

The efficacy of a handheld transcutaneous electrical nerve stimulator in menstrual pain

Abstract

The aim of this study is to carry out a trial looking at the efficacy of the handheld portable tens unit named PainGone in the management of primary dysmenorrhoea (also known as menstrual or period pain). 52 participants over the age of 18 years were selected on the basis of producing a sample representative of age and severity of symptoms, to provide a well-rounded assessment of PainGone's efficacy. Each participant completed a daily questionnaire regarding symptom severity, analgesia requirements and relief provided by the device, over a 50 day period. 94% of participants experienced pain relief suggesting that PainGone is effective at alleviating pain in sufferers of primary dysmenorrhoea.

Aim

The aim of this study is to carry out a trial looking at the efficacy of the PainGone in the management of primary dysmenorrhoea. To our knowledge, no such study has been carried out, looking at this particular unit.

Background

Painful menstruation affects approximately 50% of menstruating women, and an estimated 10 to 15 percent of women experience monthly menstrual pain severe enough to prevent normal daily function at school, work, or home. Any advantage thus bestowed by a lightweight portable unit capable of being carried around in a pocket or handbag is of obvious utility.

PainGone is a pocket sized pain relief device that works by delivering a controlled electronic frequency through the nerve pathways to the brain. The piezo-electronic crystal placed in the product works by producing a high voltage, low frequency pulse for a brief period. Clicking on the painful area, the device transmits electrical impulses to the skin surface and then to the body's pathway for pain relief. This stimulates endorphins, the body's natural painkillers.

A standard TENS unit consists of one or more electric signal generators, a battery, and a set of electrodes. The PainGone has no attachments and is similar in size and shape to a fat ballpoint pen. There are thus strong advantages of this self-contained, portable device requiring no batteries or maintenance.

Contraindications for the use of PainGone:

- Should not be used in patients with a pacemaker (especially of the demand type)
- Should not be used during pregnancy
- Should not be used by those with epilepsy

Method

52 participants over the age of 18 years were selected on the basis of producing a sample representative of age and severity of symptoms to provide a well-rounded assessment of PainGone's efficacy.

For ease and cost-efficiency, all communications took place via email. All participants were sent an information form detailing the requirements of the trial. After having read this, they were asked to carefully read and sign a consent form indicating that none of PainGone's contraindications applied to them and that they wished to partake in the trial. A PainGone pen was then sent out to each of the participants along with detailed usage instructions. The instructions explained that the PainGone can be used directly on the point of pain or on the acupoint relevant for the pain experienced, details of which were available on the Tower Health website. It was also suggested that to increase the efficacy of the PainGone, it could be used initially on the general acupoint before using on either the relevant acupoint or point of pain. Due to the episodic nature of period pain, participants were asked to begin using the PainGone on the general acupoint 1 week before their period began to accustom their body to usage of the device.

During the treatment, participants were allowed to use the device independently, day-by-day, and as many times as they pleased. They were asked to complete daily assessments of the severity of their pain and the level of pain relief received from the device using a visual analogue scale ranging from 0 ('none') to 10 ('complete pain relief'). Participants were asked to rate the device on how easy it was to use. They were given a visual analogue scale ranging from 0 (marked 'simple') to 10 (marked 'impossible'). They were also asked to make a note of any analgesia requirements as well as any confounding factors which may have affected pain relief ratings, such as exercise or the weather. Participants' qualitative responses were also assessed as they were asked to include any relevant open-ended comments regarding the efficacy and ease-of-use of the device. Participants were encouraged to specify their responses in a basic computer spreadsheet on a daily basis for 50 days. After 15 days, participants were asked to return their spreadsheets completed up to that point so that advice on the usage of the PainGone could be given in accordance with the results so far. Advice included altering the point on which the PainGone was used and increasing the frequency of usage. Once the spreadsheet had been completed, participants were asked to provide a short summary of their experiences and opinions of the PainGone.

Results

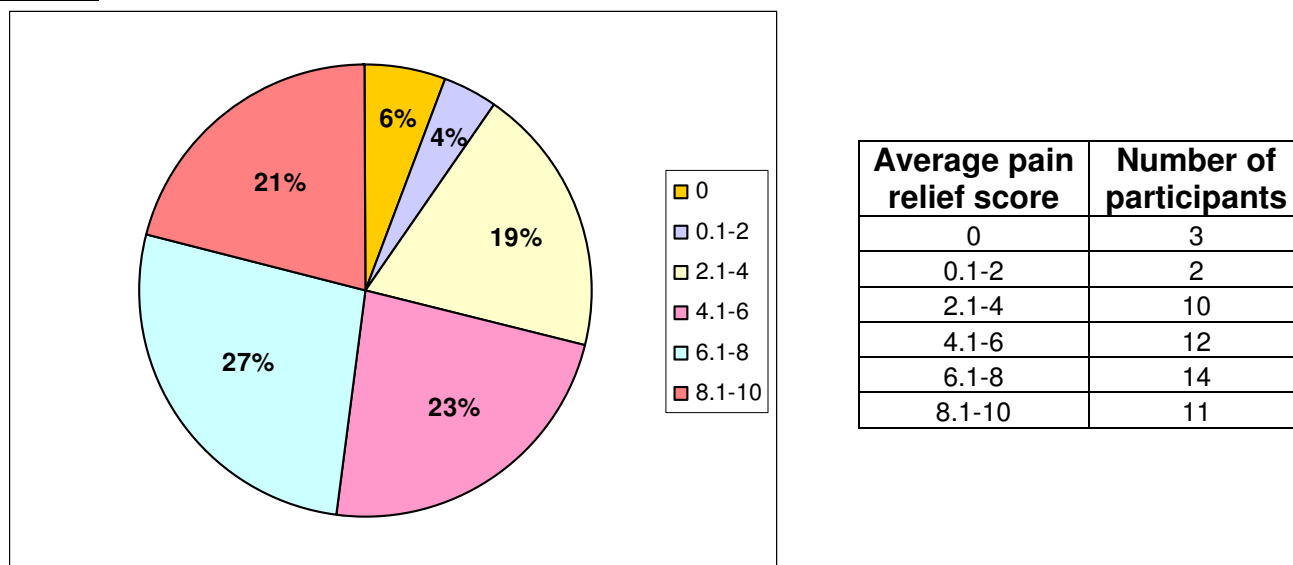


Figure 1: A pie chart depicting the average pain relief scores for each participant on the trial and a table of the raw data.

94% of participants experienced pain relief, with only 3 participants responding that they had obtained no relief from the device. 48% of participants rated their average pain relief as being between 6.1 and 10, where 0 represented ‘no pain relief’ and 10, ‘complete pain relief’.

The average rating for ease of use was 0.82 (mode = 0), where 0 represented ‘simple’ and 10 ‘impossible’

The majority of participants most frequently used the PainGone directly on the point of pain and on average found an increase in pain relief when used on the general acupoint first.

Discussion

94% of participants experienced pain relief suggesting that PainGone is effective at alleviating pain in sufferers of primary dysmenorrhoea. The qualitative comments indicate that PainGone is an effective device capable in some cases of improving the quality of life of sufferers of severe menstrual pain. By allowing some users to reduce their intake of conventional medication, PainGone also helps to prevent the potential problems associated with long-term analgesic usage.

A selection of qualitative comments is available in appendix 1.

Conclusions

PainGone pain killing pen is a safe, convenient, medication-free pain controlling device which can be used for self-treatment. Participants described the device as “so simple to use”, “extremely good for pain relief” and would recommend it “to all friends and family as a brilliant alternative to conventional pain relief”. It was also remarked that the PainGone enabled some participants to “be more active in my daily life” and “regain some control over my life during my periods which can be excruciatingly painful”.

Appendix 1: A selection of comments from participants' end of trial summaries.

Samantha Smith-Cheshire “I have found it to be very effective, hence my results and I would recommend this to anyone who suffers each month like I do”

Lisa Harding-Bedford “I found this pen so brilliant, my relief from pain was wonderful. Due to my endometriosis, I do find I have a lot more pain during my period than normal and it did help immensely”

Tara Forrest-Oxford “I found the PainGone pen very effective. The relief was instant and it was several hours before I had to use it again. The pen was so simple to use, you just put it on the point of pain and click several times. It couldn't have been easier”

Tracy Alderson-Essex “After suffering with painful periods for as long as I can remember, I've finally found something that works. I would highly recommend the PainGone and will continue using it as it has made a huge difference to me. I am no longer dreading my period as I know the PainGone will help”

Mrs Susan Raisback-Newcastle-upon-Tyne “This little pen is a godsend”

Rachel Williams-Surrey “I am very impressed with this little device that easily fits into my handbag”

Belinda McMartin-Arbroath “The results have been amazing. For the first time in a very long time I have been more normal during my period. I have not had any days off work, slept better and most importantly managed my pain without taking any drugs. It has obviously worked well for me and I would have no problems recommending it to others who have problem periods.”

Lucy Januskiewicz-Doncaster “I found the pen very easy to use and extremely good for pain relief during my period. I have recommended it to all friends and family as a brilliant alternative to conventional pain relief”

Natalie McMinn-Co. Down “I am so glad I came across this wonderful device, it has made a huge difference to my life and I can't believe the level of pain relief it provides. I am exceedingly grateful in that it has helped me regain some control over my life during my periods which can be excruciatingly painful. Before trying the PainGone I was unable to successfully manage these and had to resort to staying in bed for several days, now I can continue to work and go about my daily life”

Catherine Shotton-Plymouth “I am able to be more active in my daily life-just regular things like shopping, housework, kids etc, but it all makes a difference.”

Jill Davey-Leeds “I think the PainGone is amazing. Just looking at it you wouldn't think it would bring pain relief like it does!! It is so simple to use-at first you think it might hurt, but you don't feel any discomfort. I would certainly recommend it for pain relief-especially period pain!!”