



**Development of Immersive Virtual Reality Intervention for
Patients with Chronic Low Back Pain: Mixed-Methods Study**

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Abstract

Background: Chronic low back pain (CLBP) is a leading cause of disability worldwide. Immersive virtual reality (IVR) enables interaction with a virtual environments (VE) via a head mounted display (HMD) and is widely used for chronic pain (CP) management, however with little pre-development investigation, and its effectiveness for CP/CLBP management is inconclusive. Therefore, this thesis aims to adopt the Medical Research Council Framework to inform IVR development and implementation for CLBP management.

Methods: Three parts were conducted, using mixed-methods design: Part 1: scoping review to map underpinning theories of IVR mechanisms of action in CP management and key features including software and dose. Part 2 engaged global stakeholders (healthcare practitioners and technology developers) to understand the use of IVR in CP management, adopting a sequential-explanatory study of two phases, Phase 1 an online survey, which informed Phase 2, online interviews with subset of surveyed stakeholders. Part 3: online focus groups explored physiotherapists' opinions regarding IVR for CLBP management.

Results: Part 1: several IVR mechanisms were noted, with little theoretical basis. Customised software was frequently used, with diverse HMDs, and no optimal dose consensus. Implementation in a clinical setting was common, with adverse effects of motion sickness and HMD discomfort being noted. Part 2: the perceived IVR benefits for CP included combatting fear of movement, with VE personalisation to patient needs and culture being critical. To avoid risks, pre-screening, the initial session being a supervised clinic session and gradual dose build up were recommended. Part3: IVR was viewed as suitable for CLBP patients with low motivation to exercise, however, skills' transferability to the real world and falls risk were concerns. Part 2 and 3 found cost, practitioner acceptance and training critical to IVR adoption.

Conclusion and future implications: IVR might be valuable alternative treatment for CLBP patients. Future work is needed to establish the effective working mechanism reflecting on CLBP heterogeneity. Personalisation, safety, workforce training, financial resources and

collaboration between practitioners, technology developers and patients are key considerations.

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Published presentation

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- Astek, A.A, Sparkes, V and Sheeran, L. 2022. Key components of immersive virtual reality intervention for chronic low back pain: physiotherapists' views and opinions (from the Annual meeting of the society of back pain research, Coventry, 30 June – 1 July 2022). *Orthopaedic proceedings*. 104(9), p.32.

Abbreviations

Abbreviation	Term
ACC	Anterior cingulate cortex
CBT	Cognitive behavioural therapy
CLBP	Chronic low back pain
CNP	Chronic neck pain
CNS	Central nervous system
CP	Chronic pain
CPP	Chronic primary pain
CSP	Chronic secondary pain
fMRI	Functional Magnetic Resonance Imaging
FOM	Fear of movement
GCT	Gate control theory
HMD	Head mounted display
IVR	Immersive virtual reality
MRCF	Medical research council framework
MS	Motion sickness
NICE	National Institute for Health and Care Excellence
PAG	Periaqueductal gray
PFC	Prefrontal cortex
VA	Virtual avatar
VE	Virtual environment
VR	Virtual reality

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Chapter 1: Introduction

Low back pain (LBP) is one of the leading causes of disability worldwide (Vos et al. 2015), with almost 23% of people with LBP developing chronic symptoms (Hestbaek et al. 2003; Hoy et al. 2012). Psychological factors, including fear of movement, anxiety and depression are the main indicators of transition from the acute to chronic stage, these lead to poor functional outcomes and disability (Leeuw 2007; Linton et al. 2011). Virtual reality (VR) is a technology system that uses input/output devices to provide audio-visual experiences, this allows user interaction with computer-generated virtual environments (VE) (Trost et al. 2015; Brady et al. 2021). Virtual reality (VR) consists of three types: non-immersive VR (non-IVR), semi-immersive VR (semi-IVR) and immersive VR (IVR). In IVR technology, users wear a head-mounted display (HMD) supported by software, this enables high immersion and interaction with three dimensional VE (Mujber et al. 2004; Brady et al. 2021). The application of IVR in pain management was supported by functional magnetic resonance imaging (fMRI) studies of Hoffman and colleagues. This confirmed the analgesic effect of IVR during acute pain stimuli and reported a significant reduction in the brain activities of pain related regions (Hoffman et al. 2004; Hoffman et al. 2006). The IVR analgesic effect has been explained by a distraction mechanism, in which being immersed in VE diverts the attention away from pain through visual, auditory and tactile cues (Hoffman et al. 2006; Gold et al. 2007; Mahrer and Gold 2009; Li et al. 2011).

Recently, the use of IVR in pain management has significantly increased and several reviews have reported high quality evidence confirming the effectiveness of IVR for acute pain reduction (Shahrbanian et al. 2009; Shahrbanian et al. 2012; Pourmand et al. 2018; Mallari et al. 2019; Ramanan and Yekkirala 2021; Huang et al. 2022; Baker et al. 2022). However, the IVR effectiveness in CP and /or CLBP management is not conclusive, with great heterogeneity in the application of IVR interventions (Mallari et al. 2019; Wittkopf et al. 2019; Ahern et al. 2020; Austin 2021; Chuan et al. 2021; Trost et al. 2021; Brea-Gómez et al. 2021; Bordeleau et al. 2021; Goudman et al. 2022; Nagpal et al. 2022).

1.1 Thesis rationale

To date, the use of IVR as a newer 'immersive' technology for CP and/or CLBP has significantly increased. There is a substantial volume of research which includes IVR interventions, but it is believed that these have bypassed critical steps with regard to improving development and instead moved directly to effectiveness trials in many cases. This results in inconsistency on IVR mechanisms of action, technology specifications (hardware/software), intervention dose and contextual setting, which makes it difficult to draw a definite conclusion and to improve the uptake of the intervention in clinical practice. Therefore, pre-development investigations based on a validated framework is deemed essential to inform IVR development and implementation in the context of CLBP.

1.2 Aim of the thesis

The overall aim is to adopt the Medical Research Council Framework, to inform the development and implementation of IVR intervention for patients with CLBP.

1.3 Research approach

This thesis adopted the Medical Research Council Framework (MRCF), this is a widely recognised framework for designing complex interventions in healthcare (Craig et al. 2008). The MRCF consists of four stages: 1) development, 2) feasibility/ piloting, 3) evaluation, and 4) implementation. According to MRCF, promising interventions might be rejected and considered as ineffective due to insufficient development prior to proceeding to a full evaluation clinical trial (Craig et al. 2008). To date, the use of IVR in CP and /or CLBP management shows promise, but its effectiveness is not yet conclusive. Therefore, it is critical to understand how IVR works and to identify key elements in order to optimise its usefulness for patients. This has been reported as an essential step when applying new complex interventions in healthcare prior to testing (Craig et al. 2008; Richards and Hallberg 2015). Several key elements need to be recognised at the development stage including theories underpinning the intervention, key characteristics such as content and dose, delivery context as well as facilitators and barriers to implementation (Craig et al. 2008; O'Cathain et al. 2019). The MRCF recommends obtaining knowledge with regard to these elements through the published evidence and engagement of stakeholders including those who have been involved in developing and delivery of the intervention (Craig et al. 2008; O'Cathain et al. 2019).

Accordingly, three subsequent parts were conducted in this thesis using a mixed methods design, these are presented in the next section.

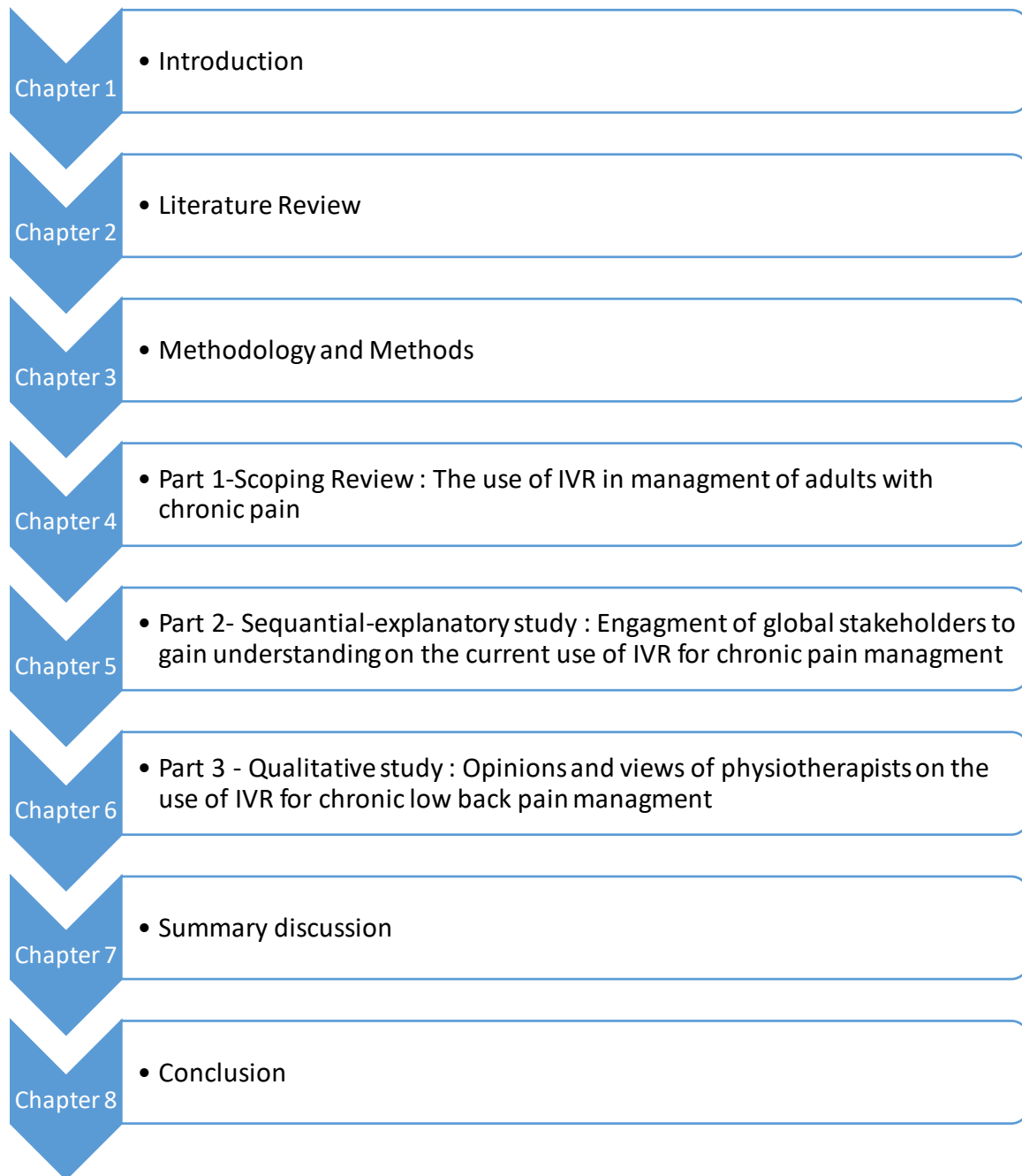
1.3.1 Overview of the thesis parts guided by the Medical Research Council Framework

The following parts were conducted:

- Part 1, Scoping review: synthesis of the contemporary evidence to map theories underpinning the IVR mechanism of action in adults with CP and identification of the key features of IVR interventions including the software, hardware, dose, and setting.
- Part 2, Sequential explanatory study: engage global stakeholders (healthcare practitioners and IVR technology developers) to gain an understanding on the current use of IVR in CP management.
- Part 3, A qualitative study: explore the views and opinions of UK physiotherapists about the potential benefits, concerns, barriers, and facilitators to using IVR for CLBP management.

Part 1 was conducted as mapping all relevant literature is recommended to identify key elements relating to the existing developed interventions (Craig et al. 2008; O'Cathain et al. 2019). Part 2 engaged global stakeholders (healthcare practitioners and technology developers who had experience in development, and delivery of IVR), adopting sequential-explanatory design of two phases, *Phase 1*: an online survey, which informed *Phase 2*: online interviews with subset of the surveyed stakeholders. Part 3 engaged physiotherapists (i.e., those with experience of treating CLBP in UK clinical practice), using online focus groups. It is recommended to engage those with relevant experience who are closely involved in the development and delivery of the intervention, as well as professionals involved in the delivery of the intervention to the target population (Craig et al. 2008; O'Cathain et al. 2019). The insights and experiences of those individuals could inform future development and implementation to optimise IVR benefits in the context of CLBP.

1.4 Thesis structure



Chapter 2: Literature review

In this chapter, a general overview of pain, CP and CLBP is presented and conventional interventions for CLBP in clinical practice. This is followed by the definition of VR technology, and its use for pain management. A comprehensive summary of key reviews using VR for CP and/or CLBP are also presented.

2.1 Introduction to pain

Pain is defined by the International Association for the Study of Pain (IASP) as “unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage” (Raja et al. 2020, p.1977). This highlights the multi-dimensional nature of pain, illustrating that pain is a complex personal experience beyond nociception (Raja et al. 2020).

Complex periphery and central processing results in the transmission of pain which is determined by the balance between the facilitatory and inhibitory interactions within the nervous system (Reddi et al. 2013). Noxious pain stimuli (i.e., chemical, mechanical, or thermal) are detected by nociceptors, which are sensory receptors located in the dorsal horn of the spinal cord (Reddi et al. 2013; Feizerfan and Sheh 2015). These receptors have afferent neurons that convert pain stimuli into electrical impulses that are transferred to the central nervous system (CNS) and higher brain centres via the ascending pathways (Reddi et al. 2013; Feizerfan and Sheh 2015). The brain centres are often referred to as pain neuromatrix which are activated during pain experience, these include the primary and secondary somatosensory cortex, insular, anterior cingulate cortex (ACC), prefrontal cortex (PFC), and thalamus as well as periaqueductal gray (PAG) (Reddi et al.2013; Feizerfan and Sheh 2015).

According to the fMRI studies of the human brain, these regions show increased activity when an individual is exposed to pain stimuli (Talbot et al. 1992; Derbyshire et al. 1997; Ladarola et al. 1998; Becerra et al. 1999; Craig et al. 2000; Hofbauer et al. 2001). The complex interaction of these brain areas determines the subjective experience of pain (Feizerfan and Sheh 2015). For instance, the ACC plays an instrumental role in the effective response to pain stimuli such as the attention and emotion which can modulate

the perception of pain (Kasanetz et al. 2022). Descending pathways from the brain can then control the pain signals in the dorsal horn of the spinal cord, which are both facilitatory and inhibitory in nature (D'Mello and Dickenson 2008). The descending pathways arise from the PAG area (i.e., primary control centre for descending pain modulation) and project to the dorsal horn, they use inhibitor neurotransmitters to reduce the intensity of pain (Dunckley et al.2005). Termination of acute pain stimuli and recovery of tissue damage should be the completion of the pain process, however in some cases the noxious stimuli continue beyond this acute phase resulting in chronic pain (CP) (Feizerfan and Sheh 2015).

2.2 Chronic pain

Pain is often classified as acute or chronic, this is based on the nature and duration of pain experience (Merskey and Bogduk 1994). Acute pain can be defined as a normal and protective physiological response to noxious stimuli associated with events such as a medical procedure, trauma and acute illness (Carr and Goudas 1999). However, when pain persists longer than the normally accepted healing time of tissue damage, it can be categorised as chronic (Merskey and Bogduk 1994; Kerns et al.2011) and CP refers to the pain that persists or recurs for longer than three months (Treede et al. 2015).

While the exact mechanisms causing the transition from acute to CP remain unknown, complex pathophysiological changes in the pain pathways are believed to contribute to this state, resulting in peripheral or central sensitization (Feizerfan and Sheh 2015; Glare et al. 2019). Repetitive nociceptive inputs may cause prolonged inflammation through changes in the periphery such as reduction of pain threshold in the afferent neurons and increased activation of nociceptors at the injury site, leading to peripheral sensitization (Feizerfan and Sheh 2015). Also, continued nociceptive inputs may result in central sensitization through exaggerated activation of multiple receptors within the spinal cord leading to changes in neuronal structure of CNS's neuroplasticity including the pain neuromatrix (D'Mello and Dickenson 2008; Feizerfan and Sheh 2015). Thus, it increases the inappropriate activation of descending facilitatory pathways from the brain and loss of descending inhibitory control, resulting in hypersensitivity and spontaneous pain (D'Mello and Dickenson 2008). Therefore, CP may exist even without acute nociception or tissue damage.

According to the World Health Organisation (WHO), the recent international classification of disease (ICD-11) classified CP based on aetiology of pain and pathophysiological mechanisms into two main categories: chronic primary pain (CPP) and chronic secondary pain (CSP) (Treede et al. 2019).

CPP is defined as the pain in one or more anatomic regions which cannot be described by another chronic condition. This pain is labelled as a 'disease' itself and is associated with severe emotional distress and functional impairment which interferes with social participation and daily life activities (Treede et al. 2019). Many CP conditions characterised by the complex interaction of biological, psychological, and social factors are classified as CPP including widespread pain (i.e., Fibromyalgia), complex regional pain, irritable bowel syndrome and musculoskeletal pain which are named 'non-specific' (i.e., low back pain (LBP), thoracic pain and neck pain) (Nicholas et al.2019; Treede et al. 2015).

Conversely, CSP is secondary to an underlying disease where pain is considered as a 'symptom' including cancer-related pain, phantom pain, neuropathic pain, and secondary musculoskeletal pain (i.e., rheumatoid arthritis, osteoarthritis) (Treede et al.2019).

2.3 Pain theories

To better understand the pain experience, it is important to consider the work of Melzack and colleagues, they proposed two influential theoretical models: the gate control theory (GCT) (Melzack and Wall 1965) and the neuromatrix theory of pain (Melzack 2001).

The GCT explains how the physiological and psychological factors contribute to pain perception. According to this theory, pain from nociceptive stimuli (i.e., injury or damaging tissue) pass through a 'gate' in the dorsal horn of the spinal cord prior to transmission to the brain (Melzack and Wall 1965). It was proposed that the 'gate' regulates a stimulus from nerve fibres including thin (pain) and large (touch, pressure) in which the thin fibre can open the 'gate' while the large fibre can close the 'gate' (Melzack and Wall 1965). The pain signals are modulated and processed a long way from the spinal cord to the brain. Pain modulation can be influenced by psychological factors including memory, attention and emotion which affect how the pain sensation is perceived (Melzack and Casey 1968). This theory improved the understanding of pain mechanisms and led to advances in pain management, and it is still supported, although it has been criticised for its simplicity as it focuses only on cutaneous

pain, without considering deep or visceral pain as well as chronic non-specific pain (Keefe et al. 2005; Moayed and Davis 2012).

Subsequently, Melzack (2001) introduced the neuromatrix theory of pain, this was based on two key elements: the source of pain without peripheral injury, and the multiple brain regions that contribute to the experience of pain. The neuromatrix model proposed that the sensation of pain was produced by the extensive neural network in the brain. This network generates 'neuro-signature' patterns which may be triggered by sensory (e.g., injury), cognitive (e.g., anxiety, attention) and affective (e.g., emotion) inputs as well as inputs from the body self-neuromatrix. These inputs contribute to outputs in the form of pain and disruption of body homeostasis (i.e., stress) which activates neural, hormonal, and behavioural programmes for self-regulation of the body (Melzack, 2001, Melzack 2005).

Melzack (2005) postulates that CP conditions, which are often accompanied by severe pain and are not associated with an underlying injury, can be explained by neuromatrix theory. This theory helps to understand the unexplained issue of pain and indicates that pain is produced by disruption of neural network outputs rather than actual or continuous tissue damage when the normal tissue healing process should have resolved (Melzack 2005). Chronic stress either physical or psychological may trigger a neuromatrix programme which causes failure of homeostasis regulation, resulting in neural distress and CP (Melzack 2005).

2.4 Biopsychosocial model

Engel (1977) proposed the need for a biopsychosocial model (BPS) of pain and advised the inclusion of psychological and social factors to expand the traditional biomedical understanding of pain. The perspective of the BPS model on CP has been discussed in pain literature and it is increasingly being recognised as a multi-dimensional condition rather than a symptom (Treede et al. 2015; Clauw et al. 2019).

The BPS model presents pain as an individual experience where a complex interaction between the neurobiological and psychosocial factors can modulate a patient's experience and their reporting of symptoms and consequent disability (Gatchel et al. 2007). In terms of the neurobiological factors, CP is usually related to a pathophysiology subset including peripheral and central sensitization (section 2.2) (Clauw et al. 2019). Negative psychosocial factors such as fear, catastrophising (i.e., negative thoughts and emotions), trauma, distress

and lack of social support can make a significant contribution to the development of CP, exacerbating pain and subsequent disability (Blyth et al. 2007; Gatchel et al. 2007; Gatchel et al. 2018; Clauw et al. 2019). In contrast, positive resilience factors such as active coping, positive emotions, acceptance, and social support may improve these outcomes (Clauw et al. 2019).

This view of CP as a multidimensional condition has transformed the assessment and treatment of CP, acknowledging that the individual's pain experience is dependent on biopsychosocial interaction (Dansie and Turk 2013; Clauw et al. 2019).

2.5 Chronic low back pain (CLBP)

2.5.1 Epidemiology and prevalence of chronic low back pain

Low back pain (LBP) is one of the leading causes of disability worldwide, it results in the highest healthcare expenditure amongst musculoskeletal disorders (Vos et al. 2015). LBP has a substantial global epidemiological impact with a current estimate prevalence of 7.6% and significant (~50%) increase within the last 20 years (Mattiuzzi et al. 2020), approximately 23% of cases go on to develop chronic symptoms (Hoy et al. 2012).

Pain and disability associated with LBP present a higher risk of being persistent with recurrent flares of painful episodes (Da Silva et al. 2017). Most cases of CLBP (~85-90%) have no definitive pathological cause and are characterised as 'non-specific' which classified recently by ICD-11 as CPP (Krismer and Van Tulder 2007; Brunner et al. 2008; Treede et al. 2015).

2.5.2 Neuroplasticity and chronic low back pain

Neuroplasticity is defined as the ability of the CNS to adapt, reorganising its structure and function due to learning or experience, or following injury (Bosnar Puretić and Demarin 2012). Continuous nociception, for example, injury or inflammation, can cause central sensitisation, which is one of the neuroplastic changes. This can lead to development of CP (Bosnar Puretić and Demarin 2012). These neuroplastic changes may lead to misinterpretation of noxious stimuli which can be exaggerated (i.e., hyperalgesia) as well as misinterpretation of non-painful stimuli as painful perception (i.e., allodynia) (Maihöfner et al. 2010).

In addition, neuroplastic changes in CLBP could cause reorganisation of the somatosensory cortex which is responsible for detecting sensations such as touch, pain, and proprioception

including self-recognition and body awareness (Flor et al. 1997). Awareness of limb position, movement and posture contribute to the perceptual aspect of body image (Gallagher 2001). Thus, neuroplastic changes may lead to body perception disturbance and this can affect body image in CLBP patients (Flor et al.1997; Moseley 2008). This disturbance in body image is evident in patients with CLBP who often have poor visual recognition of back movement and reduced proprioception (de Lussanet et al. 2012; Laird et al. 2014). In addition, these patients may have maladaptive beliefs about their back, seeing it as fragile and under threat, this results in protective behaviour which contributes to pain and disability (Moseley 2008; Darlow et al. 2015; Moseley and Vlaeyen 2015).

2.5.3 Psychosocial factors associated with chronic low back pain

The individual nature of CLBP was acknowledged in the BPS model, also the significance of psychological factors in LBP disability, activity limitation and social participation restriction related to back symptoms (Waddell 2006; World Health Organization 2012). Psychosocial factors such as pain catastrophising, fear avoidance, anxiety, depression, and maladaptive coping behaviour were found to be related to comorbidity and affected recovery (Urquhart et al.2008; George and Beneciuk 2015; Rodrigues-de-Souza et al.2016; Gatchel et al. 2018).

Based on the BPS model, it has been viewed that rehabilitation must be focused on reducing psychosocial symptoms whilst enhancing a patient's function and improving their quality of life (Gatchel et al.2018). A brief overview of psychosocial factors associated with CLBP is crucial since these factors need to be considered when proposing a new intervention.

2.5.3.1 Fear, anxiety, and self-efficacy

Fear and anxiety can result from the threat associated with pain and exert a significant impact on a person's functional level and pain tolerance (Leeuw et al. 2007; Vlaeyen and Linton 2000; Pincus et al. 2010). Fear is a response to an immediate threat, whilst anxiety is an anticipation of a threat when patients are in an environment which contains a potential threat (Leeuw et al. 2007). However, both terms are used interchangeably in the CP literature (Gatchel et al. 2007; Leeuw et al. 2007). The experience of fear can result in negative beliefs about pain including pain catastrophising and fear-avoidance (Leeuw 2007). Pain catastrophising is defined as "an exaggerated negative mental set brought to bear during actual or anticipated pain experience" (Sullivan et al. 2001, p 53). Fear avoidance refers to the behaviour of avoiding movement or activities that are assumed to increase pain (Leeuw 2007). Both have

a significant role in the progression of LBP to chronicity (Severeijns et al. 2005; Leeuw et al. 2007; Zale et al. 2013; Luque-Suarez et al. 2019).

The fear avoidance model highlights the contribution of fear/ anxiety in the development of CLBP and associated disability (Vlaeyen and Linton 2000; Leeuw 2007). The model by Vlaeyen and Linton (2000) (Figure 2-1) suggests that following an injury, patients interpreted pain using two opposing behaviours either ‘confrontation’ or ‘avoidance’. Positively, patients who confront pain are likely to maintain function and daily activities, this promotes recovery. Conversely, misinterpretation of pain (i.e., catastrophising) may lead to fear of movement (FOM) (i.e., kinaesiophobia) and avoidance behaviour. Hence, long term avoidance leads to a reduction in function/activities, physical deconditioning, maintenance of pain and results in muscle disuse and disability (Vlaeyen and Linton 2000).

A modified version of the fear avoidance model was proposed by Woby et al. (2007) (Figure 2-2), incorporating the role of self-efficacy. Self-efficacy is defined as “the confidence a person has about their ability to perform functional activities” (Woby et al. 2007, p.712). According to Woby et al. (2007), patients are more inclined to confront and perform activities in the presence of high self-efficacy, even with high FOM. Self-efficacy has been found to be a strong predictor of disability in CLBP, in which high levels of self-efficacy are associated with greater function, physical activity and lower pain intensity (Costa et al. 2011; Martinez-Calderon et al. 2018). Therefore, FOM and self-efficacy have been suggested as essential factors to include in assessment and management of CLBP patients (Klaber Moffett et al. 2004; Woby et al. 2007; de Moraes Vieira et al. 2014; van Hooff et al. 2021).

Figure 2-1: Fear avoidance model (from Vlaeyen and Linton 2000)

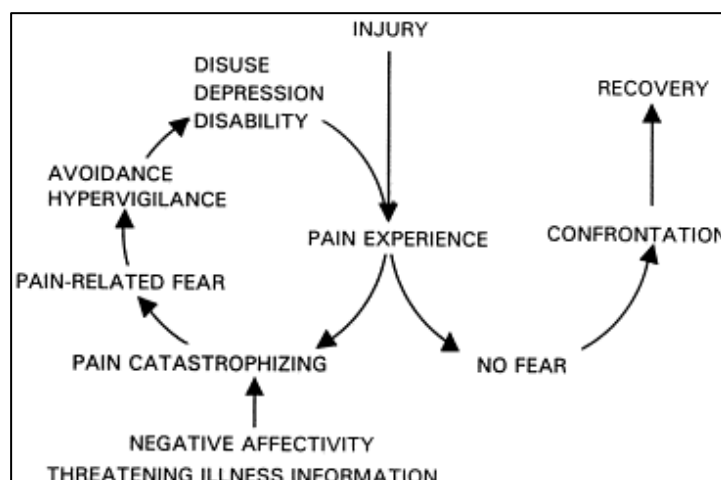
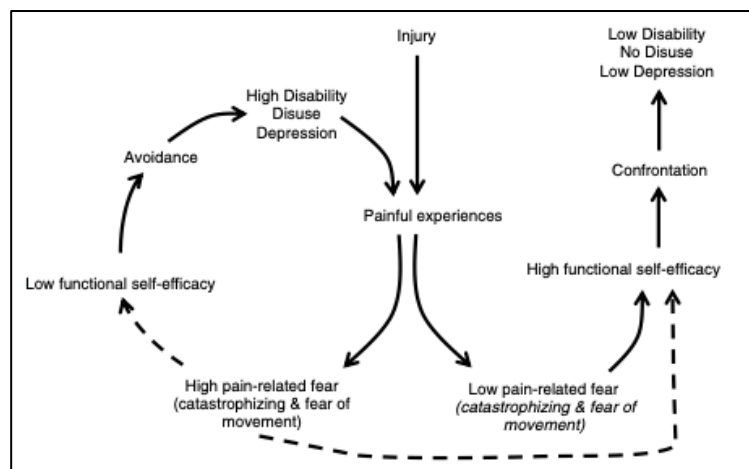


Figure 2-2: Modified version of fear avoidance model, incorporating self-efficacy (from Woby et al. 2007)



2.5.3.2 Depression

Depression is one of the most common psychological problems associated with disability amongst patients with CLBP (Hall et al. 2011; Hung et al. 2015), it is characterised by negative mood, hopelessness, and despair (Linton and Bergbom 2011). Patients with CLBP have 32.1% prevalence of depression, this is associated with a higher level of pain, greater FOM, functional disability, and poorer quality of life (Linton et al. 2011; Antunes et al. 2013). Also, high levels of depression have been linked to poor rehabilitation outcomes, in which it has been important to address depressive symptoms in the assessment and treatment of patients to achieve better outcomes (Vowles et al. 2004; Nicholas 2007; Bair et al. 2003).

2.5.3.3 Coping strategies

The disruptive nature of CP interferes with daily life, patients demonstrate diverse coping strategies to deal with their pain (Busch 2005; De Souza and Frank 2007). Coping strategies, classified into active and passive, refer to the ways that patients develop to tolerate or manage their pain (Van Damme et al. 2008). Active coping attempts to control pain, or to function despite pain, can be for example using their own resources such as exercising, problem solving and regulation of emotion (Büssing et al. 2010). Passive coping strategies, however, include withdrawal, avoidance control and reliance on external resources such as rest or dependence on medication (Büssing et al. 2010).

These coping styles have an important role for CLBP management in which active coping is associated with positive outcomes (e.g., higher physical activity, less disability), while passive coping is correlated with negative outcomes (i.e., high pain intensity and disability) (Carroll et al. 2002; Jones et al. 2006; Du et al. 2018). Replacement of maladaptive coping to foster a patient's wellbeing is one of the major goals in management of patients with CLBP (Gatchel and Rollings 2008).

2.5.3.4 Social environment

The social network (i.e., workplace, relationships with family and friends) has a significant impact on the patient's behaviour, influencing the pain experience (Blyth et al. 2007; Snelgrove and Lioffi 2013). The lack of social support has been associated with greater risk of CLBP (Rzeszutek et al. 2016). Further, patients with CLBP are often subject to social isolation and loneliness, which negatively affects their prognosis (Oliveira et al. 2015; Hawthorne et al. 2013). Where relevant, a management approach should be taken which aims to improve interaction and engagement with social activities (Melloh et al. 2013; Bailly et al. 2015; Karayannis et al. 2019).

2.5.4 General intervention approaches for chronic low back pain

The recent guidelines by National Institute for Health and Care Excellence (NICE) recommend a multimodal intervention for patients with CP, and CLBP (NICE 2020). Both pharmacological and non-pharmacological interventions are included, these aim to enhance physical function and quality of life as well as pain alleviation.

2.5.4.1 Pharmacological interventions

Current recommendations being only the use of anti-depressants (NICE 2020). The use of opioids is currently not supported for patients with CLBP, acknowledging the harmful side effects and the potential of addiction (NICE 2020).

2.5.4.2 Non-pharmacological interventions

Recommendations support patient education, in addition to a multi-dimensional approach, including both physical and psychological interventions for patients with CLBP. Also, the necessity for patient-centred assessment was acknowledged, taking individual needs and abilities into account when choosing the type of intervention (NICE 2020).

2.5.4.2.1 Patient education

Patient education such as giving advice and information on neurophysiology and the nature of CLBP have been indicated as a part of multi-dimensional approach (Pangarkar et al.2019; NICE 2020). Further suggestions include encouraging patients to engage in daily activities, to modify their lifestyle and to stay physically active (NICE 2020).

2.5.4.2.2 Physical interventions

Different forms of exercise are recommended such as aerobic, mind-body and strengthening, or a combination of exercises (NICE 2020). Group exercises were also recommended, considering the patient's need and preference when choosing the type of exercise (NICE 2020). Several reviews also supported the benefits of different types of exercises for CLBP such as structured exercise programmes (strengthening and stretching), aerobic exercises, motor control exercises, and Pilates in reducing pain and improving function (Hayden et al.2005; van Middelkoop et al. 2010; Searle et al.2015; Gordon and Bloxham 2016; Wewege et al. 2018). The evidence indicates that no single type of exercise is optimal for all CLBP patients and individualised programmes to meet patients' varying needs and preferences are recommended (Gordon and Bloxham 2016; Wewege et al. 2018).

2.5.4.2.3 Psychological interventions

The recognition of psychosocial effects on pain perception highlighted the need for a psychological intervention to address factors associated with CP, including emotional and social wellbeing as well as self-efficacy (Driscoll et al. 2021). Recently, the use of a psychological intervention was found to be beneficial for CLBP patients who have poor outcomes (Foster et al. 2018; Ketenci and Zure 2021). Although there are huge variations in the types of psychological interventions with no standardised clinical practice, most reviews support its use in CLBP rehabilitation and report positive effects on pain intensity, physical function, and quality of life (Hoffman et al.2007; Reese and Mittag 2013; Ho et al.2022).

- Cognitive behavioural therapy (CBT)

Cognitive behavioural therapy (CBT) is one of the most common psychological interventions used for CLBP, this aims to replace the patient's maladaptive thoughts, emotions, behaviour, and coping mechanisms with more adaptive ones (Skelly et al. 2018). From the biopsychosocial perspective, CBT supports management of psychological problems

associated with CLBP rather than its biological causes (Gatchel and Rollings 2008). The term CBT covers a wide variety of approaches and can include graded exposure therapy, developing adaptive coping skills such as relaxation training and /or biofeedback, and hypnosis (Gatchel and Rollings 2008; Driscoll et al. 2021).

Graded exposure therapy has been widely used for CLBP patients who have FOM (i.e., kinesiophobia) (Vlaeyen et al. 2001; Leeuw et al. 2008; George et al.2010). Based on the fear avoidance model, negative beliefs among patients (i.e., movement exacerbate pain) can result in a cycle of FOM and subsequent avoidance behaviour which increases physical deconditioning, disability, and worsening pain (Leeuw et al. 2007). In graded exposure therapy, patients interrupt the fear-avoidance cycle via patient education, this is followed by gradual exposure to fearful movements or activities (i.e., from the least to the most fearful) using an individualised hierarchy of avoided movement (Vlaeyen et al. 2001; Leeuw et al. 2008). Evidence has shown promising results from graded exposure for CLBP in reducing pain, FOM, pain catastrophising and disability (Vlaeyen et al. 2002; Bailey et al. 2010; George et al. 2010; Macedo et al. 2010).

Relaxation training and /or biofeedback and hypnosis are components of CBT and have been commonly reported as coping skills in CP management (Roditi and Robinson 2011; Driscoll et al. 2021). In relaxation training, various strategies are adopted to activate the parasympathetic nervous system and subsequently regulate stress (physical or mental). Strategies include deep breathing exercises, progressive muscle relaxation (i.e., tension/relaxation exercises of muscle group or specific muscle) and visual imagery (i.e., a technique to use all body senses in imagining a peaceful environment to achieve a sense of relaxation). In addition, biofeedback can enhance the use of these relaxation strategies in which patients develop an awareness of physiological processes (Frank et al. 2010). In the biofeedback model, patients control the physiological cues (e.g., respiratory rate, stress levels) through auditory and/or visual feedback using special equipment and they are encouraged to use these cues to cope with and regulate stress (Frank et al. 2010; Driscoll et al. 2021). The use of biofeedback as a stand-alone intervention or in conjunction with relaxation training has been reported as beneficial to improve coping with pain and reducing disability in patients with CLBP (Sielski et al. 2017).

Hypnosis is a treatment which consists of an induction to focus attention, followed by a series of suggestions to change the subjective experience of pain in order to move the focus away from pain, to alter the way pain is perceived, to increase comfort, and to adopt relaxation strategies (Dillworth and Jensen 2010). It has been demonstrated as a viable treatment to aid CLBP management in order to reduce pain and disability (Dillworth and Jensen 2010; Rizzo et al. 2018; Driscoll et al. 2021)

- Mindfulness-based intervention

Mindfulness-based intervention is another type of psychological intervention that encourages patients to change the way they relate to pain by acceptance, self-regulation of attention and acknowledgement of negative emotions (Kabat-Zinn 2006; Driscoll et al. 2021). For instance, a programme may teach patients with CLBP how to attend to body sensation, increase awareness of body, breath, and activity by techniques such as meditation, body scan and gentle stretch. Also, it includes instruction on how to use mindfulness techniques in daily life and to maintain valued movements or activities to handle stress in a more adaptive way (Hofmann and Gomez 2017). Accordingly, practising these skills could create a state of relaxation and emotional wellbeing (Hofmann and Gomez 2017; Driscoll et al. 2021).

In summary, the recommendations for CLBP management are to assess the ‘whole person’ by identifying neurobiological and psychosocial factors that contribute to the individual’s experience of pain as well as combining both pharmacological and non-pharmacological interventions (Clauw et al. 2019; NICE 2020). With the recent technology advancement and with the move to treat people in their homes, virtual reality has become an exciting treatment option. This technology came in response to the subsequent affordability and healthcare needs for alternative ways to tackle the opioids crisis associated with pharmacological CP management (Osborn 2018; Ramanan and Yekkirala 2021). Also, VR has been demonstrated as a remote delivery solution to expand the access of CP patients to CBT or multi-dimensional rehabilitation, given the present healthcare challenges of limited providers and travel burdens (Garcia et al. 2021; Darnall et al. 2020; Eccleston et al. 2022). Therefore, this digital transformation needs further exploration.

2.6 Virtual reality (VR)

Virtual reality (VR) is a technology system designed to allow users to interact with a computer-generated VE, using input and output devices (Slater et al. 1996; Brady et al. 2021). The VR system enables user interaction with VE to feel real, via a phenomenon called 'sense of presence' (Slater et al. 1996). Presence is a subjective experience of 'being here' in the VE, when the user's body is physically situated in the real world (Slater et al. 1996; Witmer and Singer 1998).

Within VR research, sense of presence is often associated with two key terms; immersion and interactivity (Slater and Wilbur 1997; Mutterlein 2018). Immersion refers to the number of sensory inputs created by the VR system (visual, auditory, and tactile) to feel physically and psychologically immersed in VE, although it can be user dependent (Slater 2003). Interactivity refers to the extent to which users can interact with or have an influence on VE as facilitated by technical setup (Slater et al. 1996; Mutterlein 2018). Both are key factors that can influence user experience, in which an increase in immersion and interactivity leads to a greater sense of presence (Slater et al. 2009).

As technology has advanced, the definition of VR has changed from an early-stage sophisticated projection system to modern portable products. The term 'virtual reality' has been misused in research which often defines any type of computer-generated image as VR, thus there is a need to distinguish between the different types of VR technology (Kardong-Edgret et al. 2019). There are three types of VR: non-immersive (non-IVR), semi-immersive (semi-IVR) and immersive (IVR), depending on the sensory stimuli provided by the system and user's isolation from the real world (Mujber et al. 2004; Slater et al. 2009; Brady et al. 2021). A non-IVR system allows the user to interact with VE on a computer screen using a handheld mouse or keyboard such as gaming platforms Nintendo Wii, Microsoft Kinect and X-box. A semi-IVR system uses a more sophisticated 3D visual display such as a large screen monitor or projector. In both systems, users can see the real world outside the screen (Mujber et al. 2004; Brady et al. 2021).

Conversely, IVR creates a total immersion where users' vision is completely enveloped using head-mounted display (HMD). It provides 3D multi-sensory experience (e.g., visual, auditory, and tactile) which allows the user to experience a more realistic VE (Mujber et al. 2004; Brady

et al. 2021). The body motion capture system associated with IVR includes devices such as hand-controllers, gloves or sensors which enable the tracking of head /body movements to allow users to explore and interact within the VE (Bamodu and Ye 2013; Brady et al. 2021).

2.7 Virtual reality and pain management

Within the past 10 years, there has been a substantial growth in VR application for pain management, with a 39.8% increase in acute clinical pain and 34.3% increase in CP conditions (Ramanan and Yekkerala 2021; Trost et al.2021). This rapid growth clearly demonstrates the scientific interest in adopting VR technology for pain management.

2.7.1 Potential VR mechanisms of action on pain

VR has been described as bringing benefits to people with pain through a range of mechanisms. The following section provides an overview of those potential mechanisms. Both distraction and mechanisms beyond distraction, including graded exposure, coping skills, physical exercises, and neuromodulation, have been employed for pain management. In the following section it should be noted that distraction and neuromodulation are more realistically delivered through IVR (i.e., HMD) (Hoffman et al. 2006; Matalama-Gomez et al. 2019). However, the remaining mechanisms of graded exposure, coping skills, and physical exercise, discussed in the literature, have used various VR types. For instance, a range of physical exercises can be delivered through HMD (IVR), or exergaming such as Nintendo Wii or Microsoft Kinect (non-IVR) (Monteiro et al. 2015; Sirag-Bahat 2018).

2.7.1.1 Distraction

Distraction is a process by which attention is diverted away from pain stimuli to reduce the sensation of pain (Johnson 2005). It has been considered as an effective method for managing pain during acute stimuli (e.g., venipuncture) or medical procedures, using traditional forms such as cognitive tasks or watching TV (Bantick et al. 2002; Cassidy et al. 2002). Recently, IVR has been studied and clinically applied as an advanced means of distraction, creating analgesia during acute pain stimuli (Hoffman et al. 2006; Gold et al.2007).

Several theories described distraction and how it may inhibit or reduce pain. The gate control theory (GCT) by Melzack and Wall (1965), states that attention, emotion, and memory have a role in the way an individual interprets pain, in which pain signals pass through 'nerve gates'

before the body develops an awareness of the level of pain. Subsequently, McCaul and Malott (1984) stated that the human brain had limited attentional capacity in which individuals felt painful stimulus when they attended to it. Further, multiple resources theory indicates that sensory systems relating to mental attention work independently (Wickens 2008). Thus, distraction from pain, particularly the multi-sensory, reduces the sensation of pain (McCaul and Malott 1984; Wickens 2008). Based on these theories, it has been argued that IVR is a powerful distractor that can consume cognitive and attentional resources through visual, auditory, and tactile inputs (Gold et al. 2007; Mahrer and Gold 2009; Li et al. 2011). Compared with the other traditional forms of distraction, the multi-sensory IVR system gives the users a sense of presence within VE, consequently this increases the cognitive loads and impedes the processing of pain stimuli resulting in reduced pain (Gold and Mahrer 2018; Hoffman et al. 2019).

In addition to the theories described above, the analgesic effect of IVR via distraction was supported using fMRI (Hoffman et al. 2004; Hoffman et al. 2006). Significant reduction was found in the pain-related activity of five brain regions (i.e., anterior cingulate cortex (ACC), somatosensory cortex, insula, and thalamus) while using IVR in healthy subjects with experimentally induced thermal pain (Hoffman et al. 2004; Hoffman et al. 2006). Based on these fMRI studies, Gold et al. (2007) hypothesised the neurobiological mechanism of IVR distraction and stated that IVR may act through ACC region by engaging the brain's cognitive and emotional centres (e.g., cognitive virtual tasks, fun gaming). During IVR distraction, alteration may take place in ACC activity, this mediates attention and emotion processes and may activate the inhibitory descending modulation (PAG), that subsequently impedes the processing of pain stimuli and potentially reduces the perception of pain (Gold et al. 2007). Alongside attentional distraction, Gold et al. (2007) further explained how positive emotions created by IVR through visualising pleasant VE or playing fun games may produce analgesia. The emotional component of IVR was postulated to reduce pain via interaction between ACC, amygdala and PAG (Gold et al. 2007). The amygdala's primary role is to regulate emotions both positive (e.g., happiness) and negative (e.g., fear and anxiety) that inhibit and facilitate pain respectively. Thereby, the positive emotions associated with VE may inhibit the work of amygdala, resulting in further analgesia (Gold et al. 2007).

Indeed, the use of IVR as a distraction tool has been supported as a means of reducing acute pain stimuli, in which the sense of presence and positive emotions have been correlated to its analgesic effect (Triberti et al. 2014; Sharar et al. 2016). Many trials confirmed that high immersion and interactivity offered by IVR contribute to a high sense of presence and a significant analgesic effect (Hoffman et al.2000a; Hoffman et al.2000b; Hoffman et al.2004; Dahlquist et al. 2007; Wender et al. 2009; Gutierrez-Martinez et al. 2011).

Notably, IVR distraction is a well-studied mechanism which can produce analgesia during acute pain stimuli, but the effect upon the daily changes in pain experience in patients with CP remains unclear (Li et al. 2011).

2.7.1.2 Mechanisms beyond distraction

In addition to distraction several other mechanisms have been identified recently for CP management, these include graded exposure, integration of coping skills, range of physical exercises and neuromodulation (Li et al. 2011; Keefe et al. 2012; Matsangidou et al. 2017; Won et al. 2017; Gupta et al. 2018; Ahmadpour et al. 2019; Matalama-Gomez et al. 2019; Austin 2021; Chuan et al. 2021; Tack 2021; Trost et al. 2015; Baker et al. 2022; Bordeleau et al. 2021; Goudman et al. 2022).

2.7.1.2.1 Graded exposure

Graded exposure was suggested as a VR mechanism which could reduce FOM and promote functional restoration in patients with CP (Trost et al. 2015; Won et al. 2017; Gupta et al. 2018; Tack 2021). Graded exposure is a cognitive behavioural intervention (CBT) which encourages patients to practise avoided activities in a progressive manner, aiming to disturb the fear-avoidance cycle (Leeuw et al. 2008, Vlaeyen et al. 2012).

The availability and motivation of VR are thought to have the potential to overcome the issues associated with the traditional form of graded exposure, such as limited accessibility and patient non-adherence derived from the anxiety provoking nature of this intervention (Trost et al. 2015; Tack 2021).

2.7.1.2.2 Coping skills

Integration of VR with coping skills such as mindfulness, hypnosis and biofeedback associated with relaxation training are assumed to be helpful for CP patients in order to regulate

unpleasant feelings, build resilience, and enhance self-efficacy (Gupta et al. 2018; Ahmadpour et al. 2019; Austin 2021; Trost et al. 2021; Goudman et al. 2022). These skills have been recognised as psychological interventions for patients with CP to replace the maladaptive coping strategies (i.e., reliance on medication and rest) and to enhance patients' well-being (Driscoll et al. 2021).

- Mindfulness-based intervention includes learning self-regulation skills such as meditation or stretching to increase awareness of body sensation and thoughts and to encourage an acceptance of pain (Hofmann and Gomez 2017; Driscoll et al.2021).
- Biofeedback is a CBT approach that can enhance relaxation through auditory and/or visual feedback cues of respiratory rate or stress level (Frank et al. 2010; Driscoll et al.2021).
- Hypnosis is a management approach, which consists of induction followed by suggestions for changes in behaviour and the perception of pain such as altering the focus away from pain, imagined analgesia or to practise relaxation (Jensen and Patterson 2006; Dillworth and Jensen 2010).

Practising these skills within VE has been suggested as a novel non-pharmacological option to tackle opioid addiction amongst CP patients (Gupta et al. 2018).

2.7.1.2.3 Physical exercises

Different types of physical exercise such as balance, strength, and proprioception were also integrated within VR (Austin 2021; Bordeleau et al. 2021; Goudman et al. 2022). Some VR applications involve aerobic or strengthening exercises, trunk stability and balance training for patients with CLBP and fibromyalgia to improve functional capacity and reduce pain (Austin 2021; Bordeleau et al. 2021; Goudman et al. 2022). In addition, kinematic and coordination exercises were incorporated in VR to promote function and reduce disability in patients with chronic neck pain (Austin 2021; Goudman et al. 2022).

Most of these reported exercises have been suggested for CP management (see section 2.5.4.2.3) (NICE 2020). In the context of VR, the gaming nature was seen as useful to encourage engagement with physical exercise (Austin 2021; Bordeleau et al. 2021; Goudman et al. 2022).

2.7.1.2.4 Neuromodulation

The recent advances in VR technology present virtual embodiment and visual manipulation, these are believed to have an analgesic effect in CP management through neuromodulation (Won et al. 2017; Matalama-Gomez et al. 2019; Wittkopf et al. 2019; Tack et al. 2021; Trost et al. 2021). The immersive nature of VR is thought to be an efficient medium in which to induce neuroplastic changes, leading to enhanced full or partial recovery in sensory and motor function (Cheung et al. 2014).

In CP conditions, neuroplastic changes may take place in the sensory and motor cortices and cause misrepresentation of the body, resulting in a false interpretation of painful states or distorted body perception (Melzack 2005; Bosnar and Demarin, 2012; Moseley and Flor 2012). Based on the neuroplasticity theory, neuromodulation is a type of intervention that provides an analgesic effect by reversing these neuroplastic changes (Rasche and Knotkova 2015). Neuromodulation interventions mainly focus on integrating visual, motor and proprioception feedback to alter the neural information of pain by creating an ownership illusion and convincing patients that their painful body part is healthy (Ramachandran and Altschuler, 2009). Mirror therapy and motor imagery are examples of such interventions, where visual feedback or reflected image of an unaffected limb or body part is used with associated progression of complex motor function to encourage cortical remapping (Ramachandran and Rogers-Ramachandran 1996; Méndez-Rebolledo et al. 2017). The effectiveness of these interventions in CP conditions was supported to facilitate the reduction in pain and disability (Bowering et al. 2013; Daffada et al. 2015; Méndez-Rebolledo et al. 2017)

The advancement of virtual embodiment and visual manipulation was believed to have a neuromodulatory effect (Matalama-Gomez et al. 2019). Virtual embodiment is defined as the perception of owning a virtual body where users have an illusion that a real body is being replaced by a virtual avatar (VA), allowing movement coordination of real / virtual body by motion trackers of either one body part (i.e., upper limb or lower limb only) or the whole body (Slater et al. 2008; Slater et al. 2010; Kilteni et al. 2012). Embodiment could potentially reduce pain by changing body perception and could act as a new medium for mirror therapy in CP conditions (Won et al. 2017; Matalama-Gomez et al. 2019; Tack 2021). Alongside, visual manipulation refers to the capability of IVR to alter the visual feedback of VA such as the size, shape, or range of movement (Won et al. 2017; Matalama-Gomez et al. 2019; Tack 2021). For

instance, modifying the appearance of the back could change the distorted body perception associated with CLBP to aid exercise performance (Tack 2021). Also, augmentation of the observed range of movements (e.g., neck, or back movement) is assumed to disconfirm the beliefs of pain associated with movement, allowing the patient to experience pain free-movement and altering their perception of movement and protective behaviour (Won et al.2017; Tack 2021).

2.7.2 The effectiveness of VR in pain management

The previous section outlined the proposed mechanisms of VR on pain and how VR contributes to pain management. The following section reviews the evidence for the effectiveness of VR in management of both acute and chronic pain.

2.7.2.1 The effect of VR on acute pain

Several reviews have been conducted on the use of VR distraction in both adults and /or children for the reduction of acute pain including pain post injury or trauma, pain during medical procedures (e.g. burn care, dental care) as well as experimental pain in healthy subjects using thermal stimuli (Shahrbanian et al. 2009; Shahrbanian et al .2012; Pourmand et al. 2018; Indovina et al. 2018; Eijlers et al. 2019; Mallari et al. 2019; Luo et al. 2019; Ding et al. 2020; Georgescu et al. 2020).

These reviews concluded that there is strong evidence to support the effectiveness of VR as a distraction tool for acute pain reduction (Shahrbanian et al. 2009; Shahrbanian et al. 2012; Pourmand et al. 2018; Indovina et al. 2018; Eijlers et al. 2019; Mallari et al. 2019; Luo et al. 2019; Ding et al. 2020; Georgescu et al. 2020).

2.7.2.2 The effect of VR on chronic pain

There is a large body of evidence on VR and pain management, which mainly focused on acute pain up until 2018. Since then, there has been surge in publications looking at VR and CP management. As this thesis focused on CLBP, the updated literature identified 8 recent systematic reviews which investigated the effect of VR on CP and/or CLBP (Wittkopf et al. 2019; Ahern et al. 2020; Bordeleau et al. 2021; Brea-Gómez et al. 2021; Baker et al. 2022; Goudman et al. 2022; Grassini 2022; Huang et al. 2022). The section below presents the key findings of those reviews and the types of VR that have been reviewed including IVR (i.e., HMD) and non-IVR (i.e., computer screen such as Nintendo Wii).

Three recent systematic reviews were conducted to investigate the effect of VR either IVR or non-IVR on CP associated with different conditions (Wittkopf et al. 2019; Goudman et al. 2022; Huang et al. 2022). Both Wittkopf et al. (2019) and Huang et al. (2022) evaluated the effect of VR on pain outcomes and compared this effect to standard care. Wittkopf et al. (2019) identified thirteen studies including 5 RCTs, six quasi-experimental studies (i.e., uncontrolled trials), one within a subject repeated measures study and 1 non-randomised controlled study. Within the review, seven studies used IVR, and six studies used non-IVR in various conditions including chronic neck pain (CNP) (n=3), phantom pain (n=3), CLBP (n=2), neuropathic pain (n=2), ankylosing spondylitis (n=1), cancer pain (n=1), subacromial impingement syndrome (n=1). The review showed inconsistent findings across the studies. Two studies in CNP found significant pain reduction, while one study showed no change in CNP. Three studies, of which two were in CLBP and one was in subacromial impingement syndrome revealed no effect of VR on pain outcome. On the other hand, the two studies in ankylosing spondylitis and cancer pain as well as the five studies in neuropathic and phantom pain showed that VR significantly reduced pain. Among the controlled studies, the review found that VR is not effective when compared with standard care. Hence, authors stated that the effect of VR on CP is not conclusive, it was associated with a high risk of bias and small sample size. Furthermore, there was inconsistency in the results attributed to no standardised intervention with heterogeneity in intervention components including software, hardware, and dose (i.e., frequency, and duration).

Subsequently, Huang et al. (2022) conducted a meta-analysis assessing only RCTs. The review found 9 RCTs, of which 4 used IVR and 5 used non-IVR. The included studies were in cancer pain (n=2), CLBP (n=2), knee pain-post arthroplasty (n=2), phantom pain (n=1), fibromyalgia (n=1) and chronic limb condition (n=1). The meta-analysis revealed that VR can effectively reduce pain intensity only during VR, however, little effect was shown on improving pain tolerance with a lack of lasting effect. Furthermore, no significant differences were found between VR and standard care. In line with Wittkopf et al. (2019), the review concluded that the effectiveness of VR in CP management remains inconclusive.

Whilst Wittkopf et al. (2019) and Huang et al. (2022) reviewed the effect of VR only on pain outcome, the recent meta-analysis by Goudman et al. (2022) investigated the VR effect on pain and functional related outcomes in patients with CP. Goudman et al. (2022) found forty-

one studies including 16 RCTs, 18 quasi-experimental and 7 case studies. The included studies were twenty-three IVR studies and eighteen non-IVR studies in un-specified pain (n=11), fibromyalgia (n=7), CLBP (n=6), CNP (n=5), complex regional pain (n=4), and phantom pain (n=3). The meta-analysis was conducted on twenty-five studies, it evaluated the effect of VR on pain, function (i.e., disability, strength, fitness, physical comfort, sleep), functional capacity (i.e., balance, step test, repetition index) and mobility (i.e., range of motion). The analysis revealed that VR had a significant impact on pain reduction and improvement of function but had no effect on functional capacity or mobility. The review concluded that good to fair quality of evidence supported the use of VR technology for CP to induce pain relief and functional improvement. This indicates that VR holds promise for CP management but their conclusion in relation to functional improvement cannot be generalised to all VR types since the meta-analysis of function included eleven studies using non-IVR and only four studies using IVR. Furthermore, the heterogeneity in the studies including the type of CP condition and VR intervention protocol was reported to be a major limitation, in which the conclusion of the meta-analysis should be interpreted with caution.

Whilst the above reviews examined the effect of different VR types on CP, the recent systematic review by Baker et al. (2022) focused only on IVR as a new advancement in technology and evaluated its effect on pain outcomes. Baker et al. (2022) identified twenty-four studies including 10 RCTs and 14 quasi-experimental trials (8 uncontrolled trials and 6 controlled trials). These studies employed IVR for un-specified CP conditions (n=6), phantom pain (n=6), complex regional pain (n=4), CLBP (n=2), arthritis (n=2), cancer (n=2), CNP (n=1) and neuropathic pain (n=1). The review found inconsistent results as well as a high risk of bias across the studies, some reported that IVR reduced pain significantly whilst others showed no significant change or inconclusive results across multiple measures of pain outcomes. Further, the IVR intervention was reported to have a heterogeneous nature including varied mechanisms of actions (i.e., distraction, virtual embodiments, meditation, and hypnosis) and interventions duration.

Two additional systematic reviews with meta-analysis, which included only RCTs, compared the effectiveness of VR either IVR or non-IVR on pain, FOM and disability to standard treatment in patients with chronic spinal pain (Ahern et al. 2020; Grassini 2022). The review by Ahern et al. (2020) identified 7 RCTs in CNP (n=3) and CLBP (n=4), 4 used non-IVR and 3

employed IVR, whilst Grassini (2022) identified 9 RCTs in CNP (n=3) and CLBP (n=6) with 5 used IVR and 4 used non-IVR. Ahern et al. (2020) found that the effectiveness of VR in chronic spinal pain was inconsistent across the studies. Two CNP studies which were involved in the meta-analysis revealed that VR had no significant effect on pain, FOM or disability when compared with conventional kinematic training. The results of one CNP study revealed a reduction in pain and disability compared with proprioceptive training. In CLBP, one study identified that VR reduced pain, disability, and FOM when compared with lumbar stabilisation exercises, whilst two studies found a reduction in pain and FOM but not in disability when compared with conventional physical therapy. Additional two CLBP studies showed that VR had no effect on pain compared with either physical modalities or no intervention. Ahern et al. (2020) concluded that the effectiveness of VR when compared with conventional treatment, or no intervention, had no clinical significance and was associated with a high risk of bias. Similarly, Grassini (2022) showed that the findings for VR effectiveness were inconsistent. Whilst VR showed significant reduction in pain and disability over the control group in CNP patients, VR had no significant effect on pain and disability in CLBP patients. In addition, VR had no effect on FOM in either CNP or CLBP. Despite the potential of VR for treating CNP, Grassini (2022) acknowledged the limited evidence of including only three studies associated with high risk of bias. Both Ahern et al. (2020) and Grassini (2022) attributed the inconsistent findings on VR effectiveness to the heterogeneity in the type of spinal pain and VR intervention protocol. Grassini (2022) highlighted the fact that VR had no clear consensus on underlying mechanism of action or optimal dose (i.e., frequency and duration).

Bordeleau et al. (2021) and Brea-Gómez et al. (2021) conducted meta-analyses to investigate the effect of VR on the management of CLBP. Both reviews included mainly non IVR studies that used an exergaming system (e.g., Wii fit) to induce a range of physical exercise such as strengthening and balance exercises. Only two IVR studies were identified in Bordeleau et al. (2021) and one IVR study was identified in Brea-Gómez et al. (2021). Bordeleau et al. (2021) evaluated the effect of VR on pain and function in CLBP. The review identified twenty-four studies including 16 RCTs, 7 quasi-experimental trials (4 uncontrolled trials, 3 controlled trials) and 1 case study. The meta-analysis was conducted on 14 RCTs and 2 controlled trials and found a significant improvement in pain intensity when compared with conventional

interventions immediately post the intervention but this improvement was not evident in a follow up period. The effect on function was not included in the meta-analysis due to the heterogeneity of the measured outcomes (e.g., physical test of range of motion, strength, balance or stability or physical activity or functional scales), however, the review reported the potential of VR for improving function. Brea-Gómez et al. (2021) investigated the effect of VR on pain, FOM and disability in CLBP using 14 RCTs, with further examination of its effect either as stand-alone or as adjunct. The meta-analysis of 11 RCTs showed that VR had a significant effect on pain and FOM in short and intermediate term, but no significant difference was found in disability. Although pain and FOM were significantly reduced after VR, this was only found when VR was employed as adjunct in young athletes under 30 years old with CLBP related to sport injury. Thus, the findings of the review cannot be generalised to patients with CLBP which is prevalent amongst older adults over the age of 60 (De Souza et al. 2019). Both Bordeleau et al. (2021) and Brea-Gómez et al. (2021) acknowledged that the included studies associated with great heterogeneity in the underlying VR mechanism (e.g., physical exercises or cognitive therapy), type of VR system and duration which influenced the reviews' results. Furthermore, Bordeleau et al. (2021) and Brea-Gómez et al. (2021) reported that the evidence supported the VR effectiveness in CLBP associated with high and unclear risk of bias, respectively.

In summary, most of the recent systematic reviews agreed that the effect of VR on CP and /or CLBP was inconclusive associated with inconsistent findings between the studies, this was attributed to the heterogeneity in underlying VR mechanism, intervention protocol (software, hardware, duration, or frequency) and type of CP condition (Wittkopf et al.2019; Ahern et al.2020; Baker et al.2022; Grassini 2022; Huang et al.2022). The promising VR effect on pain, function and FOM that has been shown in some meta-analyses is further affected by the heterogeneity across the studies and methodological bias (Bordeleau et al. 2021; Brea-Gómez et al. 2021; Goudman et al. 2022). The body of literature demonstrates the utility of all VR types in CP and /or CLBP management including non-IVR and IVR. Whilst non-IVR presents the virtual content on a flat screen, IVR has been considered as an advancement in technology employing HMDs to create immersive environment, this is discussed in the next section.

2.7.3 The immersive VR technology in pain management

The recent technological development led to a rise of more realistic immersive environments (IVR) conducive to potentially bringing further benefits to pain management (Mujber et al. 2004; Brady et al. 2021; Theingi et al. 2022). In the literature on VR and pain management, immersion, presence, interactivity, and embodiment were the key elements that moderated the overall patient experience and influenced reduction in pain-related outcomes (Won et al. 2017; Trost et al. 2021; Theingi et al. 2022).

IVR provides a multi-sensory, and 3D virtual environment whilst wearing HMDs is correlated with high immersion and interactivity (Won et al. 2017; Theingi et al. 2022). It can offer a fully immersive experience and physical interaction through head and/or body motion tracking (e.g., sensors, hand controllers), leading to an enhanced sense of presence and a subsequent analgesic effect (Theingi et al. 2022). Furthermore, the distraction properties supported by theory for the reduction of pain, referred to the use of IVR (Gold et al. 2007; Mahrer and Gold 2009) and previous reviews indicate its effectiveness as a distraction tool in pain management (Shahrbanian et al. 2009; Shahrbanian et al. 2012; Pourmand et al. 2018; Indovina et al. 2018; Eijlers et al. 2019; Mallari et al. 2019; Luo et al. 2019; Ding et al. 2020; Georgescu et al. 2020). The virtual embodiment is another key feature of IVR that involves using head and/or body tracking technology to replace the user's real body with a virtual avatar, creating a sense of presence within a virtual environment (Kilteni et al. 2012). This has been found to be particularly valuable in CP management, reducing pain through neuromodulation (Matalama-Gomez et al. 2019; Tack et al. 2021).

In practical terms, IVR brought potential advantages as the commercially available HMDs made the technology portable and accessible to support remote CP management (Garcia et al. 2021; Darnall et al. 2021). It is becoming increasingly popular and affordable as a means of reducing the need for face-to-face therapy and travel expenses (Spiegel 2018).

Although most reviews explored the effect of all VR types in CP management (section 2.7.2.2), Baker et al. (2022), who focused only on IVR studies, pointed to the inconsistency in the results of those studies and heterogeneity in the given intervention. Further, the meta-analyses that supported the positive effect of VR on pain and function in CP conditions referred mainly to non-IVR studies, this limited the generalisability of the effect to IVR

(Bordeleau et al. 2021; Brea-Gómez et al. 2021; Goudman et al. 2022). Hence, further investigation into this cutting-edge technology is needed.

2.8 Gap in literature and rationale of the thesis

To date a large number of research trials have been conducted which evaluate the effectiveness of VR interventions on CP and/or CLBP, several recent reviews reported no definitive conclusion with inconsistent findings across the trials. The heterogeneity in the underlying mechanisms of action, CP population, software, hardware, and dose was reported as the main reason for the inconsistent results, making the effectiveness of VR in CP and/or CLBP inconclusive and challenging. There are two main bodies of research trials, of which one demonstrates the use of non-immersive technology using a flat-screen and the other one represents the advancement of immersive technology using HMDs (IVR). Some meta-analyses showed promise regarding the effect of non-immersive technology on pain and function, however, the effectiveness of the immersive technology is less clearly associated with heterogeneity in the results of the studies as well as the utility of the intervention. This indicates that IVR technology is constantly evolving with lack of prior development investigation to optimise its use as an intervention. Therefore, a further in-depth investigation based on a validated framework in development and implementation of new complex interventions in healthcare is deemed necessary.

This thesis adopted the Medical Research Council Framework (MRCF), this framework is designed to guide the researcher on the development of complex interventions, aiming to improve its utility and impact (Craig et al. 2008). According to the properties reported by MRCF, the use of IVR as an intervention for patients with CP can be considered as a complex intervention (Craig et al. 2008). Firstly, the number of interacting components including hardware, software, and dose of the intervention. Secondly, the number of groups involved within the development and implementation and their role/skills including healthcare practitioners, IVR technology developers and patients (Craig et al. 2008). Hence, the adoption of such a framework is valuable to inform the development and implementation of IVR intervention for patients with CLBP.

2.9 Aim

The overall aim of this PhD thesis was to adopt the Medical Research Council Framework (MRCF) to inform the development of IVR intervention for patients with CLBP.

2.10 Objectives

Objective 1 - to synthesise contemporary evidence to map the theories underpinning the IVR mechanism of action in patients with CP as well as identification of the key features of IVR interventions including the software, hardware, dose, and setting.

Objective 2 - to engage global stakeholders (healthcare practitioners and IVR technology developers) to gain an understanding on the current use of IVR in CP management.

Objective 3 - to explore the opinions and views of UK physiotherapists about the potential benefits, concerns, facilitators, and barriers to using IVR for CLBP management.

Chapter 3: Methodology and Methods

Research methodology refers to the understanding of research approaches which incorporate philosophical assumptions and different methods and the suitability of both for evaluating the research problem (Creswell 2014; Creswell and Plano Clark 2017). As reported in Chapter 2, the current research trials using IVR intervention for patients with CP and/or CLBP have a heterogeneous nature with a lack of prior development investigation. Therefore, this thesis adopts mixed methods guided by the MRCF to inform the development and implementation of IVR intervention. This chapter presents the underlying philosophical assumption including the researcher's ontological and epistemological position, how the research design is guided by the MRCF, with an overview of the conducted methods in each part of the thesis.

3.1 Philosophical assumption

All research should be underpinned by philosophical foundations that shape the research aim, known as 'worldview' or 'paradigm' (Creswell and Plano Clark 2017). A paradigm is described as a set of beliefs which underpin the inquiry of research or the researcher's views to the real world (Creswell and Plano Clark 2007). Research paradigms are determined by the ontology, which addresses the nature of reality, and the epistemology, which focuses on who knows and how the reality can be known (Guba 1990; Guba and Lincoln 1994). Accordingly, the selection of the research design and the associated methods should be based on these ontological and epistemological assumptions (Creswell 2009; Creswell 2014).

Based on the nature of the research question, several paradigms are available in literature and worthy of consideration. Nevertheless, post positivism, constructivism, and pragmatism are the most commonly discussed paradigms (Table 3-1) (Creswell 2014). The positivists (post positivism) believe that a single reality or truth exists in the world (Creswell 2014). They see the reality as objective and are intent on seeking the knowledge by testing theories or hypotheses to understand the world, thus their lenses are associated with quantitative methods where the researchers collect information using objective measures (Creswell 2014). In contrast, constructivists (constructivism) hold an assumption that multiple realities exist, in which the reality is seen as subjective, and the knowledge needs to be interpreted based on varied meanings that are constructed by individuals depending on their experiences

(Creswell 2014). Therefore, they apply qualitative methods which allow researchers to gather data from multiple participants to generate a subjective meaning of the situation being studied (Creswell 2014).

Pragmatists (pragmatism) believe that reality is debated or interpreted, in which both objective and subjective reality can be measured, and the reality is what provides the best understanding of the research problem (Tashakkori and Teddlie 2003; Creswell 2014). Pragmatism is problem-oriented and not committed to a single philosophy, this offers a practical approach for addressing research questions. It allows the researcher to choose the appropriate method, either quantitative or qualitative, and to combine them when needed (Creswell and Plano Clark 2011; Creswell 2014). It has been argued that this is the paradigm most suited to mixed methods research, it helps to use multiple methods with different forms of data collection and analysis that best meet the research purpose (Johnson and Onwuegbuzie 2004; Johnson et al. 2007; Creswell 2014).

Table 3-1: Overview of the common paradigms in research (Creswell 2014)

Paradigms	Postpositivism	Constructivism	Pragmatism
Ontology	One existing reality or truth. (Objective perspective of reality)	Multiple realities or truths. (Subjective perspective of reality)	The reality or truth is debated or interpreted. (in between subjective and objective reality)
Epistemology	Truth/reality can be measured using reliable tools to indicate the failure to reject certain hypothesis.	Truth or knowledge needs to be interpreted to investigate the multiple participants' meanings toward certain objects.	Truth or knowledge can be investigated using whatever methods that best suited the research problem.
Researcher position	The researchers must examine the method to eliminate bias.	The researchers actively interact with human beings and interpret what they find.	The researchers consider what and how to research based on the intended outcomes.
Research type	Quantitative	Qualitative	Mixed methods (quantitative and qualitative)
Research strategy	Experimental and survey research.	Phenomenology Grounded theory	Convergent Sequential explanatory

		Ethnography Case study and Narrative	Sequential exploratory Embedded Multi-Phase (convergent or sequential)
Data collection method	Experiments and numeric surveys	Interviews, focus groups and observations	Both quantitative and qualitative methods
Data analysis	Statistical analysis	Text and image analysis	Statistical and text analysis

This thesis was conducted using pragmatists' assumptions. The reality is to understand the use of IVR technology as an intervention for patients with CLBP, in which the nature of reality (ontology) is in between objective and subjective stance. The literature informs the objective existence of IVR interventions for patients with CP and/or CLBP, while the heterogeneity in the application, or the understanding of this intervention, embraces the subjective component as it may differ from one individual to another; hence, multiple realities may exist. In terms of epistemology, the MRCF for the development and implementation of a new complex intervention has influenced the researcher's epistemological views. Based on MRCF, several aspects need to be known with regards to an intervention, these include underpinning theories, key characteristics of the intervention, whether it can be applied in certain settings, who are the most applicable patients for the intervention as well as the related harms (Craig et al. 2008). Knowledge of these aspects can be obtained through the conducted experiments with objective measures and the perspectives of those involved in development and delivery of the intervention (Craig et al. 2008). So, the concept of knowledge is multi-faceted as it is constructed from multiple sources and the researcher employs multiple methods to seek this knowledge. Therefore, based on these ontological and epistemological assumptions, pragmatism was employed as the most appropriate paradigm for this thesis.

The following section presents the way in which the MRCF guided the objectives of this thesis and influenced the research design, including the researcher decision on conducting sequential, mixed methods.

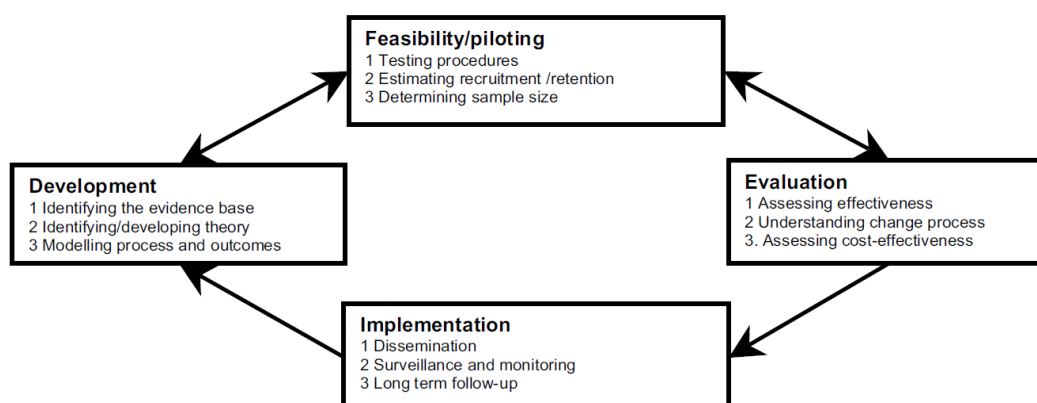
3.2 Research design

3.2.1 Medical research council framework (MRCF)

The MRCF provides guidance for the development and implementation of complex interventions in healthcare (Craig et al. 2008). As shown in Figure (3-1), it is a multi-staged framework consisting of four stages including development, feasibility/piloting, evaluation, and implementation. This helps the researcher and intervention developer to understand how the intervention can be successfully implemented to achieve its intended outcomes (Craig et al. 2008). In the development stage, the researcher identifies the evidence base of the existing or relevant interventions through systematic review and evaluates whether the intervention is effective or not for the target population (Craig et al. 2008). If a recent systematic review highlights an uncertain effect in the existing interventions, it indicates the need for further research to gain a better understanding of the intervention before moving to the feasibility or evaluation stage (Craig et al. 2008). Careful investigation at the development stage is necessary to enhance its chance of being effective and being adopted in healthcare practice (Craig et al. 2008; O'Cathain et al. 2019).

As reported in Chapter 2 several systematic reviews have been conducted recently and no definitive conclusion was reached with regard to the effectiveness of IVR intervention for patients with CP and/or CLBP. Most reviews attributed the lack of certainty to inconsistent effects on the intended outcomes (e.g., pain, function, FOM, disability) with the heterogeneity of underlying mechanisms of action, intervention components, and CP conditions (Mallari et al. 2019; Wittkopf et al. 2019; Ahern et al. 2020; Brea-Gómez et al. 2021; Bordeleau et al. 2021; Baker et al. 2022; Grassini 2022; Goudman et al. 2022). Accordingly, this highlights the contribution of this thesis, further understanding is needed to inform development and implementation of IVR prior to evaluation or feasibility trials.

Figure 3-1: The four stages of Medical Research Council Framework (from Craig et al.2008)



It should be noted that this thesis does not develop an actual IVR prototype, the MRCF was adapted to guide the researcher on the specific elements to be considered within an intervention to inform the development and implementation (Craig et al.2008; O'Cathain et al.2019). These elements include:

- The theory underpinning the intervention.
- Key components of the intervention such as content, dose, equipment, and how they interact.
- The context of the intervention including the target population, those who are at risk and those most likely to benefit from the intervention as well as the setting of the intervention and the factors affecting the implementation, such as the application in different locations.
- The concerns or harms that are associated with the intervention.
- The facilitators and barriers to future implementation of the intervention in healthcare practice.

These elements can be obtained from 1) a review of the published evidence and 2) engagement of stakeholders (Craig et al. 2008; O'Cathain et al. 2019). Stakeholders are those who deliver or use the intervention, these include individuals with relevant expertise in the development and delivery of the intervention as well as end users (e.g., practitioners, policy makers, patients, or public members) (O'Cathain et al. 2019). The inputs from these

stakeholders can help to generate ideas and aspects to change in the development and implementation process (O'Cathain et al. 2019).

The stakeholder is a broad term, in which stakeholders should be appropriately selected for different phases in the research (O'Cathain et al. 2019). Firstly, investigation relating to the content, key components, and delivery setting is critical and cannot be established without a group of individuals who have relevant experience and are closely involved in the development and delivery of the intervention (Richards and Hallberg 2015; O'Cathain et al. 2019). Given that IVR is a technology-based intervention, those individuals potentially include healthcare practitioners and IVR technology developers. The review of evidence illustrates that the individuals who are involved in the field are based in different countries, these include UK, USA, Canada, and Australia. Furthermore, the novel nature of this field requires broad access to a variety of people and/or settings to gain an understanding of the use of IVR interventions for patients with CP. Therefore, global stakeholders (healthcare practitioners and IVR technology developers), who have previously been involved in the development or delivery of IVR interventions, were engaged in this thesis.

Subsequently, gaining insights from the end users including professionals that may deliver the intervention was emphasised to identify priorities or concerns about the intervention and to help identify solutions that could change future implementation in practice (O'Cathain et al. 2019). As a result, it was essential to engage healthcare professionals who had experience in CLBP management because they would have an understanding of the challenges faced by patients and the factors which contribute to successful intervention in practice. Although different healthcare professionals may be involved in CLBP management, physiotherapists play a key role in treating CLBP conditions in UK primary care (Stanley et al. 2001). Therefore, physiotherapists with experience in treating CLBP were involved in this research.

Accordingly, three objectives were developed:

Objective 1 - to synthesise contemporary evidence to map the theories underpinning the IVR mechanism of action in patients with CP as well as identification of the key features of IVR interventions including the software, hardware, dose, and setting.

Objective 2 - to engage global stakeholders (healthcare practitioners and IVR technology developers) to gain an understanding on the current use of IVR in CP management.

Objective 3 - to explore the opinions and views of UK physiotherapists about the potential benefits, concerns, facilitators, and barriers to using IVR for CLBP management.

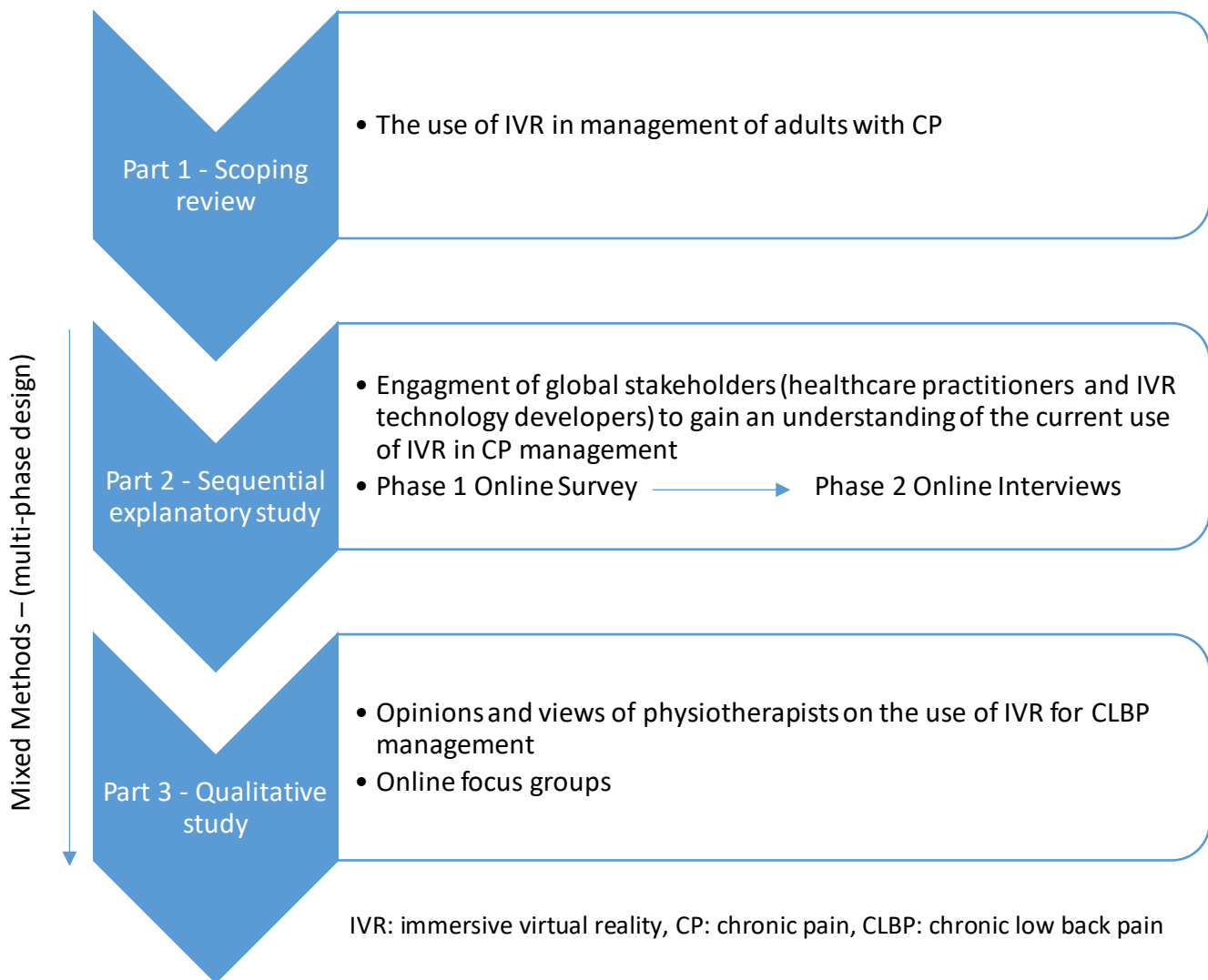
- Why CLBP patients were not involved in this thesis

Patients would be considered as stakeholders in such a thesis and their involvement in the early development of complex interventions is critical (Craig et al. 2008), but patients with CLBP are not participants in this thesis. The National Institute for Health and Care Excellence (NICE) guidelines has recently highlighted the challenges of patient involvement in assessing technology-based interventions (Norburn and Thomas 2021). The contribution of patients was reported to be significantly meaningful in the development process when they have an opportunity to test and utilise the developed technology (Norburn and Thomas 2021). This PhD thesis is time bounded, and the researcher has not developed an actual IVR prototype that can be explored or examined by patients. Therefore, we believe it would be challenging for patients to give an opinion with respect to IVR as they may have difficulty understanding how IVR could work as an intervention for CLBP without actual experience of a prototype. This thesis gathered opinions from the professionals including global stakeholders (healthcare practitioners, IVR technology developers) and physiotherapists that would inform the development of a prototype that can be tested by patients in future studies.

3.2.2 Research methods

As shown in Figure 3-2, this thesis consists of three parts which aim to meet the objectives. This section presents an overview of the methods in each part. Further details on study design and methods are presented in the following Chapter 4 (Part 1), Chapter 5 (Part 2) and Chapter 6 (Part 3).

Figure 3-2: The three parts of the PhD thesis



3.2.2.1 Part 1 - Scoping review

A scoping review was conducted in Part 1 to meet the first thesis objectives, synthesising contemporary evidence to map the theories underpinning the IVR mechanisms of action in patients with CP as well as identification of the key features of IVR interventions including the software, hardware, dose, and setting. The review design was based on the methodological framework of Arksey and O’Malley (2005).

3.2.2.2 Part 2 and Part 3 – Mixed methods (multi-phase design)

Following the scoping review, a mixed methods study with a multi-phase design was conducted (Figure 3-1). In research, mixed methods studies can be designed according to the

research aim into convergent, embedded, sequential, and multi-phase design (Creswell and Plano Clark 2011). Briefly, the convergent design is implemented when the researcher needs to merge and compare the results of concurrent quantitative and qualitative data. The embedded design, however, allows the researcher to embed the qualitative data within a predominantly experimental quantitative study. In sequential design, the quantitative and qualitative studies are conducted in subsequent phases where the researcher has the flexibility to start with either one to best address the research question. The sequential design included either explanatory or exploratory approaches. The sequential explanatory design begins with a quantitative phase, the qualitative study then explains the results in more depth. Conversely, in the exploratory design, the qualitative phase is conducted first, and the findings are used to inform the subsequent quantitative phase (Creswell and Plano Clark 2011).

The multi-phase design includes one mixed-methods study (commonly with convergent or sequential design) as well as a single quantitative or qualitative study (Creswell and Plano Clark 2011). This design is frequently used in healthcare sciences when multiple phases need to be conducted over time in a single project, one phase builds on another to address the common overall aim for developing and evaluating the health programme (Creswell and Plano Clark 2011). Based on the MRCF, the perspectives of different stakeholders are needed to inform the development and implementation of IVR for CLBP management. As such, the multi-phase design was used (Figure 3-1), starting with Part 2 of sequential explanatory study (online survey followed by online interviews), then Part 3 of a qualitative study (online focus groups).

3.2.2.2.1 Ethical considerations

Ethical approval for Part 2 and Part 3 was obtained from the Ethics Committee of the School of Healthcare Sciences, Cardiff University (3 December 2019) (Appendix 3-1). Ethical approval for Part 3 was obtained to conduct face-to-face focus groups; however, amendments were submitted to the Ethics Committee for permission to conduct online focus groups following the COVID-19 pandemic in 2020. The reason for this change was to minimise the risk of infection, in alignment with the lockdown restrictions of Cardiff University and the UK. Ethical approval following the above changes was obtained from the Ethics Committee of the School of Healthcare Sciences, Cardiff University (2 December 2020) (Appendix 3-2).

All participants in this thesis were fully informed about the studies. All personal data, including the responses to the online survey, the recordings of the online interviews and online focus groups, were stored securely in Cardiff University on a password protected computer. People’s names, locations or institutions were anonymised to protect confidentiality and were stored separately from the data. Access to the electronic database was restricted to the researcher (AA) and supervisors (LS, VS), the data will be retained for 5 years after the study’s completion and subsequently destroyed.

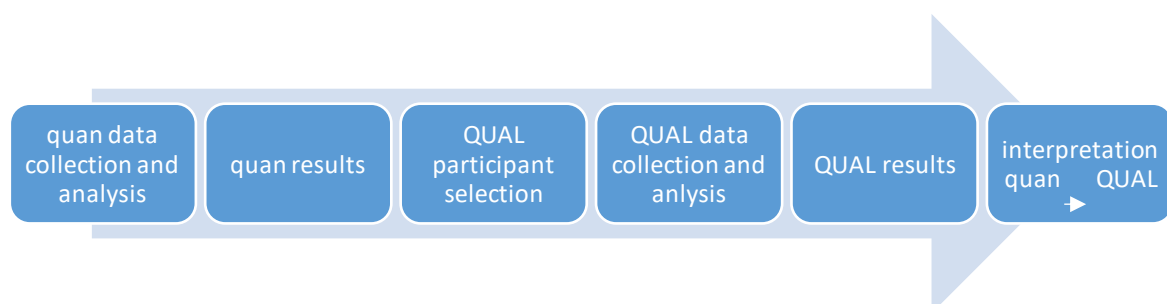
3.2.2.2.2 Data collection

- Part 2 – Sequential explanatory study

A sequential explanatory study was conducted in Part 2 to meet the second of the thesis objectives, engaging global stakeholders (healthcare practitioners and IVR technology developers) to gain an understanding of the current use of IVR in CP management. This study started with a quantitative online survey (Phase 1) and was followed by qualitative online semi-structured interviews (Phase 2) (Figure 3-1).

In mixed methods research, the sequential explanatory design has two types: follow-up explanations model and participant selection model (Creswell and Clark 2007). In the follow up explanations model, the qualitative data is used to explain or elaborate on the quantitative findings, in which the primary emphasis is often on the quantitative aspects. On the other hand, the participant selection model is employed when the researcher needs quantitative data to identify and purposively select individuals for the subsequent, in-depth qualitative study and the emphasis is on the qualitative study. In the current sequential explanatory study, the participant selection model was used (Creswell and Clark 2007) (Figure 3-3).

Figure 3-3 : Sequential Explanatory Design (participant selection model) (adapted from Creswell and Clark 2007, p.73)



Key: The use of the notation ‘quan’ and ‘QUAL’ is as per Creswell and Plano Clark (2007), who use capitalisation to indicate the relative emphasis of the qualitative phase.

The online survey (Phase 1) was designed to provide an overview about IVR utility as a treatment tool and to identify and purposively select those who use IVR in CP management. The use of IVR technology for CP is emerging and global stakeholders who are involved in the development and delivery are not yet known, thus it was deemed necessary to identify their characteristics using the online survey and quantify their use of technology prior to embarking on a deeper qualitative exploration. Subsequently, a subset of global stakeholders was interviewed online (Phase 2) to explore in depth the experiences and perceptions of those stakeholders on the current use of IVR in CP management. The data from the two phases were then synthesised. In mixed methods studies, the integration of the data from the different methods is essential at the interpretation stage (Creswell and Creswell 2018). Therefore, the findings of this sequential explanatory study were interpreted from the integration of quantitative data (Phase 1) and qualitative data (Phase 2), with greater emphasis on the latter.

- Part 3 – Qualitative study

The data from Part 1 and Part 2 including the content of IVR intervention, technological advances and delivery setting were used to create a PowerPoint presentation, informing the subsequent Part 3 study. In Part 3, a qualitative study of online focus groups was conducted to meet the third thesis objective, exploring the opinions and views of physiotherapists in the UK on the potential benefits, concerns, facilitators, and barriers to using IVR in CLBP management. The PowerPoint presentation was demonstrated to the physiotherapists during online focus groups.

3.2.2.2.3 Data analysis

- Quantitative data

The quantitative data of the online survey (Part 2/Phase 1) was analysed using descriptive statistics and the results reported as numbers and percentages (Portney and Watkins 2015).

- Qualitative data

The qualitative data, both online interviews (Part 2/Phase 2) and online focus groups (Part 3), were analysed using thematic analysis. Both thematic analysis and qualitative content analysis are systematic methods that are commonly used for analysing qualitative data with an underlying pragmatic approach (Savin-Baden and Major 2013). Historically the terms

‘thematic analysis’ and ‘qualitative content analysis’ have been used interchangeably, with confusion about their similarities and differences (Vaismoradi et al. 2013). In qualitative content analysis, systematic coding of textual data tends to produce categories which have similar meanings and rely on their frequent appearance in the text (Savin-Baden and Major 2013; Joffe and Yardley 2004). Thematic analysis or ‘reflexive thematic analysis’ also uses systematic coding to identify patterns or themes within data which capture the meaning related to the research question (Braun and Clarke 2006; Braun and Clarke 2013; Braun and Clarke 2021a).

Although both types of analysis appear to be parallel, the decision depends on the context of the research (Vaismoradi et al. 2013; Braun and Clarke 2021a). Qualitative content analysis usually focuses on the ‘content’ to report a common issue about sensitive phenomena, considering the frequency of participants’ words (Vaismoradi et al. 2013; Braun and Clarke 2021a). The qualitative content analysis has also been criticised for potentially removing the meaning from the data context as more frequent codes may not necessarily indicate its greater significance to the research question (Joffe and Yardley 2004). However, reflexive thematic analysis prioritises the meaning that data is intended to convey, and which is relevant to the research question, to provide a rich account of the data (Braun and Clarke 2021a). Also, it helps the researcher to answer questions that involve understanding the perspectives or needs of individuals about poorly explored events within healthcare practice such as: what are the concerns of people about the event? What kind of people benefit from a service and when do they use it? (Vaismoradi et al. 2013). These questions are in line with the objectives of this thesis, in which the researcher needs to explore various aspects adapted from the MRCF (e.g., benefits, target patients, delivery setting, facilitators, barriers), reflecting the complexity of IVR technology to be implemented as an intervention. Therefore, reflexive thematic analysis was the preferred method, it can provide rich insights into the complexity of the intervention by capturing the perspectives of global stakeholders and physiotherapists derived from the meaning of the collected data, rather than focusing on the frequency to describe a certain phenomenon as in the qualitative content analysis.

To conduct reflexive thematic analysis, two types of coding are usually adopted: inductive or ‘data driven’ and deductive or ‘theory driven’ (Braun and Clark 2013; Vaismoradi et al. 2013; Byrne 2022). In an inductive approach, the codes emerge from the data in response to the

specific questions that the participants were asked (Braun and Clark 2013; Byrne 2022). In contrast, the deductive approach tends to create codes which are driven by theoretical framework in the research area (Braun and Clark 2013; Byrne 2022). Consequently, the inductive approach results in themes identified within the meaning of what participants have said, while the deductive approach identifies underlying theorised themes (Braun and Clark 2013). As the use of IVR for CP and/or CLBP is novel and poorly explored area of research with no identified underpinning theory, the inductive approach was deemed appropriate to analysis the data of the online interviews (Part 2/Phase 2) and the online focus groups (Part 3) to identify themes that reflect participants' perspectives without imposing preconceived ideas or theories.

3.2.2.2.4 Rigour and trustworthiness

- Quantitative data

The quality of data in the online survey (Part 2/Phase 1) was assessed using pilot testing and face validity (Burns et al. 2008). The pilot testing improves the flow and identifies poorly worded questions (Burns et al. 2008). The face validity was evaluated by an expert in the field of IVR technology, reviewing the clarity of the included items and how likely they were to have addressed the IVR topic.

- Qualitative data

Assessing the quality of research, with qualitative data, is debated due to the nature of the knowledge generated and the criteria to judge the research method (Mays and Pope 2000). Nevertheless, four criteria need to be addressed by the researcher to ensure trustworthiness of qualitative data: 1) credibility, 2) transferability, 3) dependability, and 4) confirmability (Lincoln and Guba 1985; Shenton 2004; Connelly 2016).

1) Credibility

Credibility refers to assessing the confidence and accuracy of the research findings (Lincoln and Guba 1985; Shenton 2004; Connelly 2016). Several methods can be employed to ensure the credibility of the research study, these include identifying the researcher background and experience about the topic, member checking and triangulation (Shenton 2004; Connelly 2016).

In this thesis, the researcher has a physiotherapy background, with experience in treating patients with CLBP. The researcher's experience with VR technology is limited to an undergraduate project in Saudi Arabia, this examined 'the effect of Nintendo Wii therapy to improve upper extremity function for people with hemiplegia'. Although hemiplegic patients were a different population, this experience made the researcher aware of the benefits as well as the difficulties of using technology in healthcare. At the start of this PhD, several meetings were arranged with companies in the UK and other academic institutions outside the UK, looking for optimal IVR products for CLBP. Although the researcher was interested in using technology with this population, some of the IVR products raised concerns from the researcher point of view as a physiotherapist such as physical and usability concerns. These observations aligned with the researcher's interest to learn about the potential of using IVR for CLBP management. To enhance the researcher skills, the online interview (Part 2/Phase 2) and online focus group (Part 3) were piloted prior conduction.

Member checking refers to participants checking data accuracy at the end of data collection to ensure that their words accurately capture what they intended to say (Shenton 2004; Cypress 2017). As the researcher and some participants were not native English speakers, member checking was deemed necessary. The transcribed interviews (Part 2/Phase2) and focus groups (Part 3) were sent to the participants, and they were asked to read their transcript and add or clarify the provided data if they wished. They were given a maximum of ten days to respond, this ensured the data analysis process was not adversely affected.

Triangulation is the process of using two or more methods or data sources, in which the findings can be checked out by using one type of the data as a reference for another (Shenton 2004; Noble and Heale 2019). In the current thesis, multiple methods were used (i.e., scoping review, online survey, online interviews, and online focus groups) and different perspectives were gained including those of global stakeholders (Part 2/Phase2) and physiotherapists (Part 3). The triangulation was presented by reporting the summary of Part 1, Part 2 and Part 3 with commonalities and differences in the summary discussion of the thesis (Chapter 7).

2) Transferability

Transferability in qualitative research is the extent to which the findings are applicable to other situations or populations (Shenton 2004; Cypress 2017). This can be obtained through a detailed description of the methods including study context, the involved participants,

procedure of data collection and analysis to inform other investigators (Shenton 2004; Cypress 2017). A detailed description of the methods used for the online interviews (Part 2/Phase2) and online focus groups (Part 3) are reported in Chapter 5 and Chapter 6, respectively.

3) Dependability

Dependability refers to the consistency of the research findings over time and across different contexts, in which other researchers can replicate the study and obtain similar findings (Shenton 2004; Connelly 2016). This can also be achieved using a detailed description of the research methods (as reported in the transferability), as well as peer debriefing of a colleague who is not involved in the research project to help in the data analysis and interpretation (Connelly 2016). In this thesis, a subset of the transcribed interviews (Part 2/Phase2) and focus groups (Part 3) were coded by a colleague to enhance the data interpretation.

4) Confirmability

Confirmability refers to the neutrality and the extent to which the findings are free from potential bias or influence of the researcher (Connelly 2016; Cypress 2017). This can be achieved by maintaining reflexivity throughout the research process and demonstrating 'audit trail' (Shenton 2004; Cypress 2017). Reflexivity is defined as an ongoing process of the researcher's self-awareness to acknowledge their subjective role throughout the research (Finlay 2002; Darawsheh 2014). Practically, the researcher should describe the relationship or the extent of interaction with the participants, while being aware of how they could influence the process of data collection and analysis (Mays and Pope 2000; Tong et al. 2007).

During the work on this thesis, being reflexive comprises giving an opportunity to all participants to express their beliefs and views on the use of IVR and avoids the researcher's own views and opinions about the technology use. In addition, the researcher was aware of her position and relationship with the participants. In Part 2/Phase2, the online interviews were with global stakeholders who were previously involved in the development and delivery of IVR intervention for CP. The researcher acknowledges that her lack of experience using IVR with CP as well as her own concerns and views as a physiotherapist about usability of the technology may influence some prompts during the interviews. In Part 3, the online focus groups were with physiotherapists who had experience in treating CLBP. Having a similar

profession to the researcher helps to build trust and facilitate the data collection process. However, as the researcher becomes more knowledgeable from Part 2, they may be influenced by the global stakeholders' opinions. The researcher was aware of the importance of not projecting personal opinions, either to agree or disagree during focus groups that may influence physiotherapists' responses. Furthermore, reflective notes were taken following the data collection of the online interviews (Part 2/Phase 2) and the online focus groups (Part 3) as well as during the data interpretation (details in Chapter 5 and 6).

Finally, demonstrating 'audit trail' means to provide step by step description of the decision made during data collection and processing. In this thesis, step by step description was provided about the data processing of the online interviews and focus groups including gathering of codes, creating of themes and subthemes, this associated with examples on decision making throughout the analysis (details in Chapter 5 and 6).

Chapter 4: Part 1 – The use of immersive virtual reality in management of adults with chronic pain (Scoping review)

4.1 Introduction

As reported in Chapter 3, recent systematic reviews attributed the lack of a definitive conclusion on the effectiveness of IVR interventions, for patients with CP, to inconsistent results on the intended outcomes (e.g., pain, function) and the heterogeneity in CP conditions, the underlying mechanisms, and intervention components (software, hardware, and dose). In addition, none of the previous reviews delved into the mechanisms of action and the critical components of the software, hardware, or delivery setting, leaving a gap in understanding. Therefore, further in-depth investigations in the form of a scoping review for this technology-based intervention is deemed necessary.

A scoping review design is particularly relevant when literature has a heterogeneous nature, and the type of evidence is not consistent with conducting a full systematic review (Peters et al.2020). Also, scoping review is an exploratory type of knowledge synthesis where different study designs are included, it is a better choice compared with the systematic review when investigators need to map the available evidence to clarify gaps in knowledge and identify certain key factors in a particular research topic (Arksey and O'Malley 2005; Munn et al.2018). Essentially, there is still a need to review the studies which use IVR for CP management to address the gaps with regards to its application and to identify related key features. This includes a better understanding of how IVR mechanisms were applied, its impact on the intended outcomes and the theoretical basis underpinning these mechanisms. In addition to the effect on the intended outcomes, it is crucial to map these outcomes prior to using a newly developed intervention (Craig et al. 2008; Buhse and Mühlhauser 2015). Furthermore, it is important to identify patients' characteristics and specify the key features of the software, hardware, and dose as well as the setting and adverse effects. These investigations are crucial to inform the development and implementation of IVR intervention for patients with CP, as recommended by the MRCF (Craig et al. 2008).

In this chapter, a scoping review (Part1) was conducted to synthesise contemporary evidence and to map the theories underpinning the IVR mechanism of action in patients with CP as well

as the key features of IVR interventions including the software, hardware, dose, and setting. The methodological rigor (i.e., risk of bias/ study quality) of the included studies was not evaluated because it has already been performed by recent systematic reviews (Baker et al. 2022; Grassini et al. 2022; Goudman et al.2022). Also, assessing the quality of evidence or risk of bias is not common in scoping reviews which aim to map and identify the gaps in existing literature to direct future research (Munn et al.2018).

4.2 Review Design

The methodological framework by Arksey and O'Malley (2005) guides the protocol of this scoping review. It is a practical guide for the scoping review design, it consists of five stages which were followed in this chapter to map the literature and achieve overall results (Arksey and O'Malley 2005; Levac et al. 2010) including:

- 1) Stage 1: Clear identification of the review question.
- 2) Stage 2: Identifying relevant studies.
- 3) Stage 3: Eligibility criteria for the study selection.
- 4) Stage 4: Charting the data
- 5) Stage 5: Summary and report of the results.

4.2.1 Stage 1: Review question, aim and objectives.

The overall **scoping review question** is: How has IVR been used as an intervention for patients with CP?

4.2.1.1 Aim

To synthesise contemporary evidence to map the theories underpinning the IVR mechanism of action in patients with CP as well as identification of the key features of IVR interventions including the software, hardware, dose, and setting.

4.2.1.2 Objectives

To identify:

1. The type of study design.
2. The characteristics of patients with CP.
3. The IVR mechanisms, underpinning theories, and its effect on the relevant outcomes.
4. The IVR intervention components including software, hardware, and dose (frequency, duration, and number of sessions).
5. The setting of the intervention (e.g., home/clinic-based) and related factors (e.g., safety).
6. The overall intended outcomes of IVR intervention (e.g., pain intensity, function, disability).
7. The adverse effects (e.g., motion sickness).

4.2.2 Stage 2: identifying the relevant studies.

The health databases including CINAHL Plus, Medline, AMED, Embase, PsycINFO, ASSIA, Scopus, TripPro, CENTRAL and EmCare were searched. Since searching key journals was recommended by the Arksey and O'Malley (2005), two journals were screened including *Cyberpsychology, Behaviour and Social Networking* and *Frontiers in VR*. This step was essential for the current review to search for up-to-date work in the IVR field. All the databases were searched using search terms and keywords adopted from VR literature and the International Classification of Diseases (ICD-11) for CP (Treede et al. 2015) (Table 4-1). A manual search of reference lists of previously published systematic reviews was performed by the researcher. The search was not restricted by publication date but limited to English language literature. Initial searches were carried out between the 23rd and 30th October 2019, with an updated search on the 1st of August 2022.

Table 4-1: Search strategy

Search strategy
S1. Chronic pain
S2. "Pelvic pain" OR "nociceptive pain" OR "neck pain" OR "postoperative pain" OR "visceral pain" OR "shoulder pain" OR "muscle Pain" OR "knee pain"
S3. Chronic Primary pain
S4. Fibromyalgia
S5. Musculoskeletal pain
S6. "Back pain OR low back pain"
S7. Pain management
S8. Virtual reality
S9. "Virtual reality" OR "virtual exposure therapy"
S10. "Immersive virtual reality" OR "head mounted display"
S11. S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7
S12. S8 OR S9 OR S10
S13. S11 AND S12

4.2.3 Stage 3: Eligibility criteria

The included studies were selected based on the following inclusion and exclusion criteria.

4.2.3.1 Inclusion Criteria:

1. Studies with an experimental design such as RCT trials, quasi-experimental trails (i.e., controlled, or un-controlled trials) and case study with a single, two or three participants. This aids to scope the current work and directs more rigorous future research (Peters et al. 2020).
2. Studies which Involve adult participants >18.
3. Studies that include conditions with un-specified CP and chronic primary pain (CPP) persisting more than three months, including chronic musculoskeletal pain, widespread chronic pain and chronic visceral pain, as per the International Classification of Diseases (ICD-11) for CP (Treede et al. 2015).
4. Studies that deliver IVR as an intervention, through HMD or 3D glasses.

4.2.3.2 *Exclusion Criteria:*

1. Studies which involve children <18.
2. Studies that use IVR for acute pain management, including experimental pain, pain during surgical or medical procedures.
3. Studies that include conditions with chronic secondary pain (CSP) such as stroke pain, neuropathic pain, or phantom pain.
4. Studies that use IVR only as an assessment tool and not as intervention.
5. Studies that use non-IVR or semi- IVR, which delivered the intervention using flat computer screens or projectors (e.g., Nintendo Wii, Kinect X-box).

Studies identified in the searches were imported into bibliographic management software (Mendeley.com). Only full-text articles were obtained. Titles and abstracts were screened to identify articles that met the inclusion criteria. When it was not clear from the title and abstract whether an article should be included, the full text was reviewed before deciding on inclusion or exclusion using a data screening sheet (Appendix 4-1). The final decision on the studies selection was made by the researcher, with input from the supervisory team (VS, LS) regarding the inclusion and exclusion criteria.

4.2.4 Stage 4: Data Charting

According to Levac et al. (2010), the data extraction approach should be consistent with the purpose of the review. Thus, all relevant information pertaining to the objectives of this review was extracted from each study and shown in Tables (4-2) and (4-3).

4.2.5 Stage 5: Summary and report of the studies

The report of the results involved numerical counts of the studies, to summarise the results related to each objective reported in section 4.2.1. Also, the included studies were analysed to identify whether any factor was reported to have a negative or positive effect associated with the application of IVR to apply meaning to the summary results (Levac et al. 2010).

4.3 Results

The review included twenty-seven studies. The initial search in October 2019 identified 1,975 references, in which 12 full articles were included. The updated search in August 2022 resulted in inclusion of an additional fifteen studies. Details of study selection, inclusion and exclusion are presented in the PRISMA flow chart (Figure 4-1). Also, the key findings of this scoping review are presented in a summary diagram (Figure 4-2).

Figure 4-1: PRISMA flow diagram for the scoping review process

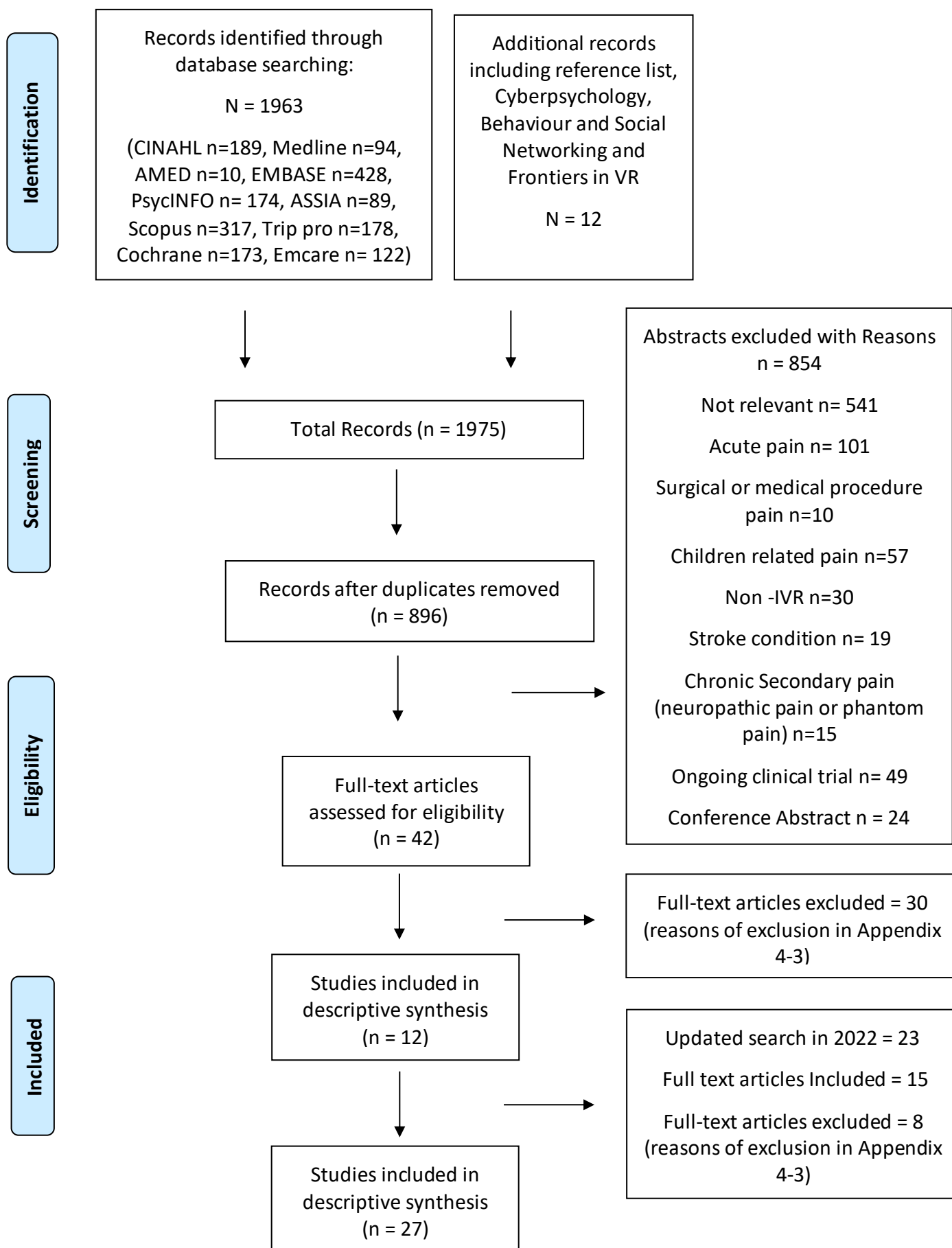
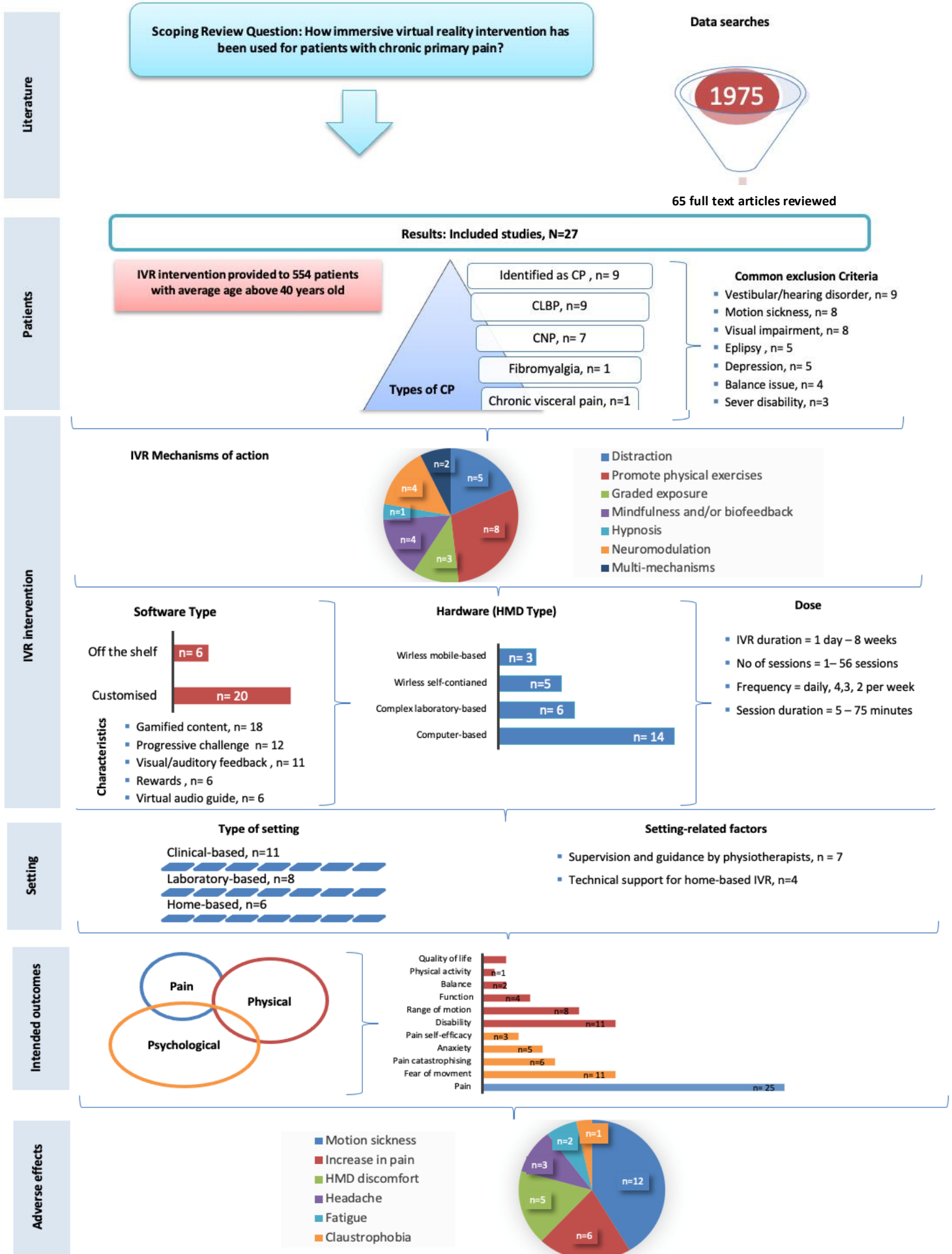


Figure 4-2: Summary of the key findings of the scoping review



4.3.1 Study Design

As shown in Table 4-2, most of the identified studies were pilot or feasibility studies which were frequently conducted in the USA (13/27). Studies were most commonly (14/27) in the form of controlled trials [RCTs (12/27), RCT cross-over (1/27), controlled trials (1/27)], with only 8 pre-post trials, 4 case studies and 1 randomised cross over trial. In addition to experimental data, 3 studies presented qualitative data on patients' experiences and ways to improve the IVR system (Garrett et al. 2017; Glavare et al. 2021; Zauderer et al. 2021).

Fourteen studies compared the effects of IVR intervention, either to the standard rehabilitation or to audio intervention or to placebo IVR (i.e., HMD involve 2D VE) (Wiederhold et al. 2014; Gromala et al. 2015; Sarig-Bahat et al. 2015; Jin et al. 2016; Sarig-Bahat et al. 2018; Darnall et al. 2020; Gulsen et al.2020; Tejera et al.2020; Garcia et al. 2021; Nusser et al. 2021; Jones 2021; Zauderer et al.2021; Eccleston et al.2022; Stamm et al.2022). Also, the IVR effect was compared to control groups which included no intervention in 4 studies (Thomas et al. 2016; Sarig-Bahat et al. 2018; Eccleston et al. 2022; Yalfani et al. 2022).

4.3.2 Characteristics of chronic pain patients

The studies included 979 patients, of which 554 patients were given IVR, with an average age above 40 years (19/27). Only two studies purposely examined older adults (Stamm et al. 2022; Yalfani et al. 2022). The studies were conducted either on specific clinical condition [CLBP (9/27), CNP (7/27), fibromyalgia (1/27), chronic visceral pain (1/27)] or conditions identified as having CP (9/27) (Table 4-2).

Few studies (6/27) reported screening patients by healthcare professionals (Soltani et al. 2011; Jin et al. 2016; Gulsen et al. 2020; Hennessy et al. 2020; Nusser et al. 2021; Stamm et al. 2022; Yalfani et al. 2022). However, the studies reported four main exclusion criteria in common: susceptibility to motion sickness (MS) (8/27), epilepsy (5/27), vestibular or hearing disorder (9/27), visual impairment (8/27), and severe or moderate symptoms of depression (5/27). Also, other studies excluded medical conditions/ severe disability which interfered with movement and/or balance in CNP (3/27), CLBP (3/27) and Fibromyalgia (1/27) (Table 4-2).

Table 4-2: General characteristics of the included studies in the scoping review (n=27)

Authors, year	Country	Design	Comparator	Characteristics of patients with CP		
				Excluded patients	Sample size	Age
Chronic Neck Pain (CNP), N= 6 studies						
Sirag-Bahat et al.2015	Australia	Pilot RCT	<ul style="list-style-type: none"> • Kinematic laser intervention 	<ul style="list-style-type: none"> • Vestibular/hearing disorder • Medical condition interferes with movement 	<ul style="list-style-type: none"> • Total N= 30 • IVR group = 16 • Laser group = 14 	<ul style="list-style-type: none"> • IVR group = 40 • Laser group = 41
Sirag-Bahat et al.2018	Australia	Single blinded - RCT (two phases)	<p>Phase 1:</p> <ul style="list-style-type: none"> • Kinematic laser intervention & no intervention <p>Phase 2:</p> <ul style="list-style-type: none"> • Kinematic laser intervention 	<ul style="list-style-type: none"> • Vestibular/hearing disorder • Epilepsy • Medical condition interferes with movement 	<p>Phase 1:</p> <ul style="list-style-type: none"> • Total N= 90 • IVR group =25 • Laser group = 26 • Control group = 25 <p>Phase 2:</p> <ul style="list-style-type: none"> • Total n= 92 • IVR group = 48 • Laser group= 44 	<ul style="list-style-type: none"> • IVR group = 38.5 • Laser group = 35.5 • Control group= 35.9

Nusser et al.2021	USA*	Pilot RCT	<ul style="list-style-type: none"> • Sensorimotor intervention (SMT) • Standard Rehabilitation 	<ul style="list-style-type: none"> • Vestibular/hearing disorder • Severe disability interfere with movement 	<ul style="list-style-type: none"> • Total N= 51 • IVR group = 17 • SMT group =16 • Control group = 18 	<ul style="list-style-type: none"> • IVR group = 51.2 • SMT group = 53.1 • Control group = 49.8
Chen et al.2017	USA	Pilot pre-post trial	<ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • Susceptibility to MS • Epilepsy • Depression • Visual impairment 	<ul style="list-style-type: none"> • N=9 	<ul style="list-style-type: none"> • IVR group = 58
Tejera et al.2020	USA	Single blinded-RCT	<ul style="list-style-type: none"> • ROM exercises 	<ul style="list-style-type: none"> • Vestibular/ hearing disorder 	<ul style="list-style-type: none"> • Total N= 44 • IVR group = 22 • Control group = 22 	<ul style="list-style-type: none"> • IVR group = 32 • Control group = 26
Zauderer et al.2021	France	Pilot pre-post trial	<ul style="list-style-type: none"> • Standard Rehabilitation exercises 	<ul style="list-style-type: none"> • Vestibular/ hearing disorder 	<ul style="list-style-type: none"> • Total N= 15 	<ul style="list-style-type: none"> • 52.8
Glavare et al.2021	Sweden	Pilot pre-post trial	<ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • Depression 	<ul style="list-style-type: none"> • Total N = 12 	<ul style="list-style-type: none"> • IVR group = 42

Chronic Low Back Pain (CLBP), N=9 studies						
Bolte et al.2016	Germany	Pilot pre-post trial	• None	• Visual impairment	• Total N =17	• 42.1
Thomas et al. 2016	USA	RCT	• No intervention	• Visual impairment	• Total N= 53 • IVR group = 27 • Control group = 26	• IVR group = 23.9 • Control group = 26.7
Trujillo et al.2020	USA	Case series	• None	• Susceptibility to MS	• N= 2	• 37 and 64 years
Harvie et al.2020	Australia	Single case study	• None	• N/R	• N=1	• 45
Hennessy et al.2020	USA	Pilot pre – post trial	• None	• Inability to stand for 15 min. • Medical condition interferes with balance	• N= 12	• 43-60
Garcia et al.2021	USA	Double- blind RCT	• Placebo non-IVR (2D visual effect)	• Susceptibility to MS • Epilepsy • Vestibular/ hearing disorder	• Total N = 179 • IVR group = 84 • Sham VR group = 84	• IVR group = 51.5 • Sham VR = 51.4

				<ul style="list-style-type: none"> • Depression • Visual impairment 		
Eccleston et al.2022	UK	Double blinded pilot RCT	<ul style="list-style-type: none"> • IVR sham • No intervention 	<ul style="list-style-type: none"> • Susceptibility to MS • Epilepsy • Depression • Medical condition interferes with balance 	<ul style="list-style-type: none"> • Total N= 42 • IVR group = 14 • IVR sham group = 17 • No intervention group = 11 	<ul style="list-style-type: none"> • IVR group = 55 • IVR sham group = 52 • No intervention group = 57
Stamm et al.2022	Germany	Pilot RCT	<ul style="list-style-type: none"> • Multi-model pain therapy 	<ul style="list-style-type: none"> • Susceptibility to MS • Vestibular/ hearing disorder • Visual impairment • Medical condition interferes with balance 	<ul style="list-style-type: none"> • Total N= 22 • IVR group = 11 • Control group = 11 	<ul style="list-style-type: none"> • IVR group = 75 • Control group = 75.5
Yalfani et al.2022	Iran	Double-blinded pilot RCT	<ul style="list-style-type: none"> • No intervention 	<ul style="list-style-type: none"> • Visual impairment 	<ul style="list-style-type: none"> • Total N =25 • IVR group = 13 • Control group = 12 	<ul style="list-style-type: none"> • IVR group=68 • Control group= 67.08

Fibromyalgia, N= 1 study						
Gulsen et al.2020	Turkey	Single blinded RCT	<ul style="list-style-type: none"> • Aerobic and Pilates exercises 	<ul style="list-style-type: none"> • Hearing disorder • Visual impairment • Medical condition interferes with movement 	<ul style="list-style-type: none"> • Total N = 16 • IVR group = 8 • Control group = 8 	<ul style="list-style-type: none"> • IVR group = 46 • Control group = 38
Chronic Visceral Pain, N= 1						
Soltani et al.2011	USA	Single Case study	<ul style="list-style-type: none"> •None 	<ul style="list-style-type: none"> •N/R 	<ul style="list-style-type: none"> •N = single case 	<ul style="list-style-type: none"> •55 years
Conditions Identified 'Chronic pain' N=9 study						
Wiederhold et al.2014	Belgium	Pilot Controlled trial	<ul style="list-style-type: none"> •Pain focus therapy 	<ul style="list-style-type: none"> •N/R 	<ul style="list-style-type: none"> •N = 40 	<ul style="list-style-type: none"> •22-68
Gromala et al.2015	Canada	Pilot RCT	<ul style="list-style-type: none"> •Audio record 	<ul style="list-style-type: none"> •N/R 	<ul style="list-style-type: none"> •Total N = 13 •VR group = 7 •Control group = 6 	<ul style="list-style-type: none"> • 49
Jin et al.2016	Canada	Pilot cross over RCT	<ul style="list-style-type: none"> • Distracting activities 	<ul style="list-style-type: none"> • Susceptibility to MS 	<ul style="list-style-type: none"> •Total N = 20 	<ul style="list-style-type: none"> • N/R
Jones et al.2016	USA	Pre – post trial	<ul style="list-style-type: none"> •None 	<ul style="list-style-type: none"> • Hearing impairment • Visual impairment 	<ul style="list-style-type: none"> •Total N = 30 	<ul style="list-style-type: none"> •50

Amin et al.2017	Canada	Randomized cross over design	•Compare Two types of HMD	• Susceptibility to MS	•Total N = 30	• 23-68
Garrett et al.2017	Canada	Case series	•None	• Susceptibility to MS • Epilepsy	•Total N = 8	• 51
Fowler et al.2019	USA	Pilot pre-post trial	•None	• Depression	• Total N= 16	• 49
Darnall et al.2020	USA	RCT	•Audio record	•N/R	•Total N = 74 •VR group = 35 •Audio group = 39	• N/R
Jones 2021	USA	Pilot controlled trial	•Biofeedback using medical device	•N/R	• Total N= 35 • IVR group = 23 • Biofeedback group = 12	• IVR group = N/R • Biofeedback group = N/R

*N/R= not reported, *USA= United State of America, *UK= United Kingdom, RCT =randomised controlled trial, IVR = immersive virtual reality, MS=motion sickness, HMD= head mounted display.

4.3.3 Mechanisms of IVR in CP management

As shown in Table 4-3, the identified studies used six distinct mechanisms for CP management, these included distraction (5/27), physical exercises (8/27), graded exposure (3/27), mindfulness and/or biofeedback (4/27), hypnosis (1/27), neuromodulation (4/27) and multi-mechanisms (2/27). None of the studies provided a clear theoretical basis underpinning these mechanisms. This section illustrates the way the studies used these mechanisms of action and the effect of IVR on relevant outcomes.

4.3.3.1 Distraction

Five studies utilised distraction, they focused only on pain outcome during and/or immediately after IVR (Wiederhold et al. 2014; Jones et al. 2016; Jin et al. 2016; Amin et al. 2017; Garrett et al. 2017). The IVR distraction was argued to work as an opioid alternative to control the acute pain episodes associated with CP (Jones et al. 2016; Jin et al. 2016; Amin et al. 2017). Two forms of distraction were used: active distraction which required patients to play a game in an interactive VE, and the passive distraction that had no interaction, patients were immersed in a relaxing VE.

Passive distraction was utilised by Wiederhold et al. (2014), the effect of IVR using relaxation to reduce pain and stress levels was evaluated only during a single session of 15 minutes (mins). Compared with the control group (CG), a significant reduction in pain and stress level was found when using IVR which claimed to induce the relaxation state. However, neither the content of the VE nor the intervention of CG was clarified. On the other hand, Jin et al. (2016), Jones et al. (2016) and Amin et al. (2017) employed active distraction using interactive games, where the analgesic IVR effect was assessed both during and after a single session. In Jin et al. (2016), the IVR effect was compared with distraction activities (e.g., reading), both for 10 mins. The IVR group were asked to play 'Cryoslide' game, where they hit creatures with snowballs in icy VE. Although IVR showed significant pain reduction during IVR when compared with the control group, no significant change in pain was reported after the session in either group. Jones et al. (2016) utilised a game called 'Cool', which enables patients to look around the VE and strike targets for 5 minutes, this showed a significant decrease in pain with an average reduction of 60% during IVR and 33% immediately after the session. Amin et al. (2017) compared the effect of two HMD types on pain level, either mobile-based (Google Cardboard) or computer-based (Oculus Rift), using the same VE of 'InMind' game, which

displays a journey in the human brain and asks the patient to shoot a specific target for 10 mins. The first group received IVR wearing an Oculus Rift followed by Google Cardboard, while the second group received IVR with the opposite HMDs order. Both HMDs showed significant pain reduction during IVR, but the use of Oculus Rift demonstrated a significant reduction post-IVR session.

In contrast to the above studies, Garrett et al. (2017) employed both passive and active distraction for multiple sessions over 4 weeks with a longer duration of 30 mins. The VE was not fully described, but the passive distraction involved relaxation which was delivered in the first and second week, the active distraction consisted of exploring VE and puzzle games which were provided in the third and fourth week. Findings showed no significant reduction in pain either post 6 hours or 24 hours or 4 weeks of IVR.

4.3.3.2 Physical exercises

Eight studies utilised IVR to promote the performance of physical exercise including motor control exercises and mobility/balance exercises (Sirag-Bahat et al. 2015; Sirag-Bahat et al. 2018; Gulsen et al. 2020; Tejera et al. 2020; Glavare et al. 2021; Nusser et al. 2021; Zauderer et al. 2021; Yalfani et al. 2022).

1) Promote motor control exercises

Six studies employed motor control exercises for patients with CNP (Sirag-Bahat et al. 2015; Sirag-Bahat et al. 2018; Tejera et al. 2020; Glavare et al. 2021; Nusser et al. 2021; Zauderer et al. 2021). They argued that being distracted from pain in VE of motor control exercises (i.e., ROM, stability, sensorimotor exercises, head-eye movement control) with induced visual feedback of the neck movement can enhance a patient's performance.

Two subsequent studies by the same research group compared the kinematic training (KT) using a gamified IVR to standard KT (via laser pointer mounted to the patient's head) at 4 weeks and 3 months follow-up (Sirag-Bahat et al. 2015; Sirag-Bahat et al. 2018). The IVR group controlled a virtual airplane for 20 mins using neck movement to train ROM, velocity, and accuracy, whilst the other group received standard KT for 30 mins, consisting of ROM, accuracy, velocity, and stability exercises (Sirag-Bahat et al. 2015; Sirag-Bahat et al. 2018). In Sirag-Bahat et al. (2015), both groups had the exercises in clinic while performing standard KT at home until they were assessed at 3 months. However, in Sirag-Bahat et al. (2018), both

groups received the exercises at home, in two phases: the 1st phase compared the effect of IVR to the standard KT and control group (i.e., no intervention) after 4 weeks, while the 2nd phase assessed the differences between IVR and standard KT after 4 weeks and 3 months follow-up. In both Sirag-Bahat et al. (2015) and Sirag-Bahat et al. (2018), there were no significant differences between IVR and standard KT in ROM, velocity, and accuracy. Although the IVR used in Sirag-Bahat et al. (2015) had some advantages in pain and disability after 4 weeks, the improvement could be attributed to standard KT assigned at home rather than IVR. Also, FOM was not changed in both studies for either group.

Tereja et al. (2020) evaluated the effect of IVR on cervical hyperalgesia, which has associated symptoms with neck pain and reduced ROM, anticipating that IVR may reduce hyperalgesia. The IVR was designed to perform ROM exercises using two VEs: 'Fulldive VR', which trained lateral flexion, moving to 'VR Ocean Aquarium' of flexion, extension, and rotation. The IVR impact was compared to standard ROM exercises after 4 weeks, 1 month, and 3-months follow-up, where both groups received 10 repetitions of 3 sets of each exercise. Both groups reported no change at any time points in the primary outcome of hyperalgesia. However, a significant reduction in secondary outcomes including pain, neck rotation, FOM, disability and catastrophising was shown in both groups at three time points. IVR showed significantly greater improvement in FOM within 3 months compared to standard ROM exercises.

Glavare et al. (2021), Nusser et al. (2021), and Zauderer et al. (2021) examined the effect of IVR as an adjunct to standard rehabilitation (SR), where VE consists of sensorimotor exercises (SM). These exercises were clearly described by Glavare et al. (2021) (i.e., ROM, predetermined figure of 8, head-eye control) and Nusser et al. (2021) (i.e., ROM, head repositioning and head-eye control), where a virtual object is controlled by neck movement to perform exercises within VE, however no details were reported by Zauderer et al. (2021). In Glavare et al. (2021), IVR was delivered for 20 mins in 12 sessions over 6 weeks during SR (i.e., combined psychological and physical therapy) and significant improvements were found in FOM, depression and quality of life (QOL), but pain, disability, or anxiety showed no significant change. Nusser et al. (2021) compared the effect of delivering 20 mins of IVR for 6 sessions with standard SM and SR. The standard SM was delivered for 30 mins over 4 sessions in a group format, while SR included both individual and group sessions of general and specific neck exercises. Nusser et al. (2021) found that IVR showed a significant increase in neck

extension and neck flexion/extension compared with standard SM and SR, respectively, but no significant differences were shown in pain, FOM or disability. Similarly, Zauderer et al. (2021) found no significant change in pain, ROM or disability, after IVR within 5 sessions and 3 months.

2) Promote mobility/balance exercises

The studies by Gulsen et al. (2020) and Yalfani et al. (2022) stated that motivation provided by IVR games for 8 weeks whilst being distracted from pain could induce the performance of mobility/balance exercises in patients with CLBP and fibromyalgia. Also, Yalfani et al. (2022) added that multi-sensory IVR games could place an emphasis on body balance control. The audio-visual feedback correlated with changes in range, and speed of body movement and repetitive motor action, restoring sensory-motor coordination and improving balance (Yalfani et al. 2022).

Gulsen et al. (2020) used 2 games “football” and “Dungeon” as adjunct to aerobic/Pilates exercises for Fibromyalgia, while Yalfani et al. (2022) employed 8 games: Fisher, Boxing, Tennis, Football, Bowling, Beat Saber, Audio-shield, and Skiing as a stand-alone IVR for patients with CLBP. Gulsen et al. (2020) reported that the use of IVR as adjunct for 20 mins showed a significant improvement in pain, FOM, fatigue, physical activity level and QOL compared with aerobic/Pilates exercises alone. Likewise, Yalfani et al. (2022) found that pain was significantly reduced and also the risk of falls, there was also an improvement in QOL of IVR used for 30 mins compared with no intervention.

In summary, the effect of IVR using physical exercises including motor control exercises and mobility/balance exercises on pain, FOM and physical outcomes such as ROM, disability, and quality of life holds promise mainly as adjunct in the short and intermediate term. However, VE does not have a significant impact when compared with standard exercises (i.e., similar to the one in the VE) and/or SR.

4.3.3.3 Graded exposure

Three feasibility studies reported the use of graded exposure within gamified VE, aiming to reduce FOM and avoidance behaviour in patients with CLBP (Thomas et al. 2016; Fowler et al. 2019; Hennessy et al. 2020). The graded exposure was informed by a Fear Avoidance Model in all the studies, but it was applied differently. Whilst Thomas et al. (2016) designed a game

which gradually exposed patients to lumbar flexion, Fowler et al. (2019) and Hennessy et al. (2020) built a hierarchy of games that were rated by the research groups to provide a graded challenge.

Thomas et al. (2016) utilised a 'Dodgeball game' which induced gradual lumbar flexion while catching /blocking a virtual ball within a virtual basketball arena. The lumbar flexion in each of 3 sessions was performed 90 times for 15 mins throughout 3 difficulty levels, starting from 15 degrees moving to 30 and 60 degrees. A significant increase in lumbar flexion was shown during the game, but no change in pain, FOM or lumbar flexion after the 3 sessions. Fowler et al. (2019) examined the effect of daily exposure to a hierarchy of 12 IVR games, as an adjunct to physical rehabilitation over 3 weeks. Although there was no detailed description of the included games, the hierarchy started with low intensity (i.e., relaxation), then gradually progressed to medium intensity (required head/neck movements) and ended with high intensity (required upper limb/trunk movements). The fourth intensity was added beyond the hierarchy to give patients autonomy to select favorite 'off the shelf' games. The study found that pain, pain interference with mobility, catastrophising, and function improved significantly, but no change was found in the primary outcome of FOM. Hennessy et al. (2020) developed a 'lucid' game, this consisted of hierarchy with 6 modules adopted from a photographic series of daily activities (PHODA), to practice real world activities across 3 sessions in 1 week. The activities of reaching, bending, and carrying weights were incorporated into VE to be performed while walking on a treadmill. Each activity was graded in difficulty from low (1st session), to medium (2nd session), and high intensity (3rd session) throughout the modules (further details in Table 4-3). The validity of the hierarchy was supported by patients with significantly higher avoidance and expected back pain for the high intensity modules compared with low intensity, however, no significant change was reported in either pain or in FOM.

4.3.3.4 Mindfulness and biofeedback

Mindfulness and biofeedback were employed within VE in four studies (Gromala et al. 2015; Darnall et al.2020; Garcia et al.2021; Jones 2021). The IVR mindfulness and biofeedback was used by Gromala et al. (2015) as a relaxation tool to reduce stress and pain. The VE named 'Virtual Meditative Walk' developed by Gromala et al. (2015) enabled patients to walk virtually through a foggy natural scene, whilst listening to relaxing instructions. Biofeedback

was presented as the disappearance of fog when patients reached a relaxation state that could be detected by a monitor. The group who received the IVR for 12 mins showed significant pain reduction after a single session, when compared with the audio group (i.e., relaxation instructions).

On the other hand, the IVR mindfulness and biofeedback developed by the AppliedVR company was used by Darnall et al. (2020), Gracia et al. (2021) and Jones (2021) as a home-based behavioural coping skill to address pain, pain interference either with activity, mood, or sleep, pain self-efficacy and catastrophising. AppliedVR developed applications entitled 'Pain care' and 'Ease VRx', these consisted of pain education, mindfulness, relaxation, and biofeedback training to regulate breathing rate (Darnall et al. 2020; Gracia et al. 2021; Jones et al. 2021). Darnall et al. (2020) and Gracia et al. (2021) compared the effect of daily IVR sessions of 15 mins to control groups over 3 and 8 weeks in turn. In Darnall et al. (2020), the use of 'Pain care' caused a greater reduction in pain and pain interference (with mood and sleep) compared to standard audio instructions, however, both groups showed a significant improvement in pain self-efficacy and catastrophising. Also, Gracia et al. (2021) found that 'Ease VRx' resulted in a greater reduction in pain, pain interference (with activity and mood) and improvement in function when compared with 'Sham VR' (i.e., 20 videos of a 2D non-interactive natural scene without skill training or relaxation), but no change in pain self-efficacy or catastrophising was shown in either group. Jones (2021) compared the use of 'pain care', to a standard biofeedback device (i.e., phone/tablet where patients interacted with the device through heart rate), over a period of 1 month, but patients had the freedom to explore 'off the shelf' IVR games, with no prescribed dose in either group. IVR showed a significant reduction in depression and catastrophising with no change in pain interference with activity, while the standard biofeedback device showed no change in any outcomes.

4.3.3.5 Hypnosis

A single study in this review employed hypnosis within VE for a patient diagnosed with chronic visceral pain (Soltani et al. 2011). The patient received a snowy 3D VE in 2 sessions of 30 minutes, this was associated with hypnotic suggestions including feeling relaxed, recalling of positive images and increased movement. A significant reduction in pain and anxiety was shown post 1 hour of the 1st and 2nd session.

4.3.3.6 Neuromodulation

The technology advancement of virtual embodiment and visual manipulation were assigned by 4 studies to help patients with CP through neuromodulation (Bolte et al. 2016; Chen et al. 2017; Harvie et al. 2020; Trujillo et al. 2020).

Virtual embodiment was used by Trujillo et al. (2020) and Harvie et al. (2020) for patients with CLBP, they assigned different forms of gamified exercises. Trujillo et al. (2020) engaged two patients in motor imagery exercise followed by functional exercises for 7 sessions of 20-45 minutes. In motor imagery exercise, patients observe a VA performing sit-to-stand tasks and they imagine performing it without physical performance, they were then encouraged to physically perform the task. The functional exercises involved 'graded' and 'corrective' while embodying a virtual hand and lumbar region, respectively. The 'graded' games facilitate lumbar flexion, extension, and rotation, while the 'corrective' games induced anterior, posterior, and lateral pelvic tilts. After each session pain was significantly reduced but there was no significant change in catastrophising.

Virtual embodiment associated with visual manipulation was employed by Harvie et al. (2020) in which a single patient practised 'body image training' for 4 weeks while embodying in athletically enhanced VA. Visual manipulation of body shape using an athletic avatar was claimed to improve distorted body image (DBI) (i.e., reduced perceived strength, with a sense of having a vulnerable body). The VE involved 3 games to practise general movement while embodying the upper body (i.e., head /hand movement) as a boxer, a superhero (Hulk) and a rock climber (further details in Table 4-3). Significant gain was reported in body image (perception of strength, reduced vulnerability) and pain during IVR, after each session, 1 week and 3 months. Also, pain self-efficacy improved within 1 week and 3 months. Disability showed a significant reduction at 3 months, but there was no significant change in FOM at any time point.

Visual manipulation was utilised in Bolte et al. (2016) and Chen et al. (2017), but manipulated visual feedback represented by giving an illusion of small rotation degree (i.e., back, neck) within VE while performing larger degree of rotation in the real world. This manipulation was believed to facilitate patients with FOM to practise movements and refute their negative beliefs (i.e., movement exacerbate pain). The game developed by Bolte et al. (2016) encouraged patients to catch a virtual basketball using back rotation and Chen et al. (2017)

designed a game to align the neck rotation with a virtual ball. The rotation of back and neck was performed initially at 45 degrees, the visual feedback was then manipulated showing 45 degrees in VE while encouraging rotation at 90 degrees and 50 degrees respectively in the real world. Although the studies illustrated the ability to increase back and neck rotation during the game with manipulated visual feedback, none of them assessed its effect on pain, rotation or FOM after IVR.

4.3.3.7 Multi-IVR mechanisms

Recent IVR advancement combined two mechanisms within VE for patients with CLBP (Eccleston et al. 2022; Stamm et al. 2022).

4.3.3.7.1 Physical exercises and psychoeducation

Stamm et al. (2022) implemented a multi-model approach combining physical exercises and psychoeducation in VE, this was delivered for 30 minutes over 4 weeks. Twelve types of exercises were integrated within gaming VE including warm up, strengthening exercises of core muscles, core stability exercises and cool down stretching exercises. Also, another VE provided psychoeducation about pain physiology, and stress management. In comparison, the control group received a group therapy of exercises and psychoeducation like those within the VE. Whilst the control group had significant pain reduction, the IVR group reported no change in pain. However, the IVR group showed significant improvement in function compared to the control group. In terms of FOM, none of the groups reported a significant change.

4.3.3.7.2 Embodiment and behaviour change

Eccleston et al. (2022) developed IVR based on cognitive behavioural therapy (CBT) and associated with virtual embodiment. Based on CBT, the core elements of IVR including immersion, interactivity and embodiment were employed to induce behavioural change in CLBP patients with FOM and a high level of disability. The VE had 24 different tasks which changed every 5 days over 8 weeks to overcome fear and increase movement, using behaviour change principles such as goal setting, repetitive tasks, pacing, feedback on movement and reward. The VE started with 'inside space' where patients were instructed by virtual mentor on pain/ avoidance behaviour, social/cognitive difficulties, problem solving tasks. The virtual mentor then asked patients to move to 'outside space' where they were

encouraged to play a 'fruit picking' game using an embodied virtual hand to accomplish a set of different movements at different intensities and ranges of movement. IVR resulted in a significant improvement in pain, FOM, disability after 8 weeks and 3 months. Compared to 'Sham IVR' (i.e., patients were asked to explore relaxing VE), superiority of IVR was shown in disability and FOM after 8 weeks, but no differences were shown post 3 months.

4.3.4 IVR intervention components

4.3.4.1 Software

Customised software was popular amongst the studies (20/27), while 'off the shelf' software was rarely (6/27) implemented. The software had common features across the studies including gamified content (18/27), progressive challenge (12/27), visual and/or auditory feedback on successful completion of tasks and/or exercises including the biofeedback on breathing rate (11/27), scores/rewards (6/27), and virtual audio guide (6/27).

The progressive challenge, visual feedback and rewards on task completion were reported to be a positive factor in patient motivation (Glavare et al. 2021; Yalfani et al. 2022). The progressive challenge had different forms, these included the range, direction, speed or complexity of the movement or exercise duration, of which 8 studies personalised the progression in level of movement or exercise duration to individual performance (Sirag-Bahat et al. 2015; Sirag-Bahat et al. 2018; Fowler et al. 2019; Gulsen et al., 2020; Trujillo et al. 2020; Garcia et al. 2021; Glavare et al. 2021; Nusser et al. 2021).

Most software for mindfulness and/or biofeedback, hypnosis and pain education involved a virtual audio guide to provide instructions on the required tasks (Soltani et al. 2011, Gromala et al. 2015, Darnall et al. 2020, Garcia et al. 2021, Eccleston et al. 2022, Stamm et al. 2022). For example, the virtual audio guide in Eccleston et al. (2022) had an extensive role within the software, this included guiding the patients to explore the VE, offering pain education, explaining the rationale of activity and avoidance behaviour, providing instructions on how to perform tasks and reinforcement cues.

4.3.4.2 Hardware

Several types of hardware were utilised, these included non-wireless and wireless HMDs with or without interactive devices. The use of computer-based HMDs (Oculus Rift, HTC vive, 5DT) was common (14/27) across the studies, of which Oculus Rift was the most frequently

reported (9/14). Six studies also reported the use of complex technology, such as laboratory-based, where HMDs were attached to a 3D TV or robot-like articulated-arm (Deep stream viewer). The wireless HMDs included the self-contained (5/27) (Oculus Quest, Pico G2, Oculus Go) and the mobile-based (3/27) (Samsung oculus gear, Google Cardboard, VR vox). Interactive devices (20/27) included hand controllers, infrared cameras, motion tracking sensors, particularly those which require positional tracking of the body movement as well as physiological sensors or microphones to track stress levels or breathing rate.

Five studies assigned two types of HMDs in the same study, and some reported essential clinical considerations. For instance, Amin et al. (2017) and Fowler et al. (2019) reported that the use of computer-based HMD (Oculus Rift) provided higher immersion and pain reduction compared with the mobile-based HMDs (Samsung Gear, Google Cardboard). In addition, the wireless self-contained HMDs (Oculus Quest and Pico) were reported to be more suitable and easier to use for home-based interventions (Harvie et al. 2020; Gracia et al. 2021)

4.3.4.3 Dose

As shown in section (4.3.3), the dose of IVR, including frequency, duration, and number of sessions, were highly varied across the studies even those who employed the same mechanism (e.g., graded exposure). The number of sessions ranged from a single session to 56 sessions, within 1 day to over 8 weeks and the duration ranged between 5 and 75 mins. The frequency reported a range between daily to two sessions per week. A rest period was noted in 6 studies that employed physical exercises, these ranged from 30 seconds to 15 minutes (Sirag-Bahat et al. 2015; Chen et al.2017; Sirag-Bahat et al. 2018; Tejera et al.2020; Gulsen et al.2020; Nusser et al.2021).

4.3.5 Setting and related factors

Clinical settings such as hospitals, clinics, rehabilitation centres (11/27) and laboratory settings (8/27), were the most common sites used. Home-based IVR was rarely implemented (6/27), but it was more common across studies which used IVR during the Covid pandemic.

Supervision, guidance by a physiotherapist and the technical aspect of IVR were frequently reported across thirteen studies. In clinical and laboratory settings, five studies reported that IVR intervention was supervised and represented the role of physiotherapist in guiding patients throughout the sessions (Harvie et al. 2020; Tereja et al. 2020; Glavare et al. 2021;

Stamm et al. 2022; Yalfani et al. 2022). For example, Harvie et al. (2020), Tereja et al. (2020) and Glavare et al. (2021) described how the physiotherapist guided patients during the performance of exercises, and provided instructions as needed. Also, a therapist in Stamm et al. (2022) had direct access to the software, they could set up exercises and monitor safety by detecting heart rate level and pausing the game when needed. Supervision and guidance were reported to play a role in safety, patient engagement, and adherence to IVR intervention, particularly those associated with physical exercises (Sirag-Bahat et al. 2018, Stamm et al. 2022, Yalfani et al. 2022).

The technical aspect of IVR was reported by 6 studies which implemented home-based interventions (Garrett et al. 2017, Sirag-Bahat et al. 2018, Darnall et al. 2020, Gracia et al. 2021, Jones 2021, Eccleston et al. 2022). This included specific eligibility criteria such as being familiar with technology, being able to wear HMD and resource availability, such as WIFI and computer (Garrett et al., 2017, Gracia et al., 2021). Essentially, the need for remote technical support was also reported (Garrett et al. 2017, Sirag-Bahat et al. 2018, Darnall et al. 2020, Gracia et al. 2021).

4.3.6 Intended outcomes and time to follow up.

As reported in section (4.3.3), the intended outcomes were varied among the studies in relation to the IVR mechanism. Overall, pain, physical and psychological outcomes were evaluated in short and intermediate terms, with a maximum of 3 months follow up. Pain (25/27), FOM (11/27) and disability (11/27) were the most commonly assessed outcomes across the studies. In addition, the studies evaluated other physical [i.e., ROM (8/27), function (4/27), balance (2/27), physical activity (1/27)] and psychological outcomes [i.e., catastrophising (6/27), anxiety (5/27), pain self-efficacy (3/27)].

Patients' experiences were also investigated (11/27), of which nine studies reported that game or virtual experience was feasible, engaging, and enjoyable (Jones et al. 2016, Fowler et al. 2019, Darnall et al. 2020, Garcia et al. 2021, Glavare et al. 2021, Nusser et al. 2021, Jones et al. 2021, Stamm et al. 2022). However, they also reported the negative aspects of IVR with regards to its usability such as technical issues (e.g., connection problem, unexpected stop of the game or hand controller) (Garrett et al. 2017, Jones 2021; Eccleston et al. 2022; Stamm et al. 2022) and other adverse effects (see section 4.3.7).

4.3.7 Adverse effects

The occurrence of adverse effects was reported in fourteen studies including: symptoms of motion sickness (MS) (12/14), HMD discomfort (9/14), increase in pain (7/14), fatigue (2/14), and claustrophobia (1/14). Whilst five studies reported that patients had no adverse effects, another 8 studies did not report whether the patients had any.

Symptoms of MS (dizziness and nausea) were the most common, of which four studies reported that patients developed MS even though those with susceptibility to sickness were excluded prior to the study (Jin et al. 2016; Garrett et al. 2017; Garcia et al. 2021; Eccleston et al. 2022). These symptoms were reported as a reason for poor engagement and dropouts (Jin et al. 2016; Garrett et al. 2017; Darnall et al. 2021; Glavare et al. 2021; Gracia et al. 2021). Whilst most studies which reported pain exacerbation during the intervention period did not provide specific reasons, two studies attributed that to challenging tasks as the physical limitations of the patients was not considered (Thomas et al. 2016; Hennessy et al. 2020). The HMD discomfort (i.e., headache, neck pain, eye strain) was a major complaint of the patients in 5 studies (Bolte et al. 2016; Fowler et al. 2019; Glavare et al. 2021; Nusser et al. 2021; Jones 2021). Also, patients who cannot tolerate wearing HMD were excluded from 5 studies (Jin et al. 2016; Amin et al. 2017; Garrett et al. 2017; Garcia et al. 2021; Zauderer et al. 2021).

Table 4-3: Summary of IVR mechanisms, IVR components, setting, comparators, intended outcomes, findings and adverse effects in the reviewed studies (n=27)

Authors, year	IVR components			Setting	Comparators	Intended outcomes & follow up	IVR effect / adverse effect Yes = significant improvement No = no significant improvement Yes/No = significant improvement but no significant differences to the comparators
	Software	Hardware	Dose				
Mechanism: Distraction							
Wiederhold et al.2014	<ul style="list-style-type: none"> • VE: - Pleasant and relaxing scenes (natural areas) • Tasks: - Exploring VE • Audio: relaxing music 	<ul style="list-style-type: none"> • HMD: N/R 	<ul style="list-style-type: none"> • IVR duration: 1 session • No. sessions: 1 session • Session duration: 15 mins 	<ul style="list-style-type: none"> • N/R 	<ul style="list-style-type: none"> • Pain focus session N/R 	<ul style="list-style-type: none"> • Intended outcomes: - Pain intensity - Heart rate and skin temperature • Follow up: only during 	<ul style="list-style-type: none"> • Pain intensity = Yes • Heart rate and skin temperature = Yes • Adverse effect: N/R

<p>Jin et al.2016</p>	<ul style="list-style-type: none"> • VE: <ul style="list-style-type: none"> - “Cryoslides” consists of sliding in the icy cave and sliding in the outdoor icy world. • Tasks: <ul style="list-style-type: none"> - Hitting different creatures showed in sequences in the icy environment with snowballs. - Cognitive tasks (memorizing a sequence of visual patterns and throwing a snowball on identifying a recurrent one) • Visual feedback: <ul style="list-style-type: none"> - Earning scores by hitting/memorizing - No punished for missing item 	<ul style="list-style-type: none"> • HMD: Oculus Rift • Headphones • Mouse 	<ul style="list-style-type: none"> • IVR <ul style="list-style-type: none"> duration: 1 session • No. sessions: 1 session • Session duration: 10 mins • Washout : 5 mins 	<ul style="list-style-type: none"> • Clinic 	<ul style="list-style-type: none"> • Self-mediated tasks including reading, playing mobile games, or listening to audiobooks 	<ul style="list-style-type: none"> • Intended outcomes: <ul style="list-style-type: none"> - Pain intensity - Pain distraction during IVR: - Time thinking about pain - Losing time track - Time thinking of unrelated things - Time of thinking inward • Follow up: during and immediately post session 	<ul style="list-style-type: none"> • Pain intensity: <ul style="list-style-type: none"> - During session = Yes - Post session = Yes / No • Pain distraction: <ul style="list-style-type: none"> - Time thinking about pain and losing track time = Yes - Time thinking of unrelated things & Time of thinking inward = Yes / No • Adverse effect: 3 dropouts / not all but some for nausea
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Jones et al.2016	<ul style="list-style-type: none"> • VE: • “Cool”: 3D caves environment. • Tasks: -Moving heads forward, left, right, above, below, and behind through a virtual landscape. -Performing small tasks (e.g., toss fish and orbs, hit flams and otters) • Visual Feedback: - No score / as they like • Auditory Feedback: - Sounds when tasks performed correctly 	<ul style="list-style-type: none"> • HMD: - Oculus rift - Deep Stream 3D viewer • Headphones • Mouse 	<ul style="list-style-type: none"> • IVR duration: 1 session • No. sessions: 1 session • Session duration: 5 mins 	• Clinic	• None	<ul style="list-style-type: none"> • Intended outcomes: - Pain intensity - Engagement - Dizziness • Follow up: during and immediately post session 	<ul style="list-style-type: none"> • Pain intensity - During session= Yes (60%) - Post session= Yes (33%) • Engagement = Yes (8.4/10) • Adverse effect: One participant had nausea
Amin et al.2017	<ul style="list-style-type: none"> • VE - “In mind VR”: rail-based first-person shooter (no avatar) • Tasks: - Journey in human brain. 	<ul style="list-style-type: none"> • HMD: alternate btw - Google cardboard - Oculus rift 	<ul style="list-style-type: none"> • IVR duration: 1 session • No. sessions: 1 session • Session duration: 30 mins. 	• Clinic	• None	<ul style="list-style-type: none"> • Intended outcomes: - Pain intensity • Follow up: during and immediately post each HMD use 	<ul style="list-style-type: none"> • Pain intensity: - During session = Yes using both HMD - Post session = Yes / oculus rift, No/ google cardboard.

	<ul style="list-style-type: none"> - shoot red enemy neurons to cured • Visual feedback: <ul style="list-style-type: none"> - The red neuron turned into green (success) 	<ul style="list-style-type: none"> • Google cardboard use Samsung galaxy note 4 	<ul style="list-style-type: none"> • Washout: 5 mins btw two HMD 				<ul style="list-style-type: none"> • Adverse effect: N/R
Garrett et al.2017	<ul style="list-style-type: none"> • VE: Passive IVR experiences <ul style="list-style-type: none"> - Travelled through the environment senzo peso). - Mindfulness and meditative introversion (sightline). Active IVR experiences <ul style="list-style-type: none"> - Exploratory (underwater environment, solar system and natural environment) - Problem solving (puzzles) • Tasks: N/R • Visual and auditory Feedback: N/R 	<ul style="list-style-type: none"> • HMD: Oculus rift • Hand controllers 	<ul style="list-style-type: none"> • Practice session :90 mins. • IVR duration: 4 wks • No. sessions: 12 sessions • Frequency: 3/wk • Session duration: 30 mins 	<ul style="list-style-type: none"> • Home 	<ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • Intended outcomes: <ul style="list-style-type: none"> - Pain intensity - Patients' experiences: Value of VR in pain management, VR experience and adverse effects. - Motion sickness • Follow up: post 6 h,24 h and 4 wks 	<ul style="list-style-type: none"> • Pain intensity = No • Patients' experiences <ul style="list-style-type: none"> - 5/8 experienced reduced pain during VR. - 1/8 reported increase in function. • Adverse effect: <ul style="list-style-type: none"> - 1 dropout due to MS - (5/8) had MS. - One had slight increase in pain. - 2 had minor claustrophobia

Mechanism: Physical exercises

Promote motor control exercises

<p>Sirag-Bahat et al.2015</p>	<ul style="list-style-type: none"> • VE: Virtual airplane controlled by neck movement. • Tasks: • ROM: <ul style="list-style-type: none"> - Move the neck to align virtual aeroplane with yellow target appeared in random different directions using neck flexion, extension, and rotation) - ROM completed: three consecutive failures to reach target. • Velocity: <ul style="list-style-type: none"> - move neck from neutral position to reach yellow ring target appeared in random direction within 7 sec before disappearing. 	<ul style="list-style-type: none"> • HMD: customised HMD + inner motion tracker system 	<ul style="list-style-type: none"> • IVR • duration: 5 weeks. • No. sessions: 4-6 sessions. • Frequency: 2-3/wk • Session duration: 15-20 mins • Rest: 2-3 mins btw kinematic measures. 	<ul style="list-style-type: none"> • Lab 	<ul style="list-style-type: none"> • Laser pointer mounted participant's head and projected to poster on the wall. • Tasks: <ul style="list-style-type: none"> - ROM in all directions - Velocity: quick head movement in between targets, - Stability: static head positioning while body moving - Accuracy: smooth head 	<ul style="list-style-type: none"> • Intended outcomes: <ul style="list-style-type: none"> - Pain intensity - FOM - Disability - Kinematics: ROM (HMD), Velocity, Accuracy - CNP Condition Change - Home exercise compliance - Patients' satisfaction - Motion sickness • Follow up: Post sessions 	<ul style="list-style-type: none"> • Post intervention: <ul style="list-style-type: none"> - Pain intensity, disability = Yes - Kinematics = Yes / No - FOM, CNP Condition Change = No - Exercises compliance = equal IVR and laser (3-5 times /week) • Post three months: <ul style="list-style-type: none"> - CNP Condition Change = Yes - Kinematics = Yes / No - Pain intensity, FOM, Disability, =No • Adverse effect: 4 dropouts due to MS
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	<p>Accuracy</p> <ul style="list-style-type: none"> - maintain head position (virtual airplane) as close as possible to moving yellow target either in vertical or horizontal line. <p>• Challenge (adapted according to individual patient):</p> <ul style="list-style-type: none"> - Positioning the target further away when successfully hit target. - Velocity practiced by reducing the lifetime appearance of the target - Accuracy practiced by increasing the velocity of the moving targets. - Positions were progressed from sitting, to standing and to dynamic positions on unstable surfaces 				<p>movement following a target</p> <ul style="list-style-type: none"> • Session duration: 30 mins • Supervised intervention + Home based laser training until 3 months 		<p>(two excluded, two withdraw)</p>
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	<ul style="list-style-type: none"> • Audio: N/R • Visual feedback <ul style="list-style-type: none"> - Change colour of target 						
Sirag Bahat et al.2018	<ul style="list-style-type: none"> • VE: Virtual aeroplane controlled by neck movement. • Tasks and challenges: <ul style="list-style-type: none"> - Similar to Sirag Bahat et al. (2015). • Audio: N/R • Visual feedback <ul style="list-style-type: none"> - Similar to Sirag Bahat et al. (2015) 	<ul style="list-style-type: none"> • HMD: Oculus Rift + 3D motion tracking 	<ul style="list-style-type: none"> • Practice session: 20 mins • IVR duration: 4 wks • No. sessions: 16 sessions • Frequency: 4/wks • Session duration: 20 mins (5 min ,4 times /day) 	<ul style="list-style-type: none"> • Home 	<ul style="list-style-type: none"> • Phase 1: <ul style="list-style-type: none"> • Laser pointer mounted. <ul style="list-style-type: none"> - Similar to Sirag Bahat et al. (2015) • Control group = no intervention • Phase 2: <ul style="list-style-type: none"> • Laser pointer mounted <ul style="list-style-type: none"> - Similar to Sirag Bahat et al. (2015) 	<ul style="list-style-type: none"> • Intended outcomes: <ul style="list-style-type: none"> - Pain intensity - FOM - Disability - Kinematics: ROM (HMD), Velocity, Accuracy - CNP Condition Change - Adherence to intervention • Follow up: <ul style="list-style-type: none"> Post sessions, 3 months 	<ul style="list-style-type: none"> • Post intervention: <ul style="list-style-type: none"> - Pain intensity, Kinematics = Yes - FOM, Disability, CNP Condition Change = No - Adherence to intervention = Laser comparator > IVR • Post three months <ul style="list-style-type: none"> - Pain intensity, Kinematics = Yes - FOM, Disability, CNP Condition Change = No • Adverse effect: <ul style="list-style-type: none"> - 8 dropouts (5 MS and headache , 3 increased pain)

<p>Tejera et al.2020</p>	<ul style="list-style-type: none"> • VE ‘Fulldive VR’: Living room with gallery of images. • Task: <ul style="list-style-type: none"> - Change images using bilateral neck lateral flexion - Motivation: new images each week. • VE ‘Ocean Aquarium’: ocean with marine animals. • Tasks: <ul style="list-style-type: none"> - Perform flexion, extension, and rotation to move forward and observe animals. • Challenge: <ul style="list-style-type: none"> - Move from simple Fulldive VR to more difficult VR Ocean Aquarium - ROM not challenging. 	<ul style="list-style-type: none"> • HMD: VR vox play glasses (mobile based) • Smartphone: LG 	<ul style="list-style-type: none"> • IVR duration: 4 wks. • No. sessions: 8 sessions • Frequency: 2/wk • Intensity of exercises: 3 sets / 10 repetitions of each ROM exercises • Session duration: N/R • Rest: 30 sec btw exercises. 	<ul style="list-style-type: none"> • Clinic 	<ul style="list-style-type: none"> • Standard ROM exercises - Flexion and Extension (assisted with ball between neck and wall). - Rotation and lateral flexion exercises. • Intensity: 3 sets / 10 repetitions of each ROM exercises (counted by therapist) • Rest :30 sec between exercises 	<ul style="list-style-type: none"> • Intended outcomes: Primary outcomes: <ul style="list-style-type: none"> - Pain intensity - Cervical hyperalgesia. Secondary outcomes: <ul style="list-style-type: none"> - ROM (Flexion, extension, rotation, lateral flexion) - FOM - Fear avoidance beliefs - Pain catastrophising - Anxiety - Disability • Follow up: post sessions (4 wks), 1 month, 3 months 	<ul style="list-style-type: none"> • Post intervention, 1 month ,3 months: <ul style="list-style-type: none"> - Pain intensity, Neck rotation, Pain catastrophising, Anxiety, Disability = Yes/ No - Cervical hyperalgesia = No • Post 3 months <ul style="list-style-type: none"> - FOM = Yes - Fear avoidance beliefs = Yes/No • Adverse effect: N/R
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	<ul style="list-style-type: none"> • Visual Feedback: Change image and move forward in VE. 						
Nusser et al.2021	<ul style="list-style-type: none"> • VE: virtual space associated with a virtual globe moving in predetermined pathways. • Tasks: performed using neck movement <p>Task 1: Head repositioning test and Head to target test</p> <ul style="list-style-type: none"> - Virtual globe led patient to 1 of 8 movement (flexion, extension, Lt&Rt rotation and diagonals in btw) - Patient asked to memorise the position. - Virtual globe disappeared. - return to neutral position and then to end 	<ul style="list-style-type: none"> • HMD: 5DT (computer-based) + motion tracking system 	<ul style="list-style-type: none"> • IVR duration: 3 weeks • No. sessions: 6 sessions. • Frequency: N/R • Session duration: 20 mins • Rest: 3 mins/btw tasks or in case of side effects 	• Hospital	<ul style="list-style-type: none"> • Sensorimotor group (SMG) (30 min/session) (4 group sessions): - Coordination skill exercises (e.g., passing an obstacle course, dribbling, rope skipping, tossing balls through rings) - Balance exercises (e.g single leg stance, standing with eye closed, and slacking) 	<ul style="list-style-type: none"> • Intended outcomes: <ul style="list-style-type: none"> - Pain intensity - Headache - ROM (Flexion, extension, rotation, lateral flexion) - Disability • Follow up: post sessions 	<ul style="list-style-type: none"> • Pain intensity = Yes / No • Headache = Yes • ROM <ul style="list-style-type: none"> - Flexion = Yes - Extension = Yes - Rotation = Yes / No - Lateral flexion = No • Disability = Yes / No • Adverse effect: None

	<p>position without virtual guide.</p> <p>Task 2: dynamic exercises</p> <ul style="list-style-type: none"> - Virtual globes move in predetermined pathways. - Track virtual object following 5 different pathways (flexion, extension, Lt&Rt rotation and diagonals in btw) <p>• Challenge (adapted according to individual patient)</p> <ul style="list-style-type: none"> - Increase range of motion from 30% to max 90% - Increase speed from 5 sec to 3 sec. <p>• Visual and auditory Feedback: N/R</p>				<ul style="list-style-type: none"> - Small games forms (e.g curling, juggling, throwing, and catching). - Partner games (table tennis, badminton) - (All above + standard rehabilitation program) <p>• Standard Rehabilitation group (SRG): (individual and group therapy of general and neck specific exercises) (duration varied according</p>		
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					<ul style="list-style-type: none"> - Strengthening - Mobilisation - Relaxation - Medical training - Functional gymnastic - Aqua therapy - Physical therapy - Tradition “back school” 		
Zauderer et al.2021	<ul style="list-style-type: none"> • VE: Sensorimotor exercises • Tasks: N/R 	<ul style="list-style-type: none"> • HMD: Kin Quantum (customized) 	<ul style="list-style-type: none"> • IVR duration: N/R • No. sessions: 5 sessions • Frequency: N/R • Session duration: N/R 	<ul style="list-style-type: none"> • Rehabilitation Centre 	<ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • Intended outcomes: • Primary outcomes: <ul style="list-style-type: none"> - Patients’ satisfaction - Patients’ acceptability • Secondary outcomes: <ul style="list-style-type: none"> - Pain intensity - ROM (Flexion, extension, rotation, lateral flexion) - FOM 	<ul style="list-style-type: none"> • Primary outcomes <ul style="list-style-type: none"> - Patients’ satisfaction = Yes (79/100) - Patients’ acceptability = Yes (75/100) - Experience = Fun, concentration, safety, and efficiency • Secondary outcomes

						<ul style="list-style-type: none"> - Cervical kinaesthetic sensibility - Disability <p>• Follow up: post sessions, 3 months</p>	<ul style="list-style-type: none"> - ROM = Yes (Flexion and left rotation) - Disability = Yes (post 3 months) - Pain intensity, Cervical kinaesthetic sensibility, FOM = No <p>• Adverse effect: None</p>
Glavare et al.2021	<ul style="list-style-type: none"> • VE: virtual disc controlled by neck movement in different scenes. <p>• Tasks:</p> <ul style="list-style-type: none"> - Task 1: 1 Move virtual disc using neck flexion, extension, and rotation in predetermined direction - Task 2: Move virtual disc through predetermined figure of 8 in 40 sec. 	<ul style="list-style-type: none"> • HMD: (N/R) mobile based 	<ul style="list-style-type: none"> • IVR duration: 6 weeks • No. sessions: 12 sessions • Frequency: 2 sessions/ week • Session duration: 20 mins 	<ul style="list-style-type: none"> • Hospital 	<ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • Intended outcomes: - Quality of pain rehabilitation (anxiety, depression, pain severity, pain related life interferences, life control and distress) - CP symptoms (pain, dizziness, nausea, stress, body/mental fatigue, difficulty relaxing) - FOM 	<ul style="list-style-type: none"> • CP symptoms post each session= worse • Post intervention: - Depression, pain related life interferences, life control, FOM, QOL, sleep problems = Yes - Pain severity, anxiety, distress, disability = No

	<ul style="list-style-type: none"> - Task 3: Eye gazing to move neck in different places to find the virtual disc in 20 sec <p>• Challenge (adapted to patient's performance):</p> <ul style="list-style-type: none"> - The difficulty of task 2 and 3 increased by: <ul style="list-style-type: none"> -increase ROM - increase speed - increase performance time. <p>• Visual feedback</p> <ul style="list-style-type: none"> - Line introduced how well movement followed suggested path. <p>• Auditory feedback: None</p>					<ul style="list-style-type: none"> - QOL - Sleep problems - Disability - Patient experiences <p>• Follow up:</p> <p>post each session, post sessions</p>	<ul style="list-style-type: none"> • Patient experiences = positive and negative • Adverse effect: Increase in pain, dizziness, and nausea
Promote mobility/balance Exercises							
Gulsen et al.2020	<ul style="list-style-type: none"> • VE 'Football game' • Task: - Counter a ball by hand or feet from different height. 	<ul style="list-style-type: none"> • HMD: Oculus Rift • Kinect sensors: 	<ul style="list-style-type: none"> • IVR duration: 8 wks • No. sessions: N/R 	• lab	• Aerobic and Pilates Exercises	<ul style="list-style-type: none"> • Intended outcomes: -Pain intensity -FOM -Balance 	<ul style="list-style-type: none"> • FOM = Yes • Pain intensity, Balance, Impact of Fibromyalgia, Fatigue, Physical

	<ul style="list-style-type: none"> • VE ‘Dungeon game’ • Tasks: <ul style="list-style-type: none"> - Tilt trunk right, left, forward and backward to avoid guillotines. - Standing on one leg or jump with both legs to avoid logs. • Challenge (adapted according to individual patient): • Football game <ul style="list-style-type: none"> - Increase ball speed. - Adjust ball directions. • Dungeon game <ul style="list-style-type: none"> - Adjust order of guillotines and logs • Visual feedback: <ul style="list-style-type: none"> - Recorded scores of performances 	<ul style="list-style-type: none"> - detect body movements • Harness system: <ul style="list-style-type: none"> -For patients’ safety 	<ul style="list-style-type: none"> • Frequency: 2/wk • Session duration: 20 mins (10 / each game) • Rest: 3 mins/btw tasks or in case of side effects 		<ul style="list-style-type: none"> • Aerobic Exercises using treadmill (30 mins) <ul style="list-style-type: none"> - Warm-up (5 mins) - Training at 60-80% heartrate (20 mins) - Cool down (5 mins) • Pilates Exercises <ul style="list-style-type: none"> - Warm up: Supine position warm up - Exercises increase in difficulty using different positions 	<ul style="list-style-type: none"> -Impact of Fibromyalgia -Fatigue -Physical activity -Functional exercise capacity -QOL • Follow up: post sessions 	<ul style="list-style-type: none"> activity, Function, QOL = Yes / No • Adverse effect: N/R
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					and elastic bands •Cool down: stretching exercises		
Yalfani et al.2022	<ul style="list-style-type: none"> • VE: different games Fisher, Boxing, Tennis, Football, Bowling, Beat Saber, Audio-shield, and Skiing. • Task: <ul style="list-style-type: none"> - Fisher: catch fish in sea island (target immersion and experience realistic VE) - Boxing: move body through punch, kick a virtual bag hanging in different directions (target strength, agility and flexibility) - Football: a goalkeeper catches a ball (target trunk movement, flexion and rotation) 	<ul style="list-style-type: none"> • HMD: HTC vive • Hand controllers 	<ul style="list-style-type: none"> • IVR duration: 8 wks • No. sessions: 24 sessions • Frequency: 3/wks • Session duration: 30 mins 	• Lab	• No intervention	<ul style="list-style-type: none"> • Intended outcomes <ul style="list-style-type: none"> - Pain intensity - Risk of fall - QOL • Follow up post sessions 	<ul style="list-style-type: none"> • Pain intensity, Risk of fall, QOL = Yes • Adverse effect: None

	<ul style="list-style-type: none"> - Beat Saber: use red/ blue virtual sword using both hands to hit away red /blue cubes with constant change of colour and direction (target trunk rotation and flexion) - Bowling: roll a bowling ball toward 10 pins (target trunk flexion, upper limb and impose force on legs) - Audio-shield: use two red and blue shields to deflect red/ blue balls using both hands with constant change of colour and direction (target cognitive function and increase reaction time) - Tennis: hit tennis ball toward target which graded in size and shape using two control sets (target trunk, upper and lower movement) - Skiing: bend body and rotate 						
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	<p>toward left or right to ski virtually (target coordination, balance and quick reaction)</p> <p>• Challenge:</p> <ul style="list-style-type: none"> - Games started from simple to more complex games <p>• Visual feedback:</p> <ul style="list-style-type: none"> - Text of success or failure appeared in the screen for 2 sec. 						
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Mechanism: Graded Exposure

Thomas et al. 2016	<p>• VE: Virtual basketball arena, 3rd person avatar.</p> <p>• Tasks:</p> <ul style="list-style-type: none"> - Block green ball by performing lumber flexion. - Avoid red ball either by Squat or lumber flexion. - Return to upright posture after each task. 	<p>• HMD: Samsung 3D shutter glasses (laboratory based)</p> <p>• Twelve reflective sensors (head, upper</p>	<p>• IVR duration: one wk</p> <p>• No. sessions: 3 sessions.</p> <p>• Intensity of exercises: each game level 2 sets of 15 reps</p>	• Lab	• No intervention	<p>• Intended outcomes:</p> <ul style="list-style-type: none"> - Pain intensity - Lumber flexion - FOM - Anxiety - Disability - Patients' experiences (game feasibility and safety) 	<p>• Lumber flexion = Yes(during) / No (post)</p> <p>• Pain intensity, FOM, Anxiety, disability = No</p> <p>• Patients' experiences = enjoyable but pain increased during the game.</p>
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	<p>• Challenge:</p> <ul style="list-style-type: none"> - Three levels start from low to high lumbar flexion by lowering the lurch of the ball to increase lumbar flexion. - Increase lumbar flexion in second session by 5% and in the third session by 10%. - Three levels completed in the same session. <p>• Visual and auditory feedback:</p> <ul style="list-style-type: none"> - Scoreboard tracked performance and cash rewards. - Crowd cheering, buzzers, and referee whistles. 	<p>arms, forearms, hands, trunk, pelvis, thighs, shanks, and feet)</p>	<p>(total 90 reps)</p> <p>• Frequency: 48h in btw sessions</p> <p>• Session duration: 15 mins</p>			<p>• Follow up: during and post sessions</p>	<p>• Adverse effect: Increase back pain during game</p>
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<p>Fowler et al.2019</p>	<ul style="list-style-type: none"> • VE “Distraction to exposure hierarchy”: 12th games - Low intensity (Distraction): mindfulness & visual imagery (minimal movement). - Medium intensity: virtual walking/swimming & controlling aircraft/watercraft (head & neck movement). - High intensity: 3D painting & music/rhythm based (torsos & upper limb movement). • Additional VE: - Fourth intensity: Self-select VR activities (fishing, basketball) • Challenge: - Start with low to high intensity. 	<ul style="list-style-type: none"> • HMD: alternate btw - Oculus rift (computer based) - Samsung oculus gear (mobile based) • Hand controllers 	<ul style="list-style-type: none"> • IVR duration: 3 wks • No. sessions: 21 sessions • Frequency: daily • Session duration: 20 mins 	<ul style="list-style-type: none"> • Hospital 	<ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • Intended outcomes: - Pain intensity - Pain interference with activities of daily living, mobility & negative affect - Function - FOM - Fear of Daily Activities - Pain catastrophizing - Patients’ experiences (facilitators, barriers and adverse effect) • Follow up: post the sessions 	<ul style="list-style-type: none"> • Pain, Pain Interference with mobility, Function, Fear of Daily Activities, Pain catastrophizing = Yes • Pain Interference with activity & negative affect, FOM = No • Adverse effect: - MS - Weight on neck (n=1)
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	<ul style="list-style-type: none"> - Each session (ask what intensity they want). <ul style="list-style-type: none"> • Tasks: N/R • Visual feedback: N/R 						
Hennessy et al.2020	<ul style="list-style-type: none"> • VE and Tasks: 1st & 2nd modules (low intensity) • 1st module: <ul style="list-style-type: none"> -Walking at preferred speed. - Reaching task: get rid of monster with one hand using sword. • 2nd module: <ul style="list-style-type: none"> - Walking quickly - Reaching task: save animals with one hand. 3rd & 4th modules (medium intensity) • 3rd module: <ul style="list-style-type: none"> - Walking at preferred speed. 	<ul style="list-style-type: none"> • HMD: HTC Vive • Hand controllers • Treadmill with special pelvic harness system • Camera with motion tracker 	<ul style="list-style-type: none"> • IVR duration: 1 wk • No. sessions: 3 sessions • Follow up: 3-5 days. • Session duration: N/R 	• Lab	• None	<ul style="list-style-type: none"> • Intended outcomes: <ul style="list-style-type: none"> - Validity of the developed hierarchy (Avoidance rank, excepted pain, expected concern for harming the back, perceived exertion) - Acceptability - Usability - Pain - FOM • Follow up: post the sessions 	<ul style="list-style-type: none"> • Validity, acceptability, and usability = Yes • Pain , FOM = No • Adverse effect: increase in pain during game.

	<p>-Reaching task: collect food and coins using two hands</p> <p>●4th module:</p> <ul style="list-style-type: none"> - Walking at preferred speed - Reaching task: explore using one hand - Bending task: crouch under trees and tunnels <p>5th & 6th modules (high intensity)</p> <p>●5th module:</p> <ul style="list-style-type: none"> - Walking at preferred speed - Reaching task: hold weighted sword with two hands - Bending: crouch under trees and tunnels. - Carry weight <p>●6th module:</p> <ul style="list-style-type: none"> - Walking quickly - Reaching task: hold weighted sword with two hands 						
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<ul style="list-style-type: none"> - Bending: use shield and bend to avoid enemies - Carry weight <p>• Challenges:</p> <ul style="list-style-type: none"> -Gradual transfer from low to high intensity -Increase walking speed, increase holding weight, increase movement difficulty. <p>• Visual/ auditory feedback: No score point</p>							
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Mechanism: Mindfulness and/or biofeedback

<p>Gromala et al.2015</p>	<p>• VE: “Virtual meditative Walk”: forest foggy environment.</p> <p>• Tasks:</p> <ul style="list-style-type: none"> - Meditation based stress reduction training audio track (instructions on relaxing & breathing) 	<p>• HMD: Deep Stream 3D viewer (3D glasses without head strap) (laboratory based)</p>	<p>• IVR duration: 1 session</p> <p>• No. sessions: 1session</p> <p>• Session duration: 12 mins</p>	<p>• Clinic</p>	<p>• Meditation-based stress reduction training audio track</p> <p>• Details N/R</p>	<p>• Intended outcomes:</p> <ul style="list-style-type: none"> - Pain intensity <p>• Follow up: post the session.</p>	<p>• Pain intensity = Yes</p> <p>• Adverse effect: N/R</p>
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	<ul style="list-style-type: none"> - Listen to audio while sensors record relaxing state. <p>• Visual Feedback: -As the stress level decreased and reach relaxing state, the fog disappeared, and the sound become more audible and spatial.</p> <p>• Virtual audio guide: instructions on breathing and relaxation</p>	<ul style="list-style-type: none"> • Biofeedback (GSR) sensors 					
Darnall et al.2020	<ul style="list-style-type: none"> • VE: “Pain Care” developed by Applied VR • Tasks: <ul style="list-style-type: none"> - Pain education: describe impact of thoughts/emotions on pain and techniques for regulation. - Relaxation training: breathing exercises with visual biofeedback of 	<ul style="list-style-type: none"> • HMD: Oculus Go • Breath amplifier 	<ul style="list-style-type: none"> • IVR duration: 3 wks • No. sessions: 21 sessions • Frequency: daily • Session duration: 15 mins 	<ul style="list-style-type: none"> • Home 	<ul style="list-style-type: none"> • Audio Group • Audio content matched the VR content without reference to visual content. • Audio record on sound cloud 	<ul style="list-style-type: none"> • Intended outcomes: <ul style="list-style-type: none"> - Pain intensity - Pain interference with activity, mood, sleep and stress. - Condition change - Pain self-efficacy - Feasibility (Engagement and Satisfaction) 	<ul style="list-style-type: none"> • Pain intensity, pain interference with activity, mood, sleep and stress = Yes • Condition change = No • Pain catastrophizing, pain self-efficacy = Yes/No

	<p>breath particles helping to slow/deep breathing.</p> <p>- Mindfulness: awareness of mind and body using somatic cues and thought release.</p> <p>• Visual Feedback: biofeedback of breathing rate</p> <p>• Virtual audio guide: instructions on breathing and relaxation technique</p>				<p>• 1 audio session daily (21 days)</p>	<p>- Motion sickness and nausea</p> <p>• Follow up: post sessions</p>	<p>• Feasibility (Engagement, Satisfaction) = Yes</p> <p>• Adverse effect: - MS (5 experienced sometimes , 1 often) - 17 % of full sample reported MS and dropout.</p>
Garcia et al.2021	<p>• VE 'EaseVR' created by Applied VR</p> <p>• Tasks: - Pain education: information about correlation of IVR and importance of skills for pain.</p>	<p>• HMD: Pico G2</p> <p>• Microphone for breath rate</p>	<p>• IVR duration: 8 wks</p> <p>• No. sessions: 56 sessions</p> <p>• Frequency: daily</p> <p>• Session duration: 16 mins</p>	• Home	<p>'Sham VR'</p> <p>• Visual: - 20 videos - Non-IVR (2D) - Nature environment with music</p> <p>• Task: - No skill training</p>	<p>• Intended outcomes: - Pain intensity - Pain interference with activity, mood, sleep, and stress - Physical function & sleep disturbance - Condition change - Pain catastrophizing - Pain self-efficacy - CP acceptance</p>	<p>• Pain intensity = Yes</p> <p>• Pain interference with activity, mood, stress = Yes</p> <p>• Pain interference with sleep = Yes/No</p> <p>• Condition change = Yes</p> <p>• Physical function & sleep disturbance = Yes</p>

<ul style="list-style-type: none"> - Relaxation: trained usefulness of progressive relaxation through progressive change in senses from active to calm scene. - Mindfulness: 3D videos with guided breathing to enhance relaxation. - Dynamic breathing: multiple levels of breathing biofeedback to enhance relaxation. - Distraction: interactive games shift focuses from pain. • Challenge: <ul style="list-style-type: none"> - Increase challenge when master skills. 					<ul style="list-style-type: none"> - Not for relaxing/ distraction / interactive 	<ul style="list-style-type: none"> - VR Satisfaction (ease of use, enjoyment, help coping, desire to continue) - Engagement (access to the device and duration of use) - Usability - Opioid use - MS - Adverse event • Follow up: Twice weekly, post sessions 	<ul style="list-style-type: none"> • Pain catastrophizing, Pain self-efficacy, CP acceptance = No • IVR satisfaction = Yes • Engagement = Yes/No • Usability = Yes/No • Opioid use = No • Adverse effect: <ul style="list-style-type: none"> - MS =VR group (7/72), 2 dropouts due to MS
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	<ul style="list-style-type: none"> • Visual Feedback: biofeedback of breathing rate and relaxation. • Virtual audio guide: voice over to guide pain education & breathing. 						
Jones 2021	<ul style="list-style-type: none"> • VE: “Pain Care” developed by Applied VR • Tasks: <ul style="list-style-type: none"> - Pain education, learning new psychological skills. - Biofeedback using patient’s breath to learn calming skills. - Distraction experiences in sunny beach • VE: Off the shelf app <ul style="list-style-type: none"> - National geographics (nature video) - Wonder land (interactive game). - YouTube videos 	<ul style="list-style-type: none"> • HMD: Oculus Go • One hand controller • Microphone for breath rate 	<ul style="list-style-type: none"> • IVR duration: 4 weeks - Details N/R according to patient desire 	• Home	<ul style="list-style-type: none"> • Biofeedback intervention (Unyte company) <ul style="list-style-type: none"> - Equipment connected to tablet or phone with sensors measuring HR. - Journey tailored to individual goals and making it harder or easier. 	<ul style="list-style-type: none"> • Intended outcomes: <ul style="list-style-type: none"> - Pain intensity and interference with life enjoyment and with general activity - Depression - Catastrophising - Patients’ experiences • Follow up. Post sessions 	<ul style="list-style-type: none"> • Depression, catastrophising = Yes • Pain interference with life enjoyment and with general activity = No • Adverse effect: <ul style="list-style-type: none"> - Discomfort and headache = (n= 7) - Fatigue = (n= 2) - Nausea = (n=2)

	<ul style="list-style-type: none"> • Visual Feedback: biofeedback of breathing rate 				<ul style="list-style-type: none"> - Interactive experiences created by signals of HR and encourage increase HR. - Increase HR result in success and reward. • No prescribed time. 		
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Mechanism: Hypnosis

Soltani et al.2011	<ul style="list-style-type: none"> • VE: - Snowy canyon 3D - Flying numbers from 1 to 10 in ascending order. - Ask to reach relaxing state at number 10 - Ask to close eye and imagine green valley. 	<ul style="list-style-type: none"> • HMD: (N/R) • Earphones (noise cancelling) 	<ul style="list-style-type: none"> • IVR duration: N/R • No. sessions: 2 sessions • Frequency: N/R 	• Hospital	• None	<ul style="list-style-type: none"> • Intended outcomes: - Pain intensity - Time spent thinking about pain. - Unpleasantness pain - Worst pain - Anxiety 	<ul style="list-style-type: none"> • Pain intensity, time thinking about pain, pain unpleasantness, anxiety = Yes
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	<ul style="list-style-type: none"> • Hypnotic suggestions provide through virtual audio guide: <ul style="list-style-type: none"> - Feel completely relaxed. - Imagine lying on back, breathing comfortably. - leave negative experiences, recall positive images and experiences from past. - immersed into comfortable sensation, improve pain, increase movements and participate in life. - Recommended change the experience of pain. - future without pain and imagine feeling of pain free. • Post hypnotic suggestions. <ul style="list-style-type: none"> - Descending order of floated numbers 10 through 1 		<ul style="list-style-type: none"> • Session duration: 30 mins 			<ul style="list-style-type: none"> - Nausea • Follow up: post 1 hour of each session. 	<ul style="list-style-type: none"> • Adverse effect: <ul style="list-style-type: none"> - Medication intake increased from day 1 to day 2.
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	- ascended back up to the snowy canyon						
Mechanism: Neuromodulation							
Bolte et al.2016	<ul style="list-style-type: none"> • VE: basketball arena • Task: <ul style="list-style-type: none"> - Using back rotation to align virtual ring with flying basketball - Rotate back without moving feet • Two task conditions: <ul style="list-style-type: none"> - Normal: perform 45-degree rotation - Manipulated: Asked to perform 45 degrees rotation but physically perform 90 degrees • Visual feedback: <ul style="list-style-type: none"> - Text of success or failure appeared in the screen for 2 sec. 	<ul style="list-style-type: none"> • HMD: Sensics zSight • Infrared camera • Sensors to detect movements of upper trunk and hip. 	<ul style="list-style-type: none"> • IVR duration: 1 session • No. sessions: one session • Intensity of exercises: 100 repetitions of each condition • Session duration: 12 mins 	• Lab	Healthy subject	<ul style="list-style-type: none"> • Intended outcomes: <ul style="list-style-type: none"> - ROM (back rotation) • Follow up: only during 	<ul style="list-style-type: none"> • Back rotation during IVR = Yes • Adverse effect: None

Chen et al.2017	<ul style="list-style-type: none"> • VE: virtual football and goal post. • Tasks: <ul style="list-style-type: none"> - Place neck in neutral position (sitting and facing forward) - Football appears in four random locations. - A goal post controlled by neck movement (flexion, extension, Lt, Rt rotation) to overlap the goal post with the football. • Two task conditions: <ul style="list-style-type: none"> - Normal: Asked to perform 45 degree of movement and physically perform 45 degrees. - Manipulated: Asked to perform 45 degrees but 	<ul style="list-style-type: none"> • HMD: Oculus Rift • Kinect: motion tracking within depth camera 	<ul style="list-style-type: none"> • IVR duration: 1 session • Intensity of exercises: 20 repetitions • Session duration: 75 mins • Rest: 15 mins/ btw exercises 	<ul style="list-style-type: none"> • Lab 	Healthy subjects	<ul style="list-style-type: none"> • Intended outcomes: <ul style="list-style-type: none"> - ROM (neck rotation) • Follow up: only during 	<ul style="list-style-type: none"> • Neck rotation during IVR = Yes • Adverse effect: N/R
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	physically perform 50 degrees						
Trujillo et al.2020	<p>Motor imagery exercise</p> <ul style="list-style-type: none"> • VE: Virtual avatar of whole body) • Task: Virtual sit to stand / first observed virtual avatar and then performed. <p>Graded exercises</p> <ul style="list-style-type: none"> • VE: (soccer, shooting and dish stack games) • Tasks: <ul style="list-style-type: none"> - Soccer: use lumber flexion & rotation to catch ball with virtual hand appeared in different location - Shooting: use lumber extension & rotation to shot arrows to target by virtual gun 	<ul style="list-style-type: none"> • HMD: HTC vive • Hand controllers • Trackers attached to lower back (limb and trunk position and movement) 	<ul style="list-style-type: none"> • IVR duration: N/R • No. sessions: 7 sessions • Frequency: N/R • Session duration: 20-45 mins (evenly between exercises) 	<ul style="list-style-type: none"> • Clinic 	None	<ul style="list-style-type: none"> • Intended outcomes: <ul style="list-style-type: none"> - Pain intensity - Pain catastrophizing (rumination, magnification, and helplessness) • Follow up: post each session and post sessions. 	<ul style="list-style-type: none"> • Pain intensity = Yes • Pain catastrophising = No • Adverse effect: N/R

	<ul style="list-style-type: none"> - Dish stack: use lumber rotation to grasp plates & stack in virtual counter. <p>Corrective exercise</p> <ul style="list-style-type: none"> • VE: virtual floating platform • Task: use ant, post, lateral pelvic tilt to roll a virtual ball. • Challenge (tailored to patient's performance): increase exercises duration when complete task successfully (first sessions 20 min– seven session 45 mins). • Visual feedback: <ul style="list-style-type: none"> - Scores awarded in soccer and shooting exercises when complete the task successfully. 						
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<p>Harvie et al.2020</p>	<ul style="list-style-type: none"> • VE: upper body avatar of Boxer, Superhero and Rock climber. • Tasks (1st clinic session): <ul style="list-style-type: none"> - Boxing game: make muscle pose, throw punches, punch virtual bag. - Superhero game: throw punches & muscle poses. - Rock climber game: scale virtual cliff. • Tasks (2nd & 3rd clinic session) <ul style="list-style-type: none"> - Patient preference/boxing - Punch virtual bag in different directions. - Spared with virtual coach. - Virtual boxing match (added in the 3rd session). 	<ul style="list-style-type: none"> • HMD: <ul style="list-style-type: none"> - Oculus Rift - Oculus Quest • Hand controllers 	<ul style="list-style-type: none"> • IVR <ul style="list-style-type: none"> duration: 5 wks - Clinic: 4 wks - Home: 1 wk • No. sessions: <ul style="list-style-type: none"> - Clinic: 3 sessions - Home: 6 sessions • Frequency: N/R • Session duration <ul style="list-style-type: none"> - Clinic: 15 mins - Home: 15 - 25 mins 	<ul style="list-style-type: none"> • Clinic / Home 	<p>None</p>	<ul style="list-style-type: none"> • Intended outcomes: <ul style="list-style-type: none"> - Pain intensity - Body image (Self-perceived strength, vulnerability, agility, confidence with activity) - Condition change - Pain Self- efficacy - FOM - Disability • Follow up: <ul style="list-style-type: none"> - Pain and body image (during, post each session, post 1 week, 3 months) - Condition change, pain Self- efficacy, FOM, disability (post 1 week, 3 months) 	<ul style="list-style-type: none"> • During, post, post 1 week, 3 months: <ul style="list-style-type: none"> - Body image and pain intensity = Yes • Post 1 week: <ul style="list-style-type: none"> - Condition change, pain self- efficacy = Yes - FOM, disability = No • Post 3 months: <ul style="list-style-type: none"> - Condition change, pain self- efficacy = Yes - FOM = No - Disability = Yes • Adverse effect: N/R
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	<ul style="list-style-type: none"> • Task (home sessions) <ul style="list-style-type: none"> - Autonomy to explore boxing game. • Visual Feedback: N/R 						
Mechanism: multi-IVR mechanisms							
Physical exercises and psychoeducation							
Stamm et al.2022	<ul style="list-style-type: none"> • VE: “ViRST” Farm gaming environment • Tasks: <ul style="list-style-type: none"> 12 games 1) Warm up exercises <ul style="list-style-type: none"> Marching on spot (lower limb) + rowing on lake (upper limb) 2) Strengthening exercises <ul style="list-style-type: none"> - Balloon bump (back extensor): bent forward and come back halfway using straight back. - Hurdles (Abs) / lift both feet in sitting and keep tension to jump over hurdle in VE. 	<ul style="list-style-type: none"> • HMD: HTC Vive • Two controllers • Trackers attached to feet 	<ul style="list-style-type: none"> • IVR duration: 4 weeks • No. sessions: 3 sessions / wk • Frequency: N/R • Session duration: 30 mins 	• Lab	<ul style="list-style-type: none"> • Multi model pain therapy (group therapy) (similar to IVR) <ul style="list-style-type: none"> - 12 Gymnastic exercises - Psychoeducation 	<ul style="list-style-type: none"> • Intended outcomes: <ul style="list-style-type: none"> - Pain intensity - FOM - Functional capacity - General physical and mental health - Immersion - Patients’ experiences (attractiveness, perspicuity, efficiency, dependability, stimulation, novelty) • Follow up: post sessions 	<ul style="list-style-type: none"> • Pain intensity, FOM, General physical and mental health = No • Functional capacity = Yes • Immersion = Yes • Patients’ experiences <ul style="list-style-type: none"> - Attractiveness, perspicuity = excellent - Efficiency, dependability, stimulation = good - Novelty = above average

	<p>3) Core stability exercises</p> <ul style="list-style-type: none"> - The bridge: bent forward and pull ropes of the bridge using controller. - Light bulbs: climb ladder by grasping rungs and screw light bulb with controllers - Shaking bottles: shake bottles with fixed shoulder blade until crotch pop (strengthen deep back muscle and improve stability) - Ball bucket: side stretch both arm and make up and down movement + lift one leg in standing. <p>4) Cool down / stretching exercises.</p> <ul style="list-style-type: none"> - Vegetable sorting: turn to right and left while sitting to sort vegetable (stretch serratus anterior) 						<p>• Adverse effect: N/R</p>
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	<ul style="list-style-type: none"> - Boiler: use controller to push one handle one up and other down (stretch latissimus dorsi and quadratus lumborum) - Apple tree: both arms above head and stretch upward. - Progressive relaxation: making a fist to grasp controllers, hold and release. <p>5) Psychoeducation</p> <ul style="list-style-type: none"> - Physiology of pain - Pain management - Stress management <ul style="list-style-type: none"> • Visual feedback: N/R • Virtual audio guide: dialog system guide user through exercises. 						
Embodiment and Behaviour change							
Eccleston et al.2022	<ul style="list-style-type: none"> • VE: “Inside space” summer cabin 	<ul style="list-style-type: none"> • HMD: Oculus Quest and Touch VR 	<ul style="list-style-type: none"> • IVR duration: 6-8 weeks 	<ul style="list-style-type: none"> • Home 	<ul style="list-style-type: none"> • Sham placebo: - VE similar to IVR but only 	<ul style="list-style-type: none"> • Intended outcomes: - Pain intensity - Pain interference 	<ul style="list-style-type: none"> • Post intervention - Condition change, FOM, disability = Yes

	<ul style="list-style-type: none"> • VE “Outside space” (Lakeshore for fruit picking activity) Pick and stack fruits from trees. • Tasks: <ul style="list-style-type: none"> - Working alliance / pain education, self-awareness, goal setting, pacing, positive reinforcement for engagement and activity. - Embodied reactivity / repeated full ROM activity (rational of movement and rewarded engagement) - Courageous engagement / education on avoidance behaviour, promote behaviour experiment to confront feared movement and reinforcement. 	<ul style="list-style-type: none"> • Two hand controllers 	<ul style="list-style-type: none"> • No. sessions: 5 sessions / week, 30 days • Session duration: 15 – 60 mins 		<p>instructed to relax and enjoy environment.</p> <ul style="list-style-type: none"> • Control group: <ul style="list-style-type: none"> - No intervention 	<ul style="list-style-type: none"> - FOM - Condition change - Disability - Quality of life - Pain medication - Adverse events (IVR related, unintended disease or injury, serious event such as death) - Patients’ experiences • Follow up: post sessions, 3 months. 	<ul style="list-style-type: none"> - Pain intensity, pain interference = Yes/No (Sham) - Quality of life = No had no change in all groups • Post 3 months: <ul style="list-style-type: none"> - Pain intensity, condition change FOM, disability = Yes/No (Sham) (no intervention) • Adverse effect: MS, back or extremity pain and headache. <ul style="list-style-type: none"> - Post sessions (17 mild, 25 moderates, 8 sever) - Post 3 months (5 mild, 6 moderates, 7 sever)
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	<p>- Mastery/ offered technique to promote problem solving, reflect on change and increase self-efficacy on change for common social and cognitive difficulties.</p> <p>• Challenge: Location and frequency of fruit appearance increase</p> <p>• Visual and Auditory feedback</p> <ul style="list-style-type: none"> - Growing plant to show progress of “fruit picking” activity. - Verbal rewarded progress. <p>• Virtual audio guide: ambient sound, mentor in a form of male voice.</p>						
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IVR = virtual reality, VE= virtual environment, HMD= head mounted display, N/R=not reported, None= no comparator or no adverse effects, mins= minutes, wks = weeks, sec=seconds, h=hour, MS=motion sickness, FOM=fear of movement, ROM=range of motion, CNP=chronic neck pain, QOL= quality of life, Reps= repetitions.

4.4 Part 1 - Discussion

The purpose of this review is to synthesise contemporary evidence to map the theories underpinning the IVR mechanisms of action in patients with CP and key features of IVR interventions including the software, hardware, dose, and setting.

The literature search yielded twenty-seven studies of which the majority were pilot/feasibility studies with a controlled design. The IVR interventions were delivered to CP patients, excluding a range of specific medical conditions. The IVR mechanisms of action included distraction, graded exposure, mindfulness and biofeedback, hypnosis, physical exercises, neuromodulation, and multi-mechanisms. The integration of these mechanisms within VE had no underpinning theories, and their applications were varied across the studies, primarily targeting pain, physical (i.e., ROM and function) and psychological (i.e., FOM, catastrophising, pain self-efficacy) attributes in short and intermediate terms. Customised software was frequently used, with different types of HMDs including wireless and non-wireless ones. The IVR interventions had no optimal dose, they widely took place in clinical/laboratory settings with some supervision and guidance from the physiotherapist. Although the IVR interventions showed promise, the usability of the interventions was adversely affected by symptoms of MS, HMD discomfort and technical issues.

4.4.1 Patient characteristics

The patients with susceptibility to MS, epilepsy, visual or vestibular impairments, symptoms of depression or balance issues were frequently excluded across the studies, this potentially reflects those who are at risk from receiving IVR intervention. These have been reported to some extent in technology and other related health literature (Schultheis and Rizzo 2001; Yildirim 2020; Health and Safety Warning 2021; Washburn et al.2021). The use of IVR technology can commonly cause the symptoms of MS (nausea or dizziness) and it is rarely associated with seizures (Yildirim 2020; Health and Safety Warning 2021), thus susceptible conditions may be better avoided. Additionally, patients with impaired vision or hearing may experience difficulty in tolerating the intense near display or the audio volume demands of the VE (Washburn et al.2021). The mental health condition of depression may be excluded for different reasons, Flower et al. (2019) reported that it could interfere with the patient's engagement in the intervention. Also, engaging those with mental health conditions in VE has

been ethically questioned in literature, emphasizing that intense visual and auditory stimuli may induce psychological harm (Schultheis and Rizzo 2001). Patients with balance problems were also excluded from the reviewed studies, mainly when the interventions promoted standing physical interactions (Hennessy et al. 2020; Eccleston et al. 2022; Stamm et al. 2022). The ability to maintain balance is essential to safely engage in fully immersive VE, as it may put patients at risk of falling (Washburn et al. 2021). Hence, these criteria seemed critical to enhance the engagement and safety of IVR implementation.

4.4.2 IVR mechanisms and intended outcomes.

In line with previous literature, the IVR mechanisms of action for CP patients included distraction and mechanisms beyond distractions such as graded exposure, mindfulness and biofeedback, hypnosis, physical exercises and neuromodulation (Matsangidou et al. 2017; Won et al. 2017; Gupta et al. 2018; Ahmadpour et al. 2019; Matalama-Gomez et al. 2019; Wittkopf et al. 2019; Austin. 2021; Chuan et al. 2021; Tack 2021; Trost et al. 2021; Baker et al. 2022; Bordeleau et al. 2021; Goudman et al. 2022). However, this review added recent studies which employed multi-mechanisms. Stamm et al. (2022) combined physical exercises with psychoeducation and Eccleston et al. (2022) supported embodiment with behaviour change.

4.4.2.1 Distraction

The reviewed studies which employed distraction reported pain reduction during and/or immediately after the IVR session, with lack of a long-lasting effect (Wiederhold et al. 2014; Jones et al. 2016; Jin et al. 2016; Amin et al. 2017). Distraction is a well-established IVR mechanism by theories, most importantly the gate control theory, to divert the attention away from pain stimuli (Gold et al. 2007; Maher and Gold 2009; Li et al. 2011). However, the findings of the reviewed studies confirmed the short-term pain reduction, which would be more appropriate for acute pain management. CP is a long-term disease that needs an intervention which focuses on function and quality of life, even though the self-reported pain is an end goal (NICE 2020). Therefore, it may not be the best option for CP management and other mechanisms may hold greater promise.

4.4.2.2 Mechanisms beyond distraction

The other mechanisms including graded exposure, mindfulness and biofeedback, hypnosis, physical exercises, and neuromodulation, might have the potential to address CP more

effectively than distraction. The use of physical exercises, graded exposure, and coping skills such as mindfulness, biofeedback, hypnosis have been recommended in CP management because they are not meant to treat pain directly, but to improve function and the ability to cope better with pain (Driscoll et al. 2021; NICE 2020). Also, the neuromodulation is a type of intervention which has been supported in CP management to induce cortical remapping and facilitate pain reduction (Daffada et al. 2015; Méndez-Rebolledo et al. 2017).

Despite the potential of these IVR mechanisms, the included studies integrated the mechanisms within VE with no underpinning theories and the application was inconsistent and, to some extent, inadequate across the studies to achieve the intended outcomes. For instance, the graded exposure within gamified VE for CLBP facilitated only lumbar flexion in Thomas et al. (2016), while Fowler et al. (2019) and Hennessy et al. (2020) developed a hierarchy of general movement or activities that were predefined as fearful movements by the research group. In clinical practice, the standard graded exposure therapy based on an individualised hierarchy that developed by patients where each one ranks their own fearful movement (Vlaeyen et al. 2012). Furthermore, the standard graded exposure usually took place over approximately 8–12 sessions for CLBP patients with FOM (Linton et al. 2008; Leeuw et al. 2008), but Thomas et al. (2016) and Hennessy et al. (2020) delivered only 3 sessions. Thereby, the lack of adequate application of the graded exposure in the reviewed studies may explain the lack of significant improvement in the primary outcome of FOM across the studies (Thomas et al. 2016; Fowler et al. 2019; Hennessy et al. 2020). Although the distraction feature of the gamified VE may have the potential to minimise the anxiety-provoking nature associated with standard graded exposure therapy (Trost et al. 2015; Tack 2021), the technology should offer solutions to build a virtual hierarchy predefined by patients' prior development and deliver IVR over a longer period.

In addition, Gromala et al. (2015) applied the coping skills of mindfulness and biofeedback and reported reduction in pain and anxiety immediately after a single session. Typically, in psychology, learning such a skill to mediate stress and manage pain requires multiple sessions over time (Hofmann and Gómez 2017). Therefore, the short-term pain reduction could be attributed to distraction rather than mastering a skill to cope with pain. The recent reviewed studies tackled this limitation by employing multiple sessions of IVR mindfulness and biofeedback over 3, 4 and 8 weeks, the studies showed some promising results in

psychological outcomes (i.e., pain interference with mood or activity, pain self-efficacy, catastrophising) (Darnell et al. 2020; Gracia et al. 2021; Jones 2021). However, limited information was reported on the virtual content and how patients practised these skills as home-based interventions, this may explain the discrepancy in the studies' findings. A detailed description of the intervention, particularly the remote intervention, has been considered crucial to improve its replication in future implementation (Hoffman et al. 2014; Rohn et al. 2022). As a result, further improvement in reporting the virtual content is imperative to fully capture the benefits yielded from such a mechanism.

The rationale for incorporating different forms of physical exercise within VE was to enhance patient engagement with physical exercise. Although the studies have shown promise, mainly as adjunct, in improving pain and physical outcomes such as ROM, function, disability and quality of life, the IVR has no great impact when compared to standard physical exercise. (Gulsen et al. 2020; Tejera et al. 2020; Nusser et al. 2021; Glavare et al. 2021; Yalfani et al. 2022). In addition, the assessment of engagement or long-term adherence is limited across the studies to support the added value of IVR over standard physical exercise. Two studies evaluated the engagement and adherence over the period of the intervention and reported that adherence to IVR was equal or less when compared with standard exercise (Sirag-Bahat et al. 2015; Sirag Bahat et al. 2018). In VR literature of neurological rehabilitation, the adherence over time needs to be assessed to support the added benefits of VR compared with standard rehabilitation (Rose et al. 2018). Consequently, the IVR integrated with physical exercise has potential in CP management, but the added benefits still need further investigation.

In terms of neuromodulation, the reviewed studies used virtual embodiment and visual manipulation, particularly in CLBP conditions, to address the misperception of back movement caused by neuroplastic changes which are associated with distorted body image, maladaptive beliefs of back vulnerability and protective behaviour (Bolte et al. 2016; Harvie et al. 2020; Trujillo et al. 2020). Trujillo et al. (2020) used a full body avatar to represent the patient and facilitated back exercises while embodying the lumbar region, this showed pain reduction after each of 7 sessions. Also, Bolte et al. (2016) manipulated the degree of back rotation, giving an illusion of lesser degree while performing larger degree in the real world. This caused a significant increase in back rotation during the game. However, these positive

findings may not reflect the neuromodulatory effect because the reduced pain after a single session or increased movement while inside VE could be attributed to the distraction nature of IVR. The brain neuroplasticity is highly dependent on the frequency and intensity of practice over time (Cheung et al. 2014). In CP management, neuromodulation interventions such as motor imagery or mirror therapy were usually delivered daily over 4 to 6 weeks, at least 10 mins every hour (Bowering et al. 2013; Wittkopf and Johnson 2017). This was also confirmed by the reviewed study of Harvie et al. (2020) which assigned the virtual embodiment and visual manipulation (using athletic avatar) for patients with CLBP over 5 weeks and showed improvement in the body image (perception of back strength, reduced vulnerability), self-efficacy and the reduction of pain and disability. Therefore, the advancement of virtual embodiment and visual manipulation need to be monitored over weeks to support its potential in producing neuromodulatory effect.

In contrast to all the reviewed studies, the recent investigation by Eccleston et al. (2022) employed IVR as a behavioural change intervention. The immersion, interactivity and embodiment of the VE were assigned to change the avoidance behaviour associated with CLBP patients who had FOM. The intervention was based on the well-known principles of behaviour change including goal setting, repetitive tasks, feedback, positive reinforcement, and reward. These principles have been shown to be effective in promoting behaviour change (Michie et al. 2013), thus, their inclusion may contribute to IVR success in reducing pain, FOM and disability post 8 weeks. This holds the potential to improve CP conditions which are associated with FOM or avoidance behaviour, however, further research is still needed to support this mechanism of action.

4.4.3 IVR intervention components (software, hardware, and dose)

The heterogeneous nature of software and hardware were indicated in previous systematic reviews, making the efficacy of IVR in the CP inconclusive (Mallari et al. 2019; Wittkopf et al. 2019; Goudman et al. 2022). However, in this review, the investigation into software and hardware focused on common key features presented across studies. The customised software was commonly used in the context of CP compared to the 'off the shelf' one, despite the fact that the latter is potentially less expensive. Potentially, most mechanisms were specifically adopted for CP management (e.g., graded exposure, coping skills), which require a custom developed software. Also, it might be preferable due to the individualised nature of

CP, in which some studies personalised the progression of movements/tasks upon individual performance. In previous reviews of VR and pain management, personalisation has been recommended as a crucial aspect to enhance the effectiveness of the intervention, considering individual differences in usability (Won et al. 2017; Pourmand et al. 2018; Spiegel 2018; Ahmadpour et al. 2019). The use of visual/auditory feedback on performance, rewards and virtual audio guide were also key features within the software. The integration of performance feedback and rewards has previously been recommended as an important factor to enhance patient engagement in VR rehabilitation (Lewis and Rosie 2012; Stamm et al. 2020).

Whilst a range of wireless and non-wireless HMDs were used for CP management, the non-wireless computer-based HMD (e.g., Oculus Rift) was the most common and might be a favourable option. Most CP software induced physical interaction which needed HMDs supported by high performance computers using hand controllers and sensors for motion detection. In pain management, the quality of the computer-based HMDs (e.g., Oculus Rift) has been reported to enable a high level of interaction and to influence the way patients perceived movement (Matsangidou et al. 2017; Won et al. 2017). The quality of Oculus Rift was also confirmed in this review, in which two studies reported that it provided greater immersion and longer analgesic effect compared to the wireless mobile-based HMDs (Amin et al. 2017; Fowler et al. 2019). Interestingly, the new technology advancement offered an easier option of wireless self-contained HMDs (e.g., Pico and Oculus Quest) which can also provide a level of interactivity through hand controllers (Harvie et al. 2020; Eccleston et al. 2022). However, these are newly released HMDs employed by recent studies and their quality compared to the computer-based ones has not yet been established.

In terms of dose, the duration and frequency of IVR intervention has no clear consensus but may depend on the mechanisms of action to achieve its intended outcomes. For instance, as previously mentioned in section 4.4.2, the graded exposure needs approximately 8 to 12 sessions to induce a change in FOM, function and disability. The use of IVR to address CP associated with physical and psychological limitations through graded exposure, mindfulness/biofeedback, physical exercises or altering brain plasticity through neuromodulation may require multiple sessions over a long period (Cheung et al. 2014; Darnell et al. 2020; Baker et al. 2022). In addition to the mechanisms of action, the use of IVR

still needs a level of consistency as a technology-based intervention considering other factors such as immersion, interactivity and embodiment. Therefore, further investigation is still required to identify the optimal dose.

4.4.4 Setting and adverse effects

The IVR interventions were frequently implemented in clinical and laboratory settings, some studies reported supervision and guidance by physiotherapists, with interventions rarely taking place in a home setting, mainly in response to the COVID pandemic. The supervised setting may be necessary when VE induced physical movement because it was essentially reported to maintain patient engagement and motivation throughout the intervention (Sarig-Bahat et al. 2018; Stamm et al. 2022). The importance of supervision was also highlighted in the VR literature, it enhances engagement and the effectiveness of therapeutic exercises in chronic musculoskeletal conditions (Lin et al. 2019). Although the technical aspects of IVR are not mentioned in earlier reviews, the technical maturity of the IVR setting appeared to be critical such as the availability of technology resources (e.g., WIFI or computer) and the need of technical support, particularly when IVR was implemented in the home setting.

The technical issues and the adverse effects including MS symptoms (dizziness and nausea), pain exacerbation, fatigue and the associated discomfort of wearing HMD (headache and eye strain) interfere with the usability of the intervention, leading to poor engagement and dropouts. The MS refers to the feeling of nausea, dizziness and disorientation either during or after IVR intervention and it has been a prevalent issue in research using a range of HMDS (LaViola 2000; Yildirim 2020; Caserman et al. 2021). In pain management, the feeling of MS and discomfort from the HMDs heavy weight have been reported as the main adverse effects (Won et al. 2017; Lin et al. 2019; Baker et al. 2022).

While the reported engagement and enjoyment across the studies is encouraging, the risk of adverse effects as well as the technical issues and the need for technical support seemed to be problematic, this could influence the uptake of technology in CP management. Further, these issues cannot rule out the need for supervision and practitioner support which could reduce the potential benefits of IVR as a home-based intervention to aid remote CP management.

4.5 Part 1- Strengths and Limitations

This scoping review was strengthened by using a systematic search to identify relevant literature and by following the methodological framework by Arksey and O'Malley (2005) to enhance the review structure. The contribution of this review to the field of IVR and CP management was an additional strength, identifying the key features of this novel intervention as well as discussing the mechanisms of action and its effect on the intended outcomes, as recommended by the MRCF. This aids in understanding the gap in development and implementation of the intervention, and to direct future research. The supervisory team (LS, VS) was engaged in the review through multiple discussions about the eligibility criteria and uncertainties related to study selection or data extraction, which improved the scoping process and reduced potential bias.

However, some limitations are present such as the exclusion of non-English studies, which may have given additional insights on the use of IVR in CP management. Also, limiting the inclusion to chronic primary pain or un-specified CP may be criticised for narrowing the scope of search, despite the fact that this was for the purpose of the PhD thesis. Given that this thesis focused on CLBP, which is commonly classified as chronic primary pain, excluding chronic secondary pain (phantom pain, neuropathic pain) was seen necessary since these conditions have distinct pathophysiology and treatment approaches.

4.6 Part 1 – Summary and future implications

This scoping review synthesises the IVR mechanisms of action in patients with CP and the key features of IVR interventions including software, hardware, dose and setting. Several mechanisms of action for CP were identified including distraction, graded exposure, coping skills, physical exercise, neuromodulation, and behaviour change. While distraction supported only immediate pain relief, the other mechanisms have the potential to improve physical and psychological outcomes in the short and intermediate term. Nevertheless, these are not yet well-established with no underlying theories.

The custom-developed software which was associated with visual feedback on patient performance and rewards were commonly used, and a wide range of wireless and non-wireless HMDs were employed with no clear consensus on the optimal duration or frequencies. The IVR interventions were implemented more frequently in clinical or

laboratory settings, with few instances of supervision and practitioner guidance, other than in the home setting, despite the latter remaining a feasible option. The implementation of the interventions in either setting was associated with multiple adverse effects, most notably MS and HMD discomfort, with the home setting having the greater incidence of technical challenges.

Despite the potential of IVR in CP management, the use of this technology is still in its infancy and needs further investigation to inform the development and implementation of the intervention. Future research should pay more attention to understand who the most appropriate patients are and how to gain the most benefit from IVR mechanisms. Given the highlighted key features of the software and hardware, further exploration is needed to provide a clear picture on how to enhance patient experience and the effectiveness of the intervention. In addition, some key questions remain to be addressed about optimal dose as well as the most appropriate setting and contextual factors for IVR implementation. As technology is rapidly developing and becoming increasingly accessible, home setting has potential for the future. However, the prevalence of adverse effects requires further investigation into prevention methods and safety measures to minimise the risks and enhance the IVR uptake for CP management.

Chapter 5: Part 2 – Engagement of global stakeholders to gain understanding on the current use of immersive virtual reality for chronic pain (Sequential explanatory study)

5.1 Introduction

In Chapter 4, the scoping review (Part 1) mapped the current IVR interventions for CP conditions. The review revealed distinct IVR mechanisms with little theoretical basis underpinning the rationale for use. Furthermore, the pool of identified key features of the software, hardware, and settings from the existing IVR interventions is limited, with no agreement on the optimum duration or frequency of the intervention and several adverse effects that raise concern about the safety of IVR. Therefore, further exploration is necessary to understand how to maximise the benefits of IVR intervention, identifying the key factors relating to technology, dose and delivery setting as well as additional insight on patient characteristics and associated harm. There is also a need to determine the factors that contribute to successful adoption of IVR, encompassing both facilitators and barriers. As recommended by the MRCF, obtaining such knowledge from stakeholders' perspectives is deemed necessary to inform the development and implementation of the intervention (Craigie et al. 2008).

The updated search of the literature (August 2022) revealed a growing initiative, looking into the key factors for development and implementation of IVR in CP management from the perspectives of stakeholders. The known factors thus far have been limited to three research papers which use different methods (Dongean et al. 2020; Stamm et al. 2020; Sarker et al. 2021). Dongean et al. (2020) was a perspective paper based on the researcher's own experiences with IVR intervention for patients with CP, while Stamm et al. (2020) conducted a qualitative study which interviewed 5 healthcare practitioners (3 physiotherapists and 2 psychotherapists). Both Dongean et al. (2020) and Stamm et al. (2020) provide the following key suggestions to enhance the utility and benefits of IVR interventions for patients with CP: 1) personalised virtual tasks, 2) technology specification (software, hardware), 3) patient education, 5) the delivery setting, supervision, and safety

- 1) Personalised virtual tasks: the virtual tasks suggested to be tailored to patient's preferences and functional limitations (Dongean et al. 2020; Stamm et al. 2020). Considering individual preferences with the inclusion of familiar VE that depict real world activities could enhance the sense of presence (Dongean et al. 2020). Furthermore, the amount and type of movements in the VE should be tailored to the functional limitations by assessing the range of movement prior the intervention to avoid exacerbation of patient's symptoms (Dongean et al. 2020; Stamm et al. 2020).
- 2) Technology specification (software, hardware): the software was recommended to involve positive feedback on performance and rewards to enhance patient engagement (Stamm et al. 2020). In terms of the hardware, it was considered crucial to have a user-friendly hardware and encourage patients to report any neck pain they experience while wearing the HMD (Dongean et al. 2020; Stamm et al. 2020).
- 3) Patient education: the education of patients has been noted to be essential, especially for elderly, to eliminate fear and foster confidence when using new technology (Dongean et al. 2020; Stamm et al. 2020). Suggestions include giving patients some time with the practitioner before the intervention to provide instructions and navigate the VE as well as brief demonstration within the software on how to use the system (Dongean et al. 2020; Stamm et al. 2020).
- 4) The delivery setting, supervision, and safety: the delivery of IVR was suggested to take place in a room with sufficient space and minimal noise (Stamm et al. 2020; Dongean et al. 2020). For safety, limiting the time within the VE to 15 mins and taking breaks throughout the intervention were suggested to reduce the risk of fatigue and MS (Dongean et al. 2020; Stamm et al. (2020). Taking safety measures in the delivery setting were recommended, integrating the emergency button within the software to enable practitioners to give support in the case of MS (Stamm et al. 2020). Also, hygiene was reported as an essential factor for safety, highlighting the need for disinfection between the patients in the clinical setting (Dongean et al. 2020).

In addition, Sarker et al. (2021) identified the factors that influence the adoption of IVR for CP management, interviewing 15 stakeholders (healthcare practitioners, digital managers, medical managers, and research directors). Several facilitators and barriers have been identified in relation to IVR implementation in the clinical setting. The reported facilitators include the opportunity to use alternatives to pain medication, the need for practitioners who are more open to adopting innovation. On the other hand, lack of personalisation to address diverse patient needs, cost and lack of insurance coverage, practitioner unfamiliarity with technology as well as their limited time and availability were identified as significant barriers to IVR adoption.

While these studies provide valuable insights, additional investigations involving stakeholders is needed to inform the development and implementation of IVR for CP management. This chapter presents Part 2 of the thesis, engaging global stakeholders (healthcare practitioners and IVR technology developers) to gain an understanding of the current use of IVR in CP management. A sequential explanatory design was conducted, this started with an online survey (Phase 1), followed by online interviews (Phase 2), the data from both phases were integrated and synthesised in the discussion.

5.2 Part 2/Phase 1: Online Survey (The utility of immersive virtual reality in healthcare)

5.2.1 Aim and objectives.

This survey aimed to:

- 1) Identify the current state of IVR as a treatment tool in healthcare including:
 - a) The demographics of individuals who previously used IVR.
 - b) The types of HMD, software, and setting.
 - c) The facilitators and barriers of using IVR.
 - d) The age and condition of the patients who received IVR.
 - e) The treatment goal of using IVR and associated adverse effects.
- 2) Scope those who use IVR for CP management and identify:
 - a) The type of IVR games/experiences.
 - b) The dose of IVR (duration, frequency, and number of sessions).
 - c) The measured outcomes to estimate patients' progress.

5.2.2 Study design and methods

A self-administered online survey was designed to collect descriptive and numerical data.

5.2.2.1 Survey instrument

The online survey was developed and hosted online using the Bristol Online Survey platform (<https://cardiff.onlinesurveys.ac.uk/utilityofimmersivevrinhealthcare>).

By clicking on the web link of the survey, an introduction (Appendix 5-1) to the research study was presented, this included the eligibility criteria and time needed to complete the survey, followed by the e-participant information sheet (Appendix 5-2) and e-consent form (Appendix 5-3). At the end of the e-participant information sheet, participants had an option to contact the researcher and ask questions prior to submitting the e-consent by directing them to the researcher contact page. The e-consent form was completed by respondents through scrolling and ticking the boxes in line with each statement. Approval to be contacted for the online interview (Phase 2) was added to the e-consent as an optional statement. At the end of the e-consent form, the 'Submit' button was clicked by respondents to access the sections of the survey.

The survey consisted of five main sections: 1) demographics, 2) delivery of IVR, 3) facilitators and barriers, and 4) IVR and users, 5) IVR and CP management. All questions were closed-ended and had a defined category. Ten of the included questions had “other response” to add further comments, this has been considered as good practice to identify new issues or to elaborate on answers to the closed questions (O’Cathain and Thomas 2004; Burns et al. 2008). Table (5-1) showed the rationale for the developed questions in each section, and each question type and level of data harnessed its response. The survey questions were adopted from the literature surveying the clinical use of VR applications (e.g., Nintendo Wii and exergames) (Fung et al. 2010; Segal et al. 2011; Levac et al. 2017), with some modifications to ensure its relevance to IVR, particularly in the scope of CP management.

A flow chart of the survey instrument presents in Figure (5-1). To identify participants for Phase 2, the last section of the online survey had a filtering question: Do you use IVR for CP management? Participants who answered (yes) were asked if they were interested in joining the subsequent online interview (Phase 2).

Table 5-1: The questions of the online survey, type of questions, responses and the rationale for use

Question	Type	Response	Rational
Section 1: Demographics			
Q1.1: Age	Closed question	Ordinal response*	Why: demographics data are important in the survey to gather information about a participant’s background. Participants’ background in this survey aimed to identify the characteristics of those who used IVR to treat patients in healthcare. How: the question adopted from other studies which investigate perceptions and experiences of clinicians in using VR games (Levac et al. 2017, Segal et al.2011, Fung et al. 2010).
Q1.2: Gender	Closed question	Nominal response*	
Q1.3: Occupation	Closed question	Other response*	
Q1.4: Country	Open question	Free text response*	
Q1.5: Work experience	Closed question	Ordinal response	
Q1.6: Work setting	Closed question	Other response	

Q1.7: Level of education	Closed question	Other response	
Section 2: Delivery of IVR			
Q2.1: What type of HMD do you use?	Closed question	Other response	<p>Why: many types of HMDs are available in the market. Therefore, it is important to identify the commonly used HMDs in healthcare as treatment tool.</p> <p>How: the question adopted from IVR literature (Matsangidou et al.2017).</p>
Q2.2: What IVR games/experiences do you use?	Closed question	Other response	<p>Why: identifying the type of IVR software either customised or off the shelf games/experiences is important to explore the current preference.</p> <p>How: the question adopted from the literature in which different software either “off the shelf” or customised games/experiences were used (Garrett et al.2017).</p>
Q2.3: In what setting do you use IVR?	Closed question	Other response	<p>Why: identification of the practical setting of IVR is important to explore the context and practicality of implementation.</p> <p>How: the question adopted from Levac et al. (2017) survey on the experiences of physiotherapists and occupational therapists in using VR.</p>

Section 3: Facilitators and Barriers			
Q3.1: What do you think are the key ingredients for successful use of IVR?	Closed question	Ranking*/ other response	<p>Why: ranking the facilitators of using IVR could inform the development and identify main aspects to consider for future implementation (Watson 2006).</p> <p>How: the question adopted from Levac et al. (2017) survey. Other response was added to provide more insight about key ingredients from participants 'opinion.</p>
Q3.2: In your experience, what are the top three significant barriers for using IVR?	Closed question	Rating* / other response	<p>Why: top three barriers of using IVR could inform the development of VR intervention and identify the main obstacles to be tackled for future implementation (Watson 2006).</p> <p>How: the question adopted from (Levac et al. 2017) survey. Other response was added to give the respondents a chance to add comments.</p>
Section 4: IVR and Users			
Q4.1: What is the age of your patients using IVR?	Closed question	Ordinal response	<p>Why: the age of patients who received IVR could inform the age range of the users in which IVR commonly used for.</p> <p>How: the question adopted from Levac et al. (2017) survey.</p>
Q4.2: In your experience, have you encountered any adverse	Closed question	Binary response* Yes/No	Why: adverse effect of IVR was discussed in the literature, thus experiences of those are essential.

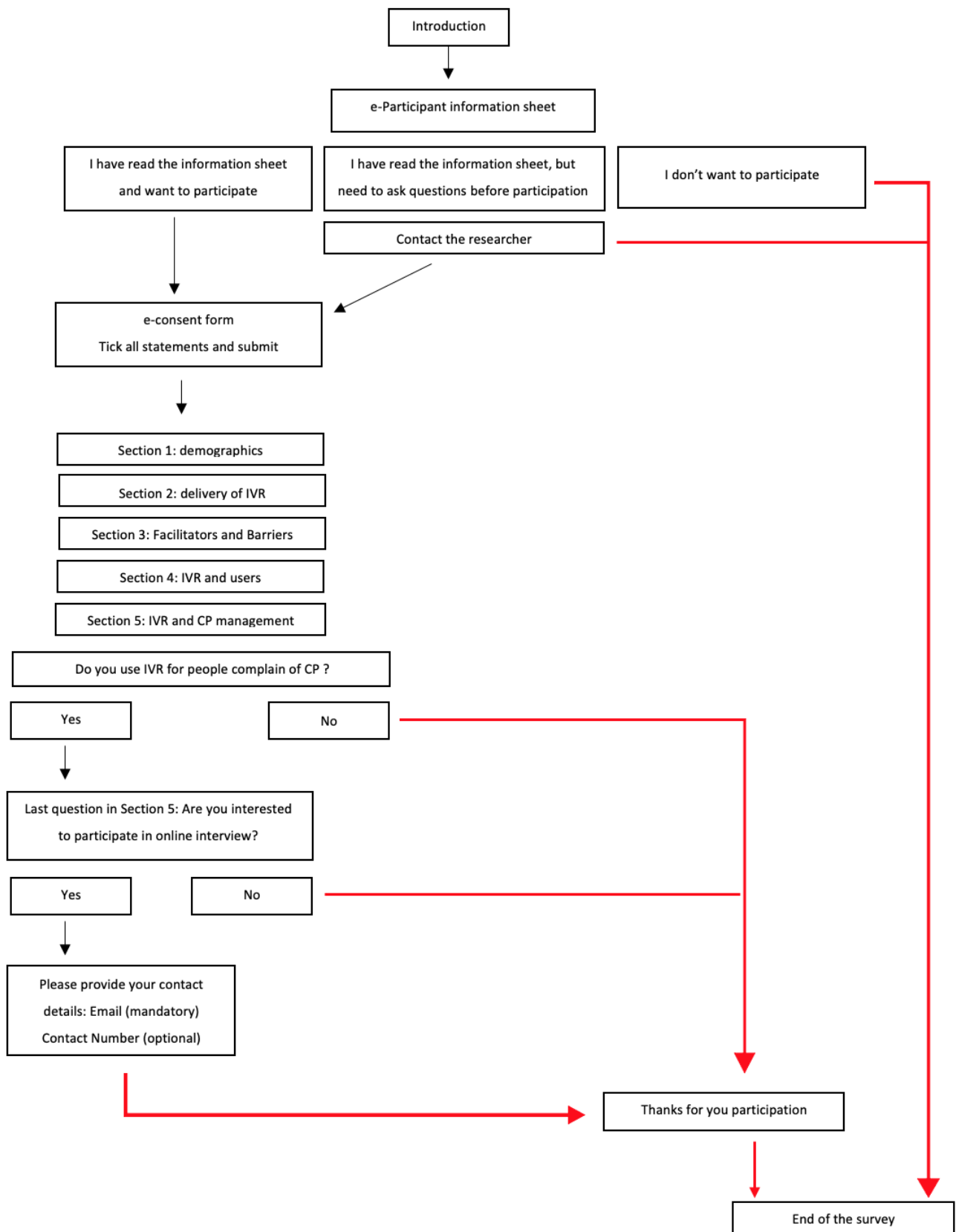
effects for using IVR?			How: Yes/No question because the adverse effect may or may not occur during IVR delivery.
Q 4.2.1: What are the adverse effects?	Closed question	Other response	Why: sub-question appeared to respondents who select (yes) in the Q4.2, while those who select (no) will moved to Q4.3. Different adverse effects were shown in the literature, thus knowing the most common is important. How: the choices adopted from (Cao 2016) which reported different possible effects.
Q4.3: In your experience, what conditions do you treat using IVR?	Closed question	Other response	Why: stratification of conditions who received IVR could identify participants background and the most common conditions that been treated with IVR. How: the question adopted from Levac et al. (2017).
Q4.4: With regards to the conditions, you ticked above, what are your IVR targets?	Closed question	Other response	Why: the main treatment goal of IVR for the conditions is essential to indicate the high priority use of IVR. How: the question adopted from (Levac et al. 2017) survey and modified to increase its relevance to IVR use.
Section 5: IVR and CP management			
Q5.1: Do you use IVR for CP management?	Closed question	Binary response Yes/No	Why: Identification of the proportion of respondents who use IVR for CP management is essential for subsequent Phase 2.

			How: Yes/No question because the respondents may or may not previously use it for CP management. Respondents who select 'yes' were directed to below questions (Q5.2-Q5.8), while those who select (no) was directed to "thank you" page.
Q5.2: What type of games/experiences do you use for patients with CP?	Closed question	Other response	Why: exploring features of IVR delivery to the users is essential to identify most common VE, dose of IVR including duration, frequency, and number of sessions, in addition to outcomes How: All questions of IVR and pain management adopted from literature (Pourmand et al.2018 and Mallari et al.2019).
Q5.4: on average, how long is the session?	Closed question	Ordinal response	
Q5.5: on average, how many sessions patients typically have?	Closed question	Ordinal response	
Q5.6: if you provide the session as a therapy on regular basis, on average how often do you deliver IVR?	Closed question	Ordinal response	
Q5.7: What outcomes do you use to estimate user's progress?	Closed question	Other response	

Q5.8: would you be interested in participating in telephone/Zoom interview?	Closed question	Binary response Yes/No	Why: to recruit respondents for the subsequent online interviews How: Yes/No question because respondents may or may not agree to participate in Phase 2.
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The table adapted from Burns et al. (2008) guide to design and conduct self-administered surveys. *Ordinal response: options consist of different ranges, *Nominal response: options consist of a list of names or labels, *Ranking response: options need to be ranked from the most to the least important, *Other response: question contain an “other, please specify” option for unanticipated answers, *Free text response: open answer, *Rating response: options need to be rated according to their significance *Binary response : Yes or No question.

Figure 5-1: Flow chart of the survey instrument



5.2.2.1 Sampling

A convenience sample of individuals who had previously used IVR as a treatment tool were recruited using special interest groups including:

- Rescape Innovation, IVR businesses representative in South Wales, UK region (<https://www.rescape.me>).
- List of national and international contacts.
- Facebook groups:
 - VR Doctors public group (<https://www.facebook.com/groups/VRDocs/>).
 - Virtually Healthy Community public group (<https://www.facebook.com/groups/2231981087114134/>).
 - International Society for Virtual Rehabilitation (<https://www.facebook.com/groups/isvr.email/>).
- Twitter groups:
 - Immerse UK (https://twitter.com/ImmerseUK_)
 - Virtual Medicine (<https://twitter.com/virtualmedconf>)
 - Applied VR Health (<https://twitter.com/AppliedVRhealth>).

Although calculating the response rate to estimate the sample size enhances the validity of a self-administered survey, it is usually challenging for the online surveys with an uncertain recruitment reach (Van Selm and Jankowski 2006, Burns et al. 2008). Therefore, an approximate sample size for the current online survey was not suggested but rather, it remained accessible for 11 months (January 2020 – December 2020).

5.2.2.2 Eligibility criteria

Inclusion criteria:

- Healthcare practitioners (e.g., physicians, nurses, psychologists, physiotherapists, and occupational therapists), researchers and IVR technology developers who had previously used IVR as an intervention tool in healthcare.
- IVR was identified as viewing a VE using HMD.
- Ability to read and understand English.

Exclusion criteria:

- Healthcare practitioners (e.g., physicians, nurses, psychologists, physiotherapists, and occupational therapists), researchers and IVR technology developers who had no previous experience in using IVR for patients in healthcare.
- The use of non-immersive or semi-immersive VR systems (i.e., using a projector screen).
- The use of IVR for the purpose other than treatment such as diagnosis, or educational training.

5.2.2.3 Survey Piloting

A pilot test was undertaken between 4th December 2019 – 4th January 2020 to assess the survey in terms of flow, administrative ease and to recognise poorly phrased questions. The pilot testing is useful to improve the survey and minimise the possibility of poor interpretation of the questions (Burns et al. 2008).

To ensure the face validity of the online survey, an expert in IVR technology who worked as an associate in a healthcare company was consulted to review the questions and provide advice on some of the defined categories. Then, an invitation to complete the online survey was emailed to 6 postgraduate research students in the School of Healthcare Science, Cardiff University, some with and some without experience of IVR in clinical populations. The email included the web link for the survey and contained information about the study and its purpose. The pilot respondents were asked to complete the survey, record the completion time, and submit their responses in the survey portal. In addition, they were asked to give feedback by email to report clarity and other functionality issues.

All respondents sent feedback via email detailing spelling, grammar errors, and functionality issues. For instance, R.P stated: *“Overall, the survey is good, and the questions make sense. As far as I can see, the only issues are several typos, mainly regarding the use of spaces, punctuation including question marks and commas”*. Also, one student indicated that the survey took almost 20 minutes to complete instead of the suggested 15 minutes. Two questions were noted to have functional issues: Q1.3 (occupation) did not allow the selection of more than one answer although it asked for the respondent to tick all that applied and Q3.1 (IVR intervention components) only allowed the ranking of 4 items instead of the 5 items

on offer. Changes were made in accordance with the feedback and the final version of the survey was created and released to the target group on 27 January 2020.

5.2.2.4 Data collection

The survey was emailed to Rescape Innovation (<https://www.rescape.me>) and the list of contacts from Facebook and Twitter with information about the study, aim of the survey and the web link (Appendix 5-4). Additionally, a flyer was distributed on social media (Facebook and Twitter groups) (Appendix 5-5). A reminder to distribute the survey was set up every 2 weeks and data were collected over an 11-month period, between 27 January 2020 and 30 December 2020. Reminders were reported to have a positive influence on the recruitment of the participants (Burns et al. 2008). All data was automatically collected in the survey platform (BOS) when participants submitted their answers.

5.2.2.5 Data analysis

The online survey platform (BOS) provided a summary of data analysis using basic descriptive statistics, including numbers and percentages. The survey included 16 multi-answer questions, with each participant having the option to select more than one variable; thus, the total participants was presented in numbers (N), while the proportion of selections for a single variable among other variables was presented in percentages (%). All the questions and the analysed number/percentage were gathered from the survey platform and exported into Microsoft Excel sheets. Only one question (Q3.1, ranking question) was analysed further using the RANK function in Microsoft Excel to rank the numeric values from the highest to the lowest. All the analysed data in Microsoft Excel was displayed in tables and charts.

The written comments under “other, please specify” was quantified using content analysis based on the recommendations by O’Cathain and Thomas (2004). In online surveys, the written comments can be considered by researchers as qualitative or quantitative data, but its status should be determined according to the depth of the written responses, the number of respondents who write and the amount they write (O’Cathain and Thomas 2004). In the current survey, the written comments under “other, please specify” were considered as quantitative data because they were not meant to be answered by all respondents. Also, they were not telling a story but merely corroborating with the closed options or short responses in one or two sentences giving new information that may not have been anticipated by the

researcher (O’Cathain and Thomas 2004). Thus, all comments were assigned codes on a Microsoft Excel sheet in which the related codes were combined under key categories based on their content. Then, quantitative data were generated by counting the number of codes in each category. All the written comments and associated categories were summarised in Appendix (5-6).

5.2.3 Results – Online Survey (Phase1)

5.2.3.1 Participants’ demographics

As shown in Table 5-2, 39 participants responded to the online survey. The sample was represented by 10 countries, these included UK, USA, Netherlands, Canada, Italy, Belgium, Saudi Arabia, United Arab Emirates, Australia, and Denmark. Out of these, participants from the UK (n=19) and USA (n=10) were the most prevalent. Participants involved 21 healthcare practitioners, 15 technology developers and 3 company founders, of which 16 had dual roles (e.g., working as healthcare practitioner, researcher and IVR developers). Most participants had work experience of more than 15 years (n=17) with doctoral degree (n=19).

Table 5-2: Participants' demographics

Participants’ demographics (n=39)	
Variable	N*(percentage)*
Age	
31-40 years old	14 (35.9%)
41-50 years old	10 (25.6%)
51-60 years old	6 (15.4%)
18-30 years old	5 (12.8%)
> 60 years	4 (10.3%)
Gender	
Male	24 (61.5%)
Female	15 (38.5%)
Occupation°	
Healthcare practitioner	21 (30%)
Researcher	20 (28.6%)
IVR developer/designer	15 (21.4%)

University lecturer	10 (14.3%)
Other (e.g., Company founder)	4 (5.7%)
Dual Roles	16 (41 %)
Country	
United Kingdom	19 (48.7%)
United State of America	10 (25.6%)
Netherlands	2 (5.1%)
Canada	2 (5.1%)
Italy	1 (2.6%)
Belgium	1 (2.6%)
Saudi Arabia	1 (2.6%)
United Arab Emirates	1 (2.6%)
Australia	1 (2.6%)
Denmark	1 (2.6%)
Work Experience	
>15 years	17(43.6%)
6-10 years	9 (23.1%)
11-15 years	6 (15.4%)
2-5 years	6 (15.4%)
< 2 years	1 (2.6%)
Work Setting°	
University	18 (26.5%)
Government / Public Healthcare setting	12 (17.6%)
Private Company	11 (16.2%)
Private Healthcare	11 (16.2%)
NHS	11 (16.2%)
Military	2 (2.9%)
Other	2 (2.9%)
Sports	1 (1.5%)
Education Level	
Doctoral Degree	19 (48.7%)

Master's Degree	10 (25.6%)
Bachelor's Degree	5 (12.8%)
Diploma Degree	4 (10.3%)
Other (Higher National Diploma)	1 (2.6%)

*N : the total number of participants, *percentage : the proportion of selections for a single variable among others, °multi-answer question, IVR : immersive virtual reality, NHS: National Health service in the United Kingdom

5.2.3.2 Delivery of IVR

The responses to the questions on the types of HMDs, types of IVR games/experiences and settings are presented in Table 5-3. Both the computer-based and the self-contained HMDs were the most selected. The Oculus Rift was the most frequently used (n=23) (22%), followed by Oculus Go (n=19) (18.3%), HTC Vive (n=18) (17.3%) and Oculus Quest (n=13) (12.5%). Also, eleven participants (10.6%) in the “other” category reported the use of Pico (n=10) and Lenovo Mirage Solo (n=1) which are self-contained HMD (Appendix 5-6). The mobile-based HMDs (Google Cardboard, Samsung Gear, Google Daydream) were reported to be the least used.

More than half the participants employed customised games either developed in conjunction with practitioners and users (n=25) (39%) or by an external company (n=20) (32%), while 18 participants (29%) reported to use ‘off the shelf’ games/experiences. In terms of setting, hospital was the most common setting (n= 19) (19.6%), followed by university (n=15) (15.5%), and home setting (n=13) (13.4%).

Table 5-3: The delivery of IVR including types of HMDs, types of IVR games/experiences and setting

Delivery of IVR	
Variable	N* (Percentage)*
Q2.1 What type of HMD do you use?°	
Oculus Rift	23 (22%)
Oculus Go	19 (18.3%)
HTC Vive	18 (17.3%)
Oculus Quest	13 (12.5%)

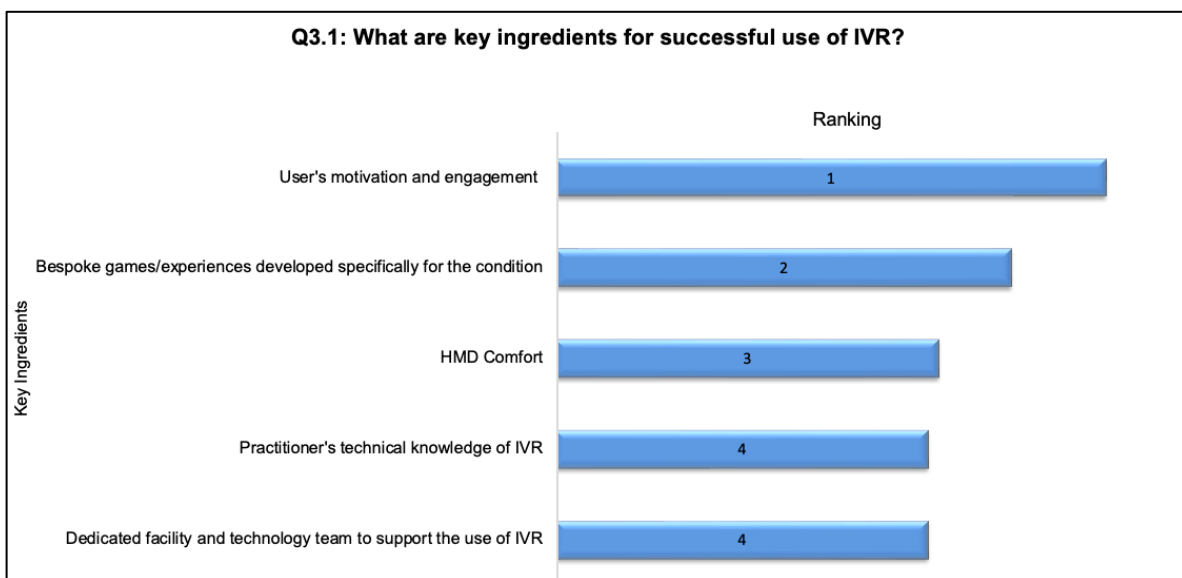
Other	11 (10.6%)
Google Cardboard	9 (8.7%)
Samsung Gear	8 (7.7%)
Google Daydream	3 (2.9%)
Q2.2 What IVR games/experiences do you use?°	
Customised games/experiences developed in conjunction with practitioners and users	25 (39%)
Customised games/experiences developed by external company	20 (32%)
'Off the shelf' games/experiences	18 (29%)
Q2.3 In what setting do you use IVR?°	
Hospital	19 (19.6%)
University	15 (15.5%)
Users' home	13 (13.4%)
Laboratory research setting	11 (11.3%)
Private clinic	10 (10.3%)
Rehabilitation centre	9 (9.3%)
Community health centre	8 (8.2%)
Long term care units	6 (6.2%)
Other	4 (4.1%)
Community based clinic	2 (2.1%)

*N = the number of participants, *percentage = the proportion of selections for each variable among others, °multi-answer question, IVR: immersive virtual reality , HMD: head mounted display.

5.2.3.1 Key ingredients and Barriers

Figure 5-2 shows the ranked key ingredients for successful use of IVR. User's motivation and engagement was considered to be the most important 'key ingredient'. The second and the third were bespoke games/experience and HMD comfort, respectively. Practitioner's technical knowledge and the dedicated facility/technology team supporting IVR came in fourth place with equal ranking. Participants reported additional key ingredients in the written comments (Appendix 5-6). These were categorised as: practitioner knowledge and the ability to educate patients (n=5), practitioner engagement (n=3), quality of VE (n=3), personalisation (n=3), ease of use (n=3) and financial support (n=3).

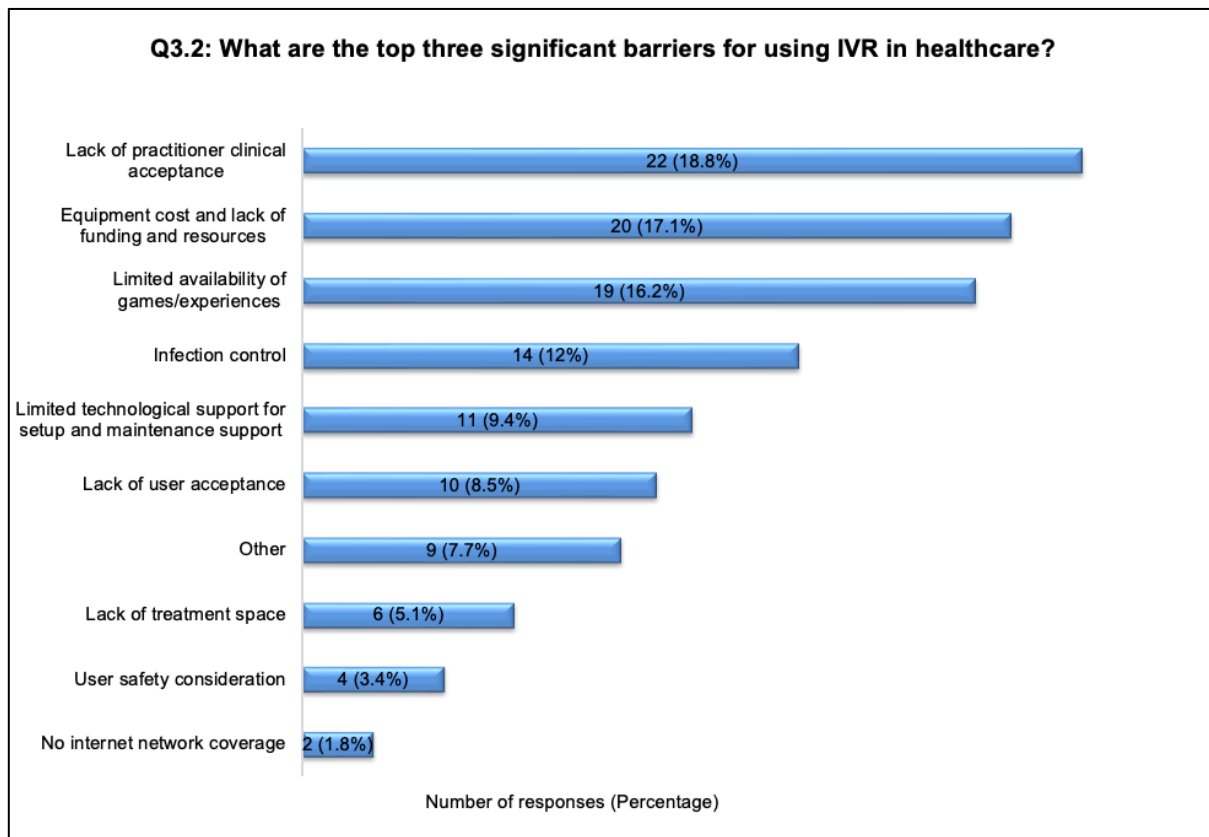
Figure 5-2: Q3.1 What are key ingredients for successful use of Immersive virtual reality?



IVR : immersive virtual reality , HMD: head mounted display

As shown in Figure 5-3, the top three significant barriers were the lack of practitioner clinical acceptance (n=22) (18.8%), followed by the equipment cost and lack of funding (n=20) (17.1%) and the limited availability of IVR games and experiences (n=19) (16.2%). In 'other' (Appendix 5-6), nine participants added further barriers including lack of financial or clinical support to adopt IVR technology (n=6) and lack of IVR clinical guidelines in healthcare (n=2).

Figure 5-3: Q3.2 What are the top three significant barriers for using immersive virtual reality in healthcare?



IVR : immersive virtual reality

5.2.3.2 IVR and users

Table 5-4 presents the age of IVR recipients and the associated adverse effects. Adult patients aged between 31-59 years old were reported as the most common recipients of IVR (n= 32) (25.8%), followed by older adults aged between 60-79 years (n=19) (24.2%), and young adults aged between 18-30 years (n=18) (22.6%). Elderly over 80 years (n=13) (14.5%) and children (n=11) (12.9%) were the least reported.

Over half of the participants (n=20) (51.3%) reported encountering adverse effects when using IVR with clinical populations. Out of those, MS was overwhelmingly the most reported (n=18) (36.7%). Other adverse effects included disorientation and eye strains (both reported by 7 participants with 14.3%), anxiety (n=6) (12.2%) and fatigue (n=5) (10.2%). Two participants reported encountering a panic attack (4.1%). Additional adverse effects were reported in 'other' including HMD discomfort (n=2), neck pain (n=1), headache (n=1) (Appendix 5-6).

Table 5-4: Immersive virtual reality and users including age and associated adverse effects

Immersive virtual reality and users	
Variable	N* (Percentage)*
Q4.1 What is the age of your patients using IVR?°	
31-59	32 (25.8%)
60-79	19 (24.2%)
18-30	18 (22.6%)
Over 80	13 (14.5%)
Under 18 years old	11 (12.9%)
Q4.2 Have you encountered any adverse effects for using IVR?	
Yes	20 (51.3%)
No	19 (48.7%)
Q4.2.1 What are the adverse effects?°	
Motion Sickness (e.g., nausea or dizziness)	18 (36.7%)
Disorientation	7 (14.3%)
Eye strains (e.g., eye dryness or discomfort)	7 (14.3%)
Anxiety relating to the virtual world	6 (12.2%)
Fatigue	5 (10.2%)
Other	4 (8.2%)
Panic attack	2 (4.1%)

*N : the number of participants, *percentage : the proportion of selections for each variable among others, °multi-answer question, IVR : immersive virtual reality

In terms of clinical conditions, 19 participants reported CP conditions as the most common conditions (20.2%) for which IVR was used, followed by psychological disorders (n= 16) (16.2%) and musculoskeletal disorders (n=15) (15.2%). Also, 11 participants utilised IVR for neurological conditions such as stroke (11%) and 6 used IVR for people with burns and autism (6.1%). The cancer, cerebral palsy and cardiac conditions were the least reported conditions. Fifteen reported other conditions under ‘other’ including anxiety /pain of medical or surgical procedure (n=5), psychological conditions (n=3), motivation for movement (n=2), patient

education on medical procedures (n=2), breathlessness (n=1), dementia (n=1) and social isolation (n=1) (Appendix 5-6).

Alongside, the most frequently reported targets for IVR use with the above conditions included the reduction of fear and anxiety (n=27) (24.4%), pain management (n=25) (22.5%) and movement improvement (n=15) (13.5%). Enhancement of exercise capacity and strength/endurance were targeted by 8.1% and 7.2%, respectively. The mobility (e.g., walking) and cognition improvement were the least chosen targets with 6.3%. In 'other', 13 participants reported using IVR to enhance cognition and body awareness (n = 5), reduce psychological symptoms (n=3), improve self- efficacy (n=2), improve mobility (n=1), improve social engagement (1) and tele-support for patients (1) (Appendix 5-6).

Table 5-5: Immersive virtual reality and users including treated conditions and related targets

Immersive virtual reality and users	
Variable	N* (Percentage)*
Q4.3 What conditions do you treat using IVR?°	
Chronic Pain (e.g., chronic low back pain, chronic neck pain, fibromyalgia)	19 (19.2 %)
Mental health/Psychological disorders	17 (17.1%)
Orthopaedic/ musculoskeletal disorders	15 (15.2%)
Other	15 (15.2%)
Neurological disorders (e.g., stroke, brain injury)	11 (11.1%)
Autism	6 (6.1%)
Burns	6 (6.1%)
Cancer	4 (4%)
Cardiac disorders	3 (3%)
Cerebral palsy	3 (3%)
Q4.4 With regards the conditions above, what are your IVR targets?°	
Reduce fear and anxiety	27 (24.4%)
Pain management	25 (22.5%)

Improve movement (e.g., rang of motion, motor control, functional task)	15 (13.5%)
Other	13 (11.5%)
Increase exercise capacity	9 (8.1%)
Improve strength/endurance	8 (7.2%)
Improve cognition/memory	7 (6.3%)
Improve general mobility (e.g., balance or gait)	7 (6.3%)

*N : the number of participants, *percentage : the proportion of selections for each variable among others, °multi-answer question, IVR: immersive virtual reality.

5.2.3.3 IVR and CP management

In Table 5-6, the results scope those who use IVR for CP management as well as the type of games/experiences, dose, and outcome measures. The survey identified 19 participants who used IVR for CP management. In terms of IVR games/experiences, relaxation, or meditation was found to be the most widely utilized for CP management (n=16) (50%). The use of active and cognitive games/experiences was reported by 7 (21.9%) and 6 (18.7 %) of the participants in turn, while highly active games/experiences where the users needed to walk around were less common (n=3) (9.4%).

Regarding the dose, most participants delivered IVR for a duration of between 5 to 20 mins and none exposed patients to IVR for more than 45 mins. The number of sessions have no definitive pattern across the defined categories and are associated with different ranges (Table 5-6). The participants did not frequently deliver IVR on a regular basis (n=9) (47.4 %), but those who did, selected a common frequency of 3 times per week (n=7) (36.8%).

The most frequently measured outcomes included pain intensity (n=17) (22.7%), psychological state such as fear or mood state (n=14) (18.6 %) and functional scale (n=12) (16%). The subsequent selected outcomes were opioids use with 10.7%, physical activity and disability with 9.3% and physical tests with 6.7%.

Table 5-6: Immersive virtual reality and chronic pain management including type of games/experiences, dose of IVR and outcomes measure

Immersive virtual reality and chronic pain management	
Variable	N* (Percentage)*
Q5.1 Do you use IVR for chronic pain management?	
Yes	19 (48.7%)
No	20 (51.3%)
Q5.1.2 What type of games and/or experiences do you use for users with chronic pain?°	
Passive game/experience with users seated (e.g., relaxation or meditation)	16 (50%)
Active game/experience with users seated/standing (e.g., task completion, head or upper limb or trunk movement)	7 (21.9%)
Memory or cognitive game/experience with users seated (e.g., Puzzle)	6 (18.7%)
Highly active game/experience with users standing and moving around (e.g., task completion, whole body movement, walking on treadmill)	3 (9.4%)
Q5.1.3 On average how long is the session(s)?	
5-10 minutes	10 (43.5%)
15-20 minutes	8 (34.8%)
30-40 minutes	4 (17.4%)
Less than 5 minutes	1 (4.3%)
More than 45 minutes	0
Q5.1.4 How many sessions users typically have?	
More than 12 sessions	4 (28.6%)
4-6 sessions	4 (28.6%)
7-9 sessions	2 (14.3%)
less than 3 sessions	2 (14.3%)
Not applicable	1 (7.1%)
10-12 sessions	1 (7.1%)

Q5.1.5 How often do you deliver the IVR?	
Not applicable	9 (47.4%)
Three times a week	7 (36.8%)
Once a week	2 (10.5%)
Twice a week	1 (5.3%)
Every two weeks	0
Q5.1.6 What outcomes do you use to estimate user's progress?	
Pain intensity	17 (22.7%)
Psychological state (anxiety, fear, or mood states)	14 (18.6%)
Functional scale	12 (16%)
Opioid use	8 (10.7%)
Physical activity	7 (9.3%)
Disability measures	7 (9.3%)
Physical tests (e.g., balance, range of motion, strength)	5 (6.7%)
Other	5 (6.7%)

*N : the number of participants, *percentage : the proportion of selections for each variable among others, °multi-answer question, IVR : immersive virtual reality.

5.3 Part 2/ Phase 2: Online Interviews (Experiences and perceptions of global stakeholders on the current use of IVR for CP management)

5.3.1 Aim

To explore the experiences and perceptions of global stakeholders (healthcare practitioners and IVR technology developers) on the current use of IVR for CP management.

5.3.2 Objectives

To explore:

1. Perceptions of IVR as an intervention for patients with CP including benefits or adverse events.
2. Experiences and views on technology specifications (software/hardware), dose of the intervention and context of IVR.
3. Opinions on the perceived facilitators and barriers to IVR adoption for CP management.

5.3.3 Study Design and methods

Semi-structured online interviews were selected for this phase. According to MRCF guidance, selection of qualitative method at the stage of developing a new healthcare intervention relies on the rationale of the research conducted (Watson 2006, Craig et al. 2008). Both individual interviews and focus groups were recommended at this stage. Interviews were deemed more appropriate to gain insights about individual experiences, with the researcher being able to adapt the questions and probe as required (Holloway and Wheeler 2010). Although focus groups are an alternative method for collecting this type of data, it is a less suitable method for a heterogeneous group of people (Braun and Clark 2013). The global stakeholders who participated in Phase 1 of the online survey were geographically dispersed across different time zones which limits the feasibility of focus groups. Also, since IVR technology is a novel method utilised in CP management, it is likely to be associated with a range of unique opinions and assumptions which would not be efficiently covered in group discussions.

Although face to face interviews are considered as the gold standard for collection of interview data, online interviews have been claimed to be an equally effective method

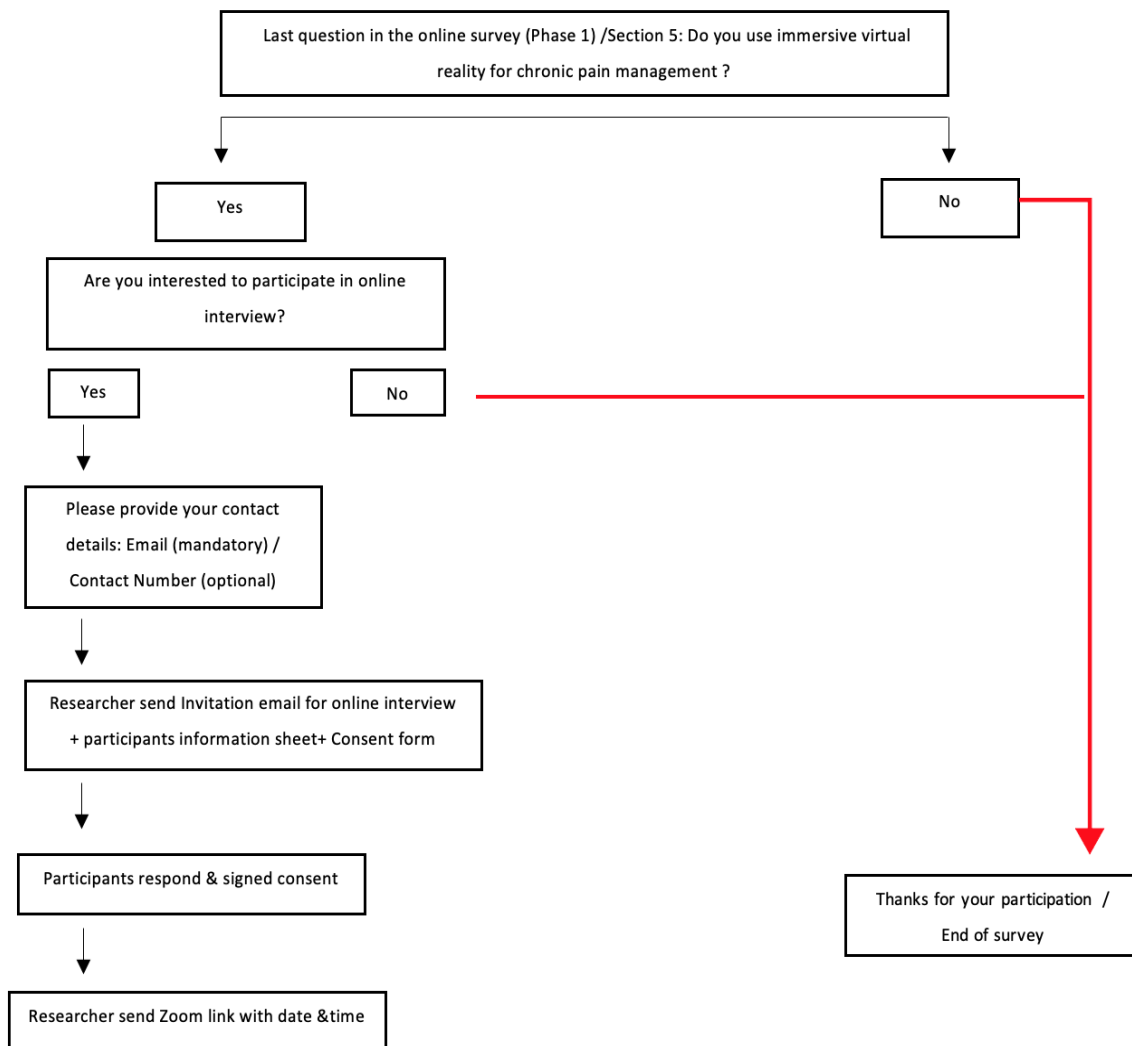
particularly when participants are located in different regions (Novick 2008, Braun and Clark 2013; Archibald et al. 2019). In addition, conducting online interviews was deemed as suitable for this thesis given the circumstances of the COVID pandemic. The Zoom platform was chosen to audio interview participants because it was considered as a convenient and cost-effective method for researchers undertaking qualitative studies (Archibald et al. 2019). Further, it has been suggested as an ideal choice for research interviews compared with other internet-based platforms (e.g., Skype, Facetime) in terms of data security and functionality of the system (Archibald et al. 2019).

5.3.3.1 Sampling

Participants were purposively selected from the online survey (Phase 1). A purposive sampling strategy allows the selection of a sample which fits specific criteria to obtain rich data and relevant knowledge to the topic (Holloway and Wheeler 2010). According to Creswell and Plano Clark (2011), the purposive sample of the participants in sequential explanatory design for subsequent qualitative study needs to be identified through the prior quantitative study. Heterogeneous sampling was recommended in the qualitative phase, since gaining perspectives from different groups or places could help to establish evidence that is applicable in different contexts (Savin-Baden and Major 2013; Robinson 2014). In the current phase, using IVR for CP management is novel and not yet fully established, thus understanding different strategies applied by individuals belonging to different groups or regions would help in building a representative picture for such an intervention.

As shown in Figure 5-4, the selected subset of the online survey participants (Phase 1) is those who were eligible with prior experience of delivering/developing IVR for CP management and who agreed to participate in the online interviews (Phase 2). Out of 19 eligible participants (Phase 1), 11 participants agreed to take part in the online interviews (Phase 2), and they were emailed with the information sheet (Appendix 5-7) and consent form (Appendix 5-8). Ten participants responded to the email, they were sent the date and time of the online interview according to their availability and a Zoom link including ID number and password. Each participant was given sufficient time to ask questions through email prior to providing the consent and identifying a mutually convenient date and time. An electronic signed consent was obtained from each participant one day prior to the scheduled date of the interview.


Figure 5-4: Flow chart of the recruitment process for participants in the online interview (Phase 2) through the online survey (Phase1)



5.3.3.2 Topic guide and development of questions

The topic guide was developed on the basis of the information from the reviewed literature and the subsections of the online survey (Phase 1). According to Braun and Clark (2013), the questions were designed to acquire information relevant to the research question and sequencing of the questions in the topic guide flowed logically from general introductory questions to specific questions. Questions were clustered into three parts: Part A) Clinical experience of IVR for patients with CP, Part B) Delivery of IVR and Part C) Recommendations and Close (Figure 5-5).

Figure 5-5: The topic guide of the online interviews



CARDIFF UNIVERSITY/School of Healthcare Sciences

Online Interview Topic Guide (Part2/Phase2)

Part A: Clinical experience of immersive VR

1. Tell me a about chronic conditions do you treat using immersive VR?
2. What in your view are the specific features of the immersive VR that make it good choice for your chronic pain?
3. Is there anything else you observed in terms of VR effects in your clinical experience?

Part B: Delivery of VR

1. You mentioned that you use (Kit) what prompted you to go for this particular type of immersive VR product?
2. In your opinion, what features (Kit) make it suitable for CP patients?
3. Is there any specific characteristics for CP patients?
4. Can you give me some examples of successful VR treatment for patients with CP?
5. Can you give me an example when it didn't work so well and why?
6. You mentioned that you use (games/experience) , how do you normally decide what games and experiences to use ?
7. In your experience what games/experience works well and not so well?
8. Do you have any thoughts on how patients' experience could be improved in management of CP?
9. Tell me a little bit about the setting of where you deliver VR.
10. In the survey you mentioned (adverse event) experienced by CP patients, Could you expand on this a little?
11. Are you able to share any details about serious or unexpected adverse event your patients have experienced?

Part C: Recommendations and Close

1. What in your view could improve the take up VR for Chronic pain management?
2. In your experience , what is the biggest challenge for embedding VR in CP management?
3. What would your advice be to other practitioners who would like to set up similar intervention for CP patients?

VR: virtual reality, CP: chronic pain

5.3.3.3 Pilot Interviews

Two pilot interviews were conducted online via the Zoom platform with colleagues from the School of Healthcare Science who were PhD candidates (AK and MM). The pilot gave the researcher an opportunity to practise their interviewing skills. Also, the topic guide was modified based on the received verbal and written feedback from these candidates to improve clarity. Based on the feedback, the following adjustments to the topic guide were

made: Part A-Q1, which concerning the proposed understood IVR mechanisms of action, created some confusion and the question was reworded from what is the theoretical basis or the mechanisms underpinning the use of IVR for CP? To what in your view are the specific features of IVR that make it good choice for CP.

Q1 and Q2 in Part B were combined into a single question, as one candidate recommended, A.K.S: *“maybe you can split in to 2 or 3 questions as it feels too long”*. Also, the other candidate felt that more information needed to be introduced by the researcher before the start of the interview, as it was conducted using the Zoom platform. Thus, the researcher becomes aware of the need to provide interviewees with more information about Zoom and how to re-join the Zoom call in case of any technical interruption. The final version of the topic guide (Figure 5-5) was created following a discussion with the supervisors (VS) and (LS).

5.3.3.4 Data Collection and Processing

The online interviews were conducted using the Zoom platform, each interview lasted for approximately 1 hour. The researcher was the host of the audio online interview, starting the interview 15 minutes prior to the scheduled time. Once the participant had joined, the researcher admitted the participant to the audio call and locked the call to prevent any unwanted disruption. At this point all participants were given an opportunity to ask any questions and advised that they could stop the interview at any time.

Permission for audio recording was requested at two time-points: written informed consent (Appendix 5-8), they verbally re-consented prior to commencing and then pressed the record button. The researcher took notes during the interviews to help the flow of the interview and in case of any additional questions or clarification required. During the interview, prompts such as ‘Can you provide an example? Could you explain more about it? How did you do this?’ were used by the researcher to expand certain answers in more detail where required. The recording function of the Zoom platform was utilised to generate an audio recording which was then saved securely on a Cardiff University computer, this was protected by a password. For security purposes, the researcher ensured to delete the audio from the library of Zoom platform.

The interview data was transcribed manually in Microsoft Word document by the researcher, anonymised and kept separate from the audio-recording file to protect confidentiality. Then,

the transcripts were sent to the participants to check the data for accuracy and add any clarification (Shenton 2004; Cypress 2017). Although the participants were given ten days to respond, limited responses were received from two participants who sent confirmation that no changes were required. After verification of the transcript from some participants, the recordings were deleted.

5.3.3.5 Data analysis

Reflexive thematic analysis, using inductive approach, was used to analyse the interview data (Braun and Clark 2013; Braun and Clark 2021b). This is a systematic method of coding and creating themes through examining the meaning of description provided from participants' perspectives (Vaismoradi et al. 2016). The code is identified as a word or brief phrase that is labelled as a feature of data, whilst the themes are the final product which emerges from a group of codes that capture something relevant to the research question (Braun and Clark 2013). The analysis was conducted following the recommendations and the six phases for inductive thematic analysis by Braun and Clark (2013; 2021b) (Table 5-7).

Table 5-7: Phases of the inductive thematic analysis

Phase	Method
1. Reading and familiarization	<ul style="list-style-type: none"> - Researcher familiarisation with the data took place during manual transcription and reading of the transcripts several times. - Following each interview, the researcher listened to the audio record, taking reflexive notes about initial ideas and thoughts for the analysis. These were used to identify the specific pattern of the ideas which appeared in the transcripts.
2. Initial coding	<ul style="list-style-type: none"> - The researcher started to generate initial codes during reading of the transcripts and formed initial ideas about codes and possible themes reviewed. - A colleague from the School of Healthcare Science who had previous experience in qualitative research joined the process of coding in one transcript and the researcher then compared

	<p>with her own coding, reflecting on the meaning from the entire participants' transcribed data. Further inspection of the remaining transcripts was undertaken by the researcher alone, refining the initial list of codes.</p> <ul style="list-style-type: none"> - Each transcript was coded using Microsoft Word where each extract was highlighted in different colours (Appendix 5-9). - Colours were used to distinguish different patterns across the data set which were previously identified in the familiarisation phase. - Coding was undertaken systematically by looking at either large or small chunks of extracts that potentially addressed the research question. - Extracts were also coded more than once when they contained multiple meanings. - All codes identified from each transcript were copied and pasted in Microsoft Excel with the participant number to prevent any data loss or error (Appendix 5-10).
<p>3. Searching for themes</p>	<ul style="list-style-type: none"> - Following the initial coding, larger codes were created, and sub-themes were generated. Then, the process was continued to group sub-themes into larger themes. - The process of grouping the codes and searching for themes was a cyclic process in which the researcher revised the transcripts and renamed the codes, if necessary, to find a more accurate description. Additionally, merging, or splitting codes when they referred to similar or different themes in turn. - Initial themes were interpreted by grouping larger codes into separate excel sheets in a code book (Appendix 5-11), to find similarities and differences in code description.

	<ul style="list-style-type: none"> - The emergence of themes is characterised by their relevance to the research question that of which dependent on the researcher's judgement.
4. Reviewing themes	<ul style="list-style-type: none"> - Multiple checking of themes and sub-themes associated with reflection from the entire dataset. - All initial themes and subthemes created from the codes were printed and transferred into diagrams for visual presentation into a thematic map to assist with refining and checking of the themes and subthemes (Appendix 5-12). - The initial diagram of multiple themes and subthemes (Appendix 5-12) was first discussed with the supervisors (VS, LS). - Following discussion and further consultation with supervisors (VS, LS), some changes were made. For example, 'the software, hardware' was separated into subthemes, but we believe that both cannot reflect valuable meaning from the data. So, different aspects related to both software and hardware were grouped under 'personalisation' and 'technology related aspects'. - Final themes were reviewed to ensure presentation of the dataset in relation to the research question by reading the coded texts in each theme and evaluating whether the coded data reflected the theme.
5. Defining themes	<ul style="list-style-type: none"> - Final refinement of thematic map is naming the themes which should describe the 'essence' of each theme to capture the overall story of the theme (Braun and Clark 2013). For example, the theme 'clinical criteria of patients' was too diverse to describe the essence of the theme, thus it was changed to

	<p>'Appropriate patient selection', which describes how patients can be selected for the intervention to get the most benefits.</p>
<p>6. Producing Report</p>	<ul style="list-style-type: none"> - Following establishing the final themes, a report of the findings was produced including either short or long quotation that best represented the themes or subthemes to ensure the validity of the findings. - Finally, the report of the result was taken further in the discussion section from the description of the data to form an argument in relation to the research question.

5.3.4 Results – Online interviews (Phase 2)

5.3.4.1 Participants

Ten participants were interviewed, with prior experience of using IVR for CP management ranging from 2 to 22 years (Table 5-8). The participants were from five different countries (USA, UK, Canada, Netherlands, and UAE), with a diverse range of professions. Six participants were healthcare practitioners including 1 surgeon, 1 physiotherapist, 2 physicians, and 2 nurses, of which two had a dual role as IVR technology developer. The remaining four were IVR technology developers (n=2) and IVR company founders (n=2).

Table 5-8: Participants' characteristics

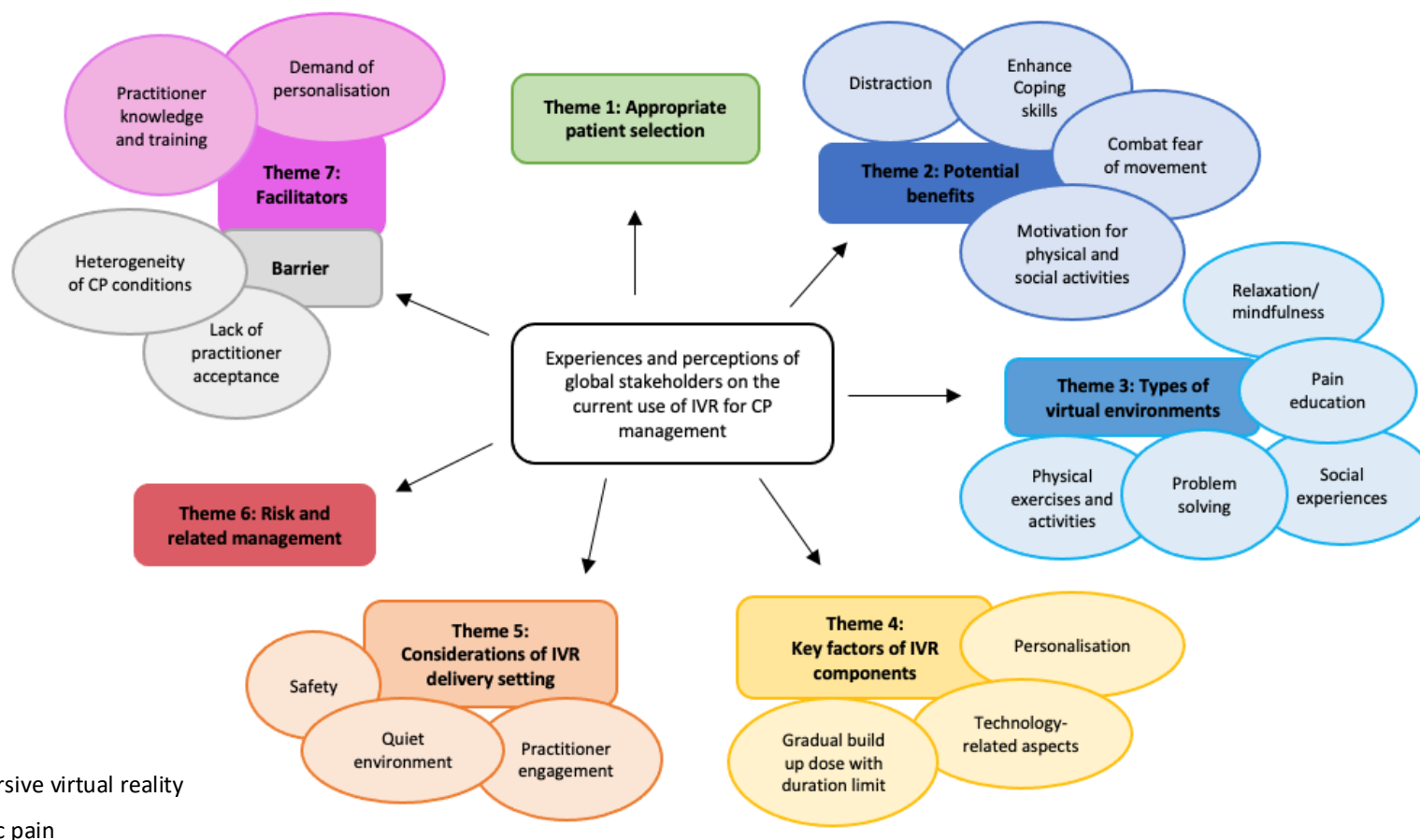
ID	Country	Gender	Occupation	Years of experience using IVR in CP management
P1	Canada	M	Healthcare practitioner (Nurse), IVR developer	5 years
P2	UAE	F	Healthcare practitioner (Surgeon)	6 years
P3	Netherlands	F	Healthcare practitioner (Physiotherapist)	5 years
P4	USA	M	IVR company founder	2 years
P5	USA	M	IVR company founder	4 years
P6	USA	M	Healthcare practitioner (Physician)	4 years
P7	Canada	F	IVR technology developer	15 years
P8	USA	M	Healthcare practitioner (Physician), IVR developer	22 years
P9	UK	F	IVR technology developer	3 years
P10	UK	F	Healthcare practitioner (Nurse)	2 years

Key: USA: United States of America, UAE: Unit Arab Emirates, UK: United Kingdom, M: Male, F: Female, IVR: Immersive Virtual Reality.

5.3.4.1 Thematic Map

As shown in Figure 5-6, seven themes were generated associated with underlying subthemes including: (1) appropriate patient selection, (2) potential benefits, (3) types of virtual environments, (4) key factors of IVR components, (5) considerations of IVR delivery setting, (5) risks and related management, (7) facilitators and barriers.

Figure 5-6: Thematic map of seven overarching themes and underlying subthemes from the online interviews



5.3.4.2 Theme 1: Appropriate patient selection

This theme identified the characteristics of patients who participants perceived to benefit and not benefit from IVR. This is illustrated by six participants suggesting that patient response is highly individual with some people having a positive effect while others may have a negative effect. *P1 (Nurse): “we have mix results, for some people it works and some people it doesn’t and that would seem to reflect the nature of [CP], which is highly individualised”, P9 (IVR developer): “I work with patient who has migraine from using [IVR] which is quite upsetting, so it’s very important to realise that everybody responds differently”.*

Half of the participants stated that patients’ attitudes toward technology and their acceptance could determine their suitability, especially those who are novice users, potentially suggesting that patient preference may be part of the screening/selection criteria. *P4 (Company founder): “some patients see [IVR] a kind of fancy thing, [they are] reluctant to technology, someone might see [IVR] is intimidating or they don’t have any experience, so they don’t perceive how it could work, so [IVR] just can’t work of them”.*

All participants stated that they routinely used screening to exclude patients who may experience side effects. “Susceptibility to motion sickness” and “epilepsy” were frequently reported as important exclusion criteria. *P1(Nurse): “obviously we don’t accept people susceptible to motion sickness, otherwise they tend to not be doing well, also people who have sort of light seizures or epilepsy”.*

In addition, six participants highlighted that patients with “visual disorder”, “facial lesion” or any type of infection may need to be excluded. *P2 (Surgeon): “if they have facial or head lesions, we also [avoid people] who have visual disorders or recent infections, as of now we are limiting any of these patients to be included”.*

Two participants (P7, P10) believed that mental health issues may need to be taken into consideration during the screening process and/or preparation for IVR. *P7 (IVR developer): “I think there is a certain subset of [CP] patients who [are] struggling with mental health issues and it is hard to know, how those fits in exclusion criteria, so like the top listed in the international association for the study of pain website, like panic disorders, extreme anxiety, and phobias”, P10 (Nurse): “It is not all to say if you got mental health issues, you cannot use it but there are additional safeguards in place, to make sure that is going to be okay for them”.*

5.3.4.3 Theme 2: Potential benefits

This theme describes the participants' understanding of how IVR benefits patients with CP. Subthemes under this theme include description of participants' accounts on how IVR could help patients with CP through 1) pain distraction, 2) enhancing coping skills, 3) combatting fear of movement and 4) motivation for physical and social activities, in which participants assume IVR is a good alternative to medications. *P2(Surgeon): "they will be able to escape the medicine which they do not want to take because it is affecting their body. So, I think for me [IVR] is a hope and it is giving the end users the encouragement that there can be alternative procedures without any systematic harm to their body system".*

Four participants indicated the change in physical or pain behaviour whilst inside IVR, highlighting the potential 'in-situ' analgesic effect although the likely short-lasting effect was appreciated. *P9(IVR developer): "there are potentially like therapeutic effect on the moment, [for example] we have one patient usually cannot stand unless he has a wall behind to lay on, but while he is using [IVR], he was fully able to move, and he was also play games and it is clearly reducing his pain experience".*

Four other participants expressed doubts about the long-term benefits of IVR on pain or quality of life. Despite this they expressed it as deemed 'important', long term effects of IVR may not be currently routinely monitored. *P1(Nurse): "most people gain sort of benefits on short term basis; it seems not persist after the therapy", P7 (IVR developer): "we planned to follow up at three, six and twelve months, but mostly follow ups have not been conducted [...] and I think that's important".*

5.3.4.3.1 Subtheme 1: Distraction

All participants mentioned that distraction and being able to shift patients' focus away from pain is the main advantage of IVR. *P1 (Nurse): "in term of how [IVR] works, we are looking at it from theoretical framework [...] of neurological distraction, the benefits seem related to a powerful sense of distraction by presence in another environment, so that seems to affect their brain and take them away from their pain".*

Half of the participants believed that distraction alone might not be enough for CP, with IVR potentially helping in CP management beyond distraction. *P7(IVR developer): "the idea is pain distraction, so the sensory capacity focusing on immersive environment is the way it is*

understood, but for people lives with [CP], they cannot distract themselves [twenty-four] hours”.

5.3.4.3.2 Subtheme 2: Enhance coping skills

Seven out of ten participants believed that IVR may offer opportunities for CP patients to enhance their coping skills. They thought that technology allowed patients to practise tasks embedded within other known psychological approaches already used for CP management such as mindfulness, offering biofeedback and breathing control. *P5(Company founder): “it is really important that people learn self-regulatory and coping skills to learn how to live a meaningful life despite pain and a lot of different treatments are used in pain psychology, biofeedback, [...] these things have been proven to be beneficial, what therapeutic [IVR] can do is make it more engaging”.*

When considering the psychological benefits of learning to cope with pain using IVR, four participants believed that IVR could enhance self-awareness and self-efficacy through real time feedback, inducing understanding of pain and thoughts to maximise recovery. *P7 (IVR developer): “When you practise the skill, you become more aware of what your body is doing, how your pain is changing , so it does not get worse and then in the real world you can think of what set you off, or you know what kind of things that seems to make it worse, so it is really more of an awareness build in order to manage your pain , it is not just relaxing, we’re trying to build resilience and awareness , so it is giving patients a tool that they can use to better manage their pain”, P9 (IVR developer): “seeing your breath in front of you and that’s how you navigate through the virtual world, so that sort of mirroring gives people a sense of empowerment because you have an effect on the world”.*

Importantly, two participants (P3, P6) felt that the desired psychological effect could be achieved faster with IVR technologies compared with conventional methods and saw this as an added advantage of IVR. For instance, P3 described how the use of IVR enhanced the learning of relaxation, illustrating the benefits of saving treatment time in clinical practice. *P3(Physiotherapist):“it helps me because it saves time, I have been [working as] physical therapist for 10 years now, so before [the use of IVR], the treatment took a lot of time to get people in a positive mindset because that very hard, but with [IVR] people immediately feel relaxed”, P6(Physician): “I think what’s nice about [IVR] is allow you to realize that something*

could be in your mind, and it does it very quick in a way of switching your perception that may have locked you from reaching a new insight”.

5.3.4.3.3 Subtheme 3: Combat fear of movement

Two participants discussed the issue of fear of movement associated with CP and how IVR might help with avoidance behaviour by enhancing awareness of movement safety despite pain. They believed that immersion and real-time feedback within VE could potentially change patients’ negative beliefs about movement as a cause of pain and enhance self-efficacy to control their own condition. *P3(Physiotherapist): “with [IVR] you contradict how people think about pain, people [usually say] ‘I’m not going to move because I’m only making it worse’, and movement is known as the best therapy but if people are too anxious, people don’t [move], so they’ve to overcome that mental state and convince people that when they have pain, movement is helping them and that’s how we can use [IVR], you show people [...] something with score, this is your movement at zero and [...], this’s how you perceive your pain at zero, and after ten minute your movement is going up and pain is going down, so they have proof [that their bodies] are working, they get self-esteem”, P4 (Company founder): “I think patients are going to gain confidence because they realise ‘oh I can move this much, and I didn’t experience pain”.*

In addition, these two participants described how IVR may combat fear of movement by gradually exposing patients to movement starting with simple tasks, followed by more complex functional exercises through well-designed games and experiences in IVR. *P3 (Physiotherapists): “so we can use [IVR] for exposure therapy to learn how to relax, so your muscles are less tense and then from that moment you go to movements which are flexion, extension, rotation, lateral flexion”, P4 (Company founder): “we design [IVR] tool to gradually increase how much patients move [...], so it starts out following a track that they move in multiple planes of movement [...] and then gradually progressive into more gamified things like stacking dishes”.*

P4 was the only participant who mentioned the advancement in technology using ‘virtual embodiment’ and ‘visual manipulation’, illustrating that new concepts being introduced are potentially seen to benefit CP management. Embodiment using a virtual avatar (VA) is believed to change perception of movement with potential impact on pain. *P4 (Company founder): “There is that concept known as virtual body embodiment where you perceive the*

movement of [VA] as your own, so with [CP] there is a very strong attentional mechanism that drives patients to constantly think about their pain [...], but in [VR], there is disconnection because you are seeing your movements in VR, which may not have one to one mapping of the sensory information you're getting from your own body".

P4 also explained the 'visual manipulation' and how it could encourage movement through creating an illusion of virtual movement when patients might not be able to perform that movement or manipulating the degree of movement and showing progression in the avatar's movement. *P4 (Company founder): "you can manipulate the [VA], so if one side painful to move [...], they can do visual near feedback augmentation within [VR], so they can perform movement with the arm that's not painful, but in [VR] they can see their painful side is moving, [...] the other type of manipulation you can do in [IVR] is augment the movement either understate or overstate, so if somebody has limited [ROM], so in [IVR], we can have the patient move [50] degrees but show the virtual avatar moving [75] degrees, we have seen patients increase their [ROM] without even realizing they're doing so, because they are recalibrating how much they move with visual feedback they get from [VA]"*.

Both advancements are described as having a potential change on body awareness, implying an increase in self-efficacy. *P4(Company founder): "the positive effect is that patients realize that they can do more than they thought capable of doing with [CP], so they gain a sense of confidence or self-efficacy in the way they perceive their own movement"*.

5.3.4.3.4 Subtheme 4: Motivation for physical and social activities

Five participants thought that motivation associated with IVR gaming could enhance patients' engagement with physical exercises/activities, indicating that practising movement in non-threatening VE encourages self-efficacy to manage pain. *P3 (Physiotherapist): "you have to do [exercises] and [IVR] helps you to make it fun, [...] so it is not boring anymore because you are doing fun games". P2 (Surgeon): "if they are walking in the park and the pain strikes, it is going to be long lasting and they will remain inactive [...], but if you experience this in your comfort zone by walking in a virtual park, you can remove the HMD when you get tired, so you have control on your activities"*.

Furthermore, IVR was perceived by three participants as a tool for social interaction, suggesting the potential to avoid isolation and promote engagement in social activities.*P9*

(IVR developer): “I get people with [CP] and they likely to be house bound, therefore they may have things like anxieties of going out and I think social [IVR] experiences and how that connects people, hopefully can encourage them to meet those people in the real world”.

5.3.4.4 Theme 3: Types of virtual environments (VEs)

The participants mentioned different types of VEs including games and /or experiences used such as relaxation, pain education, problem solving, social experiences and a diverse range of physical exercise and discussed how these could help patients with CP.

5.3.4.4.1 Subtheme 1: Relaxation/ mindfulness

Seven out of ten participants stated that relaxation/mindfulness experiences could aid in CP management by engaging patients in relaxation and pain distraction. Also, half of the participants highlighted how mindfulness VEs offer biofeedback to aid patients to control their breathing. *P1(Nurse): “We had two meditation approaches, so one was a meditative environment where people meditate and the other one was a game where people actually walk through the forest and it’s a very relaxing environment”, P6 (Physician): “We use mindfulness in our programme, they think about their breath, escape the world they have, and practice deep breathing exercises, [...] they do deep breathe where actually particularized in [IVR] to get them feedback of good breathing”.*

5.3.4.4.2 Subtheme 2: Pain education

Three participants (P2, P5, P6) suggested IVR for providing educational materials about pain processing, highlighting the benefits to enhancing patients’ understanding of pain physiology. *P6 (Physician): “We have pain education, teaching patients about what is centralization pain, how does the spine work during pain, kind of gate theory of pain, such as why do I still have pain years later, so that just encourages education”.*

5.3.4.4.3 Subtheme 3: Social experiences

Although three participants highlighted the usefulness of IVR in social interaction (Theme 2), only one participant (P2) described the use of enjoyable VE where groups of patients can be involved in social experiences, potentially bringing this aspect of IVR into play in CP management. *P2 (Surgeon): “We had two patients together on the same beach, so the patient*

who is suffering from [CP], they go to this beach in [IVR], so they can also talk inside this environment”.

5.3.4.4.4 Subtheme 4: Problem solving

Two participants (P1, P5) mentioned a “cognitive” or “problem-solving” environment such as puzzles, games or quizzes which were identified as pain distraction games. *P1(Nurse): “We have games where you solve puzzles to move through different levels to escape [...], so cognitive games where they have to move things round to hit specific targets, so the puzzle is designed to engage their brain”.*

5.3.4.4.5 Subtheme 5: Physical exercises and activities

Six participants referred to VE designed to engage patients in different types of structured exercises and general physical activities. Two participants (P3, P4) described the use of a range of motion (ROM) exercises where (P4) discussed the progression in more complex games to promote functional exercises. *P3 (Physiotherapist): “so you have three variables flexion, extension, rotation and lateral flexion, [...] we have five different [VE] which train these movements”, P4 (Company founder): “we used functional rehabilitation exercises, so it starts out in multiple planes of movement and then gradually progresses into games like shooting where you are shooting target, stacking dishes, picking up a dishes from a dish washer”.*

Also, interacting with VE, which involved general physical activities, was mentioned (P2, P9, P10) including a range of activities such as dancing, walking, yoga, or Tai Chi. *P2 (Surgeon): “we have tried to combine it with some activities such as yoga, such as Tai Chi, they would do it in a very beautiful environment [...], its involving easy physical activities, some beginners’ yoga level, some beginners physical body movement”.*

5.3.4.5 Theme 4: Key factors of IVR components

This theme summarises the factors discussed in relation to the software, hardware, and dose to optimise the use of IVR intervention including four subthemes: 1) personalisation, 2) technology related aspects and 3) gradually building up dose with duration limit.

5.3.4.5.1 Subtheme 1: Personalisation

This subtheme illustrates the importance of personalisation within **software and hardware**. The suitability of the **software** was seen as dependent on an individual patient’s engagement,

potentially linked to their sense of presence in VE. *P8 (physician): “The more engaging that is to the patient, the better the patient’s experience is going to be. There is a feature in the software and the environment that is going to create a more compelling virtual world and we call it the variable of presence, the more present that patient feels in the world the more enjoyable”.*

In relation to engagement, six participants believed that VE should be meaningful to individual patients and tailored to preference, potentially highlighting the need for diverse VEs to consider what patients like or dislike and giving autonomy over selection. *P8 (physician): “if you have a patient who really loves tennis and the [IVR] is mocking tennis, he is [going to] find it more enjoyable”, P10 (Nurse): “There is one lady who had the fear of birds, [...] there were penguins flying in [VE] and that immediately broke her engagement, and she took it off [...], so it’s equally important to be able to find out what they don’t want”, P1 (Nurse): “Different [VE] would be required for applications and it’s really patients’ choice, what they select would reflect their own interest”.*

Individual preference is also believed to be related to the patient’s familiarity with the VE such as culture or personal memory, assuming if VE could trigger a memory of past real-life situations. *P7 (IVR developer): “I have a [VE] that [patients from specific country] love it because it looks like the yellow submarine from their early adulthood, then [we] brought the same environment to [patients from other country], they didn’t like it, they think it is too weird, so you cannot really present them with something that is devoid of culture”.*

Participants also mentioned the necessity of personalising VE to the patients’ clinical needs and functional abilities. Half of the participants believed that CP is multidimensional in nature and the VE, either with psychological or physical benefits, should be afforded according to individual needs. *P5 (Company founder): “It is important to highlight that with [CP] it is never going to be a single piece of content, to see the benefits. Within the programme there are things focused on function, attention, relaxation principles and biofeedback that teach self-regulatory skills, [...] so a number of different techniques need to be embedded within the full programme”, P3 (Physiotherapist): “They can be in a relaxation environment or active environment; it depends on what your patient needs”.*

Four participants highlighted the need to consider the functional limitations of the individual patient, including their ability to perform tasks either in sitting or standing. In addition, the

difficulty of the tasks which are thought to be more suitable when tailored to patients' level of performance. *P10 (Nurse): "It depends on the individual, some of them are sat down and some of them stand up and move around, we got a lot of people with different disability", P4 (Company founder): "The movement based on how many repetitions that patients do within the exercise, how much movement they are able to produce within the exercise and then how easy it is to get through the protocol".*

In terms of the **hardware**, participants did not specify a single type of HMD as the best for CP management, instead they highlighted that the selection of hardware was more dependent on their experiences around patient comfort. *P2 (Surgeon): "Whatever new device comes on the market, we're obliged to offer the best to our patients, [...] so we've tried various devices from the basic one such as google cardboard to the most complex ones to understand what technology are offering and how it can be applied to different patients".*

The light weight of the HMD and its ease of use were the most commonly mentioned and desired features for maximising comfort. Ease of use was frequently indicated by implementing wireless HMD and reducing the number of hand controllers, this was described as much preferred and easier for patients to use. *P2 (Surgeon): "it should be lightweight and not adding any strain. It should not be very bulky, that is scaring the patient to use", P5 (Company founder): "standalone [HMD] that does not require computer, that is an important thing, CP people do not have same level of technological comfort, so we [want] make that easy to use", P10 (Nurse): "Oculus go [wireless HMD] has always been one of my favourites because it's just one controller, there's only a couple of buttons whereas the Oculus quest [wireless HMD] has two controllers with multiple buttons and it's more complex to use, so ease of use for the patient".*

In summary, personalisation of the IVR intervention was perceived as a key factor by which the VE within the software should be tailored to individual preference, clinical need, and functional ability, with selection of the HMD dependent on the patient's comfort and ease of use.

5.3.4.5.2 Subtheme 2: Technology-related aspects

Selection of the hardware was seen as more dependent on patient comfort (subtheme 1), six participants discussed how their decision on HMD selection was driven by being compatible

to the level of interactivity within the software. For instance, the computer-based HMD which enables movement tracking using sensors/ hand controllers was seen as essential for body movement induced VE unlike the wireless one. *P4(Company founder): “in lower back exercises, we need to add the sensors to the lower back to know the relative position of the pelvis to the hands, the HTC Vive [computer-based HMD] does have the advantages to add sensors to knees and feet, so you can have full body tracking, but you cannot have that in Oculus Quest [wireless HMD]”.*

Four participants also added that decision of HMD selection is restricted to their availability in the market, considering affordability for the adopted healthcare system. *P2(surgeon): “we should learn how to use the available devices, devices are becoming wireless, but they do not become completely wireless, we are forced to use what we have and it’s our duty to find out”, P7(IVR developer): “decisions are based on what is the cost, because hospitals, health insurance, clinics, patients they’re not [going] to pay a lot”.*

Six participants pointed out the importance of visual graphics in reducing the risk of MS, highlighting the need of HMD with good visual quality while avoiding the fast-paced movement or intimidating experiences. *P3 (Physiotherapist):“Games which have a lot of movement, it can provoke motion sickness”, P5(Company founder): “the performance in the headset, you know, slow refresh or proceed latency will cause uncomfortable experience, [...] you can achieve high degree of presence as long as the scene keep up to speed, if there is any lag or delays in the scene , it can create motion sickness”.*

5.3.4.5.3 Subtheme 3: gradual build up dose with duration limit

Half of the participants highlighted that no clear guidelines had yet been established about the optimal dose, suggesting a gradual build up in terms of task complexity and time spent in IVR to adapt VE. *P2 (Surgeon): “Until now there is no research that defines the exact time, we are still on the edge of achieving that. I think we are not able to answer this yet, but we usually start with a passive experience before getting in any complexity, we need to orient their brains, that they are in 360 environments, so your brain is trying to adjust, however once the patient does not have any challenges, that is the time they can move forward to an active experience”, P3 (Physiotherapist): “In the first session, use it for 5 to 6 minutes, so it is more to get [adapting] to the [VR] and within time you are going to build up”.*

Moreover, participants had conflicting views on the maximum duration that CP patients can tolerate inside VE to avoid side effects. Five participants thought 20 to 30 minutes would be the most tolerable, while others felt that depending on the task demand a maximum of 15 minutes would be deemed suitable when VE consisted of a high level of movement/exercising. *P1(Nurse): “Most people cannot tolerate [IVR] for more than half an hour without some degree of discomfort, eye ache [because] of the focus in front of their faces, also even the lightest [HMD] becomes bulky after half an hour”, P5 (Company founder): “when someone is immersed in a really engaging type of exercise, you can achieve a lot in a short amount of time and what we found is that much longer than 10 or 15 minutes can lead to fatigue because they’re so engaging and immersing”.*

5.3.4.6 Theme 5: Considerations of IVR delivery setting

This theme presents the discussion on delivery setting, indicating the potential for both clinical and home setting while considering three subthemes: 1) safety, 2) quiet environment and 3) practitioner engagement.

5.3.4.6.1 Subtheme 1: Safety

Participants described the potential use of IVR under clinical supervision or for remote delivery (i.e., at home). Although remote delivery was acknowledged as an advantage of technology to enhance accessibility to the intervention especially during the COVID pandemic, participants believed that safety should drive such a decision. *P3 (Physiotherapist): “so it helps me in COVID period, I still could treat people because I have video online and they have [IVR] and I sent them the exercises and see what they have been doing at home”, P10(Nurse): “We do not give the headset out for the people to use it by themselves, we have always been there for the sessions. We are looking for in the hospitals to give the headset when we discharge them to follow up treatment, but we must be extra safe, making sure they are aware of the risks and what to do”.*

To ensure safety, half of the participants stated that the intervention started with a supervised clinical session to observe how the patients respond to IVR, excluding any negative experiences. *P3(physiotherapy): “So the first time at the clinic, just to observe how it affect patients and then we can go further” , P7(IVR developer): “if patient use [IVR] at home, they start with a session in the clinic, we carefully observe patients and look if they feel comfortable*

or not, so if they feel uncomfortable in the [IVR], I just tell them to take it off'. A supervised clinical setting was also preferred where IVR facilitates movement particularly in standing / walking, to ensure correct performance and to avoid risk of a fall. P8(Physician): "When we are talking about enhancing movement that is usually something best under supervision, [...] you need to make sure that movement is not hurting the patient. so, it depends on how complex the [IVR] is and what you are asking the patient to do", P10 (Nurse): "keeping the environment safe, I have had individuals who just start like swimming around the room, and we had to walk with them while they engage with it".

Alongside safety, all participants considered a hygiene protocol as essential for infection control in the clinical setting, particularly during the COVID pandemic. P4 (company founder) *"many hospitals are now adopting sterilisation protocol, especially post [COVID-19] to make sure [HMD] are safe to use".* Two main methods were pointed out for hygiene protocol either ultraviolet radiation box (i.e., special cleaning equipment for HMD) or medical wipes. Four participants described ultraviolet radiation box as a faster sterilisation option, while seven reported using medical wipes and disposable covers as more affordable solutions in healthcare, although no standard procedure was mentioned. (P2, Surgeon): *"we do have a system which is fitting in the clinic, you are going to put the device in a box or cabinet, turn on the system just for sixty seconds, using ultraviolet light", P3(physiotherapist): "I clean it with alcohol wipes, I have also disposable covers around the glasses, so it is placed on the head of the patient, where everyone has [own] cover, there is cleaning VR box to put the glasses in for one minute, but it is expensive for me as a physical therapist".*

5.3.4.6.2 Subtheme 2: Quiet environment

A quiet environment was suggested to implement IVR, highlighting that interruption of engagement within VE is usually more common in the clinical setting than at home which may reduce its suitability. P10 (Nurse): *"I think with the clinical setting, it can be a bit more difficult because you got a lot of noise and motion around you [...], that does ruin the immersion, whereas at home obviously you can control the environment a lot better but that not to say it doesn't work, it's just can be a little more disrupted".*

5.3.4.6.3 Subtheme 3: Practitioner engagement

Practitioner engagement was seen as essential throughout the intervention, this includes educating patients prior to the intervention, guidance and monitoring of progression during the intervention, and communication after the intervention.

Educating patients prior to the intervention was recommended, emphasising the need for instructions about the benefits of IVR, its value compared to alternative treatments, and what is expected within VE, highlighting the patient's apprehension towards technology, especially novice users. *P9 (IVR developer): "I think the way that you introduce it is really important, there's a lot of anxiety when you use it for the first time, and I think you really need to explain what is going to happen and it is important to make that clear", P7(IVR developer): "I am talking about the importance of knowing the perceived value, because it is important for them to know how they can really trust this compared to like a hundred things".* Alongside, exploring the VE prior to the intervention was indicated as an essential part of education. *P3(physiotherapy): "They have to experience it, so I explain why I use it, but people have to try it on and see if its work for them or not".*

In addition, half of the participants reported the necessity for providing the practitioner with virtual access via e.g., video call or computer screen to have a live view of the VE. This was perceived as essential to guide and monitor patients' progress, solve technical issues, and pause the intervention in case of any issue either in clinical and/or home setting. *P4(Company founder): "We have video format, the physical therapist can see them putting their headset on and guide them through their exercises, [...] also patients with [CP] tend to be older and sceptical to technology, so it's really important to guide them to do the exercises and also [for] technical support", P2 (Surgeon) "we have the guided mood system where the healthcare practitioner has the same view of the patients, but in their device which can be a tablet or laptop screen to show the doctor what that patient is looking at. [...] This is very important because the doctor will be able to guide the patient to look at what we want them to do and if the patient is scared or something wrong happen, the guide can stop the [IVR] device and control when to play again".*

Two participants (P3, P4) believed that practitioner-patient communication following IVR is an essential pre-requisite of success. They suggested that verbal feedback should be provided and an assurance of patient capabilities in IVR and illustrate how the VE is relevant to their

pain experience in daily life. *P4(company founder): “what we always trying to do is reinforce that with [saying] ‘you see you thought you could not do it, but you spent 30 minutes in a hike [VE] that you thought you cannot do before because of your [CP]”, P3(physiotherapist): “if you put people in [IVR] and not giving them feedback, they will not [understand] how does [IVR] reflect on their daily life tasks, you still need to check with your patients what [VE] is telling, you give the feedback that they can do all the movement they thought they lost”.*

5.3.4.7 Theme 6: Risks and related management

This theme describes the risks discussed by participants and how they manage or deal with these risks. Participants reported the risks associated with IVR including symptoms of MS (i.e., nausea, dizziness), anxiety, or panic attack.

Symptoms of MS were mentioned as a common risk, and all participants assumed that could be reduced through screening (Theme1), gradual dose, and using HMD with good visual quality (Theme 4, subtheme 1,3). *P6 (physician) “The side effects are probably going to happen, if you don’t screen [patients] for [MS]”, P1(Nurse): “In cybersickness [MS], people build up tolerance, so if they are getting sick, they try small exposure and gradually build up, I think we never have one person who particularly can tolerate it all at once, everybody gradually builds up, and it goes away so they adapt”, P10 (Nurse): “I think a lot of nausea [was] when the equipment was only just coming out whereas they are a lot better now”.*

One participant (P3) also added how specific instructions, asking patients to focus and feel in control of VE could reduce symptoms of MS. *P3 (physiotherapist): “people experience a little dizziness, but you need to give them the right instruction, so you have to say, ‘feel that you’re sitting on the chair’, feel also that you are the leader of [IVR] world, then people experience less dizziness”.* Despite these suggestions, four participants pointed out that MS might be non-resolvable in a subgroup, potentially highlighting that IVR is highly individualised and not all patients would be suitable (Theme 1). *P7(IVR developer): “I would say most people might feel nauseous for the first 2 minutes and then it goes away, but there is always almost 20 percent of patients who won’t adapt, so we take them out”.*

In addition to MS, three participants discussed the few instances of anxiety and panic attacks as a serious and unexpected risk. Two participants (P3, P5) described how VE might trigger fears when patients receive non-preferable VE, while P6 mentioned inclusion of a patient with

a history of anxiety. Potentially, emphasising the need for mental health screening and the use of preferred VE prior to the intervention which presented in (Theme 1) and (Theme 4, subtheme 1), respectively. *P5 (Company founder) “We had patients [who] got panic due to the VR experience where you can swim underwater with the dolphins. Some people were afraid of being underwater or close to animals and those things we would not expect”, P6 (Physician): “We had one or more patients who get anxious but they’ve a history of eating medications for anxiety, that is literally one out of hundreds I personally treated”.*

5.3.4.8 Theme 7: Facilitators and barriers to IVR adoption

The final theme highlights the facilitators and barriers perceived by participants in adopting IVR technology for CP management. **Personalisation, and practitioner knowledge and training** were suggested to enhance the future uptake of IVR intervention, while **lack of practitioner acceptance** and **heterogeneity of CP conditions** were perceived as the main barriers.

5.3.4.8.1 Subtheme 1: Facilitators

Personalisation was recurring throughout the interviews as major facilitator, in which participants believed that IVR software/hardware should become more tailored to patients’ needs. They acknowledged that current IVR technology was yet to fulfil patient needs and that there is a still a need for collaboration between practitioners and technology experts while obtaining patient feedback to optimise the development of more therapeutic VE, and practical HMD devices. *P1(Nurse): “There are still complex, and we need to move towards things like small headsets, self-contained, light weight. [...] It is really in their early stages of development, and we need to make it a much more practical tool. I think the thing that we would suggest in the development of [CP] tools are to engage [CP] sufferers at the early stage to get sense of what is going work for them”, P7(IVR developer): “I think that the health people and tech people need to talk to each other more and get benefits for the whole area”.*

Three participants described the role of artificial intelligence to scale up personalisation, potentially bringing this aspect of IVR into play in CP management, through objective assessment of patient’s needs to build individualised meaningful experiences. *P2 (Surgeon): “I think what is going to improve [IVR] is [AI] system, embedding [AI] assessment tools which can [evaluate] patient’s condition and modify the content accordingly and will also be able to*

assess the response, so there are different parameters to assess that , so we have already started using facial expression , using the pulse, using other methods instead of having just me telling you that yes I've a good experience , you'll have a very quantitative data at the end of the day that will help you to shape up and scale up the whole [content]”.

Six participants discussed the **comprehensive knowledge of practitioners** as a facilitator for implementation, indicating the need to be informed about the entire aspect of IVR including clinical (e.g., screening, risks, communication) and technical (e.g., hardware, software) to deliver it safely to patients. *P2 (Surgeon): “We need to learn what are the features of the device and the content, then what is the safe dose to start with, what is the safe duration, how do I educate the patient and what things I need to warn the patients about, you need to learn about the whole experience from A to Z, what could go wrong and how do you act”.*

Additionally, the need for a validated training programme for practitioners to deliver IVR intervention was emphasised, with two participants (P3, P10) mentioning their own effort to educate other practitioners in clinical practice. *P10 (Nurse): “I designed our own training, there is nothing really out there at the minute, so part of what I plan is to get our training accredited, I had enquiries from all over the world about doing the training because it is not available for healthcare professionals”.*

5.3.4.8.2 Subtheme 2: Barriers

Lack of practitioner acceptance was seen as challenging for future implementation, discussing the lack of time and knowledge or familiarity with technology and its competing demand against standard practice. *P3 (physiotherapists): “It is a big challenge to get the healthcare giver engaged to use new technology, and to make time to be implemented in daily practice”, P4 (Company founder): “there is physicians, or doctors who were like ‘this is silly I will never use that with my patients’, so some doctors have a model that works for them saying ‘I have very successful practice prescribing opioids or giving subdural steroid injection why I will change that”*

Furthermore, **heterogeneity of CP conditions** was acknowledged as a barrier to IVR utility to manage CP, which makes future design to meet all patients' needs highly challenging. *P3(physiotherapist): “the difficult thing right now is there's no standard treatment for [CP], you can get ten different treatments, and also CP is [individualised]”.*

5.4 Part 2 - Discussion

This sequential explanatory study presents Part 2 of this thesis, aiming to engage global stakeholders to gain an understanding of the current IVR use for CP management. The online survey (Phase 1) provides an overview about IVR utility as a treatment tool and identifies the global stakeholders who use it in CP management. Subsequently, the online interviews (Phase 2) explore the experiences and perceptions of IVR for CP management including benefits and risks as well as opinions on technology specifications (software/hardware), dose of the intervention, context of IVR, and the perceived facilitators and barriers to IVR adoption. The key findings of both phases were interpreted and integrated for discussion in relation to the literature (Table 5-9).

Table 5-9: The key findings of phase 1(online survey) and phase 2 (online interviews)

Research Phase	Phase 1: online survey	Phase 2: online interviews
Interpretation		
Patients 'characteristics and selection	<ul style="list-style-type: none"> • Patient's age <p>Patients with wide age range are ultimately eligible to use IVR (18-80 years old).</p>	<ul style="list-style-type: none"> • Appropriate patient's selection <p>The patient's preference to use technology as intervention and screening to exclude patients with contraindications, and those with mental health problems.</p>
Potential benefits	<ul style="list-style-type: none"> • Top three targets of IVR use. <ol style="list-style-type: none"> 1) Reduce fear and anxiety 2) Pain management 3) Improve physical movement 	<ul style="list-style-type: none"> • Benefits and adopted methods. <p>Assumptions of IVR as good alternative to medication, using distraction as the main mechanism, with the preference of methods beyond distraction to enhance coping skills, combat FOM and</p>

			motivation to promote physical and social activities.
IVR components	Software/Hardware	<ul style="list-style-type: none"> • Types of software/hardware: <ol style="list-style-type: none"> 1) Customised software > off the shelf software. 2) Computer-based (Oculus rift) and self-contained HMD > mobile-based HMD. • Key ingredients for successful use of IVR <p>Motivation and engagement of the users, bespoke IVR for the condition and HMD comfort were the top three ranked ingredients in order.</p> 	<ul style="list-style-type: none"> • Key factors to optimise the selection of software /hardware. <p>Personalisation: consider individual engagement by presenting various VE to match individual preference, clinical needs, and functional abilities as well as prioritising individual's comfort/need during HMD selection (e.g., wireless, lightweight, less controllers).</p> <p>Technology-related aspects: considering graphic design, HMD visual quality, compatibility of hardware/software and accessibility to healthcare.</p>
	Dose	<ul style="list-style-type: none"> • IVR duration, frequency, and number of the sessions <p>Varied length and number of sessions, with no common application of IVR on frequent basis.</p> 	<ul style="list-style-type: none"> • The most optimal dose <ul style="list-style-type: none"> • Acknowledgment of no clear guidelines, and suggestions on gradual build up with duration limit to avoid side effects.
IVR delivery setting and related considerations	<ul style="list-style-type: none"> • IVR delivery setting <p>Hospitals, universities, and patient's home are the</p> 	<ul style="list-style-type: none"> • The most suitable setting and related considerations 	

	<p>most common setting in order.</p>	<p>Perceptions on the potential of clinical and home setting, prioritising safety with supervised clinical sessions at the start of the intervention.</p> <p>Recommendations to consider Hygiene and quiet environment.</p> <p>Views on the necessity of practitioner engagement including educating patients prior the intervention, guidance during the intervention via virtual access and communications post the intervention.</p>
<p>Adverse effect and related management</p>	<ul style="list-style-type: none"> • Encountered adverse effects. <p>MS being the most common, followed by disorientation, eye strain, anxiety, fatigue, headache or neck pain and panic attack.</p>	<ul style="list-style-type: none"> • Potential risks and management methods <p>The risks are individualised, but they can be minimised through screening and gradual dose, considering intolerable sub-group who should be excluded.</p>
<p>Facilitators and barriers to IVR adoption</p>	<ul style="list-style-type: none"> • Facilitators <ol style="list-style-type: none"> 1) Personalisation. 2) Practitioner’s knowledge and dedicated technology team to support IVR use. 	<ul style="list-style-type: none"> • Facilitators <p>Enhance personalisation through co-production and artificial intelligence as well as raising practitioner knowledge via comprehensive training in</p>

	<ul style="list-style-type: none"> • Barriers 1) Lack of practitioner acceptance. 2) Equipment cost and lack of funds. 3) Limited availability of games/experiences. 	<p>both technical and clinical aspects.</p> <ul style="list-style-type: none"> • Barriers <p>Lack of practitioner acceptance due to lack of time, knowledge, and clear guidelines as well as heterogeneity of CP conditions makes designing of suitable VE challenging.</p>
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*IVR: immersive virtual reality, FOM: fear of movement, HMD: head mounted display, VE: virtual environment, MS: motion sickness, CP: chronic pain.

5.4.1 Patient characteristics and selection

Participants in Phase 1 noted that IVR is potentially suitable for patients of any age including younger and older adults. Phase 2 findings suggested that whilst this potential for IVR to be widely used is its strength, patient selection is essential to ensure IVR suitability for each individual patient. Several selection methods have been suggested in Phase 2 including patient preference to use technology as well as potential contraindications such as susceptibility to MS (Table 5-9).

These findings are in line with previous literature which reports the use of IVR with a wide age range of adolescents, adults, and even elderly people over 75 years of age (Ahern et al. 2020, Brea-Gómez et al.2021, Stamm et al.2022; Yalfani et al.2022). In term of patient technology preference, Phase 2 illustrated that patients’ attitudes towards technology could determine their suitability for IVR. Likewise, Sarkar et al. (2021) stated that patient satisfaction with IVR as a treatment option could promote IVR implementation. Regarding contraindications, which could present risk, Phase 2 emphasised the need for screening to exclude patients with potential contraindications including susceptibility to MS, epilepsy, visual disturbance, and infection as well as taking precautions with those who have mental health problems (e.g., anxiety or panic disorder). Similarly, previous studies recommended excluding patients with these contraindications, some screened for the mental status and excluded patients with severe or uncontrolled symptoms of depression (Thomas et al. 2016; Chen et al. 2017; Fowler

et al. 2019; Garcia et al. 2021; Glavare et al.2021; Eccleston et al.2022). Screening of mental health issues, such as panic disorder, phobia or severe anxiety, has been suggested in the literature of ethical practice using IVR based interventions in the clinical population, stating that this could minimise psychological harm (Schultheis and Rizzo 2001; Botella et al. 2009; Găină et al. 2021). Hence, any diagnosed mental health problems may need to be considered as a precaution and excluded if combined with patient harm.

5.4.2 Potential benefits

As indicated in Table 5-9, participants in Phase 1 selected fear/anxiety reduction, pain management and improved physical function as the top three targets of IVR use in clinical conditions. In Phase 2, participants perceived distraction, combating FOM, enhanced coping skills and motivation to engage in physical exercise and social activities as the potential benefits of IVR. These perceived benefits were largely in line (except social interaction) with the identified mechanisms in recent literature (Ahmadpour et al. 2019; Matalama-Gomez et al. 2019; Wittkopf et al. 2019; Austin 2021; Chuan et al. 2021; Tack 2021; Trost et al. 2021; Baker et al. 2022; Bordeleau et al. 2021; Goudman et al. 2022).

Whilst most participants in Phase 2 believed that distraction was the key mechanism, they also stated that distraction alone is unlikely to be sufficient for management of long-term pain. Similarly, previous studies confirmed that distraction is likely to result in a short-term analgesic effect either during or immediately after IVR intervention, which may not be well-suited to long-term pain (Wiederhold et al. 2014; Jones et al. 2016; Jin et al. 2016; Amin et al. 2017; Garrett et al. 2017). Notably, most recent studies between 2019 and 2022 shifted the application of IVR for CP beyond distraction, incorporating exposure therapy, mindfulness/biofeedback and a range of physical exercises (Fowler et al. 2019; Darnall et al. 2020; Tejera et al. 2020; Harvie et al. 2020; Hennessy et al. 2020; Trujillo et al. 2020; Garcia et al. 2021; Glavare et al. 2021; Jones et al. 2021; Zauderer et al. 2021; Eccleston et al. 2022; Stamm et al. 2022; Yalfani et al. 2022).

Phase 2 participants noted that IVR core elements including immersion, real time feedback and virtual embodiment could change self-awareness of thoughts that contribute to pain, which assumed to improve self-efficacy. In addition, the motivational aspect was seen as helpful to enhance engagement with physical exercises. These views are in line with the literature to some extent. The participants' perceptions that IVR could enhance self-

awareness of avoided movement to combat FOM are aligned with the proposed mechanism of graded exposure, however none of the previous studies reported self-efficacy as a potential target (Thomas et al. 2016; Fowler et al. 2019, Hennessy et al. 2020). According to the FAM model, CP patients are more inclined to confront and perform activities in the presence of high self-efficacy, even with high FOM (Woby et al. 2007). Also, self-efficacy has been found as a strong predictor of disability in CP and a high level is associated with greater function, physical activity, and lower pain intensity (Costa et al. 2012, Martinez-Calderon et al. 2018). Given that Thomas et al. (2016), Fowler et al. (2019) and Hennessy et al. (2020) gradually exposed patients to movement and showed no change in FOM, it may be crucial to use self-efficacy as a potential target to establish whether IVR is beneficial for patients with FOM.

Additionally in Phase 2, integration of IVR with coping skills such as mindfulness and biofeedback for breathing control was believed to enhance the ability to cope with pain more effectively than the conventional method, through building self-awareness and self-efficacy. Consistently, previous literature reported the use of coping skills such as mindfulness and biofeedback within VE, in which self-efficacy is the primary outcome (Wittkopf et al. 2019; Darnall et al. 2020; Austin 2021; Gracia et al. 2021; Jones 2021). Also, Darnall et al. (2016) findings are aligned with participants' beliefs, indicating that IVR mindfulness/biofeedback reduce pain intensity, pain interference with mood and sleep, in a shorter period of time compared with the standard method.

The motivational aspect or the enjoyment created by IVR was also indicated in literature as a potential advantage, although the added value of gaming VE to physical exercise is still not evidently supported (Sirag-Bahat et al. 2015; Sirag-Bahat et al. 2018; Gulsen et al. 2020; Tejera et al. 2020; Glavare et al. 2021; Nusser et al. 2021; Zauderer et al. 2021; Yalfani et al. 2022). Enhanced engagement in social activity was seen in Phase 2 as an additional benefit of IVR, which has not yet been applied in the current interventions. However, its potential as an alternative platform to build relationships and share experiences with friends has previously been suggested in pain management (Won et al. 2017). Since CP patients are often affected by social isolation and increases in social engagement have been recommended in CP management (Bannon et al. 2021; Karayannis et al. 2019), incorporating social VE in the development of future interventions might be a valuable option.

According to Phase 2, it could be argued that participants' perception of IVR benefits agreed that CP patients would need mechanisms beyond distraction such as exposure to movement, coping skills, and physical exercise to achieve long lasting benefits. Phase 2 contribution to literature is the recognition of IVR as a behaviour change tool, despite participants not explicitly stating that. They believed that IVR immersion, real time feedback and virtual embodiment while integrating movements/exercises or coping skills can change self-awareness and they mentioned self-efficacy and motivation as the potential target. Both self-efficacy (i.e., beliefs about capability) and motivation are key behavioural determinants which are usually targeted in behavioural change interventions (Michie et al. 2008; Michie et al. 2011). Using IVR as a behaviour change tool was not commonly discussed in the context of CP management, however, a recent study by Eccleston et al. (2022) assigned the IVR core elements including immersion, interactivity, and embodiment to induce behaviour change in CLBP patients. The immersion within VE was supported by a virtual mentor for goal setting and providing positive feedback (Eccleston et al. 2022). Also, the interaction and embodiment were assigned to support repeated physical movement, providing feedback on progress and reward (Eccleston et al. 2022). Goal setting, repetition, feedback on performance and reward are all active ingredients of a behaviour change intervention (Michie et al. 2013). Given that current IVR interventions have disparities in the integrated mechanisms, future development may need to address how IVR core can augment behaviour change to maximise the benefits of the intervention.

5.4.3 IVR components

5.4.3.1 Software/Hardware

As shown in Table 5-9, this study's Phase 1 findings indicate the preference of personalisation including the use of custom developed software, considering individual engagement and patient's comfort wearing HMD. Phase 2 findings further detailed that the software needs to have diverse options of VEs to allow further means of personalisation to the clinical need, functional abilities, and preferences of each patient, and emphasised the priority of selecting hardware customised to patients' comfort/need. Contrasting responses in Phase 1 between the participants with regards to the most optimal HMD (wireless vs non-wireless) was clarified in Phase 2, highlighting that finding an optimal HMD was challenging and restricted by the availability, affordability, and compatibility of HMD with a range of VEs. Further technological

aspects were suggested in Phase 2, likely avoiding risk of MS, using good visual quality with specific graphics.

The clinical needs would mean to understand the symptoms of each patient with multi-dimensional CP to determine the suitable VE. In addition, the functional ability to sit and stand and to consider any limitation of movement was deemed essential. Likewise, Donegan et al. (2020) in their study addressed the considerations of IVR intervention for CP, they recommended placing the patient in a comfortable position and setting personalised tasks/movement to the patient's level, this was considered to be a key pre-requisite. In Phase 2, the potential methods of personalisation, based on clinical symptoms and functional limitation of each patient, could address the limitation in the current VEs which have been delivered irrespective of the clinical needs or functional ability of patients. For instance, lack of personalised functional level was noted in Thomas et al. (2016) and Hennessy et al. (2020), resulting in exacerbated pain symptoms while performing movement in VE. Also, some studies which assigned IVR to help patients with FOM and reverse their negative beliefs about pain, acknowledged the inclusion of patients with no clinical symptoms of FOM (Bolte et al. 2016 and Chen et al. 2017).

Additionally in personalisation, Phase 1 shows individual engagement as the first key ingredient of successful IVR intervention. Phase 2 added that engagement correlated with the sense of presence within IVR, which required the use of VEs relevant to personal preference and culture or real-life situation. This is in accordance with Donegan's et al. (2020), who stressed the importance of engaging CP patients in a familiar VE that depicts a real-world scenario to enhance the sense of presence. What the current study adds is that familiarity may be brought about by making the VEs culturally relevant to patients, while giving them the opportunity to choose the preferable VE. This was seen in an IVR intervention delivered by Fowler et al. (2019), who noted that letting CP patients select the VE led to higher engagement compared to the one pre-determined by the research group. Accordingly, engaging patients in development of IVR intervention would be critical, assessing clinical symptoms and functional level as well as discussing daily activities and interests.

Both Phase 1 and Phase 2 illustrate the need to consider individual comfort/needs when selecting IVR hardware. According to Phase 2, the use of hardware tailored to patients' comfort/need, including lightweight and wireless HMD with less controllers, should be

prioritised. However, participants acknowledged the limited availability of these ideal features since the compatibility of HMDs with interactivity level of VE, which remains critical, requires a complex set up that may interfere with patient comfort. This statement could explain the diversity in selections of HMDs including non-wireless and wireless in Phase 1, which was also evident in the current interventions. The use of non-wireless HMDs was common, this enabled high interaction via high performance computer and hand controllers, despite the patient's discomfort (Jin et al. 2016; Amin et al. 2017; Garrett et al. 2017; Garcia et al. 2021; Zauderer et al. 2021). Although the newer wireless-self-contained HMDs were reported to be an easier option in recent studies, the issue of discomfort remains (Garcia et al. 2021; Jones 2021). The HMD weight and discomfort have been reported as primary challenges in the field of IVR and CP management (Donegan et al. 2020). Thereby, practitioners may need to screen multiple options to find the optimum HMD, while giving priority to patient comfort and needs.

Additionally, Phase 2 participants believed that technical aspects such as visual quality without latency in VE and avoiding fast-paced movement should be considered to lessen the risk of MS. These considerations to reduce MS have been supported in Dongean et al. (2020), stating the need to minimise the visual and vestibular mismatch which cause latency and slowing down of movement within VE. In current IVR intervention, the issue of MS was noted in some CP patients due to virtual experiences with sudden changes in movement (Garrett et al. 2017), thus considering the speed of virtual tasks while developing would be essential for patient safety.

5.4.3.2 Dose

Phase 1 results showed varied IVR doses for CP management including number of sessions, duration, and frequency of the sessions (Table 5-9). Subsequently, Phase 2 participants assumed that the dose had no definite guidelines, they believed that a gradual build up in the progression of task difficulty and duration to adapt VE would be crucial to avoid associated risk of MS, eye strain or fatigue. Further, Phase 2 participants raised conflicting opinions with regards to the safe maximum duration within VE. Whilst some felt 20 to 30 minutes would be safe for CP patients, others believed that depend on the level of interaction and associated fatigue.

These recommendations are partially in line with Donegan et al. (2020) who similarly suggested the need for gradual progression to reduce the risk of MS. However, Donegan et al. (2020) recommended a maximum duration of 15 mins for the entire session, irrespective of VE type, claiming that IVR required great attentional capacity and CP patients often experienced mental fatigue when they concentrated for long periods. This could be valid since the power of multi-sensory IVR hypothesised to cause cognitive load which removes the attention away from pain (Hoffman et al. 2006, Gold et al. 2007; Mahrer and Gold 2009). However, no clear evidence in IVR context supports the relation between the duration and fatigue. These conflicts about duration further reflect the lack of consensus on the optimal dose in literature.

Notably, current findings could not conclude the debate in literature about the optimal dose of IVR intervention for CP (Mallari et al. 2019, Chuan et al. 2021, Baker et al. 2022, Bordeleau et al. 2021, Grassini 2022 and Goudman et al. 2022). Although considering a gradual progression with duration limit could be valuable information for practitioners and researchers to reduce adverse effects and enhance safety, the ideal frequency or number of sessions has not been discussed. Therefore, further investigations on the optimal dose of IVR intervention including number and frequency of the sessions is still needed, considering the intended outcomes.

5.4.4 IVR delivery setting and related considerations

Phase 1 participants selected hospitals, followed by universities and patients' homes as the top three IVR settings (Table 5-9). Phase 2 clarified the potential of both clinical and home setting but indicated the necessity of prioritising safety and that IVR intervention should take place under clinical supervision, particularly when VE involved a level of movement. Phase 2 found that practitioner engagement would be essential for instructions and monitoring progress, with the preference of their virtual access either in a clinical or home setting. Additional suggestions in Phase 2 included placing an IVR set up in quiet surroundings and considering hygiene.

Similarly, the implementation of IVR in both clinical and home settings was also noted in the literature. Despite the fact that the use of IVR as a home-based intervention was rarely reported, it is reported to have great potential to offer alternative solutions and expand the access of CP patients to intervention services (Darnall et al. 2020; Garcia et al. 2021; Eccleston

et al. 2022). However, as indicated in Phase 2, safety should come first, and the intervention would be better started with supervised clinical sessions to detect any negative experiences. Furthermore, the preference for clinical supervision when VE involved physical movement was consistently seen in current studies, some of which illustrated its role for safety (Sirag-Bahat et al. 2015; Gulsen et al. 2020; Hennessy et al. 2020; Tejera et al. 2020; Glavare et al. 2021; Nusser et al. 2021; Yalfani et al. 2022). According to Phase 2, clinical supervision while practising movements in VE would be essential to ensure correct performance and to avoid the risk of a fall. Given that lack of supervision, when IVR is integrated with exercise, has been shown to impact on a patient's performance and result in high dropout rates (Sirag-Bahat et al. 2018), this is an important finding. Thereby, it could be argued that higher physical interaction in VE, particularly in standing, limits its applicability for home use.

In terms of practitioner engagement, Phase 2 found that practitioners should provide a training session prior to the intervention, this should be associated with clear instructions about IVR benefits and contents, indicating patients' doubts about technology. Similarly, Donegan et al. (2020) stated that discussion with the practitioner, answering their questions and giving a chance for them to explore VE before the intervention would be helpful to eliminate fear of technology. A patient's hesitancy of IVR competing demands over other treatment approaches has been reported as a challenge in CP management (Donegan et al. 2020; Sarker et al. 2021; Jones 2021). As a result, spending time with the practitioner so that they can explain the entire set up and address any queries is a valuable investment for the implementation of the IVR intervention.

According to Phase 2, the practitioner's virtual access to the software was preferred, enabling live interface of VE, contacting patients via video or audio to monitor their progress, solve technical issues, and terminate the intervention if any problem arises. Furthermore, Phase 2 findings indicated the need for verbal feedback after the IVR intervention to reinforce how the VE is relevant to daily activities. Current IVR interventions have not shown such a method of practitioner engagement, but some studies reported the use of virtual automated mentors to guide patients throughout the intervention (Soltani et al. 2011; Gromala et al. 2015; Darnall et al. 2020; Garcia et al. 2021; Eccleston et al. 2022; Stamm et al. 2022). Eccleston et al. (2022) argued that the novel aspect of communication via non-human agent is encouraging in digital intervention. Although this statement could be valid, IVR is an emerging technology and

patients' willingness to be guided automatically has not yet been assured. Also, the technical issues associated with the automated mentor, such as latency, has hampered the usability of the current intervention (Eccleston et al. 2022; Stamm et al. 2022). Therefore, current IVR implementation in CP management would need practitioner engagement to familiarise patients with the technology, manage the associated technical faults or potential health risks and maintain communication throughout the intervention. As the technology is rapidly developing, the employment of virtual mentors may promote the delivery of the intervention and provide additional support for practitioners in the future.

The recommendations to minimise external noise and to take hygiene into consideration in the clinical setting were concurrently highlighted in Donegan et al. (2020). However, Phase 2 further clarified the various sterilisation methods including the use of an ultraviolet radiation box or medical wipes with disposable HMD covers. Each method was stated to have its own advantages with no specific preference. The ultraviolet radiation box was thought to save cleaning time within clinical practice, while using medical wipes with disposable covers are more affordable. These may offer multiple options for practitioners and researchers to select the best suited infection protocol in the healthcare organisation.

5.4.5 Adverse effects and related management

In the current study (Table 5-9), participants agreed that several adverse effects were associated with IVR intervention. In Phase 1, symptoms of MS were selected as the most prevalent. Other adverse effects such as eye strain, disorientation, anxiety, fatigue, headache or neck pain and panic attacks were less common, but they did occur. Phase 2 participants believed that the associated risks were highly individual and could be minimised through screening, good visual quality, and gradual dose.

These findings are in line with the current studies, in which MS was commonly reported with some instances of eye strain, headache, neck pain and fatigue across the studies (Sirag-Bahat et al. 2015; Jin et al., 2016; Jones et al. 2016; Garrett et al., 2017; Sirag Bahat et al. 2018; Fowler et al. 2019 Darnall et al., 2021; Garcia et al., 2021; Glavare et al. 2021; Jones et al. 2021; Eccleston et al. 2022). The suggested methods to reduce adverse effects through screening, good visual quality and gradual dose were discussed in previous sections (Section 5.5.1, 5.5.2, 5.5.3) in relation to the literature. The individualised effect of IVR was acknowledged in Phase 2 with a subset of CP patients who would not be able to tolerate the

intervention despite the control measures. These findings indicate the limited applicability of IVR interventions and practitioners should exclude patients when needed.

A notable finding was shown in Phase 2 in terms of unpredictable instances of anxiety and panic attack. Although these risks were seen as preventable by taking precautions with regard to mental health problems, participants stated that they occurred when patients were involved in VE which triggered fearful real-life experiences. This was also noted in Garrett et al. (2017), in which two patients complained of claustrophobia due to their fear of underwater VE. These findings further emphasised the importance of personalisation, considering the individual preferences of patients (section 5.5.3.1).

5.4.6 Facilitators and barriers to IVR adoption

The reported facilitators and barriers to IVR adoption in Phases 1 and 2 were nearly identical (Table 5-9). Phase 1 highlighted the need for personalisation and practitioner knowledge as facilitators. Subsequently, Phase 2 participants acknowledged the lack of personalisation in the current IVR intervention, suggesting the need for co-production and integration of artificial intelligence. They further stressed the need for practitioner knowledge and training on both clinical and technical aspects of IVR. In Phase 1, the top three significant barriers included lack of practitioner acceptance, cost, lack of funding and limited availability of suitable VE. Phase 2 further emphasised the lack of practitioner acceptance, anticipating lack of time and familiarity with technology as significant reasons. The heterogeneity of CP conditions was found in Phase 2 as an additional challenge, but the issue of cost was not addressed as a barrier.

These findings partially align with Sarkar et al. (2021), who identified the facilitators and barriers to IVR implementation in CP management. Sarkar et al. (2021), similarly discussed the lack of personalisation in the current intervention and the significance of addressing the needs of a diverse population. According to Phase 2, optimal solutions would be the co-production through collaboration of practitioners and technology experts with the assistance of artificial intelligence to address patient needs on an ongoing basis. Although the use of artificial intelligence in supporting IVR technology has not yet been implemented in the context of CP management, it has recently been involved in mobile apps to promote pain management enabling automated analysis of patient data to create personalised tasks and /or exercises (Lo et al. 2018; Piette et al. 2022). The evolution of artificial intelligence may

further address the present challenge of developing IVR intervention that considers the complexity and multi-dimensional needs of CP conditions. The practitioner training was also agreed by Sarkar et al. (2021) as an essential pre-requisite to IVR adoption. What Phase 2 additionally illustrated is the need for a more comprehensive and validated training programme in both clinical (e.g., screening, risks) and technical aspects (software, hardware) to enhance IVR adoption.

In terms of barriers, the lack of time and practitioners' familiarity with technology were also stated in Sarkar's et al. (2021) study, but unlike the current study, practitioner acceptance was not perceived as a barrier. The discrepancy might be related to the sample characteristics, participants in the current study were healthcare practitioners and IVR developers who may have encountered resistance from healthcare colleagues regarding technology. However, in Sarkar's et al. (2021) study, 10 out of 15 participants were medical administrators and innovation healthcare leaders who have more influence over the decision-making process, thus practitioners' negative attitudes were not thought as a significant barrier. Time and knowledge of healthcare practitioners have been stated as factors that predict their intention to use VR technology in clinical practice (Levac et al. 2017). As a result, communicating the benefits of IVR technology, as well as ongoing support to increase practitioner knowledge about the technology, may aid successful IVR adoption in CP management.

In the current study, the inconsistency between Phase 1 and Phase 2 with regards to cost as a barrier might be due to the nature of the data collection. The survey in Phase 1 included the cost in the list of barriers which rated as the second most significant barrier with 17.1%. However, Phase 2 interviewed 10 participants who may have been financially supported throughout their experiences, so cost is not likely to have been a significant obstacle for them. With cost being a barrier to adoption, Sarkar et al. (2021) stated that lack of insurance coverage is a critical barrier, suggesting private funding as a short-term solution. The cost and lack of insurance are two related barriers to IVR implementation. The IVR application has been too costly and unreliable to transfer to a clinical context, but this is changing, as the HMDs cost continues to fall (Spiegel 2018). Therefore, cost and lack of funding in public health services might be a current barrier, but future innovation may become affordable once the safety and benefits of IVR in the context of CP are clearly established.

5.5 Part 2- Strengths and limitations

This is believed to be the first sequential explanatory study which explored the views of global stakeholders (healthcare practitioners, IVR technology developers), on the current use of IVR for CP management. This study is strengthened by the integration of the interpretation perceived from both the quantitative and qualitative data. The emphasis of this study in using qualitative interviews enables deeper investigation on several aspects of an IVR intervention for CP patients. Further, engaging a heterogeneous group with different roles and from multiple geographical areas helps to gain diverse perspectives and provide a comprehensive understanding of the field.

However, some limitations must be considered. The findings are not globally representative due to the small sample size, which reduces the generalisability of the findings. The use of convenience sampling in Phase 1 might be criticised as participants were self-selected and other individuals in healthcare organisations or companies may have different responses about IVR utilisation. However, this could be considered as an acceptable limitation since the utilisation of IVR is still emerging and formal international associations are not yet established in order to reach a significant sample representation. Then, limited participation in Phase 2 should be acknowledged due to the critical time of the COVID pandemic. Out of 39 participants in Phase 1, 19 were identified with prior experiences using IVR for CP management. However, only 10 agreed to be interviewed in Phase 2. In qualitative sampling, a minimum of 14 participants is usually preferable when including a heterogeneous group (Holloway and Galvin 2016a). Hence, findings should be interpreted with caution.

5.6 Part 2- Summary and future implications

This sequential explanatory study engaged key global stakeholders including healthcare practitioners and IVR technology developers to explore the use of IVR in CP management. It identified the potential benefits and risks, factors related to technology and setting as well as facilitators and barriers to its adoption. The study started with 39 participants who responded to the online survey in Phase 1, followed by 10 online interviews in Phase 2.

The study found IVR can be applicable to various age ranges, suggesting technology preference as a viable selection criteria. It identified the need for pre-screening to deselect patients with potential contraindications and taking precautions are necessary for those with

mental health problems. Several benefits of IVR were perceived including combating FOM, improving coping skills and engaging in physical and social activities, all of which can be leveraged through immersion, real-time interaction, and embodiment to potentially induce changes in CP related outcomes. Personalisation was indicated as the key factor for IVR intervention, with a preference for customised software with diverse VE to meet patients' clinical needs and functional limitations, whilst addressing culture and real-life scenarios. Suggestions included the importance of tailoring hardware to patients' comfort, acknowledging that the optimal HMD is currently limited. While a gradual build up dose was seen as critical, the study conveys the lack of definitive IVR duration and frequency.

The suitability of clinical and home setting was considered, emphasising safety by starting the intervention under clinical supervision with hygiene considerations. In either setting, practitioner engagement was deemed necessary for pre-intervention education and monitoring patients via virtual access. Several adverse effects were acknowledged, most importantly MS, which was thought to be individualised and controlled via screening and gradual dose. IVR adoption was thought to be dependent on the ability to personalise the intervention, the acceptance, knowledge, and training of practitioners and financial support.

Although findings should be interpreted with caution due to small sample size, the study suggests important implications. The identified selection criteria and risk-reduction measures may inform healthcare practitioners, who would like to use IVR in clinical practice, to potentially implement a safe intervention. Nevertheless, further research is still needed to identify the characteristics of CP patients who cannot tolerate IVR. As personalisation was demonstrated as the leading edge of IVR intervention and future adoption, co-production would be deemed necessary with the involvement of IVR companies to create a patient friendly HMD. In addition, technology developers could consider artificial intelligence to precisely analyse daily activities and cultural background so that a more personalised virtual scenario can be designed.

Chapter 6: Part 3 – Opinions and views of physiotherapists on the use of immersive virtual reality for chronic low back pain management (Qualitative study)

6.1 Introduction

In Chapter 5, the sequential explanatory study (Part 2) highlights the potential benefits, risks, technological and delivery related aspects from the perspectives of global stakeholders. While this helps to gain an understanding on the current state of IVR in CP management and associated key factors, further exploration is required to comprehend the potential for incorporating IVR into CLBP practice. Following the MRCF recommendations, the insights, and concerns of end users such as professionals who have prior experience in dealing with CLBP conditions would be essential to inform development and implementation (O'Cathain et al. 2019)

Therefore, this chapter presents Part 3 of the thesis which explores the opinions and views of physiotherapists on the use of IVR as an intervention for patients with CLBP. Given the novel nature of IVR in the management of CLBP, physiotherapists with or without experience of IVR were invited to participate. This Part 3 study was informed by the data obtained from Part 1 and Part 2 (i.e., potential benefits, technological advances, and potential delivery setting).

6.2 Aim

To explore the opinions and views of UK physiotherapists about the use of IVR for CLBP management.

6.3 Objectives

To explore views and opinions on:

1. Potential benefits and concerns of using IVR for patients with CLBP.
2. Technology specifications (software/hardware), dose of the intervention and delivery setting.
3. Facilitators and barriers to future IVR adoption.

6.4 Study design and methods

Focus groups were considered the most appropriate method to obtain different opinions and to stimulate debate in specific topics (Holloway and Wheeler 2010). Although individual interviews can be an alternative, focus groups allow for shared perceptions which reflect on group experiences; exploring a wide range of views that might not be covered in individual interviews (Kitzinger 2005). In this study, focus groups were deemed appropriate because the use of IVR in management of CLBP is novel and interaction between physiotherapists, conversation and questioning each other might result in new insights and ideas about integrating this technology into CLBP practice. In addition, a homogeneous group of physiotherapists, favouring focus groups, allows open discussion between people with common interests (Kitzinger 2005; Doody et al. 2013).

Due to the COVID pandemic restrictions, the original face to face focus groups were conducted online via Zoom video. Ultimately, face to face focus groups are the ideal method, however, an online alternative can be considered in qualitative research (Kenny 2005; Gill and Baillie 2018; Santhosh et al. 2021; Falter et al. 2022). In earlier research, online focus groups were often only text-based, for example emails, chat rooms or instant messenger. These were criticised for having a limited spontaneous group response, which influenced the group interaction (Stewart and Williams 2005; Fox et al. 2007). This limitation has been reduced in recent years by using Zoom video with the advanced function of real time video, audio, and screen sharing (Santhosh et al. 2021; Falter et al. 2022). Despite the advantages of Zoom video in mimicking a face-to face format, the technical issues, and the effect on participants' attention due to environmental distractions were acknowledged (Santhosh et al. 2021; Falter et al. 2022). Therefore, this study adopted Santhosh et al. (2021) strategies to enhance the quality of online focus groups via Zoom video.

6.4.1 Sampling

Purposive convenience sampling was used to select relevant participants for this study. In qualitative research, purposive sampling is the most appropriate method to identify those who have relevant knowledge and experience to address a specific research question (Merriam 2009; Holloway and Wheeler 2010). Purposive sampling enables the researcher to choose participants who can provide rich information about the investigated topic (Merriam

2009; Holloway and Galvin 2016b). The participants were purposively selected to meet the following criteria:

6.4.1.1 Eligibility Criteria

Inclusion Criteria:

- Clinically active physiotherapists with at least two years' experience treating people with CLBP.
- Physiotherapists with or without previous experience of IVR.

Exclusion Criteria:

- Physiotherapy students.
- Physiotherapists who are not clinically active (those who might not be working but have seen people with CLBP).
- Physiotherapists who had no experience of treating CLBP.

Given that this study aimed to gather the opinions of physiotherapists about using IVR for CLBP, it was deemed important to choose those who were most likely have sufficient clinical experience of treating CLBP. Previous IVR experience on the other hand was not necessarily required due to intervention novelty.

Under the umbrella of purposive sampling which identifies those who are relevant, various methods can be used to recruit participants including typical, unique, maximum variation, convenience, and snowballing (Merriam 2009; Holloway and Galvin 2016b). The convenience sampling, which is a common and easily accessible method, was used in this study (Merriam 2009; Holloway and Galvin 2016b). Although this method has drawbacks because it limits the generalisability of the data with the potential bias of participant self-selection, it can be used when variations in the sample have no specific influence on the topic (Holloway and Galvin 2016b). Therefore, it was deemed appropriate since the target group was homogeneous with regard to the profession and the experience of treating CLBP, in which sample variations (e.g., gender or workplace) had no effect on the objectives of the study.

6.4.2 Recruitment

Participants were recruited through online advertisement (Appendix 6-1) from the Chartered Society of Physiotherapy (CSP), Society of Back Pain Research (SBPR), British Pain Society (BPS)

and those from local networks. The online advertisement was distributed as part of a newsletter to all members of SBPR, this was sent by executive assistant more than once throughout the study period (February 2021 – July 2021). The other groups were contacted via email and invitation through social media (Twitter, Facebook groups).

The online advertisement directed participants to an e-participant information sheet (Appendix 6-2) and an e-consent form (Appendix 6-3) which was developed via Bristol Online Survey (BOS) platform. Participants had the option at the end of the e-information sheet to contact the researcher or to follow a link to an e-consent form that completed by ticking each statement, providing an e-signature and date, and clicking the 'submit' button. Following e-consent, the researcher (AA) contacted each participant to confirm selection criteria and to request demographic information including age, gender, geographical location, and years of clinical experience as well as a suitable date and time.

As Santhosh et al. (2021) suggested, when a date/time was agreed across the group, a calendar invitation associated with Zoom link and protected with a password, was sent to all participants in each group. Also, the researcher sent the calendar invitation at least one week prior to the scheduled time, ensuring that all participants accepted the invitation.


6.4.3 Topic guide and PowerPoint presentation

The researcher (AA) created a PowerPoint presentation (Appendix 6-4), integrating images of IVR technology with signposts for associated mechanisms and potential benefits drawn from Part 1 and Part 2 of this thesis. The use of images and videos in focus group design has been strongly advised to stimulate group interaction (Holloway and Galvin 2016b). The researcher demonstrated this presentation at the start of each focus group to inform physiotherapists of the IVR potential for CP and /or CLBP management.

The topic guide (Figure 6-1) was developed based on the information gathered from Part 1 and Part 2. The questions in the topic guide were grouped into three parts: Part A) introductory scope, Part B) delivery of IVR and Part C) recommendations and close. The questions in the introductory scope were broad, aiming to observe views on the information demonstrated in a PowerPoint presentation. (Appendix 6-4). The sequence of the questions was in a logical flow which started with open questions and moved to more specific questions (Braun and Clark 2013). Although the topic guide sections were informed by Part 1 and Part 2,

the questions were semi-structured in which the researcher gave only a general overview about what was known. For instance, in section 4) delivery setting, the researcher told the physiotherapists that IVR had potential in both clinical and home settings without stating pre-identified ideas, allowing their responses to the proposed information to guide the flow of the focus group. This helped to expand new ideas as they emerged, even if they had contradictory opinions to the participants in Part 2.

Figure 6-1: The topic guide of the online focus groups



CARDIFF UNIVERSITY/School of Healthcare Sciences

Online Focus Group Topic Guide (Part 3)

The researcher starts with the PowerPoint presentation

Part A: Introductory scope

1. From what you saw in the presentation, do you think IVR could bring benefits to patients with CLBP? why or why not?
2. What concerns would you have about IVR technology in CLBP management?
3. Do you have any other thoughts to add specifically about using IVR to help people with CLBP?

Part B: Delivery of IVR

1. When you see VR equipment such as the glasses and type of environments patients can be immersed in, what is the first thing that comes to your mind with regards to CLBP patients?
2. What would be your main concerns about the equipment or the environments in relation to patients with CLBP?
3. As someone with experience of treating patients with CLBP, can you think of any features you would like to see in games/experiences that would help in treating people with CLBP?
4. From research there is little consensus on specific dose (how much, how long, how often), As someone treating CLBP patients, what factors related to IVR dose do you think will need to be considered when using IVR for people with CLBP?
5. IVR can be used either in clinical setting and it developed recently to allow patients to use it at home, what are your thoughts in general about the appropriateness of using IVR in clinical or home setting specifically?
6. From your experience of treating patients with CLBP, what do you think would be the considerations or criteria for selecting the setting (home or clinical) to use IVR for patients with CLBP?
7. In your opinion, what considerations would need to be taken to let patients with CLBP to use IVR at home?

Part C: Recommendations and Close

1. As someone with experience of treating patients with CLBP, what in your view would be the main barriers of using IVR to support CLBP management?
2. How could these barriers be overcome?
3. What else do you think would be needed to offer this form of therapy to patients with CLBP?

CLBP: chronic low back pain, IVR : immersive virtual reality

6.4.4 Pilot study

Two physiotherapists (AK, KW) from the School of Healthcare Sciences, Cardiff University who fulfilled the selection criteria were invited to give feedback on the initial presentation, topic guide and question clarity, and the researcher's ability to act as a facilitator.

Both thought the PowerPoint presentation was clear and useful to verbalise their ideas about the proposed IVR benefits. However, the questions related to the IVR dose did not make sense to them, illustrating that people with no previous experience might feel such a question difficult to answer and that it needed to be modified. Thus, the question was changed as below:

Original question: What do you think is the appropriate dose of IVR for people with CLBP?

Modified question: What factors related to IVR dose do you think will need to be considered when using IVR for people with CLBP?

6.4.5 Size and number of the focus groups

Four focus groups were conducted until saturation point was considered to have been achieved. In research, the number of focus groups held is variable as it depends on the complexity of the research topic and the necessity for data saturation (Morse 1995; Sandelowski 1995; Holloway and Wheeler 2010; Braun and Clarke 2013). Saturation refers to the point where no additional data is generated, and it is considered as a gold standard in qualitative research to determine the group number (Morse 1995; Sandelowski 1995; Guest et al. 2017). In this study, the conduction of 3 focus groups was decided in advance of data collection. However, during data collection and interpretation of initial codes and themes, the researcher found that the initial set of codes and themes could not create a complete storyline which would answer the research question. Therefore, it was deemed essential to conduct the 4th focus group.

A focus group with 4-6 participants was chosen in the current study. According to Holloway and Wheeler (2010) and Krueger and Casey (2014) a focus group might consist of between 4 and 12 participants, but the optimum number varies depending on the topic. Although a large group has better dynamics and can provide a variety of perspectives, it can be difficult to control (Holloway and Wheeler 2010; Krueger and Casey 2014). A small group of 4 or 6 participants is also useful to encourage good interaction if the participants share the same

background (Holloway and Wheeler 2010; Krueger and Casey 2014). Moreover, the online design affected the decision of the researcher regarding group size. A maximum of 6 participants was seen as appropriate to achieve control and to maintain the attention of participants, since an online format was criticised for participants' low attention because of environmental distractions (Santhosh et al. 2021; Falter et al. 2022)

6.4.6 Data collection and Processing

Four focus groups were conducted between 16 April 2021 and 8 July 2021 via Zoom video, each lasting 60 minutes. The researcher (AA) acted as a facilitator for the group to enhance interaction, whilst an assistant from the research team attended the session to take notes without interfering with the group discussion. The assistant also acted as a timekeeper and backup host in case the researcher or participants had technical issues. Conducting this study in 2021 aided the online process as most people by this time had adapted to online meetings due to the COVID pandemic.

Following Santhosh's et al. (2021) recommendations on conducting online focus groups, the researcher accessed the Zoom session as a host 30 minutes before the participants joined. This ensured the video; audio volume was sufficient to start the session and gave the opportunity to solve technical difficulties if any existed. Once all the invited participants had been admitted to the session the researcher (AA) locked the session for security. Participants were asked if they had any questions, then permission for video recording was obtained verbally prior to the start. The researcher greeted the participants, introduced the topic, and explained the process. They were reminded that no right or wrong answers existed and to feel comfortable when any disagreement occurred within the group. Also, participants were informed that they could 'unmute' themselves to speak and discouraged to use the 'chat' function, as it was not being recorded, unless they had a technical issue. After all participants in the group had introduced themselves, the researcher shared the screen for five mins to demonstrate the PowerPoint presentation. Then, the researcher began to ask questions.

The researcher used probing questions to encourage discussion (Holloway and Wheeler 2010). In some groups, if there was a silence the researcher reframed some of the questions to engage the participants. Those who were noticeably quiet in the group were encouraged to comment. Some conflict of opinions occurred during the discussion and the researcher

encouraged conversation by asking questions like why do you think this? , how can this be improved? During this study, a disruption in microphone connection plagued two participants whilst exchanging opinions, however they were able to re-connect in a few seconds and the researcher then asked them to continue their thoughts to obtain adequate representation from all participants. Apart from this, the four focus groups ran smoothly and without major issues. At the end of each focus group, the researcher (AA) asked if participants had any additional information or comments.

All audio recordings were saved securely on a Cardiff University computer which was protected by a password. Furthermore, the audio recordings were deleted from the Zoom library to protect confidentiality. The recordings were transcribed verbatim into a Microsoft Word document by the researcher and all participants’ names were anonymised. Then, the transcripts were sent to participants to check data accuracy and add any clarification (Shenton 2004; Cypress 2017). One physiotherapist felt that part of the dialogue needed to be clarified, thus the physiotherapist was contacted via telephone for more explanation and the given information was added to the data. Following verification of all transcripts, the recordings were deleted.

6.4.7 Data Analysis

The data was analysed using reflexive thematic analysis, inductive approach (Braun and Clark 2013; Braun and Clark 2021b). The process of analysis was conducted following the recommendations and the six phases for inductive thematic analysis by Braun and Clark (2013; 2021b) (Table 6-1).

Table 6-1: Six phases of the inductive thematic analysis

Phase	Method
1. Reading and familiarisation	<ul style="list-style-type: none"> - Manual transcription and multiple reading of the transcripts helps the researcher for data familiarisation. - After each focus group, the researcher read the notes taken by the assistant during the data collection. Also, the researcher listened to the audio recordings and took reflexive notes about

	<p>initial ideas and thoughts for the analysis. This helps to identify specific patterns which appeared in the transcripts.</p>
<p>2. Initial coding</p>	<ul style="list-style-type: none"> - Initial codes were identified during reading of the transcripts and forming initial ideas about codes and possible themes. - During the initial coding of the first transcript, a colleague in the School of Healthcare Science with prior experience in qualitative research aided the process. Then, the researcher compared codes while reflecting on the meaning from the entire participants' transcribed data. The remaining transcripts were coded by the researcher (AA) with continuous refining of initial coding list. - Each transcript was coded using Microsoft Word where each extract was highlighted in different colours to help identify different patterns across the data set (Appendix 6-5). - Systematic coding was undertaken by highlighting large or small chunks of extracts that potentially addressed the research question and extracts were coded more than once when different meanings were noted. - All codes were copied and pasted in Microsoft Excel with participant and focus group number for reference (Appendix 6-6).
<p>3. Searching for themes</p>	<ul style="list-style-type: none"> - Larger codes were created after initial coding, and sub-themes were generated. Then, the process was continued to group sub-themes into larger themes. - During searching for the themes, the researcher revised the transcripts and renamed the code, when necessary to make sure that it reflected the meaning across the entire data set. This process includes merging, or splitting codes if they referred to similar or different themes, respectively.

	<ul style="list-style-type: none"> - A codebook of themes and subthemes were created in excel sheet (Appendix 6-7), by grouping all similar codes into larger codes while refining commonalities and differences in code description. - All codes were copied into the codebook aligned with participant number to avoid data loss and the identified themes and subthemes are distinguished by their relevance to the research question.
<p>4. Reviewing themes</p>	<ul style="list-style-type: none"> - All the created themes and subthemes were transferred into the initial diagram for visual presentation to assist with refining and checking of the themes and subthemes (Appendix 6-8). - Both supervisors (VS, LS), aided the process of reviewing the themes and subthemes by discussing its relevance to research aim. - Following discussion with supervisors (VS, LS), several changes were made with more refining of themes and subthemes. For example, 'clinic vs home' and 'physiotherapist support' were separated subthemes, but upon reflecting on the entire dataset, we believed that 'physiotherapist support' is a subtheme that falls under the broader umbrella of 'clinic vs home'. So, 'clinic vs home' was created as a final theme with underlying subthemes of 'safety' and 'physiotherapists support'. - To review the final themes, the researcher read the coded text in each theme to ensure the dataset presentation in relation to research question.
<p>5. Defining themes</p>	<ul style="list-style-type: none"> - In the final refinement, the researcher ensured that naming of themes and subthemes capture the underlying story (Braun and Clark 2013). For example, the subtheme 'format of IVR' was too broad to describe the core meaning of the subtheme,

	<p>thus it was changed to 'individual vs group format'. This illuminates the underlying description of the benefits it entails.</p>
<p>6. Producing Report</p>	<ul style="list-style-type: none"> - After establishing the final themes, the findings were reported including short or long quotations that best represented the themes or subthemes to ensure the results' validity. - At the end, the findings were further discussed from the description of the data to make an argument in relation to the research question.

6.5 Results

6.5.1 Participants

Four online focus groups were conducted with sixteen physiotherapists, who had between 2 and over 15 years of experience in treating CLBP. As shown in Table 6-2, most participants practised physiotherapy in Wales. The focus group 1, 2, 3 and 4 consisted of 5, 3, 4 and 4 participants, respectively.

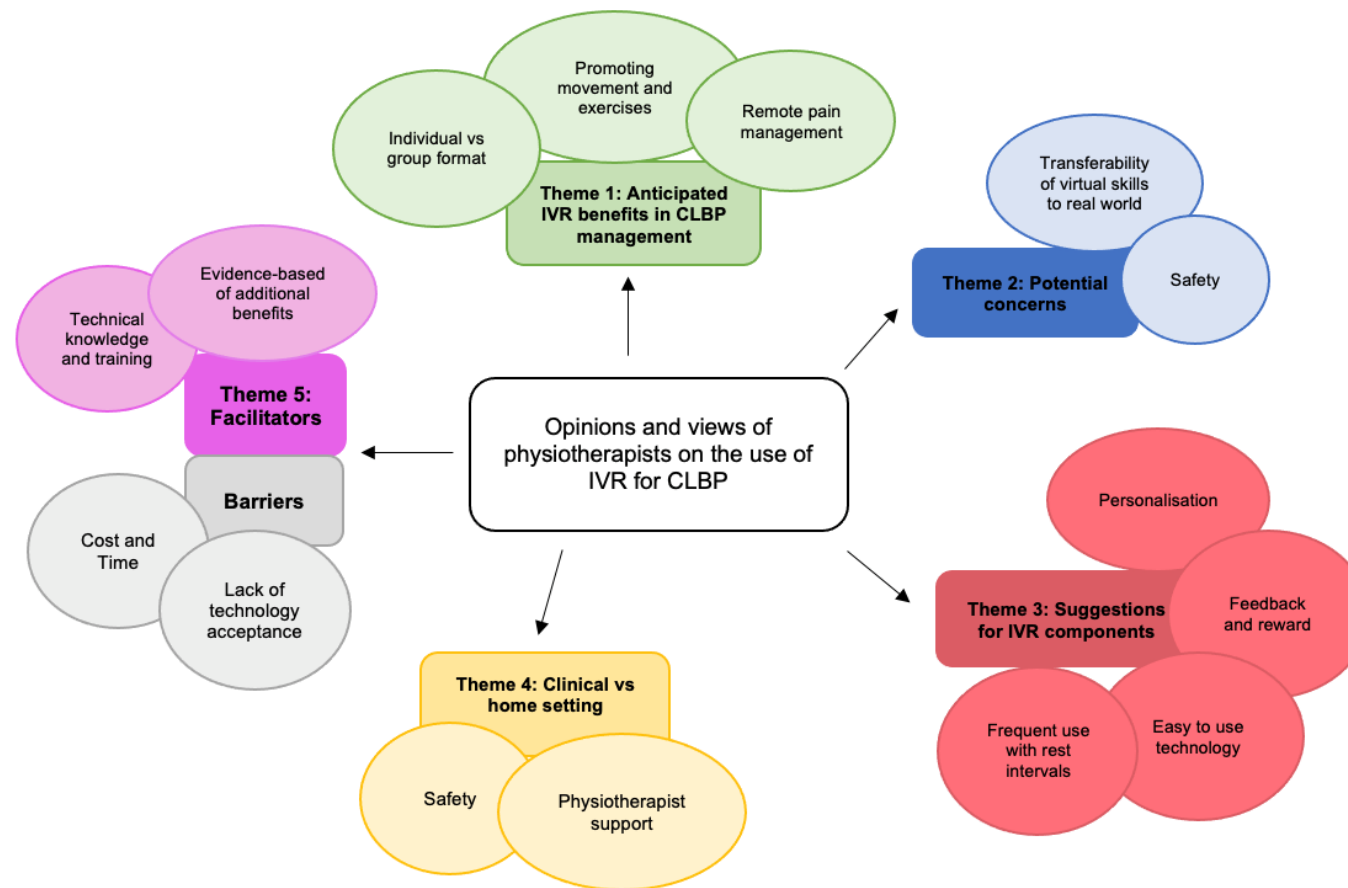
Table 6-2: Participants' characteristics

Focus group (FG) number	Participant code	Age	Gender	Region	Clinical experience treating chronic low back pain
1	PT1	45	Male	Wales	>15 years
	PT2	48	Female	Wales	>15 years
	PT3	26	Male	England	4 years
	PT4	39	Female	England	12 years
	PT5	27	Female	England	2 years
2	PT6	42	Male	Wales	11 years
	PT7	29	Male	Wales	4 years
	PT8	38	Female	Wales	12 years
3	PT9	46	Female	Wales	>15 years
	PT10	43	Male	Wales	>15 years
	PT11	49	Male	Wales	14 years
	PT12	46	Female	Wales	>15 years
4	PT13	47	Male	Wales	>15 years
	PT14	28	Female	Wales	2 years
	PT15	31	Female	Wales	2 years
	PT16	28	Female	England	2 years

6.5.2 Thematic Map

As presented in Figure 6-2, six overarching themes emerged from the focus groups: 1) anticipated IVR benefits in CLBP management, 2) potential concerns, 3) suggestions for IVR components, 4) clinical vs home setting, 5) facilitators and barriers to IVR adoption.

Figure 6-2: Thematic map of five overarching themes and underlying subthemes from the online focus groups



IVR: immersive virtual reality

CLBP: chronic low back pain

6.5.3 Theme 1: Anticipated IVR benefits in CLBP management

The theme highlights the physiotherapists' opinions on the presented ways of using IVR to aid CLBP management. Based on likely IVR mechanisms, the participants thought IVR would be more applicable for subsets of CLBP associated with passive coping, fear, anxiety, and reluctance to accept standard rehabilitation, highlighting IVR as an alternative option.

(PT5): "some group of patients who visited so many therapists or consulted a lot of practitioners but their [LBP] is always there, they're open to this kind of things, you just tell them that something might help you, they might want to try, because nothing else work for them", (PT9): "I wonder if that might be a way for initiating movement in some people who are reluctant to move".

The discussion around anticipated benefits of IVR was mainly focused on three areas (sub-themes), relating to **promoting movement and exercise, means of remote pain management, and individual versus group format.**

6.5.3.1 Subtheme 1: Promoting movement and exercise

The IVR was seen to have the potential to address the associated fear of movement (FOM), describing IVR as a bridging tool to introduce patients to physical movement in a non-threatening environment. *(PT8): "it's quite interesting idea to use it [IVR] for people with [CLBP], I think fear of movement is one of the main barriers to engage with exercises and to be active, I'm just wondering if we can use this as an opportunity to overcome fear of movement, at least few sessions with our regular treatments, I think that could be useful, because that be a real push for patients", (PT16): "It can take them away into different world without having pain and it's a way which they could feel [safer] and can move better, like a nice kind of escape, potentially if they have a lot of anxiety or emotional issues".*

Some participants expressed interest in the idea of displaying a virtual avatar while performing movements. They thought the virtual avatar would support CLBP patients who had a distorted body image, indicating the value of visual feedback in cortical remapping process. *(PT8): "I think it will give you better ways helping patients to see how they are moving, especially when they have pain, so they do not realise how stiff they are, how awkward they move, so I think if there's an avatar, it would be really helpful, (PT11): "I like the visualisation one when you see the representation of yourself, then you can do the*

lateralization, so this mean that people who have really poor representation in their brain of their physicality and if you got a good visual representation, they might be able to develop that cortical picture within yourself”.

6.5.3.2 Subtheme 2: Remote pain management

The participants viewed IVR as a method for remote pain management, offering a means of relaxation, mindfulness, and social support and highlighting the advantages of such a tool in the era of the COVID-pandemic. (PT8): *“Many elderly people are living by themselves and are quite depressed, I think if we can simply provide environment they miss, like with the current situation in the world [referred to COVID pandemic], if they can simply use that as an adjustment of the real environment, even without big task of movement, I think that would help, using the environment of mindfulness and relaxation”,* (PT9): *“it could be a good way of using [IVR] as a tool to explain how different environments can alternate the way you perceived your pain, I think of [IVR] as means of relaxation , it would be a really good way to bring people along when they are not in the clinic”.*

The potential for social support within VE was thought to be useful for CLBP patients with the anticipation that technology could allow communications to share pain experiences with a virtual friend in their own home space. (PT13): *“one of the biggest problems that we have with the persistent pain patients is that they never felt that they told their story and giving them an opportunity within a virtual world to tell a story, I think the social space can be a very good place to do that, I wonder whether is it possible to build a bot within that social space who is really incredible in listening, they get to tell their story, they get to be heard and listened to, I think that would be a brilliant addition to the physical side”.* In addition, the social VE was viewed as a means of facilitating a remote support group, highlighting the value of using an anonymous avatar to promote privacy and prevent the stigma of being identified by the group. (PT10): *“there is interest in [VE] due to COVID, [...] I guess most people enjoy that , they can develop their own [VE], so they have got their own boundaries, there is potential to work as ongoing treatment, I guess if you see each other in avatar, that can be enormous, you can select different face for you, so there is potential to still be part of group, where you can chat and make conversation with people, exchange experiences, and nobody see your house or what you look like”*

6.5.3.3 Subtheme 3: Individual vs group format

Participants perceived IVR to be beneficial in both an individual and group format, indicating the versatility of IVR as a treatment modality. Some participants preferred an individual format to enable a personalised intervention with the claim that the individualised nature of CLBP may affect the engagement with this technology. *(PT1): “if we are thinking about how we deliver our understanding of evidence behind techniques, what we do is take techniques to a group, which is non- tailored, and therefore this eliminates the effect of the technique, whereas in psychology they acknowledge the fact that the individual responds differently to different techniques, so making that patient centred is a lot clearer rather than group application”, (PT16): “I think to be able to really personalise, it can create a lot of meaning for the patient and increase engagement, so being patient specific is really important”.*

Additionally, the use of IVR in a group format was seen as suitable for CLBP patients in some instances, for example when restoring function. Participants assumed that IVR, possibly gaming, could potentially enhance group interaction and motivate patients to engage with treatment. *(PT2): “I think IVR will actually fit when you’ve got [CLBP] therapy groups, such as a functional restoration programme, where you got patients into a programme with specific traits and they already have that assessment and you can prepare something for patients within that group, so actually you can put something may be a little generic for that group”, (PT9): “I think patients with [CLBP] enjoy the classes best when there’s some kind of game involved, because it’s fun, that brings people back to interact with each other and enjoy the movement, so it sounds like a nice adjunct into kind of functional class”.*

6.5.4 Theme 2: Potential Concerns

This theme addresses the physiotherapists’ concerns on the use of IVR in CLBP management. The discussion on the potential concerns was related to two subthemes: transferability of virtual skills to real world and safety.

6.5.4.1 Subtheme 1: Transferability of virtual skills to real world

The ability to transfer the acquired skills within VE (e.g., physical movement, coping skills or social interaction) to the patient’s real world was of concern, with suggestions to practise what patients learned inside VE in the real world. *(PT13): “My only slight concern I guess*

around [IVR] is how you move from a virtual back into real world?, I guess I was going to the transition, [when they said] 'I just succeeded in the virtual world' that gives me a license to go and try it in the real world, so in terms of the depth of the virtual world, you move from something which is obviously virtual to something which is less virtual?".

6.5.4.2 Subtheme 2: Safety

Safety was of concern across the groups, anticipating the risks of exacerbating associated pain symptoms, motion sickness and the possibility of developing negative behaviour such as anxiety or signs of addiction. Participants were concerned about the suitability of a certain sub-population with visual impairment and/or migraine and assumed the treatment may have the potential hazard of exacerbating symptoms. Out of these, participants stressed balance problems in the elderly, particularly concerning the risk of falls associated with motion sickness. They believed that IVR may not well suit all patients, suggesting clinical screening to determine suitability. (PT12): *"you have to be careful about patient selection, there might be people with other comorbidities that make this unsuitable for them, I mean [CLBP] patients [with] ear problems [...], visual disturbances, people who suffer with migraines, they often suffer with a lot of headaches and you don't want to exacerbate, you have to be sure that they were suitable for it, do that whether with check list or a suitability form"*, (PT5) *"I think with older adults it may be difficult, it may cause imbalance and kind of disorientation, might results in risk of falls"*.

In terms of negative behaviour, some participants thought that being blind to the real world while wearing HMD may exacerbate anxiety, raising apprehension about worsening symptoms and limiting or guarding movement rather than promoting it. (PT11): *"one of my concerns is that people may become more guarded when they've got something which doesn't feel real and what we want them to do is really to relax and move fluently, I've not seen one, so I don't know how they would behave when they got it on"*.

In addition, developing signs of addiction to VE was of concern, including excessive use and abandoning engagement with real world activities. They mentioned that distraction features may exacerbate symptoms of "dissociation" (i.e., avoidance of real-world activities). (PT9): *"You can get so hooked into that, maybe you won't go outside to meet others and do things naturally as a progression"*, (PT11): *"Distraction isn't always a good thing, sometimes it can be an avoidance strategy, and you don't want to enhance*

distractive behaviour which means that you are dissociating more, the psychology of dissociation can be a big issue and sometimes you need to get people to accept the pain experience to allow you to behave correctly". With the addiction being a concern, careful monitoring was suggested to withdraw patients when they develop signs of addiction or showing no engagement with the real world. (PT12)"a possibility that someone could lean into this potentially and be reluctant to the amount of [IVR], they could become so stuck on this 'I can only do it in this [IVR] environment', I think we have to be careful at some point that you're [going to] have to wean somebody out of it, if they become too attached to it and they're not carrying things over into real life".

6.5.5 Theme 3: Suggestions for IVR components

This theme presents the suggestion of physiotherapists on technology specification (software, hardware), and dose to optimise the efficacy of IVR for CLBP management. This includes four subthemes: 1) personalisation, 2) feedback and reward, 3) ease to use technology, 4) frequent use with rest intervals.

6.5.5.1 Subtheme 1: Personalisation

This subtheme reflects the way participants viewed personalisation as overwhelmingly important, suggesting various personalisation methods. Most participants recommended that VE should be tailored to patients' preferences (e.g., activity, pleasant experience) and that individualised goal setting should be aligned with challenging tasks in a real-life situation. They anticipated the ability of technology to offer diverse options to manage personalisation. (PT8): *"if we can select the technique according to their preference, so it depends on the type of sport or activity that they may like, may be football or rugby players, [...] I think that would mean the most to them", (PT13): "The advantage of [IVR] is to have meaning to the individual. so 'I just achieved something in the virtual world that I never thought I would do' and 'now I feel more willing to try it in the real world', whether that is a work situation or social situation or physical sport, that would be brilliant if you get a set of goals behind it, meeting people demand", (PT12): "in any rehabilitation programme you need to personalise to their goals and what they want to achieve , so I think the VR has to feed into that really".*

In addition, it was felt that VE should be responsive to medical needs and functional abilities, highlighting a wide variation of medical history and movement dysfunction associated with CLBP including a broad spectrum of progression and levels. (PT13): *“If somebody has PTSD in their history that would be different from somebody who hasn’t, or maybe somebody with obesity or diabetes, that would be different from somebody [with] fear of movement or fear of pain, so sort of pick and mix environment where you can create individually tailored intervention within this virtual world”, (PT9): “I think within the programme, it has to be some form of progression, different levels, the therapist knows that you kind of move on because there’s a range of ability and disability with [CLBP], people can be starting at different levels, one size doesn’t fit all”.*

Some participants suggested IVR delivery should be gradually built up depending upon the individual patient, as an additional means of personalisation. They thought the amount and duration of virtual tasks/exercises should be tailored to a patient’s input, reflecting the heterogeneous nature of CLBP. (PT12): *“I would like to try it tentatively first, see what the reaction is, see if there is any carry over and may have longer session after that, it almost like you need a curve or like a build-up”, (PT11): “I think engagement will be a big factor, so for someone who doesn’t engage well, he will not spend much time in it, also how did they feel after, because sometimes people enjoy doing exercises at the time, then they may spend like a week can’t do anything, with that type of person I would limit whatever I do, whereas if there is someone who engages alright without any kind of following effect, then I will probably allow them [to have] more”.*

6.5.5.2 Subtheme 2: Feedback and reward

Participants suggested the necessity for feedback on performance during movement/exercises via scores to motivate and monitor improvement. The feedback of success and reward is believed to be essential to enhance self-efficacy, while failure feedback was discouraged as it was thought to be negatively associated with pain experiences (PT10): *“I guess give some feedback [...], if I move more from my hips, or my back that [sweet core], so you can get feedback after, like ‘look you’ve moved ten percentage more than you’ve done in the past’ and also if you have sensor on lumbar or cervical spine to give more accurate feedback that would be helpful”, (PT13): “I think in [CLBP] population, sense of failure is a significant part of their life, and they always have*

the idea of losing or failing themselves, so if we can flip that around by experiencing a great deal of success, celebration and joy, that will be really important, so that idea of success would start to turn on the feelings [of] control over their condition”.

6.5.5.3 Subtheme 3: Easy to use technology.

Easy-to-use technology was seen as critical to enhance handling of the device either by patient or practitioner in clinical practice. Several suggestions were made including the use of more wearable technology, light weight, and wireless HMD. (PT9): *“I think something that they could wear will be good, so if there is something very light weight, wireless may be like gloves or a jacket, something whether not having to do anything at all. You can’t give them much cause to complain and you don’t want to make it too fussy because you got a class or a treatment session to get into, so something that it is easy to put on and take-off”,* (PT11): *“I think a lot of people are struggling with grip, there will be an issue with the hand controllers, so whether there is a way to be not so grip based”.* Additionally, the ease of cleaning was seen as essential, implying the importance of maintaining hygiene among patients. (PT16): *“we [need to make sure] it’s easy to clean in multi-patient use, so it is absolutely essential, because as long as it is wipeable that would be beneficial”.*

6.5.5.4 Subtheme 4: Frequent use with rest intervals

While some participants mentioned the need for evidence-based studies to decide on the appropriate dose, others assumed that IVR may work as a behavioural change tool and suggested the need for repetition and consistency. (PT6): *“I think we might need to go back to evidence, so essentially we need a lot more data about it”,* (PT13): *“if it is a motivation thing or a goal setting thing, [...] so it’s enjoyable seeking habit, because they are feeling success on a regular basis, so our persisted pain patients would need to pick up their [IVR], so we can apply those principles for behavioural changes and that’s where we need a much more regular thing”.*

Also, the rest intervals thought to be deemed necessary, stating that fatigue could be associated with the performance of exercises. (PT14): *“I was thinking maybe we could have like a structured programme for the entire experience, so along with the exercises, probably some rest period in between might be beneficial for the patient, [...] probably a thirty second*

rest or one minute rest, you know continuous performance of movement might be tiring for some of the population”.

6.5.6 Theme 4: Clinical vs home setting

This theme presents the factors discussed by the participants with respect to the potential of implementing IVR in both the clinical and the home setting. This includes two related subthemes: safety and physiotherapist support.

6.5.6.1 Subtheme 1: Safety

Conflicting opinions were voiced on an appropriate IVR setting, highlighting safety as a priority. Some participants pointed out the need to deliver IVR only in the clinical setting, this would enable supervision of the patient’s performance during the exercise, particularly when IVR involved a level of movement and to avoid the risk of addiction. *(PT8): “Physiotherapist should be there to assess movement or the technique that we are doing, so if it’s more something like task based or, a bit risky so we need to do that in the clinic”, (PT12): “At home there’s a potential for someone to get over attached to it, so the clinic definitely I think it’s good for people to come in and experience it alongside all the other stuff that they’re doing with the physio team”.*

Other participants thought transferring IVR to the home setting may have potential, but they emphasised the need to establish safety parameters including establishing the type and number of virtual tasks with regular monitoring. *(PT16): “I think it’s important to de-medicalise some people that been in the system for long time, [...], I think that’s quite empowering for them to be able to pick it up and do what they want rather than relying on other people to prescribe this or that, so I think to be able to do it at home would be really good, but we need to make sure they don’t put themselves in element of danger of taking the exercise too far, I know that people do stuff at their home by their own, but we see them do it with monitored forms”.*

6.5.6.2 Subtheme 2: Physiotherapist support

Physiotherapist support and guidance throughout IVR intervention was seen as necessary in either the clinical or home setting for successful engagement with IVR. Participants pointed out that physiotherapists should adopt effective ways of educating patients and

motivating them to use IVR, illustrating that some patients may be technology hesitant. (PT8): *“I think giving a presentation or some information would be really helpful before coming into the treatment, [...] I think it’s something to do with the acceptance, because some patients could be very old school so they might be expecting regular treatment, so I think having brief information and showing them some videos would be really helpful”, (PT13) “I think we need [to speak with the patient] sufficiently to make them want to pick it every day, we have to reinforce and give them the joy that makes them [interested to use it]”.*

Participants mentioned that independency while at home should not disturb the therapeutic relationship with the therapists. Remote support was seen as critical, instructions should be provided, appropriate tasks assigned, and progression evaluated throughout the sessions. (PT13): *“if we would have to enable people to use it at home, then we should be able to collect data in term of accessing the service, you know downloading the different environments within it, which will come back to the therapist, so they can assess remotely. For instance, if a patient experience something in the virtual world today, then they should be able to contact the physio to know whether they need to download different programme, I think remote monitoring is really important, so people have access to our skills and knowledge when they need it, but also then fostering that idea of coping with this in your own and this is a way to be healthy and independent , I think you need a bit of both”.*

6.5.7 Theme 5: Facilitators and barriers to IVR adoption

The final theme presents the facilitators and barriers to IVR adoption in clinical practice. The reported facilitators were **technical knowledge and training** as well as **evidence-based additional benefits**, while the mentioned barriers were **cost, time, and lack of technology acceptance**.

6.5.7.1 Subtheme 1: Facilitators

Technical knowledge and training to use IVR in the workplace was widely referred to as essential to enhance uptake, but differing opinions were given on whom should be trained to deliver IVR. Some participants expressed interest in receiving workshops and personally experiencing VE, while others suggested the deployment of technology experts to deal with

the technical aspect and save the treatment time in clinical practice (PT7): *“We need to be trained as physio, because I suppose it’s a new thing and not so many people are being told how to use [IVR], so we need training, and we need to see ourselves how it feels like so we can really discuss it with our patients”,* (PT4): *“I think individual therapist might use not to do something like this because all the issues of the time, [...] you might have one or two people who have a specialist training in this area may be a technical expert, as I mentioned before there may be some aspects that therapists themselves don’t need to do from a time point of view”.*

Furthermore, IVR adoption was seen to be dependent on **evidence of effectiveness**, particularly cost effectiveness to show the benefits over standard care. (PT12): *“We need more research; an evidence base to build up more on the potential picture of whether it is beneficial and then that can be taken to NHS manager or private clinics saying this is worth buying”,* (PT13): *“I think being able to demonstrate outcomes, it’s really important, it’s also important to do that in comparison to current practice and pointing other pitfalls of what medicine has done to those populations over the years”.*

6.5.7.2 Subtheme 2: Barriers

The **cost and time implication of IVR application** were the most reported barriers. Physiotherapists expressed doubts on whether the benefits outweighed the cost and time of application and reported that the cost of equipment including ongoing maintenance would be un-affordable across a wide spectrum of clinical practice. (PT7): *“talking to my manager about buying the [IVR] and they were like ‘why not to spend our money somewhere else where we can use the equipment more often’, also the overall cost is not feasible either in the NHS or in private setting”* ,(PT14): *“I think it [wears] out easily, so you need to purchase those equipment and it will cost you for the servicing, [...], so it would require a lot of charges apart from the development, the maintenance part will also be considering in the funding and that would be an obstacle”.*

While some participants shared concerns related to their acceptance of IVR. (PT4): *“I need to say I don’t think I would use this”.* Others reported clearly that **lack of physiotherapists’ acceptance** can be a barrier to adoption. This was referred to as the fear of replacing the physiotherapy profession with technology and unequal treatment of those with and without technology knowledge. (PT13):*“Changing professional opinions within*

physiotherapy could be more challenging, so for people who are already immersed in highly biomedical model as clinicians who feel that they're the expert, struggle with the intervention like this which requires patients to move much more into a self-care environment and be less reliant upon you, I think the behaviour of healthcare professionals for using this will be barrier", (PT12) "who is responsible for it within a department, is it something that only may be a senior or clinical specialist is getting trained for?, so junior physios don't necessarily getting experience of using it and it might create a disparity of treatment between who's treating? , it tends to be only a certain number of physios who get to use something like this? it then end up that the hierarchy who get to use it and who doesn't?".

Lack of patients' acceptance was thought to be an additional barrier due to IVR novelty, highlighting the digital literacy, particularly among the elderly in clinical practice. (PT14): *"some people don't understand how the equipment needs to be used despite the training and everything, probably because of old age and they are not used to new technology, and you know explaining the procedure might be quite challenging for those kinds of populations, [...] they're not really appreciate the entire set up".*

6.6 Part 3- Discussion

The present study explores the opinions and views of UK physiotherapists about the use of IVR for CLBP management, using four online focus groups. Six overarching themes were identified including 1) anticipated IVR benefits in CLBP management, 2) potential concerns, 3) suggestions for IVR components, 4) Clinic vs home setting, 5) potential outcomes and 6) facilitators and barriers to IVR adoption. In the section below, the key findings of each theme are summarised and discussed in relation to the literature.

6.6.1 Anticipated IVR benefits in CLBP management

Participants perceived IVR as a useful tool for CLBP subgroups who present with anxiety, FOM and are reluctant to engage in standard care. Findings indicated several preferred methods for integrating IVR for CLBP management, these included the use of IVR as a motivational tool to practise physical movement as well as the potential for integrated coping skills (i.e., relaxation/biofeedback) and social VEs for remote pain management.

In this study, participants' views on IVR as an alternative option, for fearful and resistant patients, to traditional forms of rehabilitation could provide additional insights for patient selection. Given that anxiety and low motivation have been indicated as the main barriers of CLBP adherence to rehabilitation (Jack et al. 2010; Boutevillain et al. 2017), this suggested subgroup may be considered as a target population to use IVR in CLBP practice.

The perceived benefits of promoting movement and the value of using a virtual avatar (VA), while performing movement, in improving the distorted body image have also been prioritised in the current IVR interventions for CLBP (Fowler et al. 2019; Hennessy et al. 2020; Tack 2021; Eccleston et al. 2022; Stamm et al. 2022). The preference in this study to use relaxation/biofeedback for remote pain management was aligned with a recent suggestion to apply these IVR coping skills as self-administration skills during the COVID-pandemic (Darnall et al. 2020; Garcia et al. 2021; Jones 2021). In addition, Sarkar et al. (2021) revealed that IVR associated with coping skills such as mindfulness, relaxation and biofeedback may scale up pain management to a self-management approach. Therefore, the development of IVR for CLBP might be valuable to focus on various forms of physical movement to overcome fear, while considering coping skills applications to aid self-management.

Participants in this study provided different opinions on how IVR could support group therapy. The social VE was viewed as a means for remote group therapy, appreciating the value of being anonymous using VA to reduce the stigma of being identified by group. Furthermore, the gamifying nature of IVR was seen as a motivating factor to aid group exercises in CLBP clinical practice. The IVR implementation for group therapy was not reported in literature for CP management, but it has been used recently to support psychological disorders in response to the COVID pandemic (Arnfred et al. 2021; Dilgul et al. 2021). In accordance with this study the interviewed therapists in Dilgul's et al. (2021) study suggested that anonymity provided by VA may reduce the stigma for patients with depression (i.e., limited ability to develop social engagement), making them feel more comfortable in expressing themselves and leading to better group engagement. Given that CLBP patients often feel socially isolated, associated with stigma from the community and back pain patients (Bailly et al. 2015; Slade et al. 2009), the suggestions from this study provide additional insights for future development. While an individualised format is the

current state of IVR in CP management, it would be valuable to establish VE for a group of patients with CLBP where they can communicate, share their pain experiences, and encourage each other whilst being motivated in gamified space.

6.6.2 Potential concerns

This study revealed several concerns and suggested potential solutions for the transferability of gained virtual skills to the real world and for patient safety. In terms of safety, participants questioned the potential risks among those with associated comorbidities as well as the possibility of negative behaviour such as guarded movement and IVR addiction.

These concerns are consistent to some extent with literature. The virtual skills transferability has not been illustrated in CP management, however, recent review in IVR-based rehabilitation confirmed this was an issue and argued that IVR efficacy is limited by inconclusive evidence about the transferability of the learned virtual skills to the real world (Levac et al. 2019). In this study, physiotherapists suggested that patients should be encouraged to practise the learned virtual skills outside VE, this is consistently suggested by Levac et al. (2019). While transferability has not been discussed as an issue in CP management, practising skills outside VE was noted in few recent IVR interventions. For instance, Darnall et al. (2020) argued that improvements in pain outcomes and self-efficacy could be attributed to practising mindfulness/biofeedback skills both inside and outside the VE. Also, the VE designed by Eccleston et al. (2022) encouraged patients to practise the virtual physical activity in the real world and reported significant pain reduction and improvement in FOM, disability in 8 weeks and 3 months post the intervention. Therefore, practising virtual skills in the real world would be essential to optimise the benefits of the intervention in future implementation.

The safety concerns in this study around the potential risks of MS or headache in subgroups with visual impairments, migraine and balance problems are recognised in IVR studies, some of which excluded CLBP patients who had associated visual/vestibular disorder or balance problems (Bolte et al. 2016; Jin et al. 2016; Thomas et al. 2016; Garrett et al. 2017; Hennessy et al. 2020; Trujillo et al. 2020; Garcia et al. 2021; Jones 2021; Eccleston et al. 2022; Stamm et al. 2022; Yalfani et al. 2022). Significantly, the concerns expressed in this

study about the risk of falls in older people with balance problems was also highlighted in previous IVR studies which delivered standing or walking tasks for elderly with CLBP (Hennessy et al.2020; Eccleston et al. 2022; Stamm et al. 2022; Yalfani et al. 2022).

Alongside safety concerns, this study contributes to the ongoing discussion about the potential IVR risks which have not been addressed in the context of CP management. The participants felt that being immersed in an artificial world could enhance fearfulness for patients with concerns about they perceived as aggravating movements. Garrett et al. (2017) reported that some CP patients found VE to be intimidating, but this was due to an unpleasant experience. The perceived risk of confined movement due to a lack of awareness of their surroundings seems different. In IVR and stroke rehabilitation, Levac et al. (2019) discussed briefly similar concerns regarding upper limb movement restriction within VE, arguing that IVR may impact movement quality and leads to slower movement compared to the real world (Levac et al. 2019).

The identified risk of addiction in this study was not noted in current IVR interventions for CP, however, it has been discussed by previous reviews in IVR-based rehabilitation (Rizzo et al. 2004; Găină et al. 2021). These reviews claimed that the potential of IVR addiction was amplified by the perspective of digital gaming, although there is no clear evidence that this exists (Rizzo et al.2004; Găină et al. 2021). Further discussion with participants in this study about addiction raised apprehension that being immersed in VE may evoke “dissociation”. In research, dissociation is defined as the feeling of detachment from oneself or the real world which is a common pre-existing symptom in patients with mental health problems (e.g., depression) (Lambert et al. 2002; Tack 2021; Găină et al. 2021). Although the risk of dissociation was discussed in this study as part of IVR addiction, literature identified it separately as a potential psychological harm for those with mental health problems while being immersed in VE (Tack 2021; Găină et al. 2021).

As a result, based on the current study, screening prior to an IVR intervention should be undertaken to exclude patients with potential risks such as those with visual impairment, balance problems and mental health issues. Furthermore, restricted movement within VE, IVR addiction and induced dissociation symptoms would be potential risks that should be monitored, in which it may be better to withdraw people if real world engagement remains

unchanged or worsens. Future investigations may need to consider these additional risks and evaluate whether they could negatively impact on patient outcomes.

6.6.3 Suggestions for IVR components

Several suggestions were made in the current study about the software, hardware, and dose of IVR for CLBP management. Participants thought that an IVR intervention may need to be personalised to individuals' goals and preferences, taking into account their functional limitations in a real-life setting. Furthermore, the provision of feedback on performance and reward within VE was suggested, utilising easy to handle hardware. Diverse opinions were expressed about the IVR dose, some felt uncertain while others suggested a personalised dose with consideration for consistency and rest breaks.

The findings support physiotherapists' suggestions in Stamm's et al. (2020) study on IVR development for patients with CLBP. Stamm et al. (2020) also indicated the necessity for considering individual preferences and functional limitations, user-friendly hardware and integration of feedback score and reward. The current study added the value of goal setting, particularly focusing on achieving challenging tasks relevant to daily life. Establishing goals was not addressed in IVR interventions until recently by Eccleston et al. (2022), who developed VE to induce behaviour change in CLBP patients. The VE was designed to set multiple goals to confront fearful movements and increase physical activity (Eccleston et al. 2022). Goal setting was perceived as of high priority in CLBP clinical practice, in which patients' engagement with identifying personal goals and needs was found to be effective in enhancing self-efficacy, patient satisfaction and adherence to exercise (Hazard et al. 2009; Coppack et al. 2012; Gardner et al. 2018). Therefore, it would be of benefit to develop an IVR intervention for CLBP that incorporates patient-derived goals from a real-life setting.

In terms of feedback, participants thought scores that conveyed success and rewards correlated to motivation, whereas failure feedback was seen as a negative element which could potentially induce feelings of failure associated with pain experience. Likewise, physiotherapists in Stamm's et al. (2020) study suggested the integration of only positive feedback, never negative, to enhance the engagement of CLBP patients in IVR. This was also noted in VR-rehabilitation of chronic stroke conditions, where positive feedback and avoidance of technology failure was seen as critical for patient engagement. It enabled the

patient to feel a greater success than they would in real life (Lewis and Rosie 2012). Some of the current IVR interventions for CP conditions provide feedback scores and rewards, this can be in the form of both success and failure (Bolte et al. 2016; Jin et al. 2016; Jones et al. 2016; Thomas et al. 2016; Amin et al. 2017; Gulsen et al. 2020; Trujillo et al. 2020; Eccleston et al. 2022; Yalfani et al. 2022). Although it is still not scientifically evident whether failure feedback impedes patient engagement, the provision of success feedback scores and reward would be positive elements to consider in IVR development.

With regard to dose, some participants' uncertainty is understandable given that they are new to the topic. Other suggestions of personalised dose based on individual behaviour with consideration for repetitions and consistency, is contradictory to therapists' suggestions in Stamm et al. (2020) who specified that the duration should be 15 to 30 minutes. These contradiction and uncertainty are consistent with the lack of consensus presented in the literature about the optimal dose of VR in CP management (Mallari et al. 2019; Wittkopf et al. 2019; Baker et al. 2021; Goudman et al. 2022; Grassini 2022). Nonetheless, determining the dose based upon individual behaviour could be a valuable suggestion given the individualised nature of CLBP as well as the identified concern of transferability and addiction (section 6.6.2). According to this study, the potential risks of limited transferability to the real world and addiction highlight the need to alter the amount and duration of IVR sessions based on the patient's engagement with VE, reflecting on the benefits gained in the real world.

In summary, the above suggestions on IVR components align with behavioural change techniques which include goal setting, feedback on performance, rewards, and repetitions. These are well-known principles which are defined as an active ingredient of a behaviour-change intervention (Michie et al. 2013). The potential to use IVR as a behaviour change intervention is also reinforced by explicit statements from some participants (PT13): *"we can apply those principles for behavioural changes"*. As previously mentioned in Chapter 5, applying IVR as a behaviour change tool is currently limited. Eccleston et al. (2022) is the only study that pinpointed IVR key aspects (i.e., immersion, interactivity, and embodiment) to support goal setting, positive feedback on performance, reward, and repeated movement. Thereby, future development may need to incorporate behavioural change principles to optimise IVR benefits for CLBP.

6.6.4 Clinical versus home setting

This study revealed differing views about delivery setting, highlighting safety as a prerequisite. Whilst some participants thought IVR should be delivered only under clinical supervision, others felt that a home setting may have potential if safety parameters are put in place. Furthermore, physiotherapist support, even remotely, was seen as essential to educate, motivate patients and monitor their progression.

These findings are in line with therapists' suggestions in Stamm et al. (2020), who indicated the need for supervised clinical sessions as well as considering safety if IVR was used at home. According to this study, safety should be ensured whilst in the home with regular monitoring, consideration of potential risks including inadequate movement performance, risk of fall and addiction. With addiction being of significant concern, this study indicates the need to establish a predetermined dose prior to home implementation. The reported requirement for physiotherapist support to reinforce engagement, whether in-person or remotely, is consistent with the literature on VR-based rehabilitation which emphasises the importance of practitioner support in enhancing CLBP patient engagement with VR exercises (Palazzo et al. 2016; Lin et al., 2019). Furthermore, this study pointed out the physiotherapist's role to enhance a patient's familiarity with technology, giving detailed information and educational videos prior to the intervention. In contrast, therapists in Stamm's et al. (2020) study suggested a different educational method of demonstrating the instructions within the software, to take a closer look while being immersed in VE. Although this suggestion is valuable to consider, practitioner engagement to provide orientation and eliminate doubts prior to the IVR intervention has been indicated (Donegan et al. 2020; Sarker et al. 2021).

Therefore, based on this study, IVR intervention might be better delivered under clinical supervision, where physiotherapists can support CLBP patients with educational resources, motivate patients and closely monitor their safety. Home delivery may be encouraged to aid remote CLBP management once safety has been ensured.

6.6.5 Facilitators and barriers to IVR adoption

The results showed technical knowledge, training of providers and evidence-based effectiveness as facilitators for IVR uptake, while cost, time and lack of technology

acceptance were perceived as barriers. Therapist knowledge, time and cost were also identified factors that influenced VR technology adoption in clinical practice amongst Canadian therapists (Schwartzman et al. 2012; Levac et al. 2017).

In terms of technical knowledge and training, this study revealed differing opinions about who should be trained. Some physiotherapists expressed interest in receiving technical knowledge and training, while others felt that the assistance of a technology expert might save physiotherapists' time. In clinical practice the time factor is thought to be a barrier to its adoption. Likewise, Sarkar et al. (2021) reported the need for dedicated practitioner training and time to adopt IVR in CP management. Based on the current findings, the knowledge and training of physiotherapists would be essential for successful IVR adoption. Furthermore, it may be beneficial to assign technology expert to provide ongoing technical support and facilitate the workflow of the adopted healthcare practice.

In the current study, cost of equipment and technical maintenance was perceived as a significant barrier, with the assumption that this outweighs IVR benefits in clinical practice. In line with these findings, physiotherapists in Canada were noted to be reluctant to adopt VR in clinical practice, most likely due to the cost of the device (Schwartzman et al. 2012). This study also found that the evidence base of cost-effectiveness when compared to standard care is critical to IVR adoption. Cost effectiveness of IVR in CLBP management has not yet been investigated, however, relevant studies were conducted. For instance, an economic analysis by Delshad et al. (2018) assessed the cost effectiveness of IVR as a distraction therapy for acute pain management in hospitalised patients. This analysis, which was based on the cost estimated by 'AppliedVR' company in USA, revealed that IVR would result in cost saving by shortening hospital stays but savings from reduced opioid use are insufficient to cover IVR cost (Delshad et al. 2018). In the context of CLBP, a recent study showed that a remote VR game was cost saving for CLBP compared to McKenzie extension exercises in an out-patient physiotherapy clinic in Nigeria (Fatoye et al. 2022). However, the study evaluated the cost effectiveness of non-IVR (i.e., Microsoft's Kinect platform) (Fatoye et al. 2022). Accordingly, the cost would be a significant barrier to IVR adoption in CLBP management and further research is needed to determine whether the benefits compared to standard practice are worth the cost of implementation.

Lack of technology acceptance either by physiotherapists or patients was viewed in this study as an additional barrier to IVR adoption. Therapists' attitudes toward the VR exergame were considered as a significant predictor of adoption in clinical practice (Levac et al. 2017). In this study, lack of physiotherapist acceptance was attributed to the fears of their profession being replaced or unequal treatment between those with or without technology experience. This apprehensions around technology aligns with Sarker et al. (2021), who reported that an innovative culture in the adopted healthcare organisation is a prerequisite for IVR adoption in CP management. In addition, participants ascribed the lack of patient acceptance to the digital literacy, particularly in the elderly population, which is a consistently stated challenge in Donegan et al. (2020). Many elderly patients reject IVR as they believe they are too old or slow to handle the technology (Donegan et al. 2020). As a result, it would be important to consider the attitudes of therapists and patients toward IVR technology in clinical practice prior to its adoption and to foster a culture of acceptance by effectively communicating IVR benefits.

6.7 Part 3- Strengths and limitations

The use of the focus group method is a strength of this study. It enables the sharing of views and thoughts based on the group's experiences; this generates new ideas particularly when discussing a novel topic such as IVR technology. The participant homogeneity in professions, with a broad range of experiences in treating CLBP, strengthens the group discussion through the sharing of thoughts. This is facilitated further by using images and videos in the presentation at the start of each focus group.

There are some limitations to consider. Although participants in this study have a wide range of clinical experience in treating CLBP, the convenience sampling through online advertisement may have limited the generalisability of the findings to a wider population of physiotherapists. Further, it should be acknowledged that the online format may impact on the richness of the collected data even though the researcher made an effort to facilitate the online group sessions. The planned face to face format for this study pivoted to online due to the circumstances of the COVID pandemic. The face-to-face workshop format that allows participants to try out IVR equipment could have provided additional insights, which could not be captured in an online format. The lack of participants' experiences in using IVR could be another potential weakness. The study invitation was for those with and without

IVR experience, but none of the participants had previously utilised IVR in clinical practice. Although this was not surprising, the novelty factor and lack of knowledge may have reduced the depth and data richness. Future investigations may need to engage physiotherapists with experience in IVR or technological advances in clinical practice, this could help to generate new ideas.

6.8 Part 3 - Summary and future implications

This study explores the physiotherapists' opinions and views on the use of IVR in CLBP management. Four focus groups were used to identify the potential benefits, concerns, setting and technology specifications, as well as the facilitators and barriers to its adoption.

The physiotherapists in this study perceived IVR as a potential alternative for non-compliant CLBP patients to practise physical movement and to facilitate remote management. Additionally, an interest was found in relation to social experiences, with views on the potential value of IVR to support group therapy. However, concerns were also raised about the transferability of virtual skills to the real world as well as the potential risk of falls, restricted movement within VE and addiction. Suggestions include personalisation of the IVR intervention, considering patient-centred goals, activity preferences and functional limitations, with an individualised and consistent dose. The inputs on technology were about simple to use hardware and positive feedback -integrated software. Safety was deemed essential, in which the study indicates the preference to place IVR intervention under clinical supervision and home setting was seen as acceptable as long as remote monitoring has been put in place. In addition, physiotherapist support was seen as crucial in improving a patient's familiarity with IVR and encouraging their performance. Factors such as cost, provider knowledge, and acceptance of physiotherapists and patients were reported to influence IVR adoption in CLBP practice.

While acknowledging the potential of participant bias, this study has revealed several implications. The findings may encourage healthcare practitioners to recognise IVR as an alternative option to support CLBP patients who are not actively involved in traditional rehabilitation. The suggestions made in this study may prompt future research to explore the potential application of IVR in a group format, encouraging technology developers to design a social virtual content. Furthermore, findings indicated that IVR intervention may

still require the close support of trained practitioners in terms of screening and monitoring safety. Future investigations are warranted to evaluate the potential of movement hesitancy and the problem of addiction as well as the cost effectiveness in CLBP practice.

Chapter 7: Summary Discussion

7.1 Introduction

For each part of the thesis (Part 1, 2 and 3) a discussion of the results in relation to the literature, limitations of each part and suggestions for further research has been presented following the presentation of the data (See sections 4.4, 5.4 and 6.6)

This chapter provides an overview of the results generated from all three parts of this thesis followed by high level recommendations for future IVR development and implementation in CLBP management and future research.

The three parts of this PhD thesis aim to:

- 1) Part 1, Scoping review: synthesis of the contemporary evidence to map theories underpinning the IVR mechanism of action for patients with CP as well as the key features of IVR interventions including the software, hardware, dose, and setting.
- 2) Part 2, Sequential explanatory study: to engage global stakeholders (healthcare practitioners and IVR technology developers) to gain an understanding on the current use of IVR in CP management.
- 3) Part 3, A qualitative study: to explore views and opinions of UK physiotherapists about the potential benefits, concerns, barriers, and facilitators to using IVR for CLBP management.

7.1.1 Overview of the results

7.1.1.1 Part 1 - Scoping review

The review found that diverse IVR mechanisms were employed for CP management with limited underlying theories, including distraction, graded exposure, coping skills, physical exercises, neuromodulation, and behaviour change. These mechanisms were commonly delivered via customised software utilising a broad range of HMDs with inconsistent duration and frequency. The reviewed studies often implemented IVR in a clinical setting, and rarely in a home setting. Common exclusion criteria such as MS susceptibility and epilepsy were identified, this would reduce potential risks. Nevertheless, several adverse

effects were noted, predominately MS and HMD discomfort, with technical difficulties primarily reported in the home setting.

7.1.1.2 Part 2 – Healthcare practitioners and IVR technology developers and CP management using IVR

The study suggests considering patients' technology preferences when using an IVR intervention, while stressing the importance of initial screening to exclude those with potential risks. IVR was believed to be beneficial in combating FOM, improving coping skills and engaging in physical and social activities. To potentially achieve these benefits, personalised intervention was seen as crucial by factoring in individual comfort using hardware and tailoring VE to clinical needs, functional ability, and mimicking personal real-life situations while addressing culture. Nonetheless, several adverse effects were acknowledged, commonly MS, which it was believed could be controlled via screening and a gradual build up dose. The study recommends ensuring safety by initially implementing IVR in a supervised clinical setting, with practitioners providing instruction, maintaining hygiene, and setting up remote monitoring when the intervention is transferred for home use. Personalisation, cost, practitioner acceptance and knowledge were deemed critical for IVR adoption.

7.1.1.3 Part 3 - Physiotherapists and CLBP management using IVR

IVR was thought to be a promising alternative for CLBP patients, who resist standard care, to engage in physical movement and to aid remote management, with views on the potential for group-based therapy. The use of personalised IVR intervention was recommended, using an individualised dose, and considering personal goals, preferences, and physical limitation. Practically, software integrated with positive feedback and reward as well as easy to use hardware were suggested. Concerns were raised about the transferability of virtual skills to the real world as well as the risk of falls and addiction. While home setting was considered suitable with remote monitoring, the study participants showed a preference for using IVR under clinical supervision on the grounds of safety and the availability of support from physiotherapists to educate and reinforce patient's performance. IVR adoption in CLBP practice was believed to depend on cost, provider knowledge and technology acceptance.

7.1.2 Recommendations for future development and implementation of IVR intervention for CLBP management

7.1.2.1 The likely benefits of IVR for CLBP

There are several potential benefits of using IVR in CLBP management, which are reported in all three parts of the thesis. The results of Part 1 and Part 2 indicate the potential of IVR in combating FOM, enhancing the ability to cope with pain through mindfulness/biofeedback, promotion of engagement in physical exercise and the potential for encouraging social interaction. These benefits were also anticipated by physiotherapists in Part 3 to have potential in CLBP management, and in addition they appreciated the distinctive advantage of the IVR technology to deliver the intervention remotely. Based on Part 2 and Part 3 findings, healthcare practitioners may consider IVR technology as an alternative option in CLBP management for patients with psychologically driven types of pain (i.e., FOM, anxiety, social isolation), who experience challenges with conventional treatment. According to Part 3, remote therapy could also provide patients with access to healthcare services, especially during unforeseen circumstances such as the COVID pandemic. Furthermore, it may allow a level of privacy using anonymous virtual avatar for sharing pain experiences and practising exercises, which may be particularly useful for those who endure stigma. While these subgroups may be potential recipients of IVR interventions, future development should thoroughly evaluate which populations is most likely to gain benefits from IVR interventions.

Although some promising results of IVR in CLBP management have been reported in Part 1, it is crucial to note that the mechanisms by which the IVR produces its benefits, particularly in the long term, are not yet scientifically known. Furthermore, it is difficult to understand the process by which an intervention might be effective as several variables can interact to produce the effect including, type of software and hardware, type of environment, intensity, duration, and frequency of the intervention.

The findings highlighted the potential to use IVR as a behaviour change intervention. While Part 1 showed a single IVR intervention developed by Eccleston et al. (2022) to induce behaviour change in CLBP patients with FOM, healthcare practitioners and technology developers in Part 2 indicated that IVR through immersion, real time feedback and embodiment could enhance self-awareness and self-efficacy, which are essential

psychological constructs in changing behaviour. Moreover, physiotherapists in Part 3 viewed that behaviour change techniques such as goal setting, positive feedback, rewards and repetitions could optimise the benefits of IVR in CLBP management.

Given the knowledge gap of the working mechanism, further work is required to gain a better understanding of the underlying neural mechanisms to establish which IVR interventions can be most effective while reflecting on the heterogeneity of CLBP conditions. Based on thesis findings, future IVR development could consider behaviour change theories or technique taxonomy by Michie et al. (2013) to maximise IVR benefits in CLBP management, which may help to build a firm foundation for IVR interventions that is currently limited. Nonetheless, it should be noted that behaviour change is a much more complex and multi-faceted process in which further continued development effort is needed to fully understand the potential of such a concept in the context of IVR interventions.

7.1.2.2 The need for personalisation

This thesis underlines the need for personalisation and the engagement of patients in IVR development in various ways. In Part 1, the review found the common use of customised software with limited personalisation and a high prevalence of patient discomfort while wearing the HMD. This is recognised by healthcare practitioners and technology developers in Part 2 who indicated the lack of personalised VE and the limited availability of optimally developed HMDs that addressed patients' needs. Based on Part 2 and Part 3 findings, future development should involve patients in the decision-making process and address their acceptance and openness to use technology as an alternative tool to manage their conditions. By examining patients' technological preferences, the researchers and healthcare practitioners may also identify those who are more likely to engage with the intervention. Furthermore, co-production was seen as critical in developing a successful intervention for CLBP by adapting the VE and hardware to meet patients' requirements.

Both Part 2 and Part 3 emphasised the importance of designing VEs which are tailored to clinical needs, functional abilities, and patient preferences. In addition, Part 2 indicated the need to address culture when designing VEs and Part 3 added personal goals as another means of personalisation. Therefore, future innovation should consider effective collaboration between healthcare practitioners and technology developers to identify

these key aspects prior to designing VEs. It is imperative that technology developers and healthcare practitioners communicate with patients to identify their physical limitations, activity preferences and the desired goals of patients with CLBP, including challenging real-life situations. It would be interesting to encourage technology developers to create storylines that are representative of the diverse cultures which access the health services and to consider the different languages in the text or audio of the VEs.

As noted in Part 2, the complexity and heterogeneity of CLBP conditions make personalisation in the current development challenging, which was suggested to potentially be addressed by artificial intelligence. With the rapid technology evolution, artificial intelligence may help technology developers to precisely analyse patients' demands, paving the way for more refined and personalised virtual scenarios in future development.

Part 2 and Part 3 also indicate that individual comfort and ease of use of the hardware as a priority, implying the need for lightweight, wireless HMD and more wearable sensors. Currently, the available HMDs are primarily designed for entertainment purposes and do not adequately accommodate the needs of individuals with disabilities. Therefore, it is essential for HCPs and technology developers to select the HMD that is best suited for their patients. Future collaboration between health services and IVR companies may aid in developing patient-friendly HMD to optimise comfort and enhance patients' experiences.

While these suggestions on personalised software and hardware are potentially prerequisites, future research should continuously gather patients' feedbacks during development and implementation to enable ongoing improvements and make necessary modifications to the design and functionality of IVR technology. This can prevent the deployment of technology that may turn out to be impractical in CLBP practice, in the public health setting, thus saving time and resources.

7.1.2.3 The IVR dosage

Some indications on IVR dose have been made in this thesis, however, no agreement was found on the specific duration, frequency, or number of sessions. As shown in Part 1, the duration and frequency are inconsistent in the current IVR interventions. Part 2 and Part 3 concluded that IVR needed to be gradually adapted depending on individual patient needs

and any adverse reactions. Although Part 2 and Part 3 suggestions would be valuable to consider in future development, further research is needed to determine the optimal dose of the intervention and identify the factors that influence the effectiveness of the intervention. This may be determined when the mechanisms, by which IVR most effectively works with CLBP patients, are fully established. By identifying the specific neurological, physiological, or psychological processes that underlie IVR effectiveness, healthcare practitioners may be able to refine the dose to optimise the intervention outcomes.

7.1.2.4 Safety and healthcare practitioner's role

This thesis indicates that IVR is associated with several potential risks which need to be addressed, healthcare practitioners should engage in the implementation process to establish safety. Part 1 revealed that current IVR interventions are associated with common incidences of MS, eye strain and fatigue, which was acknowledged by healthcare practitioners and technology developers in Part 2. Additionally, the potential risks expressed by physiotherapists in Part 3 were predominantly focused on the lack of awareness of the patients' physical surroundings, leading to restriction in freedom of movement, risk of falls, and addiction. Given these potential risks, Part 2 and Part 3 suggest there is a need to ensure safety by implementing IVR in a supervised clinical setting where healthcare practitioners can adopt initial clinical screening with ongoing monitoring of the patients. Although the three parts of the thesis present the patient's home as an acceptable setting for IVR interventions, Part 2 and Part 3 stress the importance of ensuring safety prior to home implementation.

Based on Part 2 and Part 3 findings, the following recommendations would be critical to consider in future IVR implementation. Future implementation requires healthcare practitioners to incorporate a screening protocol to exclude patients with potential contraindications such as those with a history of MS, epilepsy, visual or hearing impairment as well as taking precautions with those who present with balance and mental health problems. Furthermore, it is crucial to deliver the IVR interventions gradually and adaptively while closely monitoring the patient's response, ensuring they do not experience an adverse experience or become overly reliant on IVR without any engagement with the real-world. Safety should be prioritised if the intervention is planned

for home use, considering initial IVR implementation under clinical supervision to monitor any negative experiences and ensure remote monitoring.

With safety being a critical aspect, Part 2 results highlighted the need to avoid cross infection when using the HMDs in a clinical setting. Two sterilisation methods were suggested, either the ultraviolet cleaning box or the affordable solution of medical wipes with HMD disposable covers. In future IVR implementation, the healthcare practitioners undertake appropriate infection control measures in a clinical environment and the selection of sterilisation method would depend on the available resources in the health services.

7.1.2.5 Additional role of healthcare practitioners in IVR implementation

Alongside the role of HCPs in optimising safety, this thesis highlights their crucial role in providing patients with pre-education and support throughout the intervention even remotely. Whilst Part 1 showed that some studies reported the healthcare practitioner's role in patients' guidance for performing adequate tasks or exercises, Part 2 and Part 3 emphasised their role with several suggestions. According to Part 2 and Part 3, the healthcare practitioners are required to initially introduce IVR and enhance the patient's familiarity with this novel technology by discussing its benefits and providing appropriate instructions and training to effectively navigate the IVR system. In addition, granting the healthcare practitioners a virtual access to the software can be beneficial to assign suitable tasks, set specific goals, reinforce performance, and provide timely technical support. With the current technology advancement, it is recommended to incorporate a live interface of VE and allow healthcare practitioners to communicate and effectively engage with the patients through video or audio in the software platform. By providing healthcare practitioners with the necessary tool to engage with patients, a more dynamic implementation process could be fostered.

One of the essential aspects revealed in this thesis was the role of healthcare practitioners in encouraging the transferability of the learned virtual skills to the real world, this has been discussed in Part 2 and Part 3 separately. The healthcare practitioners and technology developers in Part 2 emphasised the need for verbal feedback to reinforce the relevance between VE and daily pain experience. Physiotherapists in Part 3 were concerned about the transferability to a real-life setting, they suggested that healthcare practitioners should

encourage patients to practise the virtual skills outside the VE. Given the current limited knowledge about this aspect, it is recommended that healthcare practitioners provide verbal cues on how the virtual skills can be used and encourage patients to practise them in real life situations. In future implementation, this could help patients to recognise the practical value of what they have learnt in the VE and drive them to apply it in their daily lives.

These recommendations with regards to safety and the role of the healthcare practitioners would make a valuable contribution to future IVR implementation, particularly considering the limited information available in the current reported interventions. Future research needs to evaluate the clinical significance of these recommendations in minimising the risks associated with IVR intervention and optimising the intervention outcomes for patients with CLBP. Furthermore, it is encouraging for healthcare practitioners and researchers to investigate alternative approaches during the implementation process to refine the best clinical application of such a technology.

7.1.2.6 Considerations for implementation in today's healthcare services

This thesis indicates that practitioner acceptance, knowledge, and training and costs are critical factors to the adoption of an IVR intervention in health services currently. Both Part 2 and Part 3 highlighted the fact that lack of practitioner acceptance would be a barrier to adoption, in which comprehensive knowledge and training were thought to be essential for successful implementation. Hence, any future deployment plans should provide appropriate training and support for practitioners, which would include technical support, considering workforce and resources limitations. It would be helpful to develop or adopt comprehensive training programmes in health services, demonstrating the technical aspect, safety considerations and most importantly the added benefits of IVR to the current CLBP practice. Theoretically, the perceived usefulness (i.e., practitioner belief that technology is beneficial and can provide positive health outcomes) has been found to be a key determinant for technology acceptance and intention to use (Davis 1989). Furthermore, providing this service with appropriate technical support may need to be considered to reflect the relative novelty of IVR in a clinical environment and the rapidly changing technology.

Cost and lack of funds were discussed in Part 2 and Part 3 as a significant barrier to IVR adoption. In addition, physiotherapists in Part 3 questioned the cost-effectiveness of an IVR intervention compared to the conventional treatments in CLBP practice. The IVR as a digital intervention is associated with high-cost implications during development and implementation, these include the device cost and maintenance, the software infrastructure, allocating technical support as well as the healthcare practitioners training and resources. As CLBP is a global problem development needs to consider a global product that is accessible to a wider range of populations including those in rural communities. Therefore, consideration of financial resources is inevitably crucial in the early stages of adopting an IVR intervention. Furthermore, the future planning of development and implementation should be supported by economic analysis that demonstrates the value of IVR technology in terms of improved patients' outcomes and long-term cost savings. This would be more likely to encourage health services to invest in the necessary infrastructure and resources.

Chapter 8: Conclusion

With the recent technological advancement, IVR applications have been rapidly developed to support CP and/or CLBP management. However, the pre-investigation on the critical aspects of development have not been undertaken, and the effectiveness of this technology inconclusive. This thesis therefore adopts a mixed methods design guided by the MRCF to gain insights about the benefits, risks, technology specification and setting of an IVR intervention as well as the facilitators and barriers to adoption for CLBP management. Following MRCF recommendations, these have been obtained from the current IVR studies, this is followed by the perspectives of various stakeholders including global stakeholders (healthcare practitioners and IVR technology developers) and physiotherapists with previous experiences in treating CLBP.

Overall, the findings indicate that IVR has diverse potential benefits such as combating FOM, enhancing the ability to cope with pain and engagement with physical exercise, which stem from different mechanisms of action. Given the potential benefits, the results indicate the potential of IVR as an alternative option for CLBP patients who present in health services with low motivation and are willing to use IVR as a management tool. However, there is still a need to establish a solid foundation of knowledge and a comprehensive understanding of the underlying mechanisms by which IVR can work to achieve favorable outcomes in CLBP management.

Personalisation is recommended as the key factor when developing an IVR intervention, VE should be tailored to the patient's clinical need, goals, physical abilities, and cultural background. In addition, the present HMDs may not be the most ideal fit for all patients, this could lead to a level of discomfort. The findings emphasise the necessity to priorities individual comfort and ease of use in future development.

Safety is a key issue during IVR implementation, with several potential risks of IVR being identified, predominantly MS. Adopting safety parameters of initial screening, a gradual build up to adapt VE and ongoing monitoring in a supervised clinical setting are recommended. While home implementation is deemed acceptable, it is also crucial to establish safety under supervision with remote monitoring in place. In addition, the results

suggested the healthcare practitioner's role is crucial in promoting successful implementation by providing preparatory instructions, avoiding cross infection, guidance and technical support when needed as well as reinforcing the application of the learned virtual skills in a real-world context. Future IVR adoption in CLBP practice is likely to depend on healthcare practitioners' knowledge, training, and willingness to integrate technology in the workflow and the financial feasibility of implementing such technology in the health services.

8.1 Future Implications

The findings of this thesis may serve as a roadmap for co-designing research, engaging healthcare practitioners, IVR technology developers and, most importantly, patients to develop and adopt IVR prototype in healthcare services. Future research should seek insights from patients' perspectives to understand their concerns and preferences. This thesis demonstrates that online consultation works with professionals, taking the advantages of geographical diversity. However, this may not be the case when discussing such an intervention with the patients, as some may face challenges due to limited or no access to information technology. Therefore, it is important to consider the most suitable data collection methods for both patients and health professionals.

The IVR has the potential to work as an alternative means of supporting patients who may not actively engage in traditional rehabilitation, such as those unable to attend healthcare settings. The collaboration between healthcare practitioners and technology developers, may help in understanding patients' needs and pave the way for healthcare services to co-produce, together with patients, future remote management options using IVR technology. Incorporating artificial intelligence to precisely analyse patients' needs, opening up opportunities to utilise IVR for developing highly personalised interventions.

At this stage, it is too early to confirm whether IVR would be viable for implementation in broader healthcare settings, particularly given the current challenges of cost and technology acceptance in the context of CP management. Therefore, assessing the long term cost associated with IVR implementation would be critical to enhance acceptance and

adoption in today's healthcare services. Finally, any new intervention entering healthcare services requires regulations. If proven effective, approval of IVR from healthcare regulators may improve confidence and encourage healthcare services to accept and explore the utility of IVR as a new intervention and establish 'in-house' technical support.

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Appendices

Appendix 3-1: First ethical approval in 2019

School of Healthcare Sciences
Head of School and Dean Professor David Whittaker

Ysgol Gwyddorau Gofal Iechyd
Pennaeth yr Ysgol a Deon Yr Athrawes David Whittaker



03 December 2019

Anfal Astek
Cardiff University
School of Healthcare Sciences

Cardiff University
Ty Dewi Sant
Heath Park
Cardiff CF14 4XN

Tel Ffôn +44(0)29 20687552
E-mail E-bost harmerl@cf.ac.uk
Prifysgol Caerdydd
Ty Dewi Sant
Mynydd Bychan
Caerdydd CF14 4XN

Dear Anfal

Feasibility and Acceptability of Immersive Virtual Reality Intervention for Managing People with Chronic Low Back Pain

I am writing to inform you that the Chair of the Research Ethics Committee has, following consultation, **approved** your revised research proposal. The Committee will ratify this decision at its meeting on *10 December 2019*.

Please note that if there are any major amendments to the project you will be required to submit a revised proposal form. You are advised to contact me if this situation arises. In addition, in line with the University requirements, the project will be monitored on an annual basis by the Committee and an annual monitoring form will be despatched to you in approximately 11 months' time. If the project is completed before this time you should contact me to obtain a form for completion.

Please do not hesitate to contact me if you have any questions.

Yours sincerely

Liz

Mrs Liz Harmer Griebel
Research Administration Manager

c.c. Val Sparkes & Liba Sheeran

Cardiff University is a registered charity, no. 1136855
Mae Prifysgol Caerdydd yn elusen gofrestredig, rhif 1136855

Appendix 3-2: Second ethical approval in 2020



School of
Healthcare Sciences

Ysgol y Gwyddorau
Gofal Iechyd

Cardiff University

Eastgate House
35-43 Newport Road
Cardiff

www.cardiff.ac.uk

Interim Head of School and Dean /Pennaeth yr Ysgol Dros Dro a Deon Professor David Whitaker

2 December 2020

Anfal Astek
Cardiff University
School of Healthcare Sciences

Prifysgol Caerdydd

Ty Eastgate
35 - 43 Heol Casnewydd
Caerdydd
www.caerdydd.ac.uk

Dear Anfal

Research project title: Development of Immersive Virtual Reality Intervention for Managing People with Chronic Low Back Pain

SREC reference: REC658

The School Of Healthcare Sciences Research Ethics Committee reviewed the above application amendments electronically via its proportionate review process.

Ethical Opinion

The Committee gave:

a favourable ethical opinion of the above application on the basis described in the application form, protocol and supporting documentation.

Additional approvals

This letter provides an ethical opinion only. You must not start your research project until all appropriate approvals are in place.

Amendments

Any substantial amendments to documents previously reviewed by the Committee must be submitted to the Committee via HCAREethics@cardiff.ac.uk for consideration and cannot be implemented until the Committee has confirmed it is satisfied with the proposed amendments. You are permitted to implement non-substantial amendments to the documents previously reviewed by the Committee but you must provide a copy of any updated documents to the Committee via HCAREethics@cardiff.ac.uk for its records.

Monitoring requirements

The Committee must be informed of any unexpected ethical issues or unexpected adverse events that arise during the research project.



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The Committee must be informed when your research project has ended. This notification should be made to HCAREethics@cardiff.ac.uk within three months of research project completion.

Complaints/Appeals

If you are dissatisfied with the decision made by the Committee, please contact the School's Research Ethics Officer, Kate Button on HCAREethics@cardiff.ac.uk in the first instance to discuss your complaint. If this discussion does not resolve the issue, you are entitled to refer the matter to the Head of School for further consideration. The Head of School may refer the matter to the Open Research Integrity and Ethics Committee (ORIEC), where this is appropriate. Please be advised that ORIEC will not normally interfere with a decision of the Committee and is concerned only with the general principles of natural justice, reasonableness and fairness of the decision.

Please use the Committee reference number on all future correspondence.

The Committee reminds you that it is your responsibility to conduct your research project to the highest ethical standards and to keep all ethical issues arising from your research project under regular review.

You are expected to comply with Cardiff University's policies, procedures and guidance at all times, including, but not limited to, its [Policy on the Ethical Conduct of Research involving Human Participants, Human Material or Human Data](#) and our [Research Integrity and Governance Code of Practice](#).

Yours sincerely,

Dr Kate Button

Cc Val Sparkes



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Appendix 4-1: Data screening sheet

Eligibility	Title of the Study	Authors	Yes / No / unclear	Notes
Chronic pain condition				
Are participants adults?				
Does the intervention delivered using immersive VR (head mounted Display)?				
Include the study in the review?				

Appendix 4-2: Studies excluded from the scoping review

	Reasons for exclusion	Study
1	Type of pain either acute or chronic was not identified	Kline-Schoder et al.2004 Harvie et al.2015 Tashjian et al.2017 Benham et al.2019 Stewart et al.2019 Tong et al.2019 Abdelraouf et al.2020 Kragting et al.2021
2	Using non immersive VR	Mercier and Sirigu 2009 McDonald et al.2011 Alphonso et al.2012 Villiger et al.2012 Botella et al.2013 McDonald et al.2013 Perry et al.2013

		<p>Herrero et al.2013</p> <p>Garcia-Palacios et al.2015</p> <p>Morris et al.2015</p> <p>Roosink et al.2016</p> <p>Zavarize et al.2016</p> <p>Guarino et al.2017</p> <p>Yelvar et al.2017</p> <p>Perry et al.2018</p> <p>Alemanno et al.2019</p> <p>Rezaei et al.2019</p> <p>Martín-Martínez et al.2019</p> <p>Richardson et al.2019</p> <p>Villafaina et al..2019</p> <p>Mbada et al.2019</p> <p>Matheve et al.2020</p> <p>Nambi et al.2021 (a)</p> <p>Nambi et al.2021 (b)</p>
3	Not enough equipment details to identified VR immersive or non-immersive	Oneal et al.2008
4	Patients with chronic condition: itching sensation not pain	Leibovici et al.2009
5	Using chronic migraine patients to evaluate the effect of VR during acute laser stimulation	De Tommaso et al.2013
6	Immersive VR used only for assessment not intervention	Sarig Bahat et al.2015
7	Comparison only between two HMD without showing effect on chronic pain.	Tong et al.2016
8	Using mediated reality and artificial intelligence	Nishigami et al.2019

Appendix 5-1: Introduction of the online survey

Utility of Immersive Virtual Reality in Healthcare

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Introduction

I would like to invite you to take part in this survey, which forms the first stage of our research study. This research study is being conducted by PhD candidate Anfal Astek of the School of Healthcare Sciences, Cardiff University, United Kingdom and it aims to develop immersive Virtual Reality (VR) intervention for people with chronic low back pain. This survey is **only relevant for healthcare practitioners, researchers or game developers with experience of using or developing immersive VR* to improve the health outcomes of users (*Immersive VR means using headsets to view virtual environments). Those who use immersive VR for educational training are not eligible for participation.**

The School of Healthcare Sciences Research Ethics Committee has reviewed and approved this study. The information sheet and consent form follow this introduction. If you have any questions prior to participation you can contact me by email: AstekAA@cardiff.ac.uk

This survey explores the utility of immersive VR in healthcare in order to understand its current use and to inform the development of immersive VR as a treatment for people with chronic low back pain. The survey should take 20 minutes to complete.

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Appendix 5-2: e-participant information sheet (Online survey Part2/Phase1)

Utility of Immersive Virtual Reality in Healthcare

9% complete

Participant Information Sheet

I would like to invite you to take part in an online survey. Before you decide to take part, you need to understand why the research is being carried out and what it would involve for you. Please take time to read the following information carefully and click one of the options at the end of this information sheet.

What is the purpose of the study?

This study aims to develop immersive virtual reality (VR) as a means of managing people with chronic low back pain. The purpose of the online survey is to gather information about people's experiences and current use of immersive VR in healthcare.

Why have I been invited to participate?

You have been invited to participate in an online survey because you are a healthcare practitioner, researcher or game developer with experience of using immersive VR to improve health outcomes of users. These elements are crucial in our study because your experience will help us to understand the current practice and delivery of the treatment.

Do I have to take part?

It is up to you to decide whether to take part or not. We will provide you with a general idea of the questions involved in the online survey in this information sheet. If you agree to complete the online survey, we will ask you to sign a consent form.

What will happen to me if I take part?

If you wish to take part in the survey, you can follow the link at the end of this information sheet to sign the consent form and complete the survey. The online survey takes approximately 20 minutes to complete and contains the following sections: demographics, delivery of immersive VR, facilitators and barriers, users and immersive VR.

What will I have to do?

The online survey takes approximately 20 minutes to complete and contains the following sections:

Demographics: age, gender, level of education and years of clinical experience.

Delivery of Immersive VR: VR headset type, practice setting, content.

Barriers and Facilitators towards immersive VR in healthcare.

Users and Immersive VR: users' age, diagnosis, goal of using VR.

In the final section (Users and Immersive VR), please tick the box to confirm whether or not you would be interested in participating in a telephone/skype interview. The survey will then ask for your contact information including your email address, phone number and skype name. This feature is optional.

At the end of this information sheet, you have three options: 1) 'I have read the information sheet and want to participate', 2) 'I have read the information sheet but need to ask questions before I agree to participate' and 3) 'I do not wish to participate'.

If you choose option 1, you will proceed to the e-consent form. After completing this, please follow the link to complete the online survey.

If you choose option 2, the researcher will contact you to answer any questions. If you choose option 3, we would like to thank you for your interest in the study.

What is the device/procedure being tested?

To gather information about the current use of immersive VR in healthcare.

What are the possible disadvantages and risks of taking part?

Completion of the online survey does not involve any investigations or treatment that might put you at risk.

What are the possible benefits of taking part?

Information we obtain from the online survey will help us to understand the current use of immersive VR in healthcare in order to inform further development of treatment for chronic low back pain conditions.

What if there is a problem?

If you have any concerns about anything, you should ask the researcher and she will do her best to answer your questions and deal with your concerns. If you are still unhappy and wish to make a formal complaint, you should contact Dr Kate Button, Director of Research Governance, School of Healthcare Sciences, Cardiff University, Cardiff.

Contact number: 02920687734

Email address: buttonk@cardiff.ac.uk

Office Address: Room 13.17, 13th Floor, Eastgate House

35-43 Newport Road, Cardiff, CF24 0AB

What if relevant new information becomes available?

The researcher will use only the data about which we have informed you in this information sheet.

What will happen if I do not want to carry on with the study?

If you decide to withdraw from the study, we will destroy all of your identifiable records, but we will use the data collected up to the point of your withdrawal.

Will my taking part in this study be kept confidential?

All information that is collected about you will be kept strictly confidential. The researcher will maintain your privacy and confidentiality by securing the information using a passcode that is not accessible to anyone except the researcher. The procedures for the handling, processing, storage and destruction of data will follow the Data Protection Act 2018. All personal identifiable data will be securely stored at Cardiff University and kept on a computer protected by a password known only by the researcher. This data will only be used for this study and future studies will not have access to it unless further agreement is requested from you and your consent obtained. In addition, the data will be kept for five years and disposed of according to the recommendations of the Data Protection Act 2018.

How will my data be managed?

We will be using your information for the purpose of this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Cardiff University will keep identifiable information about you for five years from the conclusion of the study.

Your rights to access, change or move your information are limited as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use as little personally- identifiable information as possible. You can find out more about how we use your information at: <https://www.cardiff.ac.uk/public-information/policies-and-procedures/data-protection> or by contacting the University's Data Protection Officer: inforequest@cardiff.ac.uk

What will happen to the results of the research study?

The researcher may publish the study in academic journals and present the results at conferences. In addition, the main findings will be disseminated to all participants via an online link that will be sent to your email. Only anonymised results will be published. You will not be identified in any report or publication.

Who is organizing and funding the research?

This online survey is part of a PhD project funded by the Government of Saudi Arabia.

Who has reviewed the study?

The School of Healthcare Sciences Ethics Committee has reviewed and approved this study.

Further information and contact details

Researcher name: Anfal Adnan Astek

Email address: AstekAA@cardiff.cu.uk

Supervisors name: Dr Valerie Sparkes, Dr Liba Shereen

Contact number: 0920687560, 02920687757

Email address: sparkesv@cardiff.ac.uk, sheeranl@cardiff.ac.uk

Office Address: Room 13.11.13thFloor, Eastgate House

35-43 Newport Road, Cardiff, CF24 0AB

Once you have read this information sheet carefully, Please click one of the following options *

Required

- I read the information sheet and want to participate (you will be redirected to consent form)
- I read the information sheet but need to ask questions before participation
- I don't want to participate

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Appendix 5-3: e-consent form (Online survey Part2/Phase1)

Utility of Immersive Virtual Reality in Healthcare

27% complete

Consent Form

Title of Survey: Utility of Immersive VR in Healthcare

Name of Researcher: Anfal Astek

To participate in this online survey, you need to confirm your agreement with statements below.

I confirm that I have read and understand the participant information sheet for the above survey and have had the opportunity to consider the information, to ask questions and to have these questions answered * *Required*

YES

I confirm that data from the study can be used in the final report and other academic publications and may be presented at conference, I understand that these will be used anonymously * *Required*

YES

I understand that my participation is voluntary without my legal rights being affected, but any data collected up to the point of my withdrawal will be kept * *Required*

YES

I understand that the researcher will hold my contact details. I understand that all information about me will be kept in a confidential way and destroyed once the study is completed * *Required*

YES

You may contact me regarding taking part in a telephone/skype interview *Optional*

Yes

I agree for you to share my anonymised data with external collaborators in the UK and abroad, including commercial companies *Optional*

YES

You may contact me in the future to ask if I would be interested in participating in future Cardiff University research *Optional*

YES

I agree to take part in the above online survey ** Required*

Yes

Participant information

Participant Name

Date of Birth

Email Address ** Required*

Please enter a valid email address.

Today's Date ** Required*

[< Previous](#)

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Appendix 5-4: Email invitation for online survey recruitment

Utility of Immersive VR in Healthcare - PhD Project/ Online Survey


Anfal Astek

We would like to invite you to take part in a survey exploring the **utility of immersive virtual reality (VR) in healthcare**. This survey is a part of a PhD project to **develop immersive VR interventions for people with chronic low back pain** carried out at Cardiff University, United Kingdom.

The survey will take 20 minutes to complete.

Thank you very much in advance, your insight and experiences will help us to understand the current use of immersive VR in healthcare.

To participate, please click on the link
: <https://cardiff.onlinesurveys.ac.uk/utilityofimmersivevrinhealthcare>



Utility of Immersive Virtual Reality in Healthcare
Online survey BOS

Regards,
Anfal Astek
PhD student
School of Healthcare Science
Cardiff University , UK
12th Floor , Eastgate House ,Newport Road, Cardiff
CF24 0AB

Appendix 5-5: Flyer for online survey recruitment



Are you a Healthcare Practitioner, Researcher or a Developer with Experience of Using Immersive VR in Healthcare?



You are invited to participate in an online survey

“Utility of Immersive VR in Healthcare”

We are looking for people who use immersive VR for management of health conditions (excluding education purposes)

It takes about 20 minutes to complete

Appendix 5-6: Written comments and the emerged categories from the online survey analysis

Online survey questions	Categories	No. participants	Written Comments
Q2.1 What type of HMD do you use?	Pico	10	P705 "Pico"
			P812 "Pico Neo, G2"
			P840 "Pico Goblin"
			P039 "Pico G2"
			P117 "Pico Neo 2"
			P338 "Pico G24K"
			P940 "Pico G24K"
			P396 "Pico"
			P544 "Pico"
	P196 "Pico Neo"		
	Lenovo Mirage Solo	1	P669 "Lenovo Mirage Solo"
Q3.1 What are key ingredients for successful use of IVR?	Practitioner knowledge and ability to educate patients	5	P546 "Practitioner's knowledge of VR, not just in technical terms"
			P534 "Clinician's level of digital maturity and experience of using VR hardware and software"
			P826 "improving workers technical skills. Educating them of what the intervention is there for, and what mechanisms are at play"
			P546 "therapists' ability to communicate to patients WHY they are using VR specifically"
			P669 "practitioners' ability to show users what they are about to see in advance"
	Practitioner engagement	3	P041 "clinician's willingness to engage with VR"
			P832 "Practitioner's motivation to use"
			P196 "to let the Healthcare professionals to invest time in the"

			implementation of the VR tool. So, it becomes a daily routine”
	Quality of VE	3	P117 “Efficacy of experience - data backing it up” P544 “reality reduction” P237 “Quality of content, Structured Program approach”
	Personalisation	3	P599 “Appropriate content” P201 “applications designed/adapted for clinical experience” P546 “Patient-centred approaches to the design of VR and patients' use of it”
	Ease to use	3	P025 “usability of the game, intractability, space for interaction, learnability” P812 “transportable VR hardware” P039 “Being aware of users mobility e.g., placing VR content to far to the left, right or behind them when they might be chair/bedridden”
	Financial support	3	P940 “Financial support” P489 “Funding” P705 “Organisational buy in and support”
Q3.2 What are the top three significant barriers for using IVR in healthcare?	Lack of financial or clinical support to adopt IVR technology	6	P117 “Ways of VR being easily clinically validated and distributed” P490 “lack of clinical validation of the VR experiences” P490 “lack of clinical validation of the VR experiences” P669 “Care companies do not pay for anything like this, and care providers continue to do it in house without the expertise or support of the professionals” P546 “Equipment, maintenance and upgrade costs may be manageable, but only if VR is adopted into the healthcare workflow and billing system is adaptable to its specific demands” P548 “Formal billing/payment structure/reimbursement for digital therapeutics” P943 “FDA approval”

	Lack of IVR clinical guidelines in healthcare	2	P534 "Lack of clarity around need for medical device licensing and lack of NHS guidance in the area"
			P025 "Very little knowledge is available outdoor on what VR can do in healthcare"
Q4.2.1 What are the adverse effects?	HMD discomfort	2	P546 "HMDs simply aren't adjustable enough to accommodate for all patients" P997 "weight of HMD"
	Neck pain	1	P025 "neck pain"
	Headache	1	P025 "headache"
Q4.3 What conditions do you treat using IVR?	Anxiety /pain of medical or surgical procedure	5	P840 "Anxiety reduction: if a patient wants to experience Radiotherapy and is a bit worried about it, they can see what it is like in VR"
			P039 "Stress release/ distraction therapy"
			P041: "useful for distraction therapy, when a patient is on the chemotherapy day unit for 6 hours each day, this may be a welcome distraction"
			P490 "anxiety before painful procedures or during surgical procedures instead of an IV drug sedation"
			P546 "anxiety, anger"
	Psychological conditions	3	P369 "Phobia"
			P196 "Psychosomatic disorders"
			P546 "mental health issue such as depression"
	Motivation for movement	2	P025 "mobility and navigation for people with low vision"
			P369 "motivation to exercises"
Patient's education on medical procedure	2	P940 "Dental surgical skills training for caries treatment"	
		P705 "Education in healthcare"	

	Breathlessness	1	P369 "breathlessness"
	Dementia	1	P752 "dementia"
	Social isolation	1	P546 "social isolation"
Q4.4 With regards the conditions above, what are your IVR targets?	Enhance cognition and self-awareness	5	P832 "Improve body awareness"
			P205 "Gain insights into perception, cognition, and behaviour"
			P196 "Consciousness on how negative thoughts affect your physical appearances"
			P935 "Assess cognition"
	Reduce psychological symptoms	3	P534 "Increase understanding of mental health"
			P705 "stress management"
			P222 "reduction in psychological disorder symptoms"
	improve self- efficacy	2	P940 "Psychomotor skills"
			P025 "confidence building"
	improve social engagement	1	P826 "Improve self-efficacy"
			P025 "improving navigation and mobility"
	tele-support for patients	1	P489 "Social inclusion, reducing digital divide"
			P997 "telehealth and telemedicine"

Appendix 5-7: Participant information sheet (Online interviews Part2/Phase2)



CARDIFF UNIVERSITY/School of Healthcare Sciences

Participant Information Sheet

Online interview (Part 2)

Development of Immersive Virtual Reality for Managing Chronic Low Back Pain

I would like to invite you to take part in a research study. Before you decide to take part, you need to understand why the research is being carried out and what it would involve for you. Please take time to read the following information carefully and ask questions if you read anything that is not clear or you would like more information.

What is the purpose of the study?

This study aims to create evidence based for future development of immersive VR supporting the management of people with chronic low back pain (CLBP).

Why have I been invited to participate?

You have been invited to participate in an interview because you are eligible and respond to the online survey in the first stage. The interview is crucial to discuss some of the significant results from the online survey and explore in depth your experience with the immersive virtual reality (experiences, games and device) in chronic pain management. Your experiences and recommendations for potential application in clinical practice would inform the development of immersive VR intervention protocol for people with chronic low back pain.

Do I have to take part?

It is up to you to decide whether to take part. We will describe the steps of the study in this information sheet. If you agree to take part in the interview, we will ask you to sign a consent form. You are free to withdraw from the study at any time without giving a reason.

What will happen to me if I take part?

You will be invited to Online interview (30-45 minutes) via Zoom app. You may be asked questions from the sections of the online survey including : the experiences of the VR, the use of the VR in clinical practice, use of VR for chronic pain managements, barriers and enables towards VR in clinical practice. The interview will be audio-recorded and the researcher will also takes some notes.

What will I have to do?

We will ask you to sign a consent form and you should be aware of the following before you participates:

- The Interview will be conducted online via Zoom app.
- We will send the consent form to your email address.
- After signing the consent form , You may be asked questions from the online survey results , discuss some points in experiences of immersive VR, the use of it in clinical practice for chronic pain management, barriers and enables towards VR in clinical practice.
- The interview will be audio-recorded and the researcher will also take some notes.
- The whole interview will last for maximum 30-45 minutes

Version 1.1

Date: 22.11.2019

What is the device/procedure being tested?

We will explore in depth your response to the questions of the online survey and your experiences using games and device of immersive VR to be suitable and useful for managing chronic pain and recommendations for chronic low back pain.

What are the possible disadvantages and risks of taking part?

There is no disadvantages or risk in taking part in the online interview other than time burden for which you will be remunerated.

What are the possible benefits of taking part?

We cannot promise that this study will help you but the information we obtain from the study will help to improve development of immersive VR intervention for chronic low back pain conditions. Utilization of immersive VR in chronic back pain is limited and further information from experts will help to develop and design efficient treatment protocol.

What if there is a problem?

If you have any concerns about any part of the study, you should ask the researcher and she will do her best to answer your questions and deal with your concerns. If you are still unhappy and wish to make a formal complaint, you should contact Dr Kate Button, Director of Research Governance, School of Healthcare Sciences, Cardiff University, Cardiff.

Director of Research Governance: Dr.Kate Button
Contact number: 02920687734
Email address: buttonk@cardiff.ac.uk
Office Address:Room 13.17, 13th Floor, Eastgate House
35-43 Newport Road, Cardiff, CF24 0AB

What if relevant new information becomes available?

The researcher will use only the data which we informed you about it in this information sheet.

What will happen if I don't want to carry on with the study?

If you decide to withdraw from the study, we will destroy all your identifiable record, but we will use the data collected up to your withdrawal.

Will my taking part in this study be kept confidential?

All information which is collected about you will be kept strictly confidential. The researcher will maintain your privacy and confidentiality using a code not accessible to anyone except the researcher and the supervisor. The procedures for handling, processing, storage and destruction of data will follow the Data Protection Act 2018. All the data will be anonymous and given a code, known only to the researcher. The data will be stored in an encrypted and password protected computer known only by the researcher. This data will only be used for this study and future studies will not have access to it unless further agreement from you is requested and consent obtained. Data identifiable to you will be stored securely at Cardiff

University and accessed only by the researcher. In addition, the data will be kept for 5 years and disposed of securely according to the recommendations of the Data Protection Act 2018.

How will my data be managed?

We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Cardiff University will keep identifiable information about you for 5 years after the study has finished. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information at: <https://www.cardiff.ac.uk/public-information/policies-and-procedures/data-protection> or by contacting the University's Data Protection Officer: inforequest@cardiff.ac.uk

What will happen to the results of the research study?

The researcher may publish the study in academic journals and present the results at conferences. In addition, the main findings will be disseminated to all participants via an online link which will be sent to your email. Only anonymised results will be published, you will not be identified in any report or publication. .

Who is organising and funding the research?

This research is a PhD project funded by the Government of Saudi Arabia.

Who has reviewed the study?

The School of Healthcare Sciences ethics committee has reviewed and approved this study.

Further information and contact details

Researcher name: Anfal Adnan Astek
Email address: AstekAA@cardiff.cu.uk

Supervisors name: Dr.Valerie Sparkes , Dr.Liba Shereen
Contact number: 0920687560 , 02920687757
Email address: sparkesv@cardiff.ac.uk , sheeranl@cardiff.ac.uk
Office Address: Room 13.11.13th Floor, Eastgate House
35-43 Newport Road, Cardiff, CF24 0AB

Appendix 5-8: consent form (Online interviews Part2/Phase2)



CARDIFF UNIVERSITY/School of Healthcare Sciences

Consent Form

Online interview (Part 2)

Title of Study: Development of Immersive Virtual Reality for Managing People with Chronic Low Back Pain

Name of Researcher: Anfal Astek

Please insert your initials in below box

1. I confirm that I have read and understand the participant information sheet date 22.11.2019, version 1.1 interview) for the above study and have had the opportunity to consider the information, to ask questions and to have these answered.
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
3. If I withdraw from the study I understand that any anonymised data collected from me up to this point will be kept.
4. I understand that I have right to refuse to answer any question or discuss any topic that I don't want to talk about.
5. I understand that my personal data will be stored securely to ensure confidentiality.
6. I give my permission for the online interview (via Zoom) to be audio recorded. I also understand that audio recording will be destroyed at the end of the project and the transcript will be archived.
7. I confirm that data from the study can be used in the final report and other academic publications and may be presented at conference, I understand that these will be used anonymously.
8. I agree to be audio-recorded during the online interview (Zoom).
9. I give consent for the use of verbatim anonymised quotes in publications and conference presentations.
10. I agree to take part in the above study.



CARDIFF UNIVERSITY/School of Healthcare Sciences

Please type your name , date and electronic signature:

Name of subject.....

Email: Phone NO:.....

Signature Date

Name of Witness (Researcher)

Signature Date

When completed, 1 copy for participants, 1 for researcher.

Appendix 5-9: Example of a coded interview transcript

Seventh interview
 Duration : 1:23
 Date: 27.10.2020
 Participant ID: P7- 546

<p>Interviewer: so , in your clinical studies , w w tell me about the chronic conditions you treat using immersive vr ?</p>	
<p>Participant: so , again I'm a hands of pain doctors [interviewer overlap yah yes] uuh and so in there uhh the each work in uuh pain clinic , professionalize pain clinic, it's pretty typical for chronic pain patients to go about ten years trying to find what's going on umm untile five years ago , it's good ten years obviously and finally they will get diagnosed and go to specialize clinic , usually multidimensional but again it's not typical with my experience in health , umm so when the pain doctor say umm you want to conduct a study , here are the patients that would benefit and sometimes we focus on umm fibromyalgia [we almost never include people with visual issue with the three d and umm the equipment , umm but what I found over the years is that we typically have stopped uhh doing that becos most chronic pain patients that have umm suffer from more than five years usually have complex pain and its always a question of is really low back pain, is it really fibromalgya or usually a punch of pain symptoms that are mysterious uhhh so we have stopped kind of making those micro categories uuh for a research , basically asked patients if they want to participate or being interested and uhh then exclude people who obviously you know uuh wouldn't fit like migraines for example uuh [tah sound] sorry I lost track here .. which question am I answering?</p>	<p>chronic pain difficult to diagnose</p> <p>suitable pt allocated by doctor</p> <p>not suitable due to visual issue</p> <p>Patient preference without subcategories</p>
<p>Interviewer : you almost answered the question , so do you have specific characteristics for those who engage with you?</p>	
<p>Participant: yab , uuuh I could send you some of that uuh but basically it's any one who get car sick easily , has a history of vertigo , had history of migraine uuh typically part of the exclusion criteria umm that's sad that are very few pain doctors who kind of drive this kind of research which I find interesting umm usually the way that medical schools and clinical practice and health research work , it's not easy for uuh for clinicians to conduct research , it's kind of add thing they do unless they have kind of position firstly and then their ability to conduct clinical practice regularly is a question [interviewer overlap so why ..].</p>	<p>pt not suitable / history of sickness or migraine</p> <p>challenge / clinician difficult to conduct in clinical practice</p>
<p>Interviewer: so why do you think that the implementation that immersive virtual reality technology is kind of challenge for clinicians , why do you think is that?</p>	
<p>Participant: clinicians are adopters typically, but I think, they typically with the regulations and the concerns for patients long term health umm taking risks isn't the typical the way they think and so adapting new technology and you know new technology is don't for free , you need to learn how to use them , they are typically not well integrated into bigger systems like you know (codes) and something like that initially and so I think one it's just their practice isn't amenable to uuh being the first adopter of technology and second I don't think they have the kind of time it takes really to you know continually upgrade uhh look at the new staff and how do you integrated and all that they just don't have</p>	<p>challenge / risk and concerns to expose pt to tech</p> <p>challenge/ practitioner require knowledge and no time</p>

Appendix 5-10: Example of codes from interviewees' transcripts

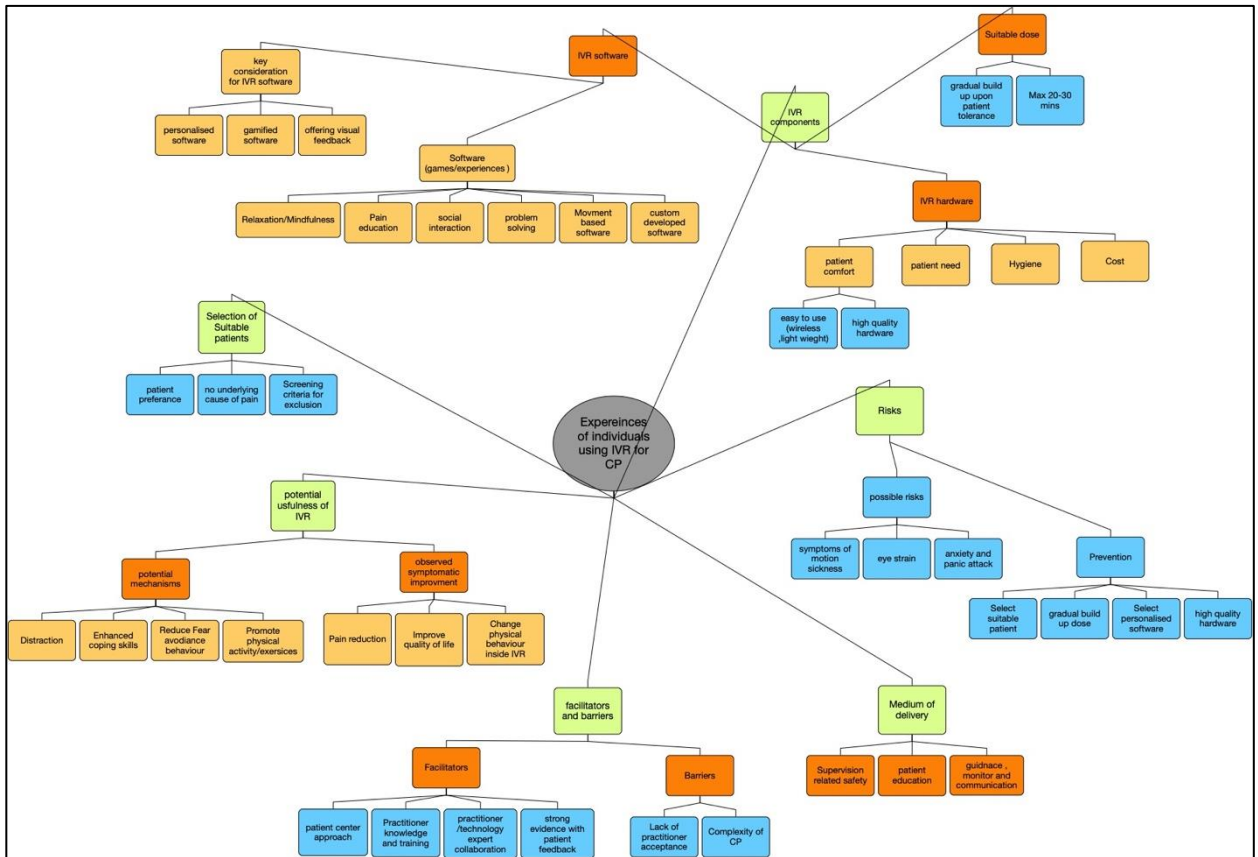
Online interviews Codes						
P1	P2	P3	P4	P5	P6	P7
P1 risk of chronic pain	P2VR / not for critical conditions	P3 base of knowledge / PT / CP associated psycho issue	P4 focus on centralize chronic pain / no underlying cause	P5 early work in acute / late in chronic pain	P6 Chronic Msc pain / shoulder or spine / vr for any chronic pain	P7 knowledge in con
P1 usefulness not sure / evidence from acute pain	P2EX why VR to manage / not resolution	P3complex CF / hard to recover / mental issue	P4 centralize CP/phantom limb	P5 mix of chronic conditions / focus on CLBP and fibromyalgia	P6 Effect depend on pt / enjoy immersion or not	P7 base of knowledge pain expert
P1Distraction / sense of presence	P2VR not therapeutic prescription	P3focus on CP of neck/vr technique (measure movement)	P4 fibromyalgia / CP with no underlying cause / no injury	P5 chronic pain / need use self regulatory coping skills instead of opioid / better life	P6 Distraction	P7 evidence from stu
P1shift attention	P2VR helping tool	P3CP has no single area	P4 technique / VR embodiment / diff sensory feedback	P5 multiple outlet / pain psychology / selffeedback / group support / lack of access (travel issue)	P6 Support delivery of difficult skills/ educate easier / deep breathing / mindfulness / ACT / enhance engagement	P7 Distraction conce
P1chronic pain complex / no standard	P2VR content / pain education journey	P3tt recover one site / motivation for other area	P4 VR tech advantages / diff perception / visual feedback of movement / diff sensory feedback	P5VR help access to self management program / accelerate learning	P6 Future pilot / full body immersion / fix abnormality in body map	P7 Distraction is the not enough for ch
P1neurological distraction	P2VR content / visual journey to understand condition	P3focus on pt need	P4 CF / strong focus on pain / VR disconnect / diff sensory feedback of movement	P5 VR support physio rehab / gamified rehab to be more engaging / increase efficacy and adherence	P6 No Full body immersion / need complex equipment / not suitable for hospital/	P7 base of work / col no-pharmacologica
P1Description how focus shifted with chronic pain	P2Current tt chronic pain / opioid / systematic ham	P3 16 VR content / to match pt interest	P4 manipulation mechanism / transfer visual feedback of movement from normal to painful side	P5 one site doesn't fit all / pt response different to VR	P6 Focus on educational mechanism not full body immersion	P7 VR approach valid stress reduction + bio
P1Distraction strategy	P2VR distraction / divert attention away from pain	P3 immersive not immersive / unlike pt interest	P4 manipulation mechanism / see movement (avatar) more or less than actual movement	P5 pt preference or clinical condition (discomfort / neck pain, no vision) affect VR use	P6 VR Cognitive intervention / support delivery of psychotherapy in home	P7 challenge / health due to lack of guide f
P1relaxation / cognitive content	P2Alternative to medication	P3 screening of pt need / get out of comfort zone to learn coping	P4 EX manipulation / pain within 60 ROM / actual movement 50 / visual feedback 70 (showing normal movement in VR without known actual ROM)	P5 pt acceptance / tolerance differ	P6 Support delivery / pt don't have access / b/w appoint	P7 chronic pain diffi
P1individualized effect	P2N sure / long term	P3 VR help comfort pain / see capability / realize thoughts had back recovery	P4 observed change / manipulation facilitate ROM without realizing / visual feedback of good movement / quality effect not supported with data	P5 translate proven skills / technique / to be more engaging	P6 VR content from pain psychology / CBT	P7 suitable pt allocat
P1Effective for some and some not (individualized)	P2Effect of Distraction / hope / alternative to medication	P3 power of VR / external focus / shift focus to VR/help moving more than they thought	P4 explanation of diff between back pain and phantom pain / sensory input from body part exist or not	P5 development work with pt / to ensure comfort, engagement and eff	P6 VR content / pain education/mindfulness / deep breathing with feedback	P7 migraine not suita
P1VR content / individual preference	P2Effective 7 Match selection (content or hardware) to patient age, condition / pt objective	P3VR use to change pt thoughts about pain	P4 CLBP vs phantom pain/no area of signals	P5 translate existing approach / make it interesting	P6 Encourage transfer skill in VR to real life	P7 mix of chronic pai
P1VR content relax environment / not preferred / negative effect	P2Effect / Hope and Alternative to undesirable medical treatment	P3 movement is best tt but people avoid due anxiety	P4 VR integrated with functional rehabilitation / increase movement + ADL	P5 VR content / different content inside one app	P6 Daily session / five min	P7 pt not suitable / h
P1VR content / problem solving / puzzle	P2Effect of Distraction / hope / alternative to medication	P3 VR help change thought that "movement is bad" / movement is helping	P4 pain education content / understand condition / low and why relaxation can help	P5 pain education content / understand condition / low and why relaxation can help	P6 Adverse effect / due to lack of screening	P7 challenge / clinic difficult to conduct in clinical practice
P1Headset/HTC vive	P2Adverse effect reason / lack of provider experience, inappropriate content	P3 attention and pain / shift focus out of pain / reduce pain	P4 graded motor imagery / start with imagination of movement	P5 VR content / breathing + biofeedback (learn to lower breath rate) / relaxation content	P6 Adverse effect / nausea / eye issue / motion sickness	

Appendix 5-11: Examples from the codebook of the online interviews

Code Source	Smaller Codes	Excerpts
larger Code	<ul style="list-style-type: none"> P1 Consider pt comfort, pt not / patient need time to accept it not all pt accept it P4 some pt reluctant to tech / not work P5 some pt don't like it / pt response differ P6 pt preference or clinical condition (discomfort / neck pain, no vision) affect VR use P7 acceptance affected by preference and psychological factor P8 clinical factors for efficacy not known / may be tech preference or comfort 	<p>I was just saying that end of the day why are we using this with the patients, for make their experience better. We don't wanna make them uncomfortable, if by any chance they thought that a lot better for chronic pain and just refused uhm to engage in that, so he gave the minimal effort with few sessions and then give up.</p> <p>I think that's one thing uhm another one would be uhm reluctant for technology someone might see that something like virtual reality as intimidating or they don't have any expert other things from use of vr uhm some patients don't like it or they would prefer to use a different modality treatment outside for some patients either due to preference or some you know preexisting conditions, you know lack of sight or sound or facial discomfort or a cervical pain that doesn't allow the effectiveness and acceptance of the treatment isn't really disease focused meaning that someone with rheumatoid arthritis versus lupus versus fibromyalgia or migraines or if we don't really have any hypothesis or clinic predictive factors of why someone would like or not like this uhm may be there's something around technological preferences or co</p>
individualized pt response	<ul style="list-style-type: none"> P1 individualized effect P2 Effective for some and some not (individualized) P3 Single not applied to all / individualized P4 important / pt response differently to VR environment P5 pt response / some positive and some negative P6 Pt response / individualized effect / negative effect P7 pt response differ / some not engaged P8 Pt diff response / some sensitive and get sick / can't tolerate P9 5% can't tolerate / pt response negatively / can't engage due to sickness / VR don't work with them 	<p>we have mix results some people it works for and some people it doesn't and that would seem to reflect the nature of chronic pain which is highly individualized.</p> <p>So for some people work and some people it doesn't and we still haven't come to conclusion yet with trials whether VR works more effectively for chronic pain patients, uhm I do reads that it not so simple as buying one product and applying it to everyone.</p> <p>also very important when using virtual reality that the same thing which you have some interpretation from people, so you can build an environment which you think oh it how people perceive immersiveness, uhm uhm, its overall positive, I've some patients so ha everything is positive dadaa negative side, some patients have senso uhm senso uhm I think that interestingly the develop that I work with that has chronic pain, actually have migraines uhm from using virtual reality uhm which is quite upsetting because you don't see some patients are not engaged or follow the program as expected and some people which is a small amount uhm you know have some headaches or motion sickness or other things there's different population, and this's where we get (travel holes) of probably there's people that hypersensitive to their motion and to their level where there are in reality very few percent of the other but five percent that weren't going to get better, they're not gonna fix, they're gonna have probably very intense uhm not intense but you know in the</p>
screening of suitability of motion sickness not suitable	<ul style="list-style-type: none"> P1 pt susceptible to sickness P2 screening / risk / sickness / headache / infection P3 screening of risk (due to motion sickness / photo sensitive) P4 screening for risk/vertigo / motion sickness P5 pt not suitable / history of sickness or migraine P6 pt not suitable / vertigo/history/panic/migraine/severe anxiety P7 check for seizures and motion sickness / no other exclusion 	<p>people who susceptible to motion sickness, other sickness is a big issue with these headsets as we known in VR uhm obviously [more] environments are better with that, but we would select and we would also ask them a detailed history which is something like uhm have you been sick lately, have you had any infection in the past two months, three months we outside history of vertigo uhm or susceptibility to motion sickness uhm also if there's been a stroke any type of photostasis or photophobia, so if they have sensitivity to light we're gonna minimize the chance someone is going to have negative reaction and so we typically screen people out for things like people port to vertigo, motion sickness, but basically its any one who get or sick easily, has a history of vertigo, had history of migraine uhm typically part of the exclusion criteria</p> <p>I mentioned history of uh vertigo, migraines, uhm, also of panic disorders like panic attack uhm kind of extreme anxiety, now I'm designing a component for that kind of [test] I think the only two factors that we concern about is the history of seizures and uhm sensitivity to motion sickness uhm but beyond be able to follow the instructions uhm and if</p>
screening of epileptic pt not suitable	<ul style="list-style-type: none"> P1 risk / seizures P2 Risk / epilepsy / critical condition P3 not suitable / epilepsy or visual issue (benzeneoination) P4 screening of epilepsy / can't use it P5 Screening to exclude seizures / facial issue / visual or hearing impairment P6 check for seizures and motion sickness / no other exclusion P7 risk control / epilepsy & seizures 	<p>people who have sort of lightly [word] of seizures or epilepsy or things like that, or stuff like that another area we totally exclude. No that is not we say people can't use the head set if they have some condition like for example epilepsy patients are absolutely contraindicated because we don't wanna anything to trigger their seizures and the seizure can happen people suffer from that, I don't use it and with sensorimotor problems that tend to use it but if give more more uhm around so that's doesn't helping [interviewer overlap] I've to ask before you start if people have epileptic consults if they're [equated] with it, and then don't use it.</p> <p>other few things anyone who has like active seizures, history of significant seizures that required medication, uhm and you know some type of issues when you can't put the head set I think the only two factors that we concern about is the history of seizures and uhm sensitivity to motion sickness uhm but beyond be able to follow the instructions uhm and if and of course with seizures you have to be careful obviously, for the epilepsy we wouldn't recommend that you use it uhm and those sort of medical contraindications.</p>
Visual related issue or infection	<ul style="list-style-type: none"> P1 Risk / infection-visual disorder / facial/head lesions P2 not suitable / cervical facial injuries / blind P3 pt visual issue / can't tolerate / heavy on eye and pressure on head / develop sickness (stop VR) P4 pt with risk (motion sickness, visual sensitive) not work P5 risk / infected eye or skin P6 migraine not suitable due to visual issue 	<p>so if they having any unexplained, undiagnosed neurological symptoms or other history we eliminate that, if they have any such facial or head lesions for example if they have their less restrictions around you know conditions although as I mentioned before, yah wanna prevent patients with cervical injuries, facial injuries uhm blind some people have a lot of problem with uhm if they look at tele or they have to read [interviewer overlap uha aha] and its very trying for their eyes uhm and they're to put the sustainable light exposure either photostasis or photophobia where they have high response to visual stimuli that come to their eye and virtual reality just can't work of them because we've got lots of different of uh we got eye conditions or anything visible skin condition as you know we mostly ask not to use the headsets</p> <p>... almost never include people with migraines because of the visual issue with the three and uhm the equipment, uhm but what I found over the years is that we typically ho</p>

larger Code	Code Source	Similar Codes	Extracts
VR content engagement / match pt preference / interest	F1	VR content/ individual preference	some people like meditative sort of relaxation (immersion focused) approaches so we go into VR environment that for example they don't have freedom as where to go in three dimensions whether in this beautiful three de environment ha, so they prefer you're making them meet with probably other patients and making them meet artists or with singers or with patients inside virt let's say for example some patients doesn't like underwater experience, so we'll not take it for them, so lets say i give you four games that engaging umm or fun are games be much more adhered to or the patients need to be much more willing to engage patients are highly engaged and satisfied with it, so um regardless if whether something has sub efficacy if patients don't like the engagement is always going to be (reflection) they're never uah there's always be finding reflection of does this person really we i think its gonna be more listening to what's important to them and what's meaningful to them so i think traditionally we just we what's, interesting is that also with immersive VR, uah i use a tool which has sidest different VR environments that's better more engaged say we're taking physical activity the more engaging that is to the patient the more they like the game the better
	F2	VR content/ game fun & engaging / pt preference / exploring freely	
	F3	VR content/ match pt interest	
	F4	VR content / pt have options / pt prefer	
	F5	VR content/ game fun & engaging / pt engagement	
	F6	pt engagement / sign of VR work or effect / assess it	
	F7	important to match content to interest/ enjoyable	
	F8	VR content / no match pt interest	
virtual content match functional ability	F9	good VR content / sit within pt ability	so you need to reach a target and the target can be set on a range on what people can do, how long they can prolong to hold ud so its start out very simple where its just following a track that they move up and down um in multiple planes of movement that i just thinking how to make this experience as accessible umm to people so that umm they can do its setting or lying down as well co design is really important as well becos in the original version them uses (need) to stand up and then one of the patients we it totally depend on the individual, so some of them are set down and some of them stand up and moving around, we got a lot
	F10	VR content / functional planes of movement (within pt comfort)	
	F11	make it suitable to sit in lying or being / when grover	
match to culture and daily scenario	F12	VR content / consider pt need (standing or setting)	what i've experienced is that people were at the beach which can be in Australia or in Netherlands or in France and it was very i can't even VR uah (uh sound) a park of milk he even if i'm taking a pack of milk ha from one bin uah i already feel it on m i even have a virtual environment that a steam punk ship and uah uah i don't know if you're familiar with steam punk but its kind this's the funny thing about it, is unlike a medication we're introducing issue of culture, right becos what patients see, they go i think that in (name of hospital in one of US cities) with children with autism i clinical condition, so it does already applicable
	F13	VR content / choose environment unlock memory of relax scene	
	F14	ED / VR content scenario from daily life	
Diversity to match patient specific needs	F15	VR content / diversity	so the way we figure out the content is based on what does the patient need to do, if its physiotherapy um for example for lum use just immersive VR doesn't matter what you give people, it's just works uah you need reassurance that uah (Interviewer overlap we have protocols and umm so being in early stage start up company like we are it was a necessity to focus on the product, so id So every body is individual and these environments can reflect a very diverse things, so looking at, you know, i don't think we eve i think um um what we found overall and we've tried a lot of different environments that ha the course of our work is this um, its important to highlight that with chronic pain or any chronic disease, it's never gonna be any singular piece of content, it if we've developed an eight weeks chronic pain management program that consist of daily models that can patients complete one thing around how to make these things accessible to people who hard of hearing, umm may be blind or partially blind umm yah there's something that people, so if like eyesight if someone got um difficulties with eyesight or hasn't got great vision, some
	F16	VR content / diversity	
	F17	VR content / diversity	
	F18	VR content / diversity	
	F19	VR content / diversity	
	F20	VR content / diversity	
Pt comfort and need to use the HMD	F21	Headset / pt comfort / need to wear glasses	the other important thing is they can wear their glasses underneath. We've tried various formats with lens in headsets but people i have to know about the technology inside out and this is the thing or the reasons ah ah why whatever device or new device you are not delivering a hardware to the user, you're not delivering a game to them, you're delivering to them a comprehensive there's like no two chronic pain patients are the same umm but so what is good for one may not be good for another uah so to get its very good right now ha you can at least track the hand without a controller, so in some patients with chronic pain for ex for the technology side an issue with allodia for example is if a patient has complex regional pain syndrome, right uah you ha so i take approach called inclusive design and that's not, its not like general approach that would fit everything, not one size fit one of he developed something called articulated arm, we don't uah the goes on right to the patient's eye and you don't have to so the technology side do have compact things to do and a lot of it is adapting what's available to people needs and trying to i think we (can do that) as well umm but again things like controllers is really important you know if you may have arthritis or so
	F22	Headset selection/ pt need / headset comfort	
	F23	Focus not on headset / focus on pt need	
	F24	pt need diff/headset selection adjusted to pt need	
	F25	Headset selection / match pt need / quest offer hand track without hold controllers	
	F26	EX pt needs should be consider / CRP inability to use controller / sensitive skull (headset big issue)	
	F27	"inclusive design" / no HMD fit all/ consider pt needs	
	F28	design specific headset articulated arm (no direct contact with head) / pt need	
	F29	select available headset / no match pt need	

Appendix 5-12: Initial diagram of themes and subthemes (Online interviews)



Appendix 6-1: Flyer for online focus group recruitment



Are you a physiotherapist with a minimum of 2 years clinical experience treating LOW BACK PAIN?

You are invited to participate in an online video focus group to discuss professionals' opinions and views towards

Immersive Virtual Reality Intervention for People with Chronic Low Back Pain

Previous knowledge/experience of using virtual reality is **not needed**

What will my participation involve?

You will be invited to take part in online video focus group taking approximately 45 to 60 minutes.

If you are interested, please follow the link below to learn more about the project in the Participant Information Sheet and sign the consent form

<https://cardiff.onlinesurveys.ac.uk/immersive-virtual-reality-for-chroniclowbackpain>

Appendix 6-2: e-participant information sheet (Online focus group)

Development of Immersive Virtual Reality for Chronic Low Back Pain / Part 3: Focus Group

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Introduction

I would like to invite you to take part in online focus group, which forms the third stage of a research study conducted by PhD candidate Anfal Astek in School of Healthcare Sciences, Cardiff University, United Kingdom. The project aims to develop immersive virtual reality (VR) intervention for people with chronic low back pain.

In the first and second stage of this research study, we conducted online survey and interviews with experts who use immersive virtual reality for chronic pain management.

The online focus group is relevant for clinically active physiotherapists with experience of treating patients with low back pain. You are invited to participate in a focus group even if you have no experience of virtual reality. Students or physiotherapists with no clinical experiences of treating low back pain are not eligible for participation.

The School of Healthcare Sciences Research Ethics Committee has reviewed and approved this study. The information sheet and consent form follow this introduction. If you have any questions prior to participation you can contact me by email: AstekAA@cardiff.ac.uk

The online focus group aims to explore your views and opinions to inform the development of immersive VR as treatment for people with chronic low back pain. The online focus group will be for approximately 60 minutes.

Participant Information Sheet

I would like to thank you for your interest in joining the focus group as a third stage in this research study. Before you decide to take part, you need to understand why the focus group is being carried out and what it would involve for you. Please take time to read the following information. You will have an opportunity to ask questions if you read anything that is not clear, or you would like further information.

What is the purpose of the study?

This study aims to create a model for future development of immersive virtual reality (VR) to support the management of people with chronic low back pain (CLBP).

Why have I been invited to participate?

You have been invited to participate in the focus group because you are a physiotherapist with experience in management of chronic low back pain patients. The focus group will discuss and gather opinions on using immersive VR. We are particularly interested in your thoughts about the content of the intervention and the equipment used to deliver the intervention i.e headset. We are also interested in if you have any recommendations for the potential application of intervention protocol delivered by VR.

Do I have to take part?

It is up to you to decide whether to take part. We will describe the steps of the study in this information sheet. If you agree to take part in the focus group, we will ask you to sign a consent form. You are free to withdraw from the study at any time without giving a reason.

What will happen to me if I take part?

You will be invited to attend one online focus group which will be for a maximum 60 minutes, using zoom application. The focus group will include between 4-6 people and will be conducted by the researcher (Anfal Astek).

At the start of the online focus group the researcher will present PowerPoint slides about Immersive VR devices and experts suggestion from stage 2 of this reasarch. Then researcher will ask about your opinion and recommendations for potential application of this intervention for people with chronic low back pain. The focus group will be audio-recorded and a researcher assistant will also takes some notes.

What will I have to do?

We will ask you to sign an e-consent form and you should be aware of the following before you participate:

- At the end of this information sheet, you have three options: 1) 'I have read the information sheet and want to participate', 2) 'I have read the information sheet but need to ask questions before I agree to participate' and 3) 'I do not wish to participate'.
- If you choose option 1, you will proceed to the e-consent form.
- After signing the e-consent form, you will be contacted and asked a number of questions including, age, years of experience since qualification, years of experience with chronic low back pain .
- You will receive an invitation to attend an online focus group via email with date ,time and security password.
- It will involve between 4-6 people who will be healthcare professionals and will be conducted by the researcher (Anfal Astek)
- The researcher will present PowerPoint slides about Immersive VR intervention.
- After the presentation, you may asked like to gather the groups opinions and recommendations about :
 - the content of immersive VR intervention.
 - The device/equipment used to deliver this intervention for chronic low back pain.
 - The potential application of a virtual reality intervention protocol including methods and outcomes of intervention for people with chronic low back pain.
- The focus group will be audio-recorded and the research assistant will also take some notes.
- The whole meeting will last up to 60 minutes.

What is the device/procedure being tested?

We will explore in depth your opinions about immersive VR that may be suitable and useful for managing patients with chronic low back pain.

What are the possible disadvantages and risks of taking part?

There are no disadvantages or risk in taking part in the focus group other than time burden. All information will be stored confidentially and anonymously.

What are the possible benefits of taking part?

We cannot promise that this study will help you to improve your treatment services for people with chronic low back pain but the information we obtain from the study will help to improve development of immersive VR intervention for these people.

The current utilisation of immersive VR in chronic low back pain is very limited and further information from professionals will help develop and design efficient treatment protocol.

What if there is a problem?

If you have any concerns about any part of the study, you should ask the researcher and she will do her best to answer your questions and deal with your concerns. If you are still unhappy and wish to make a formal complaint, you should contact Dr Kate Button, Director of Research Governance, School of Healthcare Sciences, Cardiff University, Cardiff.

Director of Research Governance: Dr.Kate Button

Contact number: 02920687734

Email address: buttonk@cardiff.ac.uk

Office Address: Room 13.17, 13th Floor, Eastgate House

35-43 Newport Road, Cardiff, CF24 0AB

What if relevant new information becomes available?

The researcher will use only the data which we informed you about it in this information sheet.

What will happen if I don't want to carry on with the study?

If you decide to withdraw from the study, we will destroy all your identifiable record, but we will use the data collected up to your withdrawal.

Will my taking part in this study be kept confidential?

All information which is collected about you will be kept strictly confidential. The researcher will maintain your privacy and confidentiality using a code not accessible to anyone except the researcher and the supervisor. The procedures for handling, processing, storage and destruction of data will follow the Data Protection Act 2018. All the data will be anonymous and given a code, known only to the researcher. The data will be stored in an encrypted and password protected computer known only by the researcher. This data will only be used for this study and future studies will not have access to it unless further agreement from you is requested and consent obtained. Data identifiable to you will be stored securely at Cardiff University and accessed only by the researcher. In addition, the data will be kept for 5 years and disposed of securely according to the recommendations of the Data Protection Act 2018.

How will my data be managed?

We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Cardiff University will keep identifiable information about you for 5 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information at: <https://www.cardiff.ac.uk/public-information/policies-and-procedures/data-protection> or by contacting the University's Data Protection Officer: inforequest@cardiff.ac.uk.

What will happen to the results of the research study?

The researcher will publish the data in her PhD thesis and may publish the study in academic journals and present the results at conferences. In addition, the main findings will be disseminated to all participants via an online link which will be sent to your email. Only anonymised results will be published, you will not be identified in any report or publication. .

Who is organising and funding the research?

This research is a PhD project funded by the Government of Saudi Arabia.

Who has reviewed the study?

The School of Healthcare Sciences ethics committee has reviewed and approved this study.

Further information and contact details

Researcher name: Anfal Adnan Astek

Email address: AstekAA@cardiff.ac.uk

Supervisors name: Dr.Valerie Sparkes , Dr.Liba Shereen

Contact number: 0920687560 , 02920687757

Email address: sparkesv@cardiff.ac.uk , sheeranl@cardiff.ac.uk

Office Address: Room 13.11.13th Floor, Eastgate House

35-43 Newport Road, Cardiff, CF24 0AB

Once you have read this information sheet carefully, Please click one of the following options: *
Required

- I read the information sheet and want to participate (you will be redirected to consent form)
- I read the information sheet but need to ask questions before participation
- I don't want to participate

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Appendix 6-3: e-consent form (Online focus groups)

Development of Immersive Virtual Reality for Chronic Low Back Pain / Part 3: Focus Group

50% complete

Consent Form

Title of the study: Development of Immersive Virtual Reality for People with Chronic Low Back Pain / Part 3: Focus Groups

Name of Researcher: Anfal Astek

To participate in this study , you need to confirm your agreement with statements below:

I confirm that I have read and understand the participant information sheet date for the above study and have had the opportunity to consider the information, to ask questions and to have these answered. * *Required*

Yes

I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason. * *Required*

Yes

If I withdraw from the study I understand that any anonymised data collected from me up to this point will be kept. * *Required*

Yes

I understand that I have right to refuse to answer any question or discuss any topic that I don't want to talk about. * *Required*

Yes

I understand that my personal data will be stored securely to ensure confidentiality. * *Required*

Yes

I give my permission for the online focus group discussion to be audio recorded. I also understand that audio recording will be destroyed at the end of the project and the transcript will be archived. * *Required*

Yes

I confirm that data from the study can be used in the final PhD thesis and other academic publications and may be presented at conferences, I understand that this data will be used anonymously * Required

Yes

I give consent for the use of verbatim anonymised quotes in publications and conference presentations. * Required

Yes

I agree to take part in the above study. * Required

Yes

Contact Details

Participant Name: * Required

Email Address: * Required

Please enter a valid email address.

Phone Number: Optional

Please enter a valid phone number.

Signature (Type your name): * Required

Date: * Required

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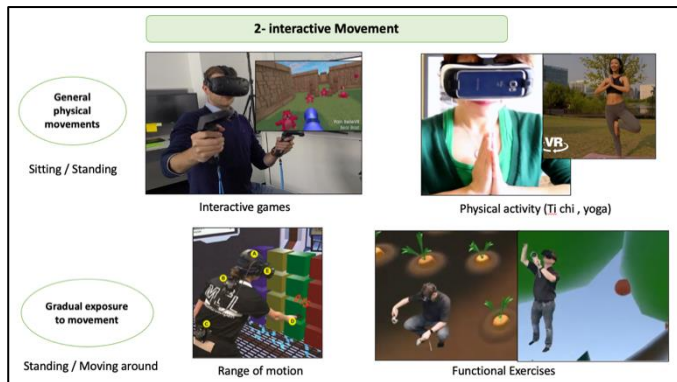
Appendix 6-4: PowerPoint presentation (Online focus groups)



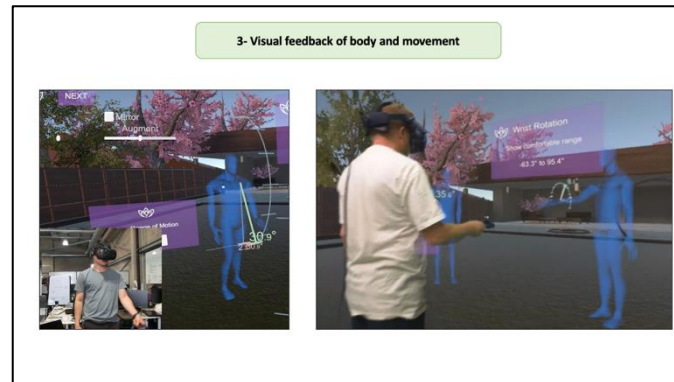
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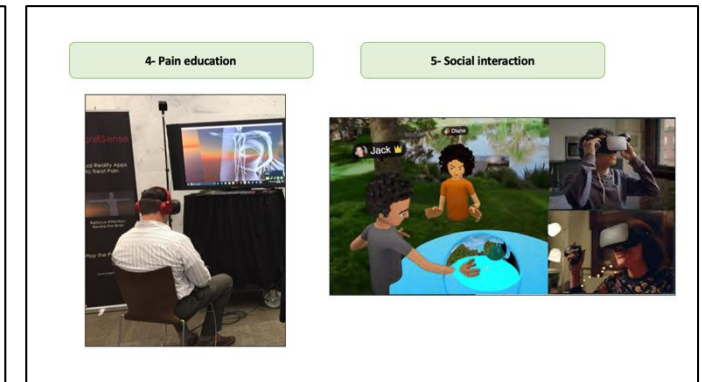
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Appendix 6-5: Example of a coded focus group transcript

Transcript Focus Group 3 (4 participants) Date: 1 July 2021 Time: 1:00	
<p>Interviewer: Anyone, what other disadvantages do you think?</p> <p>PT12: I think uuh fear avoidance, it would, especially with graded exposure approach I think it will be really helpful because you got that distraction and umm may be would help we educate movement away from a fear, sort of inhibited approach to their movement, yah umm it might encourage people just engage with that environment and maybe you can progress them uuh out of the VR to the real movement ... you know the real-life stuff then, so I can see how it would benefit you know for the fear avoidance perspective.</p> <p>PT10: uuh bending or picking up or kind of like pick up boxes or you know lumber flexion. they can practice variations of movement patterns, uuh I guess I do like the overlayer [referred to picture in the presentation, mearing of angles] angles uuh that's give some feedback to uuh to themselves of uuh. if I move more from my hips, or my back or with uuh that [sweet core] I like this. but I do this activity which is set away from angles uuh I don't know, so you can get some feedback after uuh 'look you've moved ten percentage more than you've done in the past'.</p> <p>Interviewer: yah okay anyone would you like to comment on that please?</p> <p>PT11: yah uuh I think, you've pinpointed most of the actual points within what are you saying and the useful thing that we would get from it, and I think I agree with each one. I would like to recall uuh what Yasmin said about how you need to be careful uuh that need to be monitored each one of those like with social interaction uuh it could have the opposite effect as well you actually uuh replace real uuh social interaction with that same thing with each different things uuh it could be distraction but it could be also uuh distraction isn't always a good thing uuh distraction sometimes can be avoidance strategy and uuh actually you just need actually to monitor each one carefully uuh .</p> <p>Interviewer: what kind of monitor would you mean?</p> <p>PT11: uuh will that's it , it will need to be individualised to each person because it's more about uuh if you distract because distraction is good as a pain strategy but it also uuh means by what people is trying to distract anyway and you don't want to enhance someone distractive behaviour sometimes when it's getting away from how you actually improve because the distraction is a form fear avoidance technique isn't really?, so you can develop your good strategies of avoidance which sometimes means that you uuh dissociating more , do you know what I mean , the psychology of dissociation can be a big issue and uuh sometimes you need actually get people to an acceptance theory uuum so you actually experience and allow experience of it to allow you to correctly behave towards what's going on view , each one of these is complex umm but I think well used um it could be very helpful in each different area you're saying.</p> <p>PT12: uuh one thing I want to say was ... I suppose umm uh a possibility that someone could [clean] into this potentially and be reluctant to the amount of VR</p>	<p>PT12 potential with fear avoidance / graded exposure / engage with movement because distraction</p> <p>PT12 potential to transfer movement from r to reality</p> <p>PT10 potential of practice functional movement (flex)/ visual feedback add advantage</p> <p>PT10 potential of feedback / showing pt. change and progress</p> <p>PT11 potential of usefulness / caution monitor / addiction and replace reality</p> <p>PT11 caution monitor / distraction is avoidance</p> <p>PT11 personalisation</p> <p>PT11 concern distraction increase avoidance behaviour / dissociation</p> <p>PT11 IVR issue of dissociation/ contradict acceptance theory for good behaviour (need to consider)</p> <p>PT12 concern of addiction / develop thoughts of inability to transfer to real life / need of "weaning"</p>

Appendix 6-6: Example of codes from focus groups' transcripts

Online focus group codes				
FG1	FG2	FG3	FG4	
PT4 lack of knowledge in Tech	PT7 effect depend on regularity / to make change in neuroplasticity	PT9 proposed technique / saw benefit / not sure about usefulness	PT14 previous ex / IVR for Ms condition/ use it as motivation to do ex / increase engagement / engagement key factor	
PT4 may have potential with fear avoidance / introduce to physical scary tasks	PT7 more regular more effect/ cost issue affect regularity / interested but obstacles	PT9 ex with pt using IVR/ playing game / help movement / benefits to do at home/(dis?)	PT14 previous ex/ under supervision of physiotherapist	
PT2 goal of use questioned / education, psychological or physical rehabilitation (need more knowledge)	PT6 interested in proposed technique/ IVR novel delivery of known concept	PT9 dis play at home/ isolated / no communication with real world	PT14 previous ex / customise gaming use ROM ex	
PT1 videos are too general	PT6 need knowledge if good evidence/frequency	PT9 dis versus adv / addition and refuse real world / adv learn to re-move	PT14 previous ex/ protocol (3-4 wk/15-30 min)/ potential effect in pain	
PT1 feeling IVR add feeling of anxiety / not like to use wit LBP / require confidence to use	PT6 how to convince effect/ cost issue	PT12 potential with fear avoidance / graded exposure / engage with movement because distraction	PT13 IVR is preparatory phase? / potential for proposed technq from theory and clinical ex/ safe and control environment	
PT1 lack of accepting to use it /videos not show how IVR deal with psychological and physical aspect of LBP (need more knowledge)	PT8 proposed technique interested	PT12 potential to transfer movement from r to reality	PT13 concern about how to transfer skill to real world	
PT1 too general / need for IVR to help in movement rehab of LBP	PT8 see potential in fear movement technique	PT10 potential of practice functional movement (flex)/ visual feedback add advantage	PT13 good /but transition is issue in Rehab / doing well in safe but unable in stressful real world	
PT3 previous ex for gaming/ lack of knowledge in MS	PT8 potential to overcome fear / active engage in ex/ adjunct to help initiate regular ttt/	PT10 potential of feedback / showing pt change and progress	PT13 potential of usefulness/learn safe transition to real world	
PT5 believe VR discussed in neuro research not practice	PT8 pre identified group with fear	PT11 potential of usefulness / caution monitor / addiction and replace reality	PT13 transition by reduce virtual aspect gradually to less virtual /(graded exposure)	
PT1 questions the rationale of use / potential to accept novel IVR if understand rational (need of more knowledge)	PT8 initiate ttt plan /motivate pt / few sessions	PT11 caution monitor / distraction is avoidance st	PT13 reinforcement cues inside VR to transfer to reality/ stimuli	
PT2 expecting how to work/ for psycho like mirror or for rehabilitation	PT7 concern about efficiency compared to current practice (same response?)	PT11 personalisation	PT16 interested but no previous ex	
PT4 questioned rationale (psychological or physical) (need more knowledge)	PT7 questioned cost issue if reponses similar to current cheap practice	PT11 concern distraction increase avoidance behaviour / dissociation	PT16 population tried everything / increase engagement / try something diff and new	
PT4 IVR spend time and cost / it has potential / need more knowledge about outcome to accept / private practice	PT7 concern of cost / to convince clinical adoption	PT11 IVR issue of dissociation/ contradict acceptance theory for good behaviour (need to consider)	PT16 concern how personalised / associated issue	
PT4 proposed technique has potential	PT7 concern about frequent use in clinic / once a week not sufficient for fear/ need in home	PT12 concern of addiction / develop thoughts of inability to transfer to real life / need of "weaning"	PT16 personalised/associated conditions (anxiety/PTSD)	
PT4 techniques applicable for general pain/ not specific to LBP/ don't apply to my pt	PT7 concern of feasible cost / NHS or private	PT12 feeling safe in IVR / separate from reality / negative	PT16 how it works? Need therapist interaction?	
PT4 need more knowledge / concern how it can work	PT6 concern of risks due to novelty	PT11 potential to start with during ttt/ "step / bridge to reality"/ ex manual therapy / useful unless addicted	PT16 pain education/ virtual but with therapist	
concern how it can be personalized to individual pt	PT6 need evidence to know better than current practice	PT11 monitor implementation and withdrawal	PT16 need therapist connection to see suitable task /personalisation	
PT1 proposed technique has potential / both psycho-physical approach	PT8 issue /need of experience in tech / no enough knowledge	PT12 potential of mindfulness tech/ anxiety and fear / more mental issue	PT15 potential of social interaction / group ex	
PT1 not apply to my pt / useful for complex CP	PT8 safety issue / with elderly / need pt selection / consider balance	PT12 Mindfulness not under speciality/ need of psychologist	PT13 engagement is a key/personalised to engage/	
PT1 not prefer tech to apply technique / costly / issue	PT8 Safety concern depend on technique / technique affect balance or medical condition	PT10 potential to be "bridge platform"to restore move-function/ need withdrawal point to real task	PT13 "pick and mix"/ personalisation / diverse choices to pt/ history of associated factors (PTSD)	
PT1 need of personalization	PT6 interest in virtual avatar technique	PT12 adjunct to ttt plan	PT16 Concern of practice movement above functional ability ?/ concern of safety	
PT1 issue / lack of technical knowledee / no support or	PT6 interest to trv virtual avatar personally /	PT12 not adjunct and withdraw only/ potential to enjoy		

Appendix 6-7: Examples from the codebook of the focus groups

Larger codes	Participant / Code	Extract
Concerns of subpopulation with medical conditions / disorientation and lack of balance	PT2 disorientation / LBP doing functional move / risk of fall / safety issue	well people may get disorientated with the headset, so therefore if you got someone with chronic
	PT5 disorientation / risk of fall / older adult	I think with older adults it may be difficult whether as [E5] said that imbalance and kind of disorient
	PT7 concern about risk of nausea/vertigo / balance issue/elderly	, at the same time I feel like certain people like to feel quite nauseous using this kind of virtual reality
	PT10 concern of how to behave in / if not balance enough	you're moving but not moving, uah is this extensive, you know, if you don't balance enough and ma
	PT8 Safety concern affect balance or medical condition	it largely depend on what kind of game, what kind of virtual reality technique are you going to use,
	PT11 safety of doing physical movement question/ pt usually had fear of hitting /headset blind them	I have got a question um so when you got because I've not done a virtual reality before headset it
	PT11 concern of safety for pt with bad mobility and balance issue	how do you ensure uauu and if you got someone with poor mobility as well, uah faces to hit up
	PT16 previous ex in gaming / feeling of imbalance and sickness	I've used it uah I've never used it with patient... I've used it on a Playstation for the kids and there's
	PT3 previous ex / risk of worsen epilepsy / sickness / not all get benefits	my experience I have noticed from my colleagues who dealing with neuro cases, the one they got
	PT6 concern of risks due to novelty	it's particularly new but when you considering bringing like a very novel treatment you want be ven
Transferability of virtual skills to real life /suggestions for improvement	PT1 concern about transfer generic skill (mindfulness) from VR to daily routine of individual pt	if you doing something which's generic, let's say mindfulness for the individual that's okay that's c
	PT9 dis play at home/ isolated / no communication with real world	while she's moving the disadvantage might be that she's not really in an actual community with an
	PT9 dislike idea of virtual socialisation/ need withdrawal point to socialise in real life (face to face)	I'm not quite sure, for me I wouldn't think that will be the best way uuh probably best to get peop
	PT11 concern about how to transfer it to real world	then how to make that real afterward as well.
	PT30 feeling safe in VR / separate from reality / negative	like a safe zone you mean is very safe in this environment and is detached from reality isn't it then
	PT13 concern about how to transfer skill to real world	my only slight concern I guess around the vr is how you move from a virtual back into real world.
	PT13 good /bad transition is issue in Rehab / doing well in safe but unable in stressful real world	I can understand that people experiencing something in virtual world is gonna be really good for the
Concerns of addiction /suggesting monitoring	PT13 transition by reduce virtual aspect gradually to less virtual /graded exposure	so most of the time in term of these transitions, we see this idea of graded exposure, so is there
	PT13 reinforcement cues inside VR to transfer to real/ stimuli	some of the casing and things that using in the virtual world, can somehow transmit across to the
	PT13 need point of transition when accomplished in VR	I guess that's a little bit of where I was going to uum with the transition bit, is what point just sa
	PT16 concern about transition to reality	it's about uuh the transition back um into the real world uuh but it may be like a nice kind of scapo
	PT4 concern about addiction / refusal to engage out in real	I don't know whether that will be the same with this or whether uuh uuh I guess the worry may be
	PT9 concern of addiction / in home / unable to interact with reality	I could see may be an overall concern perhaps been in the future, uah perhaps some practitioner w
	PT9 dis versus adv / addiction and refuse real world / adv learn to re-move	the only disadvantage I can see because you can get so hooked into that, may be you won't actually
Concern of gurdng /anxiety behaviour	PT10 concern about behaviour with VR / addiction versus doing good with ex	the addictive component uuh yah I don't know uah that will be same to the chronic pain uuh maybe
	PT13 interest in being independence and have control/ concern of dependent on VR (safety issue)	safety early as well, in term of people being in this foreign environment, I think it's really interest
	PT11 potential of usefulness / caution monitor / addition and replace reality	the useful thing that we would get from it, and I think I agree with each one, I would like to recall
	PT12 concern of addiction / develop thoughts of inability to transfer to real life / need of "weaning"	a possibility that someone could [lean] into this potentially and be reluctant to the amount of VR i
	PT12 need withdrawal point/addiction? (not transfer to real life/ issue not known	it definitely has to be uuh I think we have to be careful at some point that you're gonna have to lea
	PT11 monitor implementation and withdrawal	it's like any of our tool, it's like manual therapy uuh it can be useful as long as you don't hook peop
	PT1 feeling IVR add feeling of anxiety / not like to use wit LBP / require confidence to use	the requirements for the interaction with the device in virtual reality world wouldn't be necessarily

Larger Codes	Participant / Code	Extract
Practitioner training /technical support	PT4 need of technical assistance	technical assistance
	PT2 training / tech assist other than therapist (facilitator)	if you want someone to take this you would need I think very s
	PT2 technical assistance / set up device /save clinic time	just from the point of view of clinical mean time, I think if you
	PT4 assign specialist other than therapist /save time for set up device	if was used in quite specific group rehab or individual rehab set
	PT5 (facilitator) need tech support / therapist ex	I think from education point of view, in related to setting as sh
	PT3 technology improving / future potential to use / facilitator workshop	I have been following up with this for almost five years and wh
	PT7 need training / feeling IVR / to educate pt	we need to be trained as physio, because I suppose it's new th
	PT6 knowledge help to educate pt / practitioner want to try feeling of IVR	I don't know what virtual reality feels like, so I would... want t
	PT15 Facilitators / practitioner training	maybe training, yah some training
	PT14 / facilitator / practitioner knowledge /need education	virtual webinars and seminars for you know uuh education of t
Evidence support / cost effectiveness	PT4 need more evidence to know is it physio or physical change	I guess I can't quite see from a physio point of view, that woul
	PT5 facilitator / more evidence	I think the evidence and other results that obtain while studyin
	PT3 facilitator / more evidence	I think the combination of evidence and results being implem
	PT6 need evidence to know better than current practice	and that's better to what you already doing, so I would really l
	PT6 need financial support / strong evidence	it's much easier to make the case to uuhm... to the people wh
	PT7 facilitator / need strong evidence	we need more robust evidence, I know that uuh this kind of ev
	PT10 validation, benefits and relevance make it work	if it's been validated and it's been checked, and at certain poi
Cost /Time worth adoption	PT10 facilitator / evidence for improvement / benefits worth cost and money	it would have to be [buying] from mangers and uuh those sort
	PT12 facilitator / need evidence/ using in research centre to see potential	I have been following up with this for almost five years and wh
	PT13 facilitators / evidence to show benefits compared to current practice	I think uuh being able to demonstrate outcomes it's really imp
	PT16 more evidence / need to know if benefits or success worth cost	know that this not probably available yet but research that sh
	PT1 not prefer tech to apply technique / costly / issue	for people that I see with chronic low back pain is relatively str
	PT2 / issue of cost (NHS) / issue of time for settings software for individual pt	it's that fact that I'm particularly thinking in the NHS obviously
	PT2 barrier if benefits worth cost and time over traditional tech in current practice	I think you can see where it would fit with some aspects but
	PT4 need to know benefits worth cost-time	so would I buy one of those to use in my setting and when I pay
	PT6 cost issue / loan or buy / expensive	I think the only new thing really is just cost of the equipment, y
	PT6 effective ttt need more that 1 h/ expensive	you're not gonna get, you're not gonna give someone meanin

Appendix 6-8: Initial diagram of themes and subthemes (Online focus groups)

