

Research Protocol

DATE <i>Wednesday, 28th March 2023</i>	VERSION NUMBER 1
STUDY TITLE	<i>Developing a Virtual Reality Psychosocial Intervention for Youth on Dialysis in New Zealand: A proof of concept study.</i>
Short title	<i>A VR Proof of Concept Study</i>

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A) Project summary / Abstract (*provides an overview of the study*)

This project will test the potential of virtual reality (VR) technology to enhance the psychosocial health of youth on dialysis. Twelve participants representing the dialysis population in New Zealand aged 18-24 years will be identified and invited to participate in the study. This study aims to evaluate the usability and acceptability of mindful self-compassion (MSC) delivered via VR by exploring the experiences, perceptions, and preferences of youth on dialysis when using this technology. Using a mixed-methods approach, we aim to identify critical areas of improvement that can be used to enhance user engagement and satisfaction while also providing insights into potential therapeutic benefits associated with delivering psychosocial interventions using virtual reality. Additionally, this study will investigate the logistical considerations associated with implementing a home-based VR psychosocial intervention by assessing logistical challenges and constraints both for recruitment and participating in the study. Validated measures of mindfulness, wellbeing, and self-compassion (pre-test and post-test) and open-ended questions (post-test only) will be assessed.

B) Background / Rationale (*provides justification for the project*)

As of 31 December 2019, there were 187 youths aged 18-24 years on dialysis (haemodialysis and peritoneal dialysis) in New Zealand (1). A significant challenge for youth on dialysis is their low levels of wellbeing and quality of life (2-4). For example, Clavé, S. (2019) and Dingwall, KM. (2021) study found that youth on haemodialysis had significantly lower scores for physical, psychological, social functioning and poorer quality of life compared to healthy peers (2, 3). We recently conducted a systematic review that discovered young individuals on dialysis experience lower quality of life and diminished psychosocial outcomes than their healthy peers. Furthermore, only a limited number of psychosocial interventions have been created for this group (Jaganathan et al., manuscript in preparation).

There is a clear need to improve psychosocial wellbeing of youths on dialysis in New Zealand. The current psychosocial interventions for adults on dialysis are mainly focused on medical rehabilitation, coping/acceptance strategies, cognitive-behavioral therapy (CBT), family therapy, and group counseling (5). However, many of these interventions are resource and time-intensive, which are challenging to incorporate into standard care and expensive to deliver.

A brief version of Mindful Self-Compassion (MSC) may be a promising psychosocial approach for this population. MSC is an evidence-based therapy that involves being kind and understanding to yourself in times of difficulty. It involves cultivating compassionate awareness, which includes recognizing our shared humanity and the common challenges we all face. Broadly, the goal of MSC is to respond with kindness instead of self-criticism when faced with challenging situations or emotions (6). Additionally, mindful self-compassion encourages us to be present and accept difficult emotions without judgment or avoidance; through attentive observation and care for oneself (7). MSC is likely to be a good fit for this population due to its focus on self-compassion, which conceptually is a strong fit for young people who struggle with lower self-esteem (8), self-image (9, 10) and adherence to complex treatment regimens (11). We recently trialed a brief 2-session MSC intervention for youth with type 1 diabetes which yielded promising results. Further, an online version of MSC for youth with diabetes is currently in development (12). For the present study we have adapted the brief version of MSC for young people on dialysis, which we aim to deliver in an one hour VR group session.

Virtual reality is a form of immersive experience that holds great potential for improving psychological outcomes in various environments, including for people with limited access to face-to-face group interventions (13). Research has also suggested that VR-based therapies may provide relief from physical and psychological symptoms associated with chronic illnesses such as dialysis or cancer by reducing stress and improving mood (14). Furthermore, VR interventions may be used as an effective tool for helping young patients on dialysis better manage their condition by providing them with a safe (15) and engaging virtual environment (16) in which they can explore different psychosocial aspects or challenges associated with the treatment and their condition. In addition,

these interventions offer individuals the opportunity to gain greater self-awareness and insight into their own needs and capabilities, and may lead to improved quality of life overall (17-20). For example, one study found that after undergoing three months of virtual reality forest therapy, 20 haemodialysis patients between 25–65 years old reported positive changes such as lower levels of anxiety and depression, improved sleep quality, more positive moods, and higher life satisfaction scores, along with high satisfaction regarding the intervention itself (21).

Preliminary research has found that virtual reality interventions can increase self-compassion in healthy young people, leading to a reduction in self-criticism and suicidal tendencies, along with an overall improvement in mental health resulting from self-compassion (22-25). Additionally, through short sessions of VR therapy, there has been some evidence to suggest that feelings of self-compassion can be rapidly improved and potentially reduce suicidal ideation in healthy populations. Furthermore, the authors of these studies found that improvements in self-compassion could lead to better overall well-being (22-25). Although results have been encouraging there is still much work to be done when it comes to designing age-appropriate interventions catered towards the specific needs for young people on dialysis.

C1) Aims and Objectives

In this project, we are conducting a proof-of-concept study to explore the feasibility of a Virtual Reality (VR) group intervention using a brief one-session MSC intervention for youth on dialysis. The overall aim of this research is to explore the usability and acceptability of mindful self-compassion as a treatment approach delivered using VR for New Zealand youth on dialysis.

Overall aim

- To explore the usability and acceptability of a one-session MSC intervention delivered via VR.

Objective

- To explore the feasibility of recruiting up to 12 young people on dialysis to take part in this proof-of-concept study
- To explore feasibility of delivering a brief one-session MSC via VR
- To explore the conceptual fit of MSC for youth on dialysis and their feedback for improving the intervention content
- To explore the usability of the VR technology and any possible VR side-effects (e.g., dizziness, fatigue).
- To explore which psychometric questionnaires are suitable for assessing possible improvements in wellbeing in preparation for a future efficacy trial.
- To identify any other user feedback from the participants on the intervention content and VR technology using open ended questions.

D) Methodology

- Study participants and recruitment

We will aim to recruit 12 young people aged 18-24 years on dialysis (either haemodialysis or peritoneal dialysis). Potential participants will be identified by DHB staff, and invitations will be made by University of Auckland researchers who will ask the renal clinic to email interested eligible participants the PIS and study information along with the research team's contact details. In this invitation email, eligible participants will also be sent the PIS and consent forms which they can sign and return in a pre-paid envelope or via email. Participants will be recruited using a purposive sampling frame, to try to recruit both men and women and from a wide range of ethnic groups. We will try to include participants who can provide views on the Māori and Pacific experience, across the entire

age range of 18-24, with a broad socioeconomic / rurality distribution if possible. Youth with severe psychiatric or developmental disorders and youth with visual impairments or physical disabilities which prevents them from using VR will be excluded.

Participants: Purposeful sampling

- A group of 12 participants (Youth between 18-24 of age)
- Mix of males and females in each group.
- Mix of ethnic groups including a focus on recruiting Māori and Pasifika youth who are disproportionately affected by chronic kidney disease.
- Peritoneal dialysis/ Hemodialysis PD/HD in each group will be included.

Recruitment Procedure

- Invitations to participate will be made to potential participants by the UoA Research Team, after initial dissemination of information about the research study using letters and posters and emails distributed by clinical nurses and patient support staff within the DHBs. Interested potential participants will be asked to contact the research team.
- Eligible participants can either choose to give informed consent by emailing/posting consent forms prior or during the home visit when the VR headsets are delivered, prior to baseline assessments being taken.
- The group session will be video recorded with the participants' permission.

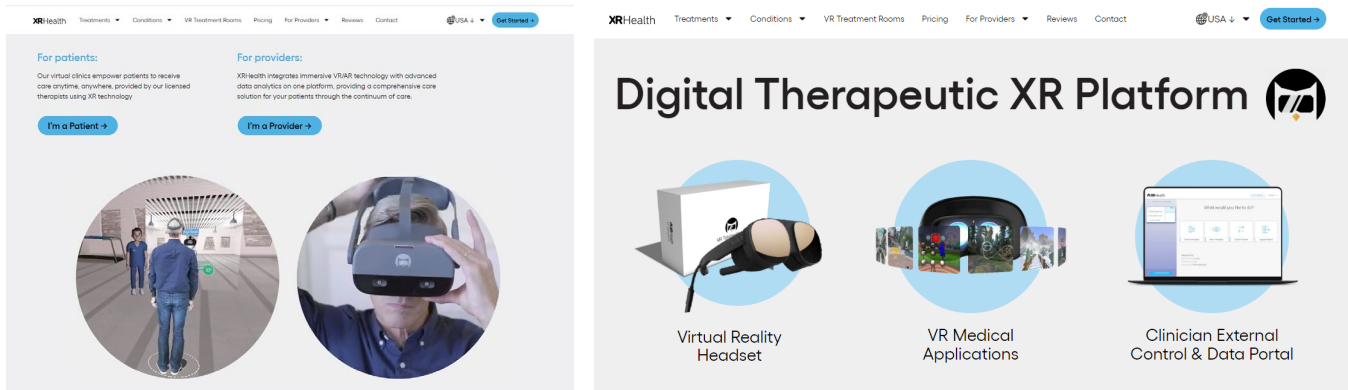
○ Study design

This is a mixed methods proof-of-concept study to explore the usability and acceptability of a brief MSC intervention delivered via VR. Quantitative measures will be collected to assess baseline demographic and clinical characteristics. Psychosocial questionnaires will also be collected at baseline and post-intervention. Open-ended questions will be administered after the intervention and analysed qualitatively to explore user experience of the intervention and the VR technology.

○ Study Procedure

A week before the VR group session, the research team will conduct a home visit to interested participants. At this home visit, participants will be asked to provide informed consent (if they have not already done so) and subsequently, they will receive a demonstration of the VR tool and headset. Baseline assessments will also be carried out (by the student researcher and the research assistant).

The following week, the intervention will be conducted with approximately six participants per group. Each group session will last approximately 75 minutes: 60 minutes of intervention with a 15-minute break after 30 minutes. Participants will take part in the intervention either from their home (if they have Wi-Fi and a private room they can use) or alternatively from the University of Auckland Department of Psychological Medicine where the PhD student and the intervention facilitator will also be based when the VR session is conducted. The participants and the facilitator will sign into the VR Application called 'Connect' developed by XRHealth, an Australian digital innovation company offering FDA approved VR applications. 'Connect' allows people to remotely participate in a group session via VR. Participants choose an avatar to represent themselves and participate in the virtual group session with the help of their VR headset (please see image below).



Screenshot of XRHealth website <https://www.xr.health/>



User Interface of the VR CONNECT Dashboard

A postdoctoral researcher from the Department of Psychological Medicine who is familiar with MSC will facilitate the group session along with Dr Anna Serlachius (Senior Lecturer in Health Psychology) using the VR portal. At the start of the VR session, they will provide a verbal introduction to outline procedures and guidelines and answer any questions participants may have. Participants will also be encouraged to ask any questions at any time during the session. The group sessions will be recorded with the participants' permission. This will include visual recordings of the virtual group session itself (the participants will not be visible, but their avatars will be), all the dialogue arising during the session, and visual recordings of participants in real-time to assess for non-verbal cues and physical issues regarding the VR technology. During the group session, the facilitators will go through the different components of MSC (mindfulness, compassion, and common humanity) and will take the group through several exercises. After 30 minutes the facilitators will suggest a 15-minute break and will check-in on how the participants are finding the session and the VR headset. The remaining session will last another 30 minutes and will cover similar topics. See below for a table of topics that will be covered in the VR session. All participants will receive \$50 Westfield/Countdown voucher as a koha to thank them for their time with the research. The intervention is discussed in more detail below.

- 1) The following questionnaires will be administered at the baseline home visit and 2 weeks after the intervention (over Qualtrics, a secure research website). We will also assess demographic and clinical measures at baseline including ethnicity (using NZ census questions), age, sex, age when diagnosed, comorbidities, and treatment.

The following questionnaires will be assessed both at baseline and after the VR group session.

- Self-Compassion Scale short form (26)
- WHO-5 Wellbeing scale (27)
- Five Facet Mindfulness Questionnaire (FFMQ-15) (28)

The following questionnaires will only be asked after the VR group session.

- Modified (customised for the study) System Usability Scale (SUS) (29)
- Participants will also be asked several open-ended questions to explore what they learnt from the intervention and if they have used any of the skills or exercises (e.g., “Over the past 2 weeks have you used any of the skills that you learned from the VR session?”)

2) VR Session:

Table 1 Components of the brief self-compassion intervention for youth on dialysis

First half/ 30 minutes	2 nd Half/ 30 minutes
An icebreaker (Participants introduction) and (establishing the ground rules for anonymity, allowing a safe space to share, etc)	A compassionate body scan meditation (relaxation exercise that can also address body image concerns)
How I treat a friend versus how I treat myself? (To introduce self-compassion and provide a rationale for why self-compassion is important)	Crossing the line (to allow for the discussion of common difficulties, adding in dialysis-related struggles, and to help ease isolation)

Data Analysis

The quantitative measures (baseline demographic and clinical measures and psychosocial outcomes) will be reported using means and standard deviations. The study is not powered to look at efficacy as this is a proof-of-concept study, therefore we will not be exploring differences between baseline and post-intervention. The open-ended questions will be analysed using qualitative content analysis to explore participants’ experiences of the VR session. The recorded VR group session will also be analysed to further explore usability and acceptability of the group session including questions asked about the session content and any reported challenges using the technology.

E) Ethics and safety

- Informed consent will be provided by all participants prior to any baseline data being collected and prior to the VR session.
- Relevant consultation – This project has been guided by Māori consultation with Iwi United Engaged and with two health psychologists at Middlemore Hospital working in the diabetes and renal department.

F) Resources Required

Virtual Reality headsets will be leased from XRHealth, Australia. PhD Press Account Research Funds will be used to lease the headsets and for koha and research related expenses.

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