Available online at www.sciencedirect.com
ScienceDirect
The Foot 18 (2008) 211–219
The Foot
www.elsevier.com/locate/foot

Audiovisual distraction as an adjunct to pain and anxiety relief during minor surgery☆

A. Drahota*, E. Galloway, R. Stores, D. Ward, M. Severs, T. Dean

School of Health Sciences & Social Work, University of Portsmouth, James Watson West, 2 King Richard 1st Road, Portsmouth, Hampshire, PO1 2FR, UK

Received 3 March 2008; received in revised form 28 May 2008; accepted 2 June 2008

Abstract

Background: Minor surgery for ingrown toenails can provoke anxiety and the anaesthetic injection can be acutely painful. Distraction techniques may reduce the associated pain and anxiety.
Objective: To investigate an audiovisual distraction (Bedscapes™) on pain and anxiety during minor surgery for the correction of ingrown toenail.
Method: In a randomised controlled trial, patients ($N = 152$) with ingrown toenails requiring surgical correction under local anaesthesia were allocated to receive Bedscapes™ + standard care or standard care alone. Pain levels due to local anaesthetic injection were assessed post-procedure, and anxiety levels were assessed pre- and post-procedure in both groups. Follow-up focus groups were conducted with 14 patients allocated to the Bedscapes™ group, and one-to-one interviews were held with four podiatrists.
Results: Participants with high pre-procedure anxiety scores experienced greater pain on injection, and older patients reported lower pain than younger patients, regardless of group allocation. Bedscapes™ did not reduce pain or anxiety, and was apparently no more effective than interpersonal interaction between podiatry staff and the patient.
Conclusions: Pain of injected anaesthesia correlates closely with pre-operative anxiety. Formal audiovisual distraction has no added benefit over interpersonal interaction in the alleviation of pain and anxiety in patients undergoing nail surgery.

Keywords: Randomised controlled trial; Mixed methods; Audiovisual distraction; Anxiety; Pain

1. Introduction

Ingrown toenails are a common disorder causing significant morbidity [1]. The most effective form of treatment in combating this condition and preventing reoccurrence is to remove all or part of the offending toenail and apply a chemical burn to the nail bed with phenol [2]. This common procedure requires administration of a local anaesthetic with a digital ring block, which can cause significant pain through the needle being inserted and the release of the anaesthetic injection [3]. Anxiety is an important component to consider in nail surgery, not least because needle phobia affects over 10% of the general population [4]; anxiety is also a strong predictor of pain [5] with studies demonstrating that reducing anxiety will reduce pain sensation [6].

According to the Broaden-and-Build Model [7], pain and anxiety are reduced when positive emotions are elicited. With healthcare environments being considered part of the holistic care of patients [8], a number of products are available on the market aspiring to instil a sense of well-being as a non-pharmacological adjunct for reducing pain and anxiety. One such product is Bedscapes™, which involves the use of a 'photomural' scene of nature, coupled with associated nature sounds, to surround the patient during treatment. It is important that products such as Bedscapes™ are evaluated in order for healthcare funds to be utilised in the most effective way.

Three studies have been conducted in the United States using Bedscapes™ [9], and one has been fully disseminated in a peer-review journal [10]. Diette et al. found

☆ This research was supported by a grant from the Dunhill Medical Trust (a registered research charity: 294286).
* Corresponding author. Tel.: +44 23 92 84 4432; fax: +44 23 92 84 4412.
E-mail address: amy.drahota@port.ac.uk (A. Drahota).

0958-2592/$ – see front matter © 2008 Elsevier Ltd. All rights reserved.
doi:10.1016/j.foot.2008.06.001

that Bedscapes™ increased perceptions of pain control for patients undergoing flexible bronchoscopy, but did not reduce anxiety levels. Diette et al. [10] explain this result by suggesting that patients may have been anxious about the diagnosis resulting from the bronchoscopy examination as opposed to the actual procedure. However, patients in Diette et al.'s study [10] were sedated and had received analgesics; consequently the self-report measurements of pain and anxiety were not obtained until the second day following the procedure, by which point some patients had returned home. Patients undergoing nail surgery typically do not undergo sedation and their anxiety is towards the procedure itself; for this group of patients, an environmental distraction maybe a viable option for improving patient care. The aim of the present study is to assess the efficacy of Bedscapes™ on pain and anxiety in patients undergoing minor surgery for ingrown toenails.

2. Methods

A mixed methods approach was utilised, which involved a pragmatic parallel randomised controlled trial, follow-up interviews, and focus groups. Ethical approval was obtained from the Isle of Wight, Portsmouth and South East Hampshire Local Research Ethics Committee. The present paper focusses primarily on the quantitative findings but draws on the qualitative findings to add further depth of understanding.

2.1. Participants

Trial participants were recruited from two Nail Surgery Clinics between February and October 2005. The inclusion criteria were to be aged 18 years or older and to undergo nail surgery with local anaesthetic injection. Those who did not meet the inclusion criteria, or had severe hearing and/or visual impairments (to the extent that the intervention could not be experienced), as well as those who were not able to understand the questionnaire (e.g. due to severe learning difficulties or language barriers), were excluded.

2.2. Setting

The Nail Surgery Clinics were based at Havant War Memorial Hospital and Paulsgrove Healthy Living Centre (Portsmouth City Primary Care Trust, UK). Clinics ran for one day a week from each venue, seeing up to 12 patients per day (2 patients per hour). The Clinic at Havant War Memorial Hospital ran from two treatment rooms (one bed per room) adjoined via an office, with a waiting room across the corridor. The Clinic at Paulsgrove Healthy Living Centre initially ran from a local Community Centre, which had one treatment room (with two beds separated by curtains) and an adjoining waiting area. Part way through the study (in May 2005) the Healthy Living Centre was moved to a brand new facility, which had two treatment rooms (one bed per room) and a separate waiting area.

2.3. Intervention

Participants in the intervention group received standard care with the addition of a large photomural (measuring 107 cm high by 132 cm wide), either hung on a screen to the side of the patient couch or (when space allowed) attached to the wall with hook and loop tape. Two factors were taken into account when assessing the best position for the photomural in each room: (1) whether it would be clearly visible for the patient, and (2) whether it would obstruct the podiatrist conducting the nail surgery. Participants in the intervention group were each given a choice of photomural scene: mountain stream or tropical beach. Each choice of scene came with its own associated sounds of nature (e.g. bird calls, waves, or stream water) played through headphones and a portable CD player. The photomurals and "soundscapes" (Bedscapes™) are manufactured by Healing Environments International Inc., USA. Participants in the control group received standard care without the Bedscapes™. As this was a pragmatic trial, no attempt was made by the researchers to alter the standard care that clinic staff provided for their patients. All participants received the same medical treatment that they would have received had they not been taking part in the study.

2.4. Outcomes

The primary outcomes (pain and anxiety) were measured via validated questionnaires. The researcher gave the patient the option to fill out the questionnaires independently or to have the statements and response choices read out loud to them if they preferred. Additional information was gathered from the patients' records on the pathology of the condition, the treatment received, and medical history.

Pain experienced during the anaesthetic injection was measured using the Present Pain Intensity (PPI) Index from the McGill Pain Questionnaire [11]. Patients were asked in their post-treatment questionnaire: "How much pain did you feel during your anaesthetic injection?" Participants had to choose one of the response choices: 0, no pain; 1, mild; 2, discomforting; 3, distressing; 4, horrible; 5, excruciating.

Anxiety was measured immediately pre- and post-treatment using the 20 'state anxiety' statements with agreement ratings from the Spielberger State-Trait Anxiety Inventory (STAI; 12). Participants were required to rate on a four-point scale (not at all; somewhat; moderately so; very much so) how much they agree with each of 20 statements relating to the anxiety felt at that moment in time.

2.5. Sample size

The study sample size calculation was based on both primary outcome measures. Based on the McGill PPI, with a standard deviation of 1 point [13], it was estimated that 150

participants (75 per group) will allow for detection of a difference between 0.5 and 0.6 with a power of 90%, assuming a two-tailed test with 5% significance level. With regards to the Spielberger STAI scores, previous studies have reported mean anxiety scores ranging from 35 to 50 with 'between subject' standard deviations ranging from 10 to 12 points in various groups of patients [13–16]. Assuming a moderate correlation of 0.7 between pre- and post-intervention scores [17], a 'within subject' standard deviation was anticipated of at most 9.3 points. A total sample of 150 participants (75 in each group) was required to detect a five-point difference between treatments with a power of 90% (assuming a two-tailed test with 5% significance).

2.6. Randomisation

The trial randomisation schedule was computer-generated in blocks of 30 and a Research Administrator organised each participant's assignment into a numbered, sealed, opaque envelope. The researcher only opened the participant's envelope after the patient consented to taking part in the study, ensuring allocation concealment. Due to the nature of the intervention, no blinding was possible.

2.7. Trial procedure

Patients were invited on to the study by means of an information letter sent along with their appointment letter by the administrative staff for the Nail Clinics. Two researchers took it in turns to attend the clinics, having spent some time at the beginning of the study attending clinics together to ensure that their methods of approaching patients and helping with the questionnaires were standardised. Consenting participants filled out the pre-treatment state-anxiety questionnaire as they waited for their appointment (typically 5–10 min before the patients' appointment).

Prior to entering the treatment room, those allocated to the intervention group were given the choice of viewing a mountain stream or tropical island photomural. They were also shown how to work the portable CD player and it was explained to them that they were in control of volume and turning the sounds on and off as they pleased. The researcher ensured that the appropriate environment was in place for the patient in the treatment room before inviting them through for their appointment. The CD player and headphones were made accessible to patients in the intervention group to put on after they had finished discussing their treatment with the podiatrist and before the local anaesthetic was administered.

At the end of their nail surgery, patients were required to sit and wait for a few minutes to ensure that there was no break-through bleeding on their bandages. It was during this period, whilst the patients were still in the treatment environment, that the researcher approached the patient and asked them to complete the post-treatment state-anxiety and pain questionnaire. The researcher then gathered baseline information from the patient's records, recording information on the pathology of the patient's condition, the treatment they had received, and other factors that may have contributed to their anxiety or pain sensation.

2.8. Data analysis

Data was double entered and verified using SPSS (version 13). The baseline characteristics of groups were compared using chi-square tests (for categorical data) and independent *t*-tests (for continuous variables). Data was analysed on an intention-to-treat basis. The pain scores were analysed using a *t*-test for independent groups, followed by an analysis of covariance (ANCOVA) to control for potential confounding factors. To assess the anxiety data, an ANCOVA was used to partial out the effect of the pre-treatment anxiety scores and focus on the possible change following the intervention [18]. A follow-up ANCOVA on post-treatment anxiety additionally factored in other potential confounding. Covariates for each ANCOVA performed were chosen on the basis of existing theory and research. Homogeneity of regression was checked for each covariate, and where regression lines between the assignment groups for a covariate were non-parallel, the interaction between the factors was checked for significance. Significant interaction effects were carried forward into the ANCOVA to partial them out.

2.9. Focus groups with patients

All participants allocated to the intervention group were invited to attend a focus group to explore their attitudes towards, and experience of, the Bedscapes^{TM}. Fifteen people were willing to participate in a focus group, and 14 people eventually took part in one of two focus groups. The two focus groups took place in a function suite above a public house. Focus groups were audio-taped and transcribed verbatim. The focus group data was analysed with an emphasis on group processes and context [19,20]. Themes emerging from the "collective voice" of each focus group were mapped and tabulated, with attention paid to dissenting voices and participants that did not contribute to a theme [21,22]. No "new" themes emerged in the second focus group, which provided a sense of data saturation. A brief overview of the focus group findings is presented here, in order to add depth to the findings of the trial.

2.10. Interviews with clinical staff

On completion of recruitment for the trial, a series of one-to-one semi-structured interviews were held with podiatrists who had worked alongside the intervention. The approach to the interviews was one of thematic content analysis [23]. All staff ($n = 10$) working from the clinics during the trial data collection were invited to interview, and four consented to participate. The same researcher conducted all the interviews, which took place at various locations of convenience to the interviewees. Interviews were audio-taped and tran-

scribed verbatim. Three researchers independently coded and analysed the transcripts and then met to agree on the coding scheme. The coding scheme (comprising seven themes) was verified against the original transcripts and then the transcripts were coded accordingly. A brief overview of the interview findings is presented here, in order to add depth to the findings from the trial.

3. Results

3.1. Participant recruitment

During the study period 372 patients attended appointments at the Nail Clinics. Fig. 1 shows the flow of these individuals through the study. Participants were excluded at different stages (pre- and post-randomisation) for not requiring surgery. At the point of recruitment some patients knew they were not going to have surgery (e.g. because they were going to refuse, they were going on holiday and wanted to reschedule, or were just attending for a simple 'cut and clear' which would not require anaesthetic); these patients were not recruited on to the trial. As well, some patients were not aware that they did not require surgery until after they had seen the podiatrist in their appointment. These latter patients were recruited onto the study in order that the appropriate environment could be established ready for their appointment in case they were to undergo surgery (as at the point of recruitment the podiatrist, patient, and researcher did not know if surgery would be required).

Of those allocated to the intervention group, 16 participants were not fully exposed to the audiovisual distraction

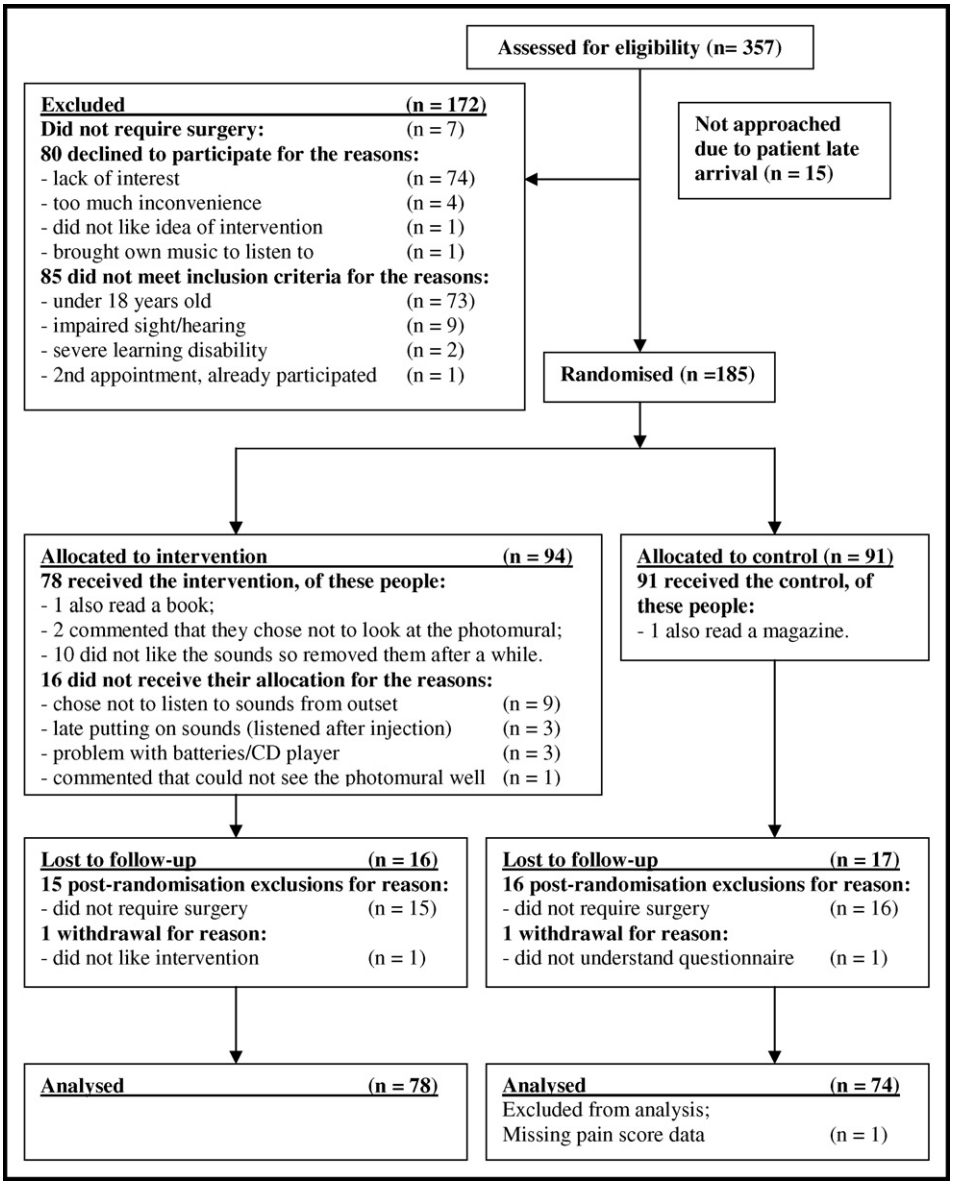

Fig. 1. Participant flow through trial.

Table 1
Baseline characteristics of trial participants

	Intervention ($N = 78$)[a]	Control ($N = 74$)[a]
Age: mean (range) years	44.5 (19–83)	41.9 (18–76)
Gender: male/female	45/33	41/33
Length of appointment: mean (range) minutes	49.7 (30–80)	52.6 (30–95)
Nail pathology: ingrown/involuted/unknown	50/15/13	47/19/8
Number of toes affected per patient		
One	60	46
Two	17	27
Four	1	0
Six	0	1
Toe condition		
Colour: normal/blanched/cyanosed/unknown	71/1/1/5	66/0/1/7
Temperature: normal/cold/hot/unknown	70/2/2/4	63/3/2/6
Infection present	19	14
Hypergranulation present	25	23
Previous nail surgery experience: ($N = 50$)		
Successful previous experience [b]	9	4
Unsuccessful previous experience	8	7
Success unknown	10	12
Procedures performed: ($N = 189$)		
Total nail avulsion	20	22
Partial nail avulsion	68	71
Missing data	3	5
Patients with two toes operated upon	11	24
Patients with three toes operated upon	1	0
Pre-treatment anxiety score: mean (S.D.)	41.4 (12.5)	39.2 (13.0)

[a] All information is given as a simple count unless otherwise stated.
[b] Previous experience is graded as successful if there is no re-occurrence.

and a number of others chose not to attend to the Bedscapes™ having been exposed to it; these participants were included in the intention-to-treat analysis. There was a comparable loss to follow-up across the two study groups, which was primarily due to post-randomisation exclusions of patients who consequently discovered they did not require surgery (and therefore did not meet inclusion criteria). Post-randomisation exclusions and withdrawals were not included in the analysis. A final corpus of 78 and 74 participants were analysed in the intervention and control groups respectively.

3.2. Baseline data

Table 1 details the baseline characteristics for the two study groups. The groups were similar in all aspects apart from the number of toes affected, which was higher in the control group; over twice as many people in the control group had

Table 2
Medical history of trial participants

	Intervention[a] ($N = 78$)	Control[a] ($N = 74$)
Anxiety/depression	7	6
Diabetic	9	3
Anaemic	0	2
Epilepsy	2	6
Neurological disorders	0	2
Heart problems	9	8
Breathing problems	13	12
Circulatory problems	10	7
Blood borne disorders/bleeding disorder	1	2
Liver/kidney condition/jaundice or hepatitis	1	4
Heart valve/murmur	3	0
Smoker	7	12
Previous adverse reaction to local anaesthetic	1	2
Major operations/serious illness	15	20
Joint surgery/implants/fractures in last 6 months	2	0

[a] All information given as a simple count.

Table 3
Findings from primary outcome measures

	Intervention	Control	*p*-value
Pain: mean (S.D.)	1.71 (1.31)	1.47 (1.26)	0.279
Adjusted for covariates[a]: mean (S.E.)	1.71 (0.13)	1.45 (0.13)	0.168
Post-treatment anxiety: mean (S.D.)	27.91 (9.86)	27.20 (7.44)	–
Adjusted for pre-treatment anxiety: mean (S.E.)	27.53 (0.90)	27.60 (0.93)	0.959
Adjusted for covariates[b]: mean (S.E.)	27.48 (0.90)	27.72 (0.92)	0.051

[a] Analysis controlled for age, gender, pre-treatment anxiety, diabetes, anxious or depressive illness, and the number of toes operated on.
[b] Analysis controlled for pre-treatment anxiety scores, gender, age, anxious or depressive illness, number of toes operated on, and a 'group × gender' interaction.

two toes operated on, χ^2 (2, $N = 152$) = 7.94, $p = 0.019$. This difference did not however lead to a significant difference in the length of appointments, nor was there any difference in the anxiety scores between the two groups prior to surgery.

Characteristics recorded from patients' medical history forms are shown in Table 2. Again it can be noted that the two groups were very similar. Although not statistically significant, nine people were noted as being diabetic in the intervention group and three in the control group. As diabetes can lead to neuropathy in the feet [24], diabetes is controlled for in the analysis of covariance for pain scores.

3.3. Analysis of outcomes

Data for the primary outcome measures (pain of anaesthetic injection and anxiety) are presented in Table 3.

3.3.1. Pain

This analysis was conducted on an intention-to-treat basis with 78 participants analysed in the intervention group and 73 in the control group (one participant in the control group had missing data). A *t*-test for independent groups demonstrated that pain in the intervention group (mean = 1.7, S.D. = 1.3) as compared to that in the control group (mean = 1.5, S.D. = 1.3), did not differ significantly ($t(149) = 1.09$, $p = 0.279$, 95% CI = −0.19 to 0.64).

Additionally an analysis of covariance, controlling for the variables of age, gender, pre-treatment anxiety, diabetes, anxious or depressive illness, and the number of toes operated on (in total accounting for 23.4% of the variance), did not show any significant difference between the intervention and control group in pain experienced during the anaesthetic injection ($F_{1,142} = 1.92$, $p = 0.168$). This ANCOVA of pain scores did highlight however, that the more anxious the patients were prior to nail surgery, the more subjective pain they experienced during their injections ($F_{1,142} = 19.35$, $p < 0.001$). Additionally, the older the patients, the more likely they were to give lower pain ratings ($F_{1,142} = 15.68$, $p < 0.001$).[1]

3.3.2. Anxiety

This analysis was also conducted on an intention-to-treat basis with 78 and 74 participants being analysed in the intervention and control groups respectively. Regardless of randomisation group, participants experienced a significant drop in anxiety scores (t (151) = 13.33, $p < 0.001$) from pre-treatment (mean = 40.55, S.D. = 12.81) to post-treatment (mean = 27.56, S.D. = 8.74). Additionally a slight 'floor' effect appeared, as post-treatment anxiety scores in both groups were skewed towards the lower end of the scale. An analysis of the difference in post-treatment anxiety scores between the intervention group (adjusted mean = 27.53, S.E. = 0.90, 95% CI = 25.7–29.3) and control group (adjusted mean = 27.60, S.E. = 0.93, 95% CI = 25.8–29.4), which adjusts for the pre-treatment anxiety scores, found no significant difference ($F_{1,149} = 0.003$, $p = 0.959$).

A further analyses of covariance, to test the difference in post-treatment anxiety scores between the two groups, which adjusts for pre-treatment anxiety scores, gender, age, anxious or depressive illness, number of toes operated on and a 'group × gender' interaction,[2] modified the mean post-treatment anxiety scores further in favour of the intervention. In this model (which accounted for 20.8% of the variance), the post-treatment anxiety adjusted mean was 27.48 (S.E. = 0.90, 95% CI = 25.7–29.3) for the intervention group, and 27.72 (S.E. = 0.92, 95% CI = 25.9–29.5) for the control group; this small difference was not statistically significant ($F_{1,143} = 3.87$, $p = 0.051$).

3.4. Findings from focus groups with trial participants

Participants discussed the relative complexities of the photomural designs and felt that more engaging visual distractions (such as moving images) would make a better distraction. Participants were generally more positive towards the sounds; however some participants found them annoying. Participants highlighted the role of staff in distracting

[1] The 13 patients recorded as having an anxious or depressive illness also gave more intense pain ratings than other patients ($F_{1,142} = 4.25$, $p = 0.041$). Diabetes did not have a significant effect on pain scores ($F_{1,142} = 1.54$, $p = 0.217$).

[2] When all the other covariates in the ANCOVA model are considered ($F_{1,143} = 4.06$, $p = 0.046$), there was an interaction between gender and allocation group for post-treatment anxiety score, with males in the intervention group having lower anxiety scores than females and the opposite being true (although to a lesser degree) in the control group.

them and putting them at ease. Some participants (particularly in the second focus group) felt that the Bedscapes™ still had a role to play, despite the amount of interaction with staff, since the intervention provided a useful 'backup' when the staff were otherwise engaged. Other participants felt that the Bedscapes™ had a redundant role in the Nail Clinic scenario, due to the role that the podiatrists played in distracting patients and putting them at ease. There were individuals in both groups who felt that they had benefited in some way from having the Bedscapes™ present. Likewise both groups contained individuals who felt the Bedscapes™ were unnecessary and did not help them. The first group were unanimous that the intervention could not help with the pain of the injection; however some individuals in the second group disagreed. The general consensus offered by focus group participants was that the Bedscapes™ do have potential, particularly with anxious people.

3.5. Findings from interviews with clinical staff

Staff opinions towards the Bedscapes™ varied widely, although a general summary of the findings is presented here. Staff felt that the photomurals did not physically intrude upon their work and unlike the focus group participants were generally more positive towards the photomurals than they were the sounds. Three of the four interviewees had issue with the barrier that the headphones created between themselves and patients (although one of these felt she could work around this). Talking emerged as a routine component to nail surgery and interviewees commonly referred to patients turning the sounds down or removing the headphones in order to engage in conversation. Some staff felt that a 'formal' distraction such as Bedscapes™ would work better than distracting conversation for some patients and that the Bedscapes™ may enable staff to focus more on conducting the surgery. Other staff felt that auditory distraction was unnecessary during nail surgery as the auditory environment is not part of the unpleasantness of nail surgery.

Interviewees felt that the distraction would work better if it was more permanently integrated into the clinic environment, then patients could use it if they felt the need, and staff would not need to do any additional work to set it up. Interviewees typically felt that the pain caused by the local anaesthetic injection is too intense to be distracted from, but some forwarded the view that a distraction may help patients *cope* with the pain better and may improve the mood of patients. Interviewees additionally felt that many patients were motivated to participate in the research so that they could be part of a research study, and questioned whether patients would have been interested in the distraction if it was independent of the research.

3.6. Exploratory analyses

Post-hoc analyses were conducted on the trial data, motivated by the findings from the qualitative enquiries. Focus group participants suggested that the Bedscapes™ may help patients presenting with elevated anxiety but patients entering the clinic with low anxiety did not perceive a need for the Bedscapes™. Patients deemed to be relaxed on entry to the study (i.e. pre-treatment anxiety score $\leq$35), as based on the norms established by Spielberger et al. [12], were removed from these exploratory analyses. Analyses of covariance were conducted on the post-treatment anxiety scores and pain scores of 54 patients in the intervention group and 44 patients in the control group, using the same covariate models as above. The exploration of post-treatment anxiety scores in the Bedscapes™ group (adjusted mean = 29.53, S.E. = 1.23) compared to the control group (adjusted mean = 29.86, S.E. = 1.37), showed a statistically significant difference ($F_{1,90} = 4.70$, $p = 0.033$) in favour of the Bedscapes™ group. No effect was found however for pain of the injection ($F_{1,90} = 0.13$, $p = 0.722$).

4. Discussion

This randomised controlled trial found that being exposed to Bedscapes™ did not reduce pain and anxiety in patients undergoing nail surgery overall, even when other potential confounding factors were controlled for. The study additionally demonstrated that regardless of which group patients were in, patients with high pre-treatment anxiety experienced more subjective pain during the local anaesthetic injection, and that older patients gave lower pain ratings. The finding that pre-treatment anxiety is related to pain experienced during the local anaesthetic injection is supported by previous theory and research which suggest that anxiety is a strong predictor of pain [5,6]. The present study found an age-related decrease in reported pain perception of the anaesthetic injection. This finding is supported by a review of other research which concludes that older people have an increased pain perception threshold [25]. Clinical evidence suggests a relative absence of pain symptoms in older people with acute inflammation [26], which maybe comparable to the pain induced by a local anaesthetic injection to the toe.

Diette et al. [10] found a positive effect of Bedscapes™ on pain. Apart from the methodological differences with this study, a number of other study differences may also explain these results. It is possible that patients in the USA are more receptive to notion of this form of intervention than the patients in the present UK study were, or that flexible bronchoscopy is a more suited procedure to this type of intervention. The "dose" of distraction that Bedscapes™ affords, may suffice for the uncomfortable pain perceived during bronchoscopy but not the intense pain of a local anaesthetic injection. There might also be important differences in the way staff deal with patients in these two settings, which resulted in either the Bedscapes™ having no added benefit, or a reduction in their potential benefit in a Nail Clinic setting. For example conversation as a means of distraction may not be routine in a bronchoscopy context.

Patients in both groups of the present study experienced a large decrease in anxiety from pre-treatment to post-treatment measurement. It is probable that the sense of relief felt once the treatment is complete accounts for much of the pre- to post-treatment difference. There was a slight 'floor' effect evident, as the post-treatment anxiety scores in both groups were skewed towards the lower end of the scale. Excluding the patients with low pre-treatment anxiety in the post-hoc analyses may have removed some of this 'floor' effect, resulting in the significant finding. The exploratory analyses provide an impetus for future studies to omit patients who do not present with anxiety and target those who do, as it is those patients with elevated anxiety who may benefit most from a distraction therapy. Despite the significance of the post-hoc analysis, the difference between the two groups remained very small (0.33 points on the STAI) with questionable clinical relevance. A properly powered, prospective evaluation of this subgroup of patients may increase the size of this effect.

The lack of difference between the two groups' anxiety and pain ratings overall, could be explained by uncontrolled confounding. Although the transferability of the qualitative analyses in the present research may be limited by relatively small sample sizes, they do provide further insight into the quantitative findings of the trial. One clear suggestion is that participants in the control group were also being distracted in other ways by the staff carrying out the surgery. Interviews with staff highlighted the importance staff place on conversing with patients and encouraging a relaxed social atmosphere. Kwekkeboom [27] found that music distraction was no better than a book on tape during medical procedures. Likewise, it is possible that conversation in the present study successfully distracted the control group from their nail surgery treatment, and possibly the intervention group from the Bedscapes^{TM} as well as their surgery.

The notion that elicitation of positive emotion reduces pain and anxiety, as stipulated by the Broaden-and-Build Model [7], may well be operational in the Nail Clinic setting; however it is engagement from staff, rather than the environment, that has the most powerful influence over patient well-being. Previous qualitative research has also arrived at this conclusion [28]. From an evolutionary perspective, much larger emphasis is placed on the adaptation of humans for interpersonal interaction as opposed to human–environment interaction (The social brain hypothesis; [29]); ergo, the potential of engagement with fellow humans to engender emotion will supersede that of engagement with the environment. This is not to say that the role of the environment is unimportant, but rather that the functions of language and emotional communication have more powerful implications for human well-being [30]. Within this framework, it could be posited that Bedscapes^{TM} had little additive benefit over the interactions already functioning within the Nail Clinic setting. These findings highlight that any future manipulation of the environment should embrace the importance of interpersonal interaction and facilitate this as best as possible. Cocooning patients in an innately pleasant environment, but one which is devoid of pleasant human interaction, may do little to help well-being when there is a more appealing interpersonal situation on offer.

It is possible that the patients presenting with elevated anxiety in the present trial felt less inclined to 'chat' with the podiatrists (indeed some staff interviewees maintained this view), and these patients may therefore prefer an environmental distraction. A view arising from the staff interviews was that of having the distraction integrated into the clinic environment as a permanent feature, so patients could use the environment to distract themselves if they desired. Focus group participants also talked about having the Bedscapes^{TM} as something to fall back on if the staff were focussing on the surgery. Providing an audiovisual distraction as a stand-alone intervention may not be the answer to improving pain and anxiety in patients undergoing clinical procedures that normally involve interpersonal interaction throughout. Rather, a focus on the environment in the most holistic sense, which affords the various patient preferences and staff ways of working, would be a more suitable solution.

Acknowledgements

This study was funded by the Dunhill Medical Trust (Registered Charity: 294286). The Dunhill Medical Trust were not involved in the study design, data collection, data analysis, data interpretation, writing of the manuscript, or decision to submit the manuscript for publication. We would like to thank all the patients and staff for their involvement in this research and Bernie Higgins for statistical support.

References

[1] Andreassi A, Grimaldi L, D'Aniello C, Pianigiani E, Bilenchi R. Segmental phenolization for the treatment of ingrowing toenails: a review of 6 years experience. J Dermatol Treat 2004;15:179–81.
[2] Rounding C, Bloomfield S. Surgical treatments for ingrowing toenails. Cochrane Database Systematic Rev 2002, Issue 4. Art. no.: CD001541.pub2. doi:10.1002/14651858. CD001541.pub2.
[3] Browne J, Fung M, Donnelly M, Cooney C. The use of EMLA reduces the pain associated with digital ring block for ingrowing toenail correction. Eur J Anaesthesiol 2000;17:182–4.
[4] Szmuk P, Szmuk E, Ezri T. Use of needle-free injection systems to alleviate needle phobia and pain at injection. Expert Rev Pharmacoecon Outcomes Res 2005;5:467–77.
[5] Eli I, Schwartz-Arad D, Baht R, Ben-Tuvim H. Effect of anxiety on the experience of pain in implant insertion. Clin Oral Implants Res 2003;14:115–8.
[6] Miller AC, Hickman LC, Lemasters GK. A distraction technique for control of burn pain. J Burn Care Rehabil 1992;13:576–80.
[7] Fredrickson BL. What good are positive emotions? Rev Gen Psychol 1998;2:300–19.
[8] Drahota A, Stores R, Ward D, Galloway E, Higgins B, Dean T. Sensory environment on health related outcomes of hospital patients. Cochrane Database Systematic Rev 2004, Issue 4. Art. no.: CD005315. doi:10.1002/14651858. CD005315.

[9] Bedscapes Healing Environments [homepage on the Internet]. Seattle (WA):Oxclove Workshop; c2001; [cited 2007 Jan 25]. Available from: http://www.bedscapes.com/.
[10] Diette GB, Lechtzin N, Haponik E, Devrotes A, Rubin HR. Distraction therapy with nature sights and sounds reduces pain during flexible bronchoscopy: a complimentary approach to routine analgesia. Chest 2003;123:941–8.
[11] Melzack R, Katz J. The McGill Pain Questionnaire: appraisal and current status. In: Turk DC, Melzack R, editors. Handbook of pain assessment. New York: Guildford Press; 1992. p. 152–68.
[12] Spielberger CD, Gorsuch RL, Lushene R, Vagg PR, Jacobs GA. State-trait anxiety inventory for adults. Sampler set, manual, test, scoring key. California: Mind Garden; 1983.
[13] Mandle C, Domar A, Harrington D, Leserman J, Bozadjian EM, Friedman R, et al. Relaxation responses in femoral angiography. Radiology 1990;174:737–9.
[14] Shuldham C, Cunningham G, Hiscock M, Luscombe P. Assessment of anxiety in hospital patients. J Adv Nurs 1995;22:87–93.
[15] Yu-Shen L, Taylor A. Effects of therapeutic touch in reducing pain and anxiety in the elderly population. Integr Med 1998;1:155–62.
[16] Hamel W. The effects of music intervention on anxiety in the patient waiting for cardiac catheterization. Intensive Crit Care Nurs 2001;17:279–85.
[17] Frison L, Pocock SJ. Repeated measures in clinical trials: analysis using mean summary statistics and its implications for design. Stat Med 1992;11(13):1685–704.
[18] Dugard P, Todman J. Analysis of pre-test̂post-test control group designs in educational research. Educ Psychol 1995;15:181–98.
[19] Reed J, Payton VR. Focus groups: issues of analysis and interpretation. J Adv Nurs 1997;26:765–71.
[20] Hydén L-C, Bülow PH. Who's talking: drawing conclusions from focus groups- some methodological considerations. Int J Soc Res Methodology 2003;6:305–21.
[21] Sim J. Collecting and analysing qualitative data: issues raised by the focus group. J Adv Nurs 1998;28:345–52.
[22] Smithson J. Using and analysing focus groups: limitations and possibilities. Int J Soc Res Methodology 2000;3:103–19.
[23] Burnard P. A method of analysing interview transcripts in qualitative research. Nurse Educ Today 1991;11:461–6.
[24] Muniz EC, Rocha RM, Reis ML, Santos VL, Grossi SA. Neuropathic and ischemic changes of the foot in Brazilian patients with diabetes. Ostomy Wound Manage 2003;49:60–70.
[25] Gibson SJ, Farrell M. A review of age differences in the neurophysiology of nociception and the perceptual experience of pain. Clin J Pain 2004;20:227–39.
[26] Gibson SJ, Helme RD. Age-related differences in pain perception and report. Clin Geriatr Med 2001;17:433–56.
[27] Kwekkeboom KL. Music versus distraction for procedural pain and anxiety in patients with cancer. Oncol Nurs Forum 2003;30:433–40.
[28] Shattell M, Hogan B, Thomas SP. It's the people that make the environment good or bad: the patient's experience of the acute care hospital environment. AACN Clin Issues 2005;16:159–69.
[29] Dunbar RIM. Coevolution of neocortical size, group size and language in humans. Behav Brain Sci 1993;16:681–735.
[30] Parr LA, Waller BM, Fugate J. Emotional communication in primates: implications for neurobiology. Curr Opin Neurobiol 2005;15:716–20.