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Hypnotic intervention for women with chronic pelvic pain: a pilot randomized control trial.

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Methods

Ethics

This study received approval from the University of South Australia Human Research Ethics Committee on 28th of August, 2020 (protocol number 202935).

Trial Registry

Our pilot RCT protocol has been registered with the Australian and New Zealand Clinical Trials Registry²⁸.

Design

The study design was a pilot RCT. This study followed the guidelines for pilot RCTs outlined in the Consolidated Standards of Reporting Trials (CONSORT) statement and 2010 extension.²⁹⁻³⁰ A parallel group design, with treatment and waitlist control groups, was utilized.

Inclusion and exclusion criteria

Our inclusion criteria required participants to be over the age of 18, female and with pain in the pelvic region of more than three months duration that was not attributable to an identified biological cause.² Participants' pelvic pain could not be solely due to pain during intercourse or periods, as these are regarded as separate groups within the research literature.

Recruitment

Recruitment was conducted between the dates of the 1st of October and the 2nd of November, 2020. Participants in the intervention group commenced the education and hypnotic intervention on November 2nd, 2020. Participants were recruited directly online using the Pelvic Pain Foundation of Australia social media sites, and via health practitioners working with PPP, who provided study information to their clients. Participants who expressed an interest were contacted by email, and provided with the Participant Information Sheet and Consent Form. Once consent forms were received, participants were sent the questionnaires for the outcome measures.

Allocation

Participants were allocated to either the intervention or waitlist control groups. The intervention group received seven weeks of hypnotic intervention therapy in the form of audio recordings of hypnosis sessions provided online. The waitlist control group received no intervention.

Blinding

Blinding for participant or psychologist was not possible, as participants required notification of the time line for hypnotic intervention. A total number of 40 participants commenced the trial, with 20 allocated to the intervention group, and 20 allocated to a waitlist control. Participant details were placed into unlabelled, sealed, envelopes.

Randomization

Randomization was conducted using a basic randomization software template. Once group allocation was complete, participants were notified of their group

allocation. The waitlist control group received support for two months upon completion of the trial. Recruitment and contact with participants were undertaken by the primary researcher, whereas randomization was undertaken by an independent statistician.

Procedure

After allocation, participants in the intervention group were sent a link to provide them with access to the hypnosis recordings when the trial commenced. The information sheet and seven hypnosis recordings were accessible on a website for the study. The intervention also contained one session of education regarding PPP and hypnosis. Participants in the intervention group were instructed to read the health resources provided, that included information on the anatomy of the pelvis and the basics of pain education before commencing the hypnosis recordings. Intervention group participants then completed seven online hypnosis recordings, one per week for seven weeks.

The intervention group were also instructed to continuing listening to recordings from the weeks prior whilst progressing through the intervention to week seven. The intervention group participants were contacted by phone or email once weekly during the trial, to discuss their progress and to seek feedback on their experience with the intervention. Following the conclusion of the intervention at week seven, participants completed the outcome scales assessed at the beginning of the study, and provided feedback on the study overall. The control group completed the concluding outcome measures at the same time. This occurred across the week of the 21st of December, 2020.

The waitlist control were given access to the study materials including information on the anatomy of the pelvis and the basics of pain education, as well as the hypnosis sessions for two months after the study concluded. This was so that they could also have the benefits of the intervention, without interfering with the results. No changes to the study methodology were made once the pilot RCT commenced.

Education

Participants in the intervention group received education about the pelvis, pelvic muscles, pelvic pain and hypnosis prior to commencing the hypnotic intervention.^{10-11,12-14} This included information on pain and the brain, how to become familiar with the pelvic muscles, and how to tense and relax the pelvic muscles. The education components were heavily based on the 'explain pain' resources for chronic pain management by Moseley and Butler³¹ and consultation with two experienced physiotherapists.

Hypnosis script development

A series of seven hypnosis scripts were developed. This number was based on the number of scripts used in other evidence-based hypnosis protocols for IBS and chronic pain.^{26,32} These scripts were developed based on resources on script structure provided by Mason³³ and Yapko.³² Induction is the process of preparing the person to go into a state where they are focused and more open to suggestion, called a 'trance' state. After promoting relaxation, every hypnosis script starts with an induction.³² The inductions chosen for the script development in this study were based on a selection commonly used for hypnosis in general, as well as those used regularly with reference to chronic

pain and IBS. The following sources were consulted with reference to the development of the inductions used for the scripts in this study.³²⁻³³

The content of the scripts related to suggestions, deepening and metaphors were drawn from a number of sources. Two expert pelvic pain physiotherapists were consulted as to suggestions that they commonly used to assist women with PPP to relax their pelvic muscles. These suggestions were then included across the scripts. Suggestions were also drawn from emotional coping skills, relaxation techniques, and a technique to de-catastrophize used in cognitive behavioural therapy for chronic pain management. Deepening exercises were drawn from those commonly used for hypnosis, using the Yapko³² and Mason³³ resources. Both direct and indirect as well as pain specific and non-specific exercises have been shown to be effective for chronic pain-related hypnosis, therefore combinations of these were used across scripts.²⁵ A brief overview of the individual scripts can be seen in Table 1 below. The scripts were examined for validity by an expert in the field.

Table 1

Brief descriptions of the seven scripts developed for the purposes of this study

Script number	Goal / script title	Induction	Deepening	Metaphor	Suggestions	Suggestion type
1	Change pain sensation to warmth	Progressive Muscle Relaxation/ body scan	Visualisation warm liquid and anatomy	Melting, liquid	Relax muscles, warmth, sensation change	Indirect
2	Protected pelvis	Diaphragm breathing	Visualisation pelvic anatomy	Protective barriers,	Protected space	Direct suggestions

				relaxed space		
3	Adjust pain severity	Eye induction	Five senses exercise	Dial	Pain dial	Direct and indirect
4	Anaesthesia	Falling leaves	Focus exercises	Strengths	Glove anaesthesia applied to the pelvis	Direct and indirect
5	Apply previously acquired skills to pain management	Candle induction	Visualisation	Transport	Regression to retrieve skills	Direct and indirect
6	Emotional self soothe, relax muscle tension	Stairs	Water visualisation	Flowing water	Notice flow of water, tension and unpleasant emotions float away	Direct and indirect
7	De-catastrophizing	Butterfly	Forest visualisation	Tracking flow of thoughts	De-catastrophize, manage anxiety about pain	Direct and indirect

Outcome measures

This study utilized a series of questionnaires at baseline and the conclusion of the pilot trial in line with the outcomes of interest. The outcome measures included the Generalised Anxiety Disorder Scale 7-item (GAD-7)³⁴, Patient-Health Questionnaire 9-item (PHQ-9)³⁵, 10-point Visual Analogue Scale measuring pain severity, Brief-COPE³⁶, Pain Catastrophizing Scale (PCS)³⁷, the Pain Disability Index (PDI)³⁸ and the Short Suggestibility Scale (SSS)³⁹. The questionnaires were converted to an online format using SurveyMonkey⁴⁰ software, then a link to the study website was emailed to participants. The questionnaires utilized are listed below.

Feedback on recording use and the study

The primary outcome was to establish the feasibility of the trial. Therefore, the intervention group was asked to provide weekly feedback on the recordings and study overall and at the end of the pilot trial. At baseline, we asked participants to give an overview of their experience with chronic pelvic pain in an open response dialogue box. Each week of the seven week trial, participants in the intervention group were asked how many times they listened to each recording and for their feedback. We also asked for feedback on the trial overall in an open dialogue box in the concluding measures.

Questionnaires for the outcome variables

Our primary outcomes of interest were anxiety and depression. The secondary outcomes of interest included perceived pain severity, life impact of pain, coping styles and pain catastrophizing. We identified our outcomes of interest from previous research on chronic pain, previous systematic reviews and a recent scoping review looking at predictors of mental health outcomes for women with CPP.¹¹⁻¹⁴

Generalised Anxiety

Generalised Anxiety was measured using the GAD-7³⁴ at baseline and trial conclusion. The GAD-7³⁴ is a 7-item self-administered scale with seven questions related to Generalised Anxiety Disorder symptoms according to the Diagnostic and Statistical Manual 5th Edition (DSM-V).⁴¹ Persons completing the GAD-7³⁴ are asked '*over the last two weeks, how often have you been bothered by the following problems*', before being presented with the seven questions about anxiety symptoms, such as '*feeling nervous, anxious or on edge*'. Each of the seven items has a four-point Likert response scale, with

responses ranging from 0 (not at all) to 3 (every day). Total scores range from 0 to 21, with a higher score representing greater anxiety.

Depression

The PHQ-9³⁵ was used to assess for depression severity at baseline and trial conclusion. The PHQ-9³⁵ contains 9 self-report questions related to depression according to the Diagnostic and Statistical Manual 5th edition (DMS-5)⁴¹.

Persons completing the PHQ-9³⁵ are asked '*over the last two weeks, how often have you been bothered by the following*', and then asked the nine questions about depression symptoms such as '*little interest or pleasure in doing things*'. Each question is rated from 0 (not at all) to 3 (nearly every day), with total scores ranging from 0 to 27, with a higher score implying more depression.

Pain severity

Participants were asked to rate their current pain severity on an 10-point Visual Analogue Scale where 0 represented no pain, and 10 represented the most severe pain imagined at baseline and at the conclusion of the pilot trial.

Coping styles

Coping styles were assessed using the Brief-COPE.³⁶ The Brief-COPE³⁶ is a 28-item self-report questionnaire designed to assess the efficacy of coping styles. Each item is rated on a scale of 1 (I haven't been doing this at all) to 4 (I've been doing this a lot). The scale is often used with patients adjusting to significant diagnoses.³⁶ There are two subscales included in the 28-item questionnaire, avoidant and approach coping, as well as 4 questions about humour and religion. The Avoidant coping subscale is composed of 12 questions (items 1, 3, 4, 6, 8, 9, 11, 13, 16, 19, 21, 26), and reflects coping

using denial, substance use, self-blame and self-distraction. The approach coping subscale is composed of 12 questions (items 2, 5, 7, 10, 12, 14, 15, 17, 20, 23, 24, 25), and is reflective of coping using active skills, positive planning, acceptance, seeking emotional and informative supports. The total score on each of the two subscales ranges from 12 to 48. We administered the Brief-COPE to establish avoidant and active coping style scores at baseline and the end of the pilot trial. A higher score represents a greater use of the coping style.

Pain Catastrophizing

The Pain Catastrophizing Scale³⁷ was used to assess for pain related anxiety. The PCS³⁷ is a 13-item self-report measure with persons completing the scale asked to rate their response from 0 (not at all) to 4 (all the time). The total score on the PCS³⁷ ranges from 0 to 52. The items on the PCS are reflect rumination about pain, the extent people magnify their pain and feel helpless to manage their pain. Example questions include '*I can't stop thinking about how much it hurts*', '*I am afraid that something serious might happen*' and '*there is nothing that I can do to reduce the intensity of my pain*'. A higher score reflects greater pain catastrophizing. Permission to use the PCS for student research purposes was sought and granted by Mapi Research Trust⁴² on the 14th of May, 2020. The PCS was administered at baseline and study conclusion.

Pain-related disability

The PDI³⁸ is a self-report questionnaire used to assess pain-related disability. The PDI³⁸ was designed to establish the extent to which pain disrupts life

across seven domains. These include: family and home responsibilities, recreation, social activity, occupation, sexual behaviour, self-care and life-support activities. People completing the PDI rate the extent that pain has impacted them on each of these seven domains on an 11-point numerical scale of 0 (no disability) to 10 (worst disability). The seven items can be added together to form a total score for pain related disability with range from 0 to 70, a higher score reflecting more disability.

Suggestibility

It is widely known that response to hypnosis can be dependent on suggestibility. Therefore, we wanted to know how suggestible our participants were and whether this impacted on the results. The SSS³⁹ was therefore administered at baseline. The SSS³⁹ is a 21-item self-report scale designed to establish suggestibility. Persons completing the SSS are asked to rate the questions as *'to what extent the following statements relate to you'* on a scale of 1 (not at all/very slightly) to 5 (a lot). Total scores range from 21 to 105. A higher score reflects greater suggestibility.

Statistical analyses

The results of the questionnaires in the online SurveyMonkey⁴⁰ format were converted to an SPSS data file. SPSS⁴³ was used to provide baseline descriptive statistics for the control and intervention groups. Independent sample t-tests were then conducted in order to establish participant results for the outcomes of interest pre and post intervention. The comparison of group differences over time was undertaken using linear mixed effects modelling with group, time and group time interaction. Group time interaction was included in the

model as the formal test for the efficacy of the intervention. Linear mixed effects modelling was conducted using Stata statistical software.⁴⁴ A second model including suggestibility was then undertaken. Results were considered statistically significant at $p < 0.05$.

Sample size justification

Power calculations for the study were carefully considered. Current recommendations for pilot RCT sample sizes vary significantly, as they are by definition investigative in nature and the standardized effect size is unknown. For a main trial planned with 90% power and two-sided 5% significance in mind, Whitehead et al.⁴⁵ recommend a minimum of 10 participants per study arm in the pilot trial.