The primary participant group comprised patients who met the eligibility criteria to participate in the trial: at least 18 years of age; undergoing haemodialysis three days per week; orientated to time and space. Patients were ineligible to participate if they had a history of severe migraines, or if the clinical staff considered the patients not suitable at that time. The second group of participants comprised clinicians (nurses) who cared for patients at either of the two locations.

Intervention

Specifications and functions of headsets and associated toolkits

The Meta Quest 2, [18] released in October 2020, is a contemporary VR headset produced by Meta, a company specialising in mass-market augmented and VR technologies. It is an all-in-one VR headset that does not require a PC or console to function. The Meta Quest 2 is comfortable to wear. It weighs only 500 g and has a resolution of 1832×1920 pixels per eye with a maximum refresh rate of 120 Hz. It delivers six degrees of freedom motion in 3D space. It uses inside-out tracking technology with two front-facing and two side-facing cameras, allowing room-scale user motion tracking without external sensors. Moreover, its controllers enable user interaction with virtual environments and objects, and its audio system allows users to experience auditory immersion via 3D positional sound. It provides an adjustable interpupillary distance of 58 mm to 68 mm, delivering a field of view between 85 to 97 degrees. Its battery is internal, rechargeable, and lasts 3 h. Its controllers use replaceable batteries lasting 8 h.

The Oculus platform powers the Meta Quest 2 [19]. The headset has the Meta Home environment, a customisable home space where users can launch apps and games. Meta's App Lab [20] hosted our VR intervention app. App Lab offers online VR app hosting with automatic distribution and updates. The Unity 3D Game Engine (https://unity.com/) with the Universal Render Pipeline (URP) was used to develop and test our VR intervention app. In particular, we used the OpenXR Unity Plugin [21] and the Oculus XR plugin [22] to handle the user camera positioning and streamline VR testing.

OutbackVR scenes

Our intervention VR app, OutbackVR, is a Unity VR project consisting of three scenes (a billabong, a beach, and a rural hillside), selectable via a simple menu system (as shown in Fig. 4). The participant uses one controller to point at waypoints. No virtual human characters exist in these scenes, only natural-looking environments and animals. In general, we implemented an instantaneous waypoint navigation system; this would minimise the likelihood of cybersickness in participants [23]. These scenes are familiar and homely for Aboriginal and Torres Strait Islander participants. (Refer to Fig. 4).

The billabong scene brings participants to a natural-looking billabong and surrounding native eucalyptus trees (Fig. 5). This scene allows participants to explore and find Australian animals (echidna, koala, kookaburra, platypus). The scene used the *CVP—Eucalyptus Forest* asset pack [24] to provide natural-looking tree assets and environmental textures. Virtual animals from the *Australian*

Fig. 3 A patient's treatment area in the in-hospital dialysis unit

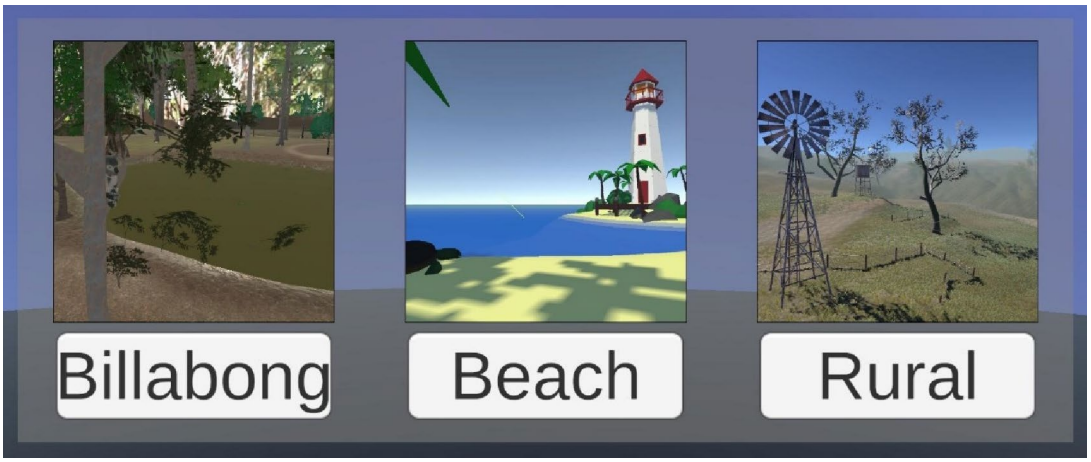


Fig. 4 The main menu of OutbackVR

Fig. 5 The Billabong scene in OutbackVR

Animals asset pack [25] populate the billabong. The environmental and animal assets were customised and streamlined in-house to suit the performance characteristics of the Meta Quest 2 headset. Additionally, participants could hear the positional audio of bird songs, insect songs, and background wind sounds as they moved around the scene.

The beach scene transports participants to a small beach with palm trees, rocks, sand, umbrellas, boats, a wooden pier, a lighthouse, and an ocean view (Fig. 6). The scene uses the *Lowpoly Beach & Palm Pack*. [26] This scene allows participants to explore the beach and discover animals swimming in the ocean. Animals from the *9t5 Low Poly Sea Creatures 1*, [27] including dolphins, sea turtles, dugongs, sharks, manta rays, and a single blue whale, were placed along the beach. The sea creatures swim and are only visible around the beach at certain times and locations. The lighthouse is on a small island, reachable by waypoints. Participants hear the ambient sounds of seagulls and ocean waves as they move around the scene (Refer to Fig. 6).

The rural hillside scene transports participants to a farm-like hillside with a windmill and a water tank (Fig. 7). The scene uses assets from the *Rural Australia Pack* [28]. The scene is relatively small and only has a few waypoints. However, every 5 min, the scene changes from daylight to night-time using the *Simple Day And Night Cycle System*; [29] the shadows move as the moon, and the sun shifts slowly overhead. Participants hear a soft breeze and distant bird songs as they move around the scene.

Table 1 summarises the characteristics of the three scenes in OutbackVR.

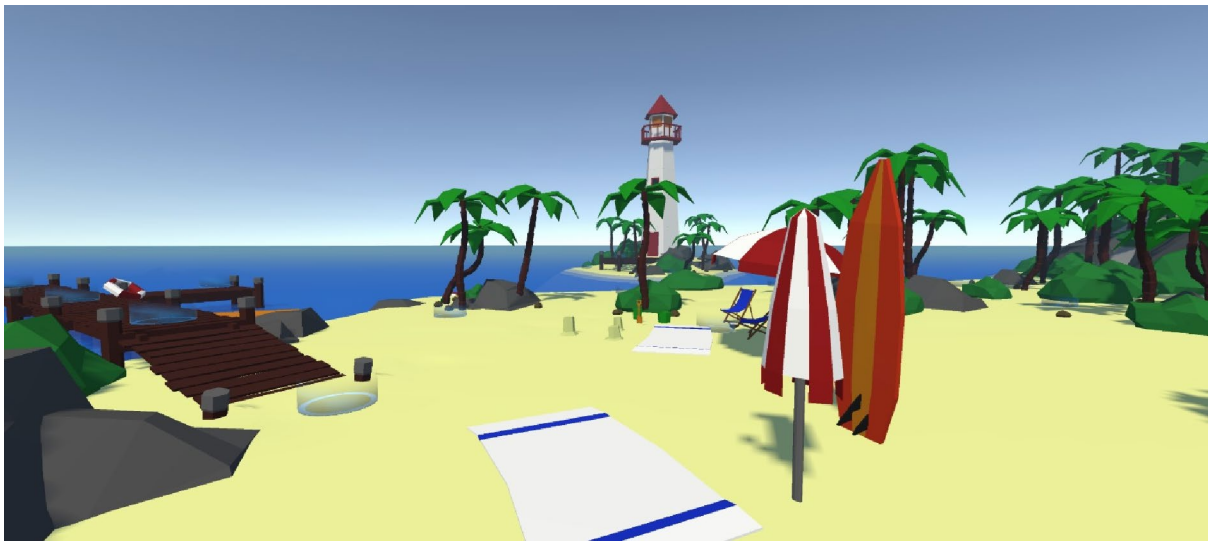


Fig. 6 The Beach scene in OutbackVR

Outcomes and outcome measures

The study's primary outcome was attendance at scheduled dialysis sessions. The study's secondary outcomes were: adherence to fluid allowances; quality of life and engagement with self-care (AQoL-6D) [30]; depression and anxiety (Kessler Psychological Distress Scale – 5, K-5) [31]; usage of VR; and patients' [32] and clinicians' satisfaction with VR [6]. Outcome measures, how and when the measures were assessed are outlined in Table 2. Data sources included the electronic medical record, questionnaires administered verbally, usage data downloaded from headsets, surveys, and feedback notes.

Sample size calculation

The crossover design allows for participants to act as their own controls [17] therefore decreasing the number required. An estimated sample size of 40 patients was based on other feasibility studies of using VR in the haemodialysis setting [6]. The sample size was also constrained by the number of headsets available and practical considerations related to recruitment and funding.

All 49 clinicians (nurses) were invited to complete the questionnaire after participation by patients was complete. A 50% response rate was expected [6].

Data analysis

Descriptive statistics were calculated for the attributes of participants. Means and ranges are provided for quantitative variables, and percentages in each category for categorical variables. The outcome variables compared for 4-week periods with and without the intervention were:

- The proportion of scheduled dialyses attended by each participant;
- The average rate of weight change (per day) of each participant;
- Change in the K5 questionnaire score for each participant (from the score before commencing the trial to the score after 4 weeks of Intervention or Control); and.
- Change in the AQoL questionnaire score for each participant.

Analysis of treatment effects used random-intercept mixed-effects logistic regression to analyse attendance proportions, and random-intercept linear mixed-effects models for other outcome variables. In each case, the patient ID was used as a random effect, and Treatment vs Control as the key fixed effect. Both unadjusted models (without additional covariates) and adjusted models (using demographic variables and the allocation order—whether the Control 4 weeks occurred before or after the Intervention 4 weeks – as covariates) were applied. Mixed-effects models used the glmmTMB package [33]. All analyses used R [34].

Randomisation and recruitment

There were three dyads, each with two clusters. At the in-hospital unit, Dyad 1 comprised patients undergoing haemodialysis on a Monday, Wednesday, Friday schedule (Cluster 1 was morning patients, Cluster 2 was afternoon patients), and Dyad 2 comprised patients undergoing haemodialysis on a Tuesday, Thursday, Saturday schedule (Cluster 3 was morning patients, Cluster 4 was afternoon patients). Dyad 3 comprised patients undergoing

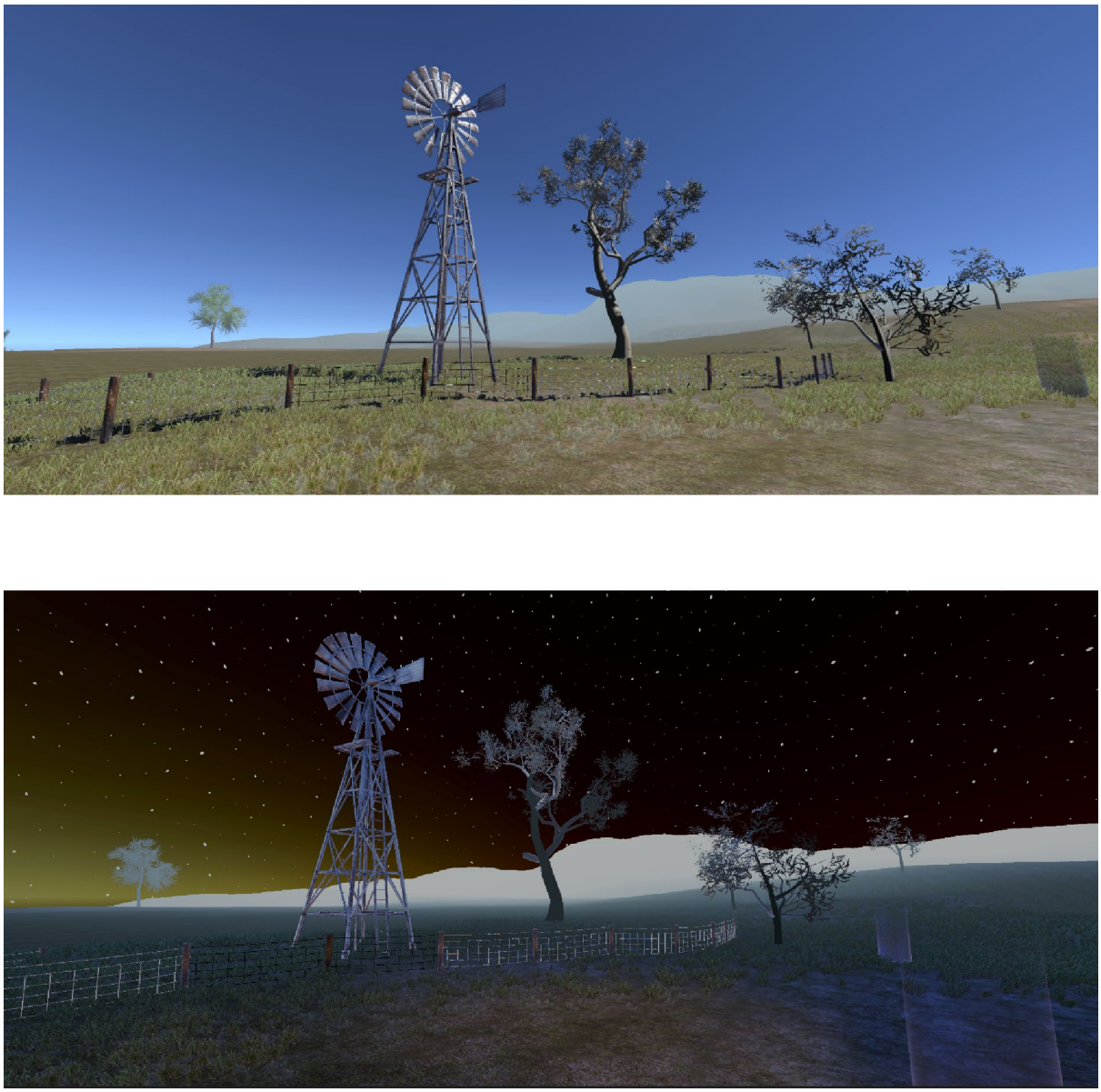


Fig. 7 The rural hillside scene in OutbackVR, daylight and night-time views

Table 1 A summary of characteristics of three scenes used in the experiment

	Billabong Scene	Beach Scene	Rural hillside Scene
Activities	Find locations to discover spot animals hidden in the trees and flying around	Find sea creatures	Enjoy the day-night cycle
Activity complexity	Moderate	Basic	Very Basic
Visual complexity	High	Moderate	Moderate
Number of waypoints	52	25	5
Sound complexity	Very basic	Very basic	Very basic
Number of scene objects (game objects including components)	~24 K	~3.5 K	~1.6 K
Dynamicity complexity	Moderate	Very basic	Very Basic
Day/Night Cycle	Day	Day	Day and Night

Table 2 Summary of outcomes, outcome measures, data sources and timepoints of data collection

Outcome	Outcome measures	Data sources and assessments	Timepoints of data collection
Attendance at scheduled haemodialysis sessions	Difference in participants' attendance rates in intervention compared to control phases	Data collected from electronic medical record	Each dialysis session, by research nurse
Adherence to fluid allowances between scheduled haemodialysis sessions	Difference in participants' adherence to no more than 1kg average daily weight gain between dialysis sessions in intervention compared to control phases	Weights as recorded in electronic medical record (pre dialysis weight minus post dialysis weight from previous session, divided by the number of days between sessions)	Each dialysis session, by research nurse
Health-related quality of life and engagement with self-care	Changes in participants' self-rating of quality of life	AQoL scale, administered verbally	At three timepoints – recruitment, washout week, week following completion of trial participation, by research nurse
Depression and anxiety	Changes in depression and anxiety scores	Kessler Psychological Distress Scale – 5 (K-5), administered verbally	At three timepoints – recruitment, washout week, week following completion of trial participation, by research nurse
Patient participants' satisfaction with VR experience	Patient feedback	Conversational interview with participant, consistent with a 'yarning' approach of Indigenous research	Conducted the week following participant's involvement in the intervention phase by researchers, research nurse. Combined with any notes of participants' comments made during the intervention phase
Usage of headsets	Amount of time headsets used by each participant	Data downloaded directly from VR headset Paper record of participants' use or decline to use	Following completion of intervention phase, by researchers Completed by clinicians, researchers each scheduled date
Clinicians' satisfaction with VR	Cross-sectional survey of nurses working in the renal unit	Specially designed questionnaire to ascertain perceptions about the acceptability, usability, feasibility of using VR during haemodialysis sessions	Invitation to complete the electronic questionnaire sent by email. Access to survey was either by clicking on a link to the survey or on a QR code. A reminder email was sent two weeks following initial email. Surveys were accessible for three weeks

haemodialysis at the satellite unit (Cluster 5 was morning patients, Cluster 6 was afternoon patients). Randomisation to the allocation sequence was by way of a toss of a coin between two of the primary investigators. Because of the nature of the trial, it was not possible to blind participants or unit staff to the intervention. Fig. 8 depicts the participant flow from screening for eligibility, allocation sequence, losses, and exclusions from the trial. One participant was withdrawn from the trial due primarily to difficulties fitting the headset, visual limitations and decline in health status.

Recruitment to and participation of the dyads were staggered. Dyad 1 recruitment and pre-trial assessments commenced on 5th September 2022, with Dyad 2 recruitment and pre-trial assessments commencing one week later on 12th September 2022. Recruitment to and pre-trial assessments for Dyad 3 began on 23rd November 2022 (over a 2.5-week period).

Study procedures

Prior to commencing the trial, training was offered to all dialysis clinicians including how to set up the devices for participants, where to access software content, basic troubleshooting, and infection control procedures. Clinicians were given opportunities to discover the device for themselves and experience the content that would be accessed by the patients. During this preparatory phase, researchers recorded any concerns expressed by the clinicians such as whether they would detect if a patient's level of consciousness deteriorated while using the headset, because they would not be able to see the patient's eyes and whole face. Some clinicians also queried how much the trial would add to their workload. The research team worked through such scenarios to allay clinicians' concerns.

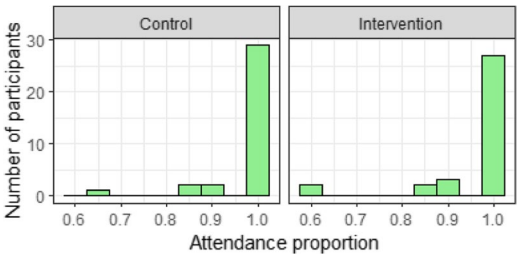
Once the randomisation for the dyad was completed, each headset with its hand controllers was placed in its own box, labelled with the participant's name. Laminated user instructions and cleaning procedures were included in the boxes, along with lens cleaning cloths, recharging cords, and two additional data collection forms. These forms were devised to encourage the clinicians and researchers to record whether the patient used or declined the VR on a given day, and the nature of any technical or clinical problems encountered. Feedback about the patient's experiences noted by the clinicians was incorporated with the answers to the interview questions following the patient's completion of the intervention phase.

Results

Data were obtained for the 34 patients who completed the trial. Although only five had relocated to the regional city for dialysis, 23 reported their hometown was more than 150 kms away. Eleven (32.4%) were female. Thirty had an arteriovenous fistula, which restricted their use of both hands when using the VR. The attributes of patients participating in the trial are summarised in Table 3.

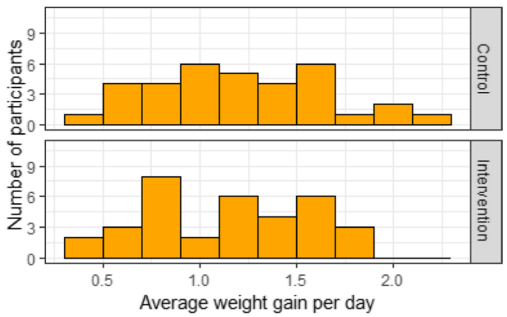
Unadjusted analyses

1. Attendance proportions.



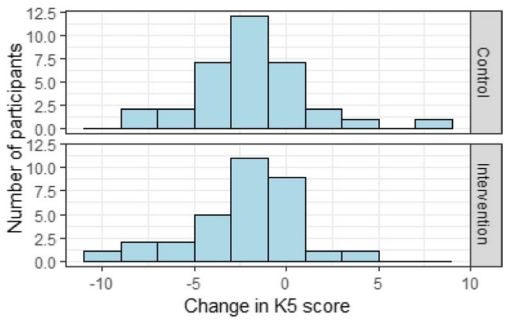
There was no significant difference in attendance proportions between Control and Intervention (Wald chi-square = 2.37, df = 1, $p = 0.124$).

2. Mean weight change.



The difference in mean rate of weight change between Control and Intervention is not statistically significant (Estimated difference = -0.71, SE = 0.46, $p = 0.124$).

3. K5 – K5Pre.



K5 scores tended to be lower in later completions of the questionnaire than they were the first time it was

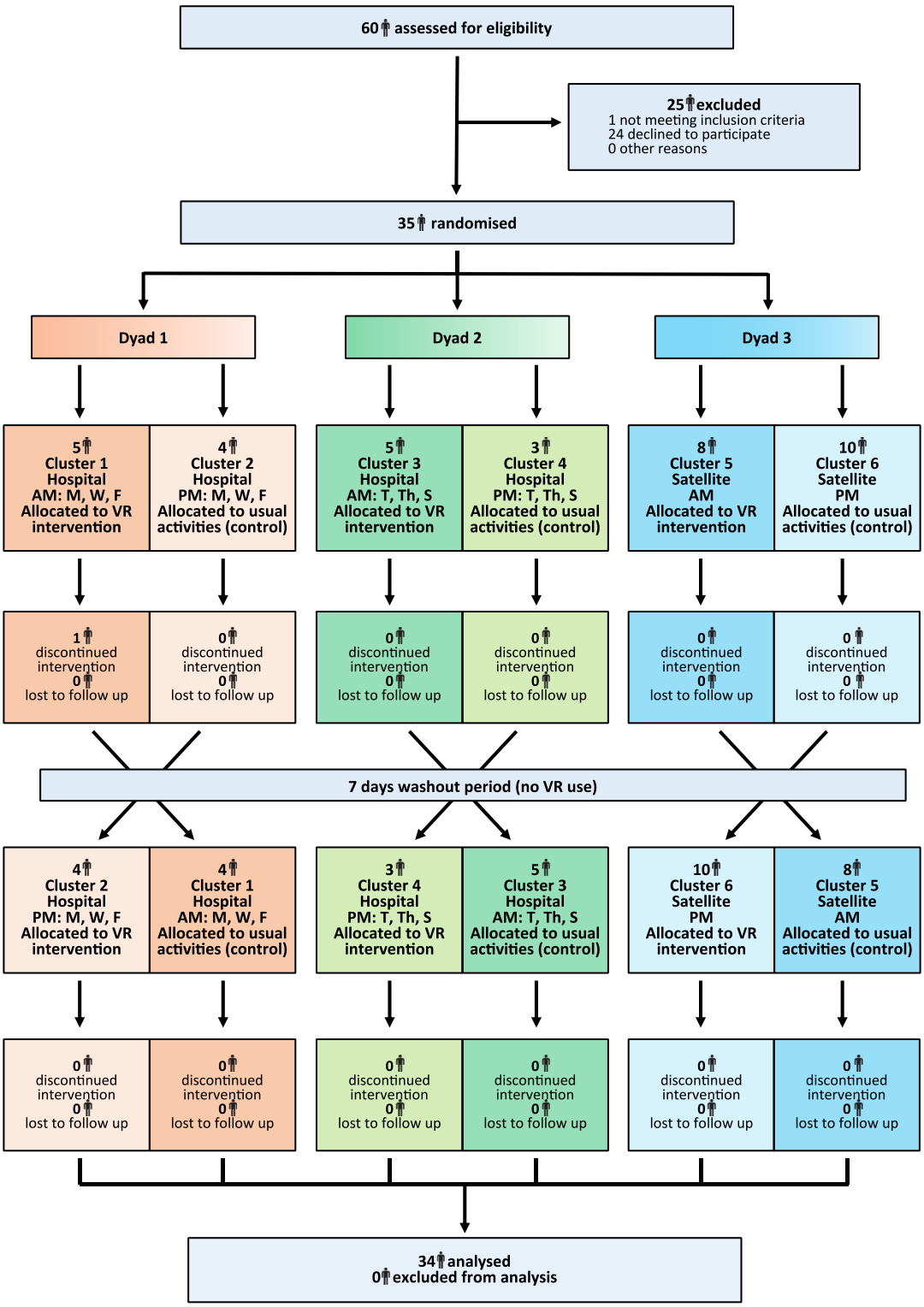


Figure 8: Participant flow diagram

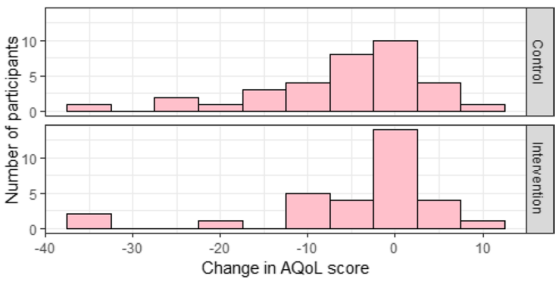
Fig. 8 Participant flow diagram

Table 3 Participant (patient) attributes

Attribute	Mean or percentages	Range
Location		
Hospital	48.5%	
Satellite	51.5%	
Age (years)	55.5	31—76
Ethnicity		
Both Aboriginal and Torres Straight Islander origin	2.8%	
Either Aboriginal or Torres Straight Islander origin	54.3%	
Neither Aboriginal or Torres Straight Islander	42.9%	
Years on dialysis	5.9	1—19
Moved to regional city for dialysis	14.3%	
Regional city within 150 kms of hometown	33.3%	
Vascular access	11.4% (Permacath) 88.6% (Arteriovenous Fistula)	
Allocation	50% (Control start) 50% (Intervention start)	

administered (at the start of the trial). However, the change in K5 score did not differ significantly between tests following the Intervention compared to tests following the Control (Estimated difference = -0.29, SE = 0.47, $p = 0.53$).

4. AQoL—AQolPre.



Similar to K5, the change in AQoL score did not differ significantly between tests following the Intervention compared to tests following the Control (Estimated difference = 1.26, SE = 1.35, $p = 0.32$).

Adjusted analyses

1. Attendance Proportions.

Model coefficients for the adjusted model shown below (the Pr(>|z|) column gives the probability value for each of the fixed effects).

```
Conditional model:
                                          Estimate Std. Error z value Pr(>|z|)
(Intercept)                                4.93322    5.96331   0.827   0.4081
Treatment Intervention                    -0.58002    0.77681  -0.747   0.4553
AllocationC.first                          1.04058    1.95885   0.531   0.5953
LocationNorth Ward                        -0.15552    1.57158  -0.099   0.9212
Age                                        0.06469    0.06857   0.943   0.3455
Years.dialysis                            -0.04191    0.16130  -0.260   0.7950
Moved.TSVYes                              -3.50411    2.10857  -1.662   0.0965 .
Home.distDistant                           1.34122    1.85110   0.725   0.4687
Vasc.accessAV.fist                         0.33417    2.87650   0.116   0.9075
K5..Pre                                    0.18722    0.33955   0.551   0.5814
AQoL..Pre                                 -0.10570    0.08316  -1.271   0.2037
TreatmentIntervention:AllocationC.first -0.16499    0.95632  -0.172   0.8630
```

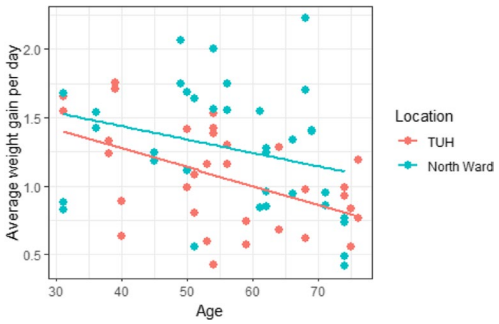
None of the demographic attributes, or the order of treatment allocation were significantly related to this outcome, and the allocation order did not appear to influence any treatment effect (see the treatment:allocation interaction).

2. Average rate of weight change.

The estimate for the intercept gives the value of the response variable for reference levels of all variables and the probability that the true value is 0. The probabilities for each subsequent row give the probability that the specified level is different from the reference level for the specified explanatory variable.

```
Conditional model:
                                          Estimate Std. Error z value Pr(>|z|)
(Intercept)                               2.047915   0.449732   4.554 5.27e-06 ***
TreatmentIntervention                    -0.026674   0.095305  -0.280   0.7796
AllocationC.first                        -0.076975   0.155743  -0.494   0.6211
Age                                      -0.010757   0.005208  -2.065   0.0389 *
Moved.TSVYes                              0.286671   0.166885   1.718   0.0858 .
Home.distDistant                         -0.099150   0.127531  -0.777   0.4369
LocationNorth Ward                        0.273594   0.119181   2.296   0.0217 *
Years.dialysis                           -0.001978   0.012609  -0.157   0.8754
Vasc.accessAV.fist                       -0.044167   0.211257  -0.209   0.8344
K5..Pre                                   0.005847   0.028364   0.206   0.8367
AQoL..Pre                                -0.007709   0.006958  -1.108   0.2679
TreatmentIntervention:AllocationC.first  -0.072400   0.136871  -0.529   0.5968
```

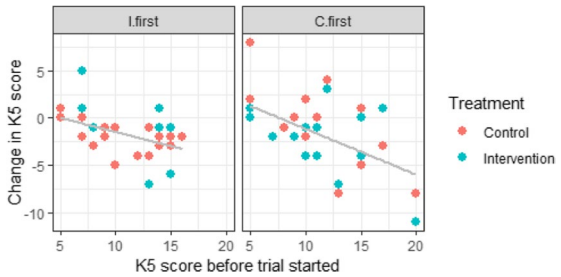
In the adjusted model, the treatment effect remained non-significant. There was a significant effect of age, with the rates of weight gain being somewhat less in older participants. Participants undertaking dialysis at the satellite unit tended to have higher rates of weight gain than those at in-hospital unit. These effects are illustrated below.



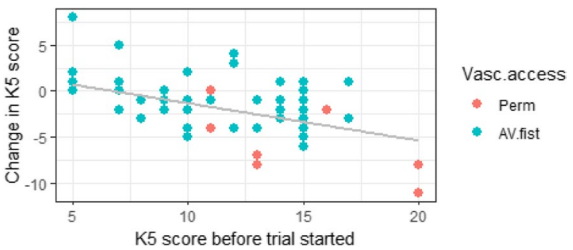
3. K5 – K5Pre.

```
Conditional model:
                                          Estimate Std. Error z value Pr(>|z|)
(Intercept)                              -0.685596   2.947884  -0.233  0.81609
TreatmentIntervention                     0.609806   0.631457   0.966  0.33419
AllocationC.first                         1.204675   0.982855   1.226  0.22032
Age                                      -0.008172   0.031816  -0.257  0.79730
Moved.TSVYes                              1.448142   1.154242   1.255  0.20961
Home.distDistant                         -0.539147   0.847430  -0.636  0.52464
LocationNorth Ward                       -0.234232   0.795467  -0.294  0.76841
K5..Pre                                  -0.319628   0.104128  -3.070  0.00214 **
Years.dialysis                            0.025172   0.090235   0.279  0.78028
Vasc.accessAV.fist                        2.979016   1.388800   2.145  0.03195 *
TreatmentIntervention:AllocationC.first  -1.797307   0.895568  -2.007  0.04476 *
```

There is a clear negative relationship between the K5 score before the trial started; participants with low scores (less anxiety, depression) before the trial generally had similarly low scores afterward, whereas those with high scores beforehand tended to have lower scores afterward. There was also an interaction between treatment and the allocation order, as illustrated in the plot below. Those who started with 4 weeks on the Control treatment tended to have lower scores after the Intervention treatment than after the Control, and vice versa. This means that participants in the second 4-week block, regardless of treatment, tended to have lower scores, and may imply that the engagement and interaction involved in participation could be the main contributor to improvement in the score.



The method of vascular access also had an effect on the change in K5 score, as illustrated below. Although few participants had a tunnelled central venous line, and they tended to have higher scores before the trial started, they also tended to reduce their scores during the trial more than patients with arteriovenous fistula.



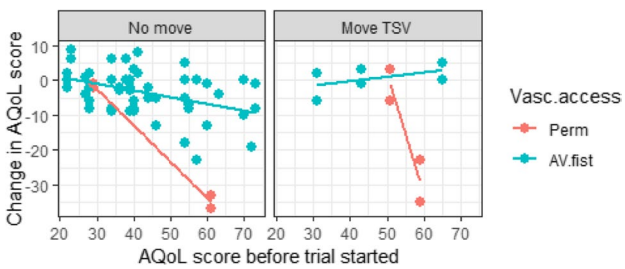
4. AQoL—AQoLPre.

The results of the adjusted analysis are quite complex. It was not possible to test all possible 2-way interactions simultaneously. The output below represents the simplest possible model which incorporates both the intervention:allocation interaction and all 2-way interactions which showed significant effects in any tested subset of possible interactions.

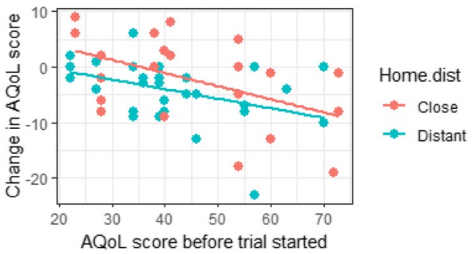
```
Conditional model:

                                          Estimate Std. Error z value Pr(>|z|)
(Intercept)                               38.10156    9.37331   4.065 4.81e-05 ***
TreatmentIntervention                      0.92549    1.93584   0.478  0.63259
AllocationC.first                         -2.42380    2.22472  -1.089  0.27594
AQoL..Pre                                 -1.15128    0.18864  -6.103 1.04e-09 ***
Vasc.accessAV.fist                       -33.71674    9.60861  -3.509  0.00045 ***
Moved.TSVMove TSV                        -11.44376    9.15768  -1.250  0.21143
Home.distDistant                          -3.64802    1.75583  -2.078  0.03774 *
LocationNorth Ward                        -0.71340    1.73371  -0.411  0.68072
Years.dialysis                             0.51531    0.20072   2.567  0.01025 *
Age                                        0.01875    0.06782   0.276  0.78221
TreatmentIntervention:AllocationC.first    0.94950    2.71424   0.350  0.72647
AQoL..Pre:Vasc.accessAV.fist               0.93243    0.19197   4.857 1.19e-06 ***
AQoL..Pre:Moved.TSVMove TSV                0.40550    0.18361   2.209  0.02720 *
```

a) Participants with higher AQoL scores (poorer quality of life) before the start of the trial were more likely to show lower scores (better quality of life) during and after the trial. In general, those who had low scores at the start changed very little.
b) Neither treatment, allocation, nor the interaction between them had a significant effect on the change in scores. Treatment and allocation also did not affect the relationship between starting score and the size of the change.
c) The method of vascular access had a striking effect on the pattern of change in scores (see the first plot below). However, the number of participants with a tunnelled central venous line access is small, and they may not be representative of all participants, so this result should be considered tentative.
d) Other attributes being equal, participants far from home showed a somewhat larger drop in AQoL score over the course of the trial.
e) Participants who moved to the regional city for dialysis did not show a drop in score during the trial (unless they had central venous line vascular access). Again, however, the numbers are small and the difference from those who did not move should be considered tentative.

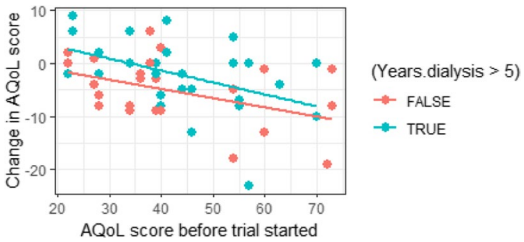


The second plot below examining the effect of distance from home includes only participants who did not move to the regional city for dialysis, and whose vascular access was via arteriovenous fistula (since – unsurprisingly – no close patients moved, and the numbers using central venous lines are so small, as is evident in the plot above).



Perhaps unsurprisingly, those whose home was more than 150 kms away tended to have a greater decrease in scores; that is, their reported quality of life improved during the trial compared to those whose home was closer.

The final plot below again includes only patients who did not move to the regional city for dialysis, and whose vascular access was via arteriovenous fistula. For the purpose of the plot, years.dialysis has been treated as a category (5 years or less, and more than 5 years). The results suggest that patients who have been on dialysis longer tended to have a smaller decrease in AQoL score over the course of the trial.



Usage of headsets

Headset usage data was available for 9 of the participants at the in-hospital site and 11 participants at the satellite unit. Participants at the satellite unit used the headsets more than the participants at the in-hospital unit (average of 2.88 times compared to 2 times). The average viewing time per session was similar for each participant group. (Refer to Table 4.)

Feedback from patients trialling the VR experience

Information and informal feedback provided by patients on each occasion they used the headsets were combined with the responses to interviews completed with participants at the end of the intervention phase. The questions

Table 4 Viewing of VR experiences per site

	In-hospital unit	Satellite unit
Range of number of VR sessions viewed	1–5	1–7
Average VR session time	12 min 32 s	12 min 8 s

asked are listed in Box 1. These questions were a guide only and were asked in a conversational manner.

There were many positive comments about the experience, including "it was different", "something new to try", "I liked it", or it "took me away from here for a while". Several patients were prepared to interrupt watching their favourite television programs (major form of 'entertainment') to use the headsets. Patients engaged with the experience and were observed to be moving their head from side to side, looking around in the scene. They interacted with the scenes and expressed happiness, for example, at being "right where I want to be, at the water's edge".

While some patients "liked whatever was available", others commented that they would like to have "more content to choose from", movies, videos, games, "something educational about renal things", "real footage of home community". One patient said they would use it again if there was more realistic content. One patient suggested that the laser pointer (controller) "was like a fishing rod, would be good if we could catch the fish". The lack of challenge and the somewhat artificial scenes were the most common negative aspects of the visual images.

No patient experienced motion sickness from the headsets, and all felt safe with the experience. Two patients commented that they "felt more relaxed when I got home", although generally the patients did not notice any such difference. However, participants described some challenges. Seven patients said that the headset was a bit heavy on the front of the head or uncomfortable, two patients noted that the headset felt hot, and others noted that they had eye strain after using it and it took a little while for their eyes to adjust after removing the headset. There were multiple challenges associated with individuals who wore glasses, and they tried the headset with and without their glasses. One patient's glasses seemed quite large and he "felt like glasses were being squashed in the headset". Another patient had to discontinue trialling the headset because it was not possible to get a clear image because of his cataracts and other refractive errors.

Patients declined using the headsets on every dialysis session for different reasons. One patient declined to use the device one day, stating "there were too many interruptions by medical staff". But the more common reason for electing not to use the headset when offered was that the three scenes were not engaging enough over time, and participants preferred something less repetitive. On occasions, technical problems associated with wi-fi connectivity or the headsets discouraged patients from using the headsets. When patients found it difficult to navigate to scenes or explain to the clinicians and researchers what they were seeing, they became discouraged and declined using the headsets. Three patients did not like that they fell asleep while using the VR. Patients sometimes declined using the headsets because they did not feel well on that day.

Participants were forthcoming about how the three scenes could be improved as well as what they would like to see if the headsets were available to them in the future. Besides suggesting that fishing could be added to the beach scene, there were suggestions that adding some kangaroos or other animals to the rural scene would add to its authenticity. Nine patients stated they would be interested in using VR again, particularly if more content was available, with statements like "Yes, please! Let me use it again".

Clinician feedback

Twenty-seven of the 49 clinicians working at the time of the survey distribution responded (response rate 55%). Respondents agreed that VR was safe, and easy for the patients to use. They acknowledged that the VR may have been uncomfortable for the patient to use during dialysis. However, they were non-committal about the benefits of VR to the patients, and whether the patients enjoyed the VR experience (refer to Table 5).

There were four open-ended questions. The first question asked, "How did the introduction of VR affect your clinical practice?". Although nine respondents said that the VR had no effect on their clinical practices, six others stated that introducing VR increased their already busy workload and that they had limited time to assist the patients with the VR. As one respondent wrote, "It made it just that little bit busier, as it was basically another job to do". One respondent stated that the clinical care they were providing to other patients was negatively affected if they were focusing on assisting one patient with the VR.

Respondents described difficulties they or the patients encountered in using the VR (question 2). Four respondents identified that it was difficult for them to explain to the patients how to use the VR and navigate to the App. Technical issues such as an unreliable Internet connection or the devices being a little temperamental at times including when the App would not appear (5 responses) presented difficulties. Patients required assistance to put on the headset every time, either because they could only use one hand, the headset was heavy, or they had to fit the headset over their glasses (3 responses), and patients found it difficult to

Table 5 Clinician feedback about the intervention

Statement	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
The patients enjoyed using VR ($n=27$)	1 (3.5%)	6 (59.26%)	10 (37.04%)	10 (37.04%)	0 (0%)
VR made the patient more comfortable during dialysis ($n=27$)	3 (11.11%)	6 (59.26%)	15 (55.56%)	3 (11.11%)	0 (0%)
VR was safe for the patient to use during dialysis ($n=27$)	0 (0%)	1 (3.7%)	5 (18.52%)	14 (51.85%)	7 (25.93%)
VR was easy for patient to use ($n=27$)	2 (7.41%)	7 (25.93%)	4 (14.81%)	12 (44.44%)	2 (7.41%)
There were technical issues with the VR headsets ($n=27$)	0 (0%)	8 (29.63%)	10 (37.04%)	8 (29.63%)	1 (3.7%)
Overall, the VR intervention was beneficial to patients ($n=26$)	1 (3.85%)	6 (23.08%)	13 (50%)	6 (23.08%)	0 (0%)

use the controller if they lacked sensation in their fingers (1 response). Although there were individual comments that the patients complained of headache, lack of sleep, boredom with the VR, lost interest, three wrote that it was relatively easy for the patient after the initial set up.

The third question asked respondents about how the use of VR in the haemodialysis setting could be improved. Most suggestions related to the sophistication of the VR App and choice of other programmes that could be accessed via the headset. Four respondents wrote that the App needed to be more challenging to keep the patients involved; seven noted there needed to be more options for the patients to access including movies, realistic images, images of country, meditation programs and more choice to move between programs. Two respondents suggested that it would be awesome to have the option of interplay between patients or programs that required greater interaction.

There were two comments about having someone in charge to assist patients, particularly with setting it up, so that VR does not impinge on the workload of the clinical staff.

Respondents were asked about what other uses the VR headsets could be used for in the haemodialysis setting. Respondents (8) identified that VR headsets offered promise for patient education, for example about diet, treatment, support for preparing for home dialysis, and for meditation or reduction of anxiety (4). The use of VR headsets for games, entertainment, distraction were other suggestions (4).

Discussion

This crossover RCT was, to our knowledge, the first to explore the feasibility of an immersive VR experience for patients undergoing haemodialysis. Conducted in a busy clinical area, it was well received by patients and clinicians, with both participant groups offering suggestions about how the experience could be improved. Several patients asked if they could use the headsets once the research was completed, having liked the distraction from the clinical aspect of dialysis, echoing research findings by Bers et al [15].

There was no significant difference in participants' attendance between the intervention and control periods (study's primary objective). Potential factors contributing to this finding were: selection of suitable participants resulting in selection bias; [35] small sample size; short duration of intervention/control periods; underlying good attendance by participants. Additionally, if patients participating in the trial were admitted to hospital during the study, their attendance at haemodialysis sessions was assured.

Participants' adherence to fluid allowances (reflected in average daily weight gain) also did not show any significant difference between the control and intervention phases. Like attendance, this could be due to the relatively small sample size and the limited duration of each phase of the trial. Again, patients who were admitted during the trial would have had restricted access to fluids whilst in hospital and a strict fluid intake monitoring regimen would have been implemented by the ward nursing staff during their stay in hospital. Additionally, average rate of weight change data showed that rates of weight gain were somewhat less in older participants compared to younger ones. This result is consistent with historical data from this renal service [36].

The K5 scale for mental wellbeing uses a scoring system where a lower score relates to a more improved mental state. Interestingly patients who reported a high score at the start of the trial went on to record a lower score later in the trial. This supports recent research on VR showing improved mindfulness, [10] increased motivation and engagement in adults [12], and greater positive shifts in mood state in paediatric participants [11]. However, this result may have been influenced by increased attention paid to participants in a clinical trial [37].

There were no significant differences in scores on the Quality-of-Life measure (AQoL 6-D) between the intervention and control phases. Although the AQoL 6D Scale was developed in Australia with demonstrated content validity, [38] our First Nations patients found some of the wording difficult to understand. It may be that another quality-of-life scale more suited to the cultural perspectives of Aboriginal, Torres Strait Islander and South Sea Islander peoples still needs to be developed [39].

Strengths and limitations of the study

The crossover RCT was conducted in a very busy clinical environment, with patients who were generally quite unwell and whose health status often fluctuated. It had been a conscious decision by the researchers and senior clinical staff during the research planning phase to develop simple scenarios, because it was not known how the VR intervention would be accepted by the participants. In hindsight, we may have underestimated the ability of the patients to manage the technology. The patients who used the VR the most proposed some novel suggestions as to how to modify the scenarios, such as adding fishing to the beach scene. Fishing is very culturally appropriate to the Torres Strait Islander patients. Both patients and clinicians commented they would engage further with the VR experience if the scenarios were more challenging or lifelike, which is something to consider for units seeking to implement VR.

Unanticipated barriers to ongoing participant engagement with VR were identified during the RCT, such as individuals' specific visual impairments, decreased sensation in fingers limiting use of the controllers, and difficulties patients encountered in describing to staff what they were seeing. Difficulties in navigating the App space on the headset and inability of staff and researchers to be able to visualise simultaneously what the patients were seeing were evident. It was perhaps these difficulties that prompted nurses to claim that the VR added to their workload. When the researchers were present in the units, there was an increased likelihood of being able to assist the patients access the VR experiences. Clinician engagement was challenging, particularly in the in-hospital unit, related to the wide spectrum of acuity of patients coming in and out of the unit each day. Furthermore, some clinicians reported not feeling confident in assisting patients due to not being 'tech-savvy'. For future research it would be important to have more researchers available at point-of-use to troubleshoot any difficulties encountered.

Whilst providing the VR experience during dialysis reduced inconvenience to the patients, it did add to the nurses' workload if they needed to assist a patient with the VR. This increased workload was a recurring theme found in the clinicians' feedback. Therefore, future VR projects in dialysis settings will require consideration of who will help patients with the device and maintain the headsets.

No formal economic evaluation was incorporated into this study. The cost of emergency air transport retrieval from a north Queensland remote community to the tertiary hospital is greater than $10,000 AUD. This is considerably more than the $6,706 AUD spent for the ten headsets and accessories which were purchased for this RCT. We recommend that future research incorporates an economic evaluation which explores the additional costs associated with emergency dialysis as well as the costs associated with developing and delivering the immersive experiences.

It was disappointing that complete usage data was not able to be downloaded from each headset. There were several information technology challenges encountered by the researchers in the clinical area, including loss of access to the wi-fi provider at the satellite unit for several weeks meaning that headsets had to be brought back to the main hospital for updating. There were frequent discussions between the nurse researchers and the App developer and computer expert to resolve some technical difficulties, including how to navigate different firewalls. For future research it is recommended that time is allocated during the planning phase to fully test the compatibility of computer resources, and to have information technology experts on site at the hospital to address difficulties promptly, as they arise.

Conclusions

In conclusion, the cross-over RCT did not yield a statistically significant difference between the intervention and control groups when evaluating the primary outcome measure. However, it is worth noting that the K5 scale for mental wellbeing employed in the study follows a scoring system where a lower score indicates an improved mental state. Interestingly, patients who initially reported high scores showed a subsequent decrease in their scores, indicating potential improvements in mindfulness, motivation, and engagement with care. This improvement in quality-of-life for patients who have had to relocate to the city from their, sometimes very distant, remote communities is notable.

Nevertheless, it is important to acknowledge that the trial's findings should be interpreted cautiously. This study was found to be feasible albeit information on several technical issues will inform future studies. Further research endeavours should consider conducting studies with larger sample sizes and longer durations to gain a more comprehensive understanding of the intervention's potential effects. Strategies to address the technical issues encountered with using this technology in clinical settings will also need to be devised for future research studies. These efforts will contribute to advancing our knowledge in the field and provide guidance for future interventions and treatments.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s44247-024-00082-z.

Supplementary Material 1.

Acknowledgements
We acknowledge the clinicians working within the hospital and satellite renal units who have taken part in this RCT, in particularly Kimberley Quayle and Constance Bogiatzis who encouraged nurses to support the trial. The assistance of research nurses Mariann Hadland, Nicole Clapham and Nina Watson is acknowledged for their commitment and involvement throughout the trial. John Body-Dempsey, Senior Indigenous Health Worker provided input into the initial planning of the study. Dr Anne Swinbourne contributed to planning the study, particularly with respect to the choice of outcome measures. Biostatistics Support was provided by Emeritus Professor Rhondda Jones, Senior Statistical Consultant, and Alexandra Hodel, Tropical Australian Academic Health Centre.

Published trial protocol
Smyth, W., McArdle, J., Body-Dempsey, J., Manickam, V., Swinbourne, A., Lee, I., Holdsworth, J., Omonaiye, O., & Nagle, C. (2022). Immersive virtual reality in a northern Queensland haemodialysis unit: Study protocol for a cross-over randomized controlled feasibility trial (ACTRN12621000732886). *Contemporary Clinical Trials Communications, 28*. https://doi.org/10.1016/j.conctc.2022.100956.

Authors' contributions
WS, JMcA, VM, IL, JH, OO, & CN contributed equally in the design of the study and in receiving funds; WS & CN led the ethics applications; Il & JH led the design of the virtual experience; WS, JMcA, & GW collected data; WS, GH & CN interpreted the findings and prepared the initial drafts of the manuscript. All authors provided critical feedback on the draft of the manuscript, and approved the final submitted version.

Funding
This study received A$49,976 from a 2020 Tropical Australian Academic Health Centre Seed Funding Scheme. The funder played no role in the conceptualisation, design, data collection, analysis, decision to publish, or preparation of the manuscript.

Availability of data and materials
Data is not able to be shared, as per the original ethics approvals for this study. Interested researchers may contact the first author if they wish to discuss aspects of the study.

Declarations

Ethics approval and consent to participate
This study was approved by the Townsville Hospital and Health Service Human Research Ethics Committee (HREC/QTHS/72273). The research met the requirements of the Australian *National Statement on Ethical Conduct in Human Research* and the *Australian Code for the Responsible Conduct of Research*, and the study was performed in accordance with the Declaration of Helsinki. Patients provided informed written consent to participate in the trial; clinicians indicated their consent to participate on the questionnaire's landing page.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

Author details
[1]Townsville Institute of Health Research and Innovation, Townsville University Hospital, 100 Angus Smith Drive, Douglas, QLD 4814, Australia. [2]Townsville Renal Service, Townsville University Hospital, 100 Angus Smith Drive, Douglas, QLD 4814, Australia. [3]College of Science and Engineering, James Cook University, Nguma-Bada Campus, PO Box 6811, Cairns, QLD 4870, Australia. [4]Centre for Quality and Patient Safety Research, Institute for Health Transformation, Deakin University, Melbourne Burwood Campus, 221 Burwood Highway, Burwood, VIC 3125, Australia. [5]Centre for Nursing and Midwifery, James Cook University, Bebegu Yumba Campus, 1 James Cook Drive, Townsville, QLD 4811, Australia.

Received: 23 November 2023 Accepted: 26 March 2024
Published online: 27 May 2024

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