Interactive Visualization, used as pain-relieving intervention

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Abstract. Psychological approaches may be both more cost-effective and have less negative health-related and environmental impacts than drugs in helping children to relax and reduce pain during medical interventions. There is a lack of knowledge concerning how children's experience, gender, background and socio-economic factors may influence their experience of interactive visualization. This paper presents a user-centered design project where the aim is to develop knowledge concerning the effect that visualization used as pain-relieving intervention in medical procedures has on children. The target group is children undergoing medical procedures.

Introduction

The challenge for society in the future is to raise self-assured people who can manage medical care. The costs of treating fear, and the costs and consequences for people who fail to attend care are today underestimated (Sabuncuoglu et al, 2005; Sabuncuoglu, 2007; Young, 2005). This fear will often start during childhood and origins from a *medical procedure* associated with an unsuccessful alleviation of pain, fear or anxiety. If the child feels fear and anxiety the medical treatment may become even more difficult. For that reason it's essential to minimize pain and distress during painful procedures for children (Klingberg, et al, 1994; von Baeyer et al, 2004). There is great profit if this management could be a non-pharmacological treatment, a *psychological intervention* such as Virtual

Reality (VR) and/or Interactive Visualization. VR is a technology that deeply affects the user's senses. This sets it apart from other technologies such as television. The effect of VR is often based on the result of presence. Presence is reached by either a head mounted display, i.e. an immersive technique, or a 3D-display, a non-immersive technique (Olsson, 2003). The benefit of VR, in this medical context, is independent of factors like the staff's education, lack of time, and motivation, which is otherwise confounding factors of many psychological techniques (Pölkki et al, 2003). Furthermore, they are believed to be both more cost-effective and have less environmental impact than drugs. In the background section of this paper we will further discuss the different types of VR used.

The *pain experience* is subjective and individual (Merskey, et al, 1979). If the pain system is exposed early in life, the individual pain experience will be modified and later create a negative pain memory (Andrews et al, 2002). It's important to help children undergo examinations and treatments without developing painful experiences. An effective pain management could be distraction, which may reduce the harmful effects of examinations and treatments for the child (von Baeyer et al, 2004). An effective pain treatment will reduce the risk for long-term effects of pain (Taddio and Katz, 2005).

Stress isn't always something negative for a person; it could even be positive and give more energy. However stress is often associated as negative and can complicate the child's possibilities to undergo medical procedures (Uvnäs Moberg, 2002). One of the best strategies to deal with stress, used today, is learning how to relax. However, relaxation can be difficult to achieve in typical real world situations. VR in combination with music could be useful strategies to carry out relaxation (Riva et al, 2007a, 2007b).

Traumatic stress reactions involve the psyche as well as the body. Upon arousal, adrenalin rushes into the system and affects memory processes so that the precipitating event becomes permanently imprinted in memory with its accompanying strong emotions of anxiety, fear, and anger. The problem with traumatic memories is that they refuse to be banished from consciousness. Traumatic memories find all sorts of ways to trouble the victim. As Judith Herman (1992) comments: "Folk wisdom is filled with ghosts who refuse to rest in their graves until their stories are told". There also is a general stress on the body that can lead to problems with sleep, irritability and anger, panic attacks, anxiety, and so on. Traumatic events produce profound and lasting changes in physiological arousal, emotion, cognition, and memory (Herman, 1992).

In an ongoing user-centered design project, described in this paper, the aim is to develop knowledge concerning the effect that interactive visualization used as pain-relieving intervention in medical procedures has on children. The target group is children undergoing medical procedures, i.e. wound dressing caused by minor traumatic accidents.

In light of the difficulties and problems connected to the psychological intervention mentioned above, this paper outlines a work in progress project. Based on earlier studies that used immersive or non-immersive VR for easing stress or pain, we suggest a framework for a project and a study, to be conducted during the second half of 2008. The findings of the project are expected to be presented during the first quarter of 2009. Result from earlier studies has indicated that non-immersive VR could be a positive experience for patients undergoing minor medical procedures. In the two following sections below the background of psychological interventions, and the research setting for the project, based on the indications on these positive effects of non-immersive VR, is outlined. The project is a joint venture between researchers representing both the medical, and the IS sector.

The argument is presented as follows. Section 2 presents the background to Psychological interventions, followed by the theoretical framework, and the research setting for the project, including aim and objectives, in section 4. These two gives the research framework of this paper. In section 5 methodological issues are presented. Participants in the study are described together with the study design and study protocol. Measurements, and data analysis are included in this section together with ethical considerations. Section 6 presents the realization of the project so far. The project is still ongoing. Finally in section 7 the conclusion summarizes the project outcome so far together with an outline for future research.

Background of Psychological Interventions

This section gives a brief background on some psychological interventions that have influence on the setting of the study described in this article. As the study is to be considered as a pilot, not all listed intervention could be used in the setting but have influenced the research question, are to be considered for future work.

Psychological interventions may increase the pain inhibitory systems' effectivity in the body and reduce the pain experience for the child. These interventions will also reduce anxiety and fear when a child undergoes examinations or treatments. The aim of these techniques is to help the child feel a *sense of control* during a situation like a medical procedure. There is today still limited evidence of many psychological interventions' use because of lacking studies (Thornberg, 2003). So far, "non-pharmacological interventions" that nurses have evaluated and used are: information, positive reinforcement, distraction and breath exercise. Examples of distraction are TV/video, humor, conversation, books/periodicals, games, music and handicraft (Pölkki, et al, 2001). Few of these have taken focus on *modern interactive technologies* that children are familiar with, i.e. computer/video games, cell phones and Internet. Moreover, few examples include researchers from other areas than medicine, and fewer included user development. In traditional VR you generally either use visualization as a static simulation, or you enter a virtual world where you can navigate. In an interactive visualization you are allowed to change and interact the virtual environment. Earlier experiments in the context of this paper have focused mainly on ordinary simulations or visualization built mainly for relaxation. Games often combines visualization with interaction and gives the user access to a virtual world where s/he can navigate freely and interact with it. We therefore use the term *interactive visualization*.

Psychological interventions focused on in this paper, and described below are: Stimulation of the senses, Intervention, and Storytelling

Stimulation of the Senses

Several studies of the brain have stated that sensatory stimulation will reduce the pain experience during examinations and treatments (Hoffman et al, 2006; Petrovic et al, 2000). Stimuli could be *sounds* (Capeda et al, 2006; Good et al, 1999, 2001, 2002; Nilsson et al, 2001, 2003a, 2003b, 2005; Thorgaard et al, 2005) or a combination of *sounds and pictures* such as an interactive world (Hoffman et al, 2000, 2001, 2006; Riva et al, 2007a, 2007b).

Intervention using VR

Perceptualization supported by *interactive visualization* can, and have been used to stimulate our senses in order to reduce stress or pain. Interactive visualization (e.g. games) have been tested as intervention on children and have included both Virtual Reality-glasses or a head-mounted display (HMD). Studies have also been performed using non-immersive VR (Marshall and Nichols, 2004), i.e. a 3D display. Marshall and Nichols (2004) referes to it as open VR. The differences between the immersive and non-immersive VR is that the immersive viariety of VR includes googles or some HMD, sometimes other devices for sensory feedback. The key for this type is that the individual is cut off from "ordinary" reality. The non-immersive variety requires no personal hardware. The person remain themselves, normal sensoru cues are not cut of. These differences in immersion and precence have been in focus in projects using visualization in different VR solutions. The differences are shown in both costs of hardware equipment, as in the expeience the patient has in having control of the course of events, or not, during the procedure.

Visualizations have in several studies been proved to ease pain during medical procedures (Gershon et al, 2004; Hoffman et al, 2000, 2001; Sander Wint et al, 2002). The effect of pain reduction has been stated in a study of brain activity. Areas in the brain, that registers pain reduce their activities during procedures where visualization has been used (Hoffman et al, 2006). According to Lange et al (2006), visualization technologies have a great potential of being a effective method to reduce stress and pain in medical procedures.

During autumn 2005 a game in which the child catches balloons, was tested on children with cancer at the Queen Silvia Children´s Hospital in Gothenburg. In this study a flat screen and a pair of VR-glasses were tested against each other. The result indicated that an ordinary display is preferable in comparison with VR-glasses. The result also included usable comments from children about the game (Nilsson and Jäderholm, 2005). This result later became the basis in another study 2006-2007 where a new game "The hunt of the Diamonds" was included. Children with cancer were exposed to an autosteroscopic display and used a remote control to catch diamonds in an amusement park. The preliminary result of the study showed that: if given the choise most children choose to play games during medical procedures. Depending on gender and age there were great differences in the choise of game. There were also a wide range of views about the graphics and technical equipment. However, trouble with technical equipments may hurt the purpose of interactive visualization. This conclusion means that *existing and working techniques* are preferable (Nilsson et al, 2007). These result also showed that there were a lack of involvment of the users during the development process.

Another researcher in this area, Albert Rizzo (2007), have used existing and simple techniques, in that case Virtual Reality-glasses, in combination with an open source game, Tux racer. In this game the child controls a penguin who catch fish in a snow landscape. Rizzo (2007) tested this concept on children undergoing procedures at the USC (University of Southern California) Children´s hospital with good results (Rizzo, 2007).

Storytelling as intervention

Guided imagery, a form of storytelling, has been used as a method for reducing both anxiety and pain in chronic pain, postoperative pain, and during medical procedures (Weydert et al, 2006; Huth et al, 2004).

Stories are, and have been, frequently used to teach, entertain and/or explain. The appearance of today's technology has changed the tools available to storytellers. From earlier oral stories to pictures and carving on walls, storytelling has evolved into modern times multimedia storytelling. The need to tell stories is said to come second in necessity after nourishment and before love and shelter. We all have stories about the events, people, and places in our lives. In a group process, the sharing of these stories connects people in special ways. Organizational consultants and managers have also discovered the power in storytelling in organizations. Storytelling has not only been used in, for example, education to tell and preserve historical moments. It has also been used, by volunteers, in the healing process as a psychosocial model of healing from traumas of war abuse (Weston, 2001). Sharing and telling their traumatic stories have helped many people to heal and to move on, and cope with their daily life.

Storytelling is becoming more and more important as a tool for communication strategies. The power of telling stories is used to communicate enterprise goals and visions or to use the power of healing by sharing your story as a therapeutic method.

Theoretical framework

In action research, methods used by practitioners, are studied through close participation of both practitioners and researchers. Feedback from practice has always had high esteem in software engineering research (Dittrich, Y., 2002). Action research is a qualitative research method that is unique in the way it associates research and practice, so research informs practice and practice informs research synergistically (Avison et al., 1999). Avison et al. (1999) argues that in action research the researcher can experiment through intervention and to reflect on the effects of that. In action research, the researcher tries out a theory together with practitioners in real situations, gaining feedback from this experience, modify the theory as a result of this feedback, and trying it again. Each iteration of the action research process adds to the theory (Avison et al., 1999).

Further discussions on how knowledge can be transferred back to development processes, is taken by Nunamaker et al. (1991) and later by Mathiassen (1998). Nunamaker et al. (1991) proposes a research framework on how knowledge can be transferred back to the research methodologies and to the research domain during the development process. Nunamaker et al. (1991) suggest that this concept with wide-ranging applicability will go through a research life cycle of the form: concept - development - impact. The role of the system development in their scheme "… is the result of the fact that the developed system serves both a proof-of-concept for the fundamental research and provides an artifact that becomes the focus of expanded and continuing research" (Nunamaker et al., 1991) i.e. system development as a research method.

In the article Reflective Systems Development Mathiassen (1998) adapt this aforementioned approach to systems development research. He distinguishes three types of approaches: Action research, Experiments, and Practice studies. Mathiassen (1998) says that all three approaches, often in combination, contribute to the building of research-based knowledge in the form of theories and methods and that Practice-related research on systems development is based on one, or a combination of these three approaches. Mathiassen (1998) is influenced by Donald Schön's (1983) ideas on how professionals think in action.

Donald Schön (1983) gave some other important concepts. He discussed the term reflection in action. The reflection occurs, Schön (1983) says through communication which consists of three different types of dialogue: an inner dialogue, an inter personnel dialogue between the participants, and the dialogue that occurs through the design of the design object. In collective design, the inner dialogue can be visualized through the design activities where the design model or the object is manipulated and reshaped. The participants also build a collection of solutions and examples, which becomes a part of their common praxis (Schön, 1983).

When a researcher participates in a collective design process this can be seen as interactive action research. Hultman and Klasson (1994) have proposed a model where the participants, researchers, and the company create knowledge and experience when they perform studies in a changing process. This model has several similarities with a collective design approach and research on the design process.

An important part in a design or development process is the understanding of the knowledge and competence that the participants bring with them. Here the role that the designer has in the design process1 is discussed, based on theories from Löwgren and Stolterman. "They contribute with »practical design theory» and connects to a design tradition that is associated with Donald Schön and his idea of the reflective practitioner" (Löwgren J., Stolterman E., 2004)2.

Löwgren and Stolterman (2004) argue that the work with digital artifacts have a character that demand a new perspective on design – a reflective perspective. They discuss further that the result of a design is not always dependent of a design decision but rather depends on unexpected or unwanted side effects. This could be regarded as negatively if the result does not work in the situation it was intended for. Löwgren and Stolterman (2004) suspect that the design in this case can suffer from a kind of lack of knowledge or limitations. This can lead to that the digital artifact is experienced as being imperfect. Design is a complex task, it is always unique and not a process that can be prescribed or described (Löwgren J., Stolterman E., 2004). The authors mean that normative efforts never can be sufficient. On the contrary a reflective attitude is called for. When investigating your own role as designer, using critical thinking refers to reflection. You are more observant vis-à-vis your own design skills and the result that you produce. To use existing theories and models demands a critical attitude (Löwgren J., Stolterman E., 2004). They argue that it is both necessary and fruitful to look upon this development as a design discipline. They also point out that the fundamental issue is what kind of knowledge the designer needs. Furthermore, they draw the field of knowledge interaction design. These theories can be seen as applicable also when roles are not clearly defined. The arguments are used to support our discussion on – different roles of the researcher. What different

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[1] Löwgren and Stolterman refer to design processes as also including design of information technology. The development of digital artifacts is a design work

[2] Preface »Den reflekterande interaktionsdesignern» av Ehn P. till boken *Design av informationsteknik* (Löwgren och Stolterman, 2004)

background or experience (pre-understanding) the researcher has can also be said to form the different role that s/he can have in a development process.

Research approach

In relation to the theoretical platform discussed above, the case described in the following section, in addition adopted some of the concepts of *flexible design* taken from Robson (2002). Robson (2002) discuss that theory doesn't need to be there from the beginning but can evolve. He argues that you should start with some early decisions about methods of data collection in order to get started, but: "… you don't have to foreclose on options about methods. Ideas for changing your approach may arise from your involvement and early data collection. Or, as you change or clarify the research questions, different means of data collection may be called for. Similarly, your sampling of who, where and what does not have to be decided in advance. Again you need to start somewhere, but the sampling strategy can and should evolve with other aspects of the design." (16). This motivated us to design the pilot study described here. This section discusses some of the questions not yet answered in known earlier research. Also, by working at the clinic, closely to the patients (children) new questions evolved that needed to be answered.

There is a requirement of efficient interventions that will help children to relax and reduce pain during medical interventions. If the child already has experienced bad pain alleviation there is an even more deserving requirement of efficient interventions to work on this problem. Interactive visualization is still rare and badly evaluated for children undergoing medical procedures or working with bad experiences from earlier procedures.

There is also lacking knowledge of how children's experience, gender, background and socioeconomic factors will influence interactive visualization in these situations.

To prevent an increased sensitivity for pain, fear, or traumatic stress it is important to treat the child's problems. For that reason there is a need to evaluate during which procedures interactive visualization has a positive effect. We have not found many studies in this area and nearly none for European children. So far some studies have shown a good effect of interactive visualization but none that we found described how these environments should or could be created. There is also a lack of knowledge whether colors, form or story affect the effect of the intervention. Neither have we found any studies on the effect of using immersive or non-immersive Virtual Reality systems and evaluation due to the child's risk of losing control when using head mounted displays or equivalents.

Another factor that we have found poorly studied is whether it is the gaming concept itself that is of importance for the distraction or not. Theories from Hoffman (2000, 2001) state that it is the game environment with color setting, and artistic design that creates a relaxing context and has an influence on the experience and effects of distraction. On the other side, studies and experiments using traditional game theories as basic concepts have shown that this might be of no importance. A recent study at the Queen Silvia Children's Hospital in Gothenburg gave, that children preferred game scenarios with traditional game parameters (competition, challenge, and reward) played on an ordinary PC without 3D glasses or head mount display rather than walking around and experience the relaxing 3D world (Nilsson, 2007).

We have found no published academic studies that have focused on findings on which design variables that have effect on stress and pain during procedures. Only one study found, with 30 participants provided data on the impact of virtual reality on self-reported pain (Uman et al, 2006). The outcome was based on only one small study, "definitive conclusions regarding the efficiency of Virtual Reality for reducing pain and distress during needle procedures cannot be made until further trials are conducted and a broader range of outcomes are assessed (Uman et al, 2006)".

Also, costs for equipment need to be held to a minimum in order to build systems for intervention that can be easily duplicated. Equipment in the medical context is often related to large expenses. Smaller care units can't afford this. Earlier studies using visualization, as a psychological intervention, are closely connected to large installations of expensive VR equipment. Recent studies have shown that it's possible to scale down to a more manageable size but however, the costs are still significant.

As an alternative in software development the use of COTS has become viable. Commercial, off-the-shelf (COTS) is a term for software or hardware that is ready-made and available for sale, lease, or license to the general public. It has seriously started to become an alternative to in-house developed products. The use of COTS can offer significant savings in many areas. For example Swedish military units have been able to practice in virtual environment developed by modifying a on-the-shelf game engine, aka a Mod. Further examples are, games in health, for education, cooking and much more. This development is called *Serious Gaming*. The motivation for using COTS is that it will reduce the overall system development costs and time.

The questions for the project are: if, by using known gaming theories and Commercial of-the-shelf (COTS) principles, can we utilize them for medical intervention? Furthermore, do children have to decrease their stress level or can it be canalized in the game situation, and thereby focus on the game rather than experience the negative stress and possible pain from the procedure?

Aim

The aim and purpose for the project is to develop transferrable knowledge on the effect and the experience that interactive visualization used for intervention in medical procedures has and could have on children, in order to prevent stress and pain. In addition, this is of great importance, as using drugs or anaestethics on children is highly undesired during minor medical procedures. More specifically the project will contribute to:

- extract concrete results by performing a both quantitative and qualitative study on the project test bed using an non-immersive interactive visualization.
- participate in increasing the benefits for the patients and hospital staff through the development of a framework based on the result from the study that can give new opportunities to prevent pain and stress.
- study the experience and the effect of interactive visualization on children undergoing medical procedures, and evaluate if this method can facilitate and increase the benefits to cope with treatment.
- analysis and to attract knowledge of design variables that are dependent on age, gender, cultural background, developmental disabilities, and diagnosis.
- analysis of technical demands and possibilities regarding interactive visualization as a method (psychological intervention) in medical service.

This framework presents new possibilities not only for society but also for industry and academy who are given opportunities to cooperate in the development process. The project will perform multidisciplinary, innovative research, and be of interest to industry, society, and academy and offer ideas and concepts that are to be tested and can be developed into new services and/or products.

Objectives and expected result

The expected result of the project is the outline of a framework where dependencies as age, gender, cultural background, and cognitive disabilities can be extracted so that design variables are identified and analyzed. The initial work will be performed in a study were the two different theories on how to use interactive visualization for distraction and coping with acute crisis are tested using both quantitative and qualitative methods for evaluation. The analysis is hoped to give the answer to the question if it is possible to use the problem with hyperactivity/attention deficit to a benefit in reducing stress by canalize it in a game situation and thereby find a better focus.

This study is expected to result in a concept for, and the implementation of tools in cooperation that are suitable for distraction during medical procedures.

There is of today a divide between the need for, and the availability of solutions and adaptive products that support specific demands during treatment.

The scientific benefit is given by the opportunity of having a large test bed for studying two concurrent theories, mentioned above. Until today we have not found any other study that compares these two in clinical settings.

Furthermore, by investigating and exploring context dependent design variables, the project is expected to outline a framework for future development of visualization methods and tools for the medical care services, not only for children but possibly also for others suffering from stress or pain related to medical procedures.

There is also great opportunity for participating companies to develop and try new adapted products and services that fit in this context.

In the following section the setting of methods used in the study will be described. Some parts have already been realized but most part of the study is still to take place. The study group and the study design will also be presented.

Methods

Participants

The target group is children between 5 – 10 years of age, undergoing medical procedures, i.e. wound dressing caused by minor traumatic injuries. In this group we find injuries from burns, traffic accidents etc. This group is non-homogenous and as divergent as the rest of the world. They can differ in age, gender, cultural background, diseases or different disorders. One large children's hospital in Sweden is in focus, the Queen Silvia Children's Hospital in Gothenburg. Children with cognitive impairment are to be excluded from the study, as will children or parents who do not have a good understanding of Swedish.
Participation is voluntary and subjects are reimbursed for their participation with a ticket for a cinema show.

Researchers from both computer science and the medical department are represented. Staff at the hospital clinic is also included in the development process.

Study Design

No child included in this study should be in an acute crisis of its disease. The children will be randomly selected to be part of one of two groups given different interventions, or the reference group using the standard treatment at the clinic. Envelopes are to be prepared with instructions for each group and randomized.

There will be two different intervention groups. One will play the game “Tux Racer” during procedure, and the other will get a lollipop as intervention. The third group (reference group) will have no intervention. The goal is to include 40 children in the respective group.

Having a lollipop as an intervention has earlier been tested at the clinic with good result, and is therefore sometimes used as an intervention. These results have only been presented locally at the hospital, and no further reference can be found.

The treatment is the same for all groups; everyone will get the same procedure. All intervention is to be regarded as additional. The purpose is not to exclude parental care, positive reinforcement, or other distraction normally used.

Study Protocol – Intervention with game

A typical treatment session at the unit takes no more than 15 minutes. During this period the child is to play the game.

In close cooperation with the staff, using a user-centered design approach, a concept has been developed. In medical research and development, researchers and practitioners often work close together. The practitioners often perform the research. Action researcher and action research theories (Avison et al, 1999) combine theory and practice, as well as researchers and practitioners. Theories from the field of Action research are to be used to assess ‘the degree of participation’, and roles between actors involved in the project.

The concept can be divided into three parts: the application, the control, and the display.

1. The application “Tux Racer[3]” (Figure 1) is a free 3D computer game. The Linux mascot, a penguin named Tux, races downhill through alpine trails as quickly as possible while collecting herrings. This game can be run on any ordinary PC with Bluetooth. No other extra equipment is needed. Some modifications on the application have been done.
2. The human interface device (HID) for controlling the game is a Nintendo Wii remote hand control using the Bluetooth protocol. This was used for elimination of unwanted cords.
3. The display is a 24” flat screen on the wall at the foot side of the bed.

These three parts, and the work done so far will be closer described in the next section.

3 TuxRacer was originally written by Jasmin Patry as a university project in 1999. He released it as free software under the GPL in 2000. The software was developed as a community project for almost a year. (http://en.wikipedia.org/wiki/Tux_Racer)

Figure 1. Screen-shot from the game "Tux Racer"

Theories from Interaction design have influenced the design process and the system design. Löwgren and Stolterman (1998) mean that the design process consists of a vision, an operative image, and a specification. A *vision* is an idea vis-à-vis a technical solution or structure, an idea concerning a function, or a certain shape. The vision in this project originates from, as mentioned earlier, several studies performed on children undergoing medical procedures using VR as an intervention. As new questions arose new visions on what could be done and explored in the area evolved.

The first instance of the vision is the *operative image*. It can be a sketch or an image that later can be refined during the process (Löwgren and Stolterman, 1998). In this project the operative image is the concept developed. The concept was to use known game theories and COTS products to develop cheaper equipment that could be easier to access for several ward units. Researchers from different areas also joined the project.

A new process begins with the task to construct "an artefact starting from the detailed given *specification*" (Löwgren & Stolterman, 1998). The specification deals with the basic technological foundation, or another way put: it describes "how the specific interaction interfaces should look and evolve." (Löwgren & Stolterman, 1998). There are close ties between the vision, the operative image and the specification. It is important to create coherency between all the levels in the design process. The specification from this process is further described in the section "Realization".

There is a great benefit in having a multidisciplinary research group. In most projects at the hospital practitioners are performing their own research, often based on quantitative methods. As the project members are represented from several academic disciplines more qualitative methods have been included. There is a larger focus on methods and design process than in their ordinary work. By using Action research, a qualitative research method, we associate research and practice, and combines quantitative and qualitative methods.

Measurements

Self-report

Pain measurement is to be recorded before, during and after the procedure in both the intervention groups and the reference group. The child will be asked to score a baseline of pain intensity and distress before the procedure by using CAS (Colour Analogue Scale) and FAS (Facial Affective Scale). Five minutes after the procedure the child does a second scoring of the pain intensity and distress during the procedure, and a third scoring after the procedure.

The CAS is a modified visual scale that has been validated to measure the intensity of pain in children aged five and above (McGrath et al, 1996). This scale is designed to provide gradations in colour, area and length, reflecting different values of pain intensity. The child or adolescent mark its pain intensity by using a shuttle transferring the evaluation to the scale from zero (no pain) to ten (most pain) on the backward side. At the same time the child or adolescent value its distress by using the faces pain scale FAS where they mark one of nine faces presented in an ordered sequence from least to most distressed on a zero to one scale (McGrath et al, 1996).

Observations

The FLACC (Face, Legs, Activity, Cry and Consolability) scale was developed to measure observational pain in children. This scale contains five categories, each of which is scored from zero to two to provide a total score ranging from zero to ten. A high score of FLACC indicates pain in the child (Merkel et al, 1997). The FLACC-scale has been recommended to be used in children aged three to eighteen undergoing procedures (von Baeyer and Spagrud, 2007). Observational pain scales are a complement to self-report scales in many clinical situations providing different and complementary information (Hadjistavropoulos and Craig, 2002). One nurse highly familiar with the FLACC-scale will observe the patient, and pain measurements are recorded five minutes before, during and three to five minutes after the procedure. In an earlier study the same nurse evaluated the concurrent and construct validity and the interrater reliability of the FLACC-scale by using this scale during several needle-related procedures (Nilsson et al, 2007).

Observational anxiety is measured via the instrument Short STAI (State- Trait Anxiety Inventory). This instrument is considered as “golden standard” within academia to measure anxiety with adults (Marteau and Bekker, 1992). Our opinion is that these questions also can be used on children age 7 – 10. The children can acquire assistance from parents or staff. The smaller children (5 – 7 year) fill in the form together with their parents.

Vital signs

The child heart rate is collected by a pulseoximeter five minutes before, during, and three to five minutes after the procedure.

Interviews

Semi-structured qualitative interviews (Kvale, 1997), based on an interview guide, are to be conducted in conjunction with the completed interventions. The interviews in this study are collected from the children in the intervention group, and are expected to catch the experience of the procedure and the intervention form the child. The child and parents are getting information about the interview simultaneously as they are to participate. The child chooses location at the hospital where they prefer to sit during the interview. The interview starts only after that the child and the researcher have introduced themselves to each other. The interview ends with a question on how much the patient was thinking, i.e. focus on, the procedure itself, asking them to point it out on the measure scale (Figure 2).

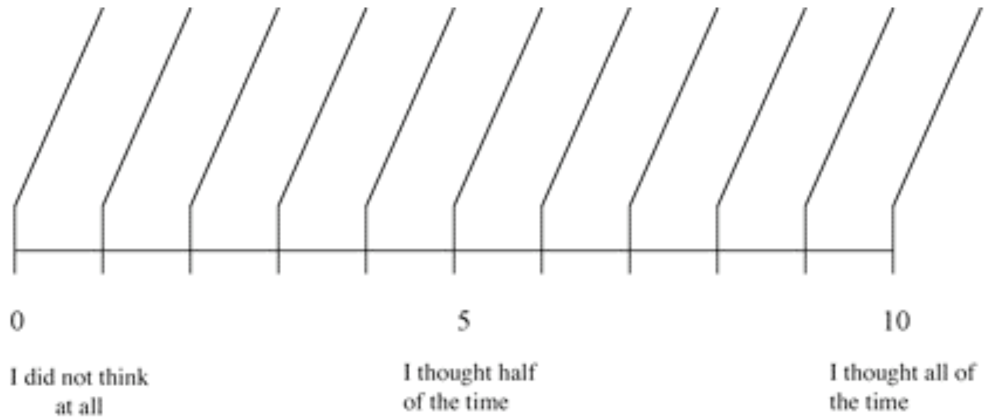

Figure 2. How much time during the wound dressing did you spend thinking about how it felt? (Scale is translated from Swedish by the author)

Median time for these interviews is planned to 20 - 30 minutes. The interviews are recorded on a MP3 player and transcribed verbatim.

Data Analysis

Quantitative data

The sample size is calculated based on the results from an earlier study in the same area (Wolitzky et al, 2005), and according to the following assumptions.

The mean off CAS in the reference group is 3,5 and in the intervention groups 2,5. The significance is 5%, power 85 %, and standard deviation (SD) is 1,5. According to these assumptions there are 40 participants in each group, and the total in the study is 120 children.

Non-parametric analysis is used and the Mann U Whitney test will be used to determine differences between the study groups in heart rates, self-reported levels of pain and distress and observed pain. In addition "Wilcoxon signed rank test" can be used for comparing changes in CAS, FAS, FLACC and heart rates before, during and after the procedure in al groups.

Qualitative data

All interviews are read and analyzed by using a qualitative content-analysis and the texts selected to condensed meaning units in an organized manner (Graneheim and Lundman, 2004). Each time a condensed meaning unit arise in the texts it is counted to value the magnitude. This step follow Krippendorffs thoughts about combining quantitative and qualitative methods in content analysis. The meaning units were hereafter abstracted to categories (Krippendorff, 2004). These categories can eventually be abstracted to themes (Graneheim and Lundman, 2004).

Ethical Considerations

The Regional Medical Ethics Review Board of Gothenburg has approved the study (Dnr: 359-07). Written informed consent is obtained from all participants after written and oral information about the study.

Realization

This section presents the work done so far. As it is an iterative design process none of the phases can be said to have ended.

The study is divided into four main phases: Pre-study, Concept-development, Design and implementation, and Dissemination. Children and staff from one unit at the project test bed is the target group of this study. Researchers will study and analyze the result. Together with the target group (children and staff), developers, and researchers have participated in a concept development. The concept has been developed, tested, and will soon be implemented. There are some companies from the medicare- and visualization industry participating in the project. Results can offer them a possibility to develop new services and products. Academic result is spread through conference articles, seminars, web, printed material and similar. Both undergraduate and graduate students will be given opportunity to participate in the process, and be given the opportunity to carry out project work and/or thesis.

The work so far has resulted in a specification of demand on hardware and software in the context of a medical procedure, e.g. cords and hardware equipment has to be put in a position not to close to the bed where the medical procedure is to take place due to clinical demands. In earlier versions of the game we used an ordinary USB Joystick, which was not suitable in the context. Moreover, all text in the game has been translated to Swedish.

According to these aforementioned demands the application “Tux Racer” was modified. The modifications consisted not only of translating all text to Swedish, but also the replacement of the keyboard/joystick with a Wii Remote (aka Wiimote, see Figure 3), a wireless hand held device manufactured by Nintendo. The Wiimote communicates via a Bluetooth wireless link. The Wiimote does not require any of the authentication or encryption features of the Bluetooth standard. A computer can detect the device by putting the controller in *discoverable* mode by pressing the 1 and 2 buttons simultaneously.

Figure 3. Picture of a Wii Remote. (Original at: http://en.wikipedia.org/wiki/Image:RVL-A-CW.jpg. Used under GFDL license)

Additionally, the use of GlovePIE (Glove Programmable Input Emulator) has been added to replace the original functions of the keyboard. GlovePIE is an application specifically designed to emulate Joystick and Keyboard input from a variety of devices, e.g. to play joystick-only games without a joystick, or keyboard-only games with a joystick. Carl Kenner[4] who needed “a control” for

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[4] A presentation of Carl Kenner and his work can be found at http://carl.kenner.googlepages.com/glovepie (last visited 080401)

his VR-glove originally wrote the software. He also programmed the application to run on Windows to handle the input from the Wiimote. The interface of GlovePIE resembles an ordinary text editor were you write some scripts that map input events like key presses and mouse movements to other, virtual input events. An example is given in Figure 4 where you assign the Wiimote's A button to a mouse-left-click and B for right-click.

```
Mouse.LeftButton = Wiimote.A
Mouse.RightButton = Wiimote.B
```

Figure 4. Example of GlovePIE code assigning Wiimote A and B buttons to correspond mouse left and right buttons.

Up to this point we have identified the following requirements:

- A Bluetooth enabled PC running Windows 98 or above
- GlovePIE version .22 or higher
- DirectX 8 or above
- A Nintendo Wiimote

Buttons have been emulated to control the game, e.g. rumble is added as an effect when the penguin brakes (back-arrow). The unit is equipped with an expansion port on the bottom to connect the remote to auxiliary controllers, also using the Bluetooth interface. One controller is the *Nunchuk* that we soon hope to support. In this study we don't intend to use the *motion sensor*, or the *speaker* of the Wiimote.

So far, problems that occurred during the development process have been:

- Instability in the Windows Vista driver utilities. During this period Vista was a relatively new operating system and a lot of interface problems could be attributed to this fact.
- Bluetooth drivers needed to be updated. The standard Windows Bluetooth stack wasn't completely compatible with the Wiimote.
- Each time the computer starts the Wiimote has to be reconnected, i.e. discovered via a windows application.

After two test of the concept on sight, performed together with the staff at the clinic, some new demands were added. Each track in the game is shorter in time than the procedure. They last between 1 – 3 minutes. The procedure lasts approximately 15 minutes. During this period the staff is occupied with the procedure and can't help the children to control the game. The child needs to be able to restart and to go back and forward in the menus by her/himself.

The design phase is soon to be ended after these above-mentioned alterations are made. After this the implementation is done and the clinical study can start.

Measures will be made according to methods described in earlier sections. Interviews are used to follow up, and end each session with the patient.

Conclusion and Further Work

One objective for this study is to examine if children undergoing medical procedures can get pain and distress reduced by using easy to understand and well known technology, in this case a game and gaming controller. It focuses on *modern interactive technologies* that children are familiar with, e.g. computer/video games, cell phones and Internet. The study described in this paper, origins from several earlier studies with inconclusive results. New questions as to how it is the choice of hardware, i.e. immersive or non-immersive VR, or the choices of games that has had effect on the result comes from there. One guess could be that both the equipment and the game should be adapted to the procedure and the player. Therefore our study focus on the development and analysis of the effects on stress and pain using an game based on standard gaming principles.

Our study also continues earlier research at a pediatric oncology unit at Queen Silvia Children's hospital where non-immersive VR was used. The virtual world in the study was designed to be nice and calm for the children. The interviews showed that the non-immersive VR game helped the children to manage the procedure. The funny experience of playing the game seemed to change the memory of the procedure. In contrast to this however, no child or adolescent reported any calming effect of the environment in the interviews and the self-reports of distress were not significant in comparison with the control group.

As in all research projects it is funding that in the end controls the outcome. There are still several questions that need to be addressed. We have discovered, based on earlier studies, that:

- There is a significant difference between children and how they respond to the intervention depending on: age, gender, cultural background, developmental disabilities, and diagnoses etc.
- Both the equipment and the game should be adapted to these aforementioned parameters as well as to the specific intervention method chosen.

Future work will not only address the problems connected to stress and pain *during* medical procedures, but also traumatic stress developed *after* an, or multiple intervention. In the research framework of this paper we include story telling. This concept is of interest to use and further develop together with the concept of digital story telling.

Furthermore, there is a great challenge in developing new concepts using different HID, e.g. VR gloves, or the use of the motion sensors of the Wiimote adapted to some context.

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