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Using virtual reality to treat subclinical health anxiety: A pilot study comparing physiological reactions between younger and older adults to determine its usefulness

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Using virtual reality to treat subclinical health anxiety: A pilot study comparing physiological reactions between younger and older adults to determine its usefulness

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Résumé

Problème : Les stratégies d'exposition traditionnelle (in vivo et en imagination) habituellement utilisées pour traiter l'anxiété liée à la santé ne sont pas toujours utilisables avec les aînés en perte de mobilité ou ayant des troubles cognitifs. L'immersion en réalité virtuelle (RV) peut représenter une solution alternative, mais aucune étude n'a testé son utilité auprès de personnes âgées qui s'inquiètent à propos de leur santé. **Objectif et hypothèses :** Déterminer si une salle d'attente d'hôpital virtuelle génère de l'anxiété (mesurée par deux réactions physiologiques : rythme cardiaque et conductance cutanée) chez les personnes âgées souffrant d'anxiété sous-clinique liée à la santé. H1 : les participants anxieux (peu importe leur âge) auront des réactions physiologiques plus élevées (vs niveau de base ou T1) que les participants non anxieux durant l'immersion dans la salle d'attente. H2 : comparativement aux personnes âgées anxieuses, les jeunes anxieux auront des réactions physiologiques significativement plus importantes (vs T1) durant l'immersion dans la salle d'attente. **Méthode :** Les réactions physiologiques de quatre groupes (n = 30) de jeunes (18-35 ans) et de personnes âgées (65 ans et plus) avec ou sans anxiété sous-clinique liée à la santé ont été comparées avant (T1) et durant (T3) une séance d'immersion dans un salle d'attente virtuelle. Pour s'assurer que les réactions physiologiques n'étaient pas causées par le simple fait d'être exposé à un environnement virtuel, les participants ont été exposés à un environnement virtuel neutre (T2) entre ces deux temps de mesure. Des analyses multi-niveaux ont été effectuées pour tester les deux hypothèses. **Résultats :** Les participants anxieux ont vu leur rythme cardiaque augmenter de façon significativement plus importante (vs groupe non anxieux) pendant l'immersion (T2: $\beta = 8.77$, $p=0.045$; T3: $\beta = 9.73$, $p=0.03$), mais aucune différence significative entre les deux groupes n'a été observée sur la conductance cutanée (T2: $\beta = 0.30$, $p = 0.70$; T3: $\beta = 0.47$, $p = 0.55$). Par ailleurs, la fréquence cardiaque des participants anxieux n'a pas augmenté

de façon significative entre le T2 (environnement neutre) et le T3 (salle d'attente) (β = -0.04, p = 0.97). Enfin, comparativement aux participants âgés anxieux, les jeunes participants anxieux n'ont pas connu d'augmentation significativement plus importante de leur fréquence cardiaque (T2: β = 1.92, p = 0.83; T3: β = -1.51, p = 0.87) et de leur conductance cutanée (T2: β = -0.65, p = 0.65; T3: β = -0.79, p = 0.58) durant l'immersion. **Conclusion :** La salle d'attente virtuelle ne fait pas plus physiologiquement réagir les personnes âgées qui s'inquiètent au sujet de leur santé que l'environnement virtuel neutre. Puisque cette étude pilote a été réalisée auprès de participants ayant des inquiétudes sous-cliniques au sujet de leur santé, d'autres recherches sont nécessaires afin de tester l'utilité de la salle d'attente virtuelle auprès de population clinique.

Mots clés : Anxiété liée à la santé, Personnes âgées, Thérapie d'exposition, Rythme cardiaque, Conductance cutanée, Réalité virtuelle

Abstract

Problem: Traditional exposure strategies (in vivo and imaginal) commonly used to treat health anxiety are not always applicable to seniors with mobility loss or cognitive difficulties. Virtual reality (VR) immersion may be an alternative solution, but no studies have tested its usefulness with seniors who are concerned about their health. **Objective and hypotheses**: To determine whether a virtual hospital waiting room generates anxiety (measured by two physiological reactions: heart rate and skin conductance) in elderly people suffering from subclinical health anxiety. H1: Anxious participants (regardless of age) will have higher physiological reactions (vs. baseline or T1) than non-anxious participants during immersion in the waiting room. H2: Compared to anxious elderly individuals, anxious young people will have significantly greater physiological reactions (vs T1) during immersion in the waiting room. **Method**: The physiological reactions of four groups (n = 30) of young adults (18-35 years of age) and seniors (65 years of age and older) with or without subclinical health anxiety were compared before (T1) and during (T3) an immersion session in a virtual hospital waiting room. To ensure that physiological reactions were not caused simply by being exposed to a virtual environment, participants were exposed to a neutral virtual environment (T2) between these two measurement times. Multi-level analyses were carried out to test both hypotheses. **Results**: Anxious participants experienced a significantly higher increase in heart rate (vs. non-anxious group) during immersion (T2: $\beta = 8.77$, $p=0.045$; T3: $\beta = 9.73$, $p=0.03$), but no significant difference between the two groups was observed on the skin conductance measure (T2: $\beta = 0.30$, $p = 0.70$; T3: $\beta = 0.47$, $p = 0.55$). In addition, the heart rate of anxious participants did not increase significantly between T2 (neutral environment) and T3 (waiting room) ($\beta = -0.04$, $p = 0.97$). Finally, compared to anxious elderly participants, anxious young individuals did not experience a significantly greater increase in their heart rate (T2: $\beta =$

1.92, p = 0.83; T3: β = -1.51, p = 0.87) and skin conductance (T2: β = -0.65, p = 0.65; T3: β = -0.79, p = 0.58) during immersion. **Conclusion**: The virtual waiting room does not generate more physiological reactivity in older individuals with health concerns than the neutral virtual environment. Since this pilot study was conducted with participants with subclinical health anxiety, further research is needed to test the usefulness of the virtual waiting room with clinical populations.

Keywords: Health Anxiety, Elderly, Exposure Therapy, Heart Rate, Skin Conductance, Virtual Reality

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CHAPTER 3 (RESULTS AND DISCUSSION)

List of Abbreviations

ANOVA	Analysis of Variance
CBT	Cognitive Behavioral Therapy
CRIUGM	Centre de recherche de l'Institut universitaire de gériatrie de Montréal
HR	Heart Rate
IAS	Inventaire d’anxiété face à la santé
N	Sample Size
p	Alpha
RQRV	Quebec Network for Research on Aging
RV	Réalité Virtuelle
SC	Skin Conductance
UQO	Université du Québec en Outaouais
VR	Virtual Reality
VRET	Virtual Reality Exposure Therapy

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CHAPTER 1: INTRODUCTION

1. Introduction

1.1 Current problem

The use of virtual reality (VR) in the treatment of various psychological disorders through its incorporation into traditional exposure treatment techniques is an emerging field. Studies have suggested that VR immersion has shown promise in treating several conditions (i.e., specific phobias, eating disorders, post-traumatic stress disorder, and panic disorder) among younger and older adults (Garcia-Palacios, Hoffman, Carlin, Furness III, & Botella, 2002; Riva, Bacchetta, Baruffi, Rinaldi, Vincelli, & Molinari, 2000; Difede, Cukor, Jayasinghe, Patt, Jedel, Spielman, Giosan, & Hoffman, 2007; Botella, García-Palacios, Villa, Baños, Quero, Alcañiz, & Riva, 2007; Gamito, Oliveira, Rosa, Morais, Duarte, Oliveira, & Saraiva, 2010). However, studies have yet to explore the usefulness of incorporating a VR environment into an exposure treatment for older people who are excessively concerned about their health. With a prevalence rate of up to 10% in the elderly, this type of anxiety requires further research to discover new ways to improve the efficacy of existing treatments (El-Gabalawy, Mackenzie, Thibodeau, Asmundson, & Sareen, 2013).

2. Theoretical Context

2.1 State of affairs regarding anxiety disorders

Anxiety disorders continue to be pervasive throughout society. With 12-month and lifetime rates ranging from 18.1% to 28.8% in the general population and 7% to 30% within the elderly, new avenues of therapy must be explored to find more effective ways of treating individuals suffering

from these disorders (Kessler, Chiu, Demler, & Walters, 2005; Kessler, Berglund, Demler, Jin, Merikangas, & Walters, 2005; Gum, King-Kallimanis, & Kohn, 2009; Beekman, Bremmer, Deeg, Van Balkom, Smit, De Beurs, Van Dyck, & Van Tilburg, 1998; Ritchie, Artero, Beluche, Ancelin, Mann, Dupuy, Malafosse, & Boulenger, 2004). Furthermore, these prevalent disorders generate heavy economic burdens on society. As mentioned by DuPont, Rice, Miller, Shiraki, Rowland, & Harwood (1996), anxiety disorders accounted for 31.5% of the total cost of mental illness (a total of $46.6 billion) in 1990 in the United States. More recent research has also demonstrated that the annual health care cost of these disorders reaches into the hundreds of millions of dollars in Canada as well (Vasiliadis, Dionne, Préville, Gentil, Berbiche, & Latimer, 2012). This is because anxiety disorders lead to increased utilization of healthcare (particularly primary care) and lower worker productivity rates (Wittchen, 2002). Considering that the number of people aged 65 and over will double by 2050, costs are becoming a growing issue (Ortman, Velkoff, & Hogan, 2014; Statistics Canada, 2011). Therefore, specific therapies targeting these illnesses in cost-effective ways will be necessary to help alleviate the over-utilization of resources, while potentially increasing overall treatment success.

2.2 Health anxiety

A specific form of anxiety that creates heavy burdens, particularly on the healthcare system, and incurs large costs on society is health anxiety. Health anxiety is a type of anxiety in which individuals interpret bodily changes as indications of a potentially serious disease being present. However, this reaction differs between individuals and its severity ranges on a continuum from mild to severe (Taylor, 2004; Fink, Ornbol, Toft, Sparle, Frostholm, & Olesen, 2004). Although considered subclinical, moderate to severe forms of this type of anxiety can still induce

unnecessary suffering and be indicative of pathology. This type of anxiety has also been conceptualized in different ways. For example, in the Diagnostic and Statistics Manual of Mental Disorders, 4th edition (DSM-IV), the terms hypochondriasis and health anxiety were both used synonymously to identify an excessive fear of illness stemming from incorrect beliefs regarding the risk of developing a serious illness (Petricone-Westwood, Jones, Mutsaers, Séguin Leclair, Tomei, Trudel, Dinkel, & Lebel, 2018). In the DSM-5, the term hypochondriasis was redefined and divided into two new nosologies called somatic symptom disorder and illness anxiety disorder (American Psychiatric Association, 2013). The former is defined by a series of distressing somatic symptoms leading to an excessive amount of thoughts and behaviors in line with these symptoms, which causes a loss in functioning. Also, there may or may not be a diagnosed medical condition underlying these symptoms. On the other hand, illness anxiety disorder involves having excessive worries regarding either having or acquiring a serious illness, without the need for somatic symptoms. Even minor bodily sensations may generate worries regarding the presence of a serious illness. Therefore, the description of the clinical manifestation of this disorder has been elaborated upon several times. However, in the context of this study, the general term of health anxiety will be used, as this type of anxiety has been conceptualized on a continuum that includes expressions not meeting full diagnostic criteria, which will be the focus of this research.

2.3 Health anxiety rates and symptoms

Severe health anxiety can be classified as hypochondriasis if symptoms are clinically significant, but it can also include symptom presentations that fail to meet all the diagnostic criteria for a diagnosis of hypochondriasis (Asmundson, Abramowitz, Richter, & Whedon, 2010). Severe health anxiety may still contribute to suffering in individuals who do not necessarily meet the full

diagnostic criteria for hypochondriasis. This is supported by Creed and Barsky (2004), Gureje, Ustun, & Simon (1997), and Barsky, Ettner, Horsky, & Bates (2001), who found that individuals with subclinical health anxiety still experience significant distress, have increased healthcare utilization, and have decreased quality of life at levels similar to individuals who meet full diagnostic criteria for hypochondriasis. Therefore, severe health anxiety is dimensional in nature and takes into account the different levels (clinical or subclinical) of health anxiety symptoms commonly found amongst individuals with this disorder (Furer & Walker, 2005). Individuals suffering from health anxiety demonstrate symptoms associated with excessive preoccupation and worry concerning their health (beliefs that bodily sensations are associated with diseases), which is accompanied by constant reassurance seeking and body checking (all of which often reinforce their maladaptive behaviors and cognitions) (Asmundson et al., 2010). This type of anxiety is also associated with higher distress, functional impairment, and depression risk amongst affected populations (Sunderland, Newby, & Andrews, 2013; Potvin, Bergua, Swendsen, Meillon, Tzourio, Ritchie, Dartigues, & Amieva, 2013). In addition to these negative symptoms, a study exploring the frequency of routine health checks, while controlling for well-defined medical conditions, found that individuals suffering from severe health anxiety utilize between 41% and 78% more healthcare services per year compared to people who do not have health anxiety, which creates a strain on the healthcare system and emphasizes the need for effective treatment methods to reduce suffering and improve their overall quality of life (Fink, Ornbol, & Christensen, 2010). With rates as high as 10% in the elderly, 6% in the general population, and 24.7% in clinics, health anxiety is a prevalent condition causing distress to many (Bleichhardt & Hiller, 2007; Tyrer, Cooper, Crawford, Dupont, Green, Murphy, Salkovskis, Smith, Wang, Bhogal, Keeling, Loebenberg,

Seivewright, Walker, Cooper, Evered, Kings, Kramo, McNulty, Nagar, Reid, Sanatinia, Sinclair, Trevor, Watson, & Tyrer, 2011; El-Gabalawy et al., 2013).

2.4 Efficacy of CBT in treating anxiety disorders

Traditionally, cognitive behavioral therapy (CBT) has been shown to be effective in treating anxiety disorders among adults (Norton & Price, 2007; Deacon & Abramowitz, 2004; Butler, Chapman, Forman, & Beck, 2006). More recently, three meta-analyses have explored the efficacy of using CBT in treating anxiety disorders in older adults. Gould, Coulson, and Howard (2012) conducted a meta-analysis in which they compared the results of 12 studies (participant mean age of 68.2 suffering from anxiety disorders), and the authors concluded that CBT is significantly effective in reducing anxiety symptoms with a moderate effect size. Additionally, both Thorp, Ayers, Nuevo, Stoddard, Sorrell, and Wetherell (2009) and Hendriks, Oude Voshaar, Keijsers, Hoogduin, and van Balkom (2008) conducted two additional meta-analyses on the efficacy of CBT on late-life anxiety disorders and both found that CBT is an effective treatment for anxiety disorders in older populations. Although these meta-analyses have supported the use of CBT in the treatment of anxiety disorders in general, they did not specifically examine its efficacy in the treatment of late-life health anxiety.

2.5 Efficacy of CBT in treating health anxiety

The benefits of CBT used for the treatment of health anxiety in adults has been demonstrated in numerous studies. A recent meta-analysis has focused on detailing the efficacy of CBT for the treatment of health anxiety in adults. Cooper, Gregory, Walker, Lambe, and Salkovskis (2017) conducted a meta-analysis in which they compared the results of 14 studies published before 2014

(N = 1544 participants with a mean age ranging from 34 to 68.7 suffering from health anxiety), and the authors concluded that CBT is an effective intervention for both clinical and subclinical levels of health anxiety regardless of the presence of a medical illness. This emphasizes the importance of offering treatment to individuals who do not meet all criteria for severe health anxiety, as they still suffer from significant distress and can also benefit from treatment. Large effect sizes were also found immediately after intervention, as well as at 6-month and 12-month intervals after the end of the treatment, indicating that CBT has long-term positive effects on health anxiety symptoms (Cooper et al., 2017). These newer results are similar to two previous reviews and meta-analyses conducted on the subject that both had similar findings with regards to CBT's efficacy for health anxiety (Thomson & Page, 2007; Olatunji, Kauffman, Meltzer, Davis, Smits, & Powers, 2014). In addition, multiple studies testing the efficacy of CBT in the treatment of health anxiety included traditional exposure techniques (imaginal or in vivo) in their treatment and found results supporting their effectiveness in treating health anxiety in adults. For example, a study conducted by Hedman, Andersson, Andersson, Ljotsson, Ruck, Asmundson, and Lindefors (2011) found that a CBT treatment incorporating both imaginal and in vivo techniques given online to adults with severe health anxiety led to a significant decrease in symptoms (with large effect sizes) that was maintained 6 months later. Furthermore, a study conducted by Visser and Bouman (2001) found that using in vivo exposure therapy techniques (viewing disease-related images or visiting a hospital) to treat adults with health anxiety also led to significant decreases in anxiety symptoms compared to a waitlist group. These results were further replicated in more recent randomized control trials conducted by multiple researchers, which all found that exposure-based therapy was effective in treating severe health anxiety (Hedman, Axelsson, Gorling, Ritzman, Ronnheden, El Alaoui, Andersson, Lekander, & Ljotsson, 2014; Weck, Neng, Richtberg, Jakob,

& Stangier, 2014). To our knowledge, only one study has tested the efficacy of CBT in the treatment of subclinical health anxiety in a sample of older adults (N = 57 with a mean age of 68.72) (Bourgault-Fagnou & Hadjistavropoulos, 2013). They found large effect sizes and lower health anxiety symptoms immediately after a 6-week CBT treatment and at 3-months post-treatment in comparison to a wait-list control. However, it should be noted that no exposure techniques were included in their CBT. Therefore, it is not known if exposure therapy is effective in treating older people suffering from subclinical health anxiety. Since health anxiety may present itself differently in the elderly compared to younger adults, it is important to further study if this type of therapy is effective for older population groups. Although there is a consistently limited representation of treatment effects on seniors in the current literature, the meta-analysis conducted by Cooper et al. (2017) highlights the potential importance and efficacy of using CBT exposure techniques to treat health anxiety in the elderly, as well as its benefits for populations with subclinical health anxiety.

2.6 Exposure therapy: types and limitations

Although CBT incorporates several treatment methods, when treating anxious individuals, it frequently utilizes exposure methods as the first line of treatment to decrease anxiety symptoms over time because of their efficacy (Kaczkurkin & Foa, 2015). Exposure therapy involves systematically exposing an individual to anxiety-inducing stimuli over multiple sessions to decrease future anxiety symptoms (Deacon et al., 2004). There are two types of exposure therapy: imaginal and in vivo. Imaginal exposure involves using memory to have the individual cognitively visualize an anxiety producing event to reduce anxiety symptoms and negative cognitions over time (Foa, Gillihan, & Bryant, 2013; Botella, Serrano, Banos, & Garcia-Palacios, 2015). It has the

advantage of allowing individuals to be exposed to anxiety-inducing stimuli that may otherwise not be readily available. For example, with health anxiety, individuals are asked to imagine catastrophic thoughts like illness or death in order to gradually decrease their use of cognitive avoidance and safety behaviors and reduce related anxiety (Prasko, Diveky, Grambal, Kamaradova, & Latalova, 2010). During imaginal exposure, individuals are explained the reasoning behind the exposure therapy and are then asked to imagine the worst illness that they could have and its consequences on themselves and family members (Prasko et al., 2010). This image creation continues until strong emotions are felt, after which the individual can feel relief and can start to learn how to manage these negative feelings over time (Prasko et al., 2010). However, imaginal exposure depends on the person's ability to create vivid mental images to produce anxiety, an ability which tends to decrease as individuals get older. The aging process brings about a natural deterioration of a person's cognitive functions and long-term memory capacities, as well as decreases in working memory and processing speed (which are necessary for the creation of emotional mental images) (Bruyer & Scailquin, 2000; Malouin, Richards, & Durand, 2010; Salthouse, 1996; Light, 2000). Detailed mental images facilitate emotional reactions and allow individuals with anxiety to work on their fears by activating specific sensory signals in the brain that are connected with emotional systems, which are necessary for imaginal exposure to function in producing anxiety (Holmes & Mathews, 2010). Although this technique may be effective in treating anxiety in younger adults, it can pose problems when applied with older populations because of this natural cognitive deterioration process. To mitigate this limitation, in vivo exposure can be used. However, it too comes with its own limitations, especially when implemented with seniors. In vivo exposure involves physically exposing the person to anxiety inducing situations to systematically decrease the total level of anxiety felt over multiple

exposure sessions (Foa et al., 2013; Botella et al., 2015). With regards to health anxiety, the individual can be exposed to feared places, such as hospitals and cemeteries (Prasko et al., 2010). However, in vivo exposure may be difficult to implement due to the lack of availability or feasibility of exposing individuals to anxiety-producing stimuli (Grenier, Forget, Bouchard, Isere, Belleville, Potvin, Rioux, & Talbot, 2015). This problem is further emphasized when treating older adults, as it may be harder to bring this population to the exposure environment due to mobility or balance limitations. Another problem with in vivo exposure is that it is impossible to completely control the fear stimulus because the therapist cannot control/manipulate all variables within the exposure environment (other people's behaviors can influence the exposure intensity). Lastly, confidentiality issues also pose problems because someone may recognize the patient. For example, during an exposure session, the patient may meet an acquaintance who is not aware of their anxiety problems, which can be embarrassing or distressing. Therefore, a new therapeutic method that fixes the problems of imaginary exposure in the elderly, as well as the feasibility and manipulation limitations of in vivo exposure would greatly benefit anxious populations.

2.7 Virtual reality: potential uses and benefits in treating anxiety

Virtual reality (in virtuo) exposure is an emerging field that shows promise as a potential cost-effective solution to these problems. During virtual reality exposure therapy (VRET), individuals are immersed within a virtual environment and are either seated using a headset with head rotation or are standing with the capability of movement. They can be systematically exposed to appropriate anxiety-inducing stimuli in order to provoke and activate the fear network with the goal of changing these reactions through the same emotion-processing model of fear modification used in traditional exposure methods (Parsons & Rizzo, 2008). This model describes the basic

mechanisms behind exposure methods and proposes that threating stimuli confrontations activate the fear network in the brain, while new information incompatible with current responses is subsequently added to the emotional network to produce change (Parsons & Rizzo, 2008; Foa & Kozak, 1986). Virtual reality exposure utilizes the same mechanisms to produce changes in anxiety responses over time. In addition, current risks and costs of traditional exposure methods can be diminished because, instead of travelling to an exposure area, the therapy can be done inside the therapist's office and all variables within the virtual environment can be controlled (Rothbaum, Hodges, Smith, Lee, & Price, 2000). Also, the anxiety-producing image is presented in a virtual format in front of the person's eyes, thus imaginal difficulties linked with natural memory deterioration can be circumvented within seniors (Grenier et al., 2015). Furthermore, as low-cost options of this technology are being developed, it is becoming more widely available to therapists and the general population (Rand, Kizony, & Weiss, 2008). Therefore, the possible benefits of virtual reality are important avenues of research that may revolutionize therapeutic methods dealing with anxiety disorders.

The results from a meta-analysis including 23 studies and 608 participants has demonstrated that virtual reality exposure therapy (VRET) is as effective as in vivo exposure therapy and more effective than imaginal exposure in the treatment of anxiety disorders (Opris, Pintea, Garcia-Palacios, Botella, Szamoskozi, & David, 2011). Another meta-analysis conducted by Meyerbroker and Emmelkamp (2010) looked at VRET's effectiveness in treating different anxiety disorders and found considerable evidence for its effectiveness in treating the fear of flying and acrophobia, as well as some positive preliminary results for its effectiveness in treating panic disorder, social phobia, and PTSD. Additionally, eight sessions of VRET were also found to be more effective than imaginal exposure at reducing anxiety symptoms in a study that looked at their effectiveness

towards treating the fear of flying (Wiederhold & Wiederhold, 2003). With regards to VRET's comparable efficacy to in vivo exposure therapy, a study looking at their respective efficacies on acrophobia found that VRET was as effective as in vivo exposure in reducing anxiety and avoidance symptoms (Emmelkamp, Bruynzeel, Drost, & van der Mast, 2001). A meta-analysis conducted by Powers & Emmelkamp (2008) reviewing VRET's effectiveness in comparison to in vivo in treating anxiety disorders (N=397) across 13 studies also found similar results. In vivo exposure treatment was not significantly more effective at reducing anxiety symptoms within acrophobia, fear of flying, social phobia, and panic disorder than VRET, with a small effect size in favor of VRET over in vivo techniques (Powers & Emmelkamp, 2008). This demonstrates its potential as an alternative to these methods. Additional studies, not included in meta-analyses cited above, have also shown that in virtuo exposure shows promise in treating PTSD, specific phobias, and social anxiety disorder among adults (Reger, Holloway, Candy, Rothbaum, Difede, Rizzo, & Gahm, 2011; Botella, Banos, Villa, Perpina, & Garcia-Palacios, 2000; Emmelkamp, Krijin, Hulsbosch, de Vries, Schuemie, & van der Mast, 2002; Garcia-Palacios et al., 2002; Klinger, Bouchard, Legeron, Roy, Lauer, Chemin, & Nugues, 2005). These promising results support VRET's use as an alternative to traditional exposure methods in treating a wide array of disorders. However, no study has yet determined its usefulness in treating late-life health anxiety within elderly populations (which may benefit greatly from this new technology because of their complications regarding imaginal exposure) (Grenier et al., 2015). Furthermore, no research has been done regarding the possibility of using this technology to treat young individuals with health anxiety. This study aims to fill the gap in the literature and determine the usefulness of a virtual environment that may eventually be incorporated into an exposure method using VR to treat both younger and older populations who exhibit anxiety towards their health.

2.8 Physiological measures

In order to determine if it is effective or relevant to use VRET to treat subclinical health anxiety, the stimuli must provoke anxiety within the phobic individual (Krijn, Emmelkamp, Olafsson, & Biemond, 2004). Since psychophysiological arousal is recognized as being essential to exposure therapy effectiveness, measuring the physiological reactions of individuals undergoing sessions is a useful way to see if anxiety is being induced (Diemer, Muhlberger, Pauli, & Zwanzger, 2014; Wiederhold, Gevirtz, & Wiederhold, 1998). Anxiety is characterized by increased physiological arousal towards perceived threats, thus physiological measures like heart rate and skin conductance provide a measure of a person's emotional response to anxiety-inducing stimuli (Laforest, Bouchard, Cretu, & Mesly, 2016; Wiederhold et al., 1998). Research has also shown that physiological responses to stress during exposure sessions differ between anxious and non-anxious individuals (phobic people have more pronounced physiological reactions) (Wiederhold, Davis, & Wiederhold, 1998). For example, Suendermann, Ehlers, Boellinghaus, Gamer, & Glucksman (2010) and Elsesser, Sartory, & Tackenberg (2004) both demonstrated that adults with post-traumatic stress disorder (PTSD) have greater increases in mean heart rate than individuals without PTSD when exposed to anxiety-inducing trauma-related images. Similar physiological increases also occur in people with social phobia, as Davidson, Marshall, Tomarken, & Henriques (2000) demonstrated that social phobics have higher heart rate increases than non-phobics when exposed to both the thought of and the act of public speaking. Furthermore, research conducted by Alpers, Wilhelm, & Roth (2005) showed that significantly larger increases in both heart rate and skin conductance occurred in adults with driving phobia (versus control) when they were exposed to driving sessions on the highway. These physiological increases have also been shown to occur within children with text-anxiety when doing tests, within problem internet users when exposed to

using the internet, and within adults with dental anxiety when exposed to dental images (Beidel, 1991; Romano, Roaro, Re, Osborne, Truzoli, & Reed, 2017; Johnsen, Thayer, Laberg, Wormnes, Raadal, Skaret, Kvale, & Berg, 2001). These studies demonstrate that individuals with a variety of anxiety disorders have increased emotional reactivity when exposed to their respective fear-inducing stimuli. Additionally, several studies have shown that physiological reactions (i.e., heart rate and skin conductance) usually decrease as individuals age (Levenson, Carstensen, Friesen, & Ekman, 1991; Tsai, Levenson, & Carstensen, 2000; Labouvie-Vief, Lumley, Jain, & Heinze, 2003). A study conducted by Tsai et al. (2000) has shown that while no differences were reported on their subjective emotional experiences, older adults had significantly lower heart rate and skin conductance responses towards emotion-eliciting films than did young adults (Tsai et al., 2000). This decreased physiological arousal was also shown to be present in both European and Chinese Americans, suggesting that different cultures experience this physiological change (Tsai et al., 2000). Furthermore, Levenson et al. (1991) demonstrated lower autonomic nervous system activity in older adults that could also not be explained by medication use. These results were further supported by Labouvie-Vief et al. (2003) who also found that age was inversely correlated with physiological reactivity towards emotional stimuli. Therefore, these age-related physiological factors must be accounted for when using exposure therapy with individuals with different anxiety severity levels and ages.

2.9 The hospital emergency room virtual environment

The virtual environment used in this study consists of a hospital emergency room designed to illicit worry in individuals with health-related anxiety. A pilot study conducted by Labbé Thibault, Côté, and Gosselin (2017) evaluated the efficacy of this virtual environment in generating anxiety (based

on self-reported measures, not physiological data) within adults with a diagnosis of generalized anxiety disorder (GAD). The researchers exposed their population to three sessions of exposure using this environment and found significant reductions in GAD symptoms and anxiety post-treatment which were maintained 2 months later. In addition, the improvements made utilizing the virtual environment were specific to health-related worries, which is consistent with its content design. Based on these preliminary results, the emergency room virtual environment shows promise in generating anxiety to help reduce health-related anxiety severity over time. This seems to indicate that this virtual scenario may also be useful in treating individuals with health anxiety specifically, as it seems to generate anxiety within this domain. Although some individuals with health anxiety overuse the healthcare system, others with this disorder often avoid situations reminding them of illness or death and tend to avoid visiting hospitals because of their anxiety (Furer & Walker, 2005; Noyes, Hartz, Doebbeling, Malis, Happel, Werner, & Yagla, 2000). These repeated avoidance behaviors decrease their abilities to cope with these situations and aggravates their anxiety over time (Furer & Walker, 2005). This virtual environment was designed to target these individuals with the goal of virtually exposing them to a hospital to generate anxiety and eventually help them cope with their symptoms through repeated exposure based on the principles of exposure therapy. A more recent study conducted by Guitard, Bouchard, Bélanger, and Berthiaume (2019) utilizing the same virtual environment found similar results when exposing individuals with GAD to the emergency room and to an imagined scenario. Both exposures generated greater anxiety than baseline. However, these preliminary studies did not evaluate the virtual environment's usefulness in generating physiological responses from participants, as they only explored its effectiveness utilizing subjective reports of anxiety within a population diagnosed with GAD. Furthermore, the reaction of older age groups towards this virtual scenario has yet to

be explored. Therefore, the ability of this environment to generate physiological responses of anxiety within a population of younger and older adults with subclinical health anxiety is currently unknown and must be studied further.

CHAPTER 2: OBJECTIVES AND METHODOLOGY

3. Objectives

The objective of this pilot study is to determine if the virtual environment employed in this research (a hospital waiting room) generates anxiety to eventually be used in the context of an in virtuo exposure therapy with younger and older adults suffering from subclinical health anxiety. Traditional exposure strategies (in vivo and imaginal) are sometimes difficult to use with older people who are overly worried about their health, thus new methods of treatment would be beneficial (Grenier et al., 2015). For an exposure strategy to be effective, it must generate anxiety in the phobic person (Krijn et al., 2004). The physiological reactions of individuals during exposure are a good indicator of anxiety, thus the extent to which the VR exposure leads to significant increases in HR and SC will be used as an indication of the usefulness of the VR protocol in provoking anxiety (Wiederhold et al., 1998). The physiological responses of individuals collected during a VR immersion session will be assessed to determine if this exposure procedure can generate anxiety to eventually enhance or replace traditional exposure strategies. The physiological responses of participants concerned about their health (young and old) will be compared to a group of non-anxious participants to measure any significant differences associated with the VR exposure and determine its usefulness as a possible exposure method for health anxiety.

3.1 Hypotheses

We hypothesize (H1) that participants worried about their health (regardless of age) will have a faster heart rate and higher electrodermal conductivity compared to non-anxious participants when exposed to an anxiety-inducing virtual environment (a waiting room of a hospital) in comparison

to baseline measures. We also propose (H2) that young people who are apprehensive about their health will have a faster heart rate and higher electrodermal conductivity compared to older participants with health anxiety between the baseline measures and the exposure to the virtual environment. This hypothesis is based on the results of studies suggesting that older people have lower physiological responses (slower heart rate and lower skin conductance) than younger adults when exposed to emotional stimuli (Levenson et al., 1991; Tsai et al., 2000; Labouvie-Vief et al., 2003).

To ensure that the observed physiological reactions are not caused by simply being exposed to a virtual environment, the participants will be exposed to a neutral virtual environment after the baseline measures are taken. The reactions observed during exposure to the neutral environment will thus be compared to the physiological reactions recorded during exposure to the anxiety-inducing environment to determine which environment is producing the physiological response.

4. Methodology

4.1 Data sources

The current research is part of a larger pilot study designed to determine if virtual reality is effective in treating older adults with health anxiety. It is financed by the Quebec Network for Research on Aging (*Réseau québécois de recherche sur le vieillissement*: RQRV) and its goal it to design and implement a cognitive behavioral therapy incorporating virtual reality exposure techniques to treat health anxiety. It has been accepted by the Ethical Committee of the IUGM (# CER IUGM 14-15-001).

4.2 Participants

Participants (N = 47) were recruited using advertisements distributed at the "Centre de recherche de l'Institut universitaire de gériatrie de Montréal" (CRIUGM) and the Cyberpsychology Laboratory located at "Université du Québec en Outaouais" (UQO). These advertisements mentioned that participants were being recruited for a new study. The ads included the purpose of the study (to test the usefulness of a new virtual reality simulation for use in individuals with health anxiety), inclusion criteria (being between the ages of 18 to 35 or 65 and over and having health anxiety or not), and a phone number and email for potential participants to express their interest. Interested participants would receive a screening call from one of the research assistants explaining to them the details of the study and the objectives (see Annex 1). Their eligibility was determined based on questions pertaining to certain inclusion and exclusion criteria. Originally, 47 participants completed the study. However, data extraction was impossible for 17 participants because of technical issues during recording and participant behavior causing problems with the VR system during experimentation. This resulted in the loss of usable physiological data and the final sample was thus comprised of 30 participants.

4.3 Inclusion and exclusion criteria

Several inclusion criteria were used to make sure that participants were eligible for the study: Participants in the younger adult group must 1) be between 18 and 35 years of age; 2) be worried about their health (or have no worry for the control group based on the results of the “Inventaire d’anxiété face à la santé”, a questionnaire described below); 3) be able to understand, read, and speak French, and; 4) be able to travel (to Montreal or Gatineau) to participate in the experiment.

Participants in the older adult group must 1) be 65 years of age and older; 2) be worried about their health (or have no worry for the control group based on the results of the "Inventaire d'anxiété face à la santé"); 3) be able to understand, read, and speak French, and; 4) be able to travel (to Montreal or Gatineau) to participate in the experiment.

In addition, various exclusion criteria were also established to control for certain variables that may have affected physiological reactions or the study outcomes: Participants must not 1) have a major depressive disorder (with or without suicidal ideation), psychotic disorder, bipolar disorder, or substance abuse/dependence disorder; 2) have been diagnosed with neurological diseases (example: Parkinson's disease, dementia, multiple sclerosis, epilepsy, etc.); 3) have problems with balance or dizziness that increase the risk of falling after exposure, as they were seated during the exposure (example: Meniere's disease, benign paroxysmal positional vertigo, labyrinthitis, neuronitis, vestibular disorders, etc.); 4) have a vision problem that prevents the person from functioning normally on a daily basis (example: unable to read, watch television, or drive); 5) suffer from recurring migraines or intense discomfort while traveling by car (motion sickness).

Once the criteria were met and the participants were eligible for the project, a 4-hour meeting was scheduled for participants to come to the laboratory and complete the study. Each participant was compensated $20.00 for their time (with an additional $4.00 if public transport was used).

4.4 Testing procedure

Testing for each participant occurred between 10:00am and 2:00pm. In order to avoid potential biases regarding data collection, the participants were informed to avoid eating a meal one hour before the assessment meeting, to not consume caffeine (coffee, tea, energy drinks, etc.), and to not smoke or chew gum for at least 60 minutes before beginning. They were also instructed to not

drink alcohol for at least 24 hours before the testing. Once a participant arrived at the lab, a female research assistant greeted them, brought them to a private room, and explained the details of the study. After this, the consent form was read and signed by the participant (See Annex 2). For the next 60 minutes, participants answered questionnaires. After the questionnaire period and a brief 10-minute break, participants were led to the virtual reality exposure room where they were seated and wired into the system (see Annex 4). The participant was asked to sit still for three minutes so that baseline measures could be gathered before the exposure. They were then immersed in two virtual reality simulations. The first VR simulation lasted three minutes and consisted of a room in a house with a few furniture pieces and light coming in from a window. The participant was standing still and could look around using their head. This allowed participants to relax and get familiar with the system by looking around the virtual room. After this session, the 7-minute exposure session began. This exposure session consisted of a hospital emergency waiting room (see Annex 4) where seven patients, three nurses, and a physician interact with each other according to a standardized scenario that has been validated with anxious adults (Labbé et al., 2017; Guitard et al., 2019). In the virtual environment, the participants were not able to move and were exposed to various stimuli, including a contagious patient wearing a mask, a man coughing, and a mother approached by a doctor who receives bad news and cries. Patients are also called in to see doctors, and a doctor is seen discussing medical issues with a patient while looking at the participant. If the participant experienced intense simulator sickness, then the researcher would stop the simulation (if not, the researcher sat by quietly until the end of the exposure session). Approximately 5% of people experience severe cybersickness during virtual reality exposure, represented by symptoms that include dizziness, motion sickness, nausea, and disorientation (Bouchard, Robillard, Larouche, & Loranger, 2012). If indicated by the participant, this led to the

end of exposure. At the end of the session, the equipment was removed. For the final part of the study, individuals were given a last set of questionnaires and the study was completed.

4.5 Questionnaires and materials

Self-reported measures were used to measure anxiety. These included the "Inventaire d'anxiété face à la santé (IAS)," the French version of the *Short Health Anxiety Inventory* (Salkovskis, Rimes, Warwick, & Clark, 2002) (see Annex 3). This scale contains 14 items designed to measure the degree of health anxiety experienced by individuals (Salkovskis et al., 2002). Particularly, it evaluates if individuals believe that they have and the degree to which they think they will acquire a serious illness (Gerolimatos & Edelstein, 2012). It has been shown to be valid and reliable with a good internal consistency (α=0.89) (Salkovskis et al., 2002). A discriminant function analysis performed by Rode, Salkovskis, Dowd, and Hanna (2006) on a population of participants with chronic pain demonstrated that a score of ≥15 on the IAS indicated that they were anxious about their health, though not clinically (Alberts, Hadjistavropoulos, Jones, & Sharpie, 2013). Tang, Wright, and Salkovskis (2007) also used this cut-off score when evaluating the presence of health anxiety within individuals with chronic pain and insomnia. Therefore, scores on this scale were used to classify participants as with or without subclinical anxiety. Participants were divided into four groups according to their age and their level of health anxiety: 12 participants aged 18 to 35, 6 of whom were anxious about their health (based on scores ≥15 obtained from the IAS) and 6 non-anxious individuals (IAS score <15); as well as 18 participants aged 65 and over, 6 of whom were anxious about their health (IAS score ≥15) and 12 non-anxious individuals (IAS score <15). It is important to note that additional questionnaires and measures not mentioned were utilized in the context of the larger pilot study, but were not analyzed in this research.

Several technologies were also used to record the participants' physiological responses during exposure: A) Heart rate: The heart rate was measured and recorded using a biofeedback system from Thought Technology which transmitted data via a heart-rate belt that participants wore on their torsos (in contact with the skin). This system included the ProComp InfinityTM (a multi-channel multi-mode device), the Tele-InfinityTM T9600 (compact flash card), and a EKGTM electrocardiograph sensor. B) Electrodermal conductivity: Sensors were placed at the ends of the ring and index fingers (dominant hand) to measure the electrodermal reactions of each participant. The system used the ProComp InfinityTM (sampling frequency at 256 Hz) to transmit data to the PC, where it was analyzed using Thought Technology's Biograph InfinityTM and Physiology SuiteTM software. Also, an oculometer was used to measure the interpapillary distance of the participant's eyes, which was entered into the VR system to make sure that it was calibrated to each person. The VR system consisted of an nVis nVisor SS head-mounted display (allowing for a 150-degree head rotation in a 360-degree virtual world), an Intersense 3dof Cube2 location sensor, and a PC. The research assistants in this study received a training given by Thought Technologies on how to correctly attach the equipment to the participants prior to the beginning of data collection.

4.6 Statistical Analyses

Nonparametric tests (i.e. Mann Whitney or Chi-Square tests) were first carried out to verify if groups differ on sex, age, and levels of anxiety at baseline. Multi-level analysis was then performed to test both hypotheses: to determine the differences in the intensity of physiological arousal (DVs: heart rate and skin conductance levels), for H1, between anxious and non-anxious individuals (IV) and, for H2, between younger and older participants with health anxiety (IV) over time (Baseline,

Time 2, Time 3). In particular, linear mixed models were applied using SAS software (PROC MIXED) to take into account the correlation between the observations of the same individual, due to repeated measurements over time, and to account for the continuous dependent variables. This is itself a generalization of a matched data model or, even more so, of a repeated measures ANOVA. One of the strengths of these models is that they take into account measures related to an individual, even if some data are missing for a given time period, while normal procedures eliminate individuals with incomplete responses. Since these analyses take into account the number of valid data based on the structure of the observations, the total number of data points then becomes 90 (versus the total number of participants, which is 30), and the power of the analyses is greater. All assumptions were verified and met before performing the analyses.

CHAPTER 3: RESULTS AND DISCUSSION

5. Results

Younger participants (n = 12) had a mean age of 23.42 years (SD = 4.81) and older participants (n = 18) had a mean age of 70.89 years (SD = 4.93). Furthermore, participants with (n = 12) and without (n = 18) health anxiety had mean anxiety scores of 19.5 (SD = 3.40) and 7.61 (SD = 2.87) on the IAS scale respectively. As shown in Table 1, the two groups of anxious participants and the two groups of non-anxious participants (young and older adults) did not significantly differ at baseline in terms of sex, age, and levels of anxiety, thus groups could be combined based on age and anxiety levels for analysis. The adjusted means and standard deviations over time for each group are shown in Table 2.

Table 1. Participant characteristics according to their group based on an IAS score of ≥15

Characteristics	Young adults without anxiety (n = 6)	Young adults with anxiety (n = 6)	*p*-value[a]	Older adults without anxiety (n= 12)	Older adults with anxiety (n= 6)	*p*-value[a]
Sex, n						
Women	3 (50%)	5 (83.3%)	0.545	8 (66.7%)	6 (100%)	0.245
Men	3 (50%)	1 (16.7%)		4 (33.3%)	0 (0%)	
Age, mean ± SD	23.33 ± 3.83	23.5 ± 6.03	0.625	71.5 ± 5.75	69.67 ± 2.73	0.742
Health anxiety scores[b], mean ± SD	7 ± 3.52[c]	20.17 ± 3.66[d]	0.004	7.92 ± 2.61[c]	18.83 ± 3.31[d]	0.001

[a] Mann-Whitney or Chi-Square tests were used to verify if groups differ at the baseline.

[b] The "Inventaire d'anxiété face à la santé" (IAS) was used to assess the level of health anxiety. Higher scores indicate a higher level of health anxiety.

[c] Both groups of participants without health anxiety do not significantly differ on their level of anxiety; ($U = 26.0$, $p = 0.345$, $r = 0.22$).

[d] Both groups of participants with health anxiety do not significantly differ on their level of anxiety; ($U = 14.0$; $p = 0.519$, $r = 0.15$).

SD = Standard deviation.

Table 2. Adjusted means and standard deviations for heart rate and skin conductance according to group and time period

Measure	Group	Time 1		Time 2		Time 3	
		adj. *M*	*SD*	adj. *M*	*SD*	adj. *M*	*SD*
Heart Rate	No Health Anxiety	65.49	9.44	66.59	8.89	65.59	8.33
	Health Anxiety	71.90	13.25	75.36	13.33	75.32	14.62
Skin Conductance	No Health Anxiety	1.32	0.98	2.47	1.86	2.52	1.92
	Health Anxiety	1.11	0.84	2.77	2.19	2.99	2.45
Heart Rate	Old Anxious	71.83	18.40	74.32	19.40	76.15	20.61
	Young Anxious	71.95	8.96	76.23	7.24	74.64	9.29
Skin Conductance	Old Anxious	1.11	0.76	3.14	2.72	3.43	3.19
	Young Anxious	1.11	0.98	2.48	1.96	2.64	2.01

adj. *M* = adjusted mean; *SD* = standard deviation

The results of the linear mixed model showed that there were no significant differences at baseline between all groups for both heart rate and skin conductance (T1 for H1 (HR): $\beta = 6.40$, $p = 0.14$; T1 for H1 (SC): $\beta = -0.21$, $p = 0.79$; T1 for H2 (HR): $\beta = 0.12$, $p = 0.99$; T1 for H2 (SC): $\beta = -0.005$, $p = 0.99$), as shown in Tables 3-6. The results presented in Table 3 also revealed that participants of all ages worried about their health demonstrated significantly larger increases in heart rate between the baseline measures (T1) and the exposure to the hospital room virtual environment (T3) ($\beta = 3.43$, $p = 0.002$). They also had significantly greater HR increases when compared to the non-anxious group during VR exposure (T2: $\beta = 8.77$, $p = 0.045$; T3: $\beta = 9.73$, $p = 0.03$). However, there was no significant difference in HR between the exposure to the neutral virtual environment (T2) and T3 within the anxious group ($\beta = -0.04$, $p = 0.97$). With regards to skin conductance, the results presented in Table 4 also showed that participants of all ages worried about their health demonstrated significantly larger increases in SC between T1 and T3 ($\beta = 1.88$, $p<0.0001$). However, they did not have significantly greater SC increases when compared to the non-anxious group during VR exposure (T2: $\beta = 0.30$, $p = 0.70$; T3: $\beta = 0.47$, $p = 0.55$). There was

also no significant difference in SC between T2 and T3 within the anxious group (β = 0.22, p = 0.59).

In addition, the results presented in Table 5 and 6 indicated that young participants with health anxiety did not have significantly larger increases in both heart rate (T2: β = 1.92, p = 0.83; T3: β = -1.51, p = 0.87) and skin conductance (T2: β = -0.65, p = 0.65; T3: β = -0.79, p = 0.58) than older anxious participants during VR exposure.

Table 3. Linear mixed model for heart rate showing the interactions between time and group (anxious vs non-anxious participants)

Effects	Time	Group	Time	Group	β	SE	95% CI	t test	*p*
TIME*Anxiety	1	1	1	2	6.40	4.26	-2.15 – 14.96	1.50	0.14
TIME*Anxiety	1	2	3	2	3.43	1.06	1.29 – 5.56	3.22	0.002
TIME*Anxiety	2	1	2	2	8.77	4.26	0.22 – 17.33	2.06	0.045
TIME*Anxiety	2	2	3	2	-0.04	1.06	-2.17 – 2.10	-0.04	0.97
TIME*Anxiety	3	1	3	2	9.73	4.26	1.18 – 18.28	2.28	0.03

Time coding: 1 = baseline, 2 = neutral VR environment, and 3 = hospital room VR environment; Group coding: 1 = non-anxious and 2 = anxious; SE = standard error; CI = confidence interval

Table 4. Linear mixed model for skin conductance showing the interactions between time and group (anxious vs non-anxious participants)

Effects	Time	Group	Time	Group	β	SE	95% CI	t test	*p*
TIME*Anxiety	1	1	1	2	-0.21	0.77	-1.77 – 1.35	-0.27	0.79
TIME*Anxiety	1	2	3	2	1.88	0.40	1.07 – 2.69	4.70	<.0001
TIME*Anxiety	2	1	2	2	0.30	0.77	-1.25 – 1.86	0.39	0.70
TIME*Anxiety	2	2	3	2	0.22	0.40	-0.59 – 1.03	0.55	0.59
TIME*Anxiety	3	1	3	2	0.47	0.77	-1.09 – 2.03	0.61	0.55

Time coding: 1 = baseline, 2 = neutral VR environment, and 3 = hospital room VR environment; Group coding: 1 = non-anxious and 2 = anxious; SE = standard error; CI = confidence interval

Table 5. Linear mixed model for heart rate showing the interactions between time and group (old anxious vs young anxious participants)

Effects	Time	Group	Time	Group	β	SE	95% CI	t test	*p*
TIME*Anxiety	1	1	1	2	0.12	8.76	-18.28 – 18.53	0.01	0.99
TIME*Anxiety	2	1	2	2	1.92	8.76	-16.49 – 20.32	0.22	0.83
TIME*Anxiety	2	1	3	1	1.83	1.78	-1.91 – 5.57	1.03	0.32
TIME*Anxiety	2	2	3	2	-1.60	1.63	-5.01 – 1.82	-0.98	0.34
TIME*Anxiety	3	1	3	2	-1.51	8.76	-19.92 – 16.90	-0.17	0.87

Time coding: 1 = baseline, 2 = neutral VR environment, and 3 = hospital room VR environment; Group coding: 1 = old anxious and 2 = young anxious; SE = standard error; CI = confidence interval

Table 6. Linear mixed model for skin conductance showing the interactions between time and group (old anxious vs young anxious participants)

Effects	Time	Group	Time	Group	β	SE	95% CI	t test	*p*
TIME*Anxiety	1	1	1	2	-0.005	1.39	0.56 – 3.48	-0.00	0.99
TIME*Anxiety	2	1	2	2	-0.65	1.39	-1.16 – 1.76	-0.47	0.65
TIME*Anxiety	2	1	3	1	0.30	0.68	-3.47 – 2.48	0.44	0.67
TIME*Anxiety	2	2	3	2	0.16	0.61	-1.15 – 1.46	0.26	0.80
TIME*Anxiety	3	1	3	2	-0.79	1.39	-3.77 – 2.19	-0.57	0.58

Time coding: 1 = baseline, 2 = neutral VR environment, and 3 = hospital room VR environment; Group coding: 1 = old anxious and 2 = young anxious; SE = standard error; CI = confidence interval

6. Discussion

6.1 Purpose of the pilot study

The purpose of this pilot study was to fill a gap in the literature and determine the usefulness of using an emergency room virtual reality environment to eventually incorporate it into a VRET to

treat health anxiety. To do so, the differences in physiological activation between anxious and non-anxious individuals, as well as the differences in physiological responses between young and older individuals were compared to see its usefulness in generating anxiety within these populations.

6.2 Differences in physiological responses between anxious and non-anxious participants regardless of their age

It was initially predicted (H1) that anxious individuals, regardless of age, would demonstrate significantly larger increases in both heart rate and skin conductance measures when compared to non-anxious individuals. At first glance it seems that H1 was confirmed for HR and partially confirmed for SC. As shown in Table 3, the hospital room environment was successful in generating significantly greater HR increases in anxious individuals than in non-anxious individuals between baseline (time 1) and time 3, but it did not create significantly more anxiety between the neutral virtual environment (time 2) and time 3 when compared. With regards to SC, the results presented in Table 4 demonstrate that a significant increase was only observed within anxious individuals between time 1 and 3. However, there were no differences in SC between time 2 and 3, and the anxious individuals also did not have significantly greater SC scores when exposed to a virtual environment than the non-anxious group. Although it first seemed that the hospital room environment was successful in generating greater HR and SC increases in anxious individuals, it did not create significantly more anxiety than the neutral virtual environment. Anxious individuals had increased physiological reactions when exposed to a neutral virtual environment, but no significantly greater increases were observed when they were subsequently exposed to the hospital room environment. The inclusion of a neutral VR simulation has thus allowed us to determine that it was being exposed to a VR simulation that led to increases in both

HR and SC, and not the content of the virtual environment itself that generated these responses. Although it first seemed like our hypotheses were supported, our decision to include the neutral environment has allowed us to determine that the hospital room environment does not generate significantly greater physiological reactions within the anxious group and thus cannot be currently recommended for use in a VRET treating subclinical health anxiety. However, as stated in the section 4.5, the cut-off of ≥15 on the IAS that we used allowed us to identify participants who were worried about their health at a subclinical level (Alberts et al., 2013). Therefore, no conclusions can be drawn about the use of this environment with older adults with health concerns that meet the diagnostic criteria of a somatic symptom disorder or an illness anxiety disorder, which are both clinical manifestations of health anxiety according to the DSM-5.

6.3 Differences in physiological responses between young and older adults with subclinical health anxiety

Our second hypothesis (H2), focusing on the differences between young and elderly individuals with regards to physiological activations, was not supported. As shown in Tables 5 and 6, young anxious people did not have significantly increased HR nor SC compared to older participants with health anxiety over the three time periods. The hospital room environment also did not induce significantly higher physiological increases within both groups than the neutral virtual environment when compared. This further supports our conclusion that the VR simulation itself is what led to increases in both HR and SC in participants and not the content of the simulation.

With regards to age differences, no significant differences in physiological response was detected. As shown in previous research, older individuals generally demonstrate lower physiological activations compared to younger people on both measures (Levenson et al., 1991; Tsai et al., 2000;

Labouvie-Vief et al., 2003). Therefore, similar results were expected regarding our different age groups. However, as stated by Kunzmann and Gruhn (2005), these past studies were using age-neutral stimuli, which seems to dampen the emotional reactions of older adults. Kunzmann and Gruhn (2005) have shown that when age-appropriate stimuli are used (for example, stimuli dealing with physical health) autonomic reactions are just as high in both young and older adults. These results were further confirmed and replicated in a larger sample (Kunzmann and Richter, 2009). Therefore, a possible reason for the lack of physiological reaction differences between age groups found in our study may be because the stimuli in our study revolved around physical health, thus it provoked similar autonomous reactions between age groups. However, future research into the nature of stimuli and their effects on age-related physiological responses is needed to better understand our findings.

6.4 Importance of incorporating a neutral environment

The results of this study highlight the importance of including a neutral VR environment when determining the usefulness of a new VR environment that is intended to eventually be used in a VRET. The inclusion of this factor was used to increase the validity of our results, as it allowed us to determine where the physiological activation occurred. The current research literature is inconsistent in the use of a neutral environment in studies utilizing virtual reality, as some researchers choose not to incorporate one. Nonetheless, based on our findings, we recommend that future studies evaluating the usefulness of a VR environment for use in an exposure therapy always incorporate a neutral environment in their study design. This would enable researchers to determine whether or not the VR exposure itself is what generates increased anxiety or if it is the content of the environments that is the determining factor. However, it is important to note that the

inclusion of a neutral environment can influence the results as well. Busscher, de Vliegher, Ling, & Brinkman (2011) showed that neutral VR environments can sometimes create a novelty effect which may increase physiological activation in participants. They demonstrated that neutral environments may at times generate larger increases in HR than the experimental environment when presented beforehand because of this novelty. This phenomenon may have occurred in this study, as large HR increases at time 2 may have subsequently led to insignificant differences at time 3. The order in which the neutral VR was presented may have affected the quality of the baseline measures. Therefore, presenting the neutral environment before taking baseline measures may neutralise the novelty effect and allow for cleaner baseline measures to be taken before placing participants into the experimental VR environment. Future studies should take care to include a neutral environment before baseline measures are taken to make sure that it is not the exposure itself, but the actual environment content that causes increases in physiology.

6.5 Factors influencing physiological reactions towards the virtual environment and future research directions

There are several reasons why anxious participants may not have reacted significantly more towards the hospital room VR environment compared to the neutral environment. One potential reason may be that the environment used in this study is not realistic enough to be used with people with milder levels of health anxiety, which were included in this study, and may generate stronger physiological activations in clinically anxious samples. Although studies have shown that the VR environment has to be just real enough (not perfect) to induce an anxiety reaction in individuals with clinical anxiety, it may be that the quality of the environment takes on a more prominent role when including individuals with subclinical anxiety (Lugrin, Wiedemann, Bieberstein, &

Latoschik, 2015; Zimmons & Panter, 2003). This threshold of realism may have to be much higher in subclinical samples to produce similar results. With this less anxious population, a more realistic representation of the phobic object or environment may be needed to induce an increase in physiological factors associated with anxiety. Therefore, future studies should explore the differential reactions between clinically anxious and subclinical populations to determine if realism becomes a key factor in the environment's ability to induce an anxiety reaction.

Furthermore, and in line with the previous explanation, the anxiety score cut-off on the IAS scale that we used may not have been high enough to detect significant differences. As our sample was comprised of individuals with subclinical levels of health anxiety, a larger anxiety cut-off score that includes clinically anxious individuals may have allowed for the detection of significant differences in physiological activation. This is based on the rationale that by forming a group of participants with a higher level of health anxiety (versus less anxious participants), significant differences on physiological measures could become easier to detect (Salkovskis et al., 2002). Therefore, this treatment method may best be used with participants having higher anxiety scores on the IAS to generate optimal physiological activation, a key factor in exposure therapy success (Diemer, et al., 2014; Wiederhold, et al., 1998). We therefore recommend that future studies include a clinically anxious sample to determine if a higher anxiety score cut-off would allow for the detection of significant increases in both HR and SC.

Another factor that may have influenced the results is group composition. As mentioned earlier, the emergency room virtual environment was designed to target individuals with health anxiety who avoid hospitals. However, there are two manifestations of this type of anxiety. Some individuals avoid seeking healthcare, and others overuse the healthcare system for fear of having an illness (Noyes et al., 2000). Although preliminary questions regarding if participants avoided

hospitals or not were not asked, it is likely that the majority of our participants had no avoidance behavior based on the presented purpose of the study. That being said, it is still possible that some of our participants were avoidant because, even if they have subclinical health anxiety, it can still have an impact on their functioning (Barsky et al., 2001). Therefore, it would be important for future studies exploring the usefulness of a VR environment designed to treat health anxiety to distinguish which sub-population their environment is targeting and to make sure that these individuals are included in their sample.

6.6 Clinical Implications

Results from our pilot study suggest that the hospital emergency room virtual environment does not cause a greater anxiety reaction, demonstrated by an increase in heart rate and skin conductance, in individuals with subclinical health anxiety when compared to a neutral virtual environment. This environment can thus not currently be recommended to be included in a VRET to treat subclinical health anxiety, and additional research is necessary to test its feasibility and usefulness in older adults with clinical health anxiety. Further studies incorporating our proposed changes are also needed to further validate and enhance our findings. Nevertheless, the eventual use of a virtual environment during exposure therapy to treat health anxiety has many clinical benefits. Since older individuals often have physical limitations, they would not need to travel to the exposure location and be able to complete their treatment inside the psychologist's office, reducing the issues currently experienced with traditional in vivo exposure therapies. Furthermore, the therapist will also be able to control all the variables within the virtual environment and circumvent imaginal difficulties that older individuals experience because of natural memory deterioration (Grenier et al., 2015). Lastly, future clinicians should be aware that this particular

environment is not designed to treat older adults with health anxiety who frequently visit hospitals in search of reassurance, since the onset of anxiety is necessary for exposure to be effective. Therefore, they should organize their treatments accordingly in order to potentially increase the positive response rate of their exposure therapy strategies.

6.7 Limitations

This study contained limitations that are important to mention. First, although we found some significance differences, the small sample size remains a limitation inherent to a pilot study. Second, the groups contain significantly more female participants. As males and females show differences in both emotional and physiological responses to stress, as well as in baseline activity, a bias was potentially included in the results of this study (Stroud, Salovey, & Epel, 2002). The resulting physiological fluctuations in the responsiveness of anxious and non-anxious individuals towards the virtual environment may have thus been influenced by the disparity in sexes. Third, the physiological indices measured could have been impacted by a variety of physical factors present in participants including sex, BMI, body size, the use of cigarettes, fitness and exercise level, current health status, and medication use, amongst others. These factors could have been controlled via stricter inclusion criteria to make sure that differences in physiological activation were not influenced by physique and lifestyle factors. Although we recognize that these factors may have influenced the results, it is unfeasible to control for all these factors in a pilot study. Lastly, technological issues were encountered during the study which led to an important reduction in the final sample size. For the analyses performed on the physiological measures in this study, the final sample size was reduced from 47 to 30 participants because of problems encountered when gathering physiological data. This important loss raises concerns as to the reliability/validity

of the data obtained for the remaining 30 participants, even if the researchers were trained by Thought Technology (the company that designed the product) on the use of the equipment. Unfortunately, the training did not cover all issues that may occur when recording participants' physiological data. One of the uncovered issues that we observed is that some participants did not sufficiently move their head during the VR simulation. This caused the helmet to go into standby mode, thus losing the picture in both eyes and prompting the researcher to break silence and inform them to move their head. This affected the physiological measures and they could not be used in these cases, as biases had been introduced. Further data were lost due to technical issues with the connections that caused the measures to not be recorded accurately. For example, the electrodes may have not been attached to the participant tightly enough or too tightly, causing the loss of one or both physiological measures. Although these issues occurred, care was taken to make sure that the remaining data were appropriate for analysis. Each recording was verified to make sure that the data was recorded throughout the experimentation and subsequent artifacts were removed from each data segment. In future research, the research assistants should receive further training on proper equipment utilization and on all technical issues that may arrive with older adults. Further studies accounting for the limitations mentioned above with a larger sample size and a greater anxiety cut-off score on the IAS scale are needed to advance our findings and to confirm the usefulness of this virtual environment. Future studies are also needed to verify the use of VRET as a potentially beneficial treatment for health anxiety.

6.8 Strengths

Although this study contained several limitations, it is the first to compare physiological reactions between younger and older adults with and without subclinical health anxiety when exposed to a

virtual environment designed to induce anxiety symptoms. Other strengths of the study include the use of rigorous selection criteria and validated measuring instruments.

7. Conclusion

This research looked at the usefulness of a new virtual environment designed to be used within the context of a VRET to treat health anxiety in young and elderly individuals. The differences in heart rate and skin conductance levels between anxious and non-anxious groups were used to determine if anxious individuals demonstrate greater physiological activation with regards to the VR exposure environment and to see if there are reactivity differences between age groups. Although the research hypotheses seemed to be partially supported at first, the inclusion of a neutral virtual environment confirmed that no statistically significant augmentations in physiological reactions occurred between time 2 and time 3. Therefore, this indicates that it was the virtual environment, and not the content, that generated physiological activation in the participants. The significance of the results may have been also influenced by the small sample size and technological limitations outlined above. However, further exploration into the factors potentially influencing the results has led to the discovery of several new avenues for future research aimed at determining the potential usefulness of VRET as a new treatment method for health anxiety in elderly individuals. Considering that VR exposure presents multiple benefits and that approximately 10% of seniors suffer from health anxiety, additional research in this domain and the successful incorporation of VRET into therapeutic sessions may benefit hundreds of thousands of anxious elderlies throughout the world (El-Gabalawy et al., 2013).

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ANNEXES

Annex 1: Preselection of Potential Participants

PRÉSÉLECTION DES PARTICIPANTS POTENTIELS

Directives :

1) Veuillez introduire l'étude en utilisant l'extrait suivant : ***«Bonjour, je sollicite votre participation pour une étude sur l'utilisation de la réalité virtuelle pour traiter l'anxiété lié à l'état de santé chez les personnes âgées qui se déroule actuellement au CRIUGM. Je pense que vous pourriez être intéressé(e) par ce projet de recherche. Dans un premier temps, cette étude a comme objectifs de comparer les réactions rapportées selon l'âge et le niveau d'anxiété des participants suite à une expérience d'immersion en réalité virtuelle. Dans un deuxième temps, elle vise à tester l'efficacité d'une thérapie cognitivo-comportementale (TCC) qui utilisera la réalité virtuelle pour traiter l'anxiété liée à l'état de santé chez les personnes âgées. Pour vérifier si vous êtes admissible, je vais vous poser certaines questions. Cela prendra environ 5 minutes. Si vous êtes admissible, vous serez rencontré(e) ou contacté(e) par un professionnel de recherche. Vous pourrez alors décider si vous participez ou non à l'étude».***

2) Répondez aux questions suivantes et assurez-vous d'obtenir le consentement de la personne à être rencontrée/contactée par le professionnel de recherche (en cochant la case appropriée à la fin du document).

- Nom/prénom du (de la) participant(e) : _____

- Sexe : M ☐ **F** ☐

- Tél. du (de la) patient(e) : (____)_____

- Lieu de recrutement: _____

- Transport assuré par : **Usager**
☐ **Famille/ accompagnateur** ☐ **Transport adapté** ☐

Transport assuré par le groupe Maurice (GM)☐

Critères d'inclusion **1)** Quel âge avez-vous? La personne doit avoir entre 18 et 35 ans (groupes de jeunes adultes) ou 65 ans et plus (groupes d'aînés)	_____		**Ne sait pas/incertain** ☐ Explications : _____ _____ _____
2) Vous êtes en mesure de comprendre, de lire et de parler le français? *Il n'est pas obligé que le français soit parfait, mais la personne doit être fonctionnelle dans cette langue.	**Oui** ☐	**Non** ☐	☐ Explications : _____ _____ _____

3) Le (la) patient(e) doit-être en mesure de se déplacer au CRIUGM pour	**Oui** ☐	**Non** ☐	**Ne sait pas/incertain** ☐

l'éxpérimentation			Explications : _____ _____ _____
4) Est-ce que vous vous inquiétez pour votre santé? Si la personne répond non (c.à.d. ne s'inquiète pas pour sa santé), elle fera partie du groupe contrôle	☐	☐	☐ Explications : _____ _____ _____
<u>Critères d'exclusion</u> **5)** Est-ce que vous souffrez d'un trouble dépressif majeur (avec ou sans idées suicidaires), un trouble psychotique, un trouble bipolaire ou un trouble d'abus / de dépendance à une substance)?	☐	☐	☐ Explications : _____ _____ _____
6) Est-ce que vous avez reçu un diagnostic de maladies neurologiques (p. ex., Parkinson, démence, sclérose en plaques, épilepsie, etc.)?	☐	☐	☐ Explications : _____ _____ _____
7) Avez-vous des problèmes d'équilibre ou de vertige (p. ex., maladie de Ménière, vertige positionnel paroxystique bénin, labyrinthite, neuronite, troubles vestibulaires, etc.)? Ces problèmes augmenteraient les risques de chute après l'exposition (les gens seront assis durant l'exposition)	☐	☐	☐ Explications : _____ _____ _____
8) Avez-vous un problème de vision (peu importe la pathologie oculaire) qui vous empêche de fonctionner normalement au quotidien (p. ex., être incapable de lire, de regarder la télévision ou de conduire)?	☐	☐	☐ Explications : _____ _____ _____
9) Souffrez-vous de migraines récurrentes ou de malaises intenses lors de voyage en voiture (mal des transports)?	☐	☐	☐ Explications : _____ _____ _____

Le (la) patient(e) est admissible à l'étude si :
1) vous avez répondu **OUI** ou NE SAIT PAS/INCERTAIN **aux quatre premières questions (1 à 4)**
ET
2) vous avez répondu **NON** ou NE SAIT PAS/INCERTAIN **aux cinq dernières questions (5 à 9)**

Selon les informations obtenues, jugez-vous que le (la) patient(e) est admissible à l'étude?

☐ **OUI** ☐ **NON**

*** La personne consent à la transmission de ces informations et à être rencontrée/contactée par le personnel de recherche : OUI** ☐ **NON** ☐ **Raisons : _____**

Nom et titre : _____ Signature : _____ Date : _____

Annex 2: Consent Form

FORMULAIRE D'INFORMATION ET DE CONSENTEMENT

Titre du projet de recherche :	L'utilisation de l'exposition en réalité virtuelle (*in virtuo*) pour traiter l'anxiété liée à l'état de santé chez les personnes âgées : une étude de faisabilité.
Chercheur responsable du projet de recherche :	Dr Sébastien Grenier, M.Ps., Ph.D, psychologue clinicien et chercheur à l'Institut universitaire de gériatrie de Montréal.
Co-chercheurs :	▪ Stéphane Bouchard, Ph.D., professeur au département de psychoéducation et de psychologie à l'Université du Québec en Outaouais (UQO). ▪ Hélène Forget, Ph.D., professeure au département de psychoéducation et de psychologie à l'Université du Québec en Outaouais (UQO). ▪ Sylvie Belleville, Ph.D., professeure au département de psychologie de l'Université de Montréal et chercheuse à l'Institut universitaire de gériatrie de Montréal. ▪ Fethia Benyebdri, Ph.D., coordonnatrice de projet de recherche au laboratoire du Dr Sébastien Grenier
Organisme subventionnaire :	Le Réseau québécois de recherche sur le vieillissement (RQRV).

Préambule

Nous vous invitons à participer à un projet de recherche. Cependant, avant d'accepter de participer à ce projet et de signer ce formulaire d'information et de consentement, veuillez prendre le temps de lire, de comprendre et de considérer attentivement les renseignements qui suivent.

Ce formulaire peut contenir des mots que vous ne comprenez pas. Nous vous invitons à poser toutes les questions que vous jugerez utiles au chercheur responsable de ce projet ou à un membre de son personnel de recherche et à leur demander de vous expliquer tout mot ou renseignement qui n'est pas clair.

Nature et objectifs du projet de recherche

Dépendamment des études, entre 3 et 15% des personnes âgées s'inquiètent de façon excessive à propos de leur santé. Les taux de prévalence sont similaires chez les jeunes adultes. Les personnes qui s'inquiètent beaucoup au sujet de leur santé peuvent être incapables de fonctionner normalement, voient leur qualité de vie diminuée et ont tendance à chercher constamment du réconfort auprès de l'entourage ou à consulter fréquemment leur médecin pour se réassurer.

À l'inverse, ce type d'anxiété peut amener certaines personnes qui en souffrent à éviter les cliniques médicales ou les hôpitaux pour ne pas être confrontées aux maladies potentielles. Les personnes qui s'inquiètent au sujet de leur santé peuvent donc remettre à plus tard leurs rendez-vous médicaux et, par conséquent, s'exposer à une détérioration de leur condition de santé qui nécessite des soins immédiats.

La thérapie cognitivo-comportementale (TCC) est une approche thérapeutique de courte durée qui permet aux personnes de s'exposer graduellement à l'objet phobique (c.-à-d., l'environnement qui déclenche la peur). La salle d'attente d'un hôpital est un environnement propice au déclenchement d'anxiété face à la santé et donc un lieu potentiel d'exposition. Cependant, pour être efficace, l'exposition doit se faire de façon contrôlée et graduelle (c.-à-d., en augmentant le degré de difficulté d'une séance

à l'autre), ce qui est pratiquement impossible à réaliser à l'hôpital, un environnement incontrôlable (p. ex., de nouveaux patients peuvent arriver à tout moment).

Une façon de contourner cette difficulté est d'utiliser un environnement virtuel qui reproduit l'objet phobique (p. ex., une salle d'attente à l'hôpital). En effet, ce type d'environnement permet de contrôler les étapes d'exposition en choisissant les stimuli qui seront présentés. Il est donc plus facile pour le thérapeute de graduer le niveau de difficulté des séances d'exposition et par le fait même d'éviter que son client abandonne la thérapie parce qu'il vit trop d'anxiété.

Dans un premier temps, notre projet vise donc à comparer les réactions rapportées selon l'âge et le niveau d'anxiété des participants suite à une expérience d'immersion en réalité virtuelle. Pour ce faire, nous comptons recruter 32 participants, hommes et femmes. Les participants seront répartis en 4 groupes de 8 personnes: 1) jeunes adultes non anxieux; 2) jeunes adultes anxieux; 3) personnes âgées non anxieuses; et 4) personnes âgées anxieuses.

Également, dans un deuxième temps, notre projet vise à tester l'efficacité d'une thérapie cognitivo-comportementale (TCC) qui utilisera la réalité virtuelle pour traiter l'anxiété liée à l'état de santé chez les personnes âgées. Pour ce faire, nous comptons recruter 5 participants âgés.

Déroulement du projet de recherche

Ce projet de recherche se déroulera au Laboratoire d'étude sur l'anxiété et la dépression gériatrique situé au Centre de recherche de l'IUGM (CRIUGM).

I. Participant du groupe immersion en réalité virtuelle :

Votre participation à cette étude impliquera une rencontre d'une durée totale d'environ 5 heures. Plus précisément, cette rencontre sera divisée en 3 étapes :

1. Nous réaliserons une entrevue d'évaluation (pré-immersion) d'une durée approximative de 60 minutes couvrant plusieurs aspects associés à l'anxiété et aux environnements virtuels. Plus précisément, les éléments suivants seront évalués :

a. Vos inquiétudes sur la santé ainsi que votre niveau d'anxiété et de dépression;
b. Vos capacités d'immersion dans un environnement virtuel et;
c. Votre degré de familiarité avec les technologies.

Aussi, durant cette évaluation pré-immersion, nous collecterons deux échantillons (dès votre arrivée au laboratoire et tout juste avant l'expérience d'immersion) de salive à l'aide d'un bout de coton que vous devrez mâcher (pendant environ 60 secondes). Ces échantillons de salive nous permettront d'analyser votre taux de cortisol (hormone du stress). Afin de ne pas biaiser les échantillons de salive, vous devez éviter de manger un repas une heure avant la rencontre d'évaluation. Il est aussi interdit de consommer de la caféine (café, thé, boissons énergisantes, etc.), et de fumer ou mâcher de la gomme au moins 60 minutes avant le prélèvement. Il est recommandé de ne pas boire d'alcool 24 heures auparavant.

Avant de débuter l'expérience d'immersion, nous vous demanderons d'attacher autour de votre torse une ceinture qui évaluera votre rythme cardiaque. De plus, nous fixerons aux extrémités de votre annulaire et auriculaire (main dominante) des capteurs afin de mesurer vos réactions électrodermales durant l'expérimentation. Ce branchement prendra environ 15 minutes.

2. Vous serez soumis à une séance d'immersion dans un environnement virtuel reproduisant une salle d'attente d'hôpital. Pour ce faire, vous devrez porter un visiocasque (des lunettes spéciales qui permettent de voir en 3D) qui sera branché à l'ordinateur et vous asseoir sur une chaise. Dans cet environnement virtuel, trois membres du personnel infirmier et un médecin interagiront devant vos yeux. Tout ce que vous devrez faire est d'observer ce qui se passe devant vos yeux. Vous n'aurez rien à manipuler avec vos mains. Cette séance d'immersion durera environ 10 minutes.

3. Nous réaliserons une entrevue d'évaluation (post-immersion) d'une durée approximative de 70 minutes durant laquelle nous ferons un retour sur votre expérience dans l'environnement virtuel. Vous remplirez les mêmes questionnaires que ceux administrés en début de rencontre (avant la séance d'immersion). De plus, nous collecterons deux échantillons supplémentaires de votre salive (après la séance d'immersion et avant votre départ du laboratoire) en suivant exactement la même procédure que celle décrite ci-dessus.

II. Participant du groupe thérapie cognitivo-comportementale :

Votre participation à cette étude impliquera deux rencontres d'évaluation pré-traitement, 8 semaines de thérapie et une rencontre d'évaluation post-traitement. Voici un aperçu du déroulement de ces rencontres.

A. Première rencontre d'évaluation pré-traitement (pré-test 1).

1. Durant cette première rencontre d'évaluation qui durera de 30 à 45 minutes, vous devrez remplir un questionnaire qui mesurera l'intensité de vos inquiétudes au sujet de votre santé. Cette évaluation nous permettra de confirmer votre éligibilité à l'étude.
2. Nous vous expliquerons le fonctionnement d'un calepin d'observations que vous devrez remplir tous les jours avant et pendant la thérapie. Prévoyez environ 2 à 3 minutes pour répondre aux trois questions. Dans ce calepin, vous noterez une fois par jour, idéalement le soir toujours à la même heure, l'intensité de votre anxiété, de vos inquiétudes et la présence de tristesse. Un assistant de recherche vous contactera une fois par jour afin de recueillir vos réponses. De plus, tous les vendredis, l'assistant de recherche vous posera des questions supplémentaires sur vos inquiétudes au sujet de la santé. Il faut prévoir environ 5 minutes pour compléter les appels téléphoniques.
3. La thérapie cognitivo-comportementale débutera 2 à 4 semaines après la première rencontre d'évaluation (pré-test 1). Nous vous l'indiquerons en temps et lieu. Le calepin devra être rempli tous les jours durant cette période.
4. Un rendez-vous pour une deuxième rencontre d'évaluation (pré-test 2) sera prévu avant de débuter la thérapie cognitivo-comportementale.

B. Deuxième rencontre d'évaluation pré-traitement (pré-test 2).

1. Durant cette deuxième rencontre d'évaluation, nous réaliserons une entrevue d'une durée approximative de 50 minutes couvrant plusieurs aspects associés à l'anxiété et aux environnements virtuels. Plus précisément, les éléments suivants seront évalués :

a) Vos inquiétudes sur la santé ainsi que votre niveau d'anxiété et de dépression;
b) Vos capacités d'immersion dans un environnement virtuel et;
c) Votre degré de familiarité avec les technologies.

2. Lorsque les deux rencontres d'évaluation pré-traitement (pré-tests 1 et 2) seront complétées, un rendez-vous sera fixé avec le psychologue.

C. Thérapie cognitivo-comportementale (TCC) avec séance d'exposition en réalité virtuelle (in virtuo)

Cette thérapie individuelle s'étalera sur 8 semaines à raison d'une rencontre de 90 minutes par semaine (les rencontres auront lieu entre 11h00 et 15h00). La TCC comprendra notamment des séances de restructuration cognitive (remettant en question les quatre croyances irrationnelles à l'origine de votre anxiété) et des séances d'exposition in virtuo.

À chaque séance, vous devrez remplir des questionnaires qui évalueront, entre autres, votre niveau d'anxiété/stress, la présence de cybermalaises et vos capacités à être immergé dans un environnement virtuel.

De plus, à chaque séance, nous collecterons quatre échantillons de salive (dès votre arrivée au laboratoire, tout juste avant l'expérience d'immersion, après l'immersion et avant votre départ du laboratoire) à l'aide d'un bout de coton que vous devrez mâcher (pendant environ 60 secondes). Ces échantillons de salive nous permettront d'analyser votre taux de cortisol (hormone du stress). Afin de ne pas biaiser les échantillons de salive, vous devez éviter de manger un repas deux heures avant les séances thérapeutiques. Il est aussi interdit de consommer de la caféine (café, thé, boissons énergisantes, etc.). Cependant, vous pouvez manger des petites collations et boire de l'eau.

Au début des séances, nous vous demanderons d'attacher autour de votre torse une ceinture qui évaluera votre rythme cardiaque. De plus, nous fixerons aux extrémités de votre annulaire et auriculaire (main dominante) des capteurs afin de mesurer vos réactions électrodermales durant. Ce branchement prendra environ 10-15 minutes.

Enfin, dépendamment du contenu prévu durant les séances thérapeutiques, vous serez immergé (de façon graduelle en respectant votre niveau d'anxiété) dans un environnement virtuel reproduisant une salle d'attente d'hôpital. Pour ce faire, vous devrez porter un visiocasque (des lunettes spéciales qui permettent de voir en 3D) qui sera branché à l'ordinateur et vous asseoir sur une chaise. Dans cet environnement virtuel, trois membres du personnel infirmier et un médecin interagiront devant vos yeux. Tout ce que vous devrez faire est d'observer ce qui se passe devant vos yeux et tolérer l'anxiété que vous ressentirez. Vous n'aurez rien à manipuler avec vos mains.

D. Rencontre d'évaluation post-traitement (post-test).

À la fin des 8 semaines de thérapie, vous remplirez à nouveau les mêmes questionnaires remplis lors du pré-test 2.

Avantages associés au projet de recherche

Il se peut que vous retiriez un bénéfice personnel de votre participation à ce projet de recherche, mais nous ne pouvons vous l'assurer. Par ailleurs, les résultats obtenus contribueront à l'avancement des connaissances scientifiques dans ce domaine de recherche.

Inconvénients associés au projet de recherche

I. Exposition à l'environnement virtuel :

L'exposition à l'environnement virtuel peut entraîner des cybermalaises. Les cybermalaises représentent une forme de malaise que l'on ressent pendant ou après une exposition en réalité virtuelle. Ils proviennent d'un conflit entre deux types d'information : les yeux qui perçoivent un mouvement alors que le reste du corps ne bouge pas, un peu comme lorsqu'on lit en voiture. Les symptômes ou effets secondaires temporaires associés aux cybermalaises peuvent impliquer: fatigue des yeux, vision embrouillée, maux de tête, vertiges, déséquilibre, désorientation, nausées, étourdissements.

Les cybermalaises se dissipent généralement en ajustant la sensibilité des lunettes aux mouvements de la tête. Les problèmes oculaires sont dus au fait que la personne porte un casque et que l'écran se retrouve près des yeux. Toutefois, ces conséquences sont temporaires et comparables à quelqu'un qui regarde la télévision de près. De plus, l'œil s'adapte rapidement et les casques de réalité virtuelle sont développés afin de minimiser ce phénomène. Il est habituellement recommandé de limiter la durée de l'exposition virtuelle à 20-30 minutes et accorder 5 minutes de pause entre les expositions. Parce que dans de rares occasions, ces effets peuvent être ressentis après l'exposition en réalité virtuelle, il est recommandé d'attendre au moins 15 minutes avant de quitter les lieux.

Évidemment, si ces effets deviennent trop importants ou inconfortables, vous pourrez cesser immédiatement la séance d'immersion virtuelle.

II. Mesure de cortisol salivaire :

Les seuls inconvénients associés à la mesure de cortisol salivaire sont l'assèchement de la muqueuse buccale et le fait d'avoir faim. En effet, vous devrez éviter de manger un repas deux heures avant la rencontre d'évaluation qui aura lieu entre 11h00 et 15h00. Il est aussi interdit de consommer de la caféine (café, thé, boissons énergisantes, etc.). Cependant, vous pouvez manger des petites collations et boire de l'eau.

Nous vous suggérons de prendre un bon déjeuner (plus de deux heures avant l'expérimentation) et de prévoir un moment pour manger après l'expérimentation.

Découverte fortuite

Bien qu'ils ne fassent pas l'objet d'une évaluation médicale formelle, les résultats de tous les tests, examens et procédures que vous aurez à faire durant votre participation à ce projet peuvent mettre en évidence des problèmes jusque-là ignorés, c'est ce que l'on appelle une découverte fortuite. C'est pourquoi, en présence d'une particularité, le chercheur responsable du projet vous appellera.

Participation volontaire et possibilité de retrait

Votre participation à ce projet de recherche est volontaire. Vous êtes donc libre de refuser d'y participer. Vous pouvez également vous retirer de ce projet à n'importe quel moment, sans avoir à donner de raisons, en faisant connaître votre décision au chercheur responsable de ce projet ou à l'un des membres de son personnel de recherche.

Votre décision de ne pas participer à ce projet de recherche ou de vous en retirer n'aura aucune conséquence sur votre relation avec le chercheur responsable de ce projet et les autres intervenants.

Le chercheur responsable de ce projet, le Comité d'éthique de la recherche de l'IUGM ou l'organisme subventionnaire peuvent mettre fin à votre participation, sans votre consentement, si de nouvelles découvertes ou informations indiquent que votre participation au projet n'est plus dans votre intérêt, si vous ne respectez pas les consignes du projet de recherche ou s'il existe des raisons administratives d'abandonner le projet.

Si vous vous retirez ou êtes retiré du projet, l'information déjà obtenue dans le cadre de ce projet sera conservée aussi longtemps que nécessaire pour rencontrer les exigences réglementaires.

Toute nouvelle connaissance acquise durant le déroulement du projet qui pourrait affecter votre décision de continuer d'y participer vous sera communiquée sans délai verbalement et par écrit.

Confidentialité

Durant votre participation à ce projet, le chercheur responsable de ce projet ainsi que son personnel recueilleront dans un dossier de recherche les renseignements vous concernant. Seuls les renseignements nécessaires pour répondre aux objectifs scientifiques de ce projet seront recueillis.

Ces renseignements peuvent comprendre les informations concernant votre état de santé passé et présent, vos données de cortisol salivaire, vos habitudes de vie ainsi que les résultats de tous les tests, examens et procédures qui seront réalisés. Votre dossier peut aussi comprendre d'autres renseignements comme votre nom, votre sexe, votre âge, vos coordonnées, votre niveau de scolarité et votre statut matrimonial.

Tous les renseignements recueillis demeureront confidentiels dans les limites prévues par la loi. Afin de préserver votre identité et la confidentialité des renseignements, vous ne serez identifié que par un numéro de code. La clé du code reliant votre nom à votre dossier de recherche sera conservée par le chercheur responsable.

Le chercheur responsable du projet utilisera les données à des fins de recherche dans le but de répondre aux objectifs scientifiques du projet décrits dans le formulaire d'information et de consentement.

Les données de recherche pourront être publiées dans des revues spécialisées ou faire l'objet de discussions scientifiques, mais il ne sera pas possible de vous identifier. Également, les données de recherche pourraient servir pour d'autres analyses de données reliées au projet ou pour l'élaboration de projets de recherches futurs. Par ailleurs, vos renseignements personnels, tels que votre nom ou vos coordonnées, seront conservés pendant 5 ans après la fin du projet par le chercheur responsable et seront détruits par la suite.

À des fins de surveillance et de contrôle, votre dossier de recherche pourra être consulté par une personne mandatée par le Comité d'éthique de la recherche de l'IUGM ou par l'établissement ou par une personne mandatée par des organismes publics autorisés. Toutes ces personnes et ces organismes adhèrent à une politique de confidentialité.

En conformité avec la loi sur l'accès à l'information, vous avez le droit de consulter votre dossier de recherche pour vérifier les renseignements recueillis et les faire rectifier au besoin, et ce, aussi longtemps que le chercheur responsable de ce projet détient ces informations.

Études ultérieures

Acceptez-vous que vos données de recherche soient utilisées pour réaliser d'autres projets de recherche soit dans le domaine de la neuroscience du vieillissement ou soit dans le domaine de la promotion de la santé, des soins et des interventions.

Ces projets de recherche seront évalués et approuvés par le Comité d'éthique de la recherche de l'IUGM avant leur réalisation. Vos données de recherche seront conservées de façon sécuritaire dans la Banque de données du Centre de recherche de l'IUGM, et ce, conformément à la politique de gestion de la Banque de données du Centre de recherche de l'IUGM. Afin de préserver votre identité et la confidentialité de vos données de recherche, vous ne serez identifié que par un numéro de code.

Vos données de recherche seront conservées aussi longtemps qu'elles peuvent avoir une utilité pour l'avancement des connaissances scientifiques. Lorsqu'elles n'auront plus d'utilité, vos données de recherche seront détruites. Par ailleurs, notez qu'en tout temps, vous pouvez demander la destruction de vos données de recherche en vous adressant au chercheur responsable de ce projet de recherche.

Acceptez-vous que vos données de recherche soient utilisées à ces conditions? □ **Oui** □ **Non**

Participation à des études ultérieures

Acceptez-vous que le chercheur responsable du projet ou un membre de son équipe de recherche reprenne contact avec vous pour vous proposer de participer à d'autres projets de recherche? Bien sûr, lors de cet appel, vous serez libre d'accepter ou de refuser de participer aux projets de recherche proposés. □ **Oui** □ **Non**

Possibilité de commercialisation

Les résultats de la recherche découlant notamment de votre participation pourraient mener à la création de produits commerciaux. Cependant, vous ne pourrez en retirer aucun avantage financier.

Financement du projet de recherche

Le chercheur responsable du projet a reçu un financement d'un organisme subventionnaire pour mener à bien ce projet de recherche.

Compensation

I. Participants du groupe immersion en réalité virtuelle :

Les participants recevront un montant de 20 dollars en guise de compensation pour votre déplacement et votre participation au projet de recherche. Par ailleurs, si vous vous retirez ou si vous êtes retiré du projet avant qu'il ne soit complété, vous recevrez un montant proportionnel à votre participation.

II. Participants du groupe thérapie cognitivo-comportementale :

Les participants recevront un montant de 10 dollars par visite pour un total de 110 dollars en guise de compensation pour votre participation au projet de recherche et vos déplacements.

Par ailleurs, si vous vous retirez ou si vous êtes retiré du projet avant qu'il ne soit complété, vous recevrez un montant proportionnel à votre participation.

Indemnisation en cas de préjudice et droits du sujet de recherche

Si vous deviez subir quelque préjudice que ce soit dû à votre participation au projet de recherche, vous recevrez tous les soins et services requis par votre état de santé, sans frais de votre part.

En acceptant de participer à ce projet, vous ne renoncez à aucun de vos droits ni ne libérez le chercheur responsable de ce projet, l'organisme subventionnaire et l'établissement de leur responsabilité civile et professionnelle.

Procédures en cas d'urgence médicale

Veuillez noter que l'IUGM n'est pas un centre hospitalier de soins de courte durée qui offre des services d'urgence et qui compte sur la présence sur place d'un médecin 24 heures sur 24. Par conséquent, advenant une condition médicale qui nécessiterait des soins immédiats, les premiers soins vous seront dispensés par le personnel en place et des dispositions seront prises afin de vous transférer, si nécessaire, aux urgences d'un hôpital avoisinant.

Identification des personnes-ressources

Si vous avez des questions concernant le projet de recherche ou si vous éprouvez un problème que vous croyez relié à votre participation au projet de recherche, vous pouvez communiquer avec madame Fethia Benyebdri coordonnatrice du projet de recherche au (514) 340-3540, poste 4788. Aussi, vous pouvez communiquer avec le chercheur responsable du projet de recherche, Sébastien Grenier au (514) 340-3540, poste 4782.

Pour toute question concernant vos droits en tant que sujet participant à ce projet de recherche ou si vous avez des plaintes ou des commentaires à formuler, vous pouvez communiquer avec le commissaire local aux plaintes et à la qualité des services de l'IUGM au (514) 340-2109.

Surveillance des aspects éthiques du projet de recherche

Le Comité d'éthique de la recherche de l'IUGM a approuvé ce projet de recherche et en assure le suivi. De plus, il approuvera au préalable toute révision et toute modification apportée au protocole de recherche et au formulaire d'information et de consentement. Pour toute information, vous pouvez joindre le secrétariat du Comité, par téléphone au (514) 340-2800, poste 3250 ou par courriel à l'adresse suivante: karima.bekhiti.iugm@ssss.gouv.qc.ca

Consentement

Titre du projet de recherche :	L'utilisation de l'exposition en réalité virtuelle (*in virtuo*) pour traiter l'anxiété liée à l'état de santé chez les personnes âgées : une étude de faisabilité.

I. Consentement du sujet

J'ai pris connaissance du formulaire d'information et de consentement. Je reconnais qu'on m'a expliqué le projet, qu'on a répondu à mes questions et qu'on m'a laissé le temps voulu pour prendre une décision.

Je consens à participer à ce projet de recherche aux conditions qui y sont énoncées.

Nom du sujet de recherche
Date

II. Signature de la personne qui a obtenu le consentement si différent du chercheur responsable du projet de recherche.

J'ai expliqué au sujet de recherche les termes du présent formulaire d'information et de consentement et j'ai répondu aux questions qu'il m'a posées.

Nom de la personne qui obtient le consentement
Date

III. Signature et engagement du chercheur responsable du projet

Je certifie qu'on a expliqué au sujet de recherche les termes du présent formulaire d'information et de consentement, que l'on a répondu aux questions que le sujet de recherche avait à cet égard et qu'on lui a clairement indiqué qu'il demeure libre de mettre un terme à sa participation, et ce, sans préjudice.

Je m'engage, avec l'équipe de recherche, à respecter ce qui a été convenu au formulaire d'information et de consentement et à en remettre une copie signée au sujet de recherche.

Nom du chercheur responsable du projet de recherche Date

Annex 3: Inventaire d’anxiété face à la santé (IAS)

Échelle IAS (version 14 items : six derniers mois)

Chacune des questions de cette section est constituée de 4 énoncés. S'il vous plaît, veuillez lire ces énoncés attentivement et sélectionnez celui qui décrit le mieux les sentiments que vous avez ressentis au cours des six (6) derniers mois. Identifiez l'énoncé en encerclant la lettre qui y est associée, c'est-à-dire que si vous croyez que l'item (a) est correct, vous encerclez la lettre (a). Dans le cas où plusieurs énoncés s'appliqueraient à votre situation, s'il vous plaît, encerclez tous ceux qui s'appliquent.

1. a) Je ne m'inquiète pas à propos de ma santé.

   b) Je m'inquiète occasionnellement à propos de ma santé.

   c) Je passe beaucoup de mon temps à m'inquiéter à propos de ma santé.

   d) Je passe la plupart de mon temps à m'inquiéter à propos de ma santé.

2. a) Je remarque moins de maux/douleurs que la plupart des autres personnes (de mon âge).

   b) Je remarque autant de maux/douleurs que la plupart des autres personnes (de mon âge).

   c)Je remarque plus de maux/douleurs que la plupart des autres personnes (de mon âge).

   d) Je suis tout le temps conscient(e) de maux/douleurs dans mon corps.

3. a) En règle générale, je ne suis pas conscient(e) des changements ou sensations physiques.

   b) Parfois, je suis conscient(e) des changements ou sensations physiques.

   c) Je suis souvent conscient(e) des changements ou sensations physiques.

   d) suis constamment conscient(e) des changements ou sensations physiques.

4. a) Résister aux pensées liées à la maladie n'est jamais un problème.

   b) La plupart du temps, je peux résister aux pensées liées à la maladie.

   c) J'essaie de résister à des pensées liées à la maladie, mais je suis souvent incapable de le faire.

   d) Mes pensées liées à la maladie sont si fortes que je n'essaie même plus de leur résister.

5. a) En règle générale, je n'ai pas peur d'avoir une maladie grave.

   b) J'ai parfois peur d'avoir une maladie grave.

   c) J'ai souvent peur d'avoir une maladie grave.

   d) J'ai toujours peur d'avoir une maladie grave.

6. a) Je n'ai pas d'images mentales de moi étant malade.

   b) J'ai occasionnellement des images mentales de moi étant malade.

   c) J'ai fréquemment des images mentales de moi étant malade.

   d) J'ai constamment des images mentales de moi étant malade

7. a) Je n'ai pas de difficulté à chasser de mon esprit les pensées qui concernent ma santé.
   b) J'ai parfois de la difficulté à chasser de mon esprit les pensées qui concernent ma santé.
   c) J'ai souvent de la difficulté à chasser de mon esprit les pensées qui concernent ma santé.
   d) Rien ne peut chasser de mon esprit les pensées qui concernent ma santé.
8. a) Je suis soulagé(e) de manière durable si mon médecin me dit qu'il n'y a rien d'anormal.
   b) Je suis d'abord soulagé(e), mais les inquiétudes reviennent parfois ensuite.
   c) Je suis d'abord soulagé(e), mais les inquiétudes reviennent toujours ensuite.
   d) Je ne suis pas soulagé(e) si mon médecin me dit qu'il n'y a rien d'anormal.
9. a) Si j'entends parler d'une maladie, je ne pense jamais l'avoir moimême.
   b) Si j'entends parler d'une maladie, je pense parfois l'avoir moi-même.
   c) Si j'entends parler d'une maladie, je pense souvent l'avoir moi-même.
   d) Si j'entends parler d'une maladie, je pense toujours l'avoir moi-même.
10. a) Si j'ai des sensations ou changements physiques, je me demande rarement ce que cela signifie.
    b) Si j'ai des sensations ou changements physiques, je me demande souvent ce que cela signifie.
    c) Si j'ai des sensations ou changements physiques, je me demande toujours ce que cela signifie.
    d) Si j'ai des sensations ou changements physiques, je dois savoir ce que cela signifie.
11. a) Je me sens habituellement à très faible risque de développer une maladie grave.
    b) Je me sens habituellement à assez faible risque de développer une maladie grave.
    c) Je me sens habituellement à risque modéré de développer une maladie grave.
    d) Je me sens habituellement à haut risque de développer une maladie grave.
12. a) Je ne pense jamais que j'ai une maladie grave.
    b) Je pense parfois que j'ai une maladie grave.
    c) Je pense souvent que j'ai une maladie grave.
    d) Je pense généralement que j'ai une maladie grave.
13. a) Si je remarque une sensation physique inexpliquée, je ne trouve pas difficile de penser à autre chose.
    b) Si je remarque une sensation physique inexpliquée, je trouve parfois difficile de penser à autre chose.
    c) Si je remarque une sensation physique inexpliquée, je trouve souvent difficile de penser à autre chose.
    d) Si je remarque une sensation physique inexpliquée, je trouve toujours difficile de penser à autre chose.
14. a) Ma famille / mes amis diraient que je ne m'inquiète pas assez de ma santé.
    b) Ma famille / mes amis diraient que j'ai une attitude normale face à ma santé.
    c) Ma famille / mes amis diraient que je m'inquiète trop de ma santé.
    d) Ma famille / mes amis diraient que je suis hypocondriaque.

Annex 4: Virtual Reality System and Virtual Environment

Virtual Reality System and Virtual Environment

Annex 5: Ethics Approval Form

Ethics Approval Form

Centre intégré universitaire de santé et de services sociaux du Centre-Sud-de-l'Île-de-Montréal
Québec

Comité d'éthique de la recherche vieillissement-neuroimagerie

Montréal, le 24 mai 2017

Monsieur Sébastien Grenier, Ph.D. Centre de recherche – IUGM
4545, chemin Queen-Mary
Montréal (Québec) H3W 1W4

Objet: CER IUGM 14-15-001 : Renouvellement annuel 2017 – 2018.

L'utilisation de l'exposition en réalité virtuelle (in virtuo) pour traiter l'anxiété liée à l'état de
santé chez les personnes âgées : une étude de faisabilité.

Monsieur,

Vous avez soumis au Comité d'éthique de la recherche vieillissement-neuroimagerie, par courriel, le 25 avril 2017, une demande de renouvellement pour votre projet cité en rubrique.

J'ai le plaisir de vous informer que votre demande de renouvellement a été approuvée par le Comité d'éthique de la recherche vieillissement-neuroimagerie. Ainsi, vous pouvez poursuivre votre étude pour un an, et ce, **du 13 avril 2017 au 13 avril 2018.**

Un mois avant la date d'échéance vous devrez faire une nouvelle demande de renouvellement auprès du Comité, en utilisant le document prévu à cet effet, accompagné du formulaire d'information et de consentement que vous utilisez.

Nous vous rappelons que dans le cadre de son suivi continu, le Comité vous demande de vous conformer aux exigences suivantes en utilisant les formulaires du Comité prévus à cet effet :

1. De soumettre toute demande de modification au projet de recherche ou à tout document approuvé par le Comité pour la réalisation de votre projet.
2. De soumettre, dès que cela est porté à votre connaissance, tout nouveau renseignement ou toute modification à l'équilibre clinique susceptible d'affecter l'intégrité ou l'éthicité du projet de recherche, d'accroître les risques et les inconvénients pour les participants, de nuire au bon déroulement du projet ou d'avoir une incidence sur le désir d'un participant de continuer à participer au projet.
3. De soumettre, dès que cela est porté à votre connaissance et en lien avec la réalisation de ce projet, tout accident survenu dans votre site.

4. De soumettre, dès que cela est porté à votre connaissance, l'interruption prématurée du projet de recherche, qu'elle soit temporaire ou permanente.
5. De soumettre, dès que cela est porté à votre connaissance, tout problème constaté à la suite d'une activité de surveillance ou de vérification menée par un tiers et susceptible de remettre en question l'intégrité ou l'éthicité du projet de recherche
6. De soumettre, dès que cela est porté à votre connaissance, toute suspension ou annulation de l'approbation octroyée par un organisme de subvention ou de réglementation.
7. De soumettre, dès que cela est porté à votre connaissance, toute procédure en cours de traitement d'une plainte ou d'une allégation de manquement à l'intégrité ou à l'éthicité ainsi que des résultats de la procédure.
8. De soumettre, dès que cela est porté à votre connaissance, toute déviation au projet de recherche susceptible de remettre en cause l'éthicité du projet.
9. De soumettre une demande de renouvellement annuel de l'approbation du projet de recherche.
10. De soumettre le rapport de la fin du projet de recherche.

Vous pouvez obtenir les formulaires du Comité téléchargeables à partir du site web du Centre de recherche IUGM, à l'adresse suivante: http://www.criugm.qc.ca/fr/la-recherche/ethique.html

De plus, nous vous rappelons que vous devez conserver pour une période d'au moins un an suivant la fin du projet, un répertoire distinct comprenant les noms, prénoms, coordonnées, date du début et de fin de la participation de chaque participant à la recherche.

Finalement, nous vous rappelons que la présente décision vaut pour une année et pourra être suspendue ou révoquée en cas de non-respect de ces exigences.

Le Comité d'éthique de la recherche vieillissement-neuroimagerie est désigné par le ministre de la Santé et des Services sociaux, en vertu de l'application de l'article 21 du Code civil du Québec et suit les règles émises par l'Énoncé de politique des trois conseils et les Bonnes pratiques cliniques.

Avec l'expression de nos sentiments les meilleurs.

Johane de Champlain
Présidente du CER vieillissement-neuroimagerie
JdeC/kb