UNIVERSIDAD SAN FRANCISCO DE QUITO USFQ

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Research Proposal: Mindfulness Intervention Using Virtual Reality in Hemodialysis Patients with Anxiety and Depression Symptoms in Ecuador.

.

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RESUMEN

La enfermedad renal crónica es una condición caracterizada por cambios en la estructura renal y disfunción progresiva e irreversible de los riñones, que se ve principalmente adultos mayores. Según el progreso de la enfermedad, las funciones renales de los pacientes son tratadas con hemodiálisis. Debido a los síntomas de la enfermedad renal crónica y los efectos secundarios de la hemodiálisis, se ha estimo una alta prevalencia de ansiedad y depresión en esta población que puede desencadenar más complicaciones que atentan hacia su salud. Existe evidencia que apoya la viabilidad del uso de terapias basadas en Atención Plena o Mindfulness en pacientes con hemodiálisis, pero no se ha explorado en su totalidad los efectos que puede tener su combinación con realidad virtual sobre la ansiedad y la depresión. En base a ello, se presenta una propuesta de investigación que compara los efectos de una intervención basada en mindfulness en combinación con tecnologías de realidad virtual, con una intervención de mindfulness sin uso de realidad virtual. Se pretende con esta propuesta diseñar un modelo de intervención que

Palabras clave: Hemodiálisis, Enfermedad Renal Crónica, Atención Plena, Realidad Virtual, Depresión, Ansiedad.

ABSTRACT

Chronic kidney disease is a condition characterized by changes in the renal structure and progressive and irreversible dysfunction of the kidneys, which is seen mainly in older adults. Depending on the progression of the disease, patients' kidney functions are treated with hemodialysis. Due to the symptoms of chronic kidney disease and the side effects of hemodialysis, there is an estimated high prevalence of anxiety and depression in this population that can trigger further complications that threaten their health. There is evidence supporting the feasibility of the use of Mindfulness-based therapies in hemodialysis patients, but the effects of their combination with virtual reality on anxiety and depression have not been fully explored. Based on this, a research proposal is presented that compares the effects of an intervention based on mindfulness in combination with virtual reality technologies with a mindfulness intervention without the use of virtual reality.

Key words: Hemodialysis, Chronic Kidney Disease, Mindfulness, Virtual Reality, Depression, Anxiety.

TABLE OF CONTENT

ABBREVIATIONS:

CKD: Chronic kidney disease

GFR: Glomerular filtration rate

ESRD: End-stage renal disease

HD: Hemodialysis

MBI: Mindfulness-based intervention

VR: Virtual reality

MVR: Mindfulness with virtual reality

CBT: Cognitive Behavioral Therapy

Introduction

Dialysis in Chronic Kidney Disease

Definition and Physical Symptomatology

Chronic kidney disease (CKD) is a condition characterized by irreversible and progressive changes in kidney structure and functional impairment during a time-lapse of at least 3 months (Webster et al., 2017). The onset of CKD has been related to other conditions such as acute kidney injury (Yang, 2019), diabetes, or hypertension (Webster, et al., 2017). Genetic heritability, overweight, and heart diseases are also considered risk factors for CKD (Centers for Disease Control and Prevention [CDC], 2021).

The disease's severity level is measured and classified into five categories based on glomerular filtration rate (GFR), which indicates the kidney's capacity to filter blood and eliminate waste products such as creatinine, and urea (Levey & Croesh, 2012). Patients are typically diagnosed with CKD when the GFR is under 60mL/min per 1.73 m² or show other types of abnormalities, such as albuminuria and hematuria (Kalantar-Zadeh et al., 2021). End-stage kidney disease (ESKD) is the fifth and most severe phase of CKD. To preserve his life, the patient must replace kidney functions imperatively through kidney transplants or regular dialysis interventions. Besides, the chance of premature death is higher for CKD patients than their likelihood of progressing into the fifth stage (Webster, et al., 2017).

Other kidney functions that are compromised by the damage are the release and metabolism of hormones (Habas, et al., 2021), regulation of fluid levels (Borrelli, et al., 2020), and minerals (electrolytes) balance (Abdulla et al., 2020). The most common consequences of CKD involve the accumulation of toxins within the body, high blood pressure, lack of insulin metabolism, and liquid retention (Mitsides et al., 2019). Depending on the severity of CKD, the

patient is at risk of developing brain damage (Wyld & Webster, 2021), cardiac arrhythmias, heart failure, pulmonary edemas, or bone disorders (Cannata-Andía, et al., 2021).

Epidemiology

Recent literature reviews depict that a range between 10-13% of the adult global population suffers from CKD considering all 5 stages (Hill et al., 2016; Kovesdy, 2022; Lv & Zhang, 2019). The distribution of CKD divided by stage is the following: 3.5% are in stage 1, 3.9% in stage 2, 7.6% are in stage 3, 0.4% in stage 4, and 0.1% in stage 5 (Hill et al., 2016).

Regarding gender, when male and female samples of patients with CKD were compared, researchers found that men tend to have a faster progression of the disease, causing more damage in a shorter period of time, while women present a higher prevalence of CKD, but a slower progression of the symptoms (Valdivieso, et al., 2019).

Other sociodemographic factors need to be considered to gain a precise prevalence of CKD, such as the country and age of the patients. Patients living in low- and middle-income countries tend to have a higher prevalence of CKD. Based on this, 10.6% of the male population from low- and middle-income countries suffer from this condition, compared to 12.5% of female individuals in the same socioeconomic situation (Kovesdy, 2022).

Age is also a significant factor in CKD prevalence, due to the high incidence in elderly population. Worldwide, half of CKD patients are aged over 70 (Dolati et al., 2020). According to the United States Renal Data System (USRDS, 2022), 33.2% of adult individuals aged 65 years old or more suffered CKD in the US during the 2017-2020 period. Of them, more than 60% were in the stage 3 of the disease. Only 9% of individuals under 65 years old had CKD in the same period of time (USRDS, 2022).

In regard to CKD mortality, studies show a significant increase in deceases in the last 30 years by 41.5% (Bikbov, et al., 2020). Only in 2017, CKD took the lives of 1.2 million patients (Bikbov et al., 2020). In the US, 103.9 per 1000 person-years died due to CKD in 2020 (USRDS, 2022).

Hemodialysis

Hemodialysis (HD) is a renal replacement therapy, which consists of a process of blood filtration through a machine, in order to excrete waste products and balance liquid levels in the blood (Cavalli et al., 2010). It is used in patients with both, acute and chronic kidney failure, as well as other kidney complications, but only CKD are dependent on HD for life. It is recommended that CKD patients recur to HD before stage 4 to avoid complications (Murdeshwar & Anjum, 2023).

Before the HD, an intravenous graft is used to extract the patient's blood from his vein and an intravenous fistula is used to connect directly to the patient's artery. Both tubes are connected to a machine that pumps the blood out of the body, filtrates it with dialyzer fibers, and returns the blood to the body (Murdeshwar & Anjum, 2023). Since it is a medical treatment that requires filtrating all the patient's blood, it usually lasts between three and six hours and the standard administration frequency is three times per week (Himmelfarb & Ikizler, 2010). This process can be administered at a dialysis center or at the patient's home, but the current tendency is receiving HD at a center (Himmelfarb & Ikizler, 2010).

There is a higher number of people that recurs to HD instead of other renal replacement therapies like perinodal dialysis or renal transplantation. Recent data indicates that approx. 2.62 million CKD patients depend on HD to replace their kidney functions and continue living (Luyckx et al., 2018). 88% of CKD patients receive hemodialysis in the US, instead of peritoneal

dialysis, which is applied to 9% of the patients (Kaplan, 2017). There is a little prevalence of patients waiting for a kidney transplantation because this possibility also depends on the availability of a compatible donor (Kaplan, 2017).

Regarding gender, in a study that evaluated hemodialysis patients from high-income countries, 59% were men and 41% were women (Hecking et al., 2014). The average age of the female CDK population starting hemodialysis tends to be older than men (Carrero et al., 2018).

Reports of pain are frequent in the HD population. Gamondi et al. surveyed patients undergoing HD in Switzerland and, in the month prior to the interview, more than 65% reported experiencing pain, more than 55% experienced chronic pain, more than half of their sample scored pain level at 5 in the Visual Analogue Scale (2013). The most common unpleasant physical symptoms that influenced the experience of pain were anxiety, sleep disorders, nausea, and breathing difficulties (Gamondi et a., 2013). In the senior HD population, all aforementioned pain sources increase their prevalence and intensity (Dolati et al., 2020).

Dialysis and Mental Health

Depression

Depression is known in psychiatry as a mood clinical condition characterized mainly by constant decay prolonged in time, which is accompanied by feelings of grief, loneliness, guilt, and hopelessness (American Psychiatric Association, 2013). The expression of depression is multidimensional, thus showing affections at different levels in an individual's life, for example, work performance (Guannarsson, et al., 2023), sleep habits (Fang et al., 2018; Pandi-Perumal et al., 2020), difficulties in cognitive skills (Dotson, et al., 2020), significant weight changes (Konttinen, 2019), and lack of energy (Wang, et al., 2022). Likewise, suicidal behavior is a frequent element in depression patients, which can be reflected in self-injurious behaviors,

suicidal planning, or suicide attempts (Pompili, 2019). The relationship between depression and suicide is believed to lay in psychological pain, a concept that encompasses the feeling of dissatisfaction of an individual with himself, his context, his psychological needs, and his social ties (Conejero, et al., 2018).

When patients are diagnosed with CKD and their symptoms require renal replacement therapy, patients are classified under the stage called predialysis, a term used to define the process of physical exhaustive evaluation to determine the best treatment possible (Broers et al., 2015). Thus, during the process of predialysis, Wang et al. (2019) evaluated depression in CKD patients. Results showed them not only a prevalence of 23% of depressed patients in their sample, but also a higher chance of developing depression in patients in stages 4 and 5 than in stages 1 and 2. In predialysis it is common for patients to isolate themselves from their support network, and report feelings of denial, irritation, and anger (Almutary, 2023). Quality of life (QoL), a term used to define elements that increment wellbeing in an individual, is also affected due to HD (Gerasimoula et al., 2015). During the first year of hemodialysis implementation, patients report decreased levels of quality of life (Kurella et al., 2018; Kalantar-Zadeh et al., 2017).

In HD patients, depression is the most common psychological condition with an estimated prevalence between 21.7 and 84.9% (Al-Shammari et al., 2021; de Alencar et al., 2019; Khan et al., 2019; Meng et al., 2022; Mosleh et al., 2020; Muthukumaran et al., 2021; Semaan et al., 2018; Shahrin et al., 2019; Tian et al., 2021). Compared to the World Health Organization (WHO, 2021), which indicates a prevalence of depression in the global population of 3.8% and 5.7% in individuals aged over 60 years, it is more likely to find symptoms of depression among HD patients.

Some experiences reported by HD depressed patients are feelings of grief because of the loss of their health, reduced autonomy, guilt for the economic burden, decreased quality of life, lack of hope, fear of death, frustration due to the lack of instant improvement, and physical symptomatology such as inflammation or pain (Almutary, 2023; Shirazian, 2019). All these symptoms contribute to an increase in the mortality rate (Muthukumaran et al., 2021; Ma & Li, 2016).

Also, sociodemographic variables that may influence the prevalence rates were studied. In a 6-month longitudinal prevalence study by Kahn et al. (2019), researchers found no significant correlation between gender, socioeconomic status, and years of treatment in the incidence of depression in HD patients. Instead, a significant difference was discovered between the depression and no-depression groups in relation to their body mass index (BMI) and the status of their treatment center (Khan et al., 2019). These allowed them to conclude that having a normal and an overweight BMI, as well as being treated in a governmental or non-governmental organizations (NGO) dialysis center, were predictors of developing depressive symptoms in their sample (Khan et al., 2019). The authors also noted an increase in the depression incidence between their first and final visit respectively with a 6-month interval (Khan et al., 2019). Age was also found as a significant influence on depression, being those patients with higher ages in more likely to report depressive symptoms (Mosleh et al., 2020).

In regards to suicide, the incidence of suicidal ideation has been reported between 12.8% and 21.5% depending on the sample (Chen et al., 2010; Jhee et al., 2017). Presenting symptoms of anxiety and depression is considered a risk factor for suicidal ideation (Chen et al., 2010).

Anxiety

Anxiety itself is a natural survival response of our organism to situations that are considered threatening or dangerous (American Psychiatric Association, 2013). The clearest signs of anxiety are worry, fear, and nervousness, which are expressed as responses in the sympathetic nervous system, rumination, or, in some cases, somatization (American Psychiatric Association, 2013). Anxiety becomes maladaptive when the situation perceived as stressful is imaginary or has no solution, when it is maintained chronically (more than 6 months), or when the intensity or presence of anxiety in a certain situation do not fit the facts (Ball & Gunaydin, 2022). There are several classifications of anxiety disorders in the psychiatric model (American Psychiatric Association, 2013) and most of them are characterized by the extreme avoidance of the feared object or situation (Ball & Gunaydin, 2022).

Since anxiety activates physical responses to fear, the prolongation of these mechanisms can negatively affect patients' health status. For instance, cardiovascular complications and hypertension are associated with anxiety symptoms (Celano, et al., 2016). In CKD patients, anxiety affects their quality of life, nutrition, treatment adherence, and elevates the risk of mortality (Cohen et al., 2016)

The prevalence of anxiety in HD population is ranged between 19.7% and 49.6% depending on the sample (Al-Shammari et al., 2021; Alshogran et al., 2022; Chen et al., 2010; Meng et al., 2022; Marthoeins et al., 2021; Mosleh et al., 2020; 2021; Nagy et al., 2023; Semaan et al., 2018).

In individuals with CKD, there are different studies and reports where the correlation between anxiety and sociodemographic variables is analyzed. Regarding gender, some authors report that women were more likely to report anxiety symptoms (Chen et al., 2010; Mosleh et al.,

2020) and others found more incidence of anxiety in male patients (Nagy et al., 2023). The age of the patients had no significant correlation with anxiety symptoms (Mosleh et al., 2020). There is still controversy in the results that correlate marital status and levels of anxiety. Those patients who were divorced or widowed reported more anxiety symptoms than their married peers with children (Al-Shammari et al., 2021). Semaan and colleagues differ in the results of their sample, where patients who lived alone showed less anxiety (Semaan et al., 2018). There has also been found that working status has an influence on anxiety levels, where those patients that had a job presented more anxiety (Nagy et al., 2023).

Moreover, the comorbidity of anxiety and depression was estimated in 12.6% of the sample of Al-Shammari et al. (2021) and 24.1% in Semaan et al. (2018). Anxiety presented a positive correlation with depression (Marthoeins et al., 2021).

Additionally, other physical complications that contributed to the onset of depressive and anxious symptomatology were Glomerulonephritis (Al-Shammari et al., 2021), and severe pruritus (Meng et al., 2022).

Current Treatment of Depression and Anxiety in HD

Different psychosocial interventions have been implemented for HD patients, which include acupressure, psychoeducation, spiritual practices, cognitive-behavioral therapy, counseling, physical exercise, meditation techniques, relaxation exercises, social activity, and telephone support (Natale et al., 2019). Acupressure had significant effects on depression and anxiety scores compared to usual care in the sample of Hmwe et al. (2015) and reflexology in Dehghanmehr et al. (2019). From both studies, only Dehghanmehr et al. (2019) reported significant differences between the groups in depression and anxiety scores after the intervention in their sample.

Psychoeducation sessions showed effectiveness in reducing depression levels but had no significant effects on anxiety (Espahbodi et al., 2015). Besides, Espahbodi et al. (2015) did not find significant differences in those patients who received psychoeducation in comparison to the control group, which received usual care. When psychoeducation was compared to Cognitive Behavioral Therapy (CBT), researchers observed significant improvement in depressive symptomatology, but the group that received psychoeducation presented better results (Al Saraireh, et al., 2018).

It has been found that relaxation techniques through breathing can effectively reduce depression (Tsai et al., 2015). Guided imagery was also found successful at reducing anxiety and depression when combined with nature sounds in HD patients (Beizaee et al., 2016). Breathing-based relaxation strategies, specifically Benson's relaxation technique, had significant effects compared to usual care decreasing depression and anxiety alone (Heshmatifar et al., 2015) and in combination with music therapy (Eroglu, 2022).

Other interventions have also been administered. As a spiritual practice intervention, Babamohamadi et al. (2016) found effectiveness in applying recorded recitations of the Quran to reduce depression in HD patients. Also, when exercise was combined with Quran recitation, there was also found an improvement in anxiety and depression (Frih et al., 2017).

In regard to psychopharmacology, Nadort et al. (2020) posited a literature review, in which those studies where Selective Serotonin Reuptake Inhibitors were administered to HD patients reported no significant improvement in depression.

Mindfulness in Hemodialysis

Mindfulness is the ability to focus attention voluntarily on the present moment (Creswell, 2017). It has its origins in Buddhist philosophy and Christian contemplative practices, where the

individual seeks awareness of their context in small features, such as breathing, in order to develop the capacity to notice (Siegel et al., 2009). Usually, depending on the therapeutic model and perspective, mindfulness practice is characterized by observation and description of the present moment without judgment in order to increase the openness to reality as it is (Baer et al., 2019). There are different techniques used in the mindfulness practice focused on inner and external experiences, which pretend to cultivate a mindful mind-set applied on a daily basis (Linehan, 2014). Some exercises include body scan, mindful walking, paused breathing, and surfing emotions and thoughts (Baer, 2015; Linehan, 2014). Other models apply the practice of loving-kindness, which describes the cultivation of kindness for oneself, and others based on nonjudgmental compassion (Baer, 2015).

In the general population, mindfulness has been implemented as an effective intervention for depression and anxiety (Khoury et al., 2013). In a diverse sample, Bell (2015) contrasted the effects of a mindfulness-based intervention (MBI), eyes-closed relaxation, and time of silence and noted that only the MBI was able to decrease levels of depression and increase awareness significantly. Anxiety, blood pressure, and heart rate were successfully reduced in all conditions (Bell, 2015).

During the Coronavirus pandemic, Dehghan et al. (2021) studied the relationship between mindful features and stress due to the virus in HD patients in ESRD. They noted that those individuals with higher levels of mindfulness reported less anxiety related to the Coronavirus, than those subjects that scored lower on the mindfulness scale (Dehghan et al., 2021). In contrast, researchers also assessed spiritual health, a concept that defines the meaning of life and a sense of link to a superior power. They did not find a correlation between spiritual health and Coronavirus-related anxiety (Dehghan et al., 2021).

Igarashi et al. (2021) implemented a mindfulness-based meditation technique that consisted in directing the attention of HD patients to their body, their breathing, their own mind, and loving-kindness. Through these four modules, patients learned the ability to mindfully observe themselves and their environment, which resulted in an estimated decrease in depressive symptomatology of 23% from the baseline (Igarashi, 2021).

Adamoli et al. (2021) designed an MBI format and presented it with an experience report of their 15-participant sample. Even though, the effects of the program on depression and anxiety were not quantitatively reported, some testimonies of the patients agreed that it was a calming and pleasurable experience (Admoli, et al., 2021).

Thomas et al. (2017) posited the difficulties they had applying a mindfulness intervention for depression and anxiety in HD patients, which include: "frequent hemodialysis shift changes, interruptions by staff or alarms, space constraints, fluctuating participant medical status, and participant fatigue" (p.1). In their sample, these kinds of obstacles were frequently reported during the sessions, and recommended the use of headphones to help the patients focus their attention. No significant effects were found on depression and anxiety levels after the treatment.

Additionally, mindfulness has been compared to other interventions. Nassim et al. (2021) encountered that a brief mindfulness intervention was superior to a Health Enhanced Program dealing with anxiety symptoms, yet both presented similar effectiveness in reducing depression symptoms. After 6 months after the last session, Rigas et al. (2022) found in the same sample that the effects prevailed, showing that the symptoms were not only during the intervention time but also in the longer term.

Moreover, when combined with other interventions, the practice of mindfulness has been found significantly helpful with depressive and anxious symptoms. Sohn et al. (2018) combined

a CBT intervention with a mindfulness-based meditation in ESRD patients. Their subjects scored lower on anxiety and depression scales after the intervention (Sohn et al., 2018).

As additional benefits, Alhawatmeh et al. (2022) applied mindfulness in HD patients and discovered an increase in emotion regulation, quality of life (related to their kidney condition), and perceived stress in a group that practiced mindfulness compared to eyes-closed relaxation. Their treatment regime consisted of 30-minute meditation (or eyes-closed meditation) during HD, 3 times per week, for a lapse of 5 weeks (Alhawatmeh et al., 2022). These effects on QoL agree with Sohn's et al. (2018) results. Likewise, Noorifard et al. (2019) found significant effects of an MBI in patients' cognitive emotion regulation strategies. Other effects of mindfulness in HD patients are reduced heart rate, and both, systolic and diastolic blood pressure (Park et al., 2014; Igarashi et al., 2021), as well as an improved controlled of serum phosphorus levels (Igarashi et al., 2021; Sohn et al., 2018). In the same sample of Nassim et al. (2021), Lavin et al. (2021) measured the effects of an MBI on patients' insomnia and found that patients had better sleep quality after the mindfulness intervention compared to the baseline measures.

Virtual Reality in Hemodialysis

Virtual reality (VR) is a visually immersive experience in which an individual uses a head-mounted display to simulate places and images and to have the sensation of being in a specific scenario (Horvath et al., 2023).

Omonaiye et al. (2021) depict a literature review of the effects of VR on HD patients and conclude that the implementation of these technologies decreased the report of fatigue in the patients, increased quality of life, and incremented treatment adherence. Several studies of their sample reported that using VR was safe and was perceived as an enjoyable experience (Omonaiye et al., 2021).

Additionally, VR technologies have been implemented in HD patients for exercise interventions and nature therapy. Hsieh and Li (2022) incorporated VR into nature therapy, giving HD users the experience of walking through a virtual forest, significantly reducing their heart rate and improving their cardiovascular health. Also, implementing physical exercise in combination with VR resulted in no significant effects on depression, despite its positive effects on quality of life compared to their control (Maynard, et al., 2019). In contrast, the sample of Zhou et al. (2020) found significant differences in the depression levels reported by HD patients after intradialytic exercises. Depression reduction was the same in both experimental and control groups, with and without VR technologies respectively (Zhou et al., 2020).

Mindfulness and Virtual Reality in Hemodialysis

Limited research has studied the combination of mindfulness and VR in HD patients. Hernandez et al. (2021) measured the safety and the level of immersion of mindfulness with virtual reality (MVR) intervention in HD patients and concluded that it is not only safe and easy to apply, but also that it improved the symptoms of nausea. Patients could effectively immerse themselves into the VR experience in two 25-minute sessions and reported calm, enjoyment, and distraction (Hernandez et al., 2021).

For this research proposal, no studies were found about the effects of MVR interventions to treat anxiety and depression in HD samples. Therefore, it is necessary to consider the effects of administering MVR on the depression and anxiety of other populations.

Mindfulness and Virtual Reality for Anxiety and Depression in Other Populations

The evaluation of the effects of MVR interventions have been studied in diverse populations. In a primary care setting, Navarro-Haro et al. (2019) compared the effects of an MBI, and an MVR intervention, based on VR Dialectical Behavioral Therapy. Both groups

presented better scores in anxiety, and depression after the interventions (Navarro-Haro et al., 2019). The difference between the groups was in terms of treatment adherence, in which, the MVR group had no attrition incidence and 30% of all participants in the MBI group dropped out.

Moreover, in a case study with two patients with spinal cord injury, after an intervention of MVR, both individuals reported less depression and anxiety than before (Flores et al., 2018). One of the patients also showed short-term improvements in his symptoms of acute stress disorder / post-traumatic stress disorder (Flores et al., 2018).

Also, in fibromyalgia patients, Botella et al. (2013) implemented MVR in a CBT program with moderate effects on depression when the scores pre- and post-intervention were measured. During the intervention, patients were invited to refocus their attention from their pain to other present elements not related to it (Botella et al., 2018). Mindful abilities such as observation and description without judgment were extremely relevant for the patients to change their experience of their own pain (Botella et al., 2018). Even after six months after the intervention, patients reported significantly lower levels of pain and depression, as well as healthier coping abilities (Botella et al., 2018).

As additional benefits, Pascual et al. (2023) applied MVR sessions in healthcare workers and measured their levels of relaxation based on heart-rate variability as a biomarker. Their study aimed to compare a group that used MVR and a group with mobile app meditations (Pascual et al., 2023). Those participants in the MVR group completed more sessions and showed more relaxation levels than the group with the mobile app (Pascual et al., 2023).

Objectives

General objectives

Assess the effects, acceptability, and feasibility of a mindfulness-based intervention in combination with virtual reality technologies on depressive and anxious symptomatology of a sample of Ecuadorian elderly hemodialysis patients.

Specific objectives

1. Evaluate the prevalence and comorbidity of depression and anxiety in an Ecuadorian hemodialysis sample of patients.

2. Assess the efficacy of mindfulness-based interventions in depression and anxiety in hemodialysis patients with pre- and post-intervention measures.

3. Compare the effects of a mindfulness-based intervention with and without the implementation of virtual reality in depression and anxiety symptoms in the post-intervention testing.

4. Contrast the results based on demographic variables such as gender, age, marital status, ethnicity, medical history, habits, history of meditation, time in dialysis, and chronic kidney disease stage.

5. Measure the acceptability of the intervention through completed sessions and dropouts.

6. Identify possible obstacles during the intervention that may interfere with its efficacy.

Hypothesis

H1: Individuals of both groups will report significantly fewer symptoms of depression and anxiety in the post-intervention measures.

H2: Those patients undergoing the mindfulness-based intervention combined with virtual reality will report significantly reduced scores of anxiety and depression in the post-intervention evaluation in comparison to the group that only received a mindfulness-based intervention without virtual reality technologies.

H3: Demographic variables will not have an influence on the levels of depression and anxiety after and before the intervention.

H4: Those individuals in the mindfulness-based intervention with virtual reality will present a reduced incidence of attrition.

H5: In both groups, mindfulness scores will improve from the pre- to the post-evaluation.

Methods

The present project proposes a randomized controlled trial to evaluate the efficacy of a mindfulness-based intervention combined with virtual reality in the symptoms of anxiety and depression of an elderly individual's sample undergoing hemodialysis. The results will be compared to a control group that will receive a mindfulness-based intervention without virtual reality technologies, where the same constructs will be evaluated.

Previous research, that implemented MBIs to treat depression and anxiety in HD patients, was considered as the basis to create this research proposal due to the lack of literature about MVR interventions in anxiety and depression of HD patients (Table 1). Nassim et al. (2021) designed an 8-week intervention regime, where patients received 2 sessions per week for 20 minutes. Igarashi et al. (2021) also implemented a 12-week intervention, but they incremented the number of sessions to 3 per week for 20 minutes each. Controversially, Thomas et al. (2017) did not report significant results on depression on anxiety in their 8-week intervention of 3

sessions weekly for 15 minutes. All aforementioned authors implemented the intervention during the first two hours of the dialysis process.

Table 1

Previous research on mindfulness intervention for anxiety and depression in hemodialysis patients.

	Study	Protocol			Number of sessions	Number of patients
		Session Time (min)	Sessions x Week	Number of Weeks		
M in HD	Thomas et al., 2017*	15	3	8	24	41
	Nassim et al., 2021	20	2	8	16	55
	Igarashi et al., 2021	20	3	12	36	22

*No significant results in depression and anxiety

Population

Inclusion Criteria

This study will include hemodialysis patients aged greater or equal to 60 years old that assist at dialysis centers, in any stage of CKD, regardless of the time they have been on HD. Subjects are required to have non or mild cognitive impairment and must be able to give consent on their own. Only those individuals whose depression scored 16 or higher in CES-D and whose anxiety scored 10 or higher in GAD-7 will be included, which means that their depressive and anxious symptoms are moderate or severe.

Exclusion Criteria

Individuals with moderate and severe cognitive impairment will not be included (MoCA scores under 18). Individuals with moderate and severe sensory impairment, such as blindness or deafness, will not be considered as well as subjects that present psychotic symptoms. Patients with current psychosocial or pharmacological treatment for their depression will not be included.

If a person is not able to give consent on his own, this will also be considered as grounds for exclusion from this research.

Recruitment

The sample will consist of patients from local dialysis centers who will be contacted and invited to participate in this research. After their institutional approval, hemodialysis users will be contacted directly to know their desire to participate. Interested HD patients who meet inclusion criteria will be evaluated with the following screening questionnaires: informed consent, Center for Epidemiologic Studies Depression Scale (CES-D), Montreal Cognitive Assessment (MoCA), and Generalized Anxiety Disorder scale (GAD-7). Only those patients that meet all the minimum scores will be asked to fulfill the Mindful Attention Awareness Scale (MAAS), Hospital Anxiety and Depression Scale (HADS), Dizziness Handicap Inventory (DHI), and demographic questionnaire.

Materials

Informed Consent:

Informed consent will be read by researchers to eligible patients individually. After this, HD users will have enough time to read the consent by themselves. At any moment of this process, interested patients will have the chance to ask all their questions to the research staff if they require additional information or want to clarify a matter. Informed consent is annexed to this proposal as Annex 1.

Demographic questionnaire:

A demographic questionnaire was designed to gather patients' relevant information. It will contain the questions of Annex 2 and will be delivered virtually.

Montreal Cognitive Assessment (MoCA):

Montreal Cognitive Assessment (MoCA) is used to detect cognitive impairment in elderly population and classifies it in mild, moderate, and severe (Julayanont et al., 2017). It is scored over 30 points and its administration lasts approximately 10 minutes (Julayanont et al., 2017). It has an internal consistency measured with a Cronbach alpha coefficient of (α=0.83) and showed a 0.92 test-retest reliability (Julayanont et al., 2017). The MoCA has been validated in Latinx population (Loureiro et al., 2018). This test will be applied to assess prospective participants' cognitive status before the intervention.

Mindful Attention Awareness Scale (MAAS)

The Mindfulness Attention Awareness Scale (MAAS) will measure mindfulness features, such as attention and awareness (Brown and Ryan, 2003). It consists of 15 items evaluated on a Likert scale of 6 points, with being 1 less frequent and 6 most frequent (Brown and Ryan, 2003). It has an internal consistency of α=0.82 and test-retest reliability of 0.81 (Brown and Ryan, 2003). The MAAS has been validated in Latinx population (Ruiz et al., 2016; López-Maya et al., 2015)

Generalized Anxiety Disorder scale (GAD-7)

To measure anxiety levels in this sample, the Generalized Anxiety Disorder scale (GAD-7) will be administered due to its high sensibility to anxiety disorders such as panic disorder and social anxiety disorder (Williams, 2014). It consists of 7 items and has a maximum score of 21 (Williams, 2014). This self-reported questionnaire has a high internal consistency (α=0.79-0.91) (Williams, 2014) and test-retest reliability (0.87) (Bischoff et al., 2020).

Hospital Anxiety and Depression Scale (HADS)

Hospital Anxiety and Depression Scale (HADS) has been used for screening in medical samples (Al-Shammari et al., 2021; Mosleh et al., 2020; Semaan et al., 2018). It consists of 14 items and has been found to be effective in assessing depression and anxiety in hemodialysis patients with the following cutoffs ≥7 and ≥6 respectively (Preljevic et al., 2012). HADS was developed to have two subscales: HADS-D and HADS-A, and presents good test-retest reliability (r=0.85) as well as internal consistency for depression α=0.86 and anxiety α=0.86 (Quintana et al., 2003). HADS has also been validated in elderly population (Djukanovic et al., 2017).

Center for Epidemiologic Studies Depression scale (CES-D)

Center for Epidemiologic Studies Depression (CES-D) scale is a 20-item self-report scale with an internal consistency of α=0.88 and a 4-point Likert scale (Ros et al., 2011). It has been validated in elderly population (Karim et al., 2015) and in hemodialysis patients with the recommended cutoff score of ≥10 points (Lopes, et al., 2004). In the present study, the CES-D scale will be used for screening.

Dizziness Handicap Inventory (DHI)

The Dizziness Handicap Inventory (DHI) is a self-report 25-item questionnaire with test-retest reliability of r=0.97 and internal consistency of α=0.89 (Jacobson & Newman, 1990). It is divided into three subscales: functional, emotional, and physical, which cover all dimensions of dizziness (Jacobson & Newman, 1990). It has been used in hemodialysis patients (Dai et al., 2017).

Procedures

As mentioned beforehand, the sample will be divided into two groups: a control group where participants will receive an MBI, and an experimental group in which a mindfulness intervention with VR technologies will be applied.

The intervention duration will be based on Nassim et al. (2021) since their study has the largest sample size (n=55) and showed effectiveness. Also, during the MVR intervention of Hernandez et al. (2021) with a 25-minutes exposure to VR, patients showed no adverse effects. Thus, the intervention protocol will consist of sixteen 20-minute sessions divided into 2 sessions weekly for 8 weeks. The intervention will be administered according to participants' scheduled HD sessions.

Moreover, the question of when an MVR intervention is most effective during hemodialysis, should also be considered. In MBIs for HD patients, Adamoli et al. (2020) delivered their intervention in the second hour of dialysis, with the intention of not interfering with the dialysis process, and Igarashi et al. (2021) implemented their protocol between the first and second hour of HD. On the other hand, regarding VR application, Omonaiye et al. (2021) reviewed a study where HD patients showed no difference at any time of the VR exposure. Therefore, the intervention administration will be during the second hour of dialysis.

Considering if headphoneare a required material, Thomas et al. (2017) recommended the use of headphones used for a better delivery due to several auditory distractions. All other mindfulness studies, Adamoli et al. (2020), Nassim et al. (2021), Igarashi et al. (2021) also implemented the recordings for the delivery of the sessions. Omonaiye et al. (2017) also consider that headphones will promote a better immersive experience for the VR application. Consequently, in order to have the best efficacy possible, control and experimental groups will

use recorded interventions under supervision. Likewise, this method allows the administration of multiple participants at the same time. For Igarashi et al. (2021), an alternative was implementing the intervention in a separate room.

Intervention design

All sessions will implement the following topics (Table 2) based on the content exposed by Baer (2015) and Linehan (2014) combined with the adaptation of mindfulness practice in HD patients by Adamoli et al. (2020) and Assarian et al. (2019):

Table 2:

Intervention procedure

Week:	Topics reviewed	Sessions:
1.	Introduction to mindfulness abilities	1 and 2
	● Promotion of non-judgmental and present-oriented mindset.	
	● Introduction to doing one thing at a time.	
	● Managing mind-wandering.	
2.	Mindful observation and description of external stimuli	3 and 4
	● Connection with sensory stimuli	
	● Exploration of an environment focusing on detail	
3.	Mindful observation and description of internal stimuli	5 and 6
	● Awareness of internal experiences before the session.	
	● Focusing attention on internal experiences produced by the VR (in the experimental group) or hemodialysis center(in the control group) scenarios.	
	● Comparing emotional status before and after the sessions.	

- Differentiating urges from behavior, and thoughts from facts.

- Introduction of wave ability.

4.	Mindful breathing	7 and 8

- Introduction to bodily stimuli.

- Application of paused breathing techniques.

- Insertion of breathing as an anchoring strategy.

5.	Body scan	9 and 10

- Guided meditation through body parts.

- Awareness of bodily positions and sensations.

- Muscle tension and relaxation exercises.

6.	Mindful movement	11 and 12

- Imagery exercise with movement in the scenario

- Application of description ability learned previously.

7.	Guided meditation about pain	13 and 14

- Surfing through distressful emotions, thoughts, and memories.

- Self-compassion implementation in physical suffering.

- Radical acceptance of the present situation.

8.	Loving-kindness meditation	15 and 16

- Guided meditation about self-care, and compassion toward

  loving ones.

Data Analysis

In order to test the first hypothesis, the mindfulness intervention is considered the qualitative independent variable and divided into two categories: pre- and post-intervention. The scores of anxiety and depression tests are considered the numerical dependent variable in which we measure the effectiveness of the intervention. Thus, four paired Student t-tests need to be run comparing pre- and post-intervention scores of both groups in anxiety and depression (Table 2).

For the second hypothesis, depression, and anxiety scores are still considered the dependent numeric variable, whereas the type of intervention is the categorical independent variable, which is divided into two categories (Mindfulness Based Intervention group [MBI] and Mindfulness with Virtual Reality group [MVR]). Based on this, four multivariate analyses of variance (MANOVA) will be used (Table 2).

Regarding the third hypothesis, to determine if there exists an actual significant influence of any demographic variable (independent) on depression levels (dependent) in the pre- or post-intervention measures, lineal regression analyses and independent Student t-tests will be used for numerical and categorical variables respectively.

Lastly, χ^2 test will be used to determine if there are differences in the incidence of attrition (dependent) between control and experimental groups (independent) since both variables are categorical. Student t-tests will be used to evaluate the difference in mindfulness levels from the pre- to the post-evaluation. In all aforementioned statistical tests, $P < 0.05$ will be considered significant.

Table 3:

Statistical models of hypotheses 1 and 2

	Anxiety		
MBI	Pre	Post	Paired t-test
MVR	Pre	Post	Paired t-test
	MANOVA	MANOVA	

	Depression		
MBI	Pre	Post	Paired t-test
MVR	Pre	Post	Paired t-test
	MANOVA	MANOVA	

Future Directions

Since there is research that supports the correlation between serum phosphorus and C-reactive protein with depression in HD patients (Cirillo et al., 2018), further research should focus on evaluating the effectiveness of MVR with those biomarkers. It is known that VR interventions are effective to distract patients with chronic pain or under painful treatments (Malloy & Milling, 2010). Therefore, it could be interesting to study if HD patients' pain perception changes after an MVR intervention program. Future research should also focus on the specific ideal time for administering the intervention during dialysis. No significant effects were identified in other interventions (García-Testal, et al., 2022), but it may be relevant to MVR due to the required attentional capacity for mindfulness practices. Emotion regulation, quality of life, sleep quality, suicidal ideation, and fatigue levels are also promising variables, should be investigated after the effects of a MVR intervention.

Limitations

A possible limitation of the application of this proposal could be rooted in viability. The lack of sufficient budget, materials, or staff to administer the MVR intervention in a large sample may hinder its implementation. The research budget should contemplate the real number of VR headsets needed depending on the number of HD patients that will be treated at the same time.

Also, considering that this proposal emphasizes the relevance of using headphones for HD patients, meaning that high economic investment is needed, leading to a potential challenge.

Additionally, this proposal elaborated an intervention plan of 16 sessions of 20 minutes for 8 weeks. Researchers should evaluate the viability of this proposal based on the time spent for each patient, as well as the personnel they count on to administer it.

Moreover, the use of headsets may cause discomfort in some patients, considering that the experimental group is already wearing a VR headset. Therefore, a pilot study with a limited number of participants is recommended to evaluate the viability of this proposal.

Reflection

During the process of writing this research proposal, I have been able to expand my knowledge about the reality under which people with CKD live. I have been able to delve into their pains and sufferings through theory and research. Many of the facts have been shocking to me, especially because I live with my grandmother, who will turn 92 years old. In this journey, I have come to deeply value the life and health of my grandmother, as well as the time I spend with her. I have come to recognize how fragile life is and what a privilege it is to be healthy.

Annexes

Annex 1: Informed Consent

Si usted se encuentra interesado en la investigación de "*Mindfulness con Realidad Virtual en Pacientes con Hemodiálisis de Tercera Edad con Síntomas de Ansiedad y Depresión"*, por favor, lea con detenimiento todas las preguntas a continuación. Recuerde que, si le surge alguna duda, puede usted contactarse con los miembros de la investigación Cristina Crespo, María Sol Garces, Camila Merino o Esteban Proaño.

Puesto que se han visto efectos positivos de intervenciones de Atención Plena o Mindfulness en otras poblaciones similares, esta investigación tiene el propósito de medir los efectos de una intervención de Mindfulness con Realidad Virtual en los síntomas de ansiedad y depresión de pacientes sometidos a diálisis mayores de 60 años.

Previo a la investigación deberá usted llenar una encuesta demográfica y algunas pruebas psicométricas para conocer el estado actual de su salud mental. Después, los investigadores coordinarán con usted el horario de su preferencia para agendar 2 sesiones semanales de Mindfulness con o sin realidad virtual durante las siguientes 8 semanas, dando un total de 16 sesiones. Al final de las sesiones, se le pedirá a usted que complete nuevamente aquellos cuestionarios llenados en un inicio.

Su identidad en todo este proceso será anónima, sus datos serán recolectados bajo un código y almacenados bajo encriptación. Su participación es completamente libre y voluntaria, por lo que tiene derecho a dejar de participar en cualquier momento de la investigación si así lo desea. En ningún momento, su decisión de dejar de participar traerá consecuencias para sus derechos. Sus datos serán eliminados si decide dejar de participar. El único momento en que sus datos ya no podrán ser retirados sucede cuando estos ya hayan sido analizados tras las 16 sesiones. Si quisiera retirar su consentimiento por favor, contáctese con los miembros de la investigación Cristina Crespo, María Sol Garces, Camila Merino o Esteban Proaño.

Los posibles beneficios que pueden tener su participación en esta investigación son:

- Mejor manejo de sus emociones

- Sensaciones de relajación

- Aumento en sensaciones de bienestar

Los posibles riesgos que puede conllevar su participación en esta investigación son:

- Incomodidad por los equipos

- Sensaciones de mareo

Si tiene usted alguna duda, no repare en contactar a los miembros del equipo de investigación:

Cristina Crespo, María Sol Garces, Camila Merino o Esteban Proaño. Queda a su disposición

Esteban Proaño, bajo el número de teléfono 0994669146 y el correo

esteban.proanop@gmail.com

Consentimiento: Toda la información anteriormente expuesta acerca de esta investigación se me

ha explicado con claridad y mis dudas han sido esclarecidas satisfactoriamente. He tenido tiempo

para leer adecuadamente este documento y tomar mi decisión de participar. Entiendo los

derechos que poseo con respecto a mi información y mis datos y sé que se adoptarán las medidas

necesarias para asegurar mi confidencialidad. Comprendo cuáles son los contactos a los cuales

debo dirigirme en caso de tener alguna duda o querer retirarme de la investigación.

Comprendo y estoy de acuerdo en participar con la investigación:

- o Sí
- o No

Annex 2: Demographic questionnaire

Por favor responda a las siguientes preguntas:

¿Cuál es su edad actualmente?

_____

¿Cuál es su género?

- Femenino

- Masculino

- Otro

¿Cuál es su estado civil?

- Soltero/a

- Casado/a

- Viudo/a

Indique la etnia con la que se identifica:

- Montuvio

- Indígena

- Mestizo

- Afrodescendiente

- Blanco

- Otro

¿Cuántos años de educación formal tuvo?

- 6 años, Primaria

- 12 años, Bachillerato

- +16 años, Título Universitario de pregrado

- +18 años, Título de maestría

- +20 años, Título de doctorado

¿Tiene algún diagnóstico médico además de enfermedad renal crónica (ej. Hipertensión,

diabetes, etc.)?

- No

- Sí

  - Por favor, especifique otros diagnósticos que se le hayan dado _____

Toma alguna medicación actualmente

- No

- Sí, especifique _____

¿Ha recibido algún diagnóstico psicológico o psiquiátrico?

- No

- Sí, especifique _____

¿Recibe usted actualmente tratamiento psicofarmacológico (ej. Antidepresivos, antiansiolíticos,

etc.)?

- No

- Sí, especifique _____

¿Asiste usted a psicoterapia actualmente?

- No

- Sí

Por favor marque si usted tiene alguno de estos hábitos (+2 veces por semana):

- Fumar

- Consumir alcohol

- Consumo de sustancias recreativas

Tiene experiencia en meditación:

- No

- Sí

Medita usted actualmente

- No

- Sí

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