MASTER THESIS

Virtual Reality training for patients with non-specific persistent low back pain and pain-related fear of movement: A single-subject experimental study

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Preface

As a physical therapist, I am particularly fascinated by the complexity of the nervous system and the role of the brain in persistent pain. This led me to enrol in a master's program at the University in Bergen, where I have had the pleasure of diving into contemporary pain- and neuroscience theories. For the past two years, I have been so lucky to collaborate with two of the most outstanding researchers I know of, namely, Dr. Tasha Stanton, senior research fellow at University of South Australia, Adelaide, Australia, and Dr. Kjartan Vibe Fersum, manual therapist and assistant professor at the University of Bergen, Norway. I am truly grateful for their guidance, professional support, patience, enthusiasm and friendship, and very humbled that they have taken the time to be my supervisors throughout this process.

I would also like to thank the the physiotherapy-department at the University in Bergen and key persons at Western College of Applied Sciences in Bergen. In particular, Bård Erik Bogen; thanks for great input along the way, and for putting me in contact with the people who made this project possible. Lars Peder Vatshelle Bovim; thanks for incredibly valuable discussions and for access to SimArena for the past year. Harald Soleim and Atle Geitung; thanks for exquisite domain knowledge in software development. Professor Jan Sture Skouen and the Outpatient Spine Clinic at Haukeland University Hospital; thank you for the open-mindedness towards this innovative master's project and help with patient recruitment. I would also like to thank my dear friend Thomas Fiskeseth Larsen, master student in Software Development at Western College of Applied Sciences and University of Bergen, for interest in this novel idea from the get-go, and great work in the software engineering domain. I am very humbled and grateful for the opportunity to collaborate with such great people; I could not have done this without any of you. Last, but not least, I would like to thank friends and family for their support and encouragement through the past two years.

Maja Sigerseth

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Abstract

Introduction: Non-specific persistent low back pain is one of the most prevalent musculoskeletal conditions in modern society. A growing body of evidence shows graded exposure therapy is the most preferable treatment to target pain-related fear of movement. However, graded exposure therapy has some limitations, e.g. low patient preference and high drop-out rates. Therefore, the emerging nature of Virtual Reality (VR) provides an interesting medium to investigate whether pain and pain-related fear can be targeted through graded exposure using immersive virtual environments.

Method: In a sequential replicated and randomized single-subject experimental design with multiple measurements, 10 patients with non-specific persistent low back pain had a 35-day intervention with 6 to 9 VR training sessions. Primary outcome measures (measured daily) were pain intensity, pain-related fear of movement, pain catastrophization and pain anxiety symptoms, while secondary outcome measures (measured pre- and post-intervention) were related to disability and activities of daily life.

Results: VR training resulted in a statistically significant reduction of pain intensity, pain-related fear of movement, pain catastrophizing, and pain anxiety. Clinically relevant improvements were observed for disability.

Conclusion/Future implications: There is a need to reduce the costs and suffering caused by persistent low back pain. VR may provide opportunities to exercise in specifically tailored virtual environments, with the goal of achieving meaningful and valued life-activities in an engaging fashion. However, the technology is only in its infancy, and thus, opportunities and challenges with implementation must be further investigated. Finally, given the nature of the present study design, the results cannot be generalized to a larger population, and therefore, further research involving rigorous trial designs (randomised controlled trial) is also warranted.

Key words: Virtual Reality – Virtual Rehabilitation – Physical therapy – Non-specific persistent low back pain – Pain intensity – Pain-related fear – Single-subject experimental design

Sammendrag

Introduksjon: Langvarige korsryggsmerter er blant de mest prevalente muskel- og skjelettplagene i det moderne samfunnet. Stadig mer forskning viser at smerte-relatert frykt for bevegelse kan opprettholde funksjonstap hos mange ryggpasienter, og at gradvis eksponeringsterapi er blant de mest effektive behandlingsmetodene. Men gradvis eksponeringsterapi har begrensninger som bl.a. lav pasient-preferanse og høy drop-out rate. På bakgrunn av den nylige teknologiske utviklingen av Virtual Reality (VR), åpnes det utforskning av effekten av gradvis eksponeringstrening for ryggpasienter i ulike virtuelle miljø.

Metode: I et sekvensielt replisert, randomisert singel-subjekt eksperimentelt design med gjentatte målinger, gjennomgikk 10 ryggpasienter en 35-dagers intervensjon som bestod av et minimum av 6 VR-treninger og maksimum av 9 VR-treninger. Primære utfallsmål bestod av smerteintensitet, smerte-relatert frykt, katastrofetanker og angst for smerte, mens sekundære utfallsmål målte endringer i funksjonsnivå og aktiviteter i dagliglivet.

Resultater: Studien viste at VR-trening hadde en statistisk signifikant effekt på smerteintensitet, smerte-relatert frykt, katastrofetanker og angst for smerte. Klinisk relevante endringer ble observert for endringer i funksjonsnivå.

Konklusjon/Fremtidige implikasjoner: Det er et stort behov for å redusere kostnader og lidelse forbundet med ryggsmerter. Tilpasset trening i ulike virtuelle miljø i VR bør undersøkes nærmere ettersom det fremstår som et motiverende og kostnadseffektivt hjelpemiddel for bruk i fysioterapipraksis. Men teknologien er fortsatt i utviklingsstadiet, og det trengs fortsatt oversikt over muligheter og utfordringer ved implementering. Forskerne i denne studien anerkjenner at resultatene av studien ikke kan generaliseres til en større populasjon grunnet studiedesign, og at det er behov for studier randomiserte kontrollerte studier på dette feltet.

Nøkkelord: Virtuell Realitet – Virtuell rehabilitering – Fysioterapi – Uspesifikke korsryggsmerter – Smerte intensitet – Frykt for bevegelse – Singel-subjekt design

Abbreviation list

MS = Maja Sigerseth

TFL = Thomas Fiskeseth Larsen

KVF = Kjartan Vibe Fersum

TS = Tasha Stanton

JSS = Jan Sture Skouen

ADL = Activities of Daily Life

LBP = Low Back Pain

VE = Virtual Environment

VR = Virtual Reality

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1.0. Theoretical Background

1.1. The Global Burden of Low Back Pain

Low back pain (LBP) is a very common diagnosis, and the leading cause of disability world-wide (Buchbinder et al, 2018). Globally, the number of years lived with disability caused by LBP increased by 54% between 1990 and 2015 (Buchbinder et al, 2018). The lifetime prevalence is reported to be as high as 84% (Airaksinen et al, 2006), and although most episodes of LBP improve substantially within six weeks, 67% of people with LBP still report pain at three months. Further, approximately 33% of people are reported to have a recurrent episode of LBP within one year (da Silva et al, 2017). Three to 10% of people with LBP go on to develop persistent LBP (Koes et al, 2010), and a study from 2015 estimated that at any given time, 540 million people are suffering from LBP (Buchbinder et al, 2015).

LBP is also the leading persistent health problem that forces people out of the workplace and forces older workers to retire prematurely – more than heart disease, diabetes, hypertension, neoplasm, respiratory disease, and asthma combined (Schofield et al, 2008). People with physically demanding jobs, physical and mental co-morbidities, smokers and obese individuals are at greatest risk of reporting LBP (Hartvigsen et al, 2018). For the individual, LBP can have profound economic consequences as they accumulate less wealth than those without the problem, and the negative effect on wealth increases with the presence of comorbidities (Schofield et al, 2012; 2015). In 2003, almost 43.000 Norwegian citizens received disability benefits due to LBP, and every year, approximately 4000-5000 Norwegian citizens start receiving disability pension because of LBP (Rikstrygdeverket, 2004). LBP is estimated to cost Norway 13-15 Billion Norwegian Kroners (NOK) every year, and most costs are related to sick leave, disability fees, loss of production and utilization of health care services (Brage & Lærum, 1999). Studies from Hashemi et al. (1998) and Williams et al. (1998) suggest that replacement wages accounts for 80-90% of the total costs related to LBP, and consistently, only a small percentage of LBP cases account for these costs.

Most LBP is characterized as non-specific, meaning that for most people (an estimated 90%) the pain cannot be attributed to a specific cause (Koes et al, 2006). Deyo & Weinstein (2001) estimated that of patients with LBP in primary care, in only 10% could LBP be attributed to a specific cause. In their study, of those patients with a specific cause for their LBP, approximately 4% had a compression fracture, 3% had spinal stenosis, 2% had visceral disease,

0,7% a tumour or metastasis, and 0,01% an infection. A vast majority of LBP patients have traditionally been screened with x-ray or Magnetic Resonance Imaging (MRI), as the "gold standard" to discover disc- or spinal pathology. While imaging can play an important role in revealing "red flags" in a small number of LBP patients, recent evidence suggests that both symptomatic and asymptomatic adults have a high prevalence of common degenerative features in the imaging reports (Brinjikji et al, 2014), limiting the diagnostic value of these findings. Pressingly, the communication of perceived abnormal spinal imaging findings (i.e. bulging discs or disc degeneration) has been suggested to increase patients' fear of re-injury and reduce the likelihood of a good outcome (Roland & Van Tulder, 1998). Moreover, adverse effects of early imaging of the lumbar spine have also been reported, including worse disability and increased medical and surgical costs, unrelated to LBP severity (Graves et al, 2012; Webster & Cifuentes, 2010). In the recently published Lancet series viewpoint by Buchbinder et al. (2018), one of the key messages is to promote "positive health", i.e. "the ability to adapt and to self-manage, and address widespread misconceptions in the population an among health professionals about the causes, prognosis, and effectiveness of different treatments" (Buchbinder et al, 2018, p. 2384). As persistent LBP continues to burden our society, it is crucial that stakeholders, researchers and clinicians understand the multidimensional aspects of non-specific LBP, and that looking to the future, we focus on health-promoting factors such as lifestyle, behaviours, thoughts and beliefs related to LBP, rather than continuing to look for a solely peripheral cause for a multidimensional health problem.

1.2.Multidimensional framework for non-specific Low Back Pain

The lack of diagnostic value in screening for biomedical causes of non-specific LBP has led to a conceptual shift in underlying theories of LBP and in its treatment. Contemporary scientific theories propose that non-specific LBP can be considered a neuro-biological and behavioural response to an individual's actual and/or perceived threat to their body, lifestyle, social circumstances and/or disruption to their homeostasis (Marchand et al, 2005; Moseley & Butler, 2015; Wand et al, 2011). As described by O'Sullivan et al. (2012; 2016; 2018a), our biological system constantly interacts and is influenced by physical, psychological, social, and lifestyle factors as well as by other comorbidities and non-modifiable factors (i.e. genetics, gender, life stage). Recent findings have therefore shifted both researcher's and clinician's awareness and

understanding of LBP towards modifiable and non-modifiable factors in non-specific persistent LBP (Figure 1).

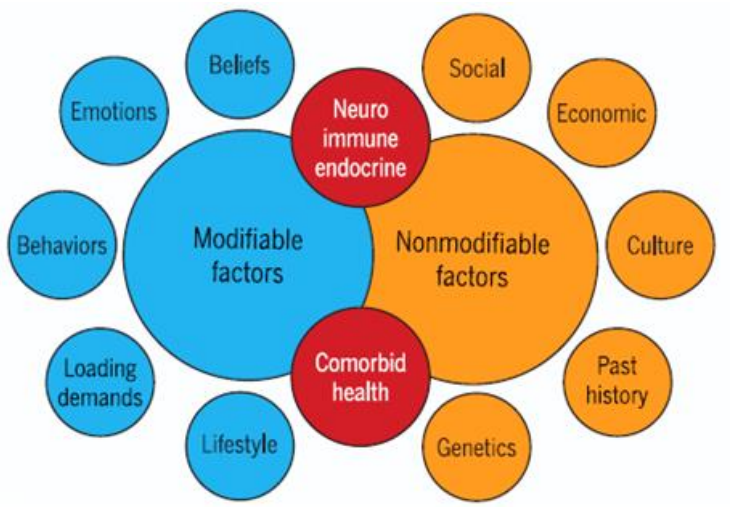


Figure 1: Modifiable and non-modifiable factors in an individual's LBP experience (O'Sullivan et al, 2018a)

As depicted in Figure 1, both co-morbid health factors and neuro-immune-endocrine factors, and an array of modifiable and non-modifiable factors contribute to a person's LBP experience. Therefore, non-specific LBP must be considered as a multidimensional disorder (O'Sullivan, 2016, 2018a), without any "quick fixes" or "magic bullets". Due to the complexity and heterogeneity of the condition, the challenge of getting the patient, the treatment, and the timing "right", is a formidable one.

1.3.Current consensus on Low Back Pain treatment

There is almost an endless list of treatment options currently available to patients with LBP, but according to Foster (2011), "no conservative treatment has large, significant and consistent benefits for patients with NSCLBP". Recommendations from a recent systematic review in the Lancet state that "a bio-psycho-social framework to guide management with initial non-pharmacological treatment, including education that supports self-management and resumption of normal activities and exercise, and psychological programmes for those with persistent symptoms" is needed (Foster et al, 2018, p. 2368). Systematic reviews of passive therapeutic interventions (so-called "hands-on" treatments) such as muscle energy techniques (Franke et

al, 2015), chiropractic treatment (Walker et al, 2010), spinal manipulation (Assendelft et al, 2013), massage (Furlan et al, 2015), ultrasound (Ebadi et al, 2014) and traction (Wegner et al, 2013) show small or non-significant clinical effects. Other systematic reviews investigating active treatments (so-called "hands-off" treatments) such as Pilates (Yamato et al, 2015), behavioural therapy (Henschke et al, 2010), back schools (Poquet et al, 2016), motor control exercises (Saragiotto et al, 2016), stabilization exercises (Smith et al, 2014), patient education (Louw et al 2011; 2013; Moseley & Butler, 2003; 2017) and multidisciplinary rehabilitation (Kamper et al, 2015) show that active therapies have an overall better treatment effect than passive therapies. However, active therapies are also largely consistent in terms of clinical effect (i.e. one active treatment is not better than another).

The overall, current consensus is that multidimensional rehabilitation with the use of behavioural therapy and supervised exercise should be first-line treatment (Chou et al, 2007; Daffada et al, 2015; Kamper et al, 2015; Koes et al, 2010; Savigny et al, 2009; Turk, 1996). The recent development of Cognitive Functional Therapy (CFT) may be an example of this suggested approach (O'Sullivan et al, 2015; Fersum et al, 2013). CFT is defined as an integrated, flexible behavioural approach for people with disabling, non-specific LBP, based on a multidimensional "clinical reasoning framework" to identify and treat key modifiable factors from the clinical history and assessment (O'Sullivan et al, 2018). Additionally, behavioural-educational approaches like Explain Pain (Moseley & Butler, 2003; 2017) and Therapeutic Neuroscience Education (Louw et al, 2013) have gained considerable attention amongst health-care professionals over the past 10-15 years, due to their usefulness in patient education and behavioural change. The unifying aspect of Explain Pain and Therapeutic Neuroscience Education is to provide a functional pain literacy and help make sense of a patients' subjective pain experience, based on explanations of the key (neuro)-biological (and neurophysiological) concepts that underpin pain (Louw et al, 2013; Moseley & Butler, 2015).

Furthermore, a new line of research from experimental clinical neuroscience has investigated the role of the brain in persistent pain, and suggests that re-organisation in different areas and networks in the brain may contribute to persistent pain (Flor et al, 1997; Moseley & Flor, 2012). Experimental studies have shown that there is evidence for perceptual dysfunctions in people with LBP, i.e. alterations in perceived shape of the back (Moseley, 2008a); reduced tactile acuity at the back (Catley et al, 2014, Moseley, 2008b; Wand et al, 2010; 2011a); impaired motor imagery of the back (Bray & Moseley, 2011); and impaired trunk voluntary motor control

(Luomajoki & Moseley, 2011). Further, studies have shown that therapies targeting these perceptual dysfunctions improve symptoms in LBP (Kählin, 2016; Wand et al, 2011b; 2015; Louw et al, 2015; Daffada et al, 2015). Further, recent work by Stanton et al. (2017) suggests that perceptual dysfunction in people with LBP may also extend to feelings of stiffness in the back, which is one of the most common complaints for LBP patients alongside pain. Further research in this field may help provide researchers and clinicians to develop increased knowledge about pain perception, which can be then translated to the clinic for patients struggling with LBP. However, robust scientific trials (i.e. randomised controlled trials) are needed.

The current challenges facing modern physiotherapists appear to be having the skills to: 1) to navigate in the "landscape" of modifiable factors in LBP, 2) to become "strategists" that can educate and provide short- and long-term health promoting strategies for the patient, and 3) promote self-efficacy and resilience (focus on salutogenesis – focus on health – versus pathogenesis) to improve clinical outcomes. To achieve these goals, new technology may provide us with helpful tools to facilitate learning and behavioural change (see further discussion of these topics in Subsection 1.4., 1.5. and 1.6).

1.4. The Fear-Avoidance Model

One leading cognitive-behavioural theory underpinning why certain individuals develop persistent pain and disability following acute back injury, derives from the "Fear-Avoidance (FA) Model of Musculoskeletal Pain" (Figure 2) (Vlaeyen, 2000; Vlaeyen & Linton, 2012).

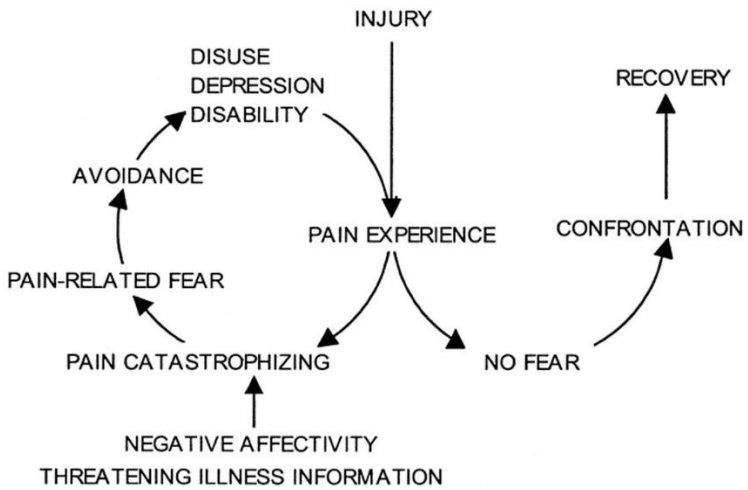


Figure 2: FA model (Vlaeyen, 2000)

In brief, the FA model postulates that fear of re-injury and catastrophization play an important role in shaping maladaptive behaviours, such as avoidance and disuse, which may then predispose to chronicity. Kori et al. (1990) defined "kinesiophobia" as an excessive, irrational and debilitating fear of movement and activity stemming from a feeling of being more fragile or vulnerable to experiencing a painful injury or re-injury. A variety of conceptual definitions have been suggested through the years, e.g., "kinesiophobia", "fear-avoidance beliefs", "fear of movement", while "pain-related fear of movement" seem to be the most currently valid definition. In a critical review, Lundberg et al. (2011) argued that the different definitions of pain-related fear of movement are merely constructs (i.e., rather than a disorder or pathological state itself), which is important for researchers and clinicians to be aware of as it creates challenges with construct validity and when attempting to create reliable assessment tools related to the construct. Therefore, pain- and behavioural researchers are currently attempting to unravel the intertwined relationship between the development of pain-related fear of movement and development of persistent pain.

A challenge in LBP is that pain is often unpredictable, making it difficult limit avoidance behaviour to only one activity. Further, the experience of unpredictable pain fluctuations can trigger anticipatory pain-related fear of movement (Meulders & Bennett, 2018), and it has been shown that associative learning processes and neuroplasticity plays an important role for the acquisition of pain-related fear of movement (Meulders, Vansteenwegen & Vlaeyen, 2011). Moreover, a patient may implicitly generalise the threat value of one movement to another, negating the need to learn a new association between that new movement and fear (Meulders et al, 2017). For example, pain while lifting a heavy box may result in fear of lifting a box (and avoidance of this activity), however, over time this may lead to generalization of fear and thus avoidance of all lumbar spine flexion movements regardless of the situation (e.g., bending forward in a chair). A recent study found that people with LBP showed implicit associations between perceived danger and images of a "rounded" or "neutral" lumbar spine position in lifting (Caneiro et al, 2017). The notion of implicit association in persistent pain may warrant further investigation, because there is some evidence that assimilation of perceptual danger-relevant cues (that we are unaware of) can influence movement and behaviour (Moseley & Vlaeyen, 2015). Pressingly, persistently avoiding valued activities of daily life (ADL) negatively affects physical performance, mood and sense of self (Meulder & Bennett, 2018), and is therefore an important aspect to target (if present). One promising approach is to address

pain-related fear of movement with graded exposure therapy, which will be further discussed in the next subsection.

1.5. Graded exposure for pain-related fear of movement in Virtual Reality

Evidence suggests that graded exposure, a type of cognitive-behavioural therapy, is among the most effective means of reducing pain-related fear of movement, catastrophizing, and disability (Grotle et al, 2004a; Martinez et al, 2011; Turner et al, 2002; Vlaeyen et al, 1995). Research has shown that excessive fear responses may be signs of a dysregulated anxiety (Parsons & Trost, 2014), and that changes in the emotional circuitry of the brain may contribute to stress-related psychopathology (Parsons & Trost, 2014). Graded exposure therapy provides patients an opportunity to discover and correct misinterpretations about cues as warning signals for an impeding catastrophe (Grotle et al, 2004a; Heuts et al, 2004; Meulders et al, 2016; Somers et al, 2009; Sullivan et al, 2009; Turner et al, 2002). As a result of correcting erroneous interpretations, patients will learn which movements or stimuli are safe, which in turn, reduces fear (Hermans et al, 2006). Despite considerable promise, existing graded exposure protocols are characterized by Woods and Asmundson (2008) as having a number of limitations. First, as delivered in the clinical setting, graded exposure protocols are expensive and time consuming, relying on trained therapists over an indefinite number of sessions (Vlaeyen et al, 2012). Another challenge acknowledged by graded exposure developers is that of patient engagement; while empirically most effective, graded exposure does not appear to be a preferred manner of treatment by patients and is characterized by a high drop-out rate (ranging from 38-50%) and low patient preference rates (Vlaeyen et al, 2012, Woods & Amundson, 2008). Patient non-adherence is likely due to the anxiety-provoking nature of an intervention designed to challenge fearful pain beliefs (Hadjistavropoulos et al, 2004). Third, graded exposure is challenged by the generalizability of treatment gains from the treatment clinic to the home environment, as well across discrete physical activities (Crombez et al, 2002; Goubert et al, 2002; 2005; Trost et al, 2005). Finally, fear-avoidance models have been criticized for not taking into account a motivational perspective in which goal context factors may affect behavioural performance as well (Crombez et al, 2012, Vlaeyen et al, 2009). Together, these limitations provide a compelling motivation to enhance graded exposure interventions so that treatment appear more attractive to patients, and thereby establishing reliable therapeutic change; and to explore the

utility of new technology using principles of graded exposure aiming for development of a cost-effective physiotherapeutic tool.

Parsons & Trost (2014) argued that the emergence of Virtual Reality (VR) may be beneficial to optimize graded exposure therapy for people with persistent LBP. Thus, in the present thesis, a protocol for a VR-intervention was developed with the intention of investigating whether graded exposure towards lumbar spine movements in a rewarding and non-threatening virtual environment could benefit persistent LBP patients.

1.6.Virtual Reality training

Virtual Reality (VR) was originally a science fiction idea, which began to emerge in concrete form via an immersive film-viewing cabinet created in the 1950s (World Economic Forum, 2014). For a long time, VR was solely recognized for its entertainment value but over the past 10 years its application has been expanded to a variety of clinical areas, including pain management, physical rehabilitation and the treatment of psychiatric disorders (e.g. phobias, post-traumatic stress disorder and anxiety disorders) (Gershon et al, 2000; Zimand et al 2002). VR is now defined as "an approach to user-computer interface that involves real-time stimulation of an environment, scenario or activity that allows for user interaction via multiple sensory channels" (Adamovich et al, 2009). New VR approaches capitalise on recent technological advances including improved robotic design, the development of haptic interfaces and the advent of human-machine interactions in virtual reality (Burdea, 2003; Merians et al, 2006), and offers the possibility for delivering patient-specific interactions within the virtual environment via head-mounted displays (Figure 3) or with screen-technology (Rose et al, 2005) such as Microsoft or Xbox Kinect (Figure 4 and 5).

Figure 3: Immersive Virtual Reality equipment with a head-mounted gear and two handheld controllers (Image downloaded from: https://bgr.com/2016/03/20/macbook-laptops-virtual-reality/, 24.09.18)

Figure 4 and 5: Non-immersive Virtual Training using a screen- and video-based technology developed by Welfare Denmark. Figre 4 and 5 illustrate a training session for an elderly patient in bydel Nordstrand, Oslo, Norway. Reference: Fysioterapeuten, Issue 8, 2017.

One advantage of implementing VR technology in rehabilitation is the rapid development of different virtual environments and games, which allow for interactive behaviour for patients while being monitored and recorded (Bohil et al, 2011). As a relatively new technology, immersive VR is still quite expensive. A head-mounted gear (e.g., Oculus Rift) costs approximately 500 US Dollars and needs a 1000 US Dollar computer to run the VR-software, which currently is quite expensive for rehabilitative purposes. Nevertheless, VR hardware and

software show is on the rise, with an estimated global VR industry revenue of 74.82 Billion US Dollars by 2021 (Figure 6).

Figure 6: Virtual Reality Industry Report, 2017: https://www.greenlightinsights.com/industry-analysis/2017-virtual-reality-industry-report-spring/

With continued development and economic interest from large technological companies, costs related to VR equipment are expected to drop as the technology matures and hits the mainstream marked (Li et al, 2011). "Serious gaming" is now a multi-billion-dollar industry (Ma et al, 2014), and while technological barriers and a lack of content have prevented mass adoption of VR, commercial forces claim that VR and Augmented Reality (AR) are forefront technological platforms that eventually will replace smart-phones and tablets. Furthermore, a recent statement by the Facebook-VR leader (i.e. one of the leading companies in development of Oculus Rift) is that approximately 10 million users are needed using the VR-platform before the technological ecosystem can flourish (https://www.cnbc.com/2018/09/26/facebook-vr-leader-talks-about-the-future-of-virtual-reality.html). Moreover, leading experts in technology refer to the "12 Gutenberg Moments" (i.e. rapidly developing fields such as AI and big data, or robotics and automation, drones and transportation, VR and AR), which is estimated to have a disrupting effect in their respective fields (Silvija Seres, Bergen Næringsråd Årskonferanse, 2017). The "fourth industrial revolution", which is currently emerging, is presumed to challenge many

aspects of our societal structure through the advancements of cyber-physical systems (Colombo et al, 2017). While certainly of interest, this goes beyond the scope of this thesis. However, given the technological landscape, the development and use of technologies such as VR and AR specific to rehabilitation may be tools for exploiting resources in the health care system in a more sustainable way and may set the scene for a new era in physical therapy rehabilitation.

1.7. From acute to persistent pain management with Virtual Reality

While VR gaming has shown meaningful clinical effect in the treatment of acute pain, few studies have applied VR to persistent pain management. In terms of acute pain management, VR-based interventions have been primarily used to distract patients from pain (Hoffman et al, 2000; 2008; Wiederhold et al, 2014). While distraction is a powerful tool in the case of both acute and persistent pain, interventions that rely exclusively on distraction are insufficient to address the needs of many individuals with persistent pain, for whom pain is an ongoing (rather than temporary) experience (Eccleston & Crombez, 2007). VR-interventions for persistent pain are therefore challenged to not just distract individuals but to also incorporate activities consistent with real-life patient goals related to tasks in activities of daily living (ADL). For example, for persistent LBP patients, the hesitation towards certain movements such as lumbar spinal flexion may lead to development of maladaptive and avoidant movement patterns when getting dressed and picking up objects from the floor (Thomas et al, 2008). By introducing graded exposure training towards various movements in VR, individuals may be encouraged to practice progressively more avoided activities with the aim of breaking the association between the movement itself and the perceived pain and/or physical harm. With specifically tailored virtual environments, interventions may be matched specifically to patients' interests, goals and valued life activities.

1.8. Research on Virtual Reality and persistent Low Back Pain

Research using VR in rehabilitation is only in its infancy, although publication rates in this area are increasing (See Figure 7). Regardless, to date, only one systematic review related to the use of VR in medical settings has been published. Dascal et al. (2017) reviewed 11 randomised, controlled trials for pain distraction (Carrougher et al, 2009; Hoffman et al, 2008; Kipping et al, 2012; Morris et al, 2010; Patterson et al, 2010; Schmitt et al, 2011), eating disorders/obesity

(Cesa et al, 2013, Manzoni et al, 2009), and cognitive and motor rehabilitation (Larson et al, 2011). The authors suggested that VR is a promising intervention with several potential applications in the inpatient medical setting (Dascal et al, 2017).

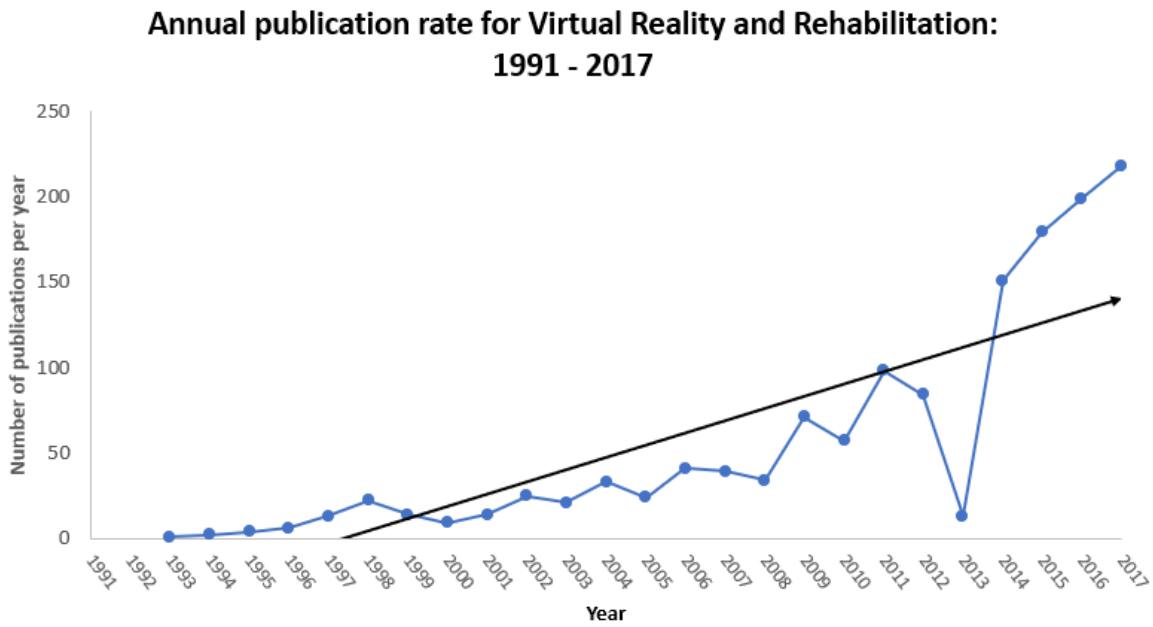


Figure 7: Annual publication rate for Virtual Reality and Rehabilitation: 1991-2017.

Systematic searches for "low back pain" + "virtual reality" were completed in Pubmed, Google Scholar, EMBASE, Medscape, Cochrane, and Clinical Trial Gov., from August 2016 to October 2018. The term "virtual reality" included both immersive (head-mounted gear) and non-immersive (screen) technology, although we were most interested in the use of immersive head-mounted VR equipment. Results of the searches found that there have been no systematic reviews or meta-analysis published for the use of VR in persistent LBP to date, and only a handful of clinical trials were found across all available search engines.

More specifically related to the present thesis, only one randomised clinical study (n=52) by Thomas et al. (2016) has investigated the feasibility of a VR-dodgeball game for kinesiophobic non-specific persistent LBP patients. Thomas et al. found that although VR-dodgeball (3 sessions of 15 minutes each) did not elicit significant group differences in lumbar flexion at post-game testing, the results indicate that individuals with persistent LBP and high fear levels can be encouraged to increase lumbar spine flexion within gameplay sessions. They concluded that the proof-of-concepts study demonstrate that virtual dodgeball is safe, feasible, and capable

of shaping changes in lumbar spine flexion during gameplay (Thomas et al, 2016). In addition, a published phase 2 randomised controlled trial protocol by France & Thomas (2018), aims to evaluate Virtual Immersive Gaming to Optimize Recovery (VIGOR) intervention in people with persistent LBP. However, at the time of this thesis preparation, the research is ongoing.

Results for non-immersive VR-studies such as screen technology (Kinect, Wii Fit, etc) are also interesting to consider, and in total, six articles have been published in the time period 2011 – 2016. In 2016, Zadro et al., published a protocol paper for a video-based exercise for older people (n=60) with persistent LBP, a feasibility randomised controlled trial (GAMEBACK trial). However, results are not yet available. Su et al. (2015), tested a VR-based LBP rehabilitation system utilizing wireless sensor technology in 20 participants, in a system design and user-acceptance analysis. Roosink et al. (2015), assessed the perception of trunk movements in military personnel (n=30) with persistent non-specific LBP using a virtual mirror in 30 participants. Kim et al. (2014), investigated the effects of VR-based Wii Fit Yoga-game on physical function in 30 middle-aged female LBP patients. Additionally, two trials were found on the Clinical Trial Gov website and appear ongoing (no results published): "Virtual Reality and pain perception during exercises for patients with persistent non-specific LBP" (Matheve et al, 2016), and "Analgesic effect of a prototype device of VR in a population of patients with persistent LBP (REVLOC)" (Poiraudeau et al, 2011).

In summary, the systematic search reveals that research in the field of VR rehabilitation in persistent LBP is scarce. Phase 1 and phase 2 clinical trials are needed, followed by rigorous testing in randomised controlled trial study designs. Such testing will allow for full scientific evaluation which can then inform translation to clinical practice. RC

1.9. Opportunities and challenges with Virtual Reality

1.9.1. Opportunities with Virtual Reality for Low Back Pain rehabilitation

The ability to instantly transport the patient into a virtual world for the purposes of distraction and exposure to a feared situation makes VR a tremendously powerful tool (Trost, 2015). Through immersive multimodal stimuli (i.e., visual, auditory, tactile and/or even olfactory), VR may be used to engage the patients in immersive gaming to actively achieve valued life-goals (Li et al, 2011). With an appropriate virtual environment, immersive VR training can provide a feeling of moving freely in a virtual space, and the tasks may give the patient a sensation of

achievement and empowerment. VR-technology may also be used to capture and store metrics that cannot easily be detected by an observer (e.g. with movement sensors), which can be used to facilitate motor learning. Additionally, the development of virtual environments may be used to deliver meaningful and relevant stimuli for active rehabilitation of valued life activities (Weiss, Kesher & Levin, 2014), and further, it may address maladaptive movement behaviours. Studies by Thomas et al (2007; 2008a; 2008b) has repeatedly shown that LBP patients with high fear specifically avoid flexion of the lumbar spine, and subsequently, that avoidance (or inactivity) may contribute to shortening of peri-articular connective tissues change in the surrounding musculature (Hides et al, 1995; 1996; Lieber et al, 2002). A case-controlled study (n=14) by Karayannis et al. (2013) demonstrated that although weakly related, pain-related fear of movement was associated with trunk stiffness in people with persistent LBP. Thomas et al. (2016) hypothesize this may increase the risk of injury if a person is exposed to "common, unexpected environmental challenges" (e.g., missing a step or slipping). Nevertheless, whether tailored training in VR may motivate for amelioration of avoidance behaviour and increase physical capacity, remains to be investigated. However, protocols for graded exposure training as suggested by Parsons & Trost (2014) appears to be promising for this patient group.

Further, research shows that LBP patients may fail to generalize "safety learning" across contexts or physical activities during conventional training tasks (Crombez et al, 2002). For example, a patient may learn that bending to tie a shoe is safe for the back, but may hesitate to perform a similar amount of lumbar flexion for a different task (e.g., picking up a piece of clothing on the floor). Practicing movement across different activities and contexts (with and without VR) may therefore be a key to treatment success (Trost et al, 2015). We know that transfer is a key concept of learning, and that virtual environments used to train complex skills in surgical, flight, or military situations have demonstrated that it is possible to learn skills in virtual environments and then transfer this learning into skilled performance in the real world (Bossard et al, 2008; Holden, 2005). According to Rose et al. (2000), transfer is dependent on the virtual environment and cognitive processing required for task performance being similar to the real-world tasks, and may be facilitated if the patient is required to "adapt to changing demands, problem-solve, learn from mistakes, simplify and segment tasks, and repeat various complex tasks in various contexts" (Bossard et al, 2008).

Finally, adherence to exercise and/or therapeutic recommendations are important in physical rehabilitation as patients are often required to change behaviour over time to achieve

improvement from a multidimensional LBP management approach. Adherence to home-based exercise commonly ranges between 50 – 70% (Friedrich et al, 1996; Medina-Mirapeux et al, 2009), and as previously mentioned, adherence to graded exposure therapy ranges from only 30-58% (Linton et al, 2008; Woods & Amundson, 2008). Whether new technology may improve these numbers, this remains to be investigated. However, gaming interventions report strong retention and adherence rates, reduced perception of effort and fatigue, as well as enjoyment of exercise-related activities (Warbuton, 2013). Therefore, gaming interventions should be considered in rehabilitation as we strive for better clinical outcomes (which would be predicted by improved adherence) as well as a more cost-effective and sustainable health-care system.

1.9.2. Challenges with Virtual Reality in Low Back Pain rehabilitation

While VR training may have a positive impact on a variety of domains, concerns about its safety and potential danger to health are critical to consider. Beyond transient motion sickness and nausea that can be caused by disconnect in vision and movement (primarily related to current technological limitations), long-term effects such as addictive behaviour need to be carefully investigated and avoided. Current limitations with VR-gaming in rehabilitation are also related to costs, availability, technical competency, and the lack of evidence-based protocols or research investigating its effectiveness. In terms of practicality, non-immersive screen technology may require less set-up and effort to provide a patient with an opportunity to interact with the virtual environment (Weiss, Keshner & Levin, 2014). However, to date there is still no evidence published regarding whether immersive or non-immersive virtual environments provide the most cost-effective alternative, given that they may have differing clinical effectiveness. Such clinical and cost consideration are important for clinicians when exploring the wide variety of both immersive and non-immersive equipment available on the market. Further, individual differences related to acceptability (e.g. immersive tendencies, technological literacy, socioeconomic status), may modulate treatment success and thus must be explored (Trost et al, 2015). It is also unclear whether advantages of VR over real-world-training exist, and if so, an explanation of precisely what these advantages are lacking (Weiss, Keshner & Levin, 2014). Future research needs to investigate whether we can capitalize on something unique with VR training, or whether VR training is merely more effective because of the entertaining nature that keeps patients more engaged and motivated throughout the

rehabilitation. Thus, VR training parameters associated with optimal transfer to real-world functional improvements, remain to be discovered – such research is preferably completed using a person-centred approach. While aforementioned limitations exist, the potential favourable opportunities afforded by such technology undoubtedly warrant further investigation in physical therapy rehabilitation.

2.0. Method

2.1. Purpose of the study and research hypothesis

VR-training is a new and innovative intervention that has not yet been fully explored in persistent musculoskeletal disorders. Some forefront rehabilitation centres in Norway (e.g. Sunnaas Rehabilitation centre and Sykehuset Innlandet) have been the first to utilize VR training in musculoskeletal rehabilitation in Norway, but to date, only one feasibility study from the United States (U.S.) by Thomas et al. (2016) has investigated a VR-intervention for non-specific persistent LBP patients with pain-related fear of movement. As the initiators of the first Norwegian VR study, we hypothesize that VR-technology may play an important role in patient management and education in the future, and that we should start to explore how it may facilitate learning in person-centred persistent pain management. The purpose of the study was therefore was to evaluate whether Virtual Reality (VR) training had an effect on pain intensity and pain-related fear of movement, pain catastrophizing and pain anxiety symptoms in 10 non-specific persistent LBP patients with pain-related fear of movement. The underlying rationale for the study is based on findings from health technology, neuroscience, pain science and behavioural research.

The primary research hypothesis was that a VR gaming intervention would reduce pain intensity (H1), and the secondary research hypothesis was that VR gaming intervention would reduce pain-related fear of movement, pain catastrophizing and pain anxiety symptoms (H2). Pain intensity was measured using a Numeric Rating Scale (0-10 NRS), and pain-related fear of movement, pain catastrophizing and pain anxiety symptoms were measured using items from the Tampa Scale of Kinesiophobia (TSK), the Pain Catastrophizing Scale (PCS) and the Pain Anxiety Symptoms Scale-20 (PASS-20). The independent variable of the study was VR training, while the primary dependent variables included registrations of daily permutations of pain intensity and pain-related fear of movement, pain catastrophizing and pain-anxiety symptoms. To evaluate whether VR training resulted in a significant reduction in the above outcome measures (as hypothesized), the difference between the baseline daily outcome scores and the daily outcome scores during the intervention period (n=35 measures for each participant) would have to be large enough to reject the null hypothesis (H0), i.e. falsify the assumption that the two phases had identical distributions. The secondary dependent variables

included the secondary outcome measures (see below), which were analysed via calculating the percentage change between baseline and follow-up in each participant.

2.2. Single-Subject Experimental Design

In science there are two main research paradigms: quantitative and qualitative. A specialised type of quantitative study design is that of the single-subject paradigm. In the present study, a sequential, replicated, randomised single-subject experimental phase design (SSED) with multiple measurements was used. An SSED can be used as the first step in the preparation of a large-scale trial (e.g. 'randomised controlled trial' or RCT) or it may provide an empirical generalizability test in one's own clinical practice of findings known from large-scale research (Onghena, 2005a). The SSED, "single-case design", or "N-of-1 RCTs", can be broadly categorized into two main types: phase designs and alternating designs (Michiels et al, 2018). We used the former, which divides the sequence of measurement occasions into separate treatment phases, and each phase includes multiple (≥5) measurements (Edgington, 1975, 1980; Onghena, 1992). We aimed to measure each participant's response to the VR gaming intervention with an AB-phase design (i.e. phase A = baseline, and phase B = treatment). In the study, a 7-day follow-up phase was also used. A study with a withdrawal period may be commonly referred to as an ABA-design. However, since the treatment in question is considered "irreversible", that is, its' effects are unlikely to discontinue once treatment has ceased, the term AB-design is used.

It should be acknowledged that history, maturation bias and statistical regression to the mean are three important threats to the internal validity in a SSED. History bias refers to the confounding influence of external factors on the treatment effect during the course of the experiment (e.g., events or changes in a participant's life that prior to or during the intervention). Maturation bias refers to changes within the subject during the course of the experiment that occur as a function of the passage of time and are unrelated to the treatment effect (Carter & Lubinsky, 2017). Regression to the mean is a widespread statistical phenomenon, that may occur when an extreme group is selected from a population based on the measurement of a particular variable. When a second measure is taken from the same group, the second mean will be closer to the population mean, which may be mistakenly attributed to a treatment effect (Morton et al, 2005). Several methodological features have been proposed to increase internal validity within an SSED, including: random assignment of AB-phase duration,

replication of multiple AB-design across participants, and using adequate statistical techniques (Michiels & Onghena, 2018). In the present study, an attempt to maximize internal validity via study design was made. Firstly, the design was made more robust by being replicated across several participants. The two ways one can replicate in an SSED, is simultaneously or sequentially (Onghena & Edgington, 2005b). Considering that this was an innovative approach to LBP management, we chose a sequential replication, which allowed us to carry out and test the same design for several patients. Secondly, sequential refers to the replications being carried out one by one. In other words, the design is repeated separately for each patient (de Jong et al, 2012; Onghena et al, 2005a). Thirdly, we used random assignment of phase duration length (for baseline and intervention), while standardising the total duration of both phases between participants. Indeed, the benefits and importance of random assignment of the different phases are emphasized in the recent CONSORT extension for reporting N-of-1 trials (Shamseer et al, 2015; Vohra et al, 2015), in addition to the single-subject reporting guideline in behavioural interventions statement for making valid inferences (Tate et al, 2016). One argument is that the lack of random assignment of phase duration in a SSED makes it more difficult to rule out alternative explanations that may weaken the internal validity of the design (Dugard et al, 2012; Dugard, 2014; Edgington & Onghena, 2007; Heyvaert et al, 2017; Kratochwill & Levin, 2010). Thus by randomising the phase duration, it is more likely that any change detected is due to the start of the intervention.

In the present study, the combined duration for the baseline and intervention phase was chosen to maximise the number of baseline measures and interventions applied while minimising participant fatigue (due to daily measures). For all participants, the baseline (phase A_1) and intervention phase (phase B) lasted 28 days, and the follow-up (phase A_2) lasted for 7 days. To randomise baseline duration for all participants, a computer-generated random table was used (Appendix 1). The time window for randomisation of the baseline duration was pre-set based on earlier studies using a similar design (de Jong et al, 2012), with a baseline ranging from 5-14 days and a treatment duration ranging from 14-23 days (the latter allowing a minimum of 6 and a maximum of 9 VR treatments). Finally, each patient was then observed repeatedly (as with a longitudinal or time series design), and daily self-reported measures were collected throughout the study. This allowed for a statistical analysis using a linear mixed model.

2.3. Strengths and limitations with the design

The AB-design is the most basic and practically feasible experimental designs for evaluating treatments in single subject research (Michiels & Onghena, 2018). However, scarce attention has been paid to single-subject experiments as a useful and valid strategy for pain management. This is unfortunate because single-subject experiments may be ideally suited to "customize" treatments, or "to build, fit, or alter treatments to individual specifications" (Onghena, 2005a). SSEDs are cheap, relatively easy to execute, provide a robust design for a pilot study, and help to validate clinical practice. SSEDs can be considered to have rigorous designs due to multiple measurements that strengthen the validity of the design. Therefore, SSEDs may play a key role when evaluating novel treatments that do not yet have evidence for their effect (i.e., when performing a randomised trial would not yet be recommended). Accordingly, we would classify the present study as a phase 2 clinical trial, but with a limited number of participants compared to recently developed guidelines (UK Cancer Research, 2015; National Health and Medical Research Council, Australia, 2015).

Although widely used, the AB-design has received criticism for its low internal validity (Kratochwill et al, 2010; Shadish et al, 2002; Tate et al, 2016; Vohra et al, 2015). Several authors have rated the AB-design as "quasi-experimental" or even "non-experimental" because a lack of a treatment reversal phase and control group leaves the design vulnerable to the internal validity threats of history and maturation (Kratochwill et al, 2010; Tate et al, 2016; Vohra et al, 2015). While some criticize the design, others (e.g. Michiels & Onghena, 2018) argue that a randomized AB-phase design can be used as a basic experimental design for situations where this design is the only feasible way to collect experimental data (e.g., when evaluating treatments that cannot be reversed due to the nature of the treatment or because of ethical concerns). Such is the case in the present thesis, where the effects of treatment are unlikely to be reversed solely due to removing the intervention. Michiels & Onghena (2018) argue that in this situation the threats of history and maturation have to be taken into account and acknowledged when considering the results. While important to consider, Kratochwill et al. (2010) suggest that designs with multiple AB-phases (e.g. ABAB) offer better protection from threats to internal validity than only AB designs, the internal validity of the basic AB-design can be strengthened via study design features and through adequate statistical analysis, strategies we have employed here (see Subsection 3.2 for full statistical analysis details).

2.4. Participants

Participants were included in the study based on pre-specified eligibility criteria (See Table 1). We recruited 14 patients from waiting lists in primary health care through the Outpatients Spine Clinic at Haukeland University Hospital, Bergen. To be included in the study, a minimum score of 25/52 on the Norwegian version of Tampa Scale for Kinesiophobia (TSK-11) and a minimum pain NRS score of 4/10 for the past two weeks was required. Ethical approval was attained from the University of Bergen and the Regional Ethics Committee of Western Norway (2017/1199/REK vest) (Appendix 2). Table 1 shows an overview of inclusion and exclusion criteria for the present study.

Inclusion Criteria	**Exclusion Criteria**
Low back pain ≥ 3 months	Not fully sick listed for more than 6 months
Age between 18-65 years	Ongoing treatment from other therapists (e.g.: physiotherapist, manual therapist, chiropractor, osteopath, 'naprapat' or other).
Localized pain from T12 to gluteal folds, provoked with postures, movements and activities.	Specific LBP diagnosis (radicular pain, disc herniation, spondylolisthesis, stenosis, modic changes).
Pain intensity ≥4/10 on Numeric Rating Scale (NRS), lasting ≥14 days	Acute exacerbation of LBP at the time of testing (to avoid regression to the mean).
Minimum score on Tampa Scale for Kinesiophobia (TSK-11 Norwegian Version): ≥ 25/52.	Visual disorders, dizziness and/or Benign Paroxysmal Positional Vertigo (BPPV).
	Other: - Any lower limb surgery in the last 6 months - Previous surgery involving the lumbar spine - Currently pregnant or less than 6 months post-partum - Diagnosed psychiatric disorder

	- Widespread constant non-specific pain disorder - Active rheumatoid arthritic disease - Progressive neurological disease - Serious cardiac or other internal medical conditions - Malignant diseases - Contradictions to general exercise.
Table 1: Overview over inclusion and exclusion criteria	

2.4.1. Key inclusion criterion 1: TSK-11 Norwegian Version

One of the underlying hypotheses of the present study was that patients with maladaptive pain-related fear of movement could benefit from a VR intervention that aimed to expose participants to lumbar spine movements. TSK-11 score level recommended by Neblett et al. (2013) were used to determine cut-off levels for participation in the study: subclinical levels (≤23), mild levels (23-32), moderate levels (33-42) and severe levels (43-52). We first aimed to use a pre-determined score of ≥33/52 (including moderate and severe level) on TSK-11 Norwegian version. However, in conversations with the Outpatient Spine Clinic regarding their typical patient referrals, it was decided to recruit participants with at least "mild" levels of pain-related fear in order to recruit sufficient participants during the available Masters time period.

2.4.2. Key inclusion criterion 2: pain NRS-ratings ≥ 4/10 over the past 14 days.

Another important inclusion criterion for the present study, was that NRS had to be ≥ 4/10 over the past 14 days for the patients to be included in the study. This criterion was important to reduce the chances of a "floor effect" (i.e., insufficient ability to detect any changes in pain because of low baseline levels) that would be compounded by history bias, maturation bias or statistical regression to the mean (Carter & Lubinsky, 2016).

2.5. The intervention – Tailored VR-training

Inspired by health technology, neuroscience, pain science and behavioural research, we conducted a SSED with 10 non-specific persistent LBP patients with a tailored VR training intervention. The aim was to gradually expose patients to movement in different VR-games, tailored to their daily measures of pain intensity, pain-related fear of movement, pain catastrophizing and pain anxiety symptoms. Three different VR games were chosen and tested by MS and TFL, and a protocol for "easy", "medium" and "hard" levels was developed (Table 2). As Thomas et al. (2016) argues, the fear-avoidance model posits a generic avoidance of all forms of movement that are perceived as threatening, and it is repeatedly shown that individuals with LBP that have high levels of fear specifically avoid flexion of the lumbar spine (Thomas et al, 2007; 2008a; 2008b). Thus, trunk flexion was a key movement targeted in the present VR intervention. All participants started at an "easy" level in all three VR games, with natural clinical progression if they showed signs of a reduction in pain intensity, pain-related fear of movement, pain catastrophizing and pain-anxiety symptoms.

Difficulty Level	**Amount of movement required**
Easy Level	Targets were approximately between head and solar plexus height, patients required minimal to little lumbar flexion to play the VR games.
Medium Level	Targets were approximately between shoulder and hip height; some trunk and lumbar spine flexion was required to play the VR games.
Hard Level	Targets were approximately between solar plexus and middle thigh height, patients needed to either bend their knees and/or flex their trunk and lower back to play the VR games.

Table 2: Difficulty levels in the VR games

2.5.1. The VR games

Patients were encouraged to move as freely as possible in the virtual world, and reported pain intensity and fear-levels during and after each VR session (Appendix 3). Consistent with the aims of a phase 2 clinical trial, we were also interested in whether participants experienced some side effects from the intervention. Therefore, participants also reported any discomfort and amount of nausea during and after each intervention. The most important clinical tenet was their feeling of safety and autonomy during each VR gaming intervention, and we informed

them that we could both increase or decrease the difficulty levels during the session. All patients began exercising at "easy" level during VR training number 1. At each session, the patients played three different VR games for 10 minutes each, with a 2-3 minutes breaks in between, for a total of 30-45 minutes of VR training per session. A description and overview is provided in Table 3, and screenshots of the different VR-games are shown in Figure 8-16.

VR game	**Description**
HoloBall	HoloBall is a fun and entertaining squash game that can be adjusted in terms of height-, width-, room size, ball size and speed, and the opponent's reaction speed. The patients warmed up in the "Zen"-level, playing squash for a few minutes, and subsequently started playing against a computer-generated contestant in "Campaign"-level – "Easy", "Medium", or "Hard" level.
RoBow Agent	RoBow Agent is a software game developed specifically for this project (by another masters student - TFL). In this 10-minute game the player is an agent on a space station, equipped with either a bow or a gun, and must defend the space station. When the player runs out of ammunition, he/she have to bend forwards and/or rotate the trunk to pick up objects in a pre-defined height. The amount of forward flexion and rotation can easily be adjusted in real-time to each patient by the clinician, to fit an "easy", "medium", or "hard" level.
HoloDance	HoloDance is a dragon-based VR game where the patient plays against a dragon, who hides in different environments (under water, the desert, or in the jungle). In a rhythmic fashion, the dragon sends out lightning fireballs, which the player must catch with one or two shields (the hands). The player must move the arms, trunk and lower back to catch the lightning fireballs to earn points and progress to the next level. There are many different levels in this game, which can be individually adjusted in real-time.
Table 3: Description of the VR games	

Figure 8: Zen settings with adjustments possible (for warm-up) in Holoball

Figure 9: Difficulty levels in Holoball

Figure 10: Screenshot of animated player in Holoball

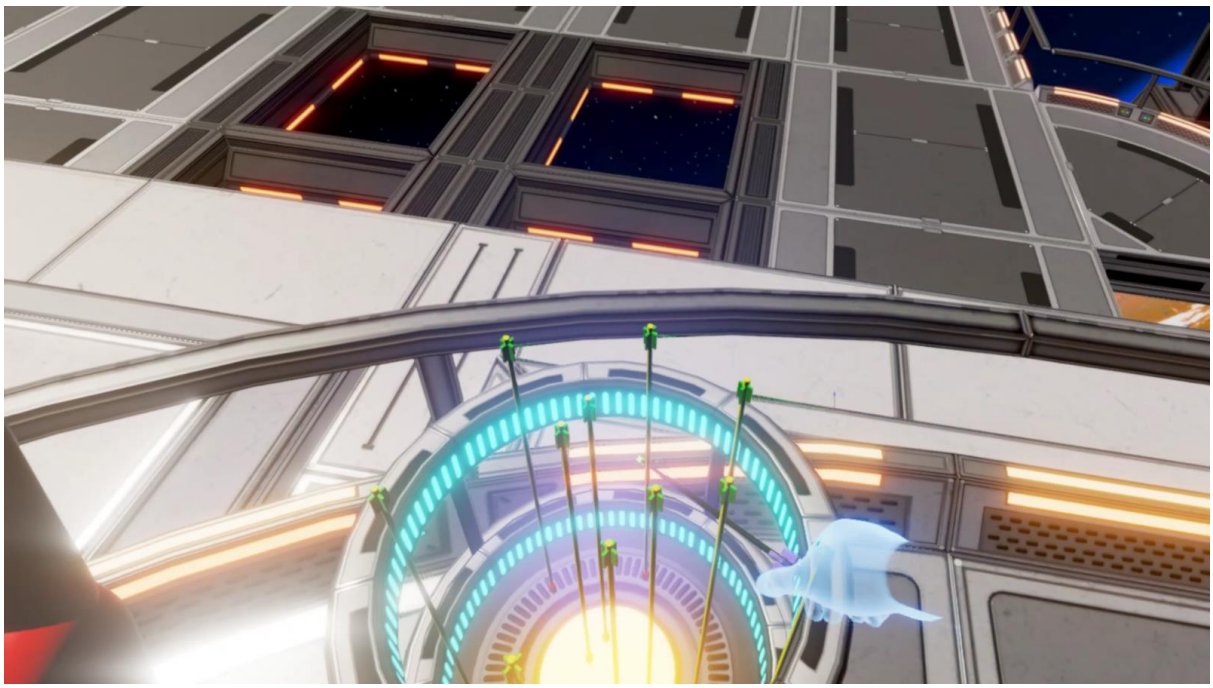


Figure 11: One of the tasks in RoBow Agent is to reach forward and pick up objects. These objects can be placed in different heights

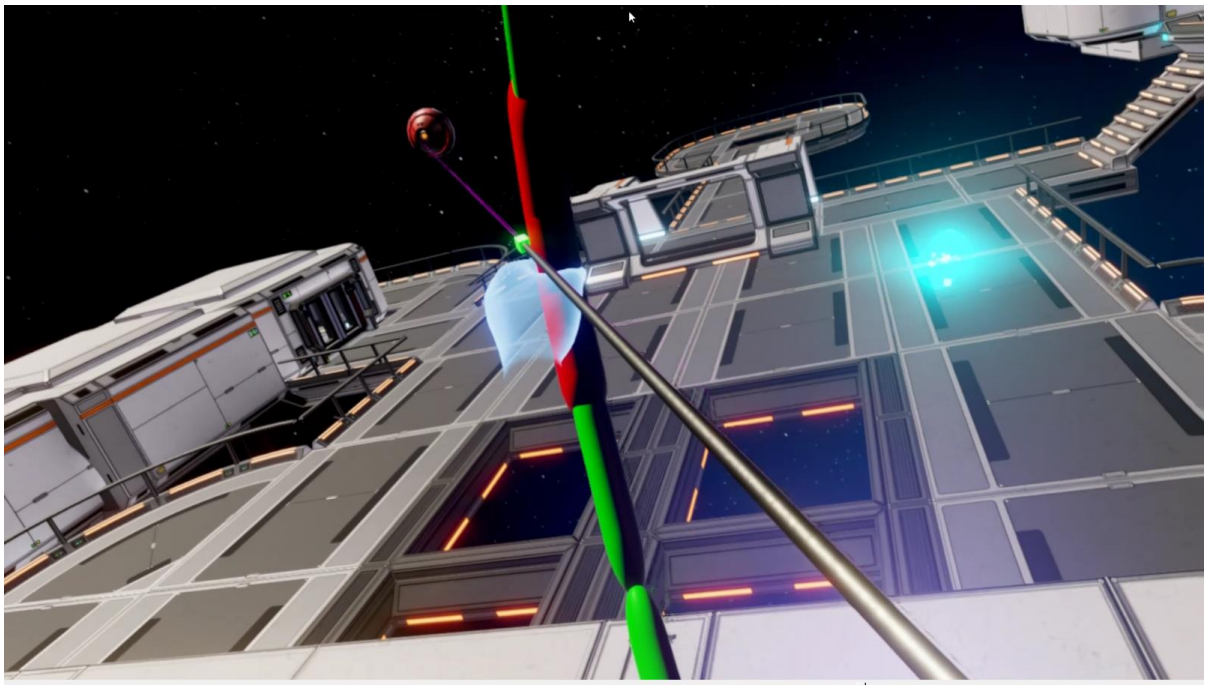


Figure 12: A player firing an arrow to hit a moving object in RoBow Agent

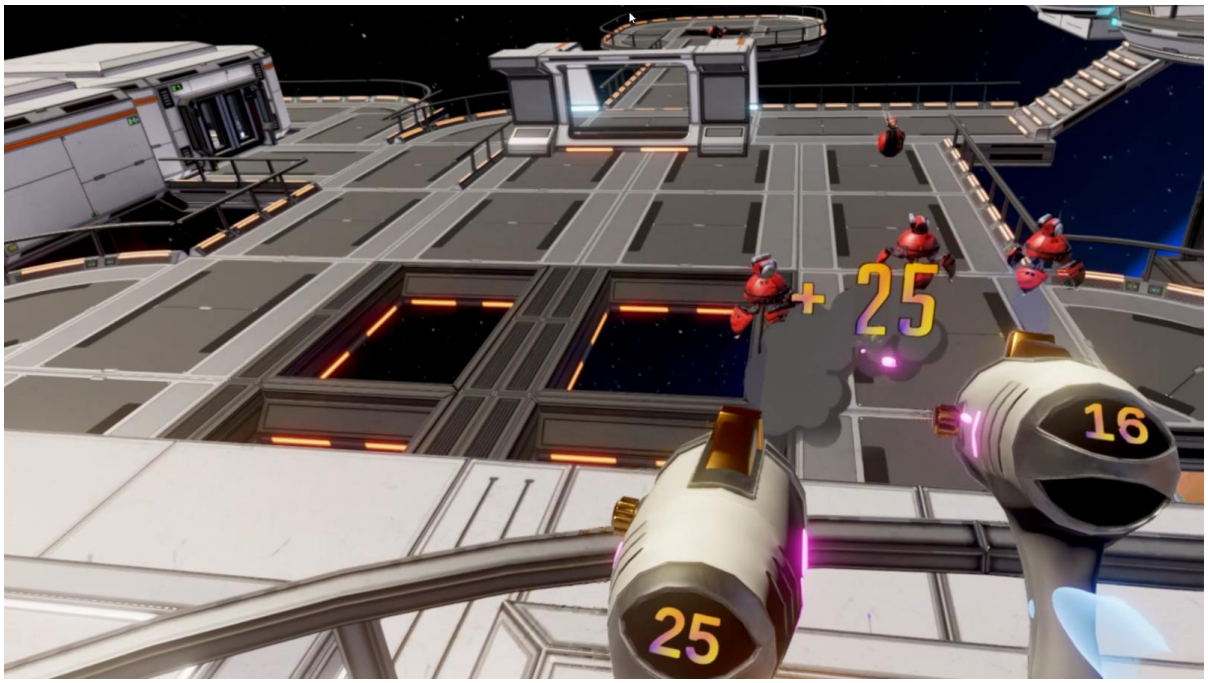


Figure 13: Using two guns to hit moving targets in RoBow Agent. When running out of ammunition, one has to locate and collect new ammunition somewhere in near proximity, and must flex or rotate the upper body to pick it up

Figure 14: One of the first levels in Holodance, where one must catch lightning fireballs with two shields

Figure 15: Demonstration of possible arm, trunk and low back movement required in Holodance.

Figure 16: Underwater-level in Holodance

2.6. Equipment

Immersive VR technology includes powerful computers to run the software, head-mounted displays, body tracking sensors, specialized interface devices and real-time graphics to fully immerse the user in a computer-generated simulated world that updates in a natural way consistent with head and body motion (Lange et al 2009; 2012). In the present study, we used an Oculus Rift with a head-mounted gear and hand-held controllers to track movement in space (Figure 17). System requirements include an Intel Core i5-4590 or AMD FX 8350 equivalent or better processor, a NVIDIA GeForce GTX 1060 or AMD Radeon RX 480, equivalent or better graphics. In addition, 4 GB RAM, 1x HDMI 1.4 port, and operating system from Windows 7 SP1, 8,1 or 10. All hardware was borrowed from SimArena at Western College of Applied Sciences in Bergen, Norway, while software was either bought from Steam (https://store.steampowered.com/) or developed by a master's student (TFL) in Software Engineering at the University of Bergen and Western College of Applied Sciences.

Figure 17: Oculus Rift headset from: https://www.oculus.com/

2.7. Data collection

2.7.1. Primary outcomes measures

Daily measures were collected over a total period of 35 days in order to investigate how people with persistent LBP responded to the VR interventions, and whether pain intensity, pain-related fear of movement, pain catastrophizing and pain-anxiety symptoms changed over time. We asked participants to complete daily measures of pain intensity (NRS), and 10 selected items from three different questionnaires representing kinesiophobia (Tampa Scale of Kinesiophobia, TSK) (Goubert et al, 2004; Kori et al, 1990; Roelofs et al, 2007), pain catastrophizing (Pain Catastrophizing Scale, PCS) (Sullivan et al, 1995; Van Damme et al, 2002) and pain-anxiety symptoms (Pain Anxiety Symptoms Scale, PASS-20) (McCracken et al, 2002). Based on a large database of patients with persistent musculoskeletal pain (Roelofs et al, 2007), the internal consistency of these subscales was sufficient to good (Cronbach a = .60, .72, and .73, respectively) (de Jong et al, 2012). Participants were instructed to complete the daily measures consistently at 8 P.M. throughout the total 35 days.

The specific items collected daily included TSK-item 1: “I am afraid that I might injure myself if I exercise”, TSK-item 3: “My body is telling me that I have something dangerously wrong”, TSK-15: “I can’t do all the things normal people do because it’s too easy for me to get injured”. The items chosen from the TSK-17 were related to activity avoidance (TSK-item 1), somatic focus (TSK-item 3), and activity avoidance (TSK-item 15). All these items have been translated

to Norwegian by Haugen et al. (2008). Further, we investigated PCS-item 1: "I worry all the time whether the pain will end", PCS-item 2: "I feel I can't go on", and PCS-item 13: "I wonder whether something serious may happen". The items chosen from the PCS are related to helplessness (item 1 and 2) and to pain magnification (item 13). Finally, four PASS-item were selected, item 3: "When I hurt I think about pain constantly", PASS-item 4: "I find it hard to concentrate when I hurt", PASS-item 5: I worry when I am in pain", and PASS-item 10: "I try to avoid activities that cause pain". The items chosen from PASS are related to cognitive aspects of stress and anxiety (items 3, 4, and 5) and to escape or avoidance (item 10) (McCracken & Dhingra, 2002). The PCS was translated and found to have acceptable psychometric properties in terms of comprehensibility, consistency, construct validity, and reproducibility for subacute and persistent LBP patients (Fernandes et al, 2012). While PASS-items could only be found in English versions (no Norwegian translation available) we chose to include still include the PASS-items given their relevance to an intervention aiming to reduce anxiety related to movement.

2.7.2. Secondary outcome measures

Secondary outcome measure questionnaires included the Oswestry Disability Index (ODI) (Fairbank et al, 1980; 2000), the Örebro Musculoskeletal Pain Questionnaire Screening Questionnaire short form (ÖMPSQ short form) (Linton et al, 2011), Patient Specific Functional Scale (PSFS) (Stratford et al, 1995), and the Fremantle Back Awareness Questionnaire (FreBAQ) (Wand et al, 2014). Additionally, the Neuro Orthopaedic Institute (NOI)-app Recognise™ (http://www.noigroup.com/en/Product/BTRAPP) was used to evaluate motor imagery performance (Bowering et al, 2014). Importantly, secondary outcome measures were only collected at baseline and follow-up. An overview over primary and secondary data collection is presented in Figure 18.

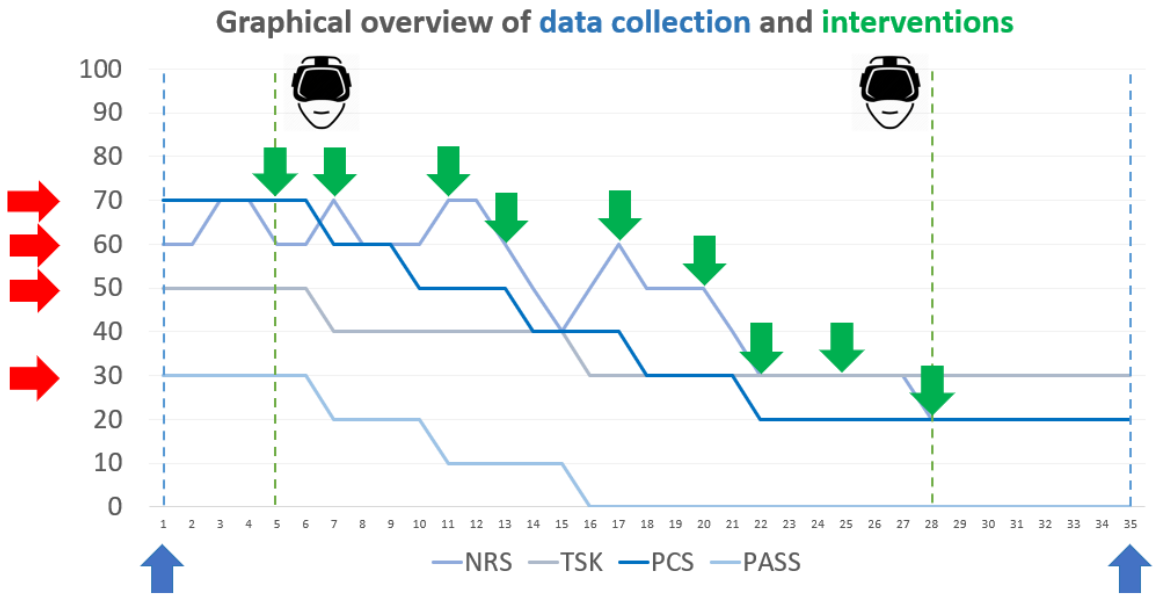


Figure 18: Example of data collection for a participant with 9 VR-interventions (VR-interventions marked as green arrows during the intervention phase). The x-axis represents days and the y-axis represents percentage of total score for the outcome measures. Procedures for data collection are marked with red and blue arrows, including red arrows showing the trajectories for the primary daily outcome measures (NRS, TSK, PCS and PASS), and the blue arrows showing when the secondary outcome measures were taken (only collected at Day 1 and Day 35).

2.7.2.1. Oswestry Disability Index (ODI)

ODI is a 10-item questionnaire developed by Fairbank et al (1980; 2000) to assess pain-related disability in people with LBP. The questionnaire was translated to Norwegian in 2003 (Grotle, 2003), and validated by Fernandes et al. in 2012. The suggested use is for patients with severe or persistent disabilities, but according to Grotle et al. (2004b), the form is also valid for both acute and persistent LBP patients, with and without sciatica. The first item in ODI is related to pain, while the remaining 9 items are related to function in ADL. Each item is rated on a 6-point Likert scale. A minimal detectable change is estimated to be 10-12 points (Ostelo et al, 2008). A study by Saltychev et al. (2017) showed that the ODI has good internal validity (Cronbach's $\alpha = 0.85$), with an exploratory factor analysis showing that the ODI is a unidimensional test specific to measuring functional level. A confirmatory factor analysis demonstrated that the standardized regression weights of all ODI-items were relatively high, varying from 0.5 and 0.7. The item response theory analysis suggested that 8 out of 10 ODI items have a close-to-perfect ability to measure functional limitations in accordance with the actual severity of disability experienced by the respondents. Discrimination of all the items was high to perfect (1.08 – 2.01) (Saltychev et al, 2017).

2.7.2.2. Örebro Musculoskeletal Pain Screening Questionnaire – Short Form (ÖMPSQ -short form)

The Örebro Musculoskeletal Pain Screening Questionnaire is one of the most widely used screening questionnaires for the prediction of patients developing work disability due to LBP or neck pain (Linton & Halldén, 1998). It was first developed in 1998 and has been validated for use in acute and subacute LBP, but also for neck and shoulder patients, as well as for patients with more generalized pain disorders. Grotle et al. (2006) translated the questionnaire to Norwegian. A study by Grotle et al. (2007) showed that acute LBP patients with a score higher than 112/210 were significantly more likely to develop persistent pain and disability. In 2011, Linton et al. abbreviated the original 25-item questionnaire to a 10-item questionnaire. The items in the short version are scored 0-10, where 0 refers to absence of impairment and 10 to severe impairment, with three items reversed when calculating total score (Linton et al, 2011). The reliability of the Norwegian and Swedish version of the original ÖMPQ has been reported to be good (Linton & Halldén, 1998; Grotle et al, 2006), and while the correlation between the original and short questionnaire was 0.91, the receiving operator characteristic curve was nearly identical for the two versions. For LBP patients screened for the risk of developing disability, using a cut-off of 50/100 on the short version identified 85% in the occupational sample and 83% in the primary care sample that developed disability; performance which is comparable to that of the full version (Linton et al, 2011).

2.7.2.3. Fremantle Back Awareness Questionnaire (FreBAQ)

Several lines of evidence suggest that body perception is altered in people with persistent LBP (Wand et al, 2015, Kregel et al, 2015). Maladaptive perceptual awareness of the back might contribute to the pain experiences as well as serve a target for treatment. The FreBAQ is a 10-item questionnaire developed to assess back-specific altered self-perception (Wand et al, 2016; 2014). Although the questionnaire is fairly new and only exists in English to date, it proposes some interesting aspects warranting further investigating in persistent LBP patients, and show reasonable psychometric properties. A person reliability index of 0.74 and a Cronbach a value of 0.80 indicated that the internal consistency of the FreBAQ was adequate (Wand et al, 2014). Another study by Wand et al. (2016) show that FreBAQ appears unidimensional with no redundant items, has minimal ceiling and floor effects, and that FreBAQ correlated with sensitivity, distress and beliefs and were uniquely associated with pain and disability. Pilot work

has shown that in persistent LBP, mediated reality resulted in pain relief for only the participant with altered back perception (as assessed by the FreBAQ), therefore we felt it relevant to assess here.

2.7.2.4. Recognise™

Left/right discrimination tasks are used for evaluating motor imagery performance using the application Recognise™ (Figure 19), a commercially available online software program (http://recognise.noigroup.com/recognise). The app was developed in 2016 and using similar procedures to the online test. Research has shown that persistent LBP is associated with disruptions of the working body schema of the trunk (Bray & Moseley, 2011), which might be an important contributor to motor control abnormalities seen in this population. The speed and accuracy in Recognise™ are hypothesized to reveal dysfunctional motor imagery performance due to cortical reorganisation. Bowering et al. (2014) tested Recognise™ on 1008 participants and found that those with back pain at the time of testing were less accurate than healthy controls ($p=0.027$), as were participants who were pain-free but had a history of back pain ($p=0.01$). These results were driven by an interaction such as those with current back pain and a history of back pain were less accurate (mean=76% [95%CI: 74-78%]) than all other groups (≥84% [95% CI: 83-85%]). Given that the VR intervention aims to have participants complete movements of the trunk, we were interested to see if motor imagery performance improved alongside with pain.

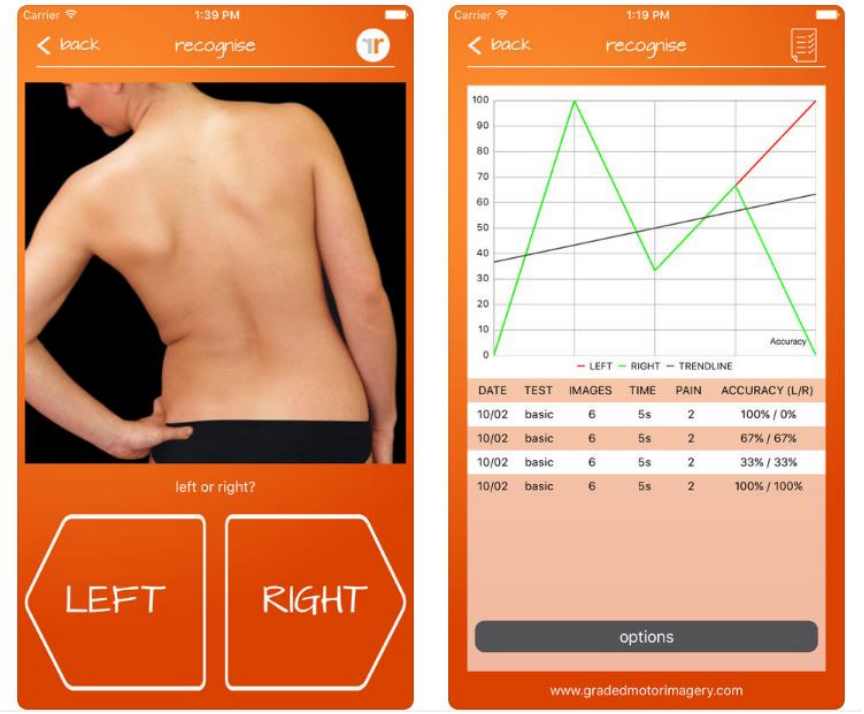


Figure 19: Recognise ™

Accuracy on this task in pain-free individuals is ≥ 80%, while reaction times of 1,6 seconds +/- 0,5 seconds (Bowering et al, 2014). Accuracy and speed should be reasonably equal for left and right side.

2.7.2.5. Patient Specific Functional Scale (PSFS)

The PSFS was developed by Stratford et al. (1995) and is a brief interview-format questionnaire used to assess functional disability and a change in performance for activities of daily living. The PSFS has gained wide acceptance over the years, as a component of the set of patient-specific (aka patient-centred) health related quality of life instruments (HRQoL), which allows for individuals to generate their own, unique items for each questionnaire (Jolles, 2005). In the PSFS, patients nominate three functional activities that are important to them and with which they are experiencing some activity limitation (original metric: a 0-10 scale for each item, where 0 = unable to perform activity, 10 = able to perform activity at the same level as before injury or problem). Validity, reliability, responsiveness for persistent LBP has been tested for PSFS, and studies show that the PSFS was more responsive than NRS and the Roland-Morris Disability Questionnaire (RMDQ), and that PSFS is valid for group-level change comparisons and between-group discrimination (Horn, 2012). A minimum detectable change (90%

Confidence Interval) for average score is 2 points, and 3 points for single activity score (Stratford et al, 1995).

In addition to these five secondary outcome measures, two undergraduate physiotherapy students from Western College of Applied Sciences, Bergen, collected pre- and post-measures of "Deyo's 7 myths" (Deyo, 1998) in the first four participants of the study. The questionnaire was developed based on the hypothesis that several myths regarding LBP were still believed in the general population in Norway, i.e., beliefs that were not concordant with current guidelines (Ihlebæk et al, 2003). "Deyo's 7 myths" will not be included in the data analysis for the master thesis, considering we already had pre-selected five other secondary measures that we wanted to look further into. All questionnaires related to primary and secondary outcome measures can be found in Appendix 4.

2.8. Statistical analysis

Linear mixed models are powerful and flexible tools, well suited for single-subject designs (Winter, 2013). The advantage of using a multi-level linear mixed model is that it provides flexibility when accounting for between participant differences in the number of data points and thus takes the full data into account. Traditional analysis on group data (i.e. RCTs) will perform an average-calculation and disregard daily variation in response to treatment. On the contrary, the analysis in the present study provides valuable information on a number of measures across each participant throughout the course of a new therapeutic intervention.

2.8.1. Primary outcome measures (Daily measures)

In the present study we investigated whether there was a significant change between baseline and intervention for the daily primary outcome measures (pain NRS, TSK, PCS, and PASS) in the participants. In order to derive an effect size and t-value from a linear mixed model, the researcher must be willing to make the same assumption as a t-test does, i.e., that all recorded observations are independent of each other. We used a multi-level linear mixed model to analyse the primary outcome data. The multi-level model regards the replicated case series data as 'nested data'. Thus, individual measurement occasions are nested in cases (the individual) and the model takes into account that the measurement occasions are not independent of the person in which they are measured. Previous SSED work has used randomization tests;

however, such an analysis is best suited when the intervention immediately results in a treatment effect. Given our intervention was not expected to immediately change pain/fear, it made more sense to evaluate overall differences between baseline and intervention scores, taking into account individual variability. The multilevel linear mixed analysis generates a t-value from which we derived a p-value from the reference distribution table (Appendix 5), indicating whether our findings were statistically significant. While the assumption of independent data of a t-test is not met, multilevel modelling is still recommended for SSED data (Baek & Ferron, 2013) given that the analysis is conservative rather than liberal (more chance of a type II error rate than type I) and the reduction in power from using a between group comparison is offset by the multiple measures at baseline and intervention (which are treated as dependent data).

For the primary outcome measures, we also evaluated whether participants achieved a clinically significant or minimally important change (MIC). We therefore used existing guidelines for Minimal Important Change (MIC) or Minimal Clinical Important Difference (MCID) to explore our data further, as the terms are used interchangeably. The current consensus states that a 30% improvement in pain and functional status from baseline may be considered a clinically meaningful improvement when comparing pre- and post-measures (Ostelo et al, 2008). The proposed MIC value for NPS-change in LBP is 2,0 points (Ostelo et al, 2008). While there is no current consensus regarding the MIC for TSK, PCS and PASS rating scales, if patients achieved a 30% reduction in score from baseline to follow-up, we reported it as a meaningful change. We based this decision on de Jong's (2012) study design, who used the same approach to determine meaningful change for TSK, PCS, and PASS when investigating graded exposure therapy for patients (n=8) with work-related upper extremity pain.

All statistical analyses were performed with lme4 and R package in SPSS. Bates et al. (2012; 2014) developed the lm4 package for R (R Core Team, 2012) in SPSS, as it provides functions to fit and analyse linear mixed models for single-subject experimental designs. Some of the proposed statistical modeling techniques for single-subject experimental designs include: interrupted time series analysis, generalized mixed models, multilevel modelling, Bayesian modelling techniques and structural equation modelling (Michiels & Onghena, 2018). In the present study, a multilevel modeling, or linear mixed model, was used. Further, techniques for statistical analysis of randomised AB phase designs can be divided into three subgroups: effect size calculation, statistical modeling, and statistical inference. In this study, we chose a

statistical modelling technique, which means constructing adequate description of the data by fitting the data to a statistical model (Michiels & Onghena, 2018). Additionally, a random slope was fitted with the linear mixed model, which means that the size of the treatment effect is allowed to vary across participants. Researchers in ecology (Schielzeth & Forstmeier, 2009), psycholinguistics (Barr, Levy, Scheepers, & Tilly, 2013) and other fields have shown that designs without random slopes are prone to a high Type I error rate (i.e. they tend to find a lot of significant results which are actually due to chance) (Winter, 2013), therefore we wanted to maximize the random effects structure for primary outcomes measurements in the study.

Different techniques have been proposed for carrying out the analyses in a linear mixed model, i.e., visual inspection of graphs, or statistical modelling. In order to evaluate internal and external validity in SSEDs, visual analysis tended to be the "gold standard" for single-subject data because of a presumed low Type 1 error rate and consistency across raters (Nelson et al, 2012). Thus, in the past, many researchers therefore saw little need for statistical aids (as described by Nelson et al, 2010, p. 3). However, recent research found that visual analysis of SSED data was less accurate and reliable than typically assumed (Nelson et al, 2012). In the present study, we have depicted all the primary outcome measurements in graphs to visualize change across all participants, but have not included a visual-based analysis. Statistical inference is not suggested as a replacement for visual analysis but is rather an aid for enhancing reliability and consistency, and for giving researchers and clinicians a means to corroborate visual analysis decisions, especially when considering important treatment decisions (Nelson et al, 2012). Statistical inference may also provide an empirical "check" for researchers and clinicians, either by forcing them to examine data more closely when contrasting decisions arise or by reducing the likelihood of overestimating treatment effects (Nelson et al, 2012). Finally, it may provide a common metric for discussing effects across participants, studies, and treatments (Nelson et al, 2012).

2.8.2. Secondary outcome measures (Non-daily measures)

Secondary outcome measure changes were analysed by calculating the percentage changes scores. The difference between pre-treatment and post-treatment scores was expressed as a proportion of the baseline score to get percentage change. No formal statistical analysis was performed.

3.0. Results

3.1. Participants

Participants were recruited from the Outpatient Spine Clinic at Haukeland University Hospital, Bergen, Norway over a 6-month period (January to June 2018). A total of 14 participants were invited to participate, with 10 participants providing written informed consent and included in the study. Data from nine participants were analysed – data from one participant was excluded because the baseline pain ratings dropped after screening at the Outpatient Spine Clinic. Specifically, the participant rated pain at 4/10 on NRS during screening (26.04.18), but when meeting with MS and TFL for enrolment in the study (11.05.18), pain levels had dropped to 1/10 (Appendix 6). The participant should therefore have been excluded before entering the study and thus will be removed from the data analysis. Of the included participants, 8 were male and the average age was 44.1 ± 13.2 (range: 28-63). See Figure 20 for a flow chart of study participation, and Table 4 for demographic and baseline characteristics.

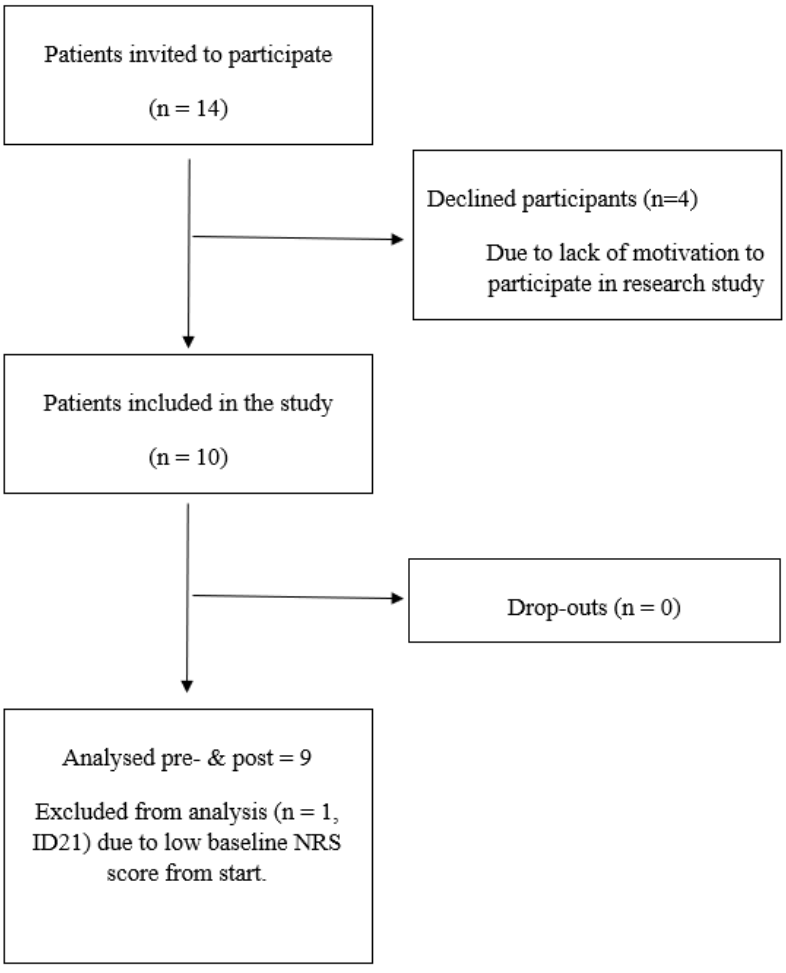


Figure 20: Flow chart of study participation

ID#	Demographic factors	Baseline NRS	Marked painful areas	Pain in other body areas	TSK	ODI	ÖMPQ	The NOI-app Recognise™	FreBAQ	PSFS
ID22	Male, 63 years, married, 2 children. Profession-based education (plumber). On full sick leave for 5 months. Been sick listed for the same complaint 2-5x before.	5.91	Lumbar spine, bilateral.	Yes (leg and foot: 9/10)	25/52 (mild)	56%	74/100	Speed: l/r: 0.95/2.95 sec. Accuracy: l/r: 25%/85%	8/36	Lifting heavy: 4 Carrying heavy: 3 Vacuuming: 4
ID23	Male, 38, married, 4 children. Primary school (runs own company). Partial sick leave for 5 months. Been sick listed for the same complaint more than 10x before.	4.83	Lumbar spine, bilateral, but most pain on the left side. Pain of both sides of the buttocks.	Yes (leg and foot: 8/10)	37/52 (moderate)	48%	57/100	Speed: l/r: 1.2/2.0 sec. Accuracy: l/r: 80/75%.	16/36	Sitting in excavator: 3 Sitting in truck: 3 Sitting in office: 3
ID24	Male, 31, single. Primary school (maintenance work with tunnels). Full sick leave for 3 months. Never been sick listed for this complaint before.	3.87	Right side lumbar spine and buttocks, and right anterior thigh and testicle.	Yes (leg and foot: 8/10)	35/52 (mild)	38%	46/100	Speed: l/r: 0.8/1.3 sec. Accuracy: l/r: 75%/90%.	7/36	Driving far: 7 Certain tasks at work: 5 Strength training: 7
ID25	Female, 54, 1 divorced, 1 child. Profession-based education (working in health care). On full sick leave for 1 year. Been sick listed for the same complaint 2-5x before.	5.14	Lumbar spine, bilateral.	Yes (leg and foot: 7/10, neck and shoulder: 7/10)	28/52 (mild)	54%	35/100	Speed: l/r: 2.5/1.55 sec. Accuracy: l/r: 35/30%.	24/36	Sitting: 2 Walking uphill: 2 Shower: 4

ID26	Male, 47, married, 2 children. Profession-based education (off-shore). On full sick leave for 5 months. Been sick listed for the same complaint more than 10x.	6.11	Lumbar spine, bilateral, mostly right side with radiating pain right leg towards buttocks and hamstrings.	Yes (leg and foot: 8/10)	32/52 (mild)	70%	66/100	Speed: l/r: 0.8/1.2 sec. Accuracy: l/r 90/90%.	4/36	Walking: 4 Sitting: 4 Bending forwards: 2
ID27	Male, 28, single. Primary school (truck driver). Not sick listed. Been sick listed for the same complaint 2-5x before.	2.00	Lumbar spine, slightly more pain on the right side.	No	34/52 (moderate)	36%	24/100	Speed: l/r: 1,.5/1.1 sec. Accuracy: l/r: 95/100%.	10/36	Working: 4 Hiking: 6 Lifting: 6
ID28	Male, 48, married, 3 children. Profession-based education (car salesman and mechanic). Not sick listed. Have never been sick listed for the same complaint before.	2.07	Lumbar spine, bilateral, but slightly more pain on the left side.	Yes (leg and foot: 8/10)	25/52 (mild)	30%	21/100	Speed: l/r: 0.9/1.2 sec. Accuracy: 90/95%.	0/36	Missing
ID29	Male, 59, divorced, 2 children. Primary school (technician). On full sick leave for 5 months. Been sick listed for the same complaint 2-5x before.	8.20	Lumbar spine, bilateral, both buttocks, left anterior thigh (numb sensation).	Yes (leg and foot: 6/10)	25/52 (mild)	62%	58/100	Speed: l/r: 1.35/1.9 sec. Accuracy: 100/95%.	8/36	Doing the dishes: 0 Dressing: 4 Bowling: 2
ID30	Male, 29, single. University education (working in IT). Partly sick listed for 3 months. Never been sick listed for the same complaint.	8.07	Lumbar spine and lower thoracic spine bilateral. Radiating to buttocks each side.	No	38/52 (moderate)	44%	56/100	Speed: l/r: 0.8/1.0 sec. Accuracy: l/r: 85/95%.	0/36	Sitting: 2 Lifting: 3 (missing activity)

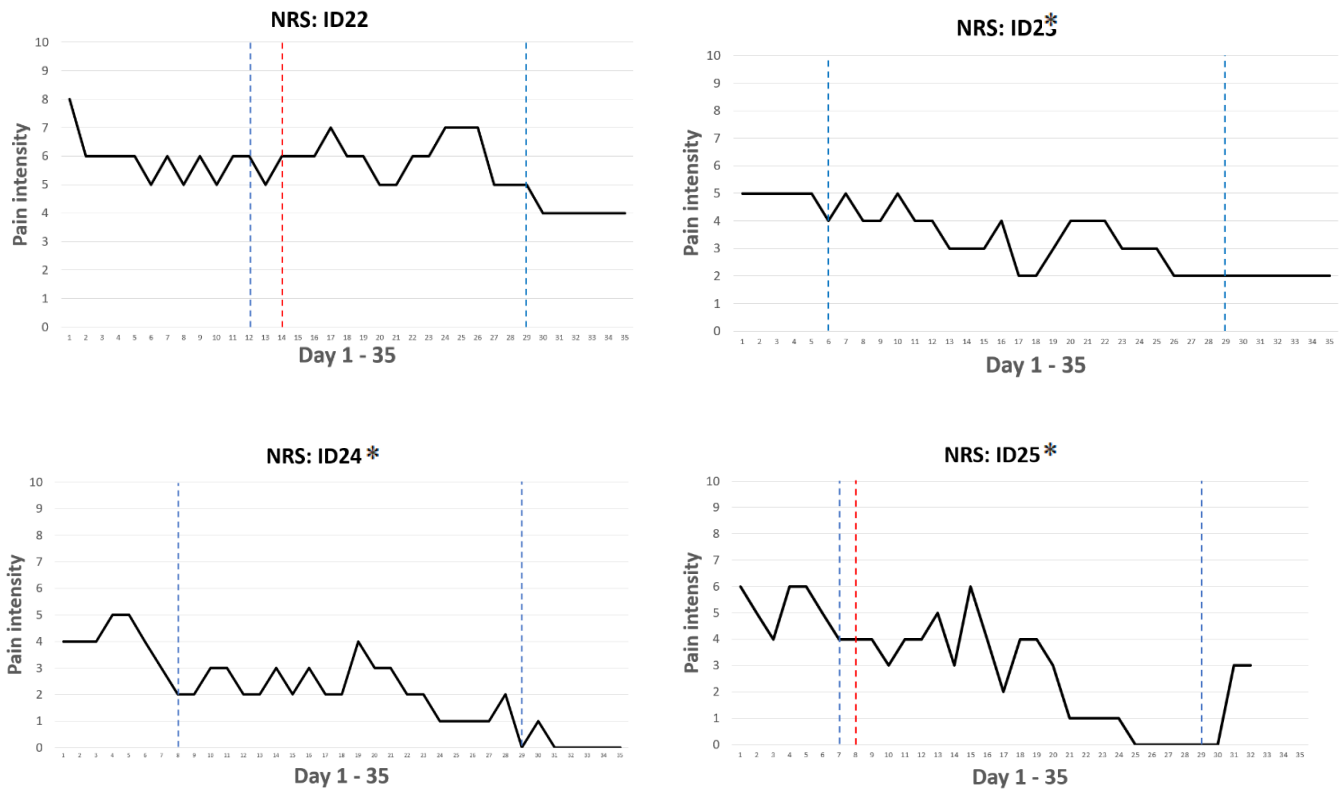
Mean ± SD or count, %:
Female: 1 (11.1%)
Age mean ± SD (range): 44.1 ± 13.2 (28-63)
Pain intensity (NRS) baseline mean ± SD (range): 4.96 ± 2.33 (range:1-9)
Demographic factor: Is the pain intensity present all the time, ID30: “yes”, other participants: “no”.
Demographic factor: Shift work: ID26: “yes”, other participants: “no”.

Table 4: Demographic and baseline characteristics. Baseline Numerical Rating Scale (NRS) is presented as mean baseline score for all participants. Pain in other body locations was derived by analysing the marked areas of pain location on a full body figure with grids.

3.2. Primary outcome measures

3.2.1. Pain intensity changes

The lme4 (Bates et al, 2012) and the R package (R Core Team, 2012) in SPSS was used to perform a multi-level, linear mixed effects analysis of the relationship between baseline and follow-up for each participant. As fixed effects, we entered pain and baseline duration (without interaction term) into the model. As random effects, we had intercepts for each subject, as well as random slopes for the effect of pain. There was a statistical reduction in pain intensity levels as a result of the intervention ($t_{9,350}$ = -4.613, p = <0.001). Specifically, the effect estimate for pain intensity (NRS) was -1.0240 (standard error = 0.22). That is, pain intensity ratings during treatment decreased by an average of 1 point on an 11-point NRS from baseline pain intensity ratings. P-values (<0.001) were conservatively derived from the t-value (-4.613) in the analysis for 8 degrees of freedom (n-1). Statistical analysis of residual plots did not reveal any obvious deviations from homoscedasticity or normality. Figure 21 shows the daily pain score ratings for each participant across the study period.



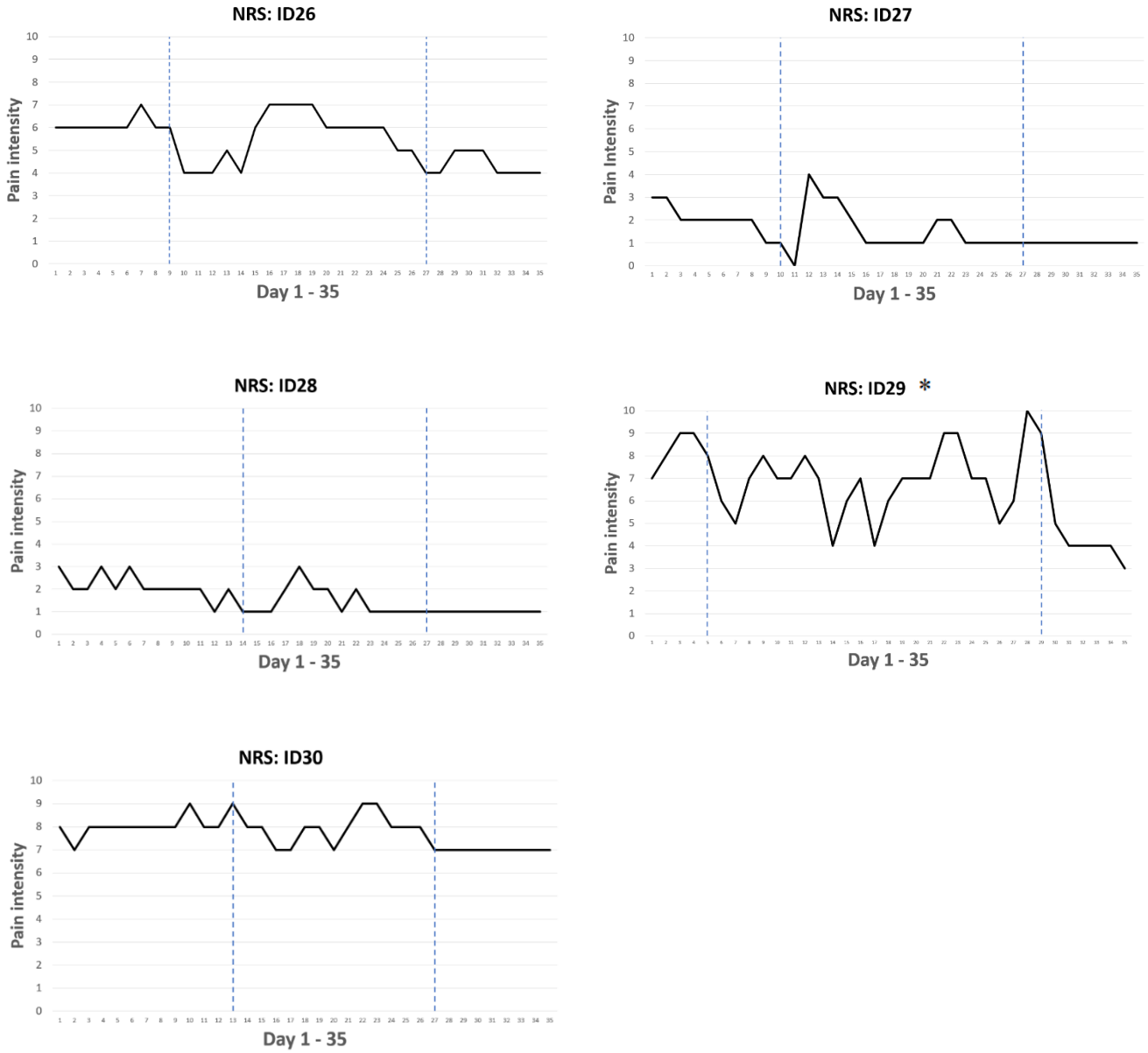


*Figure 21: Participants with a MIC for pain intensity (NRS). The dashed vertical lines in blue represents the changes between experimental phases. The first period is the baseline, the second is the treatment phase, and the third is the follow-up phase. The red dashed vertical lins represents an extended baseline duration for ID25. * = pain reduction was greater than the MIC*

In participants that achieved the MIC for pain intensity (NRS) following treatment, the individual response to treatment was variable (See Figure 21, * participants). Some participants experienced significant pain relief (ID23, ID24, ID25) while one participant had highly fluctuating pain levels throughout the study, but with a gradual reduction in pain as compared

with baseline scores (ID29). Similarly, the responses were also variable for participants (n=5) that did not achieve a reduction in pain intensity greater than the MIC for the pain NRS. Notably, all 5 participants still did experience reduced pain intensity. ID26 had large fluctuations in pain levels throughout the study, which gradually decreased by 1.71 points on NRS from baseline to follow-up. Two of the participants (ID27 and ID28) had lower mean pain intensity scores (NRS) throughout the baseline phase compared to other participants (Table 5), which may have contributed to a floor-effect in the primary analysis. In contrast, ID30 had high pain scores throughout the study and only a minimal change in NRS (1.07 points change). ID25 had total pain relief for approximately 6 days before experiencing some days of increased pain. Despite two participants (ID26 and ID27) having low NRS scores at baseline of the present study, the results for pain intensity (NRS) were still statistically significant. Further, a sensitivity analysis (indentical to above) was run excluding those two participants and there was still a significant effect of pain ($t_{7,242} = 7.416$, $p<0.001$, effect estimate -1.40, standard error 0.19). Pain intensity ratings during treatment decreased by an average of 1.4 points from baseline on a 11-point NRS.

When considering the changes in pain intensity from baseline to follow-up (7 days of pain measures post-intervention), the results suggest that the effect on pain was maintained or even increased (Table 5).

Participant	Mean baseline score	Mean intervention score	Mean follow up score	Change, (%), from baseline to intervention	Change, (%), from baseline to follow-up
ID22	5.91	5.96	4.14	-0.02 (-0.33%)	-1.77 (-29.94%)
ID23	4.83	3.23	2.00	-1.52 (-31.47%)	-2.83* (-58.59%)
ID24	3.87	2.20	0.14	-1.68 (-43.31%)	-3.73* (96.38%)
ID25	5.14	2.57	0.85	-2.57 (-50%)	-4.29* (83.46%)
ID26	6.11	5.42	4.42	-0.69 (-11.29%)	-1.69 (27.65%)
ID27	2.00	1.50	1.00	-0.5 (-25%)	-1.00 (50%)
ID28	2.07	1.42	1.00	-0.64 (-30.92%)	-1.07 (51.69%)
ID29	8.20	6.78	4.71	-1.42 (17.31%)	-3.49* (42.56%)
ID30	8.07	7.80	7.00	-0.27 (-3.34%)	-1.07 (13.25%)

*Table 5: Change in NRS scores. * = MIC for pain intensity (NRS)*

3.2.1.1. MIC on the Pain NRS

The number of participants that experienced a minimal important change (MIC) in pain intensity (defined as a NRS score reduction greater than 2.0 points (Ostelo et al, 2008) with treatment was considered. In the current sample, four out of nine participants had a pain intensity reduction greater than 2.0 points on 0-10-point NRS. Table 5 shows the participant-specific percentage change scores (Participants with a MIC for pain intensity in Figure 21 are indicated with a *).

3.2.2. Changes in pain-related fear of movement (TSK), pain catastrophizing (PCS) and pain anxiety symptoms (PASS) scores

The same statistical analysis (as per pain intensity) was performed for pain-related fear of movement (TSK), pain catastrophizing (PCS) and pain anxiety symptoms (PASS) was performed using lme4 (Bates et al, 2012) and R package (R Core Team, 2012) in SPSS. As fixed effects, we entered TSK, PCS and PASS-values and baseline duration into the model. As random effects, we had intercepts for each subject, as well as random slopes for the effect of pain-related fear of movement, pain catastrophizing and pain anxiety symptoms. There was a statistically significant reduction in pain-related fear of movement ($t_{9,347}$ = -8.670, p = <0.0005), pain catastrophizing ($t_{9,347}$ = -3.45, p = <0.005) and pain-anxiety symptoms ($t_{9,347}$ = -8.40, p = <0.0005) from receiving VR-based treatment (compared to baseline levels) for participants in the study (See Table 6 and Figure 22 for individual participant outcome).

	Changes in TSK scores					**Changes in PCS scores**					**Changes in PASS scores**				
	Mean baseline score	**Mean intervention score**	**Mean follow up score**	**Change, %, baseline to intervention**	**Change, %, baseline to follow-up**	**Mean baseline score**	**Mean intervention score**	**Mean follow up score**	**Change, %, baseline to intervention**	**Change, %, baseline to follow-up**	**Mean baseline score**	**Mean intervention score**	**Mean follow up score**	**Change, %, baseline to intervention**	**Change, %, baseline to follow-up**
ID22	44.0	40.7	14.14	-7.5%	-67.86%	16.67	13.02	9.52	-21.89%	-42.9%	35	35	35	0%	0
ID23	75.44	76.8	77.33	+1.8%	+2.5%	75.00	78.78	75.00	+5.04%	0%	88.33	85.00	85.83	-3.76%	+2.83%
ID24	55.00	52.25	53.42	-5%	-2.87%	32.14	15.41	8.33	-52.05%	-74.08%	39.28	23.50	25.71	-40.17%	-34.54%
ID25	40.85	39.80	42.43	-2.57%	+3.84%	41.67	11.50	0	-72.40%	-72.40%	47.85	23.80	5	-50.26%	-89.55%
ID26	55.33	29.75	22.00	-46.23%	-60.23%	25.00	32.45	36.90	+29.8%	+47.6%	77.85	77.89	80.00	0%	+2.76%
ID27	33.00	33.00	33.00	0%	0%	8.33	8.33	8.33	0%	0%	25.71	3.33	0.71	-87.04%	-97.2%
ID28	33.00	11.00	11.00	-66.67%	-66.67%	0	0	0	0%	0%	12.85	0	0	-12.85%	-12.85%
ID29	0	0	0	0%	0%	8.33	2.17	0	-73.94%	-73.94%	35.00	20.00	8.00	-42.85%	-77.1%
ID30	55.00	46.93	44.00	-14.67%	-20%	0	0	0	0%	0%	65.71	67.66	60.00	+2.96%	+8.68%

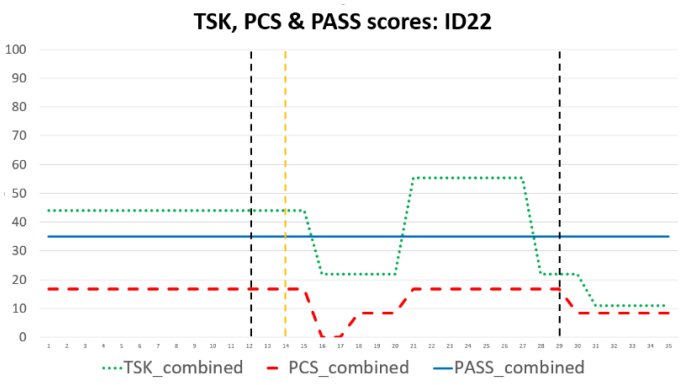
Table 6: Changes in pain-related fear of movement (TSK), pain catastrophizing (PCS) and pain anxiety symptoms (PASS). Reductions in TSK, PCS or PASS scores are marked with lighter green backgrounds, while ≥30% reduction from baseline is marked with darker green backgrounds.

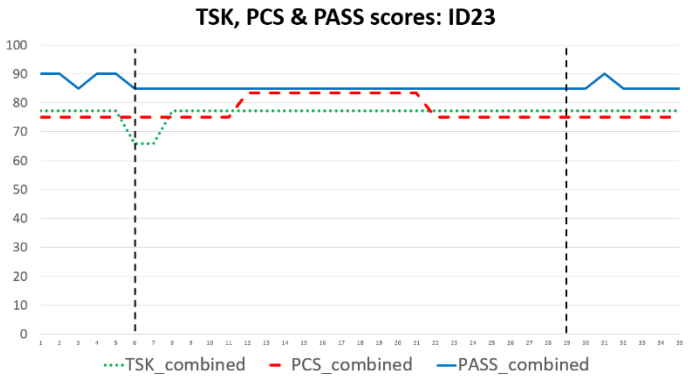
The effect of treatment on pain-related fear of movement (TSK) was -7.9 (standard error = 0.91) for participants in the study. That is, TSK scores during the intervention decreased, on average, by 7.9 points from baseline scores. Statistical analysis of residual plots did not reveal any obvious deviations from homoscedasticity or normality. The P-value (<0.0005) was derived from the t-value (-8.670) with 9 degrees of freedom. Two participants showed more than a 30% reduction in TSK scores from baseline (See Table 6).

The effect of treatment on pain catastrophizing was -3.2 (standard error = 0.93) for participants in the study. That is, PCS scores during the intervention decreased, on average, by 3.2 points from baseline scores. Statistical analysis of residual plots did not reveal any obvious deviations from homoscedasticity or normality. The P-value (<0.005) was derived from the t-value (-3.453) with 9 degrees of freedom. Three participants showed more than a 30% reduction in PCS scores from baseline (See Table 6).

The effect of treatment on pain-anxiety symptoms scale (PASS) was -9.8 (standard error = 1.2) for participants in the study. That is, TSK scores during the intervention decreased, on average, by 9.8 points from baseline scores. Statistical analysis of residual plots did not reveal any obvious deviations from homoscedasticity or normality. The P-value (<0.0005) was derived from the t-value (-8.404) with 9 degrees of freedom. Five participants showed more than a 30% reduction in TSK scores both from baseline (See Table 6).

When considering the changes in TSK, PCS, and PASS from baseline to follow-up (7 days of pain measures post-intervention), improvement was maintained or increased. Table 6 provides a breakdown of the percentage that TSK, PCS, and PASS ratings changes between baseline and the intervention period and between baseline and the 7-day follow-up period.





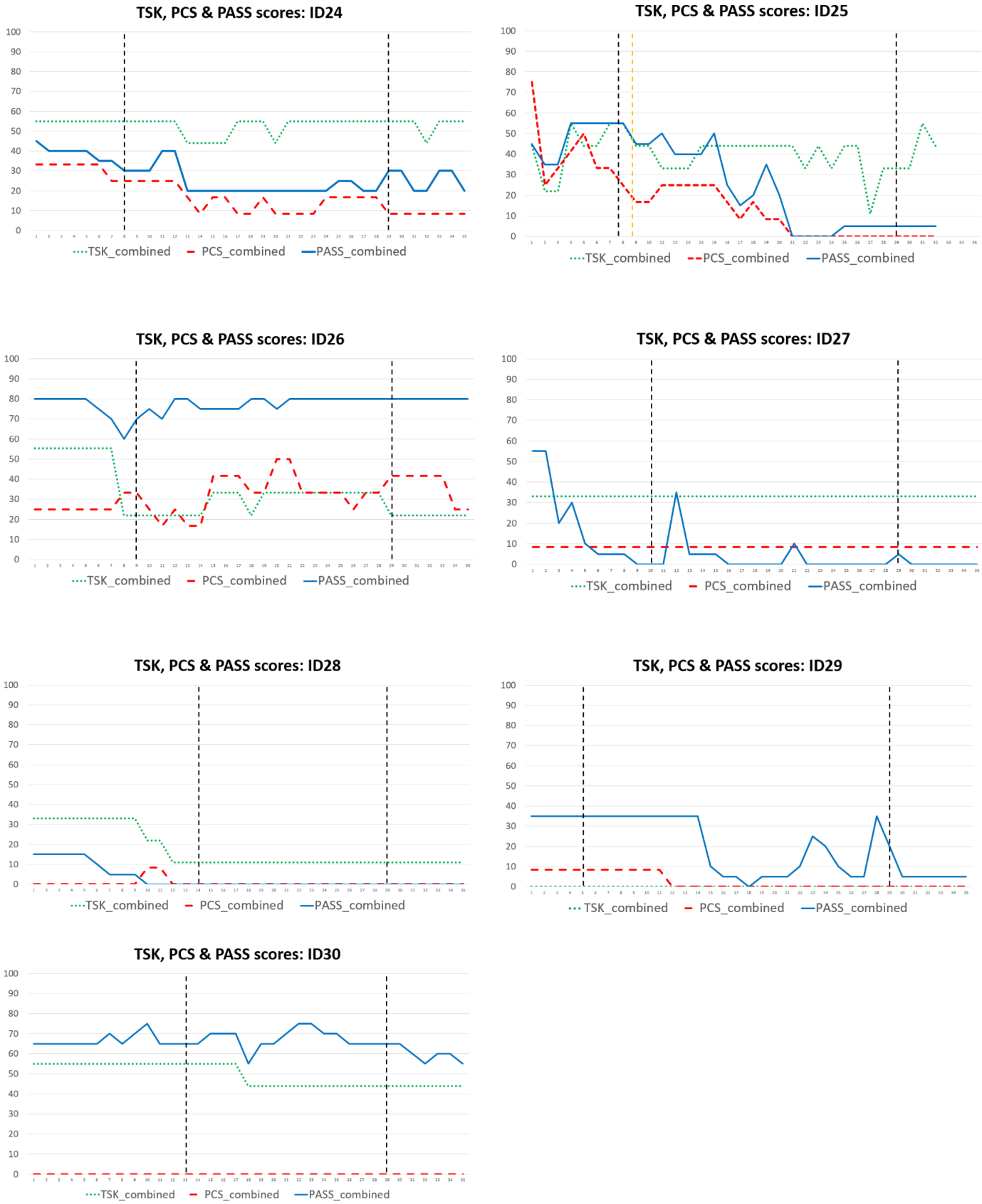


Figure 22: Change in pain-related fear of movement (TSK), pain catastrophizing (PCS) and pain anxiety symptoms (PASS) for all participants. The dashed black vertical lines represent the changes between experimental phases: baseline, treatment, and follow-up phase. The dashed orange vertical line represents an extended baseline duration for ID22 and ID25.

3.2.2.1. Clinically meaningful changes for TSK, PCS, and PASS ratings

As shown in Table 6, results for TSK, PCS and PASS scores had a large variation. While some participants had an increase in TSK, PCS or PASS scores from baseline, the overall trend was a reduction in scores between baseline, intervention and follow-up. ID25 showed the greatest overall reduction when combining all three measures. In summary, three participants had a meaningful change (≥30% reduction) for pain-related fear of movement (TSK), four participants had a meaningful change for PCS, and five participants had a meaningful change for PASS. As visually depicted in Figure 22, ID25 showed the most obvious connection to phase shift when the VR-based intervention was introduced. Nevertheless, all participants showed a statistically significant effect for pain-related fear of movement (TSK), pain catastrophizing (PCS) and pain anxiety symptoms (PASS). A full overview in Figure 22.

3.2.2.2. Change in pain NRS related to number of VR-trainings

Since the number of VR-interventions were randomized between participants, we were also interested in investigating whether the duration of the pre-treatment phase (i.e. baseline) and the number of interventions led to a more nuanced result for pain intensity (NRS) ratings. Table 7 shows that participants who had a shorter pre-treatment phase (5-8 days) and a higher dosage of VR-trainings (8 or 9) had a MIC. The remaining participants who did not have a MIC, had longer pre-treatment phases (10-14) and a lower dosage of VR-training. Meanwhile, ID26 had an 'intermediate' pre-treatment phase (9 days) and dosage of VR-trainings (8 VR-trainings), but no MIC (although close at -1.69). A discussion on these results are provided in subsection 4.2.1.

ID	Duration of baseline (days)	Number of interventions (descending number)	NRS change from baseline to follow-up
25	7	**9**	-4.29* (83.46%)
29	5	**9**	-3.49* (42.56%)
23	6	**9**	-2.83* (-58.59%)
24	8	**8**	-3.73* (96.38%)
26	9	8	-1.69 (27.65%)
22	12	7	-1.77 (-29.94%)
27	10	7	-1.00 (50%)
30	13	6	-1.07 (13.25%)
28	14	6	-1.07 (51.69%)

*Table 7: The implication of number of VR-trainings on pain intensity (NRS) reduction. The table shows that participants with 8 or 9 VR-trainings had a greater reduction in NRS score. * = MIC for NRS.*

3.3. Secondary outcomes measures

In the secondary outcome measure analysis, a comparison of scores from baseline to follow-up (post-intervention) was performed. The change in outcome for each participant was calculated as a percentage improvement for ODI, ÖMPSQ short form, FreBAQ and Recognize™ from baseline. Change scores are presented in Table 8, while a full overview of scores for secondary outcome measures can be found in Appendix 7 and Appendix 8. Unfortunately, one questionnaire, PSFS, had to be excluded from the analysis due to missing data at follow-up (Appendix 9). Of all participants in the present study, ID25 was the only participant with a MIC in pain intensity (NRS), and ≥30% reduction in pain catastrophizing (PCS), pain-anxiety symptoms (PASS), and reduced scores in all secondary outcome measures.

	ODI	**ÖMPSQ short form**	**FreBAQ**	**Recognise ™**			
	Change, %	Change, %	Change, %	Speed, left	Speed, right	Accuracy, left	Accuracy, right
ID22	-14%	-13.5%	-75.2%	+47%	-59%	+30%	-20%
ID23	-4%	-19.3%	-31.3%	+60%	-15%	0%	-15%
ID24	-14%	-26.1%	+29.0%	+20%	-11%	+5%	0%
ID25	-18%	-20.0%	-79.2%	-34%	-10%	+30%	+25%
ID26	-18%	+7.6%	+25.1%	+11%	-29%	+5%	-5%
ID27	-4%	-33.3%	-90.0%	-19%	-27%	-5%	-25%
ID28	-2%	+23.8%	0.0%	-11%	-17%	+5%	+5%
ID29	+2%	-17.2%	-12.3%	-22%	-55%	-15%	-25%
ID30	+12%	-7.1%	+44.0%	-25%	-25%	0%	-10%

Table 8: Secondary outcome measures: change (%) from baseline. Reduction in ODI, ÖMPSQ short form, FreBAQ and Recognize ™ scores are marked with lighter green backgrounds, while reductions (≥10% for ODI, and ≥30% for the remaining questionnaires) from baseline is marked with a darker green backgrounds.

3.3.1. Oswestry Disability Index

In total, 7 out of 9 participants had a reduction in ODI scores. Four out of 9 participants (ID22, ID24, ID25 and ID26) showed a MIC, i.e. 10% reduction in ODI score from baseline to follow-up (Fairbank & Pynsent, 2000). One participant (ID26) moved from the category 70% disability (crippled) at baseline to 52% (severe disability) at follow-up. A complete overview of the change scores can be found in Appendix 7.

3.3.2. Örebro Musculoskeletal Pain Screening Questionnaire - short form

ÖMPSQ short form ranges between 1-100, and a score ≥50 indicates higher estimated risk for future work disability (Linton, Nicholas & MacDonald, 2011). In total, 7 out of 9 participants had reduced ÖMPSQ short form scores at follow-up. Only ID27 had a ≥30% reduction for ÖMPSQ short form from baseline to follow-up. Two participants (ID23, ID29) went from above, to beneath, the original cut-off score (50/100) throughout the course of the study (See Appendix 7 for more details).

3.3.3. Fremantle Back Awareness Questionnare

Analysis of the FreBAQ questionnaire data showed variable outcomes when comparing baseline and follow-up. In total, 5 out of 9 participants showed a reduction in score, while 4 out of 9 showed a ≥30% change in FreBAQ score from baseline to follow-up. However, the change scores showed high inter- and intra-case variance, with no consistent direction or trends towards a negative or positive change across all 9 participants. Full data is provided in Appendix 7.

3.3.4. Recognise™

The Recognise ™ data showed variable outcomes, as shown in Table 8, with the exception of performance on "Speed: right side images", which showed a consistent reduction across all 9 participants. Data for "Speed left side" and "Accuracy left side" and "Accuracy right side" did not show any particular trends. Full data is provided in Appendix 8.

3.4. Compliance with baseline, intervention and follow-up phases

Significant effort was made to fit participants' schedules into the present research design that involved randomising participants to a variable baseline and intervention duration. With some minor adjustments, most participants' baseline and intervention phases occurred as randomised. The randomised baseline duration was implemented for all participants, except for two, who were delayed by 1 and 2 days (Table 9). All participants received their randomized number of

interventions (between 6 and 9) within the first 28 days of the study as planned. For the 7-day follow-up, all participants filled in daily measures for at least 35 days as planned. However, due to unforeseen events (work-related issues, vacations and illnesses), some participants were unable to meet again at day 35. This resulted in some additional "daily measures" and secondary measure assessment was delayed (ranging from 1-5 days) for some participants.

		Baseline duration		**Baseline + intervention duration**			**Follow-up duration**	
	Start	**Plan**	**Actual**	**Plan**	**Actual**	**I***	**Plan**	**Actual**
ID23	08.01.18	6 days	6 days	28 days	28 days	9	7 days	12 days*
ID26	09.01.18	9 days	9 days	28 days	28 days	8	7 days	10 days*
ID24	23.01.18	8 days	8 days	28 days	28 days	8	7 days	9 days*
ID28	26.02.18	14 days	14 days	28 days	28 days	6	7 days	7 days
ID22	19.02.18	12 days	14 days*	28 days	28 days	7	7 days	8 days*
ID25	26.02.18	7 days	8 days*	28 days	28 days	9	7 days	7 days
ID30	23.02.18	13 days	13 days	28 days	28 days	6	7 days	7 days
ID29	09.04.18	5 days	5 days	28 days	28 days	9	7 days	9 days*
ID27	15.04.18	10 days	10 days	28 days	28 days	7	7 days	7 days

Table 9: overview over baseline, intervention and follow-up phase. Note: =discrepancy and planned and actual phase duration marked in red.*

3.4.1. Side effects

Participants did not report any side effects during VR training. One participant (ID26) expressed that he did not feel that the VR training was relevant to the specific complaints that he had in ADL. This remains one of the challenges with the novel intervention provided in the present study, which must be addressed in future research.

4.0. Discussion

Overall, this study found that a VR-training program resulted in significant reductions in pain intensity (NRS), pain-related fear of movement (TKS), pain catastrophising (PCS), and pain anxiety symptoms (PASS) in people with persistent LBP. These improvements were maintained or improved following treatment completion (7-day follow-up). This section will discuss the influence of methodological features on the study findings and how this impacts the interpretation of the present results. Further, this section will discuss the findings, comparing the present results to previous literature in the area. Last, this section will discuss the overall study strengths/limitations, discuss the implications of this work to future research directions, and last, provide a clinical perspective based on these results.

4.1. Methodological features: influence on the study findings and their interpretation

4.1.1. Influence of study design

When deciding which study design to implement, performing an SSED or a pilot-RCT were the two primary design candidates to choose between. An SSED was eventually chosen given the need for a study design to investigate the use of new type of technology, software and protocol. The benefit of an SSED is that it allowed us to follow participants with daily measures throughout the intervention using a rigorous research method and statistical analysis, as seen in other pilot studies developing psychological treatments for pain and medicine (Morley et al, 2015). The study design also provided insight via daily pain measures on the effect of an innovative approach (VR) that eventually aims to provide highly cost-effective interventions in the field. Having detailed information about such an intervention is important, given that meta-analysis have shown that compared with no treatment or treatment as usual, psychological, physical, and pharmacological treatments for persistent pain can be effective, but the effects are small (Morley et al, 2015); thus rich information about a new intervention can help guide refinement. Additionally, the study design satisfied the practical needs for a master's project that has a limited time frame, particularly given the challenges that accompany development of a new treatment using innovative technology. For example, as part of the Masters, we needed to borrow VR-equipment for the study, find appropriate software and IT-competence, develop a protocol for the study, find a test location that matched the technical demands, and recruit and test participants. However, limitations relevant to the design exist: we do have measures of

effect size relevant to a control group (and thus external generalizability) that occur with RCT's (the "gold standard" design).

The present phase 2a clinical trial (i.e. proof of concept study), evaluated the efficacy (and side effects) of VR training in people with persistent LBP. Use of this study design, thus allowed us to provide proof of concept evidence that VR training results in a statistically significant reduction in pain intensity (NRS), pain-related fear of movement (TSK), pain catastrophizing (PCS) and pain-anxiety stress symptoms (PASS), and that we therefore could reject the null hypothesis (H0). If this intervention was to be further investigated, the next step would be to perform a phase 2b clinical trial whose aim is to determine the correct therapeutic dosage of interventions. As will be discussed further in subsection 4.2.5., the present study demonstrated that a higher dosage (≥8) of VR-sessions compared to Thomas et al.'s feasibility study (2016) may be beneficial to achieve a statistically significant effect. Further, a phase 3 clinical trial, would be relevant to compare the VR-intervention with another treatment alternative using a between-subjects design (Cancer Research UK, 2015, National Health and Medical Research Council, Australia, 2015). We found it reasonable and ethically sound to skip the first testing phase for clinical trials (i.e., testing the protocol on healthy participants,) since the protocol we developed could be easily adjusted to provide different levels of exposure to movement to ensure that participants were not placed in situations that could be harmful.

4.1.2. Considerations relevant to participants recruited

Participants were screened by a rehabilitation team consisting of general practitioners, physiotherapists, occupational therapists and nurses at the Outpatient Spine Clinic from Haukeland University Hospital, Bergen. Participants are therefore representative of the type of LBP patients commonly seen in primary health care. This provides us with confidence that our results are relevant to patients that are seeking care for their LBP. The sample was heterogenous with varying age, education level, duration of LBP (≥3 months) and duration of sick-listing due to LBP. Most participants were men (89.9%), which is merely an unintended result of consecutive sampling of patients entering the Outpatient Spine Clinic in the time period January to June 2018, since we did not randomise participants for enrolment in the study. As we continue to rely more on games for education and training in health care, software developers need to ensure that future health technology games are attractive and motivating for both men and women of all ages (Veltri et al, 2014).

4.1.3 Inclusion and exclusion criteria

All inclusion and exclusion criteria were upheld according to the protocol (Subsection 2.4, Table 1), with two exceptions, 1) one of the included participants' NRS score was too low (did not meet formal eligibility criteria), and 2) minor adjustments in the eligibility cut-off score on TSK-11 were made to ensure sufficient participant recruitment.

Ten participants were recruited for the study, nine were considered eligible for data analysis. One participant (ID21) was excluded from data analysis due to low pain intensity (NRS) score (1/10) at baseline (Appendix 6). Further, all remaining nine participants had 4/10 on NRS at screening at the Outpatient Spine Clinic. However, for two participants, the pain intensity had continued to drop from screening and throughout enrolment in the study, which means that ID27 had a mean baseline score of 2.0 points, and ID28 had 2.07 points (Table 5, Subsection 3.2.1.). This may have led to less variable scores throughout the study, and a potential "floor effect" compared to other participants. In Figure 21, these two participants account for two of the five participants who did not show any MIC for pain intensity. Although we discussed excluding the participants from the analysis, we chose to include them in the analysis since they had 4/10 at screening at the Outpatient Spine Clinic. We did, however, perform a sensitivity analysis without these two participants, and showed that pain intensity is still significantly reduced with VR training.

Additionally, the original aim was to include highly kinesiophobic LBP patients (≥42/52). However, upon discussions with the recruiting clinic, it became evident that the Outpatient Spine Clinic have had very few participants who scored severe on TSK-11 (≥42/52) over the past years, an adjustment of the inclusion criterion was considered necessary. As suggested by the Outpatient Spine Clinic (and based on clinical experience), we altered the minimum score to ≥25 on TSK-11 (25/52) – thus including participants with mild, moderate and severe levels of kinesiophobia. Subsequently, five participants had a mild level of kinesiophobia, and four had moderate levels of kinesiophobia. None of the participants had subclinical levels (≤22/52). (Appendix 10).

4.1.4. Considerations relevant to the procedure for data collection and outcome measures (and their assessment)

The purpose of any experiment is to rule out plausible rival hypothesis or threats to internal validity (Cook & Campbell, 1979), such as history and maturation bias or statistical regression to the mean, familiarity with testing, and/or error with instrumentation. In an SSED, the use of standardized outcomes with known psychometric characteristics allows for determination of whether a person has made a reliable change and whether the change is significant (Jacobson et al, 1999). However, the SSED cannot rule out other threats to the validity (Morley et al, 2015). The essence of a single-subject design is the repeated assessment over time of a target outcome and the manipulation of treatment condition (Morley et al, 2015). Specifically, an AB-phase design requires a minimum of three measurement occasions per phase (Kratochwill et al, 2010) which was successfully carried out across all participants. In addition, we selected specific outcomes that are functionally related to the treatment (Morley et al, 2015). In the present study, a representation of "highly salient items from standard questionnaires" (Morley et al, 2015) was chosen to track viable variables of fear and catastrophizing (similar to methodology used by Vlaeyen et al, 2012 and de Jong et al, 2012). A large database of patients with persistent musculoskeletal pain showed that the internal consistency of primary outcome measure subscales was sufficient to good (Chronbach a = 0.60, 0.72, and 0.73) for TSK, PCS and PASS, respectively (Roelofs et al, 2004).

Participants were instructed to complete all daily measures (via self-report questionnaires) at the same time point each day: 8 p.m. every night. The approach has been shown sensitive to graded exposure therapy in previous studies (de Jong et al, 2005a; 2005b; 2008, Vlaeyen et al, 2001; 2002a; 2002b), and although not tested for VR-interventions yet, the approach was evaluated as the most viable alternative to date. Consequently, participants were given 2-3 daily measure forms after each VR-training session, which they had to return to MS and TFL at the next appointment. Such regular check-in with the researchers ensured low levels of missing data. Further, participants adhered to the treatment schedule and appointments as planned. Only two participants had a prolonged baseline-period, of 1 and 2 days. As depicted in Table 9, all participants adhered to the 28-day schedule, while some participants had more than 7-days follow-up. ID22 and ID25 had a 2 and 1-day prolonged baseline, respectively. Five of the participants had an extended 7-day follow-up period (1-5 days) due to a number of reasons which we could not control, including work-related issues, illness, vacation and other reasons. All secondary outcome measures were collected successfully within a satisfactory time frame.

We are open to the possibility that collecting daily measures may be exhaustive as participants had to fill in 11 questions every day. This may be a particularly concern for pain intensity scores (NRS), which may prime the participant to focus on pain intensity every day, and thus may not be beneficial from a clinical perspective. Further, a current trend that may be discussed in future studies is whether we should rather focus on improvements in disability levels (i.e. scores related to ADL), because pain levels tends to come and go, occur in "flare-ups", or sometimes be somewhat unpredictable for persistent LBP patients. However, the use of daily measures was considered ethically sound and necessary in the present study to adequately analyse how the participants responded to a new intervention. In the novel context of VR-training, it was also important to understand the daily fluctuations, as opposed to only seeing pre- and post-measures, and long-term follow-up.

Most participants filled in the forms without asking for help. However, we included one questionnaire in English (FreBAQ) in the secondary outcome measures, which led to need for translation and interpretation from some of the participants. We also included Recognise™, which seemed to work very well amongst the younger participants, but the older participants struggled with understanding the task at hand. This should be taken into consideration when looking at the results, and for future studies. Emphasis should be put on providing a careful explanation for all participants, ensuring that the task is well understood.

Further, the two testing points for secondary measures were 5 weeks (35 days) apart, implying that there is a minimal risk of recall bias (i.e. that participants remembered which answer they gave at the different questionnaires). De Vet et al. (2015) suggests that the ability to recall a pain state accurately may be significantly reduced two weeks after the initial assessment. It should be noted that most of the data collection was completed and all the interventions were provided by MS and TFL. Participants could therefore have experienced response bias when filling out questionnaires, due to the double role MS and TFL had in the study (i.e., not wanting to let the clinician know that a treatment was not helpful). However, none of the participants had any former relationship to the researcher MS or TFL, which does reduce the chance of this response bias. For future studies, a research assistant responsible for carrying out the intervention is preferable.

4.1.5. Considerations related to responsiveness of outcome measures

When selecting assessment outcomes, researchers face the challenge of choosing between a myriad of objective and subjective assessments. Responsiveness of a measure to changes in status generally involve identification of a true change in the underlying construct of interest (Carter & Lubinsky, 2017). In the present study, NRS was selected over visual analogue scale (VAS) for pain intensity due to better psychometric properties. Specifically, previous studies have shown that NRS has been found to be a reliable scale in terms of inter- or intra-rater repeatability and its ability to detect change (Bijur et al, 2001; Boonstra et al, 2008; Hawker et al, 2011). Further, Ostelo et al. (2008) and Wright (1996) argues that a statistical significance does not necessarily mean that the change is clinically important. MIC values depend not only on empirical evidence but also on clinical interpretation and judgement (Ostelo et al, 2008). Therefore, we were also interested in the clinical relevance of the intervention, using MIC as an assessment outcome. A 30% improvement from baseline is considered a useful threshold for identifying clinically meaningful improvement for NRS (Ostelo et al, 2008). Although MIC is only validated for NRS and ODI in this context, we replicated the approach to investigate whether there was a MIC for TSK, PCS, PASS and the remaining secondary outcome measures. The authors of the study acknowledge the limitation with this approach, however; the study design is well suited for looking at clinical important changes across each participant. The final tenet related to responsiveness is that the TSK, PCS and PASS-items were collected as Likert scales (with 4, 5 and 6 questions, respectively), and subsequently transformed to percentage agreement (0-100) in order to be fitted into the linear mixed model analysis. One might argue that if we collected the items as numeric rating scales instead of Likert scales, it may have influenced the responsiveness of the questionnaires. However, converting the Likert scale to 0-100 is not inconsistent with past research in this area.

4.1.6 Considerations relevant to the statistical analysis

In the present study, a sequential randomized and replicated single-subject experimental phase design with multiple measurements was analysed using a fitted linear mixed model (also referred to as a multilevel model) in lme4 with the R package in SPSS. The design and the analysis have the advantage of being valid for single-subject experiments, of being easy to apply, and for being versatile for even the most complex single-subject designs (Onghena & Edgington, 2005b). Although some researchers may prefer randomisation tests over linear

mixed effect analysis, the latter was considered the best approach when analysing the data set in the present study. The multilevel model regards the replicated case series data as "nested data". So individual measurement occasions are nested in cases and the model takes into account that the measurement occasions are not independent of the person in which they are measured. The analysis computes a t-value based on the difference between baseline measures (programmed as 0 in the R-package and lme4) to intervention measures (programmed as 1) across all nine participants. The p-value is thereafter derived from a t-table (Appendix 5), depending on degrees of freedom. A randomisation test would perhaps address this limitation, as the analysis is more preferable as it makes less assumptions about the data. However, randomization tests are less flexible in terms of detecting an effect when the data show unexpected characteristics (i.e. high inter-subject variability, gradual treatment effects, trends, etc.), which makes linear mixed models better equipped to handle such complex data sets. In brief, that we used an analysis that takes into account interdependence of an individual's scores as well as one that uses all available data (all daily scores regardless of differences in numbers between participant – e.g., different baseline and treatment durations), provides confidence in the study's results.

In our statistical analysis, we have depicted all daily measures in graphs showing daily changes in NRS, TSK, PCS and PASS. While we did not use the graphs to infer statistical effects of the intervention, they are useful tools to see daily fluctuations for each participant.

4.1.7 Ethical considerations

This study was approved by the regional ethics committee (2017/REK Vest/1199) 13.06.2017, and has been performed in a sound ethical and professional way. It has not been possible for MS or TFL to connect the ID-numbers received from the Outpatient Spine Clinic with participants' names or other personal factors. Only JSS had the key to unlock this code at the Outpatient Spine Clinic, and all VR interventions were carried out at a different location. For future studies, a larger team with a research assistant blinded to treatment group (or, in this case, phase of the study) is preferable, but for this master's project, this was not possible.

All participants who were included in the study volunteered to participate after receiving written and oral information about the study. To ensure a thorough follow-up of all participants, the participants were offered a further follow-up in primary health care after the data collection was

completed (day 35), and MS was responsible for referring them back to the Outpatient Spine Clinic. Two participants (ID29 and ID30) decided to take this offer, because they still had a high pain levels and/or disability throughout the study, and accordingly when the present study was over, they were interested in accessing further primary health care services provided by the Outpatient Spine Clinic. Considering that the intervention was only five weeks long, and that participants had been screened by a whole team and evaluated as safe to start exercising prior to entering the VR study, and that participation was voluntary, the study was considered ethically sound. Finally, the study was considered an innovative and potentially important pilot study for the Outpatient Spine Clinic, who specialized on treatment on this patient group.

4.2. Discussion and implications of the study results

4.2.1. Primary outcome measure: Pain intensity (Numerical Rating Scale)

This study found that pain intensity decreased by 1 point across all participants on an 11-point NRS during the VR intervention. Further, when considering the percentage change in scores between baseline and follow-up, improvements were maintained or increased in all participants. We were interested in whether the changes were reliable and statistically significant, and how the nine participants responded to the intervention. With the current design, we account for the number of days where the participants did not receive any intervention, versus the time period where they did. Hence, a reduction of -1.0 points represents the reduction across participants when accounting for a randomised baseline. In this way, we have strengthened the internal validity (i.e. maximized the design) of the study as much as possible.

In the present study, four out of nine participants showed a MIC for pain. Of the remaining participants who did not have a MIC, two participants (ID27 and ID28) had decreasing pain intensity (NRS) levels during the baseline period, which may have caused a “floor effect” due to history, maturation or statistical regression to the mean. ID27 and ID28 were included in the primary data analysis, despite having low baseline scores because they did have 4/10 at screening at the Outpatient Spine Clinic. Indeed, when these participants were removed from the analysis (sensitivity analysis), pain intensity was still significantly reduced and pain intensity levels reduced by an average of 1.4 points. ID26 did have a pain intensity reduction, but not sufficient to be classified as a MIC.

On the opposite side of the scale, ID30 only showed high pain rating throughout the study, only a 1.07-point reduction in NRS, and little overall change in both primary and secondary outcome measures. Surprisingly, ID30 also experienced increased disability (+12% on ODI) at follow-up (Day 35). One may speculate whether this patient had a more acute pain characteristic compared to other patients and that the VR training triggered unfavourable responses. Also, in contrast with the other 8 participants, ID30 was sick-listed for LBP for the first time, in contrast to others who had been sick listed 10 or more times for the same complaint. If we look to Kongsted et al.'s (2016) suggested principal trajectories, ID30 may be classified as having severe intensity (between 6-10 on NRS), persistent pain (as opposed to fluctuating, episodic or a single episode) with less than 1.0-point NRS variability over the course of 4 days, and no change pattern (as opposed to rapidly improving, gradually improving or progressive pain). Other participants show trajectories associated with fluctuating variability, or rapidly or gradually improving pain (Kongsted et al, 2016). Importantly, individual factors such as pain characteristics, time aspects and loading responses are therefore important components to consider when implementing VR as a tool in clinical practice.

As shown Table 7 (See Subsection 3.2.2.2.), four participants had a MIC for pain intensity reduction. Interestingly, all four participants that achieved MIC for pain reduction were those randomised to a longer intervention phase, thus receiving the highest intervention dosage (8 or 9 VR-training sessions) possible. Participants whose pain reduction did not exceed the MIC for pain were the ones randomised to a longer baseline duration (pre-treatment phase: 9-14 days) and thus, a lower dosage (6 or 7 VR-training sessions). The only exception to this was ID26 who had 8 VR-training sessions (and a pre-treatment phase of 9 days), and pain reduction did not reach MIC (although it was close at -1.67). While not formally evaluated, such findings suggest that treatment dosage may be important. These findings may also explain why our study results showing a significant reduction in pain differed from that of Thomas et al. (2016) in which no significant effects on group change on expected pain or expected harm was observed. Thomas et al. (2016) had LBP participants perform only 3 VR-training sessions of 15 minutes each, and argue that their findings were not surprising given that graded exposure therapy for pain-related fear for persistent LBP patients usually consists of 8-12 treatments (as cited in Thomas et al (2016): Boersma et al, 2004; Leeuw et al, 2008; Linton et al, 2008; Woods & Amundson, 2008). While the Thomas' study and our study also differed in the nature of the intervention protocol (i.e. they had a semi-immersive virtual environment (i.e. 3D-TV) while we used fully immersive VR-games in Oculus Rift), the intent of the VR games was similar in

both studies – to promote increased movement into trunk flexion and other trunk movements. Thus it is more likely that a higher dosage (6-9 VR-training sessions of 30 minutes in the present study vs 1-3 training sessions of 15 minutes in Thomas et al. 2016) may be behind the differing effects seen here. Therefore, this study adds value in the field by showing that a higher dosage of VR-training sessions with fully immersive VR-technology demonstrated a statistically significant effect on pain intensity (NRS), pain-related fear of movement (TSK), pain catastrophizing (PCS) and pain anxiety symptoms (PASS). However, more research is needed to investigate how to optimize graded exposure training in VR for persistent LBP patients.

4.2.2. Primary outcome measures: Pain-related fear of movement (TSK), pain catastrophizing (PCS) and pain anxiety symptoms (PASS)

The present study also suggests that pain-related fear of movement (TSK), pain catastrophizing (PCS) and pain anxiety symptoms (PASS) are statistically significant reduced with VR training. The analysis of changes in TSK, PCS and PASS show that the reduction is small, and most participants do not have scores that are a 30% reduction from baseline scores. Only ID25 showed a clinically meaningful reduction for TSK, and only ID22 showed a meaningful reduction for PCS and PASS. Additionally, the graphs for TSK, PCS and PASS show high intra-case variability across participants (Figure 22).

With regards to the aforementioned outcome measures, two pressing questions are: 1) Do the questionnaires used in the present study reflect the construct we are trying to assess changes in (i.e. what is the construct validity and responsiveness?), and 2) If pain and fear are complex intertwined emergent properties, would objective measurements (i.e. self-reported questionnaires) be the best way to describe a subjective embodied experience? To discuss the first question, we may look to Lundberg et al. (2011), who wrote that questionnaires investigating pain-related fear of movement, kinesiophobia, fear-avoidance beliefs and so forth were all developed earlier than the emergence of the Fear-Avoidance Model by Vlaeyen in 1995. One may therefore wonder what the underlying conceptual framework for all these questionnaires are, and the authors of the critical review argue that in most cases, the conceptual framework is missing. Lundberg et al. (2011) concluded that the weak construct validity implies that no measure can currently identify who is fearful, and that the lack of evidence for responsiveness restricts current use of the instruments to identify clinically relevant change from treatment (Lundberg et al, 2011). These are important suggestions to take into account

when investigating pain-related fear of movement in LBP participants. To date, only one study (which is not yet peer-reviewed) has looked at the neural correlates that underlie the different constructs (Meier et al, 2018), and more research in this field is likely to follow.

To discuss the second question, we might touch upon the relevance of implicit evaluations of danger and safety (Moseley & Butler, 2016). Contemporary pain science theories propose that pain and fear are dependent on implicit evaluations of danger to the body, and that thoughts or beliefs such as "lifting something heavy may cause more damage to my lower back" or "the severe pain I'm experiencing must indicate that something is terribly wrong with my back" may sometimes represent implicit (unconscious) and not explicit evaluations (information that need conscious reflection, that you are aware of, and willing to disclose) (Fazio et al, 2003; Greenwald et al, 1998; Leeuw et al, 2007; Van Ryckeghem et al, 2013). Another question is whether these implicit evaluations may drive behaviour in an adaptive (e.g. health-promoting) or maladaptive (e.g. fear-avoidant) direction. This raises two points; whether there is a presence of self-protect bias, meaning that participants may be hesitant to reveal sensitive information about themselves, and whether the best way to evaluate pain-related fear of movement is via of self-report questionnaires. Thus, more research is needed to investigate whether existing self-report questionnaires are adequate for clinical and research purposes when looking into pain-related fear of movement. One recent study by Caneiro (2017), investigated physiological responses (i.e. eye-blink reflex, startle response and skin conductance) in relation to images perceived as "dangerous" (i.e. lifting with round back) to LBP patients, but no connections were found. It may be argued that pain-related fear of movement is a very context-dependent state-type of fear, which is indeed hard to conceptualize, and equally, challenging to detect with the measurement tools currently available.

4.2.3. Secondary outcome measures

In the present study, four secondary outcome measures were collected at Day 1 and Day 35 for all participants. More specifically, we found that 4 out of 9 participants met the MIC for the ODI, which is interesting considering that the interventions only ranged between 6 and 9 treatments applied over 14-23 days. ODI is an important clinical measure, because changes in disability may be a more stable measure than daily fluctuations in pain. Disability levels represents changes in function in ADL, such as getting dressed, sitting or standing, but it also has to do with social aspects of life such as being able to function at work (sitting or standing),

or travelling. However, whether tailored VR-training may aid in reducing disability through the development of cost-effective therapeutic tools will have to be investigated with full scientific rigour in future studies, controlling for history and maturation bias, as well as statistical regression to the mean.

The ÖMPSQ short form was included in the present study because the questionnaire addresses some important "yellow flag" risk factors in LBP patients, namely related to pain or harm expectancies as a result of movement. Our study showed a reduction in ÖMPSQ short form score for 7 out of 9 participants. Two participants went from above the cut-off score (i.e. ≥50/100) for risk of future disability, to beneath. In total, 1 patient had a ≥30% reduction in ÖMSPQ short form from baseline to follow-up. Although the questionnaire is only validated as a screening tool, we wanted to include it because it addresses some points for LBP patients that are consistent with what we wanted to investigate for future studies (i.e. Item 9: "An increase in pain is an indication that I should stop what I'm doing until the pain decreases", and Item 10: "I should not do my normal work (at work or home duties) with my present pain"). Interestingly, some of these aspects changed in our participants during the course of the study (i.e. ID26 went from scoring 10 to 8 on item 9, and 10 to 7 on item 10 from baseline to follow-up). Future studies may provide researchers and clinicians with more information about whether VR-training sessions can be used to educate the patients differentiation between "pain and harm expectancies" (Weermeijer & Meulders, 2018), i.e. that the expectancy of pain may increase in the course of introducing a new exercise regimen, but that the expectancy of harm should decrease concurrently with implementation of graded exposure therapy targeting correction of erroneous interpretations of an impeding catastrophe (Meulders et al, 2017). However, the authors of the present study acknowledge that other questionnaires may inherent improved psychometric properties to assess "yellow flag" risk factors and pain or harm expectancies than the ÖMPSQ short form. Nevertheless, the ÖMPSQ short form provided us with information about pre- and post-assessments that may be valuable for future studies in the field.

The FreBAQ scores showed high inter-case variability, and no particular trends towards a change in a positive or negative direction. Four out of nine participants had a reduction in FreBAQ scores equivalent to a MIC (30% reduction from baseline), but some participants also had increase in FreBAQ score, or no change from baseline to follow-up. The high inter-case variability may have been influenced by language barriers, because the questionnaire only exists in English to date. The results should therefore be interpreted with caution. However, similar to ÖMSPQ short form, FreBAQ also represent interesting aspects related to persistent

pain that we would like to investigate in future studies with VR-training. More specific, we were interested in the response to items such as item 1 and 6: “My back feels like it is not part of the rest of my body” and “I can’t perceive the exact outlines of my back” and whether the present LBP sample showed any responsiveness to questions related to body perception. There is a growing body of evidence about the altered body perception in persistent pain (Kregel et al, 2015; Wand et al, 2014), which might contribute to the pain experience as well as serve as a target for treatment (Louw et al, 2015, Wand et al, 2016). Therefore, future research is warranted to investigate whether the use of VR may be specifically programmed to challenge and re-train perceptual dysfunctions, and whether these changes are related to reductions in pain scores and disability.

Implicit motor imagery assessment (via Recognise ™; Noigroup) was conducted to explore body perception – specifically working body schema (the cortical maps that underlie movement planning, coordination, and execution). Our results showed that all participants became significantly faster at judging images of right-side trunk rotation/lateral flexion after VR-based treatments. It is unclear why the improvement was specific to right side images, but the results may indicate familiarity with the test-method, random fluctuations, or greater ability to mentally manoeuvre their own body part to fit the pictured image (Parsons, 2001). Moreover, accurate left/right judgements depend on intact working body schemas (Parsons, 2001). Only two participants showed improvements with left-sided judgements. The present study showed improved accuracy scores with left sided judgements for five out of nine participants, while two participants had improvements in right sided accuracy judgements. However, accuracy scores show a high inter- and intra-case variability, so the results should be interpreted with caution.

Although we did not specifically tailor the VR-intervention towards improving motor imagery performance in the present study, it was still interesting to investigate LBP participants’ responses to the Recognise ™ app, and whether the scores changed between the two measurement points in relation to the VR-intervention. What we found in the present study was that the participants had speed responses that were overall faster at follow-up (Table 8). More specifically, speed responses were faster than expected for LBP patients (1.8 seconds +/- 0.5 seconds) (compared to Bowering et al (2014) study), but both speed and accuracy seemed to have a high inter- and intra-case variance. Interestingly, we saw that younger participants scored higher on accuracy throughout the study, which may be due to user acceptance. Only ID25 and ID28 showed improvements in both speed and accuracy from baseline to follow-up.

Emerging advances in neuroscience and brain imaging studies have shown that decreased movement in the lumbar spine leads to functional changes in the brain (Flor et al, 1997; Wand et al, 2011a), which is related to a dynamically maintained neuronal representation of body parts (Flor et al, 1997, 1998; Lotze & Moseley 2007, Maihofner et al, 2003, Moseley et al, 2005a, Moseley et al, 2008b). Whether these cortical changes play a causal role in non-specific LBP has not been established (Apkarian et al, 2009). However, treatments such as graded motor imagery (GMI) targeting the restoration of cortical function have been shown effective in phantom limb pain (Flor et al, 2001; Moseley, 2006) and complex regional pain syndrome (CRPS) (McCabe et al, 2003; Moseley, 2004; 2006; 2008a). In line with these findings, a SSED study (n=3) on graded sensorimotor retraining demonstrated effectiveness on pain intensity for persistent LBP patients (Wand et al, 2011b), and a case-study (n=16) by Louw et al. (2015) demonstrated immediate effects on pain intensity and MIC for forward flexion using sensory discrimination training in persistent LBP patients. Thus, it may appear that changes related to tactile acuity (Luomajoki & Moseley, 2010; Moseley, 2008b; Wand et al, 2010), altered body perception (Moseley, 2008) and disrupted body schema (Bray & Moseley, 2010) could be viable therapeutic targets for persistent LBP management. However, in a recent systematic review, Bowering et al. (2013) suggested that although GMI and mirror therapy alone may be effective, further rigorous studies is needed to evaluate the effectiveness of GMI for a wider population of persistent pain conditions. Future studies may also explore the utilization of VR technology in order to develop novel therapeutic interventions in this field.

4.2.4. Results related to patient satisfaction

In the present study, we were primarily interested in quantitative results as presented earlier, but because the study design and protocol had never been tested before, we also included a qualitative evaluation questionnaire for each participant at the end of each trial with five open questions related to participants' experiences with the VR-training (i.e. "How did you experience the VR-training?", or "In your opinion, how could a VR-intervention be tailored the individual patient during LBP rehabilitation?"). In summary, all participants expressed that they felt motivated, engaged, and would like to continue using VR-training in the future. Further, they expressed that the intervention was fun and entertaining, and some participants also expressed that they were less fearful in ADL during and after, the VR-training. One participant wrote in the evaluation form that "Continuity in the training is very important to me. Being

supervised and experiencing progress in the different VR-games was very motivating", and another participant wrote: "During this study, I got to train muscle groups that I do not use on a daily basis, which I think is very good for my lower back in the long run". Some participants expressed that they would be interested in playing VR-games that was more tailored to their own interests, and more related to their challenges in ADL. This is important feedback for future studies to address in order to achieve meaningful and clinically relevant changes, considering that is was not the primary emphasis of the present study. Importantly, the participants did not report any side effects from the VR-training and no patients dropped out of the study. A full overview over patient feedback is provided in Appendix 11.

4.2.5. Strengths and limitations with the study

4.2.5.1. Strengths

All patients were screened by the Outpatient Spine Clinic and evaluated as safe to start exercising. This was very beneficial for us as researchers, considering that all red flags, serious neurological injuries and/or neuropathic LBP pain was ruled out by a team of experts at the Outpatient Spine Clinic. Participants where thus ready to start exercising with VR-training based on safe premises. We also recruited a consecutive sample of patients attending the clinic, which may represent the type of LBP patient typically seen in this particular primary health care setting. Another strength is the concept of the study, i.e. to target underlying psychological and/or behavioural factors in treatment of persistent LBP. The intervention combined encouragement of graded exposure towards lumbar spine flexion and trunk rotation while providing distraction from pain-related fear and confrontation of feared movement (i.e. lumbar spine flexion). Additionally, the VR-training was used to explore movements in a safe virtual environment, with a tailored, person-centred approach (n = 1). The tailored approach consisting of: "easy", "medium" or "hard" levels was adjusted similar to exercise programs in the clinic, based on scores on daily questionnaires of pain intensity (NRS), pain-related fear of movement (TSK), pain catastrophizing (PCS), pain-anxiety symptoms (PASS), in addition to feedback from the patient and clinical observations. Furthermore, the daily measures allowed us to track the individual changes in each participant over time. The study design, the randomisation of baseline and intervention duration strengthened the internal validity and provided a robust and maximized SSED. There were no drop-outs in the study, and adherence between planned and

actual execution of treatment schedule was satisfactory carried out, which was important for the validity of the statistical analysis.

Another strength is that the games used in the protocol were flexible and easy to adjust in real-time. We got permission to use two commercial games from the software developers of Holoball and Holodance, and TFL developed the third VR-game "RoBow Agent". The protocol for the VR-training was developed by a team of experienced physiotherapists and researchers (TS, KVF, MS), in collaboration with the master student in software engineering (TFL). Participants of all ages were able to use the equipment and understood how to navigate in the VR-platform, which makes the intervention available and scalable for use in rehabilitation centres, in the clinic or home settings. The trans-disciplinary collaboration in the present study was beneficial for the development of a viable intervention for LBP, as we could learn from each other to create a new therapeutic treatment tool. In the larger perspective, the collaboration between health care professionals and computer engineering may provide cost-effective treatment options in the future. Persistent musculoskeletal pain has been under-prioritized and under-funded for decades, mainly because it is categorized as a non-fatal disease (Hoy et al, 2010). More specifically, a report showed that persistent musculoskeletal research received only 6% of national funding budget in Norway in 2003 (Lærum et al, 2013), while at the same time, accounting for 46% of sick leave and 33% of disability pension. New technological advancements and innovative therapies may be necessary to create a sustainable primary health care system in response to the global burden of persistent LBP. Importantly, LBP management must be driven by the administration of treatments with the highest probability for success (i.e. high-value treatments versus low-value treatments) (Foster et al, 2018). The development of novel therapeutic interventions also needs to consider this.

4.2.5.2. Limitations

The present study had some limitations. First and foremost, the study design involves a low number of participants needed (due to the increased power conferred by within subject analyses) and does not provide us with a control group. Specifically, the lack of control group makes it more difficult to control for history and maturation bias or statistical regression to the mean (Carter & Lubinsky, 2017). More research is therefore needed to investigate whether the results shown in the study are replicable and generalizable to larger samples. However, in a replicated case series design we do have adequate participant numbers needed to perform robust

statistical analysis as suggested by several lines of research (e.g. Onghena et al, 1995; 2005a; 2005b; Michiels & Onghena, 2018).

Other methodological aspects that could have been improved include: daily measures of fear/catastrophising/pain-anxiety could have been converted to NRS continuums instead of using the original Likert scales during the data collection (i.e. replicate de Jong (2012)). This may have improved responsiveness of pain-related fear of movement (TSK), pain catastrophizing (PCS) and pain-anxiety symptoms (PASS). However, converting the original Likert scale to 0-100 scales is not inconsistent with past research in this area. Further, the use of the English questionnaire (FreBAQ) may have showed improved responsiveness if it was translated for a Norwegian population. However, we did not do any analysis using the questionnaire, we merely calculated change scores between to assessment points. Administering PSFS at Day 35 should have been better implemented to prevent omission. Employment of a research assistant blinded to the interventions, that could carry out the outcome measurement collection could potentially reduce response bias (i.e., not wanting to let the clinician know that a treatment was not helpful) amongst the participants. Additionally, it would have been interesting to not only have a 7-day follow-up, but also have a longer follow-up (e.g., 3-months) to see how the participants did some time after the intervention. Unfortunately, we did not have time or resources for that in this master's project.

The protocol for the VR-training had not been tested on healthy participants, with the exception of the researchers, prior to the present study with LBP patients. The researchers MS and TFL were responsible for finding and adjusting two commercial games (Holoball and Holodance) with permission from the developers, and TFL developed the third game (RoboBow). Through significant clinical testing and software programming, we managed to create a protocol that we thought would fit our participants. The intervention could have been improved by administering pilot testing with LBP patients before we initiated the present study, but we were limited by time constraints of the master's program. Importantly, two of the games were already commercially available, they would have been tested by healthy people, and the third game was tailored specifically for this target population (i.e. LBP-patients with fear of movement). However, this pilot study may serve that purpose for other, larger studies, and we were satisfied with the VR-games that we chose as they were considered safe, fun, engaging and easily adjustable in real-time (while participants played the game). Further, as seen in Table 7 (See Subsection 3.2.2.2.), some participants received only 6 VR-interventions, while others were randomized to receive 7, 8 or 9 training. It would have been interesting to investigate whether

the results would have been different if all participants received the same dosage (i.e., ≥8) or whether it is possible to develop a flexible protocol that accentuates a MIC for pain and disability with a minimal amount of interventions per patient (i.e. provides high costs-effectiveness).

Some researchers argue that pain is likely to fluctuate in persistent LBP patients, and that disability changes is a much more interesting variable to investigate. Others argue that having an intense focus on pain as a measure may "prime" the patient towards a negative focus. That our results showed a reduction in pain following VR-based treatment suggest that daily pain measures did not prime patients towards a negative focus. Further, any changes in pain medication were not assessed. Instead, we asked participants to qualitatively describe and report whether their pain medication intake had changed throughout the study. This was therefore not included as an outcome measure in the present study but will remain important for future studies. Finally, the notion of non-specific LBP may include a variety of pain characteristics, which may have become evident in primary and secondary outcome measures for ID30. Namely, ID30 may have had a more severe and persistent pain characteristic (according to characteristics described by Kongsted et al, 2016), experienced constant pain, and severe exacerbations with minimal activity (i.e. 5 minutes of standing). Therefore, a screening procedure that differentiated between different pain characteristics may be helpful for future studies to determine which patients could benefit the most from VR-based interventions for LBP. In summary, all these limitations are acknowledged by the authors of the present study and must be addressed in future studies to improve methodological and scientific rigour.

4.2.6. Comparison to previous studies in this area

There is a current lack of evidence for the effectiveness of VR training for non-specific persistent LBP, so it would be relevant to discuss existing literature VR in health care to create perspective. Finally, suggestions for future directions are presented in the next subsection.

While VR gaming shows considerable success in the area of acute pain, few studies have applied VR to persistent pain management. To date, only one systematic review related to the use of VR in inpatient medical settings has been published. Dascal et al. (2017) reviewed 11 randomised, controlled trials and found that VR is a promising intervention for pain distraction (Carrougher et al, 2009; Hoffman et al, 2008; Kipping et al, 2012; Morris et al, 2010; Patterson

et al, 2010; Schmitt et al, 2011), eating disorders/obesity (Cesa et al, 2013, Manzoni et al, 2009), and cognitive and motor rehabilitation (Larson et al, 2011). However, no systematic review for the use of VR in physical rehabilitation of persistent pain has been published to date. A number of recent studies have demonstrated that virtual feedback interventions can provide pain relief for a variety of persistent pain conditions (e.g., for hand osteoarthritis (Gilpin et al, 2015; Preston & Newport, 2011); hand dystonia (Llobera et al, 2013); upper extremity neuropathic pain (Mouraux et al, 2016); knee osteoarthritis (Stanton et al, 2018)). More specifically related to persistent LBP and pain-related fear of movement, Parsons & Trost (2014) have developed VRGET (Virtual Reality Graded Exposure Therapy), defined as a therapeutic approach that aim to address several major limitations characterizing traditional graded exposure therapy. This includes "mitigating costs associated with traditional graded exposure therapy, enhance participant engagement, provide real-time assessment of important metrics such as affective response and kinematic adaptation, and provide generalizability of rehabilitation gains across clinic and home environments" (Parsons & Trost, 2014, p: 523). A protocol for a pilot study was published in 2015, but no studies have been published to date.

Therefore, Thomas et al. (2016) published the first feasibility study (n=52) on VR-dodgeball for kinesiophobic LBP patients, and a phase 2 clinical trial for Virtual Rehabilitation to Optimize Recovery (VIGOR) is expected to follow based on a protocol published in 2018. Importantly, as mentioned previously, Thomas et al. provided patients with 3 VR-interventions of 15 minutes each, and the study did not demonstrate any statistically significant effect on expected pain or expected harm across participants. In contrast, the present study with 6 to 9 VR-intervention of 30 minutes per intervention, 2-3x per week, over 14-23 days, did demonstrate a statistically significant reduction in pain intensity (NRS), pain-related fear of movement (TKS), pain catastrophizing (PCS) and pain-anxiety symptoms (PASS). Additionally, the present study showed that participants who had 8 or 9 VR-sessions had a larger reduction in pain intensity scores (NRS) compared to participants who only received 6 or 7 VR-sessions. Further research seems necessary to explore the importance of dosage of VR-trainings to achieve treatment effects related to pain and disability in persistent LBP patients.

4.2.7. Perspective and future directions

Considering the rising epidemic of persistent musculoskeletal pain, it is important to investigate innovative solutions that may improve persistent LBP management. Researchers and clinicians

have come a long way implementing the biopsychosocial, cognitive, functional, behavioural, person-centred approach, but there is still a way to go in order to assimilate contemporary pain- and neuroscience theories and LBP research into clinical practice and public knowledge. Leading researchers in the field rightfully suggests a cultural shift (i.e. paradigm shift) is needed to translate updated knowledge to the general population through mass media campaigns (Foster et al, 2018; Hartvigsen et al, 2018; O'Sullivan et al, 2018b). The authors' impression is that a cultural shift will take time and sustainable efforts over many decades. On the contrary, VR and AR are emerging forefront technological platforms which may benefit health care providers and patients alike. VR and AR may be useful to motivate and engage in physical activity during rehabilitation, and for educating patients about how thoughts and feelings (e.g. catastrophic thinking or pain-related fear of movement) are connected to movement strategies, and even so, how it may drive pain-related fear or avoidance behaviour. The possibility and opportunity to create "optimal learning environments" with VR is an exciting new field for physical therapists and patients. However, the effectiveness of VR-interventions is likely to depend on immersiveness, content, quality and relevance of the tasks and the virtual environments provided. Further, more research is needed with regards to dosage in relation to individual characteristics. Subsequently, investigating whether VR may be effective merely due to its entertainment value, or whether there are unique qualities that we can capitalize on in the clinical setting, seems necessary. Considering that VR-training is a novel therapeutic intervention, it is equally important to investigate possible side-effects, limitations, barriers and challenges with implementing new technology in physical rehabilitation. In summary, VR-training as proposed to date may seem like a promising treatment persistent LBP patients, but larger studies with robust scientific designs in this field is warranted.

5.0. Conclusion

VR training is an exciting tool for non-specific persistent LBP patients in primary health care. In the present study, we have shown that there was a statistically significant reduction in pain intensity (NRS), pain-related fear of movement (TSK), pain catastrophizing (PCS) and pain-anxiety symptoms (PASS). The authors of the study acknowledge the threats to internal validity provided by the design of the study and suggests that larger studies with robust designs and a control group investigate VR for non-specific persistent LBP further in the future. However, to our knowledge, this study is the first study in Norway to investigate VR-training for persistent LBP-patients. This can be an important pilot study for future work in the field that combines physical therapy rehabilitation and the use of immersive virtual tools. Virtual tools may aid in creating a more sustainable health care system by providing patients with viable alternatives to improve health-promoting behaviour.

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Holodance creator Jashan Chittesh

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8.0. Appendix

Appendix 1 – Random number tables

Appendix B. Random Number Tables

Reproduced from Million Random Digits, used with permission of the Rand Corporation, Copyright, 1955, The Free Press. The publication is available for free on the Internet at http://www.rand.org/publications/classics/randomdigits.

All of the sampling plans presented in this handbook are based on the assumption that the packages constituting the sample are chosen at random from the inspection lot. Randomness in this instance means that every package in the lot has an equal chance of being selected as part of the sample. It does not matter what other packages have already been chosen, what the package net contents are, or where the package is located in the lot.

To obtain a random sample, two steps are necessary. First it is necessary to identify each package in the lot of packages with a specific number whether on the shelf, in the warehouse, or coming off the packaging line. Then it is necessary to obtain a series of random numbers. These random numbers indicate exactly which packages in the lot shall be taken for the sample.

The Random Number Table

The random number tables in Appendix B are composed of the digits from 0 through 9, with approximately equal frequency of occurrence. This appendix consists of 8 pages. On each page digits are printed in blocks of five columns and blocks of five rows. The printing of the table in blocks is intended only to make it easier to locate specific columns and rows.

Random Starting Place

Starting Page. The Random Digit pages numbered B-2 through B-8. You can use the day of the week to determine the starting page or use the first page for the first lot you test in a location, the second page for the second lot and so on moving to the following page for each new lot.

Starting Column and Row. You may choose a starting page in the random number table and with eyes closed, drop a pencil anywhere on the page to indicate a starting place in the table.

For example, assume that testing takes place on the 3rd day of the week. Start with Table 3 of Appendix B. Assume you dropped your pencil on the page and it has indicated a starting place at column 22, row 45. That number is 1.

If 1-digit random numbers are needed, record them, going down the column to the bottom of the page and then to the top of the next column, and so on. Ignore duplicates and record zero (0) as ten (10). Following on from the last example, these numbers are 3, 2, 9, 8, etc. If two-digit random numbers are needed, rule off the pages, and further pages if necessary, in columns of two digits each. If there is a single column left on the page, ignore this column, and rule the next page in columns of two. Again, ignore duplicate numbers and record 00 as 100. For example, using the same starting place as in the last example (Table 3, column 22, row 45), the recorded two-digit recorded numbers would be 11, 34, 26, 95, etc.. When three-digit numbers are needed, rule the page in columns of three. Record 000 as 1000. Starting on Table 3, column 22, row 45, the recorded numbers would be 119, 346, 269, 959, etc..

B-1

TABLE 1 - RANDOM DIGITS

11164	36318	75061	37674	26320	75100	10431	20418	19228	91792
21215	91791	76831	58678	87054	31687	93205	43685	19732	08468
10438	44482	66558	37649	08882	90870	12462	41810	01806	02977
36792	26236	33266	66583	60881	97395	20461	36742	02852	50564
73944	04773	12032	51414	82384	38370	00249	80709	72605	67497
49563	12872	14063	93104	78483	72717	68714	18048	25005	04151
64208	48237	41701	73117	33242	42314	83049	21933	92813	04763
51486	72875	38605	29341	80749	80151	33835	52602	79147	08868
99756	26360	64516	17971	48478	09610	04638	17141	09227	10606
71325	55217	13015	72907	00431	45117	33827	92873	02953	85474
65285	97198	12138	53010	94601	15838	16805	61004	43516	17020
17264	57327	38224	29301	31381	38109	34976	65692	98566	29550
95639	99754	31199	92558	68368	04985	51092	37780	40261	14479
61555	76404	86210	11808	12841	45147	97438	60022	12645	62000
78137	98768	04689	87130	79225	08153	84967	64539	79493	74917
62490	99215	84987	28759	19177	14733	24550	28067	68894	38490
24216	63444	21283	07044	92729	37284	13211	37485	10415	36457
16975	95428	33226	55903	31605	43817	22250	03918	46999	98501
59138	39542	71168	57609	91510	77904	74244	50940	31553	62562
29478	59652	50414	31966	87912	87154	12944	49862	96566	48825
96155	95009	27429	72918	08457	78134	48407	26061	58754	05326
29621	66583	62966	12468	20245	14015	04014	35713	03980	03024
12639	75291	71020	17265	41598	64074	64629	63293	53307	48766
14544	37134	54714	02401	63228	26831	19386	15457	17999	18306
83403	88827	09834	11333	68431	31706	26652	04711	34593	22561
67642	05204	30697	44806	96989	68403	85621	45556	35434	09532
64041	99011	14610	40273	09482	62864	01573	82274	81446	32477
17048	94523	97444	59904	16936	39384	97551	09620	63932	03091
93039	89416	52795	10631	09728	68202	20963	02477	55494	39563
82244	34392	96607	17220	51984	10753	76272	50985	97593	34320
96990	55244	70693	25255	40029	23289	48819	07159	60172	81697
09119	74803	97303	88701	51380	73143	98251	78635	27556	20712
57666	41204	47589	78364	38266	94393	70713	53388	79865	92069
46492	61594	26729	58272	81754	14648	77210	12923	53712	87771
08433	19172	08320	20839	13715	10597	17234	39355	74816	03363
10011	75004	86054	41190	10061	19660	03500	68412	57812	57929
92420	65431	16530	05547	10683	88102	30176	84750	10115	69220
35542	55865	07304	47010	43233	57022	52161	82976	47981	46588
86595	26247	18552	29491	33712	32285	64844	69395	41387	87195
72115	34985	58036	99137	47482	06204	24138	24272	16196	04393
07428	58863	96023	88936	51343	70958	96768	74317	27176	29600
35379	27922	28906	55013	26937	48174	04197	36074	65315	12537
10982	22807	10920	26299	23593	64629	57801	10437	43965	15344
90127	33341	77806	12446	15444	49244	47277	11346	15884	28131
63002	12990	23510	68774	48983	20481	59815	67248	17076	78910
40779	86382	48454	65269	91239	45989	45389	54847	77919	41105
43216	12608	18167	84631	94058	82458	15139	76856	86019	47928
96167	64375	74108	93643	09204	98855	59051	56492	11933	64958
70975	62693	35684	72607	23026	37004	32989	24843	01128	74658
85812	61875	23570	75754	29090	40264	80399	47254	40135	69916

TABLE 2 – RANDOM DIGITS

40603	16152	83235	37361	98783	24838	39793	80954	76865	32713
40941	53585	69958	60916	71018	90561	84505	53980	64735	85140
73505	83472	55953	17957	11446	22618	34771	25777	27064	13526
39412	16013	11442	89320	11307	49396	39805	12249	57656	88686
57994	76748	54627	48511	78646	33287	35524	54522	08795	56273
61834	59199	15469	82285	84164	91333	90954	87186	31598	25942
91402	77227	79516	21007	58602	81418	87838	18443	76162	51146
58299	83880	20125	10794	37780	61705	18276	99041	78135	99661
40684	99948	33880	76413	63839	71371	32392	51812	48248	96419
75978	64298	08074	62055	73864	01926	78374	15741	74452	49954
34556	39861	88267	76068	62445	64361	78685	24246	27027	48239
65990	57048	25067	77571	77974	37634	81564	98608	37224	49848
16381	15069	25416	87875	90374	86203	29677	82543	37554	89179
52458	88880	78352	67913	09245	47773	51272	06976	99571	33365
33007	85607	92008	44897	24964	50559	79549	85658	96865	24186
38712	31512	08588	61490	72294	42862	87334	05866	66269	43158
58722	03678	19186	69602	34625	75958	56869	17907	81867	11535
26188	69497	51351	47799	20477	71786	52560	66827	79419	70886
12893	54048	07255	86149	99090	70958	50775	31768	52903	27645
33186	81346	85095	37282	85536	72661	32180	40229	19209	74939
79893	29448	88392	54211	61708	83452	61227	81690	42265	20310
48449	15102	44126	19438	23382	14985	37538	30120	82443	11152
94205	04259	68983	50561	06902	10269	22216	70210	60736	58772
38648	09278	81313	77400	41126	52614	93613	27263	99381	49500
04292	46028	75666	26954	34979	68381	45154	09314	81009	05114
17026	49737	85875	12139	59391	81830	30185	83095	78752	40899
48070	76848	02531	97737	10151	18169	31709	74842	85522	74092
30159	95450	83778	46115	99178	97718	98440	15076	21199	20492
12148	92231	31361	60650	54695	30035	22765	91386	70399	79270
73838	77067	24863	97576	01139	54219	02959	45696	98103	78867
73547	43759	95632	39555	74391	07579	69491	02647	17050	49869
07277	93217	79421	21769	83572	48019	17327	99638	87035	89300
65128	48334	07493	28098	52087	55519	83718	60904	48721	17522
38716	61380	60212	05099	21210	22052	01780	36813	19528	07727
31921	76458	73720	08657	74922	61335	41690	41967	50691	30508
57238	27464	61487	52329	26150	79991	64398	91273	26824	94827
24219	41090	08531	61578	08236	41140	76335	91189	66312	44000
31309	49387	02330	02476	96074	33256	48554	95401	02642	29119
20750	97024	72619	66628	66509	31206	55293	24249	02266	39010
28537	84395	26654	37851	80590	53446	34385	86893	87713	26842
97929	41220	86431	94485	28778	44997	38802	56594	61363	04206
40568	33222	40486	91122	43294	94541	40988	02929	83190	74247
41483	92935	17061	78252	40498	43164	68646	33023	64333	64083
93040	66476	24990	41099	65135	37641	97613	87282	63693	55299
76869	39300	84978	07504	36835	72748	47644	48542	25076	68626
02982	57991	50765	91930	21375	35604	29963	13738	03155	59914
94479	76500	39170	06629	10031	48724	49822	44021	44335	26474
52291	75822	95966	90947	65031	75913	52654	63377	70664	60082
03684	03600	52831	55381	97013	19993	41295	29118	18710	64851
58939	28366	86765	67465	45421	74228	01095	50987	83833	37216

TABLE 3 – RANDOM DIGITS

37100	62492	63642	47638	13925	80113	88067	42575	44078	62703
53406	13855	38519	29500	62479	01036	87964	44498	07793	21599
55172	81556	18856	59043	64315	38270	25677	01965	21310	28115
40353	84807	47767	46890	16053	32415	60259	99788	55924	22077
18899	09612	77541	57675	70153	41179	97535	82889	27214	03482
68141	25340	92551	11326	60939	79355	41544	88926	09111	86431
51559	91159	81310	63251	91799	41215	87412	35317	74271	11603
92214	33386	73459	79359	65867	39269	57527	69551	17495	91456
15089	50557	33166	87094	52425	21211	41876	42525	36625	63964
96461	00604	11120	22254	16763	19206	67790	88362	01880	37911
28177	44111	15705	73835	69399	33602	13660	84342	97667	80847
66953	44737	81127	07493	07861	12666	85077	95972	96556	80108
19712	27263	84575	49820	19837	69985	34931	67935	71903	82560
68756	64757	19987	92222	11691	42502	00952	47981	97579	93408
75022	65332	98606	29451	57349	39219	08585	31502	96936	96356
11323	70069	90269	89266	46413	61615	66447	49751	15836	97343
55208	63470	18158	25283	19335	53893	87746	72531	16826	52605
11474	08786	05594	67045	13231	51186	71500	50498	59487	48677
81422	86842	60997	79669	43804	78690	58358	87639	24427	66799
21771	75963	23151	90274	08275	50677	99384	94022	84888	80139
42278	12160	32576	14278	34231	20724	27908	02657	19023	07190
17697	60114	63247	32096	32503	04923	17570	73243	76181	99343
05686	30243	34124	02936	71749	03031	72259	26351	77511	00850
52992	46650	89910	57395	39502	49738	87854	71066	84596	33115
94518	93984	81478	67750	89354	01080	25988	84359	31088	13655
00184	72186	78906	75480	71140	15199	69002	08374	22126	23555
87462	63165	79816	61630	50140	95319	79205	79202	67414	60805
88692	58716	12273	48176	86038	78474	76730	82931	51595	20747
20094	42962	41382	16768	13261	13510	04822	96354	72001	68642
60935	81504	50520	82153	27892	18029	79663	44146	72876	67843
51392	85936	43898	50596	81121	98122	69196	54271	12059	62539
54239	41918	79526	46274	24853	67165	12011	04923	20273	89405
57892	73394	07160	90262	48731	46648	70977	58262	78359	50436
02330	74736	53274	44468	53616	35794	54838	39114	68302	26855
76115	29247	55342	51299	79908	36613	68361	18864	13419	34950
63312	81886	29085	20101	38037	34742	78364	39356	40006	49800
27632	21570	34274	56426	00330	07117	86673	46455	66866	76374
06335	62111	44014	52567	79480	45886	92585	87828	17376	35254
64142	87676	21358	88773	10604	62834	63971	03989	21421	76086
28436	25468	75235	75370	63543	76266	27745	31714	04219	00699
09522	83855	85973	15888	29554	17995	37443	11461	42909	32634
93714	15414	93712	02742	34395	21929	38928	31205	01838	60000
15681	53599	58185	73840	88758	10618	98725	23146	13521	47905
77712	23914	08907	43768	10304	61405	53986	61116	76164	54958
78453	54844	61509	01245	91199	07482	02534	08189	62978	55516
24860	68284	19367	29073	93464	06714	45268	60678	58506	23700
37284	06844	78887	57276	42695	03682	83240	09744	63025	60997
35488	52473	37634	32569	39590	27379	23520	29714	03743	08444
51595	59909	35223	44991	29830	56614	59661	83397	38421	17503
90660	35171	30021	91120	78793	16827	89320	08260	09181	53616

START: Table 4, Column 2:

54806

TABLE 4 – RANDOM DIGITS

54723	56527	53076	38235	42780	22716	36400	48028	78196	92985
84828	81248	25548	34075	43459	44628	21866	90350	82264	20478
65799	01914	81363	05173	23674	41774	25154	73003	87031	94368
87917	38549	48213	71708	92035	92527	55484	32274	87918	22455
26907	88173	71189	28377	13785	87469	35647	19695	33401	51998
68052	65422	88460	06352	42379	55499	60469	76931	83430	24560
42587	68149	88147	99700	56124	53239	38726	63652	36644	50876
97176	55416	67642	05051	89931	19482	80720	48977	70004	03664
53295	87133	38264	94708	00703	35991	76404	82249	22942	49659
23011	94108	29196	65187	69974	01970	31667	54307	40032	30031
75768	49549	24543	63285	32803	18301	80851	89301	02398	99891
86668	70341	66460	75648	78678	27770	30245	44775	56120	44235
56727	72036	50347	33521	05068	47248	67832	30960	95465	32217
27936	78010	09617	04408	18954	61862	64547	52453	83213	47833
31994	69072	37354	93025	38934	90219	91148	62757	51703	84040
02985	95303	15182	50166	11755	56256	89546	31170	87221	63267
89965	10206	95830	95406	33845	87588	70237	84360	19629	72568
45587	29611	98579	42481	05359	36578	56047	68114	58583	16313
01071	08530	74305	77509	16270	20889	99753	88035	55643	18291
90209	68521	14293	39194	68803	32052	39413	26883	83119	69623
04982	68470	27875	15480	13206	44784	83601	03172	07817	01520
19740	24637	97377	32112	74283	69384	49768	64141	02024	85380
50197	79869	86497	68709	42073	28498	82750	43571	77075	07123
46954	67536	28968	81936	95999	04319	09932	66223	45491	69503
82549	62676	31123	49899	70512	95288	15517	85352	21987	08669
61798	81600	80018	84742	06103	60786	01408	75967	29948	21454
57666	29055	46518	01487	30136	14349	56159	47408	78311	25896
29805	64994	66872	62230	41385	58066	96600	99301	85976	84194
06711	34939	19599	76247	87879	97114	74314	39599	43544	36255
13934	46885	58315	88366	06138	37923	11192	90757	10831	01580
28549	98327	99943	25377	17628	65468	07875	16728	22602	33892
40871	61803	25767	55484	90997	86941	64027	01020	39518	34693
47704	38355	71708	80117	11361	88875	22315	38048	42891	87885
62611	19698	09304	29265	07636	08508	23773	56545	08015	28891
03047	83981	11916	09267	67316	87952	27045	62536	32180	60936
26460	50501	31731	18938	11025	18515	31747	96828	58258	97107
01764	25959	69293	89875	72710	49659	66632	25314	95260	22146
11762	54806	02651	52912	32770	64507	59090	01275	47624	16124
31736	—	11523	64213	91190	10145	34231	36405	65860	48771
97155	48706	52239	21831	49043	18650	72246	43729	63368	53822
31181	49672	17237	04024	65324	32460	01566	67342	94986	36106
32115	82683	67182	89030	41370	50266	19505	57724	93358	49445
07068	75947	71743	69285	30395	81818	36125	52055	20289	16911
26622	74184	75166	96748	34729	61289	36908	73686	84641	45130
02805	52676	22519	47848	68210	23954	63085	87729	14176	45410
32301	58701	04193	30142	99779	21697	05059	26684	63516	75925
26339	56909	39331	42101	01031	01947	02257	47236	19913	90371
95274	09508	81012	42413	11278	19354	68661	04192	36878	84366
24275	39632	09777	98800	48027	96908	08177	15364	02317	89548
36116	42128	65401	94199	51058	10759	47244	99830	64255	40516

TABLE 5 – RANDOM DIGITS

47505	02008	20300	87188	42505	40294	04404	59286	95914	07191
13350	08414	64049	94377	91059	74531	56228	12307	87871	97064
33006	92690	69248	97443	38841	05051	33756	24736	43508	53566
55216	63886	06804	11861	30968	74515	40112	40432	18682	02845
21991	26228	14801	19192	45110	39937	81966	23258	99348	61219
71025	28212	10474	27522	16356	78456	46814	28975	01014	91458
65522	15242	84554	74560	26206	49520	65702	54193	25583	54745
27975	54923	90650	06170	99006	75651	77622	20491	53329	12452
07300	09704	36099	61577	34632	55176	87366	19968	33986	46445
54357	13689	19569	03814	47873	34086	28474	05131	46619	41499
00977	04481	42044	08649	83107	02423	46919	59586	58337	32280
13920	78761	12311	92808	71581	85251	11417	85252	61312	10266
08395	37043	37880	34172	80411	05181	58091	41269	22626	64799
46166	67206	01619	43769	91727	06149	17924	42628	57647	76936
87767	77607	03742	01613	83528	66251	75822	83058	97584	45401
29880	95288	21644	46587	11576	30568	56687	83239	76388	17857
36248	36666	14894	59273	04518	11307	67655	08566	51759	41795
12386	29656	30474	25964	10006	86382	46680	93060	52337	56034
52068	73801	52188	19491	76221	45685	95189	78577	36250	36082
41727	52171	56719	06054	34898	93990	89263	79180	39917	16122
49319	74580	57470	14600	22224	49028	93024	21414	90150	15686
88786	76963	12127	25014	91593	98208	27991	12539	14357	69512
84866	95202	43983	72655	89684	79005	85932	41627	87381	38832
11849	26482	20461	99450	21636	13337	55407	01897	75422	05205
54966	17594	57393	73267	87106	26849	68667	45791	87226	74412
10959	33349	80719	96751	25752	17133	32786	34368	77600	41809
22784	07783	35903	00091	73954	48706	83423	96286	90373	23372
86037	61791	33815	63968	70437	33124	50025	44367	98637	40870
80037	65089	85919	74391	36170	82988	52311	59180	37846	98028
72751	84359	15769	13615	70866	37007	74565	92781	37770	76451
18532	03874	66220	79050	66814	76341	42452	65365	07167	90134
22936	22058	49171	11027	07066	14606	11759	19942	21909	15031
66397	76510	81150	00704	94990	68204	07242	82922	65745	51503
89730	23272	65420	35091	16227	87024	56662	59110	11158	67508
81821	75323	96068	91724	94679	88062	13729	94152	59343	07352
94377	82554	53586	11432	08788	74053	98312	61732	91248	23673
68485	49991	53165	19865	30288	00467	98105	91483	89389	61991
07330	07184	86788	64577	47692	45031	36325	47029	27914	24905
10993	14930	35072	36429	26176	66205	07758	07982	33721	81319
20801	15178	64453	83357	21589	23153	60375	63305	37995	66275
79241	35347	66851	79247	57462	23893	16542	55775	06813	63512
43593	39555	97345	58494	52892	55080	19056	96192	61508	23165
29522	62713	33701	17186	15721	95018	76571	58615	35836	66260
88836	47290	67274	78362	84457	39181	17295	39626	82373	10883
65905	66253	91482	30689	81313	01343	37188	37756	04182	19376
44798	69371	07865	91756	42318	63601	53872	93610	44142	89830
35510	99139	32031	27925	03560	33806	85092	70436	94777	57963
50125	93223	64209	49714	73379	89975	38567	44316	60262	10777
25173	90038	63871	40418	23818	63250	05118	52700	92327	55449
68459	90094	44995	93718	83654	79311	18107	12557	09179	28416

TABLE 6 – RANDOM DIGITS

96195	07059	13266	31389	87612	88004	31843	83469	22793	14312
22408	94958	19095	58035	43831	32354	83946	57964	70404	32017
53896	23508	16227	56929	74329	12264	26047	66844	47383	42202
22565	02475	00258	79018	70090	37914	27755	00872	71553	56684
49438	20772	60846	69732	07612	70474	46483	21053	95475	53448
65620	34684	00210	04863	01373	19978	61682	69315	46766	83768
20246	26941	41298	04763	19769	25865	95937	03545	93561	73871
09433	09167	35166	32731	73299	41137	37328	28301	61629	05040
95552	73456	16578	88140	80059	50296	07656	01396	83099	09718
76053	05150	69125	69442	16509	03495	26427	58780	27576	31342
34822	35843	78468	82380	52313	71070	71273	10768	86101	51474
07753	04073	58520	80022	28185	16432	86909	82347	10548	83929
04204	94434	62798	81902	29977	57258	87826	35003	46449	76636
96770	19440	29700	42093	64369	69176	29732	37389	34054	28680
65989	62843	10917	34458	81936	84775	39415	10622	36102	16753
06644	94784	66995	61812	54215	01336	75887	57685	66114	76984
88950	46077	34651	12038	87914	20785	39705	73898	12318	78334
21482	95422	02002	33671	46764	50527	46276	77570	68457	62199
55137	61039	02006	69913	11291	87215	89991	26003	55271	08153
98441	81529	59607	65225	49051	28328	85535	37003	87211	10204
57168	30458	23892	07825	53447	53511	09315	42552	43135	57892
71886	65334	38013	09379	83976	42441	14086	33197	82671	05037
40418	59504	52383	07232	14179	59693	37668	26689	93865	78925
28833	76661	47277	92935	63193	94862	60560	72484	29755	40894
37883	62124	62199	49542	55083	20575	44636	92282	52105	77664
44882	33592	66234	13821	86342	00135	87938	57995	34157	99858
19082	13873	07184	21566	95320	28968	31911	06288	77271	76171
45316	29283	89318	55806	89338	79231	91545	55477	19552	03471
22788	55433	31188	74882	44858	69655	08096	70982	61300	23792
08293	86193	05026	21255	63082	92946	28748	25423	45282	57821
29223	70541	67115	84584	10100	33854	26466	77796	70698	99393
22681	80110	31595	09246	39147	11158	43298	36220	88841	11271
74580	90354	43744	22178	38084	60027	24201	71686	59767	33274
69093	71364	08107	96952	50005	30297	97417	89575	04676	35616
40456	91234	58090	65342	95002	28447	21'700	43137	13746	85959
72927	67349	83962	58912	59734	76323	02913	46306	53956	38936
61869	33093	81129	06481	89281	83629	81960	63704	56329	10357
40048	16520	07638	10797	22270	57350	72214	36410	95526	87614
68773	97669	28656	89938	12917	25630	08068	19445	76250	24727
09774	30751	49740	11385	91468	28900	76804	52460	52320	70493
46139	36689	82587	13586	35061	76128	38568	62300	43439	53434
26566	95323	32993	89988	12152	01862	93113	33875	31730	62941
06765	57141	48617	18282	13086	76064	83334	70192	15972	80429
35384	90380	12317	89702	33091	68835	62960	38010	52710	87604
49333	78482	36199	11355	86044	88760	03724	22927	91716	92332
45595	14044	56806	99126	85584	87750	78149	22723	48245	78126
79819	15054	76174	12206	06886	06814	43285	20008	75345	19779
11971	62234	74857	46401	20817	57591	41189	49604	29604	30660
11452	89318	53084	21993	62471	74101	61217	76536	58393	63718
38746	81271	96260	98137	60275	22647	33103	50090	29395	10016

TABLE 7 – RANDOM DIGITS

93369	13044	69686	78162	29132	51544	17925	56738	32683	83153
19360	55049	94951	76341	38159	31008	41476	05278	03909	02299
47798	89890	06893	65483	97658	74884	38611	27264	26956	83504
69223	32007	03513	61149	66270	73087	16795	76845	44645	44552
34511	50721	84850	34159	38985	75384	22965	55366	81632	78872
54031	59329	58963	52220	76806	98715	67452	78741	58128	00077
66722	85515	04723	92411	03834	12109	85185	37350	93614	15351
71059	07496	38404	18126	37894	44991	45777	02070	38159	23930
45478	86066	31135	33243	01190	47277	55146	56130	70117	83203
97246	91121	89437	20393	76598	99458	76665	83793	37448	32664
22982	25936	96417	34845	28942	65569	38253	77182	12996	19505
48243	62993	47132	85248	79160	90981	71696	79609	33809	60839
93514	14915	67960	82203	22598	94802	75332	95585	69542	79924
69707	98303	93069	16216	01542	51771	16833	20922	94415	27617
87467	91794	70814	12743	17543	04057	71231	11309	32780	83270
81006	81498	59375	30502	44868	81279	23585	49678	70014	10523
15458	83481	50187	43375	56644	72076	59403	65469	74760	69509
33469	12510	23095	48016	22064	39774	07373	10555	33345	21787
67198	07176	65996	18317	83083	11921	06254	68437	59481	54778
58037	92261	85504	55690	63488	26451	43223	38009	50567	09191
84983	68312	25519	56158	22390	12823	92390	28947	36708	25393
35554	02935	72889	68772	79774	14336	50716	63003	86391	94074
04368	17632	50962	71908	13105	76285	31819	16884	11665	16594
81311	60479	69985	30952	93067	70056	55229	83226	22555	66447
03823	89887	55828	74452	21692	55847	15960	47521	27784	25728
80422	65437	38797	56261	88300	35980	56656	45662	29219	49257
61307	49468	43344	43700	14074	19739	03275	99444	62545	23720
83873	82557	10002	80093	74645	33109	15281	38759	09342	69408
38110	16855	28922	93758	22885	36706	92542	60270	99599	17983
43892	91189	87226	56935	99836	85489	89693	49475	31941	78065
93683	09664	53927	49885	94979	88848	42642	93218	80305	49428
32748	02121	11972	96914	83264	89016	45140	20362	63242	86255
49211	92963	38625	65312	52156	36400	67050	64058	45489	24165
63365	64224	69475	57512	85097	05054	88673	96593	00902	53320
63576	26373	44610	43748	90399	06770	71609	90916	69002	57180
41078	47036	65524	68466	77613	20076	71969	47706	22506	81053
70846	89558	64173	15381	67322	70097	82363	90767	17879	32697
68800	64492	20162	32707	69510	82465	26821	79917	34615	35820
44977	89525	51269	63747	30997	97213	53016	65909	05723	50168
79354	63847	24395	53679	07667	67993	24634	78867	78516	00448
14954	22299	40156	52685	19093	06090	23800	06739	76836	19050
01711	98439	09446	33937	98956	85676	89493	05132	45886	49379
62328	55328	45738	93940	15772	81975	91017	21387	57949	13992
73004	62109	81907	71077	50322	66093	79921	61412	18347	21115
34218	89445	03609	52336	19005	15179	94958	99448	11612	76981
99159	01968	45886	86875	05196	64297	59339	39878	61548	56442
92858	29949	15817	93372	34732	61584	72007	58597	43802	51066
27396	97477	65554	71601	01540	26509	19487	39684	18676	41219
37103	45309	30129	43380	66638	10841	77292	40288	25826	61431
57347	97012	48428	20606	54138	75716	23741	50462	13221	47216

Appendix 2 – Ethical approval from REK Vest

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK vest	Fredrik Rongved	55978498	24.10.2017	2017/1199/REK vest
			Deres dato:	Deres referanse:
			19.10.2017	

Vår referanse må oppgis ved alle henvendelser

Kjartan Vibe Fersum
Kalfarveien 31

2017/1199 Tilpasset Virtuell Realitetstrening for pasienter med langvarige ryggsmerter

Forskningsansvarlig: Universitetet i Bergen, University of South Australia
Prosjektleder: Kjartan Vibe Fersum

Vi viser til søknad om prosjektendring datert 19.10.2017 for ovennevnte forskningsprosjekt. Søknaden er behandlet av sekretariatet for REK vest på fullmakt, med hjemmel i helseforskningsloven § 11.

Vurdering

Ønsket endring

Prosjektleder ønsker å bytte ut et spørreskjema med et annet som er validert på norsk. I tillegg ønsker prosjektleder å legge til et nytt spørreskjema om myter forbundet med ryggplager.

REK vest ved sekretariatet vurderte saken.

Vurdering

REK vest har ingen innvendinger til ønsket endring.

Vedtak
REK vest godkjenner prosjektendringen i samsvar med forelagt søknad.

Klageadgang
Du kan klage på komiteens vedtak, jf. helseforskningsloven § 10 og forvaltningsloven § 28 flg. Klagen sendes til REK vest. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK vest, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Med vennlig hilsen

Fredrik Rongved
rådgiver

Kopi til: *post@uib.no; tasha.stanton@unisa.edu.au*

Besøksadresse:
Armauer Hansens Hus (AHH), Tverrfløy Nord, 2 etasje. Rom 281. Haukelandsveien 28

Telefon: 55975000
E-post: rek-vest@uib.no
Web: http://helseforskning.etikkom.no/

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK vest	Øyvind Straume	55978497	01.09.2017	2017/1199/REK vest
			Deres dato:	Deres referanse:
			13.06.2017	

Vår referanse må oppgis ved alle henvendelser

Kjartan Vibe Fersum
Kalfarveien 31

2017/1199 Tilpasset Virtuell Realitetstrening for pasienter med langvarige ryggsmerter

Forskningsansvarlig: Universitetet i Bergen, University of South Australia
Prosjektleder: Kjartan Vibe Fersum

Vi viser til søknad om forhåndsgodkjenning av ovennevnte forskningsprosjekt. Søknaden ble behandlet av Regional komité for medisinsk og helsefaglig forskningsetikk (REK vest) i møtet 16.08.2017. Vurderingen er gjort med hjemmel i helseforskningsloven (hfl.) § 10.

Prosjektomtale
I prosjektet er det tatt utgangspunkt i pasienter med frykt for bevegelse (kinesiofobi) og langvarige uspesifikke korsryggsmerter (NSCLBP). Forskergruppen vil ta i bruk Virtual Reality-eknologi (VR), for å utforske hvorvidt VR kan redusere frykt for bevegelse og smerteintensitet. Ni pasienter skal gjennom åtte

VR-treninger på Haukeland universitetssjukehus. I tillegg ønsker prosjektgruppen en oppfølging av deltakerne sju dager og tre måneder etter siste VR-trening.

Vurdering
Forsvarlighet og datainnsamling
Prosjektet innebærer trening med VR-briller. Det vil kreve en god del tidsbruk for deltakerne, men utover det vurderer komiteen studien til å ha minimal risiko eller ulempe.

Ikke oppsøk behandling
I søknaden står det: "Deltakerne vil ikke miste sin plass på ventelisten i primærhelsetjenesten dersom de samtykker til deltakelse i studien. Det krever likevel at de ikke kan få behandling hos fysioterapeut, kiropraktor e.l. parallelt med forskningsstudien. Deltakelse krever også at de ikke får noen behandling frem til oppfølgingen 3 måneder etter er fullført." I informasjonsskrivet står det: "Vi ber om at du ikke oppsøker behandling andre steder i løpet av forskningsstudien." Komiteen antar det her er snakk om behandling som går utenom ordinært helsevesen. Komiteen presiserer at studien ikke kan komme til hinder for nødvendig helsehjelp. REK vest setter derfor som vilkår at dersom deltakere får tilbud om behandling via ordinært helsevesen skal deltakerne ekskluderes fra studien.

Informasjonsskrivet
Informasjonsskrivet må revideres noe. Et revidert informasjonsskriv skal ettersendes til REK vest på post@helseforskning.etikkom.no. Komiteen ber om følgende revisjoner på informasjonsskrivet:

- Dato for prosjektslutt skal legges til.
- Informasjon om forsikringsordning skal legges til
- Logo for forskningsansvarlig institusjon skal legges til.

Prosjektslutt og håndtering av data
Prosjektslutt er satt til 31.05.2018, og ifølge søknaden vil prosjektdata slettes ved prosjektslutt. REK vest har ingen innvendinger til dette, men presiserer at prosjektperioden kan forlenges ved en søknad om prosjektendring dersom prosjektgruppen trenger mer tid på å fullføre prosjektet.

Vilkår

- Prosjektet kan ikke komme til hinder for nødvendig helsehjelp.
- Informasjonsskrivet skal revideres og ettersendes REK vest.

Vedtak
REK vest godkjenner prosjektet på betingelse av at ovennevnte vilkår tas til følge.

Sluttmelding og søknad om prosjektendring
Prosjektleder skal sende sluttmelding til REK vest på eget skjema senest 30.11.2018, jf. hfl. § 12. Prosjektleder skal sende søknad om prosjektendring til REK vest dersom det skal gjøres vesentlige endringer i forhold til de opplysninger som er gitt i søknaden, jf. hfl. § 11.

Klageadgang
Du kan klage på komiteens vedtak, jf. forvaltningsloven § 28 flg. Klagen sendes til REK vest. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK vest, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Med vennlig hilsen

Marit Grønning
prof. dr. med
komiteleder

Øyvind Straume
rådgiver

Kopi til:post@uib.no; tasha.stanton@unisa.edu.au

Appendix 3 – Assessment during VR-training

Målinger underveis i VR-treningen

Smerte

Hvordan vil du gradere de smertene du opplever?

0 1 2 3 4 5 6 7 8 9 10

Ingen smerter Så vondt som det går an å ha

Frykt

Hvordan vil du gradere de frykten du opplever?

0 1 2 3 4 5 6 7 8 9 10

Ingen frykt Så mye frykt som det går an å ha

Ubehag

Hvordan vil du gradere ubehaget du opplever?

0 1 2 3 4 5 6 7 8 9 10

Ingen ubehag Så ubehagelig som det går an å ha det

Kvalme

Hvordan vil du gradere kvalmen du opplever?

0 1 2 3 4 5 6 7 8 9 10

Ingen kvalme Så kvalm som det går an å bli

Appendix 4 – Primary and secondary measures

Daglige målinger

Numerisk smerteskala **Dato: ……..**

Hvordan vil du gradere de smertene du har hatt i løpet av den siste uken. Sett ring rundt ett tall.

0 1 2 3 4 5 6 7 8 9 10

Ingen smerter Så vondt som det går an å ha

Tampa Scale for Kinesiophobia (TSK) - Norwegian Version

		Svært uenig	Uenig	Enig	Svært enig
1	Jeg er redd for at jeg kan skade meg ved et uhell				
2	Kroppen min forteller meg at noe er alvorlig galt				
3	Jeg kan ikke gjøre alle de tingene folk fleste gjør, fordi jeg har så lett for å bli skadet.				

Pain Catastrophizing Scale (PCS) - Norwegian version

	Når jeg har smerter……	Ikke I det hele tatt	Litt	I moderat grad	I stor grad	Hele tiden
1	Det er forferdelig og jeg tror at det aldri vil bli bedre					
2	Jeg føler at jeg ikke klarer å fortsette					
3	Jeg lurer på om noe alvorlig kan komme til å skje					

Pain Anxiety Symptoms Scale (PASS-20 Short form) – English version

		Never 0	**1**	**2**	**3**	**4**	**Always 5**
1	When I hurt I think about pain constantly						
2	I find it hard to concentrate when I hurt						
3	I worry when I am in pain						
4	I try to avoid activities that cause pain						

Secondary outcome measures

Oswestry Disability Index

Section 1 – Pain Intensity

I have no pain at the moment.

The pain is very mild at the moment.

The pain is moderate at the moment.

The pain is fairly severe at the moment.

The pain is very severe at the moment.

The pain is the worst imaginable at the moment.

Section 2 – Personal Care (washing, dressing, etc.)

I can look after myself normally but it is very painful.

I can look after myself normally but it is very painful.

It is painful to look after myself and I am slow and careful.

I need some help but manage most of my personal care.

I need help every day in most aspects of my personal care.

I need help every day in most aspects of self-care.

I do not get dressed, wash with difficulty, and stay in bed.

Section 3 - Lifting

I can lift heavy weights without extra pain.

I can lift heavy weights but it gives extra pain.

Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently positioned (i.e. on a table).

Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned.

I can lift only very light weights.

I cannot lift or carry anything at all.

Section 4 – Walking

Pain does not prevent me walking any distance.

Pain prevents me walking more than 1mile.

Pain prevents me walking more than ¼ of a mile.

Pain prevents me walking more than 100 yards.

I can only walk using a stick or crutches.

I am in bed most of the time and have to crawl to the toilet.

Section 5 – Sitting

I can sit in any chair as long as I like.

I can sit in my favorite chair as long as I like.

Pain prevents me from sitting for more than 1 hour.

Pain prevents me from sitting for more than ½ hour.

Pain prevents me from sitting for more than 10 minutes.

Pain prevents me from sitting at all.

Section 6 – Standing

I can stand as long as I want without extra pain.

I can stand as long as I want but it gives me extra pain.

Pain prevents me from standing more than 1 hour.

Pain prevents me from standing for more than ½ an hour.

Pain prevents me from standing for more than 10 minutes.

Pain prevents me from standing at all.

Section 7 – Sleeping

My sleep is never disturbed by pain.

My sleep is occasionally disturbed by pain.

Because of pain, I have less than 6 hours sleep.

Because of pain, I have less than 4 hours sleep.

Because of pain, I have less than 2 hours sleep.

Pain prevents me from sleeping at all.

Section 8 – Sex life (if applicable)

My sex life is normal and causes no extra pain.

My sex life is normal but causes some extra pain.

My sex life is nearly normal but is very painful.

My sex life is severely restricted by pain.

My sex life is nearly absent because of pain.

Pain prevents any sex life at all.

Section 9 – Social Life

My social life is normal and cause me no extra pain.

My social life is normal but increases the degree of pain.

Pain has no significant effect on my social life apart from limitingmy more energetic interests, i.e. sports.

Pain has restricted my social life and I do not go out as often.

Pain has restricted social life to my home.

I have no social life because of pain.

Section 10 – Traveling

I can travel anywhere without pain.

I can travel anywhere but it gives extra pain.

Pain is bad but I manage journeys of over two hours.

Pain restricts me to short necessary journeys under 30 minutes.

Pain prevents me from traveling except to receive treatment.

Ørebro screening skjema

1. Hvor lenge har du hatt dine nåværende plager? Merk av (X) **ett alternativ**.

☐0-1 uker [1] ☐ 1-2 uker [2] ☐3-4 uker [3] ☐4-5 uker [4] ☐6-8 uker [5]

☐9-11 uker [6] ☐3-6 måneder [7] ☐6-9 måneder [8] ☐9-12 måneder [9] ☐Over ett år [10]

Sett sirkel rundt det tallet som BEST beskriver dine opplevelser på følgende spørsmål/påstander:

2. Hvor mye smerte har du hatt den **siste uken?**

0 1 2 3 4 5 6 7 8 9 10 [ ]

Ingen smerte *Verst tenkelige smerte*

3. Jeg kan utføre lettere arbeid under en time.

0 1 2 3 4 5 6 7 8 9 10 (10-) [ ]

Kan ikke gjøre det p.g.a. smerte *Kan gjøre det uten smerteproblem*

4. Jeg kan sove på natten.

0 1 2 3 4 5 6 7 8 9 10 (10-) [ ]

Kan ikke gjøre det p.g.a. smerte *Kan gjøre det uten smerteproblem*

5. Hvor anspent eller stresset har du kjent deg den **siste uken?**

0 1 2 3 4 5 6 7 8 9 10 [ ]

Fullstendig rolig og avslappet — *Veldig anspent*

6. I hvilken grad har du kjent deg nedstemt den **siste uken**? Sett ring rundt ett tall.

0 1 2 3 4 5 6 7 8 9 10 [ ]

Ikke i det hele tatt — *Svært mye*

7. Hvor stor risiko mener du det er for at dine nåværende plager kan bli langvarige?

0 1 2 3 4 5 6 7 8 9 10 [ ]

Ingen risiko — *Svært stor risiko*

8. Ut fra din vurdering, hvor stor er sjansen for at du er i arbeid om **tre måneder**? Sett ring rundt ett tall

0 1 2 3 4 5 6 7 8 9 10 (10-) [ ]

Ingen sjanse — *Svært stor sjanse*

9. Om plagene øker, er det et signal på at jeg bør slutte med det jeg holder på med, til plagene minker.

0 1 2 3 4 5 6 7 8 9 10 [ ]

Ikke enig — *Helt enig*

10. Jeg bør ikke utføre mine normale aktiviteter eller arbeid med den smerten jeg har nå.

0 1 2 3 4 5 6 7 8 9 10 [ ]

Ikke enig — *Helt enig*

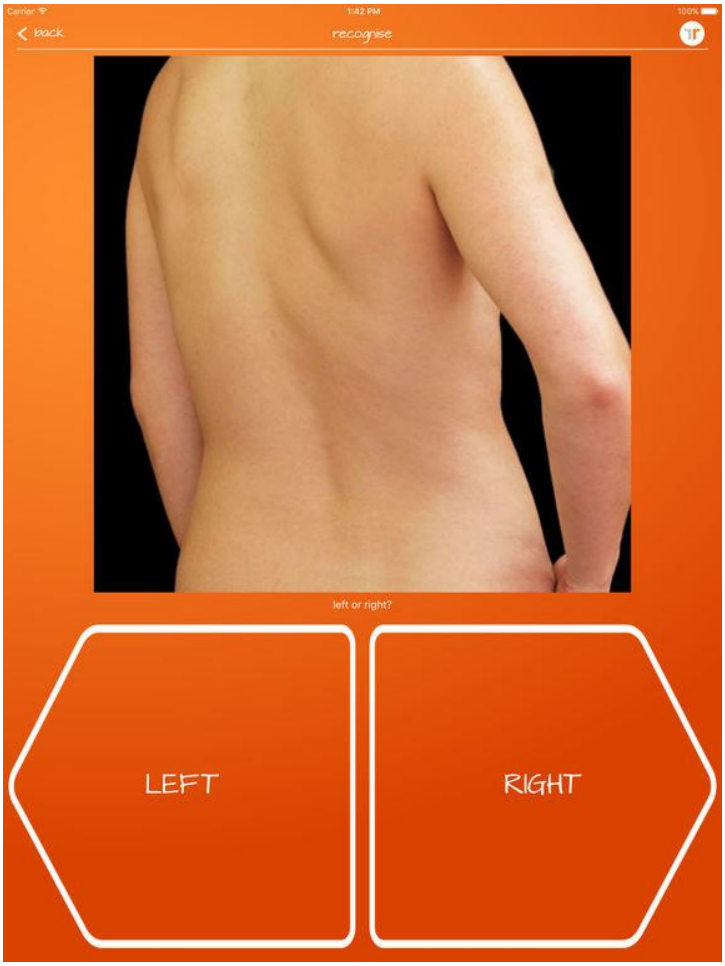
Fremantle Back Awareness Questionnaire (FreBAQ)

Item	Never	Rarely	Occasionally	Often	Always
1. My back feels as though it is not part of the rest of my body					
2. I need to focus all my attention on my back to make it move the way I want it to					

3. I feel as if my back sometimes moves involuntarily, without my control					
4. When performing everyday tasks, I don't know how my back is moving					
5. When performing everyday tasks, I am not always sure where my back is in space					
6. I can't perceive the exact outline of my back					
7. My back feels like it is enlarged (swollen)					
8. My back feels like it has shrunk					
9. My back feels lopsided (asymmetrical)					

Protocol for the Recognise ™

1. Patients will be informed that they will look at pictures and then quickly decide whether the person in the picture is rotating towards the left or right.
2. The person is told to use left index finger to press "left" and the right index finger to press "right".
3. The participant will be introduced to the app via "Vanilla", which is an easy introduction level with 20 images, max time of 5 seconds.
4. Then the participant is tested using: "test".
5. The participant will be going through 2 x 40 images.
6. The researcher will collect reaction time and accuracy for both left and right images.



The Patient-Specific Functional Scale

This useful questionnaire can be used to quantify activity limitation and measure functional outcome for patients with any orthopaedic condition.

Clinician to read and fill in below: Complete at the end of the history and prior to physical examination.

Initial Assessment:

I am going to ask you to identify up to three important activities that you are unable to do or are having difficulty with as a result of your _____ problem. Today, are there any activities that you are unable to do or having difficulty with because of your _____ problem? (Clinician: show scale to patient and have the patient rate each activity).

Follow-up Assessments:

When I assessed you on (state previous assessment date), you told me that you had difficulty with (read all activities from list at a time). Today, do you still have difficulty with: (read and have patient score each item in the list)?

Patient-specific activity scoring scheme (Point to one number):

0 1 2 3 4 5 6 7 8 9 10

Unable to perform activity

Able to perform activity at the same level as before injury or problem

(Date and Score)

Activity	**Initial**					
1.						
2.						
3.						
4.						
5.						
Additional						
Additional						

Total score = sum of the activity scores/number of activities

PSFS developed by: Stratford, P., Gill, C., Westaway, M., & Binkley, J. (1995). Assessing disability and change on individual patients: a report of a patient specific measure. Physiotherapy Canada, 47, 258-263.

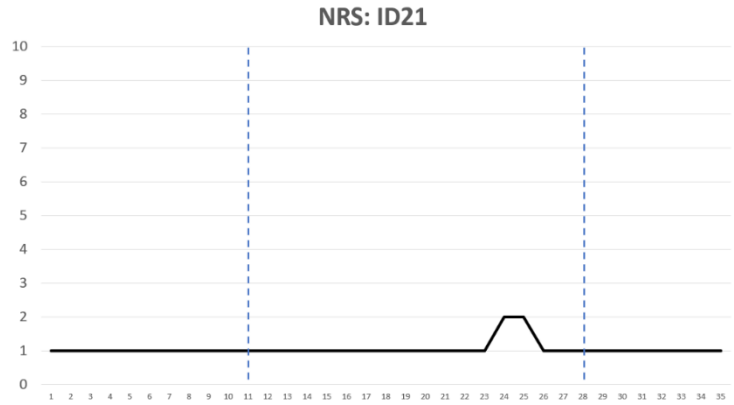
Appendix 5 – t-table

t Table

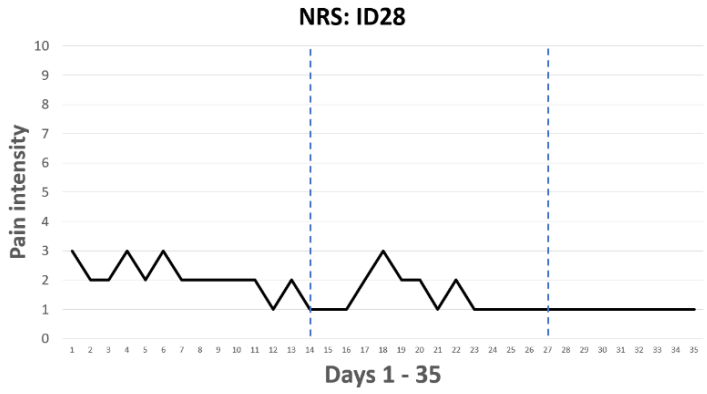
cum. prob	$t_{.50}$	$t_{.75}$	$t_{.80}$	$t_{.85}$	$t_{.90}$	$t_{.95}$	$t_{.975}$	$t_{.99}$	$t_{.995}$	$t_{.999}$	$t_{.9995}$
one-tail	**0.50**	**0.25**	**0.20**	**0.15**	**0.10**	**0.05**	**0.025**	**0.01**	**0.005**	**0.001**	**0.0005**
two-tails	**1.00**	**0.50**	**0.40**	**0.30**	**0.20**	**0.10**	**0.05**	**0.02**	**0.01**	**0.002**	**0.001**
df											
1	0.000	1.000	1.376	1.963	3.078	6.314	12.71	31.82	63.66	318.31	636.62
2	0.000	0.816	1.061	1.386	1.886	2.920	4.303	6.965	9.925	22.327	31.599
3	0.000	0.765	0.978	1.250	1.638	2.353	3.182	4.541	5.841	10.215	12.924
4	0.000	0.741	0.941	1.190	1.533	2.132	2.776	3.747	4.604	7.173	8.610
5	0.000	0.727	0.920	1.156	1.476	2.015	2.571	3.365	4.032	5.893	6.869
6	0.000	0.718	0.906	1.134	1.440	1.943	2.447	3.143	3.707	5.208	5.959
7	0.000	0.711	0.896	1.119	1.415	1.895	2.365	2.998	3.499	4.785	5.408
8	0.000	0.706	0.889	1.108	1.397	1.860	2.306	2.896	3.355	4.501	5.041
9	0.000	0.703	0.883	1.100	1.383	1.833	2.262	2.821	3.250	4.297	4.781
10	0.000	0.700	0.879	1.093	1.372	1.812	2.228	2.764	3.169	4.144	4.587
11	0.000	0.697	0.876	1.088	1.363	1.796	2.201	2.718	3.106	4.025	4.437
12	0.000	0.695	0.873	1.083	1.356	1.782	2.179	2.681	3.055	3.930	4.318
13	0.000	0.694	0.870	1.079	1.350	1.771	2.160	2.650	3.012	3.852	4.221
14	0.000	0.692	0.868	1.076	1.345	1.761	2.145	2.624	2.977	3.787	4.140
15	0.000	0.691	0.866	1.074	1.341	1.753	2.131	2.602	2.947	3.733	4.073
16	0.000	0.690	0.865	1.071	1.337	1.746	2.120	2.583	2.921	3.686	4.015
17	0.000	0.689	0.863	1.069	1.333	1.740	2.110	2.567	2.898	3.646	3.965
18	0.000	0.688	0.862	1.067	1.330	1.734	2.101	2.552	2.878	3.610	3.922
19	0.000	0.688	0.861	1.066	1.328	1.729	2.093	2.539	2.861	3.579	3.883
20	0.000	0.687	0.860	1.064	1.325	1.725	2.086	2.528	2.845	3.552	3.850
21	0.000	0.686	0.859	1.063	1.323	1.721	2.080	2.518	2.831	3.527	3.819
22	0.000	0.686	0.858	1.061	1.321	1.717	2.074	2.508	2.819	3.505	3.792
23	0.000	0.685	0.858	1.060	1.319	1.714	2.069	2.500	2.807	3.485	3.768
24	0.000	0.685	0.857	1.059	1.318	1.711	2.064	2.492	2.797	3.467	3.745
25	0.000	0.684	0.856	1.058	1.316	1.708	2.060	2.485	2.787	3.450	3.725
26	0.000	0.684	0.856	1.058	1.315	1.706	2.056	2.479	2.779	3.435	3.707
27	0.000	0.684	0.855	1.057	1.314	1.703	2.052	2.473	2.771	3.421	3.690
28	0.000	0.683	0.855	1.056	1.313	1.701	2.048	2.467	2.763	3.408	3.674
29	0.000	0.683	0.854	1.055	1.311	1.699	2.045	2.462	2.756	3.396	3.659
30	0.000	0.683	0.854	1.055	1.310	1.697	2.042	2.457	2.750	3.385	3.646
40	0.000	0.681	0.851	1.050	1.303	1.684	2.021	2.423	2.704	3.307	3.551
60	0.000	0.679	0.848	1.045	1.296	1.671	2.000	2.390	2.660	3.232	3.460
80	0.000	0.678	0.846	1.043	1.292	1.664	1.990	2.374	2.639	3.195	3.416
100	0.000	0.677	0.845	1.042	1.290	1.660	1.984	2.364	2.626	3.174	3.390
1000	0.000	0.675	0.842	1.037	1.282	1.646	1.962	2.330	2.581	3.098	3.300
z	0.000	0.674	0.842	1.036	1.282	1.645	1.960	2.326	2.576	3.090	3.291
	0%	50%	60%	70%	80%	90%	95%	98%	99%	99.8%	99.9%
	Confidence Level										

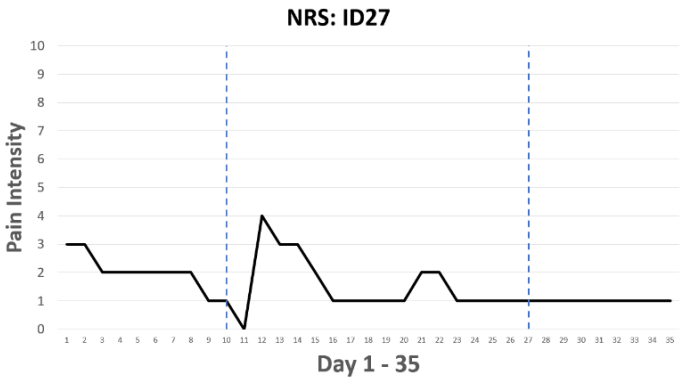
t-table.xls 7/14/2007

Appendix 6 – Outliers in NRS score: ID21, ID27 and ID28



ID21 was removed from the data analysis due to a very low NRS-score at baseline, which should have been detected earlier. The participant registered 4/10 on NRS scale during screening at the Outpatient Spine Clinic 26.04.18, but when meeting with MS and TFL 11.05.18 for enrolment in the study, pain levels had continued to drop to 1/10. The participant should therefore have been excluded before entering the study and will be excluded from the data analysis. Additionally, two participants (ID26 and ID27) showed abnormal low NRS scores and we chose to do a sensitivity analysis on these two participants. Results are shown in subsection 3.2.1. and Table 5.





Appendix 7 – Secondary outcome measures (full table)

	ODI			ÖMPSQ short form			FreBAQ		
	Baseline	FU	Change,%	Baseline	FU	Change	Baseline	FU	Change
ID22	56%	42%	**-14%**	74	64	**-13,51%**	17,8%	4,4%	**-13,4%**
ID23	48%	52%	+4%	**57***	**46***	**-19,29%**	35,5%	24,4%	**-11,1%**
ID24	38%	24%	**-14%**	46	34	**-26,08%**	15,5%	20%	+4,5%
ID25	54%	36%	**-18%**	35	28	**-20%**	53,3%	11,1%	**-42,2%**
ID26	70%	52%	**-18%**	66	71	+7,57%	8,88%	11,1%	+2,23%
ID27	36%	32%	**-4%**	24	16	**-33,33%**	22,2%	12,2%	**-20%**
ID28	30%	28%	**-2%**	21	26	+23,80%	0	0	0
ID29	62%	64%	+2%	**58***	**48***	**-17,24%**	17,8%	15,6%	**-2,2%**
ID30	44%	56%	+12%	56	52	**-7,14%**	0	4,4%	+4,4%

Table 1: secondary outcome measures for ODI, ÖMPSQ short form and FreBAQ. Notes: Reductions in scores are marked in "bold" headings.

Appendix 8 – Recognize ™ (full table)

	Time (seconds)						**Accuracy (percentages)**					
	Left			**Right**			**Left**					**Right**
	Baseline	FU	Change %	Baseline	FU	Change %	Baseline	FU	Change	Baseline	FU	Change
ID22	0,95	1,8	+47,2%	2,95	1,2	**-59,3%**	25%	55%	**+30%**	85%	65%	-20%
ID23	1,2	3	+60%	2,0	1,7	**-15%**	80%	80%	0	75%	60%	-15%
ID24	0,8	1	+20%	1,3	1,15	**-11,5%**	75%	80%	**+5%**	90%	90%	0
ID25	2,5	1,65	**-34%**	1,55	1,4	**-9,7%**	35%	65%	**+30%**	30%	55%	**+25%**
ID26	0,8	0,9	+11,1%	1,2	0,85	**-29,1%**	90%	95%	**+5%**	90%	85%	-5%
ID27	1,05	0,85	**-19%**	1,1	0,8	**-27,3%**	95%	90%	-5%	100%	75%	-25%
ID28	0,9	0,8	**-11,1%**	1,2	1	**-16,7%**	90%	95%	**+5%**	95%	100%	**+5%**
ID29	1,35	1,05	**-22,2%**	1,9	0,85	**-55,3%**	100%	85%	-15%	95%	70%	-25%
ID30	0,8	0,6	**-25%**	1	0,75	**-25%**	85%	85%	0	95%	85%	-10%

Table 1: Recognise ™ change scores. Notes: Improvements in Recognise™ scores are marked in "bold" headings.

Appendix 9 - Patient Specific Functional Scale (PSFS)

Due to an administrative error at follow-up, we decided to exclude the questionnaire from the analysis. Participants were given two different form: one at baseline and one a follow-up, which resulted in participants registering difficulties with different tasks from testing point 1 to testing point 2 (e.g. making it harder to measure change in the same task). This resulted in many missing values at follow-up. Explanation of scores: score: 0 = unable to perform activity, 10 = able to perform activity at the same level as before injury or problem. The questionnaire was excluded from the analysis.

ID	Q#	Question	Baseline	Follow-up	Change
ID22	Q1	Lifting heavy	4	5	1
	Q2	Carrying heavy things	3	5	2
	Q3	Vacuuming	4	4	0
ID23	Q1	Sitting in excavator	3	5	2
	Q2	Sitting in a truck	3	5	2
	Q3	Sitting in the office	3	missing	0
ID24	Q1	Driving far	4	missing	
	Q2	Certain tasks at work	4	5	1
	Q3	Strength training	2	missing	missing
ID25	Q1	Sitting	2	missing	missing
	Q2	Walking uphill	2	missing	missing
	Q3	Shower	2	missing	missing
ID26	Q1	Walking	4	5	1
	Q2	Sitting	4	5	1
	Q3	Bending forwards	2	8	6
ID7	Q1	Working	4	7	3
	Q2	Walking/hiking	6	9	3
	Q3	Lifting	6	8	2
ID28	Q1	missing	missing	missing	missing
	Q2	missing	missing	missing	missing
	Q3	missing	missing	missing	missing
ID29	Q1	Doing the dishes	0	0	0
	Q2	Dressing	4	5	1
	Q3	Bowling	8	8	0
ID30	Q1	Sitting	2	2	0
	Q2	Lifting	3	3	0
	Q3	missing	missing	missing	Missing

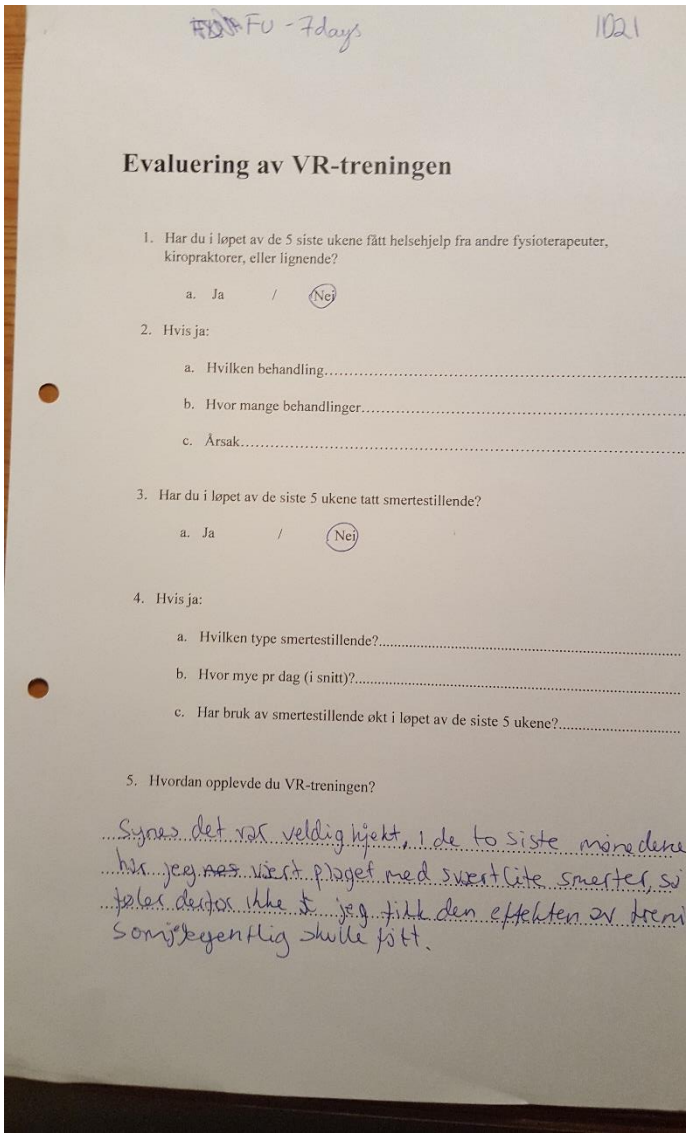
Table 1: only ID26 and ID27 show MIC for some tasks. However, there are too many missing values to interpret the data according to procedure.

Appendix 10 – Mild and moderate TSK-11 scores

Participant	TSK score
ID22	25/52 (mild)
ID23	37/52 (moderate)
ID24	35/52 (moderate)
ID25	28/52 (mild)
ID26	32/52 (mild)
ID27	34/52 (moderate)
ID28	25/52 (mild)
ID29	25/52 (mild)
ID30	38/52 (moderate)

Table 1: TSK-11 score at baseline

Appendix 11 – Patient evaluation of the VR-study

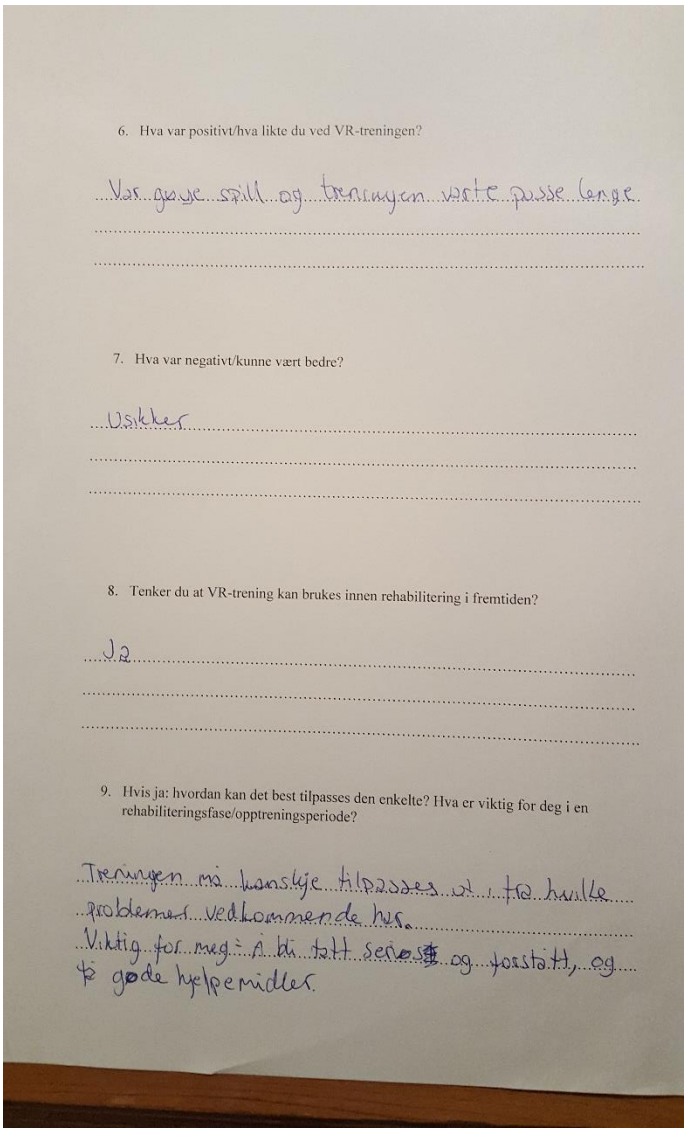


FU - 7days 1021

Evaluering av VR-treningen

1. Har du i løpet av de 5 siste ukene fått helsehjelp fra andre fysioterapeuter, kiropraktorer, eller lignende?
   a. Ja / (Nei)
2. Hvis ja:
   a. Hvilken behandling.....
   b. Hvor mange behandlinger.....
   c. Årsak.....
3. Har du i løpet av de siste 5 ukene tatt smertestillende?
   a. Ja / (Nei)
4. Hvis ja:
   a. Hvilken type smertestillende?.....
   b. Hvor mye pr dag (i snitt)?.....
   c. Har bruk av smertestillende økt i løpet av de siste 5 ukene?.....
5. Hvordan opplevde du VR-treningen?

Synes det var veldig hjelpt, i de to siste månedene har jeg ~~ass~~ vært plaget med svært lite smerter, så føler derfor ikke at jeg fikk den effekten av treningen som egentlig skulle sitt.



6. Hva var positivt/hva likte du ved VR-treningen?

Var gøye spill og treningen varte passe lenge

7. Hva var negativt/kunne vært bedre?

Usikker

8. Tenker du at VR-trening kan brukes innen rehabilitering i fremtiden?

Ja

9. Hvis ja: hvordan kan det best tilpasses den enkelte? Hva er viktig for deg i en rehabiliteringsfase/opptreningsperiode?

Treningen må kunstig tilpasses ut i fra hvilke problemer vedkommende har.
Viktig for meg: å bli tatt seriøst og forstått, og få gode hjelpemidler.

7.2. FU 19.mars 1922

Evaluering av VR-treningen

1. Har du i løpet av de 5 siste ukene fått helsehjelp fra andre fysioterapeuter, kiropraktorer, eller lignende?

   a. Ja / (Nei)

2. Hvis ja:

   a. Hvilken behandling.....

   b. Hvor mange behandlinger.....

   c. Årsak.....

3. Har du i løpet av de siste 5 ukene tatt smertestillende?

   (a. Ja) / Nei

4. Hvis ja:

   a. Hvilken type smertestillende? Paracet forte

   b. Hvor mye pr dag (i snitt)? 1 til 2

   c. Har bruk av smertestillende økt i løpet av de siste 5 ukene? Ja

5. Hvordan opplevde du VR-treningen?

Veldig positiv burde ha vært mere
Treningen har hjelpet meg.

6. Hva var positivt/hva likte du ved VR-treningen?

Variasjon i treningen, kjekke folk

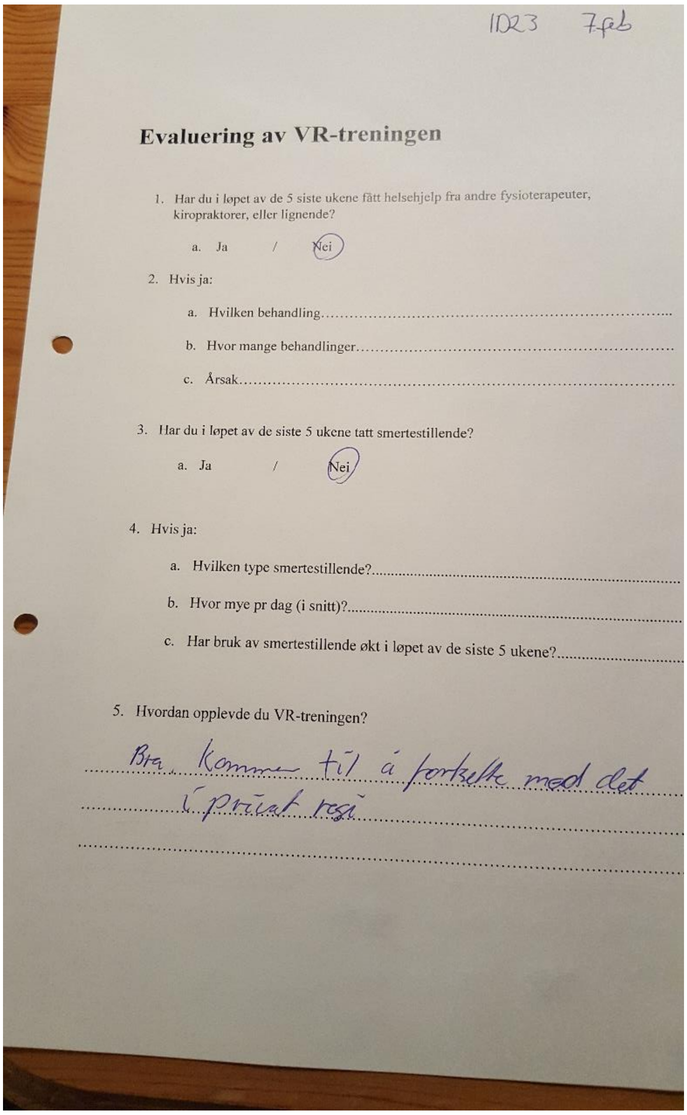
7. Hva var negativt/kunne vært bedre?

8. Tenker du at VR-trening kan brukes innen rehabilitering i fremtiden?

Absolutt positivt

9. Hvis ja: hvordan kan det best tilpasses den enkelte? Hva er viktig for deg i en rehabiliteringsfase/opptreningsperiode?

~~Kontinuis~~ Kontinuitet

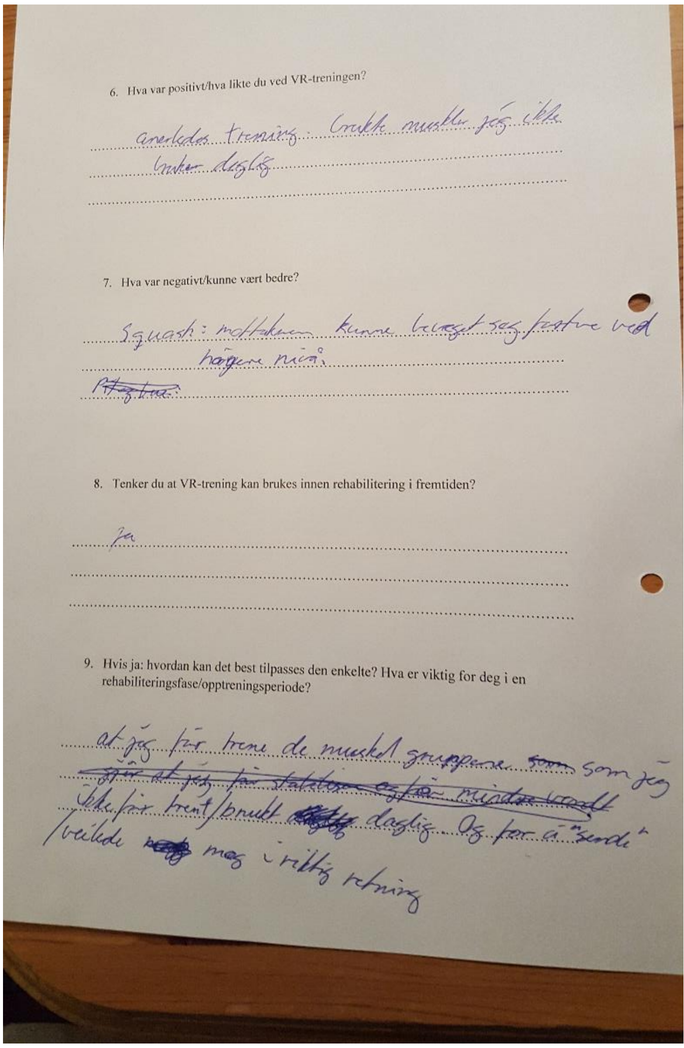


ID23 7.feb

Evaluering av VR-treningen

1. Har du i løpet av de 5 siste ukene fått helsehjelp fra andre fysioterapeuter, kiropraktorer, eller lignende?
   a. Ja / (Nei)
2. Hvis ja:
   a. Hvilken behandling........
   b. Hvor mange behandlinger........
   c. Årsak........
3. Har du i løpet av de siste 5 ukene tatt smertestillende?
   a. Ja / (Nei)
4. Hvis ja:
   a. Hvilken type smertestillende?........
   b. Hvor mye pr dag (i snitt)?........
   c. Har bruk av smertestillende økt i løpet av de siste 5 ukene?........
5. Hvordan opplevde du VR-treningen?

   Bra, kommer til å fortsette med det i privat regi



6. Hva var positivt/hva likte du ved VR-treningen?

   annerledes trening: brukte muskler jeg ikke bruker daglig

7. Hva var negativt/kunne vært bedre?

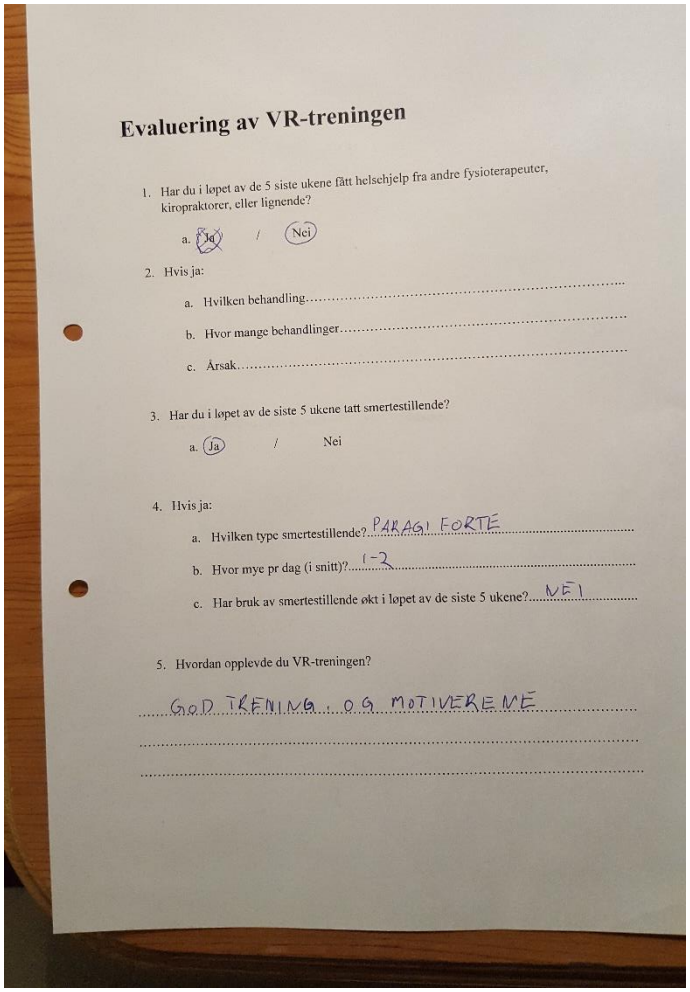
   Squash: motstanderen kunne beveget seg fortere ved høyere nivå.

8. Tenker du at VR-trening kan brukes innen rehabilitering i fremtiden?

   Ja

9. Hvis ja: hvordan kan det best tilpasses den enkelte? Hva er viktig for deg i en rehabiliteringsfase/opptreningsperiode?

   at jeg får trene de muskelgruppene som jeg ikke får trent/brukt daglig. Og får å "sende"/veilede meg i riktig retning



Evaluering av VR-treningen

1. Har du i løpet av de 5 siste ukene fått helsehjelp fra andre fysioterapeuter, kiropraktorer, eller lignende?

   a. (Ja) / (Nei)

2. Hvis ja:

   a. Hvilken behandling.....

   b. Hvor mange behandlinger.....

   c. Årsak.....

3. Har du i løpet av de siste 5 ukene tatt smertestillende?

   a. (Ja) / Nei

4. Hvis ja:

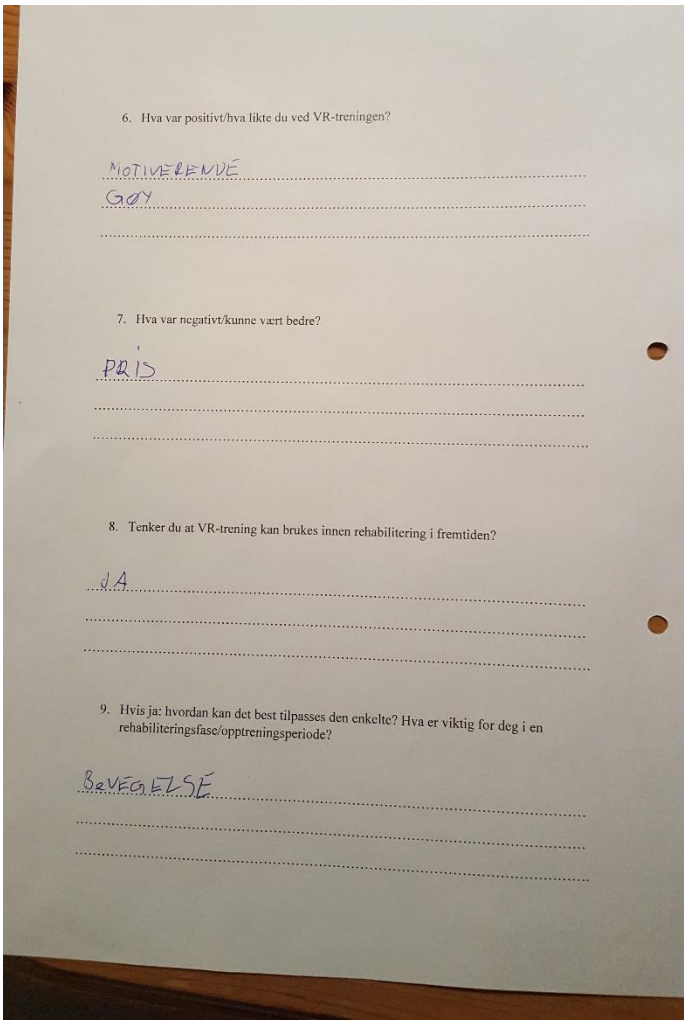
   a. Hvilken type smertestillende? PARAGI FORTE

   b. Hvor mye pr dag (i snitt)? 1-2

   c. Har bruk av smertestillende økt i løpet av de siste 5 ukene? NEI

5. Hvordan opplevde du VR-treningen?

   GOD TRENING, OG MOTIVERENDE



6. Hva var positivt/hva likte du ved VR-treningen?

   MOTIVERENDE
   GØY

7. Hva var negativt/kunne vært bedre?

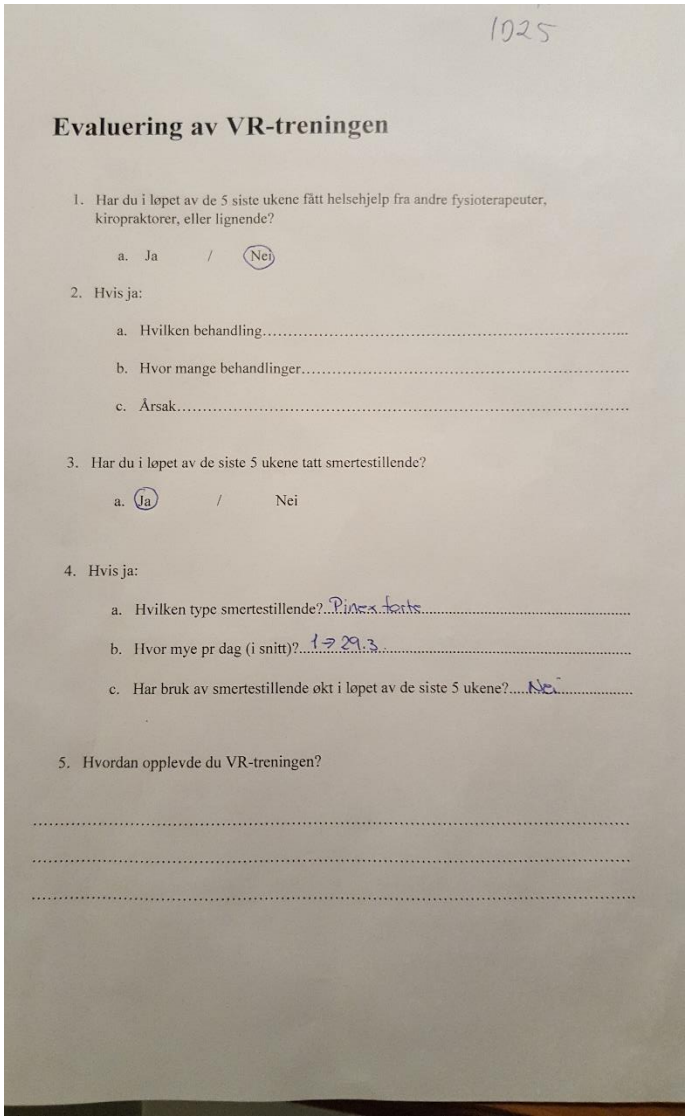
   PRIS

8. Tenker du at VR-trening kan brukes innen rehabilitering i fremtiden?

   JA

9. Hvis ja: hvordan kan det best tilpasses den enkelte? Hva er viktig for deg i en rehabiliteringsfase/opptreningsperiode?

   BEVEGELSE



1025

Evaluering av VR-treningen

1. Har du i løpet av de 5 siste ukene fått helsehjelp fra andre fysioterapeuter, kiropraktorer, eller lignende?

   a. Ja / (Nei)

2. Hvis ja:

   a. Hvilken behandling.....

   b. Hvor mange behandlinger.....

   c. Årsak.....

3. Har du i løpet av de siste 5 ukene tatt smertestillende?

   a. (Ja) / Nei

4. Hvis ja:

   a. Hvilken type smertestillende? Pinex forte

   b. Hvor mye pr dag (i snitt)? 1 -> 29.3

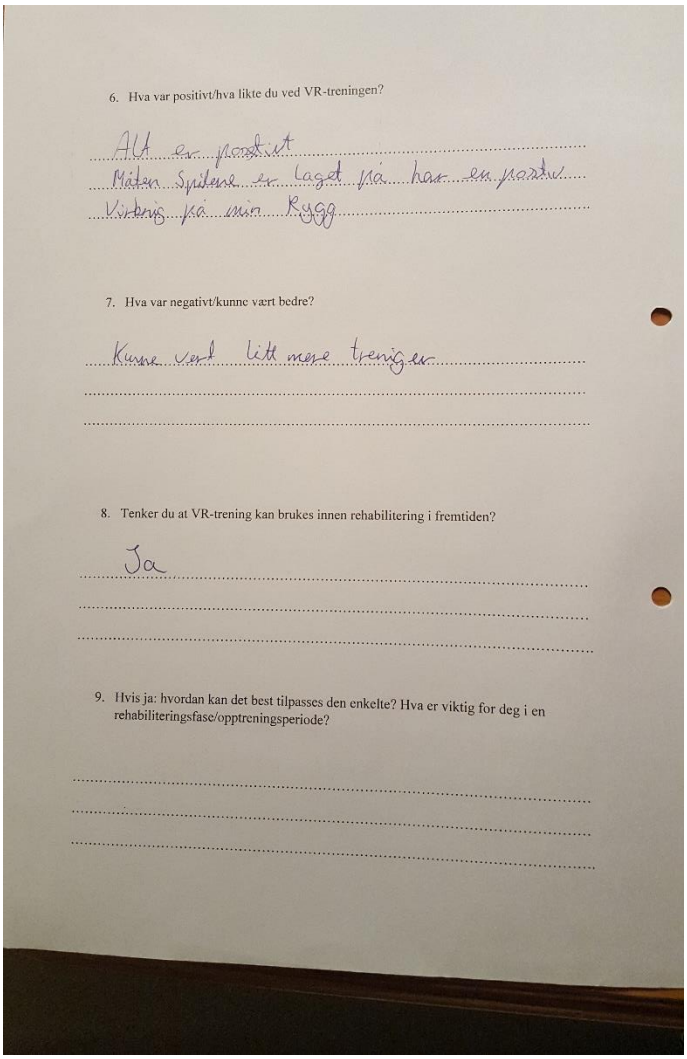
   c. Har bruk av smertestillende økt i løpet av de siste 5 ukene? Nei

5. Hvordan opplevde du VR-treningen?

.....

.....

.....



6. Hva var positivt/hva likte du ved VR-treningen?

Alt er positivt
Måten Spillene er lagd på har en positiv
Virkning på min Rygg

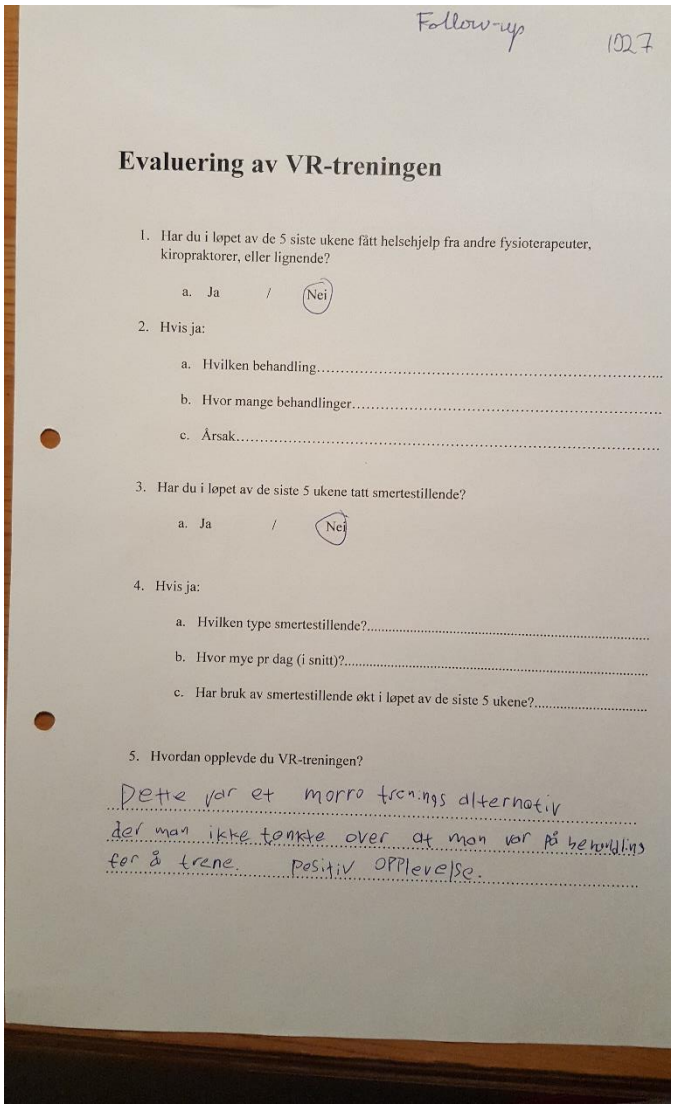
7. Hva var negativt/kunne vært bedre?

Kunne vært litt mere treninger

8. Tenker du at VR-trening kan brukes innen rehabilitering i fremtiden?

Ja

9. Hvis ja: hvordan kan det best tilpasses den enkelte? Hva er viktig for deg i en rehabiliteringsfase/opptreningsperiode?

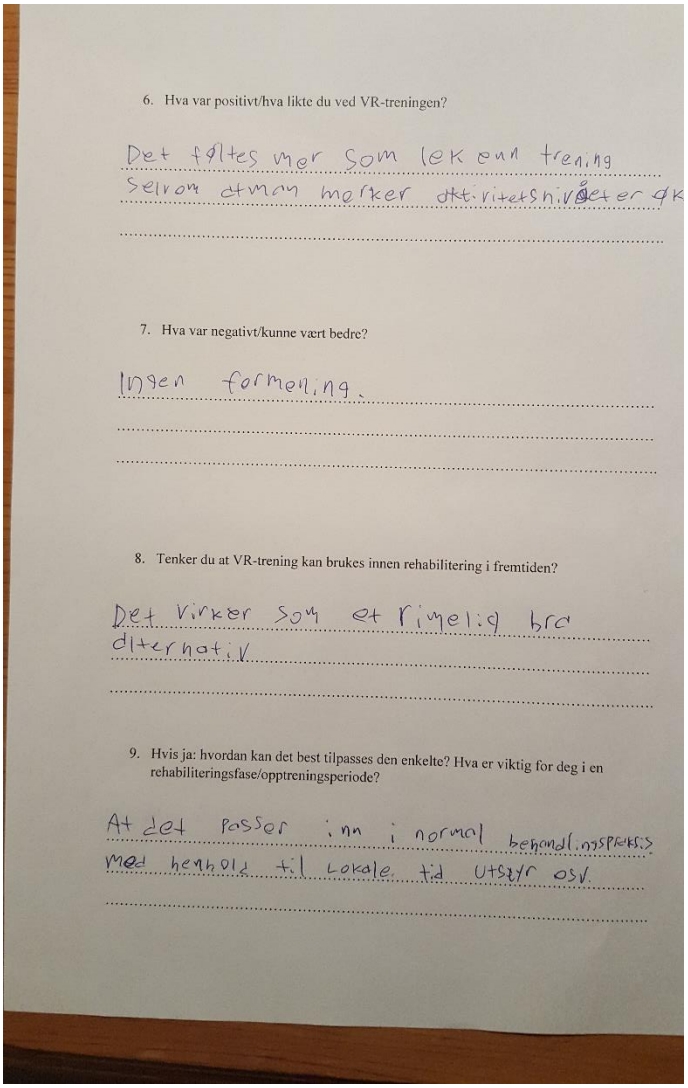


Follow-up 1027

Evaluering av VR-treningen

1. Har du i løpet av de 5 siste ukene fått helsehjelp fra andre fysioterapeuter, kiropraktorer, eller lignende?
   a. Ja / (Nei)
2. Hvis ja:
   a. Hvilken behandling.....
   b. Hvor mange behandlinger.....
   c. Årsak.....
3. Har du i løpet av de siste 5 ukene tatt smertestillende?
   a. Ja / (Nei)
4. Hvis ja:
   a. Hvilken type smertestillende?.....
   b. Hvor mye pr dag (i snitt)?.....
   c. Har bruk av smertestillende økt i løpet av de siste 5 ukene?.....
5. Hvordan opplevde du VR-treningen?

Dette var et morro trenings alternativ der man ikke tenkte over at man var på behandlings fer å trene. positiv opplevelse.



6. Hva var positivt/hva likte du ved VR-treningen?

Det føltes mer som lek enn trening selvom man merker aktivitetsnivået er øk

7. Hva var negativt/kunne vært bedre?

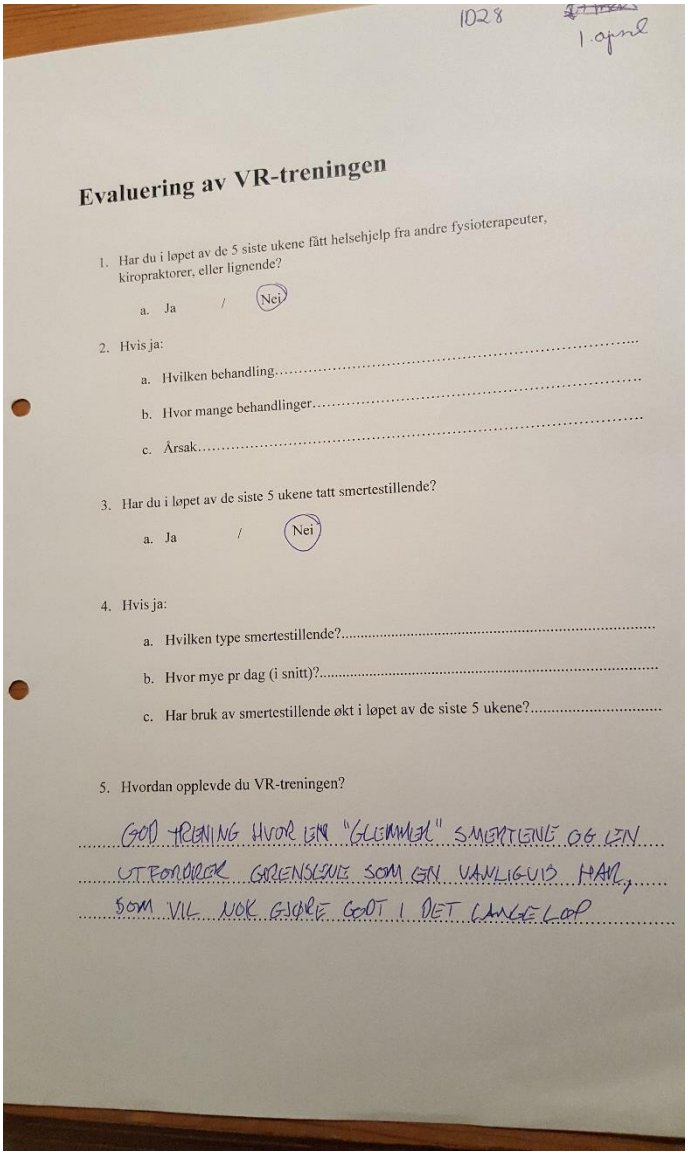
Ingen formening.

8. Tenker du at VR-trening kan brukes innen rehabilitering i fremtiden?

Det virker som et rimelig bra alternativ

9. Hvis ja: hvordan kan det best tilpasses den enkelte? Hva er viktig for deg i en rehabiliteringsfase/opptreningsperiode?

At det passer inn i normal behandlingspraksis med henhold til lokale tid utstyr osv.



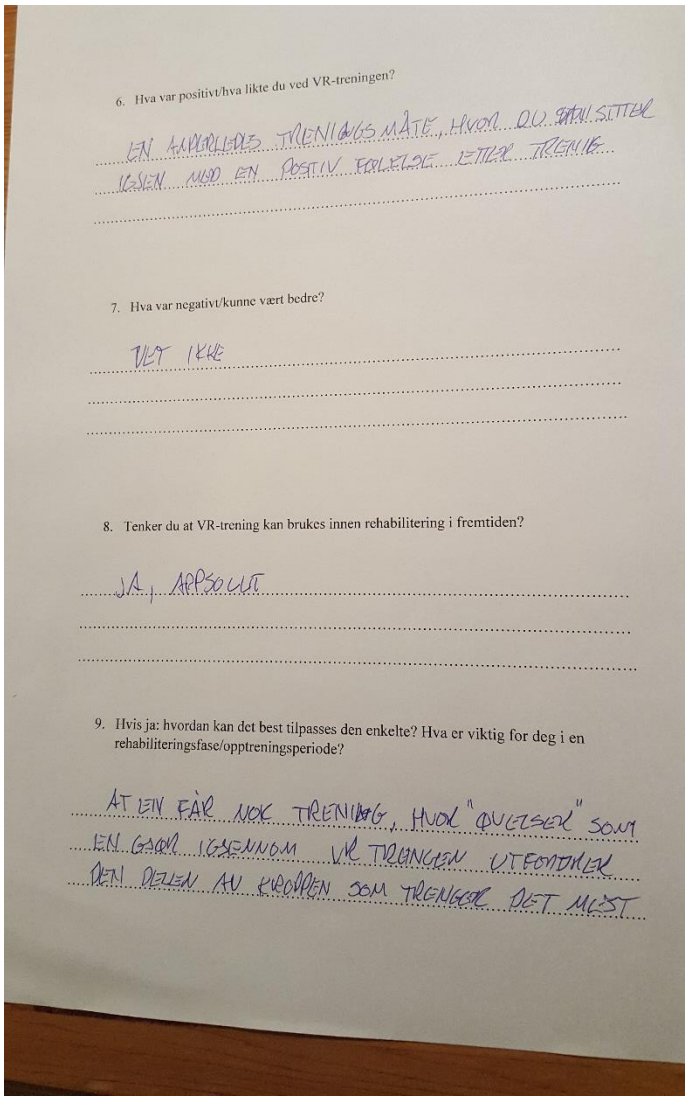
1028

1. gang

Evaluering av VR-treningen

1. Har du i løpet av de 5 siste ukene fått helsehjelp fra andre fysioterapeuter, kiropraktorer, eller lignende?
   a. Ja / (Nei)
2. Hvis ja:
   a. Hvilken behandling.....
   b. Hvor mange behandlinger.....
   c. Årsak.....
3. Har du i løpet av de siste 5 ukene tatt smertestillende?
   a. Ja / (Nei)
4. Hvis ja:
   a. Hvilken type smertestillende?.....
   b. Hvor mye pr dag (i snitt)?.....
   c. Har bruk av smertestillende økt i løpet av de siste 5 ukene?.....
5. Hvordan opplevde du VR-treningen?

GOD TRENING HVOR EN "GLEMMER" SMERTENE OG EN UTFORDRER GRENSENE SOM EN VANLIGVIS HAR, SOM VIL NOK GJØRE GODT I DET LANGE LØP



6. Hva var positivt/hva likte du ved VR-treningen?

EN ANNERLEDES TRENINGS MÅTE, HVOR DU BARE SITTER IGJEN MED EN POSITIV FØLELSE ETTER TRENING

7. Hva var negativt/kunne vært bedre?

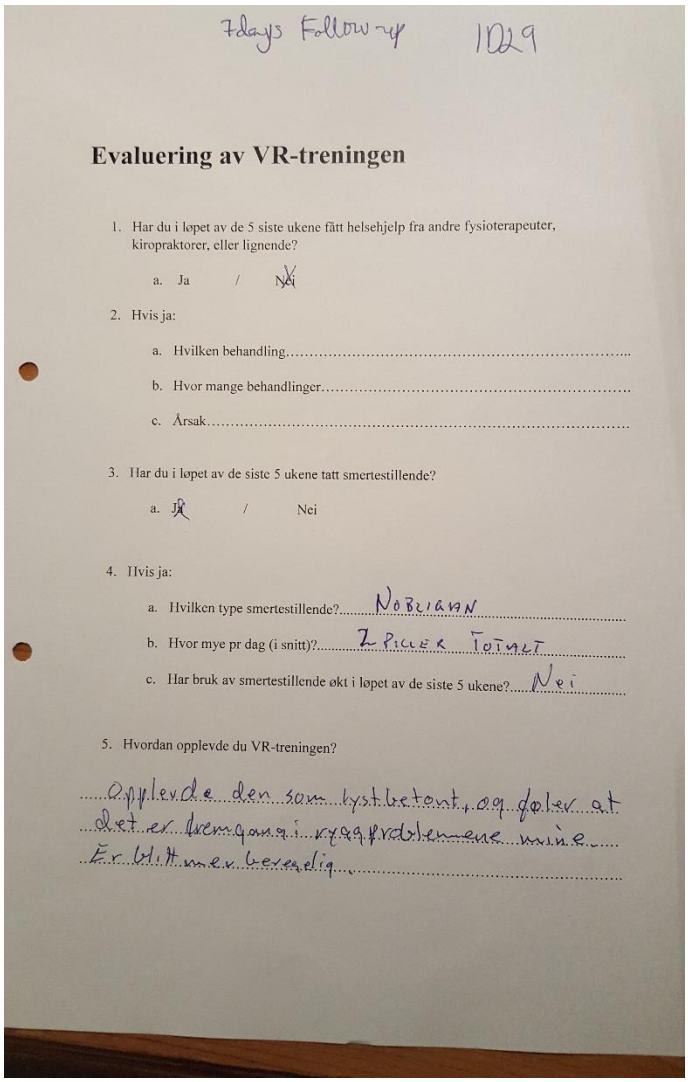
VET IKKE

8. Tenker du at VR-trening kan brukes innen rehabilitering i fremtiden?

JA, ABSOLUTT

9. Hvis ja: hvordan kan det best tilpasses den enkelte? Hva er viktig for deg i en rehabiliteringsfase/opptreningsperiode?

AT EN FÅR NOK TRENING, HVOR "ØVELSER" SOM EN GÅR IGJENNOM VR TRENINGEN UTFORDRER DEN DELEN AV KROPPEN SOM TRENGER DET MEST



7days Follow-up 1029

Evaluering av VR-treningen

1. Har du i løpet av de 5 siste ukene fått helsehjelp fra andre fysioterapeuter, kiropraktorer, eller lignende?
   a. Ja / Nei

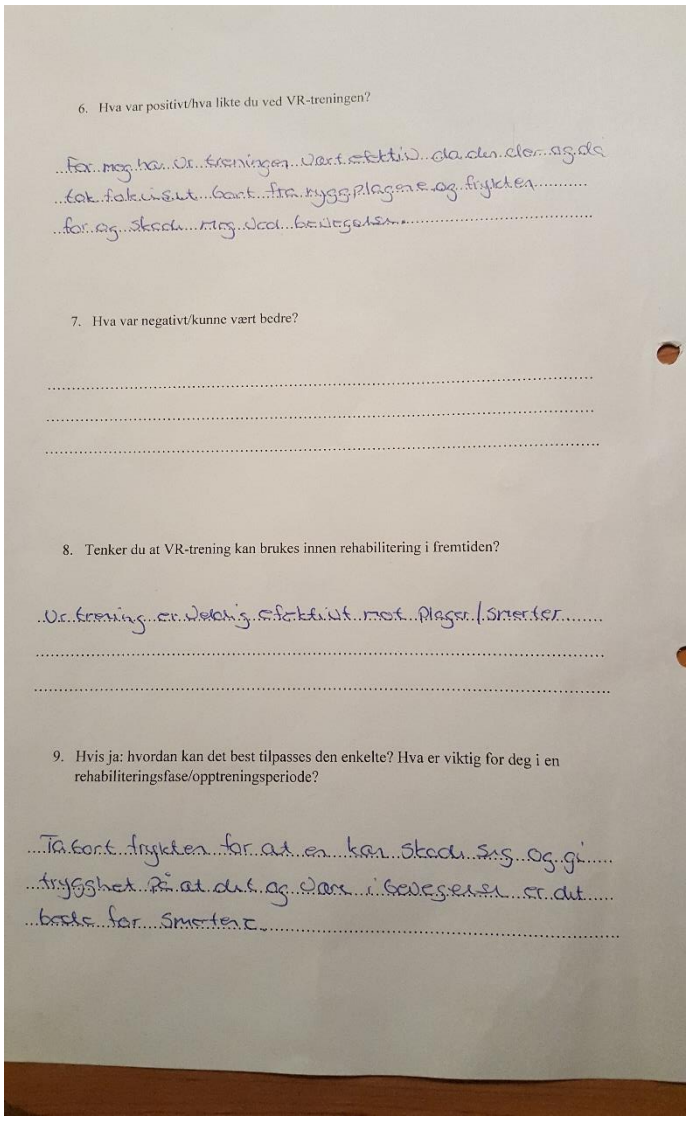
2. Hvis ja:
   a. Hvilken behandling.....
   b. Hvor mange behandlinger.....
   c. Årsak.....

3. Har du i løpet av de siste 5 ukene tatt smertestillende?
   a. Ja / Nei

4. Hvis ja:
   a. Hvilken type smertestillende? NOBLIGAN
   b. Hvor mye pr dag (i snitt)? 2 PILLER TOTALT
   c. Har bruk av smertestillende økt i løpet av de siste 5 ukene? Nei

5. Hvordan opplevde du VR-treningen?

Opplevde den som kystbetont, og føler at det er fremgang i ryggproblemene mine. Er blitt mer bevisstlig.



6. Hva var positivt/hva likte du ved VR-treningen?

For meg har VR-treningen vært effektiv da den ble lagt fokus ut fra ryggplagene og frykten for og skade meg ved bevegelse.

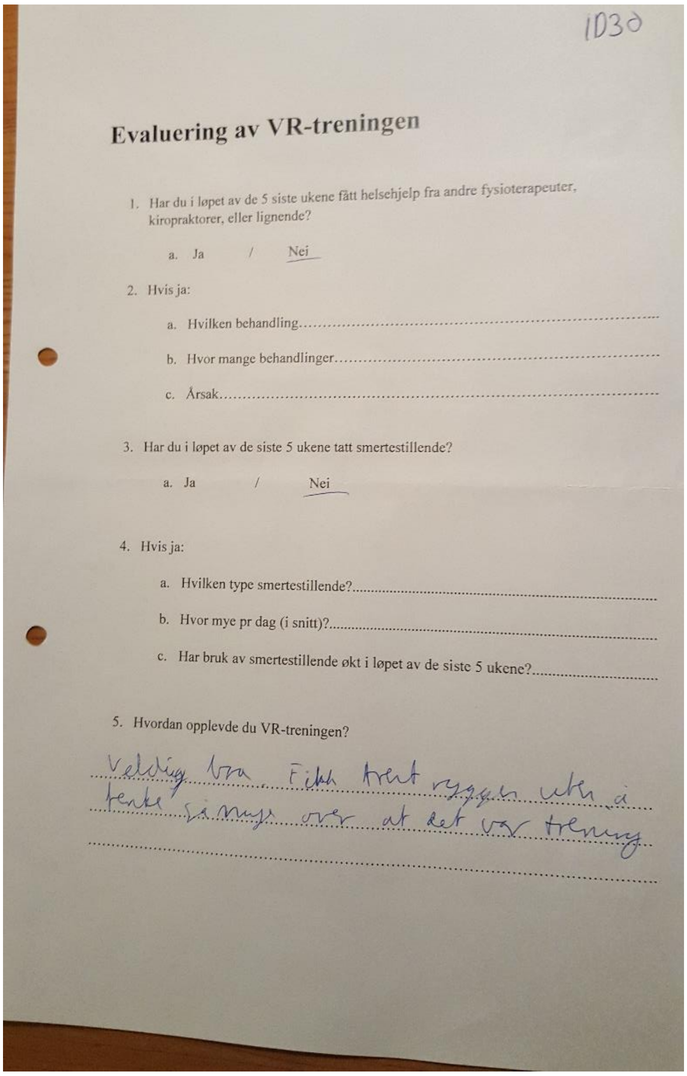
7. Hva var negativt/kunne vært bedre?

8. Tenker du at VR-trening kan brukes innen rehabilitering i fremtiden?

VR-trening er veldig effektivt mot plager/smerter.

9. Hvis ja: hvordan kan det best tilpasses den enkelte? Hva er viktig for deg i en rehabiliteringsfase/opptreningsperiode?

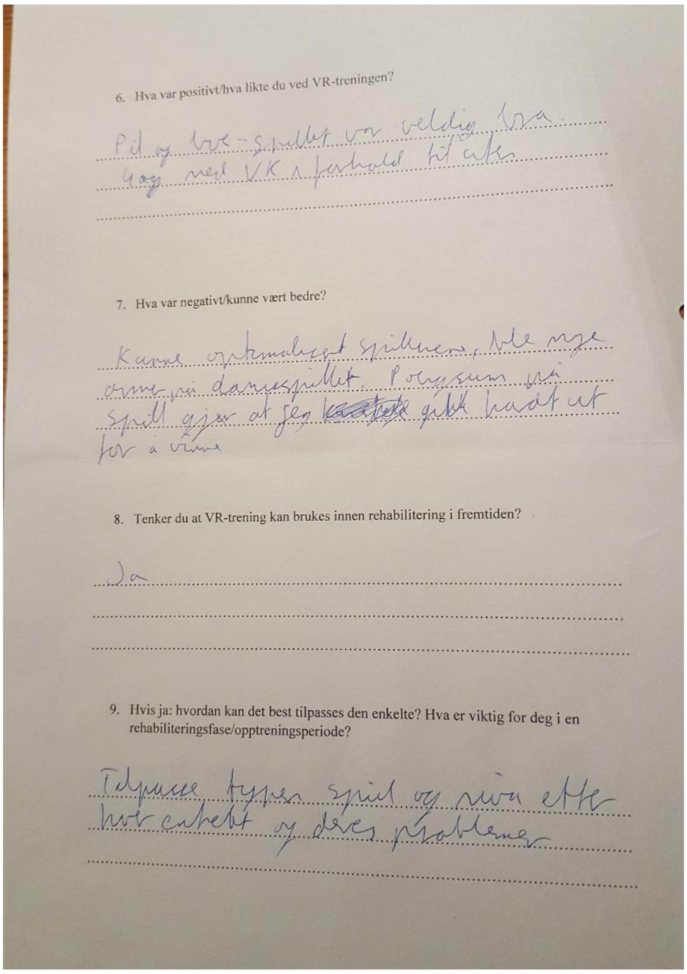
Ta bort frykten for at en kan skade seg og gi trygghet på at det og vare i bevegelse er det beste for smerte.


ID30

Evaluering av VR-treningen

1. Har du i løpet av de 5 siste ukene fått helsehjelp fra andre fysioterapeuter, kiropraktorer, eller lignende?
   a. Ja / Nei
2. Hvis ja:
   a. Hvilken behandling……
   b. Hvor mange behandlinger……
   c. Årsak……
3. Har du i løpet av de siste 5 ukene tatt smertestillende?
   a. Ja / Nei
4. Hvis ja:
   a. Hvilken type smertestillende?……
   b. Hvor mye pr dag (i snitt)?……
   c. Har bruk av smertestillende økt i løpet av de siste 5 ukene?……
5. Hvordan opplevde du VR-treningen?

Veldig bra. Fikk trent ryggen uten å tenke så mye over at det var trening


6. Hva var positivt/hva likte du ved VR-treningen?

Pil og bue-spillet var veldig bra. Yoga med VR i forhold til uten.

7. Hva var negativt/kunne vært bedre?

Kunne optimalisert spillene, ble mye armer på dansespillet. Porsjonen på spill gjør at jeg ~~[illegible]~~ gikk hardt ut for å vinne

8. Tenker du at VR-trening kan brukes innen rehabilitering i fremtiden?

Ja

9. Hvis ja: hvordan kan det best tilpasses den enkelte? Hva er viktig for deg i en rehabiliteringsfase/opptreningsperiode?

Tilpasse typen spill og nivå etter hver enkelt og deres problemer