PAUL N. DAVIES BA MSc

HYPNOSIS, RESPONSE EXPECTANCY AND MIGRAINES AND TENSION-TYPE HEADACHES: "THEY CAN BECAUSE THEY THINK THEY CAN: HOW WOULD IT BE IF YOU IMAGINED IT TO BE?"

Section A: Do response expectancies mediate hypnosis-based intervention outcomes for experimental and clinical conditions? A narrative review.
Word Count: 7809 (26)

Section B: A pilot randomised controlled trial of an intervention comprising a single online group hypnosis session followed by self-hypnosis for migraines and tension-type headaches
Word Count: 7932 (247)

Overall Word Count: 15741 (273)

A thesis submitted in partial fulfilment of the requirements of
Canterbury Christ Church University for the degree of
Doctor of Clinical Psychology

MAY 2021

SALOMONS INSTITUTE FOR APPLIED PSYCHOLOGY
CANTERBURY CHRIST CHURCH UNIVERSITY

Acknowledgements

Thank you to Dr Fergal Jones and Dr Rob Agnew for such fantastic supportive and committed supervision, without which, this thesis would not have been possible.

Thank you to my Mum, Dad, my brother, Drew, and Reuben who have all made it possible for me to get to this point.

MRP Summary

SECTION A

Response expectancies have been suggested to mediate hypnosis intervention outcomes. This review examined relevant studies to determine the quality of evidence for this proposed association. A systematic search produced ten studies that fulfilled inclusion criteria. The review provided some evidence for an association between response expectancy and mediation of hypnosis outcomes. However, study quality, generalisability and evidence for mediation were mixed. Further controlled trials of hypnosis-based interventions with varied clinical populations are needed to validate response expectancy as a mediator of hypnosis outcomes.

SECTION B

The methodological rigour of studies examining the effects of hypnosis upon migraines and tension-type headaches has been limited. This study developed and evaluated a single online-group session plus self-hypnosis intervention for this population. People with diagnoses of migraines or tension-type headaches (N = 35) participated in a pilot randomised controlled trial. The hypnosis group demonstrated significantly greater decreases in mean daily headache ratings and increases in medication-free days at four-week follow-up compared with waitlist-controls. Outcomes were not moderated by expectancy, attitudes to hypnosis, suggestibility or mediated by post-intervention changes in expectancy. Secondary improvements in depression, wellbeing, self-efficacy and internal-locus-of-control were not observed. Findings are discussed and future research recommendations provided.

Contents

Section A: Literature review

Section B: Research Paper

List of Tables and Figures

Section C: List of Appendices

Section B: Empirical Research Paper

Section A: (7809 words)

Do response expectancies mediate hypnosis-based intervention outcomes for experimental and clinical conditions? A narrative review.

Abstract

Aim: Although hypnosis has an evidence base for providing improved outcomes across several health conditions, there remains debate over its defining characteristics and underlying mechanisms. Mediators are the constructs through which an intervention's effects are funnelled to produce outcomes. Response expectancies have been proposed as mediators of hypnosis outcomes. Response expectancies are the anticipation of automatic, non-volitional responses within specific contexts. There has not been a review of studies examining response expectancies as mediators of hypnosis-based outcomes. This review seeks to evaluate study findings and critique methodological quality.

Methods: A systematic search of three electronic databases (Web of Science, PubMed and PsycINFO) identified ten studies examining response expectancies as mediators of hypnosis outcomes. These were synthesised and critiqued to provide an overview and implications of findings.

Results: Response expectancies partially statistically-mediated hypnosis-based outcomes for experimental pain, post-surgical pain, fatigue, public speaking anxiety, but not hot flushes nor nausea. The evidence for causal mediation was less strong.

Discussion: All studies were randomised controlled trials; however, most examined experimental pain, contained methodological weaknesses and poor reporting of demographic variables, therefore limiting generalisability. Replication with varied clinical populations is required to validate preliminary findings supporting response expectancy as a mediator of hypnosis-based outcomes.

Key words: hypnosis, response expectancy, mediation, mechanisms

1.Introduction

1.1 What is hypnosis?

Despite hypnosis' longstanding use as a therapeutic tool, its precise definition remains debated (Lynn et al., 2020). Hypnosis-type procedures used to treat individuals for various ailments via ceremonies that induced 'trance-like' states have been reported for centuries (Hammond, 2013). These ranged from shamanistic rituals to ancient Egyptian and Western religion-based healing procedures where direct commands for symptom relief were provided. These processes were crystallised and brought into broader societal awareness in the 1760s by Franz Mesmer's mesmerism (Green et al., 2014).

Mesmer proposed there was an invisible "animal-magnetism" force, which when individuals entered a trance, could be used to ameliorate various illnesses (Green et al., 2014). Although his contention of animal-magnetism as the mechanism of change was discredited, the outcomes of people getting better were not. It was considered improvements occurred due to people's beliefs the process relieved their symptoms (Hammond, 2013).

Modern hypnosis is considered to have developed in the mid-1800s with the emergence of James Braid's scientific-based conceptualisation of hypnosis as a process where suggestions are more readily received and responded to by participants during a process of 'neuro-hypnotism,' or quieting of the nervous system (Kittle & Spiegel, 2021).

Using a parsimonious definition, hypnosis is a process that involves a person designated as the 'hypnotiser' who guides a motivated participant through a series of suggestions, to which the individual responds, and changes to imagined and experienced physical, perceptual and voluntary actions occur (Kihlstrom, 1985). This definition does not endorse a 'trance-like state,' but requires the experiencer understand they are partaking in hypnosis.

1.2 Hypnosis' evidence base

Considerable research supports hypnosis' efficacy for symptom reduction across several conditions. Perhaps the strongest empirical support for hypnosis is for acute and chronic pain (Thompson et al., 2019). Montgomery et al.'s (2000) meta-analysis demonstrated a medium effect size (d=.67) for hypnosis-induced analgesia, with those receiving hypnosis on average achieving 75% greater pain decreases than no-treatment-controls. Support for hypnosis' beneficial effects extends to depression (Alladin, 2010; Milling et al., 2018), anxiety (Valentine et al., 2019), migraines (Milling, 2014), dental surgery (Patel et al., 2000), and weight-loss regimen adherence (Kirsch et al., 1995). Furthermore, when added to cognitive-behavioural therapy (CBT), hypnosis has demonstrated significantly improved outcomes over CBT for anxiety, insomnia, obesity and hypertension (Kirsch et al., 1995, Ramondo et al., 2021). Within the British National Health Service (NHS) hypnosis is a National Institute for Health and Clinical Excellence (2017) recommended treatment for irritable bowel syndrome.

Despite this, hypnosis does not hold mainstream scientific and medical acceptance. This may reflect caricatured media portrayal, association with stage-hypnosis, and heterogeneity of research methodology and treatment protocols (Milling, 2014). Additionally, hypnosis has long been shrouded in mystery and mythological lore. This could be considered a strength for enhancing expectancy for 'miraculous' outcomes, but also a weakness due to 'fears of the unknown' engendered within clinicians and the public alike (Lynn et al., 2020).

1.3 Theories of hypnosis

Hypnosis' theoretical underpinnings have historically been separated between state, and non-state (social-cognitive) theories (Jensen et al., 2015). The most significant debate has surrounded whether hypnosis is considered a unique cognitive state. This position is held

within state theories which maintain individuals enter a trance-state of altered-consciousness (Jensen et al., 2015). Neuroimaging studies however have not provided reliable findings to support this (Landry et al., 2017).

Non-state theories refer to hypnosis as a construct of combined psychological and social factors. Hypothesised psychological factors include motivation (Lynn et al., 2019), expectancy (Kirsch, 1985), imaginal absorption (Nadon et al., 1991), placebo (Ploghaus et al., 2003), dissociation (Hilgard, 1992), compliance (Wagstaff, 1991) and attitudes to hypnosis and its perceived credibility (Spanos, 1986). Social-cognitive theories prioritise the importance of the hypnotic context and how the participant enacts socially constructed roles between the hypnotist and hypnotisee (Lynn et al., 2017). Spanos' (1986) socio-cognitive role theory proposes thoughts, feelings and imaginings are transformed into behaviours believed consistent with what "one does," during hypnosis. The social-psychobiological model (Jensen et al., 2015) stresses the influence of the hypnotist/participant relationship and emphasises the interaction of psycho-biological factors with personality characteristics to produce hypnosis (Jensen et al., 2015). However, the field lacks a definitive framework, and this has contributed to questions regarding the mechanisms that explain hypnosis' effects.

1.4 Response expectancies

Within the above theories a contended key ingredient is response expectancy. Response expectancy theory (Kirsch, 1985) maintains response expectancies are the anticipation of automatic, non-volitional responses following specific stimulus presentations or situational cues (Wickless & Kirsch, 1989). For example, expectation of increased alertness following caffeine consumption, will cause this to occur, even if the coffee is decaffeinated (Milling et al., 2002). Response expectancies can equally apply to sexual

function, situation-specific emotional responses, or the anticipation of automatic responses to varied medication or cancer-treatment protocols (Devlin et al., 2019).

Following this theoretical-framework, hypnosis is hypothesised to achieve its effect via individuals' heightened expectancy for nonvolitional responses following suggestion. Response expectancies are therefore self-generative processes that elicit automatic responses sufficient to create the consequent experiences (e.g. the thought of experiencing pain post-surgery heightens pain response expectancy which translates to increased pain). Response expectancies differ from outcome expectancies which are premised upon how likely individuals believe outcomes will occur based upon voluntary or goal-directed behaviours (Cardena & Terhune, 2019).

Response expectancies have been implicated within psychotherapy (Weiberger & Eig, 1999), placebo (Brody & Brody, 2000) and cancer treatment side-effect occurrence (Devlin et al., 2017). Sohl et al. (2009) demonstrated moderate associations between chemotherapy side-effect response expectancies and increased patient medication-related toxicities. Roscoe et al. (2004) evidenced individuals who rated "very likely" as opposed to "very unlikely" as their expectancy for chemotherapy side effects were five-times more likely to experience these. During initial placebo drug trials in the mid-20th century, it was observed that placebo drug effects depended on the individual's beliefs about which drug they had consumed. Montgomery and Kirsch (1997) explored placebo analgesic treatment effects on pain and evidenced significant mediation by response expectancies. Lidstone et al. (2010) demonstrated that people with Parkinson's Disease when given a placebo drug, experienced elevated endogenous dopamine levels by 75% and reduced symptoms. Subsequently, the placebo effect is associated with response expectancy.

Response expectancies are hypothesised mediators of hypnosis outcomes due to the proposed contributions of placebo to the hypnotic process alongside heightened expectancy for automatic responses. It is considered once someone experiences hypnosis, they develop increased expectancy for non-volitional responses to occur (Sliwinski & Elkins, 2017). If this theory is correct, then response expectancy would be a meditator of hypnosis' outcomes.

1.5 Mediation criteria

Kazdin (2007) asserted that to understand how therapeutic intervention-based changes occur, mediation analysis is required. This assesses the indirect impact of a treatment on an outcome through a mediating variable. Baron and Kenny (1986) defined a mediator as a generative mechanism through which an independent variable (e.g. treatment) influences the dependent variable (e.g., outcome). Mediation represents hypothesised causality.

Several methods of statistical mediation analysis exist. These range from hierarchical regression, to Baron and Kenny's (1986) causal-steps model, which sequentially tests linear regression models for significance; to structural equation modelling, which facilitates concurrent investigation of indirect and direct relationships between constructs (Kline, 2011). Mackinnon et al. (2002) and Iacobucci et al. (2007) recommend bootstrapping (Preacher & Hayes, 2004) approaches over causal-steps and Sobel tests (Sobel, 1982) due to their increased statistical power. Despite this, the Baron and Kenny (1986) framework has been used most within mediation analyses.

Beyond statistical-mediation, Kazdin (2007) specifies additional criteria necessary to support mediation occurrence: 'temporal-precedence' requires changes demonstrated in the mediator prior to outcome-changes. This reduces the possibility the outcome created change in the mediator first. 'Gradient' refers to increased experience of intervention/dosages being associated with increased treatment outcomes (e.g. as session frequency designed to enhance

response expectancy increases, associated outcome improvements are observed). ‘Strong association’ asserts that demonstration of large effect size or high variance supports statistical mediation. ‘Consistency’ refers to stronger inferences about mediation being made if findings are replicated across similar studies and participants. ‘Specificity’ refers to increased mediation-likelihood if other constructs cannot potentially explain the mediation. ‘Experimental manipulation’ refers to direct manipulation of the hypothesised mediator leading to direct outcome changes, which supports mediation. ‘Plausibility/coherence’ requires a credible theoretical account that fits with wider psychological understanding reasonable processes by which the mediator can be explained as the construct causing outcome change. Collectively, the demonstration of these factors, increases the likelihood of mediator presence.

1.6 Review aims

The present review is required as no previous reviews have examined the evidence for response expectancy in the mediation of hypnosis-based intervention outcomes. This narrative review aimed to conduct a systematic search of the literature examining hypnosis interventions that included a measure of response expectancy as a mediator of outcome. The review sought to examine the evidence-base to highlight the potential value of response expectancy enhancement for increased therapeutic benefit from hypnosis interventions.

2. Methods

2.1. Literature search

Searches were performed on 27/02/2021. Databases searched included Web of Science, Psychinfo and Pubmed, from response expectancy theory’s inception in 1985 to the date of the search. Search terms included: ("response expectancy" OR outcome expectancy

OR expectanc* OR “expected outcome”) AND (hypnosis OR hypnotherapy OR self-hypnosis).

Variations on the word expectancy were included to ensure relevant papers were not missed, as some authors used terms to mean slightly different things, but the focus was on response expectancy. Searches included relevant terms in “title,” “abstract” and “keyword”. Articles were first screened by title, abstract, and then full text. Reference sections of included studies were searched, and Google Scholar forwards and backwards searching was used to determine presence of additional relevant studies.

2.2. Eligibility criteria

The below inclusion criteria were utilised:

1. Studies were included if authors carried out a hypnosis-based intervention with pre and post measures of outcome for either an experimentally induced or clinical condition (e.g. pain). This included studies that incorporated hypnosis alone or hypnosis combined with CBT (where the separate effects of hypnosis could be examined).

2. Response expectancy (the anticipation of automatic non-volitional responses (Kirsch, 1985) was measured at pre- and post-intervention, and its relationship with intervention outcome was statistically examined.

3. Because this literature is small, both clinical and non-clinical populations were included.

4. The study was published in a peer-reviewed, English language journal.

The exclusion criteria below were utilised:

1. Studies that solely utilised outcome measures of hypnotic-depth. This was because hypnotic-depth is not a treatment target (e.g. such as pain or anxiety-reduction).

2. Where there was no statistical analysis provided of the mediating role/contribution of response expectancy to the hypnosis intervention outcome.

Figure 1: PRISMA literature search diagram (Moher, Liberati, Tetzlaff & Altman, 2009)

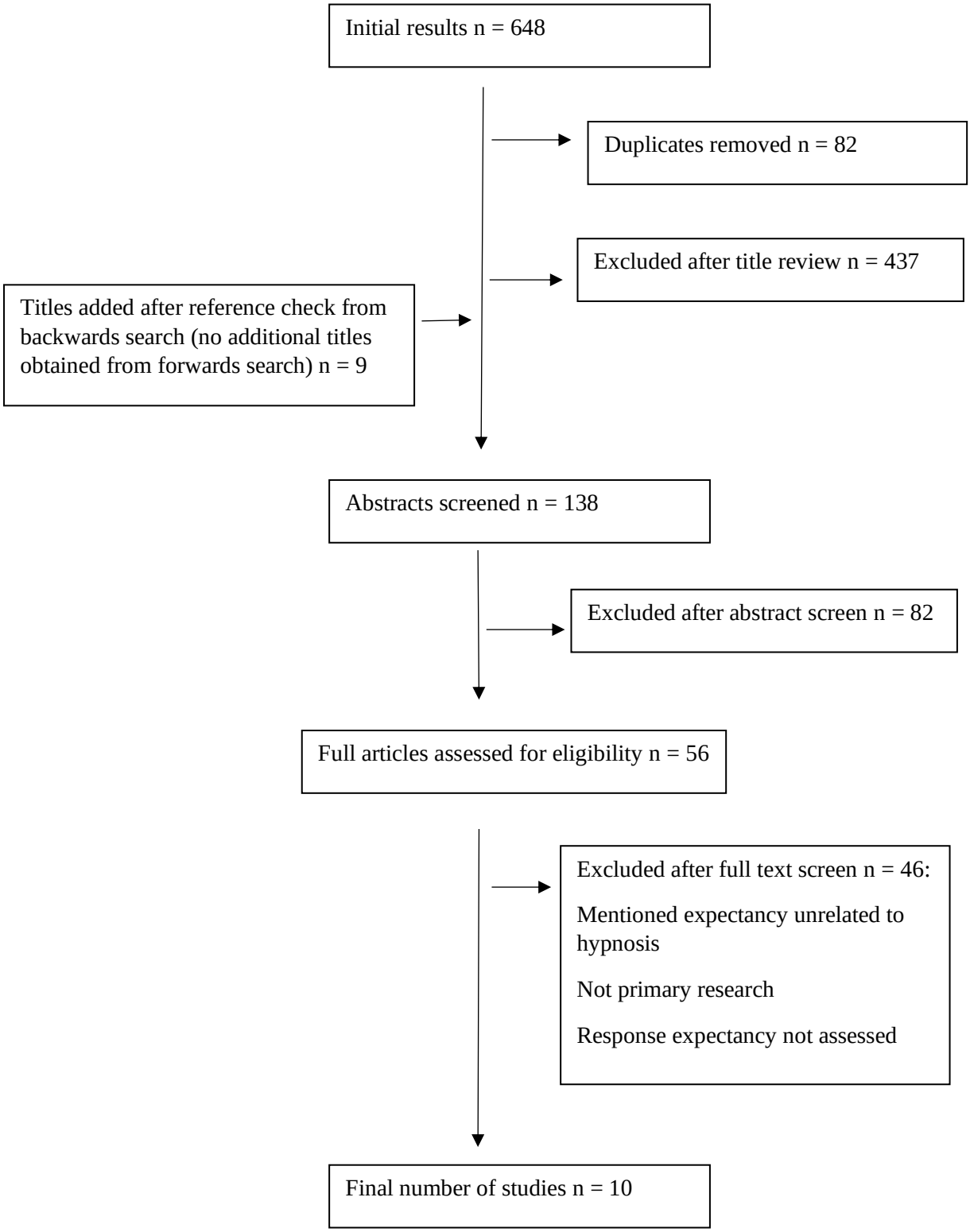


Figure 1 illustrates articles found at each search-stage. Ten studies were identified. All were randomised controlled trials (RCTs).

2.3. Quality assessment tool

Study quality assessment followed the mediational study analysis applied by Gu et al. (2015). They adapted the Jadad (Jadad et al., 1996) and CONSORT (Schulz et al., 2010) checklists, which evaluate RCTs, and combined these with some of Kazdin's (2007) mediation criteria. Total study scores were calculated by assigning a value of 1 if met, 0.5 if partially met or 0 if not met to the 16 questions detailed in Table 2. Scores of 0–5 were categorised as low-quality studies with high-bias risk, 6–11 as medium-quality with moderate-bias risk and 12–16 high-quality with low-bias risk. These bandings are indicative only, and further detailed quality analysis is provided by study appraisal within the review and critique section.

Table 1: Key study information

Study **Authors (Year) Location** **Study score**	**Sample** **Recruitment**	**Design** **Groups**	**Study summary**	**Hypnosis intervention**	**Measures** **Primary outcome** **Response Expectancy**	**Key findings** **Mediation analysis**
Milling, Kirsch, Meunier & Levine (2002) **USA** **8 (moderate bias risk)**	**N=83** (68% female) volunteer psychology students. Age and ethnicity not stated. **Recruitment:** From pool previously screened for suggestibility and asked to participate in pain management study.	**RCT** Blocked randomisation: Groups matched for gender, suggestibility Hypnosis (22), CBT (23), HCBT (20), No treatment control (18)	Evaluated hypnosis' individual and combined effects with CBT on experimental pain: placing finger in pain stimulator machine for 60 seconds. Assessed if pain expectancy changes post-intervention mediated pain outcomes.	**Single session**: hypnosis information, induction, pain analgesia suggestions before experiencing a 45-second glove pain-relief suggestion. Participants then guided by presenter with pain relief suggestions during pain stimulus.	**Primary:** Pain intensity measured on 11-point Visual Analogue Scale (VAS) anchored by 'no pain at all' (0) and 'pain as intense as can imagine' (10). **Response expectancy** Pain expectancy measured on same VAS scale except asked what they expected pain to be. Measured pre and post intervention.	**Primary findings:** Hypnosis, HCBT (and CBT) reported greater pain reduction than controls. No intervention between group differences observed. **Response expectancy:** Decreases in pain associated with changes in pain expectancy reduction following hypnosis and HCBT conditions (but not CBT). Authors suggested response expectancies may perform a larger mediatory function in hypnosis for pain than CBT. **Mediation analysis** Hierarchical regression Temporal-precedence demonstrated
Milling & Breen (2003) **USA** **8.5 (moderate bias risk)**	**N=167** (63% female) volunteer psychology students. Age and ethnicity not stated **Recruitment:** From pool of 1100 students previously screened for suggestibility, asked to partake in pain study. .	**RCT** Blocked randomisation. Groups matched for gender, suggestibility. Hypnosis (28), HCBT (27) distraction (28) CBT (28), Placebo (27) No treatment control (29)	Evaluated changes in pain expectancy as mediator of effects of hypnosis, HCBT (and CBT, distraction) on experimentally induced pain, compared with placebo.	**Single session**: hypnosis information, induction, pain analgesia suggestions before experiencing a 45-second glove pain-relief suggestion. Participants then guided by presenter with pain relief suggestions during pain stimulus.	**Primary:** Pain intensity: 11-point VAS scale (0-10). **Response expectancy** Pain expectancy measured on same VAS scale except asked what they expected pain to be. Measured pre and post intervention.	**Primary:** Changes in pain expectancy partially mediated effects of hypnosis, HCBT (and CBT and placebo) significantly greater than no treatment controls. All reduced pain intensity more than controls. Only CBT reduced pain more than placebo. Authors contended response expectancy may be greater for placebo. **Mediation analysis** Baron and Kenny Causal-steps Temporal-precedence demonstrated

Milling, Kirsch, Allen & Reutenauer (2005) **(USA)** **8.5 (moderate bias risk)**	N=60 (75% female) psychology students. Age and ethnicity not stated. **Recruitment:** From pool of 300 previously assessed for suggestibility.	**RCT** Blocked randomisation groups matched for gender, suggestibility. Hypnosis (15), Imaginative suggestion (15), Placebo (15) No-treatment control (15)	Evaluated whether hypnotic and imaginative pain relief suggestions compared with placebo produced differential pain outcomes. Mediator role of pain response expectancies evaluated.	**Single session:** hypnosis information, induction, pain analgesia suggestions before experiencing a 45-second glove pain-relief suggestion. Participants then guided by presenter with pain relief suggestions during pain stimulus.	**Primary:** Pain intensity: 11-point VAS scale (0-10). **Response expectancy** Pain expectancy measured on same VAS scale except asked what they expected pain to be. Measured pre and post intervention.	**Primary:** Hypnosis and Imaginative suggestion groups did not differ significantly from placebo in reducing pain, but all more effective than controls. **Response expectancy:** Hypnosis (and imaginative suggestion and placebo) pain reduction partially mediated by expectancy. Authors contended hypnosis and imaginative suggestions may be equally effective in lowering pain, and response expectancies are mechanisms of hypnotic, placebo and suggested pain reduction. **Mediation analysis:** Hierarchical regression Temporal-precedence demonstrated
Milling, Reardon, Carosella (2006) **USA** **8.5 (moderate bias risk)**	N=188 (64% female). Mean age: 18.9 years (SD 3.31). Caucasian: 64%, 14% African American: 14%, 5% Hispanic: 5%, Native American 4% Other: 2.5%, No response: 10%. **Recruitment:** from pool of 1000 previously assessed for suggestibility	**RCT** Randomly assigned in blocks matched for gender. Hypnosis (31), HCBT (31), CBT (31), Distraction (31) placebo (31), no-treatment control (33)	Further evaluated potential mediation by pain expectancies in experimental pain. Participants asked to take part in study exploring topical analgesics with pain control techniques.	**Single session** hypnosis information, induction, pain analgesia suggestions before experiencing a 45-second glove pain-relief suggestion. Participants then guided by presenter with pain relief suggestions during pain stimulus.	**Primary:** Pain intensity: 11-point VAS scale (0-10). **Response expectancy** Pain expectancy measured on same VAS scale except asked what they expected pain to be. Measured pre and post intervention.	Response expectancies partially mediated hypnosis and HCBT effects on pain outcomes (and CBT). Authors suggest results indicate response expectancies are central mechanism of hypnosis (and CBT) pain interventions **Mediation analysis:** Causal-steps Temporal precedence demonstrated
Milling, Shores, Coursen, Menario & Farris	**N= 123** (83 = Female) introductory psychology students. Age: M= 19.4 years (SD 3.6). Caucasian:	**RCT,** randomly assigned in blocks matched for gender	Assessed mediation by pain expectancies (as well as treatment credibility) in	**Single session:** hypnosis information, induction, pain analgesia suggestions before experiencing a	**Primary:** Pain intensity: 11-point VAS scale (0-10).	Pain expectancies (and credibility) mediated hypnosis (and CBT) independently. Mediation increased with more experience of intervention.

(2007) **USA** **7.5** **(moderate bias risk)**	69%, African American:12%, Asian or Pacific Islander: 4%, Hispanic: 2% Other: 0.8%, Not stated:13%. **Recruitment:** from pool of 300 previously screened for suggestibility.	across conditions Hypnosis (42), CBT (42), Placebo (41)	hypnosis (and CBT, placebo) pain reduction. Developed upon previous studies by exploring whether mediation increases with further experience of intervention.	45-second glove pain-relief suggestion. Participants then guided by presenter with pain relief suggestions during pain stimulus.	**Response expectancy** Pain expectancy measured on same VAS scale except asked what they expected pain to be. Measured pre and post intervention.	Authors contended treatment credibility also mediated hypnosis outcomes, in addition to response expectancies and are specific mechanisms of hypnosis and CBT pain treatments. **Statistical analysis:** Baron and Kenny causal-steps method followed by Sobel Test. Temporal precedence and Gradient demonstrated
Milling **(2009)** **USA** **7.5** **(moderate bias risk)**	N= 172 introductory psychology students (104 female). Age and ethnicity not specified **Recruitment**:	Blocked randomisation so groups matched for gender and suggestibility: Hypnosis (46), Imaginative suggestion (43), Placebo (41), No treatment controls (42)	Assessed whether response expectancies were mediators of hypnosis, imaginative suggestion and placebo experimentally induced pain (compared with no treatment control).	**Single session**: hypnosis information, induction, pain analgesia suggestions before experiencing a 45-second glove pain-relief suggestion. Participants then guided by presenter with pain relief suggestions during pain stimulus.	**Primary:** Pain intensity: 11-point VAS scale (0-10). **Response expectancy** Pain expectancy measured on same VAS as above except modified to ask what expected pain to be if placed finger in pain stimulator machine	**Primary:** Hypnosis, and placebo and imaginative suggestion all more effective than no-treatment controls in experimental pain reductions. Hypnosis more effective than placebo. **Response expectancy:** All treatments partially mediated by pain expectancies: hypnosis (25%), imaginative suggestion (29%) and placebo (41%). Authors posited response expectancies a major mechanism of hypnosis and similalry in placebo and imaginative suggestion pain relief. **Statistical analysis** Causal-steps and Sobel Test used. Temporal precedence and Association demonstrated
Montgomery, Weltz, Seltz & Bovbjerg (2002) **USA** **9** **(moderate bias risk)**	N=20 female excisional breast biopsy patients **Recruitment:** From a single medical practice **Age:** 30-81 (M= 50.11, SD = 10.94). 50% Caucasian, 35%	**RCT:** with random assignment to hypnosis (10) or control group of standard care (10). These were compared with a healthy	Explored effects of brief hypnosis on post-surgery pain and distress for breast biopsy patients and the contributions of post pain expectancy (and distress) as mediators of	**Single session**: "10-minute induction of imagery for PMR; suggestions to imagine a special place, relaxation; deepening procedure; instructions for self-hypnosis. Positive suggestions (e.g., you will feel comfortable, confident)	**Primary:** Post-surgery pain and distress measured by 10 cm VAS: "How emotionally upset are you feeling right now? And "How much pain do you feel right now? Anchored by 'Not at all upset'	**Primary:** Post-surgery pain and distress reductions were significantly greater for the hypnosis group. **Response expectancy as mediator** Change in pain response expectancies post-hypnosis intervention partially mediated effects of hypnosis on pain outcomes. Effects of hypnosis on reducing post-surgery distress mediated by postintervention expectation.

	African American, 15% Hispanic.	volunteer group to control for baseline distress.	hypnosis on postsurgical pain.	and negative suggestions (e.g., you feel less pain). Effects suggested to occur before, during, and after surgery."	and 'As upset as I could be' **Response expectancy:** 10cm VAS scale asking "How much pain do you expect to feel after the biopsy?	**Mediation statistical analysis** Causal-steps Temporal precedence demonstrated
Montgomery, Hallquist, Schnur, Silverstein & Bovbjerg (2010) **USA** **13.5** **(low bias risk)**	N=200 females receiving breast conservation surgery. Mean age: 48.50 years (SD= 13.05). Ethnicity: 63% White, 15% Hispanic, 13% African American, 9% Other, 13% **Recruitment** from sample scheduled for breast conserving surgery at a single medical centre.	**RCT** random assignment to hypnosis (105) or attention controls (95)	Assessed whether response expectancies and emotional distress independently mediated effects of pre-surgery hypnosis on post-surgery pain, nausea and fatigue.	**Single session:** A 15-minute relaxation-based induction, deepener, suggestions for pleasant imagery, relaxation peace and specific symptom-suggestions (e.g., reduced postsurgical pain, nausea), and instructions for how could use self-hypnosis	**Primary**: Pain, nausea and fatigue response expectancies captured using 10cm VAS scales. (e.g. VAS for expected pain asked, "After surgery, how much pain do you think you will feel? Anchored by "no pain at all" and "as much pain as there could be." Scores ranged from 0–100 based on mm from left side. Emotional distress assessed via anxiety subscale of Short Version of Profile of Mood States and VAS scale.	**Primary (response expectancy):** Pain expectancy partially mediated hypnosis' effect on post-surgical pain (emotional distress did not). Nausea expectancy did not mediate post-surgery nausea (but presurgical distress did). Fatigue expectancy partially mediated post-surgery fatigue (and by presurgical distress). **Mediation analysis** Separate models constructed for pain, nausea, fatigue. Each model tested mediation by the relevant expectancy for that outcome, and pre-surgical emotional distress. Statistical mediation assessed via calculating product of path coefficients which composed the indirect effect divided by the bootstrapped product standard error. Temporal precedence demonstrated.
Schoenberger, Kirsch & Gearan (1997) **USA** **10** **(moderate bias risk)**	N=95 (68% female) people with public speaking anxiety and determined clinically anxious (>19) on the Anxiety Expectancy (AE) scale taken from PRCS. Ages: 18-56. Mean age and ethnicity not stated.	**RCT:** HCBT (36), CBT (38), No treatment controls (21)	Assessed if HCBT versus CBT for public speaking anxiety demonstrated improved public speaking outcomes (experienced anxiety during a speech) and if this	**Group sessions:** 5 x 2-hours (2-4 members). HCBT= relaxation based hypnotic induction, suggestions to enter hypnosis and CBT framework for social phobia: cognitive restructuring, exposure work, progressive	**Primary:** SUDS taken during impromptu speech **Expectancy:** Anxiety Expectancy (AE) scale. Asked to predict extent of anxiety during a speech, using 5-point	**Primary:** Participants improved in both conditions compared with controls, however HCBT group had greater improved outcomes. **Expectancy:** HCBT generated greater change expectancies than CBT group. These correlated positively with improved treatment outcome. HCBT generated greater expected and decreased anxiety outcomes than CBT.

	Baseline differences on AE present. **Recruitment:** From community via newspaper adverts and undergraduate student population.		was associated with changes in anxiety expectancy post-intervention.	muscle relaxation. These framed as hypnotic suggestions as opposed to automatic thoughts. CBT group received same sessions as HCBT, except term hypnosis removed, and suggestions called automatic thoughts.	scale ranging from "not at all" to "very much." Treatment Credibility also assessed.	Improvement in HCBT correlated with positive attitudes toward hypnosis. Anxiety expectancy scale, indicated participants in HCBT expected less anxiety following intervention than CBT group. **Mediation analysis** Correlational. ANCOVA to account for pre-treatment group differences on expected anxiety. Temporal precedence demonstrated.
Sliwinski & Elkins (2017) **USA** **12** **(low bias risk)**	N=172 post-menopausal females. Age: *M:* 54.7 years (SD =6.9). Ethnicity: White 60% **Recruitment:** Professional referral and adverts.	**RCT** Randomised by sealed envelopes. Computer generated differing sized blocks determined randomisation: Hypnosis (84) Structured attention counselling (88)	Assessed whether response expectancies mediated outcomes for hot flashes frequency following hypnosis. .	**Five face-to-face sessions and self-hypnosis** over 5-week period. Each involved induction, suggestions for coolness, an imagined safe place and relaxation. Also used recording for self-hypnosis.	**Primary:** response expectancy measured via 10cm VAS pre and post intervention **Secondary:** Hot flash frequency diary	**Primary (expectancy)** Effects of hypnosis on hot flush frequency not mediated by response expectancy. Authors hypothesised response expectancy for hot flash relief may function differently for hot flashes than pain. **Statistical analysis** Ordinary least squares path analysis used to test 3 simple mediation models of indirect group effect on hot flushes via response expectancy change after first session. Bootstrap sampling used.

Note: AE = Anxiety expectancy, ANCOVA= analysis of covariance, CBT = cognitive behavioural therapy, CURSS, PCRS= Personal Report of Confidence as a Speaker (Paul, 1966), HCBT = hypnosis combined with CBT, PMR= progressive muscle relaxation, RCT= Randomised Controlled Trial, SD= standard deviation, SUDS= subjective units od distress scale, VAS = visual analogue scale

Table 2: Study quality checklist

Quality criteria	Milling *et al.* (2002)	Milling & Breen. (2003)	Milling *et al.* (2005)	Milling *et al.* (2006)	Milling *et al.* (2007)	Milling (2009)	Montgomery *et al.* (2002)	Montgomery et al., (2010)	Schoenberger et al. (1997)	Sliwinski *et al.* (2017)
1) Was a theoretical framework cited?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
2) Was the mediator's psychometric characteristics tested and within accepted ranges (e.g. Cronbach's alpha > .7)?	No	No	No	No	No	No	No	Partial	Yes	No
3) Was the outcome variable's psychometric characteristics tested and within accepted ranges (e.g. Cronbach's alpha> .7)?	No	No	No	No	No	No	No	No	No	No
4) Was sample size determined from a power calculation and adequately powered to detect mediation?	No	No	No	No	No	No	No	Yes	No	Yes
5) Was there an active control group?	Yes	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes
6) Was it a randomised study?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
7) Was randomisation method described and appropriate (e.g. random numbers table, computer-generated)?	No	No	No	No	No	No	No	Yes	No	Yes
8) Were experimenters/participants blind to group assignment?	No	No	No	No	No	No	No	No	No	No

9) Was flow of participant information described (numbers assigned to groups, analysed and dropped out)?	No	No	No	No	No	No	Yes	Yes	Yes	Yes
10) Were qualifications of facilitators reported?	No	No	No	No	No	No	Partial	Yes	Yes	Yes
11) Did measurement of change in proposed mediator occur before outcome?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
12) Was change in proposed mediator used in mediation analysis measured during treatment?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No
13) Was the proportion of intervention participants who received adequate dose of intervention reported?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
14) Was mediation analysis carried out only with participants who received adequate intervention doses?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
15) Was post-intervention outcome controlled for baseline outcome?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
16) Was the statistical mediation analysis used the most appropriate?	No	Partial	Partial	Partial	Partial	Partial	Partial	Yes	No	Yes
Quality score (/16)	8	8.5	8.5	8.5	7.5	7.5	9	13.5	10	12

3. Review and critique

All studies were RCTs and incorporated either a hypnosis or hypnosis plus CBT (HCBT) intervention for the purpose of alleviating specific symptoms (e.g., experimental or post-surgical pain or anxiety), and an examination of whether the outcomes were mediated by response expectancies (e.g. pain expectancy, fatigue expectancy). The studies can be separated into four examining clinical conditions (Montgomery et al., 2002, 2010; Schoenberger et al., 1997; Sliwinski & Elkins, 2017) and the remaining six, which assessed experimental pain within the laboratory environment.

Because the clinical studies possess increased heterogeneity, these are given longer overviews to provide context of relative strengths and weaknesses, followed by briefer non-clinical study descriptions due to their relative homogeneity. All studies are then synthesised collectively by methodological considerations: design, sample, intervention, outcome measures and mediation. This is to aid understanding of study variations that may have contributed to different mediation outcomes and the requirement for mediator presence to be determined from across collective study findings. See Table 1 for study-specific information and Table 2 for the quality appraisal checklist.

Studies with clinical populations

Montgomery et al. (2002)

This study explored whether hypnosis was more effective than standard medical care in reducing post-surgical pain and distress for 20 females following excisional breast biopsy surgery; and whether the effects were mediated by post-hypnosis intervention changes in pain response expectancy, in addition to pre-surgical distress. The participants were recruited from a single American medical centre's waitlist and were randomised to standard medical care or hypnosis groups. At baseline, measures in pain response expectancy and distress using a 10 cm visual analogue scale (VAS) This ranged from 0: "no pain at all" to 10: "as much pain as

there could be," and were taken prior to the single 15-minute hypnosis session administered prior to surgery. This consisted of induction, deepening, progressive muscle relaxation and suggestions for relaxation and to visualise a "special-place." Additionally, provision of positive suggestions (e.g., 'you will glow with health') and negative suggestions (e.g., 'you will feel less pain') for pain relief were administered. Pain response expectancy and distress were measured immediately after the hypnosis intervention and pre-surgery. Post-surgery pain and distress reductions were significantly greater for the hypnosis than the standard medical care group. The hypnosis intervention effects on pain and distress were partially statistically mediated by post-hypnosis pain response expectancies, while post-surgery distress was also statistically mediated by postintervention expectation.

Study strengths included measurement of post-intervention pain expectancy immediately after the hypnosis session, prior to surgery (temporal-precedence demonstrated) and clear sample-characteristics reporting, with ethnic composition broadly representative of the general American population. The study was limited by a small sample recruited from the same Texas medical practice, therefore limiting generalisability. Additionally, there was no active control group comparison, therefore limiting determination of hypnosis as the reason for observed outcome changes. The study scored eight, indicating moderate-bias risk.

Montgomery et al. (2010)

Montgomery et al. (2010) broadly replicated the above study design with several alterations made. In addition to pain response expectancy, they assessed the roles of post-hypnosis nausea and fatigue expectancies, and pre-surgical distress in independently mediating post-tumour excision pain, nausea, fatigue and distress in females with breast cancer. A larger sample size of 200 was recruited and an active comparison group (structured counselling) was utilised, which controlled for hypnotherapist attention and time. The same hypnosis intervention was used as in the Montgomery et al. (2002) study. Response

expectancies (pain, nausea, fatigue) and distress were also assessed at baseline and post-intervention prior to surgery, along with outcome measures using VAS scales. These showed postsurgical pain was partially mediated by pain response expectancy. Postsurgical nausea was not mediated by nausea response expectancy but partially mediated by presurgical distress. Post-surgery fatigue was partially mediated by fatigue response expectancy and presurgical distress. The authors hypothesised pain response expectancies may have differing mechanisms to nausea expectancies.

Study strengths included its large sample size from a clinical population, representative ethnic diversity, and an intervention well controlled with temporal-precedence demonstrated and an active-comparison-group used. Improved statistical-mediation analysis was used that assessed independent contributions of response expectancies and distress within simultaneous regression models, and structural equation modelling and bootstrapping to increase power. Study limitations included reduced generalisability due to recruitment from a small geographical region and although this was one of the more methodologically rigorous studies, the regression models showed response expectancies still only accounted for 30% of total variance of outcomes, however this was twice that of what pre-surgical distress predicted as a mediator. This study produced the highest methodological quality score with 13.5 out of 16.

Schoenberger et al. (1997)

This study assessed whether a five-session group hypnosis plus CBT intervention alleviated public-speaking-anxiety more than CBT alone, while also assessing if outcomes were mediated by response expectancy (expected anxiety). The study sample was 95 people deemed to possess public speaking anxiety as operationalised by a score of 19 or above on the Personal Report of Confidence as a Speaker (PRCS) questionnaire. Participants were recruited from both community and university samples. Anxiety response expectancy was

measured at baseline as well as the primary outcome measure of subjective units of distress (SUDS) obtained from a four-minute impromptu speech performed to study administrators. Participants were randomised to hypnosis plus CBT, CBT or no treatment control groups. In the hypnotic CBT treatment (HCBT), participants received five two-hour sessions in a group format (2-4 members). The format was identical to the CBT format but consisted of relaxation labelled as hypnotic, followed by induction and suggestions to enter hypnosis. HCBT participants received the same CBT-based framework for social phobia, which included cognitive restructuring, exposure work, and progressive muscle relaxation, however, these were framed as hypnotic suggestions as opposed to automatic thoughts.) Anxiety response expectancy was re-measured immediately after the first intervention session. Upon treatment completion, a final four-minute speech was given, and SUDS recorded. Outcomes showed the HCBT group had greater anxiety reductions than CBT alone. The HCBT group generated greater reductions in anxiety expectancy than CBT and these change in expectancies were correlated positively with anxiety reduction as operationalised via SUDS for the final four-minute speech. Change in expected anxiety was the only predictor of improved outcomes.

Study strengths included: mediation was measured before outcome to demonstrate temporal precedence and hypnosis was well controlled for with the comparison CBT group. The study was limited by poor sample demographics reporting and recruitment from an undergraduate and self-selected community sample making generalisability limited. Additionally, given sessions were delivered in group format over five-weeks, it is possible benefits were from group interaction as opposed to solely the hypnosis intervention. The use of SUDS to assess anxiety reduction potentially compromised internal validity due to increased subjectivity from this self-report measure. Furthermore, the use of correlational

methods to statistically assess mediation were less powerful than regression analysis. This produced a score of 10, representing moderate bias-risk.

Sliwinski and Elkins (2017)

This study explored whether changes in response expectancies post a five-session hypnosis intervention, mediated hot flush frequency outcomes in 172 post-menopausal women. Participants were randomised to hypnosis or active comparison control (structured attention counselling) groups. At baseline, measurements of hot flash expectancies measured via VAS were taken (as used within Montgomery et al., 2002; 2010). Participants received weekly individual hypnosis sessions over a five-week period which consisted of induction and suggestions for coolness, safe place visualisation, and relaxation. Participants also used self-hypnosis with a recording of the hypnosis session. Change in response expectancy was measured after the first intervention session. Outcomes demonstrated significantly reduced hot flush frequency for the hypnosis group, however findings did not support statistical mediation of reduced hot flush frequency by response expectancy. A study score of 12 was produced.

Study strengths included the large sample size, good sample characteristic reporting and use of an active control comparison group. Powerful methods of statistical mediation analysis were used with ordinary least squares path analysis and bootstrapping techniques to increase power. A measure of effect size and follow-up at five-weeks were also incorporated. Response expectancy was measured at baseline and immediately post first intervention session to demonstrate temporal precedence.

Limitations included poor detailing of the hypnosis intervention, administrator credentials and frequency of self-hypnosis use. This limits the extent of inference that can be made regarding why response expectancy mediation did not occur. Additionally, the sample was disproportionately white and non-representative of the general population.

In sum, the clinical studies demonstrated significant post-hypnosis outcome reductions of pain, nausea, public-speaking anxiety and hot flush frequency reductions. These were mediated by respective response expectancies for pain, fatigue and anxiety, but not for nausea or hot flushes. Findings were limited by sample representativeness and generalisability, but also raise the question whether there are differential mediatory mechanisms for hypnosis across pain, fatigue and anxiety versus hot flushes and nausea. Collectively they demonstrated temporal precedence and suggested statistical mediation, but it is worth recalling these are just two aspects of Kazdin's (2007) mediation criteria. This will be considered in the discussion. The strongest studies methodologically were Montgomery et al. (2010), and Sliwinski and Elkins (2017), both deemed to be 'high quality', and lower scores were held by Schoenberger et al. (1997) and Montgomery et al. (2002), both 'moderate-bias' risks.

Non-clinical experimental pain studies

The six remaining studies were highly similar in design and assessed non-clinical experimentally induced pain and included hypnosis interventions designed to reduce pain intensity outcomes. These studies were all based at the same north-eastern United States university, recruiting all participants from an undergraduate student population. All studies compared hypnosis with a variety of analogue interventions (e.g. CBT, non-hypnotic suggestion, distraction, placebo and control conditions). All experimentally induced pain and hypnosis intervention procedures were the same. These consisted of participants placing their index finger in an apparatus which administered mechanically induced pressure on the finger for a 60-second period. Baseline measures of pain intensity were recorded via the VAS to rate at 20 second intervals pain intensity out of ten. A total pain intensity score out of 30 was recorded. Participants were also asked to provide a pain expectancy rating using the VAS, pre-hypnosis intervention. All participants assigned to hypnosis interventions listened to a

recording of information to correct unhelpful beliefs about hypnosis, then underwent hypnotic induction from the Carleton University Responsiveness to Suggestibility Scale, (Spanos et al., 1983) then received information about hypnotic pain relief, received a hypnotic suggestion of 45-seconds to visualise a glove-like analgesia over the hand. After completion, a post-intervention pain expectancy rating was taken. The participant then repeated the same mechanically included pain procedure for another 60-second period. During the pain administration, the experimenter delivered the hypnotic glove analgesia suggestions in-vivo (while the participant remained in hypnosis). A final VAS outcome of pain intensity was then recorded. These procedures were replicated in all of the following studies with minor variations described by study below.

Milling et al. (2002)

This study examined 83 participants randomised to hypnosis, CBT or hypnosis-plus-CBT (HCBT) intervention pain outcomes, while assessing the mediatory role of pain response expectancy. The hypnosis intervention was performed as above, while the CBT intervention consisted of progressive muscle relaxation, self-coping statements and use of guided imagery to be utilised during the pain administration. Reminders to implement these techniques during the pain administration were provided by the administrator. The HCBT condition relabelled self-coping strategies as hypnotic self-suggestions and progressive muscle relaxation as hypnotic relaxation. All groups reported significantly greater pain reduction than controls although no significant group differences were observed. Decreases in pain were associated with changes in pain expectancy reduction following the hypnosis and HCBT conditions, but not the CBT condition. Study strengths included the control afforded by the laboratory environment for precise between-group intervention comparisons and demonstration of temporal precedence of mediator change prior to change in outcomes. Weaknesses included a homogeneous university undergraduate sample with age and ethnicity

not reported, which limited generalisability. Additionally, hierarchical regression with reduced statistical power was used and non-clinical pain assessment limited real-world applicability.

Milling and Breen (2003)

This study replicated the preceding experiment (with modification of comparison groups) and further assessed the mediatory function of response expectancies in hypnosis. A larger sample of 167 participants was randomised to either hypnosis, CBT, hypnosis plus CBT (HCBT), distraction, placebo or no-treatment control to assess differential response to pain. The hypnosis, CBT, HCBT interventions remained the same. The distraction group were trained to repeat monosyllabic words during pain presentation. The placebo group were given an inert topical solution from a bottle labelled 'Trivaricaine' and told it was a medical analgesic, before applied to the finger. Outcomes showed changes in pain response expectancy partially statistically-mediated the effects of hypnosis, HCBT (and CBT and placebo) more than no-treatment-controls. All interventions experienced reduced pain intensity more than controls. Relative strengths of this study were its larger sample size, carefully controlled comparison groups along with temporal precedence demonstration and the use of Causal-steps statistical mediation analysis (over hierarchical regression), but shared the previous study's limitations of non-representative sample and limited generalisability of findings.

Milling et al. (2005)

This study explored whether hypnotic and nonhypnotic imaginative pain relief suggestions in comparison with placebo produced differential pain outcomes in 60 participants, while assessing the mediatory role of pain response expectancy. The intervention groups were the same as described in the above studies, while the imaginative suggestion group was identical to hypnosis except it was framed as guided imagery without

the use of the term hypnosis. Hypnosis and the nonhypnotic suggestion groups did not differ significantly from placebo in reducing pain but were all more effective than no-treatment-controls. The hypnosis intervention (and the non-hypnotic imaginative suggestion) pain reduction was partially mediated by pain response expectancy. The authors contended imaginative suggestions (nonhypnotic) may be as effective as hypnosis in reducing pain and that pain response expectancies may be shared mechanisms of placebo, hypnotic and suggested pain reduction. The study was constrained by lower powered hierarchical regression in addition to the previous studies' limitations but also had a relatively lower sample making conclusions less reliable.

Milling et al. (2006)

This study assessed whether hypnosis, HCBT, CBT, placebo or no-treatment control conditions differentially contributed to the experience of pain in 188 participants, while assessing the mediatory role of pain expectancy (replicating previous studies' intervention protocols). Intervention effects on pain outcomes were all significantly greater than no-treatment-controls (but non-significantly different to each other). Pain response expectancies again partially mediated treatment effects on pain outcomes in hypnosis (and CBT interventions). Similar study limitations were repeated (predominantly female sample), while strengths included better powered causal-steps mediation analysis, its much larger sample size and reported sample demographics, with ethnicity being broadly representative of the general American population, therefore increasing generalisability.

Milling et al. (2007)

This further assessed the role of pain expectancies in mediating pain outcomes and additionally assessed the potential mediatory role of treatment credibility. This was conducted with 123 participants for the differential impact of hypnosis, CBT or placebo reduction of pain. The study also explored whether mediation increases with greater

experience of further intervention sessions. Pain response expectancies and treatment credibility independently mediated hypnosis (and CBT) while as further repetition of the intervention occurred, so did further reductions in pain intensity. Study strengths included demonstration that mediation increased with increased intervention repetition. Additionally, increased rigour of statistical analysis was applied, with four simultaneous regressions using Baron and Kenny causal-steps method followed by Sobel Tests implemented. Like the previous study, demographics was reported in this study, therefore increasing findings generalisability.

Milling (2009)

This study assessed whether response expectancies were mediators of hypnotic suggested and placebo analgesia in 172 participants and incorporated a more detailed statistical mediation analysis by reporting the total variance percentages of mediation accounted for in the outcomes. Hypnosis, placebo and imaginative suggestion were all more effective than the no-treatment controls in reducing experimentally induced pain. Hypnosis was more effective than placebo. All interventions were partially statistically mediated by pain response expectancies: hypnosis (25%), imaginative suggestion (29%) and placebo (41%) conditions. Study strengths included its increased rigour of statistical mediation analysis and increased sample size which facilitated calculation of variances. Despite being reported in the two previous studies, age and ethnicity was not reported in this study therefore limiting generalisability of findings.

Collectively the non-clinical experimentally induced pain studies demonstrated hypnosis and HCBT interventions reduced laboratory-induced pain outcomes. Additionally, these effects appear to be partially statistically mediated by pain response expectancies. Strengths of these studies were the careful control of active comparison groups and that replication of study outcomes was found across several studies within close time-proximity of

each other. This satisfies Kazdin's (2007) mediation criteria of 'consistency.' Additionally, these studies demonstrate temporal precedence of mediator change prior to outcome change. Utilising the study checklist criteria, all scored within the moderate risk of bias range. The studies also showed that mediation of pain outcome reductions by response expectancies may not be unique to hypnosis, but also shared by analogue interventions including CBT, placebo and non-hypnotic suggestions. Further evidence for mediation was supported in the Milling et al. (2007) study with increased experience of the intervention and mediator leading to increased pain outcome reductions. Weaknesses included the predominant non-reporting of sample characteristics. When it was, it was primarily a young undergraduate population and disproportionately female and all from the same university. Importantly, all studies examined mechanically induced pain within the laboratory environment, therefore greatly limiting applicability to real-world settings and to clinical conditions of acute and particularly chronic pain.

Methodological considerations

3.1 Design

All studies benefited from random allocation and utilised a control-group comparison but were limited by lack of participant and experimenter blinding. Montgomery et al. (2002) randomised to standard-care or hypnosis. Montgomery et al. (2010) randomised and matched according to lumpectomy or excision surgery; while like Sliwinski and Elkins (2017), utilised an attentional control group. Schoenberger et al. (1997) randomised within stratified blocks so community and student participants were matched and utilised a waitlist-control group in their comparison of HCBT with CBT. All experimental pain studies matched groups for gender and suggestibility while comparing hypnosis with active-comparison groups.

All study participants and experimenters were unable to be blinded to intervention due to hypnosis' requirement to be named as part of hypnotic procedures. The experimental pain

studies blinded experimenters to participant suggestibility and participants were not informed experiments involved hypnosis until after baseline scores were taken. These participants were recruited from a pool of individuals previously screened for suggestibility. It was reported that to minimise connection between this and the experimental studies, activities were carried out in different locations by different therapists. However, this does not eliminate the possibility of anticipation of hypnosis and may have led to contamination-effects between conditions due to increased expectancy and therefore compromised subsequent statistical mediation analyses. While the experimental pain studies benefited from increased control of confounding variables within the laboratory environment, they were limited by non-reporting of randomisation-method, potentially compromising internal validity.

Comparatively, for the clinical studies, the Montgomery et al. (2010) and Sliwinski and Elkins (2017) clinical study designs demonstrated the most methodological rigour with power calculations, computer-generated randomisation processes and reporting of study attrition rates and intention-to-treat analyses. Within the experimental-pain studies, while some pre-group differences were matched, and attrition rates appeared low, these findings were compromised as neither intention-to-treat-analyses were pre-specified, nor completion rates reported.

3.2 Sample

All studies took place in the United States with ages ranging from 17-61, and all comprised female majorities, ranging from 60.5-100%. Where reported, the majority ethnicity was “Caucasian” ranging from 50-69%. Sample characteristics were well reported in Montgomery et al. (2010) and Sliwinski and Elkins (2017) while ethnicity was not reported in Schoenberger et al. (1997), Milling et al. (2002), Milling and Breen (2003), Milling et al. (2005) and Milling (2009). Age ranges were infrequently reported in the

experimental studies; however, all were undergraduate students so it can be assumed they were disproportionately young.

Participants were recruited from single medical surgeries (Montgomery at al., 2002, Montgomery et al., 2010), a large clinical trial (Sliwinski & Elkins, 2017) and mixed community and university samples (Schoenberger et al., 1997). The experimental pain studies recruited all participants from the same university.

Minimal or no inclusion/exclusion criteria were applied to the non-clinical pain studies, while Montgomery et al. (2002), Montgomery et al. (2010) and Sliwinski et al. (2017) incorporated criteria specific to either hot flashes (e.g., requiring seven per day, not using hormone replacement therapy) or breast cancer (mastectomy or lumpectomy with full dissection).

Collectively, the studies' poor sample characteristics reporting restricts study generalisability to the United States, and white females. For the experimental pain studies, generalisability beyond healthy university students is limited and means there is reduced applicability to clinical acute and chronic pain conditions. Not only is pain context-specific but significantly milder and predictable within the laboratory environment (Edwards et al., 2005).

3.3 Intervention

Hypnosis intervention varied considerably across studies and makes cross-study comparison difficult. The experimental pain studies and Montgomery et al. (2002) and Montgomery et al. (2010) were brief single sessions, while Schoenberger et al. (1997) and Sliwinski et al. (2017) were delivered weekly over five weeks. Additionally, Schoenberger et al. (1997) was HCBT, which was similarly used within several of the experimental pain studies. Schoenberger et al. (1997) delivered sessions within a group format. Additionally, intervention comparison is difficult when comparing conditions as diverse as hot flushes and

post-surgical pain and nausea. Hypnosis intervention detail was poorly reported in Sliwinski and Elkins (2017). Given no statistical mediation by hot-flush response expectancies was observed, it is unknown whether poor choice of non-automatic suggestions attuned to response expectancy were used and contributed to the non-significant statistical mediation. Subsequent determination of hypnosis intervention components that work best for who, is particularly difficult to establish across reviewed studies.

3.4 Outcome measures

Nearly all studies used 10 cm visual analogue scales (VAS) for outcomes except for Schoenberger et al. (1997) which used SUDS. The VAS scales incorporated a scale of 11 numbers ranging from zero to ten and consisted of anchoring questions adapted to each intervention. As reflected in Table 2, Cronbach's alpha was unable to be reported for these measures.

Similarly, all the outcome measures were self-report. This opens the possibility for bias and demand characteristics and potentially compromises the internal validity of study findings. Only Schoenberger et al. (1997) included a validated questionnaire measure of anxiety, and Montgomery et al. (2010) a secondary measure of emotional distress (non-response expectancy) via the Short Version of the Profile of Mood States (SV-POMS) anxiety subscale.

Measures of response expectancy between studies varied depending on outcomes assessed but were predominantly VAS scales. These ranged from pain, anxiety, fatigue, nausea to hot flush expectancy. This raises the question of how suitable this measure is for capturing more nebulous experiences such as hot flashes, and if more direct physiological measures would be better suited (e.g., blood pressure, cortisol). Bijur et al. (2001) however, report high reliability of the VAS for pain measurement, with 90 percent of ratings reproducible within 9 mm when assessing acute pain (Bijur et al., 2001). Devlin et al. (2019)

assessed the measure with a male population undergoing radiotherapy in comparing the VAS with five-point Likert scales assessing response expectancies. Findings showed that the VAS detected more response expectancies, as the midpoint of the Likert scale produced more uncertain answers (Devlin et al., (2019).

3.5. Mediation analysis

Most studies used Baron and Kenny's (1986) causal-steps regression method to assess if hypnosis-based interventions were statistically mediated by response expectancy. This involved assessment that the intervention produced change in the mediator, that the mediator was correlated with the outcome and that the mediator accounted for variance previously only associated with the intervention in univariate analysis. Implementation of this methodology varied slightly. Schoenberger et al. (1997) utilised a sub-optimal and depowered correlational measure of the post hypnosis change in expectancy with outcome. In the Milling et al. (2007) study, four simultaneous regressions equations were employed. Montgomery et al. (2010) utilised separate mediation models for each of pain, fatigue and nausea using structural equation modelling with Hayes' (2004) bootstrapping methodology. They tested two mediators within each model: presurgical distress and relative measure of post hypnosis expectancy. Sliwinski and Elkins (2017) utilised ordinary least squares path analysis and Hayes' (2004) bootstrapping methodology.

The use of Baron and Kenny's (1986) method of causal-steps regression analysis has the significant limitation of being less powerful than subsequently developed statistical techniques. which may have limitations, particularly when working with smaller sample sizes, and the bootstrapping methodology as employed by Montgomery et al. (2010) and Sliwinski et al. (2017) may have been more appropriately applied.

All studies measured response expectancy at baseline and immediately after intervention. This supports Kazdin's criteria of temporal precedence, ensuring change in the

mediator occurred prior to change in the outcome. Multiple groups and conditions examined across these studies supports Kazdin's idea of 'Consistency' with converging evidence from multiple sources to support the role of response expectancies as mediating pain, fatigue and anxiety. Additional support of Kazdin's specification of 'gradient' demonstration was provided in Milling et al.'s (2007) study. This demonstrated that increased experience of the intervention dose, more change in the outcome was observed. Also, plausibility of response expectancy mediating outcome is provided given the extensive theoretical basis (e.g. Kirsch, 1985, 1997) and the multiple studies within this review supporting this theory.

Collectively, the weight of studies demonstrating this effect is of importance when reviewing the potential role of response expectancies as mediators of hypnosis-based intervention effects. The multiple findings across studies are supportive of the role played by response expectancies in mediating hypnosis outcomes, however, this may be limited to conditions of pain, and possibly fatigue and anxiety (given the non-significant findings for hot flushes and nausea).

4.Discussion

4.1 Summary

All hypnosis interventions reported significantly greater pre-specified outcome reductions (pain, hot flash frequency, anxiety, nausea, fatigue) than comparison no-treatment-control and attention control conditions. Consistent with response expectancy theory (Kirsch, 1985), all reported partial statistical mediation of hypnosis outcomes by their respective response expectancies (pain, fatigue and anxiety) except Sliwinski and Elkins (2017) for hot flush expectancy. Montgomery et al., (2010) while finding fatigue and pain mediation by expectancy, did not observe this for nausea.

Only two hypnosis studies demonstrated significantly greater post-intervention changes in response expectancy than CBT alone (Schoenberger et al., 1997; Milling et al.,

2002). All remaining experimental pain studies observed non-significant differences between hypnosis and analogue pain treatments (CBT, placebo, imaginative suggestion, distraction) and increased post-intervention response expectancy changes.

As discussed, according to Kazdin's (2007) mediation criteria, this review has shown 'association' has arguably been met due to demonstrated statistical mediation, 'temporal precedence' has been met due to experimental control and brief intervention designs facilitating this observation. 'Consistency' across studies was met, however this could have been improved with increased sample diversity. 'Plausibility' was also demonstrated across studies via their strong use of theoretical underpinning by response expectancy theory. Comparatively, 'gradient' and 'experimental manipulation' were less demonstrated. Although Milling (2007) demonstrated that increased experience of the intervention and mediator lead to increased pain reduction outcomes, response expectancy was not directly manipulated. Therefore, the reviewed studies broadly support the mediatory role of hypnosis by response expectancies for pain, fatigue and public-speaking anxiety, however, several limitations are applied to these findings.

The findings are based on a relatively small number of studies and methodological questions were raised via the risk of bias tool, so results should be interpreted cautiously. This particularly applies to the non-clinical studies which all demonstrated medium risk-bias and limited external validity, raising the question whether similar findings would be observed in real-world settings. All studies relied heavily on subjective self-report measures, which may have led to shared variance (Podsakoff et al., 2003), and compromised internal validity. All studies were based in the United states, and most participants were University students. Additionally, the preponderance of relatively homogenous, white female populations further limits finding generalisability.

4.2 Review limitations

It should also be noted that demonstration of mediation is not definitive, and Kazdin's (2007) multiple non-binary criteria reflects this. Therefore, the use of the study quality checklist holds these same limitations. This checklist may have also been more attuned to longer-term interventions (e.g., CBT/mindfulness delivered over 12 sessions) as reflected in some questions asked (e.g., "was adequate dose of intervention received"). Nonetheless, it functioned as an approximation of mediation/study-bias and broad categories of "medium" and "low" risk-bias were helpful to determine the more robust studies from which to draw conclusions regarding likely response expectancy mediation. Despite limitations, the checklist highlighted preliminary findings supportive of the mediatory role of response expectancies in hypnosis interventions.

4.3 Theoretical implications

Speaking broadly to hypnosis' evidence base these findings are in line with Thompson et al.'s (2019) robust pain meta-analysis, with pain being perhaps the condition most strongly evidentially supported for hypnosis-influenced condition symptom reduction. The present review's findings are aligned with this evidence, as the pain response was most consistently demonstrated to be mediated by pain response expectancies.

Response expectancy theory is predicated upon expectation of automatic non-volitional responses to specific situational contexts. Given that hot flushes and nausea are less predictable in their occurrence, the reduced temporal-contiguity between the intervention and potential symptom presentation may have contributed to the failure to find statistical mediation.

Sohl et al.'s (2009) and Devlin et al.'s (2017) meta-analyses of cancer treatment side effects and response expectancies demonstrated larger effect sizes in studies where there was greater specificity between assessed outcomes and response expectancies. These studies methodologically incorporated likelihood of treatment related side-effects' temporal and

geographical occurrence within designs. Although public-speaking anxiety may be a broad construct to define, this was very clearly linked in the Schoenberger at al. (1997) study to a specific task outcome and measure of anxiety response expectancy. This was reinforced by Montgomery et al.'s (2002; 2010) findings and the experimental pain study series which evidenced response expectancy statistical mediation and close temporal proximity between the intervention, and the outcome for which the hypnosis is intended to ameliorate and pain response expectancies mediate. Therefore, a common theme emerges of increased specificity of targeted event/outcome and immediacy of time contiguity between response expectancy measurement and targeted event of observed outcomes as important.

4.4 Research implications

Overall, the findings observed within this review, while broadly consistent with response expectancy theory and supportive of the mediatory role of response expectancies (particularly pain) in hypnosis interventions, speaks strongly to the requirement to validate the results with further research. A natural consequence from the above discussion would be to ensure future response expectancy mediatory research is enhanced by increased specificity and time contiguity between the response expectancy/mediator-influenced hypnosis intervention and specific proposed outcomes to fully capture and assess the mediatory effects. This would appear beneficial, given the benefit demonstrated by brief interventions such as single-session hypnosis prior to surgery which alleviated post-surgical pain and fatigue (Montgomery et al., 2002; 2010). This research seems vital in providing validation to a method that may provide considerable benefits to individuals undergoing surgery.

Incorporating the mediatory role of response expectancies in influencing hypnosis' outcomes, future research should ideally incorporate direct manipulation of response expectancies, however in practice, this is difficult to achieve. One possibility could be to experimentally manipulate expectancy via stating participants will receive hypnosis of

"greater strengths/intensity" and assess whether this increases response expectancy after this intervention and subsequently predict outcomes. Additionally, given emotional responses are implicated within response expectancies, the emotional-valent framing of information during informed consent processes could be a way of manipulating response expectancy to lead to improved outcomes (e.g., instead of specifying "60% likelihood of side effects, one could specify a 40% likelihood of highly positive outcomes"). Additionally, given that in the Milling et al. (2006) study, increased exposure to the intervention, lead to increased response expectancy changes it would be valuable to see if findings are replicated. Therefore, establishing studies which compare single versus multiple hypnosis sessions will be important in determination of optimal repetition of intervention to enhance response expectancy and therefore client outcome.

Further research with populations beyond predominantly white females will be important to establish whether benefits generalise to males, children, and non-white ethnicities. This is highlighted by Pieretti et al.'s findings supporting differential gender pain responses and Hoffman's (2012) study finding females and younger age predicted greater response expectancies for cancer side-effects. Furthermore, it may well be that this previous research has inflated effect sizes for response expectancies within the present evidence-base due to relative sample female-homogeneity. Therefore, it will be important to recruit from non-female populations to see if the results are generalisable.

4.5 Clinical implications

While findings indicative of response expectancies mediating hypnosis-based interventions are only preliminary and tempered by methodological limitations, the findings highlight several potential areas of application (if validated with subsequent research).

Given what has been demonstrated in the more rigorous clinical pain studies within surgical environments (e.g., Montgomery et al., 2010), findings are promising. The ability to

utilise a brief hypnosis intervention of 15-20 minutes to reduce pain and fatigue outcomes has immense significance for individual wellbeing and limited health service resources if people can leave hospitals sooner, post-surgery. Given that hypnosis is a procedure with few contraindications and safety risks (Häuser et al., 2016), this may be a simple and quick procedure to bring significant relief when factoring a risk benefit analysis of its implementation. If benefits have been observed in this environment, it is easy to conceive that these can be readily transferred to dental surgery or vaccine administration scenarios.

Subsequently, if response expectancy is mediating these outcomes, then this raises the broader question of how clinicians can increase 'buy-in' with clients and heighten an individual's response expectancy, optimism, and hope for improved outcomes. This could be achieved via direct experience of suggestion that enhances expectancy (e.g. hypnosis induced relaxation via suggestion that emphasises automatic and non-volitional outcomes).

Interestingly, as highlighted within the experimental pain studies, hypnosis had comparable response expectancy mediatory and treatment outcomes to that of placebo and imaginative suggestions. As discussed, the placebo effect suggests people align outcomes with their response expectancies, while even just using the term 'placebo' can improve outcomes. Carvalho et al. (2021) demonstrated significant pain reductions in individuals with back pain just by being told they were given placebo medication. Placebo administration of course has ethical problems, but hypnosis circumvents these issues by the intervention being presented as a transparent means of suggestion-provision that is likely to benefit the individual. Hypnosis ultimately provides the socially constructed 'vehicle' to ethically deliver a non-deceptive means for placebo-based suggestions which encourage hope and optimism for improved outcomes. Hypnosis provides a direct and immediate physical feedback response that offers a potential self-generative loop of experienced change that then leads to heightened response expectancies for improved outcomes. Further empirical demonstration of

hypnosis' clinical utility may hopefully soon bring its benefits to increased clinician endorsement and ultimately wide transmission to clients who may benefit significantly.

5. Conclusion

Consistent with response expectancy theory, response expectancies may mediate hypnosis interventions for specific conditions. This review highlighted mediation of conditions of pain, fatigue, and public-speaking anxiety, but not nausea or hot flushes. However, paucity of studies and present methodological limitations and measurement difficulties mean interpretations can only be cautionary. Therefore, more robust and statistically rigorous procedures that fully take into account Kazdin's (2007) criteria are required to further research to validate with more diverse populations. If findings are replicated and validated then this may pave the way for simple, brief methods to rapidly enhance response expectancy for improved hypnosis outcomes and self-generatively lead to improved outcomes across a range of conditions, health-settings and populations.

References

Alladin, A. (2010) Evidence-Based Hypnotherapy for Depression. *International Journal of Clinical and Experimental Hypnosis, 58*:2, 165-185. DOI: 10.1080/00207140903523194

Baron, R., Kenny, D. (1986). The moderator–mediator variable distinction in social psychological research: Conceptual, strategic, and statistical considerations. *Journal of personality and social psychology*, *51*(6), 1173. DOI: 10.1037/0022-3514.51.6.1173

Bijur, P., Silver, W., Gallagher, E. (2001). Reliability of the visual analog scale for measurement of acute pain. *Academic emergency medicine*, *8*(12), 1153-1157. https://doi.org/10.1111/j.1553-2712.2001.tb01132.x

Brody, H., Brody, D. (2000). Three perspectives on the placebo response: Expectancy, conditioning, and meaning. *Advances in Mind-Body Medicine 16*(3), 216–232. DOI: 10.1054/ambm.2000.0183

Cardeña, E., Terhune, D. (2019). The roles of response expectancies, baseline experiences, and hypnotizability in spontaneous hypnotic experiences. *International Journal of Clinical and Experimental Hypnosis*, *67*(1), 1-27. https://doi.org/10.1080/00207144.2019.1553759

Carvalho, C., Pais, M., Cunha, L., Rebouta, P., Kaptchuk, T. J., & Kirsch, I. (2021). Open-label placebo for chronic low back pain: a 5-year follow-up. *Pain*, *162*(5), 1521-1527. doi: 10.1097/j.pain.0000000000002162

Devlin, E., Denson, L., Whitford, H. (2017). Cancer treatment side effects: a meta-analysis of the relationship between response expectancies and experience. *Journal of pain and*

symptom management, *54*(2), 245-258. https://doi.org/10.1016/j.jpainsymman.2017.03.017

Devlin, E., Whitford, H., Denson, L., Potter, A. (2020). 'Measuring up': A comparison of two response expectancy assessment formats completed by men treated with radiotherapy for prostate cancer. *Journal of psychosomatic research*, *132*, 109979. https://doi.org/10.1016/j.jpsychores.2020.109979

Edwards, R., Sarlani, E., Wesselmann, U., Fillingim, R. (2005). Quantitative assessment of experimental pain perception: multiple domains of clinical relevance. *Pain*, *114*(3), 315-319. doi: 10.1016/j.pain.2005.01.007

Green, J., Laurence, J., Lynn, S. (2014). Hypnosis and psychotherapy: From Mesmer to mindfulness. *Psychology of Consciousness: Theory, Research, and Practice*, *1*(2), 199-212. https://doi.org/10.1037/cns0000015

Hammond, D. (2013). A review of the history of hypnosis through the late 19th century. *American Journal of Clinical Hypnosis*, *56*(2), 174-191. https://doi.org/10.1080/00029157.2013.826172

Häuser, W., Hagl, M., Schmierer, A., Hansen, E. (2016). The efficacy, safety and applications of medical hypnosis: a systematic review of meta-analyses. *Deutsches Ärzteblatt International*, *113*(17), 289. doi: 10.3238/arztebl.2016.0289

Hilgard, E. (1992). *Dissociation and theories of hypnosis.* In E. Fromm & M. Nash (Eds.), *Contemporary hypnosis research* (p. 69–101). Guilford Press.

Iacobucci, D., Saldanha, N., Deng, X. (2007). A mediation on mediation: evidence that structural equation models perform better than regressions, *Journal of Consumer Psychology, 17*, (2), 140–154. https://doi.org/10.1016/S1057-7408(07)70020-7

Jadad, A., Moore, R., Carroll, D., Jenkinson, C., Reynolds, D., Gavaghan, D., McQuay, J. (1996). Assessing the quality of reports of randomized clinical trials: is blinding necessary? *Controlled clinical trials*, *17*(1), 1-12. https://doi.org/10.1016/0197-2456(95)00134-4

Jensen, M., Adachi, T., Tomé-Pires, C., Lee, J., Osman Z., Miró J. (2015). Mechanisms of Hypnosis: Toward the Development of a Biopsychosocial Model, *International Journal of Clinical and Experimental Hypnosis, 63*:1, 34-75. DOI: 10.1080/00207144.2014.961875

Kazdin, A. (2007). Mediators and mechanisms of change in psychotherapy research. *Annual Review Clinical Psychology*, *3*, 1-27. https://doi.org/10.1146/annurev.clinpsy.3.022806.091432

Kihlstrom, J. (1985). Hypnosis. *Annual Review of Psychology, 36*:385-418. https://doi.org/10.1146/annurev.ps.36.020185.002125#

Kirsch, I. (1985). Response expectancy as a determinant of experience and behavior. *American Psychologist*, *40*(11), 1189. DOI:10.1037/0003-066X.40.11.1189

Kirsch, I., Montgomery, G., Sapirstein, G. (1995). Hypnosis as an adjunct to cognitive-behavioral psychotherapy: a meta-analysis. *Journal of consulting and clinical psychology*, *63*(2), 214. https://doi.org/10.1037/0022-006X.63.2.214

Kittle, J., Spiegel, D. (2021). Hypnosis: The Most Effective Treatment You Have yet to Prescribe. *The American Journal of Medicine*, *134*(3), 304-305. DOI:https://doi.org/10.1016/j.amjmed.2020.10.010

Kline, R. (2011). *Principles and practice of structural equation modeling*. Guilford publications.

Landry, M., Lifshitz, M., Raz, A. (2017). Brain correlates of hypnosis: A systematic review and meta-analytic exploration, *Neuroscience & Biobehavioral Reviews, 81*, 75-98. https://doi.org/10.1016/j.neubiorev.2017.02.020

Lidstone, S., Schulzer, M., Dinelle, K., Mak, E., Sossi, V., Ruth, T., Stoessl, A. (2010). Effects of expectation on placebo-induced dopamine release in Parkinson disease. *Archives of general psychiatry*, *67*(8), 857-865. doi:10.1001/archgenpsychiatry.2010.88

Lynn, S., Maxwell, R., Green, J. (2017). The hypnotic induction in the broad scheme of hypnosis: A sociocognitive perspective. *American Journal of Clinical Hypnosis*, *59*(4), 363-384. https://doi.org/10.1080/00029157.2016.1233093

Lynn, S., Green, J., Polizzi, C., Ellenberg, S., Gautam A., Aksen, D. (2019) Hypnosis, Hypnotic Phenomena, and Hypnotic Responsiveness: Clinical and Research Foundations—A 40-Year Perspective, *International Journal of Clinical and Experimental Hypnosis, 67*:4, 475-511. DOI: 10.1080/00207144.2019.1649541

Lynn, S., Kirsch I., Terhune, D., Green, J. (2020). Myths and misconceptions about hypnosis and suggestion: Separating fact and fiction. *Applied Cognitive psychology 34*: 1253-1264.

DOI: 10.1002/acp.3730

MacKinnon, D., Lockwood, C., Hoffmann, J., West, S., Sheets, V. (2002). A comparison of methods to test the significance of mediation and other intervening variable effects. *Psychological Methods, 7,* 83-104 https://doi.org/10.1037/1082-989X.7.1.83

Milling, L. Kirsch, I., Meunier, S., Levine, M. (2002). Hypnotic analgesia and stress inoculation training: Individual and combined effects in analog treatment of experimental pain. *Cognitive Therapy and Research*, *26*(3), 355-371. https://doi.org/10.1023/A:1016029028002

Milling, L., Breen, A. (2003). Mediation and moderation of hypnotic and cognitive-behavioural pain reduction. *Contemporary Hypnosis*, *20*(2), 81-97. https://doi.org/10.1002/ch.268

Milling, L., Kirsch, I., Allen, G., Reutenauer, E. (2005). The effects of hypnotic and nonhypnotic imaginative suggestion on pain. *Annals of Behavioral Medicine*, *29*(2), 116-127. https://doi.org/10.1207/s15324796abm2902_6

Milling, L., Reardon, J., Carosella, G. (2006). Mediation and moderation of psychological pain treatments: response expectancies and hypnotic suggestibility. *Journal of Consulting and Clinical Psychology*, *74*(2), 253. https://doi.org/10.1037/0022-006X.74.2.253

Milling, L., Shores, J., Coursen, E., Menario, D., Farris, C. (2007). Response expectancies, treatment credibility, and hypnotic suggestibility: mediator and moderator effects in hypnotic and cognitive-behavioral pain interventions. *Annals of behavioral medicine*, *33*(2), 167-178. https://doi.org/10.1007/BF02879898

Milling, L. (2009). Response expectancies: a psychological mechanism of suggested and placebo analgesia. *Contemporary Hypnosis, 26*(2), 93-110. https://doi.org/10.1002/ch.379

Milling, L. (2014). Hypnosis in the treatment of headache pain: A methodological review. *Psychology of Consciousness: Theory, Research, and Practice, 1*(4), 431-444. doi.org/10.1037/cns0000031

Milling, L., Valentine, K., McCarley, S., LoStimolo, L. (2018). A Meta-Analysis of Hypnotic Interventions for Depression Symptoms: High Hopes for Hypnosis? *American Journal of Clinical Hypnosis*, *61*(3), 227-243. https://doi.org/10.1080/00029157.2018.1489777

Moher, D., Liberati, A., Tetzlaff, J., Altman, D., Prisma Group. (2009). Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *PLoS medicine*, *6*(7), e1000097. https://doi.org/10.1093/ptj/89.9.873

Montgomery, G., Kirsch, I. (1997). Classical conditioning and the placebo effect. *Pain*, *72*(1-2), 107-113. https://doi.org/10.1016/S0304-3959(97)00016-X

Montgomery, G., Duhamel, K., Redd, W. (2000). A meta-analysis of hypnotically induced analgesia. *International Journal of Clinical and Experimental Hypnosis, 48*, 138–153. https://doi.org/10.1080/00207140008410045

Montgomery, G., Weltz, C., Seltz, M., Bovbjerg D. (2002) Brief presurgery hypnosis reduces distress and pain in excisional breast biopsy patients, *International Journal of Clinical and Experimental Hypnosis, 50*:1, 17-32. DOI: 10.1080/00207140208410088

Montgomery, G., Hallquist, M., Schnur, J., Silverstein, D., Bovbjerg, D. (2010). Mediators of a brief hypnosis intervention to control side effects in breast surgery patients: Response expectancies and emotional distress. *Journal of Consulting and Clinical Psychology*, *78*(1), 80–88. https://doi.org/10.1037/a0017392

Nadon, R., Hoyt, I., Register, P., Kihlstrom, J. (1991). Absorption and hypnotizability: Context effects reexamined. *Journal of Personality and Social Psychology*, *60*(1), 144–153. https://doi.org/10.1037/0022-3514.60.1.144

National Institute of Health and Care Excellence (2017). Irritable bowel syndrome in adults: diagnosis and management. CG61. Retrieved from https://www.nice.org.uk/guidance/cg61/chapter/1-Recommendations#psychological-interventions

Patel, B., Potter, C., Mellor, C. (2000). The use of hypnosis in dentistry: a review. *Dental update*, *27*(4), 198-202. https://doi.org/10.12968/denu.2000.27.4.198

Paul, G. (1966*). Insight vs desesitization in psychotherapy*. Standford: Standford University Press.

Pieretti, S., Di Giannuario, A., Di Giovannandrea, R., Marzoli, F., Piccaro, G., Minosi, P., Aloisi, A. (2016). Gender differences in pain and its relief. *Annali dell'Istituto superiore di sanita*, *52*(2), 184-189. Retrieved from https://annali.iss.it/index.php/anna/article/view/422

Ploghaus, A., Becerra, L., Borras, C., Borsook, D. (2003). Neural circuitry underlying pain modulation: expectation, hypnosis, placebo. *Trends in cognitive sciences*, *7*(5), 197-200. https://doi.org/10.1016/S1364-6613(03)00061-5

Podsakoff, P., MacKenzie, S., Lee, J., Podsakoff, N. (2003). Common method biases in behavioral research: a critical review of the literature and recommended remedies. *Journal of applied psychology*, *88*(5), 879. https://doi.org/10.1037/0021-9010.88.5.879

Preacher, K., Hayes, A. (2004). SPSS and SAS procedures for estimating indirect effects in simple mediation models. *Behavior research methods, instruments, & computers*, *36*(4), 717-731. https://doi.org/10.3758/BF03206553

Ramondo, N., Gilles, E., Gignac, C., Pestell F., Byrne, S. (2021) Clinical Hypnosis as an Adjunct to Cognitive Behavior Therapy: An Updated Meta-Analysis, *International Journal of Clinical and Experimental Hypnosis, 69*:2, 169-202. DOI: 10.1080/00207144.2021.1877549

Roscoe, J., Bushunow, P., Morrow, G., Hickok, J., Kuebler, P., Jacobs, A., Banerjee, T. (2004). Patient expectation is a strong predictor of severe nausea after chemotherapy: a University of Rochester Community Clinical Oncology Program study of patients with breast carcinoma. *Cancer: Interdisciplinary International Journal of the American Cancer Society*, *101*(11), 2701-2708. https://doi.org/10.1002/cncr.20718

Schoenberger, N., Kirsch, I., Gearan, P., Montgomery, G., Pastyrnak, L. (1997). Hypnotic enhancement of a cognitive behavioral treatment for public speaking anxiety. *Behavior Therapy*, *28*(1), 127-140.

https://doi.org/10.1016/S0005-7894(97)80038-X

Schulz, K., Altman, D., Moher, D. (2010). CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *Trials*, *11*(1), 1-8. https://doi.org/10.1186/1745-6215-11-32

Sliwinski, J., Elkins, G. (2017). Hypnotherapy to Reduce Hot Flashes: Examination of Response Expectancies as a Mediator of Outcomes. *Journal of evidence-based complementary & alternative medicine*, *22*(4), 652-659. https://doi.org/10.1177/2156587217708523

Sobel, M. (1982). Asymptotic confidence intervals for indirect effects in structural equation models. *Sociological methodology*, *13*, 290-312. https://doi.org/10.2307/270723

Sohl, S., Schnur, J., Montgomery, G. (2009). A meta-analysis of the relationship between response expectancies and cancer treatment-related side effects. *Journal of pain and symptom management*, *38*(5), 775-784. https://doi.org/10.1016/j.jpainsymman.2009.01.008

Spanos, N., Radtke, H., Hodgins, D., Stam, H., Bertrand, L. (1983). The Carleton University Responsiveness to Suggestion Scale: normative data and psychometric properties. *Psychological Reports*, *53*(2), 523-535. https://doi.org/10.2466/pr0.1983.53.2.523

Spanos, N. (1986). Hypnotic behavior: A social-psychological interpretation of amnesia, analgesia, and "trance logic." *Behavioral and Brain Sciences 9*(3), 449-467. doi.org/10.1017/S0140525X00046537

Thompson, T., Terhune, D., Oram, C., Sharangparni, J., Rouf, R., Solmi, M., Stubbs, B. (2019). The effectiveness of hypnosis for pain relief: A systematic review and meta-

analysis of 85 controlled experimental trials. *Neuroscience & Biobehavioral Reviews, 99,* 298-310. https://doi.org/10.1016/j.neubiorev.2019.02.013

Valentine, K., Milling, L., Clark, L., Moriarty, C. (2019) The Efficacy of Hypnosis as a Treatment for Anxiety: A Meta-Analysis, *International Journal of Clinical and Experimental Hypnosis, 67*:3, 336-363. DOI: 10.1080/00207144.2019.1613863

Wagstaff, G. (1991). *Compliance, belief, and semantics in hypnosis: A nonstate, sociocognitive perspective.* In S. J. Lynn & J. W. Rhue (Eds.), *The Guilford clinical and experimental hypnosis series. Theories of hypnosis: Current models and perspectives* (p. 362–396). Guilford Press.

Weinberger, J., Eig, A. (1999). *Expectancies: The ignored common factor in psychotherapy.* In I. Kirsch (Ed.), *How expectancies shape experience*. 357–382. https://doi.org/10.1037/10332-015

Wickless, C., Kirsch, I. (1989). Effects of verbal and experiential expectancy manipulations on hypnotic susceptibility. *Journal of Personality and Social Psychology, 57*(5), 762–768. https://doi.org/10.1037/0022-3514.57.5.762

Major Research Project (MRP) Section B: Empirical Research Paper

A pilot randomised controlled trial of an intervention comprising a single online group hypnosis session followed by self-hypnosis for migraines and tension-type headaches

Word count: 7932

For submission to The International Journal of Clinical and Experimental Hypnosis

Abstract

Non-pharmacological interventions for migraines and tension-type headaches (TTHs) have a limited evidence base. Some evidence supports hypnosis as efficacious for alleviating migraine and TTH symptoms. These studies are predominantly over 25-years-old and have several methodological limitations. The present study assessed a single online group-hypnosis session plus 14-days of self-hypnosis. Thirty-five people with migraine or TTH diagnoses (85.7% female) participated in a pilot randomised controlled trial, comparing hypnosis against waitlist-controls. Data analysis was performed with analysis of covariance (ANCOVA). The hypnosis group showed significantly decreased mean-daily headache ratings (d=.46, 95% CI -.30 to 1.21) and increased medication-free-days (d=.52, 95% CI -.24 to 1.27) at four-week follow-up compared with waitlist-controls. Non-significant differences were observed across depression, wellbeing, internal-locus-of-control and self-efficacy measures, while trends towards decreased anxiety and migraine/TTH frequency for the hypnosis group were observed. Expectancy, treatment-credibility, and attitudes towards hypnosis did not moderate outcomes. Post-intervention expectancy changes did not mediate outcomes. Findings suggest migraine/TTH symptom reductions may be achieved at four-week follow-up via a single online group hypnosis session plus 14-days of self-hypnosis. The predominantly white, female, and small sample size make conclusions regarding efficacy and generalisability limited. Obtained effect sizes may power a larger trial to explore promising preliminary findings.

Keywords: hypnosis, online, group, migraines, tension-type headaches

1.Introduction

Hypnosis is a process which involves a person designated as a hypnotist, guiding a motivated participant (who understands they are partaking in hypnosis) via suggestions to achieve imagined and actual physical, cognitive and perceptual changes (Kihlstrom, 1985). Considerable research supports hypnosis' efficacy in reducing symptoms across numerous conditions. These include chronic and acute pain (Adachi et al., 2014, Montgomery et al., 2000), anxiety (Valentine et al., 2019), depression (Milling et al., 2018) and post breast-surgical pain and fatigue (Montgomery et al., 2010). Additionally, when combined with cognitive behavioural therapy (CBT), hypnosis has evidenced improved outcomes compared with CBT alone for depression and pain (Ramondo et al., 2021). It is also a National Institute for Clinical Health and Excellence (NICE) Guideline (2017) recommended treatment for irritable bowel syndrome (IBS). Despite this, hypnosis has not achieved conventional medical acceptance and only holds complementary therapy status within the United Kingdom. This may reflect misconceptions due to stage hypnotism, incorrect media portrayal, and varied research and treatment protocol quality (Lynn et al., 2020).

Theories and mechanisms of hypnosis

Debate surrounds theoretical explanations of hypnosis (Jensen et al., 2015). Differing positions have categorised hypnosis as either a unique 'state' or a conglomerate of psychosocial factors that produce favourable physical and cognitive outcomes. Neuroimaging studies provide insufficient evidence that hypnosis is a unique state, with few reliable patterns demonstrated (Landry et al., 2017). Proposed psychological factors include expectancy, motivation and attention (Kirsch, 1999), placebo, imagination, and attitudes towards hypnosis (Lynn et al., 2008). Environmental and social factors have also been hypothesised as important contributors. Spanos' (1986) socio-cognitive role theory proposes individuals

transform thoughts and imaginings into behaviours believed consistent with how one "should" respond within hypnosis. Response expectancy theory (Kirsch, 1985) posits people experience what they expect to, in an automatic, non-volitional manner. This is predicated upon socio-culturally created expectations of what hypnosis "is" and "does."

More recent perspectives (e.g., Jensen et al., 2015) merge these positions and conceptualise hypnosis as an optimised 'state' of focused-attention and suggestion-receptivity, entered via biopsychosocial factors. Given this process involves both cognitive and physical influences, this places hypnosis well to alleviate conditions like pain where significant physical and cognitive interactions occur (Shariff et al., 2009).

Hypnosis and pain relief

The psychological behaviorism theory of pain and placebo (Staats et al., 2004) posits suggestion can ameliorate pain. Hypnosis utilises suggestion as a procedural cornerstone and has substantial support for pain-relief, with reviews summarising hypnosis' efficacy across RCTs of chronic and acute pain conditions (Elkins et al., 2007; Jensen & Patterson, 2006). Thompson et al.'s (2019) meta-analysis of hypnosis for pain relief across 85 controlled-trials, demonstrated a medium effect size of between .54 to .76. Considering significant pain is generally experienced by people with migraine/TTHs, hypnosis would seem a natural application to these conditions (Ebied et al., 2020).

Migraines and Tension-Type Headaches

Migraines are complex neurological conditions affecting 15% of the general population and are the world's third most prevalent disorder (Chaibi et al., 2011). The International Headache Society (IHS) defines migraines as "a common disabling headache disorder" lasting between 4-72 hours, predominantly unilateral, pulsating of moderate-severe intensity, exacerbated by normal activity and accompanied by nausea or light and sound

sensitivity. A minimum six headache-days per month, over a minimum 12-month period is required for diagnosis (IHS, 2013). Tension-type headaches (TTHs) are the most common headache, with 78% lifetime prevalence within the general population (IHS, 2013). They are distinguished from migraines by bilateral head pain, and absence of sensitivity to light/sounds (IHS, 2013). Migraines and TTHs produce multiple physical, cognitive, and emotional symptoms and sequalae (Buse et al., 2013). These can include intense pain, fatigue, impaired concentration, and an inability to engage in daily activities, work or socialise (Leonardi et al., 2005). Both are associated with elevated comorbid depression and anxiety rates (NICE Guidelines, 2015).

While migraine/TTH causes are complex and poorly understood (Goadsby, 2007), causal-factors are hypothesised to not only be genetic and neurological but maintained and exacerbated by psychosocial and environmental influences (e.g., thinking-styles, stress, socioeconomic-status) (Børte et al., 2019). Migraine/TTH pain can therefore be conceptualised as a multi-layered construct comprised of several biopsychosocial factors (Chapman, 2004). Over longer time-periods, these may exacerbate migraine/TTHs in 'vicious-cycles' whereby individuals feel reduced hope for condition improvement (Børte et al., 2019).

Hypnosis for migraines/TTH

Several RCT's have supported hypnosis' efficacy in migraine/TTH symptom reduction when delivered face-to-face (Hammond, 2007). This includes hypnosis demonstrating reduced migraine/TTH frequency and intensity compared with waitlist-controls (e.g. Friedman & Taub, 1984; Llaneza-Ramos, 1989, Melis et al., 1991), decreased frequency and severity compared with participants taking Stemetil medication (Anderson et al., 1975), reduced intensity compared with participants receiving autogenic training at six-

months follow-up (Zitman et al., 1992), and equivalent decreased frequency with participants receiving biofeedback interventions (Andrechuk & Skriver, 1975).

However, as reflected in the reviews of Hammond (2007), Milling, (2014) and Flynn, (2018), these studies are over 25-years old and have numerous methodological limitations. These include non-standardisation and detail of intervention, measures, and control. Additionally, poorly reported sample demographics and heterogeneous treatment-protocols have limited replicability (Milling, 2014). Collectively, these have hindered hypnosis' endorsement as an effective migraine/TTH intervention (Lynn et al., 2020). Furthermore, this research has not fully explored hypnosis delivery-formats (Nicholson et al., 2005). Although hypnosis has traditionally been delivered one-to-one and face-to-face over several sessions, some studies have demonstrated delivery modifications that may widen treatment reach.

Hypnosis delivery modifications and outcome predictors

Gerson et al. (2013) assessed group-hypnosis for IBS and demonstrated significant symptom reductions at one-year follow-up. Spanos (1993) demonstrated equivalent outcomes for migraine experiencers from hypnosis delivered over one versus four sessions. Hasan et al. (2019) evidenced comparable IBS symptom reduction when delivered online or face-to-face. Flynn (2019) conducted an RCT for migraine experiencers which demonstrated significantly reduced durations for self-hypnosis participants compared with waitlist-controls. Therefore, combining hypnosis delivery-formats could be a means to increase treatment access.

Additionally, determination of treatment-outcome predictors and the mechanisms of hypnosis are important to optimise therapy but have generally been overlooked in hypnosis research (Lynn et al., 2020). Exceptions have included: James et al. (1989) finding hypnosis influenced internal locus of control (ILOC), Holroyd et al. (2009) finding higher self-efficacy mediated improvements in a chronic-TTH population. Patterson and Jensen's (2003) review

of hypnotic analgesia studies concluded participants higher in suggestibility demonstrated increased pain reductions, while Milling et al. (2007) evidenced positive attitudes towards hypnosis and treatment-credibility were correlated with greater pain reductions. Additionally, Kirsch's (1985) response expectancy theory has demonstrated expectancy changes following hypnosis have mediated pain outcomes (Montgomery et al., 2010). These factors are therefore important to consider in hypnosis research-design optimisation.

In summary, hypnosis research for migraines/TTH, has demonstrated promising outcomes, but is limited by study age and methodological concerns. There has since been varied delivery methods that increase treatment reach alongside several purported moderators and mediators of hypnosis outcomes suggesting further exploration. Additionally, given changes to NICE guidance for chronic pain (2021), recommending reduced long-term medication use due to deleterious health impact (alongside sub-group medication contraindications like pregnancy, heart-conditions), the further validation of a non-medication-based intervention for migraines/TTH like hypnosis may be of heightened value.

The present study

This study was designed to explore whether a single hypnosis online group session plus 14-days of self-hypnosis could demonstrate improved migraine/TTH outcomes. While addressing previous hypnosis research limitations it is hoped to evidence a potentially standardised protocol for migraine/TTHs that might widen treatment reach and lower medication use. Considering limited NHS resources, a brief and cost-effective intervention predicated upon self-efficacy and ILOC that maximises treatment accessibility may be of benefit. This would help clinicians widen access, improve care and outcomes in line with client choice. In line with Medical Research Council guidance (Craig et al., 2008), this pilot

study also intends to provide estimated effect sizes for future larger-scale research. It is hoped this will help contribute to increased hypnosis research methodological rigour.

Based on the above literature, and in accordance with pre-study clinicaltrials.gov registration it was hypothesised that:

1. As the primary measure, participants allocated to the hypnosis intervention group would show greater decreases in mean daily headache ratings compared to waitlist-controls following intervention at post-intervention.
2. Participants allocated to the hypnosis intervention group would show greater decreases in headache frequency compared to waitlist-controls following intervention at post-intervention.
3. Participants allocated to the hypnosis intervention group would show greater decreases in related medication-use compared with waitlist-controls at post-intervention.
4. Participants allocated to the hypnosis intervention group would show greater reductions in secondary outcomes of total Depression, Anxiety and Stress Scale (DASS), and depression and anxiety sub-scale scores compared to waitlist-controls.
5. Participants allocated to the hypnosis intervention group would show greater increases in secondary measures of wellbeing, ILOC and self-efficacy compared to waitlist-controls following intervention.
6. Reductions in mean daily headaches and their frequency, and all secondary measures would be maintained at four-week follow-up.
7. Higher scores in treatment credibility, expectancy, attitudes towards hypnosis and suggestibility would moderate the above changes.
8. Also, following completion of the Section A literature review but after trial registration, an additional hypothesis was developed. This was that changes in expectancy from baseline to post-intervention would mediate outcomes at four-week follow-up.

2. Methods

2.1. Design

The study used a pilot randomised control trial (RCT) to compare an intervention comprising a single online group hypnosis session plus 14-days of self-hypnosis, for adults with migraine or TTH, with a waitlist-control group. The single group plus self-hypnosis intervention was designed to maximise treatment reach. A one-off group session, followed by participants continuing the work at home on their own, resulted in the intervention being less dependent on therapist/resource availability that would have been required if delivered over several group sessions.

Measures (questionnaires and headache diaries) were collected at three time-points: baseline (weeks 0-1), post-intervention (weeks 7-8) and follow-up (weeks 11-12). The waitlist-control group was offered the same intervention upon study completion. Feedback questionnaires were administered to the intervention group at study completion. Control group follow-up data was not collected because the study was designed as an RCT, therefore data was collected for the pre-specified experimental period only.

Prior to commencement, study registration with an international register of trials kept by the United States Library of Medicine was completed (clinicaltrials.gov; registration number: NCT04523311; Appendix A).

2.2. Participants and recruitment

Participants were recruited via Facebook and Twitter. This included study advertisements posted by the National Migraine Centre, the Migraine Trust and two Facebook migraine support groups (Appendix B for advert and information-sheet). Participants were also recruited from snowball-sampling.

Table 1: Study inclusion and exclusion criteria

Inclusion	**Exclusion**
Aged between 18-80	Current use of psychiatric medication
Resident of the U.K.	Diagnoses of epilepsy, psychosis, personality disorder, medication overuse headache
Understand spoken and written English	
Self-reported diagnosis of migraine/TTH from GP or specialist (e.g. neurologist). Access to I.T. equipment	
Minimum 1 headache every 2-weeks over the 3-month period prior to study commencement	
Otherwise healthy physically and mentally	
Scoring above cut-off scores on the HS-Q for migraine or TTH	

As seen in Table 1, the above criteria were applied for study inclusion. TTHs and migraines were both included as a pragmatic consideration to maximise recruitment. Additionally, previous psychological and hypnosis research (e.g., Martin et al., 2015; Spanos et al., 1993) has utilised this dual migraine and TTH diagnosis inclusion criteria.

The exclusion criteria were established following the Guidelines for Trials of Behavioural Treatments for Recurrent Headache (Penzien et al. 2005). Additionally, due to ethical and risk considerations inherent in a new online trial, it was decided to begin with relatively tight inclusion criteria, so that a group of persons relatively less vulnerable to distress would be included. Therefore, to minimise these risks and ensure the wellbeing of participants, persons with diagnoses of personality disorder, epilepsy, psychosis, and people using psychiatric medication were excluded from participation.

The Headache Screening Questionnaire (HS-Q) (van der Meer et al., 2017) was used as a screening tool to ensure participants experienced migraine/TTH symptoms as reported (Appendix C). This is based upon IHS diagnostic criteria (IHS, 2013) and is recommended as the best single measure to identify TTH and migraines (van der Meer et al., 2019).

Determination of study sample size was based upon Whitehead et al.'s (2016) assertion that a pilot study's aims are more pragmatic, and a "rule-of-thumb" is recommended rather than a power calculation. Based upon Browne's (1995) estimated 30 participants needed to approximate a parameter, and Julious' (2005) recommended minimum 12 participants per treatment-arm, a minimum sample size of 30 and maximum of 36 was sought and obtain 15 participants minimum per study-arm**.**

Figure 1: CONSORT diagram showing participant flow within RCT

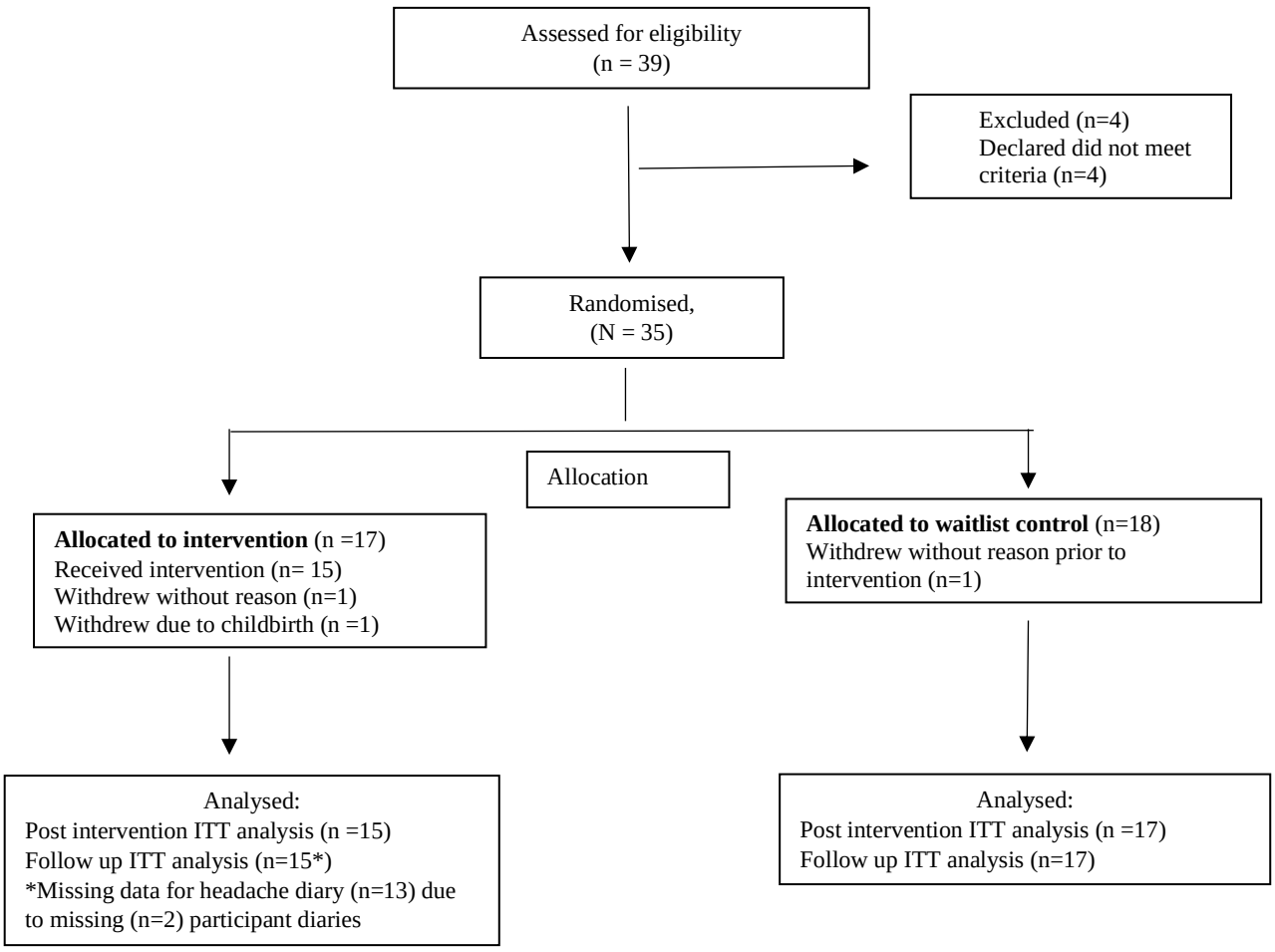


Figure 1 shows 39 individuals were screened for eligibility and 35 randomised to group. Three participants withdrew after randomisation and 32 completed all questionnaires and headache diaries at post-intervention, while 30 completed all at follow-up.

Table 2: Participant demographic characteristics

	Both groups *N*=35 Mean (SD)	**Intervention group *N*=17** Mean (SD)	**Control group *N*=18** Mean (SD)	**Between group comparison**	**P value**
Age (years)	42.35 (11.03)	43.05 (11.15)	41.67 (11.19)	U = 142, z = -.363	*p* = .717
Gender					
Female	30 (85.7%)	14	16		
Male	3 (8.6%)	2	1		
Agendered or non-binary	2 (5.7%)	1	1		
Diagnosis					
Migraine	14 (40%)	5	9		
Migraine with aura	9 (25.7%)	7	2		
Chronic migraine	7 (20%)	4	3		
Tension type headache	2 (5.7%)	1	1		
Hemiplegic migraine	2 (5.7%)	1	1		
Atypical migraine with aura	1 (2.9%)	0	1		
Time since diagnosis	15.82 (13.2)	17.01 (13.3)	14.70 (13.3)	*U* = 134, Z = -.627	*p* = .531
Ethnicity					
White	32 (91.4%)	15	17		
Asian	1 (2.9%)	0	1		
Dual ethnicity	1 (2.9%)	1	0		
Other	1 (2.9%)	1	0		
Employment status					
Fulltime	14 (40%)	7	7		

Part time	11 (31.4%)	5	6
Self employed	5 (14.3%)	3	2
Retired	2 (5.7%)	1	1
Unemployed	2 (5.7%)	0	2
Fulltime carer	1 (2.9%)	0	1

Participant demographic data is presented in Table 2. Participant ages ranged from 22–61 years (mean = 42.35 years). The majority were female (85.7%) and of white ethnicity (91.4%). The most frequent diagnosis was migraine (40%) followed by migraine with aura (25.7%) and chronic migraine (20%). Two participants had a TTH diagnosis (5.7%). The average time since diagnosis was 15.82 years. Fourteen participants (40%) were in fulltime employment, eleven (31.4%) part-time and five (14.3%) self-employed. No significant differences were observed between participants allocated to the intervention and control groups on demographic variables of age and time-since-diagnosis ($p > .05$). Due to the small sample and individual cell sizes of other demographic variables, Chi squared analyses for statistical differences were unable to be tested.

2.3. Measures

Measures (Appendix D) were all collected online via Qualtrics, while the migraine/TTH diary was collected via Excel spreadsheet.

Migraine/TTH diary

Recorded hourly headache intensity ratings are considered the ‘gold standard’ in headache research (Andrasik et al., 2005). Therefore, mean daily headache was captured via an Excel spreadsheet that recorded hourly intensity ratings from 0-5 (0 = no headache, 5 = headache of maximum intensity) for each hour of the day. Headache intensity ratings were averaged to produce the mean daily headache rating over each two-week monitoring period.

Therefore, the primary outcome was a composite index which combined headache frequency, intensity and duration. Mean daily headache ratings were taken at baseline for two-weeks pre-intervention; two-weeks post-intervention; and two-weeks starting four-weeks post-intervention completion, as a follow-up. Throughout this thesis, this is referred to as the mean daily headache rating and headache to refer to migraine/TTH incidence. It is acknowledged by the author that migraines and TTH are two separate conditions, and this is used for descriptive simplicity only. Total headache frequency was calculated by summing headache diary daily totals for each 14-day monitoring period. Measurement of medication usage was recorded as total number of medication-free-days recorded in the headache diary for each measurement period. Due to participant medication-type use variation between measurement periods, meaningful comparisons were not possible (17 participants altered medication-types used). Therefore, total number of medication-free days was used to measure changes between time-points.

Depression, anxiety, and stress

To measure depression, anxiety and stress, the Depression Anxiety and Stress Scales (Short Form; DASS-21; Lovibond & Lovibond, 1995; Henry & Crawford, 2005) was utilised. This incorporates 21 questions (seven per depression, anxiety and stress scale) that measure depression (e.g. “I felt that I had nothing to look forward to”), anxiety (e.g. “ I found that I was using a lot of nervous energy”), and stress (e.g. “I found myself getting agitated”) over the previous week. These are scored from 0 (never) to 3 (almost always) and totalled to produce total individual scale scores. Scores are multiplied by two, to produce final scores (ranging between 0 and 42). Higher scores indicate increased distress. All scales demonstrate high internal consistency: depression (α= 0.88), anxiety (α = 0.82), stress (α= 0.90), and good convergent and discriminant validity (Henry & Crawford, 2005). Within the present study,

high internal consistency was shown for anxiety (α = 0.82), depression (α = 0.90), stress (α = 0.86), and overall score (α = 0.94).

Wellbeing

Wellbeing was measured via the Warwick-Edinburgh Mental Well-being Scale WEMBS (Tennant et al., 2007). This assesses psychological well-being over the previous two-week period. It consists of 14 items (e.g., "I have been feeling confident"), rated on a scale from 1 (none of the time) to 5 (all of the time). Individual scores are combined to produce total scores ranging from 14 to 70. Higher scores indicate increased well-being. The measure has good test-retest reliability, internal consistency, and discriminant and convergent validity (Tennant et al., 2007). Within the present study, the WEMBS internal consistency for total score was (α = 0.93).

Internal-locus-of-control specific to headaches

Internal-locus-of-control (ILOC) specific to headaches was assessed via the ILOC subscale of the Headache specific Locus of Control Scale (HSLC). This is a validated measure (Martin et al., 1990) comprised of three subscales. Two are external-locus-of-control subscales: The Health Care Professionals subscale and the Chance subscale. The third is the ILOC subscale which has demonstrated good internal consistency (α = 0.88). This consists of 11 items (e.g., "If I remember to relax, I can avoid some of my headaches") rated from 1(strongly disagree) to 5 (strongly agree). Within the present study, this subscale demonstrated good internal consistency of (α = 0.78).

Self-efficacy specific to headaches

Self-efficacy in relation to participants' beliefs they can manage their migraines/TTH was measured via The Headache Management Self-Efficacy Scale (HMSE). This is a validated and reliable measure with high internal consistency (α =.90) (French et al., 2000).

This consists of 25 items (e.g., “There are things I can do to reduce headache pain”) rated from 1 (strongly disagree) to 7 (strongly agree). Within the present study, the scale demonstrated good internal consistency of (α = 0.88).

Moderators and mediators

Treatment credibility and expectancy

Beliefs about treatment-credibility and expectancy were assessed via The Credibility/Expectancy of Change Questionnaire (Devilly & Borkovec, 2000). This possesses a two-factor structure of perceived treatment credibility and expectancy for condition improvement (Thompson-Hollands et al., 2014). It is a reliable and valid measure with good internal consistency (credibility: α = .81 to .86; expectancy α = .83) (Devilly & Borkovec, 2000). Expectancy is derived from item four: “by the end of the course, how much improvement in your functioning do you think will occur?” This is rated from 0 to 100%. Credibility is calculated from the total of the first three items to produce total treatment credibility (e.g., “At this point how logical does the course offered seem to you?” 0 = not at all, 9 = very). Within the present study, good internal consistency of (α = 0.84) was shown.

Attitudes to hypnosis

The Attitudes Toward Hypnosis and Hypnotherapy Scale (ATHHS) (Spanos et al., 1987) is a 14-item, (e.g., “I am totally open to being hypnotised,” 1= not at all true, 7= very true), scale containing questions regarding fears, positive attitudes, and beliefs that susceptibility to being hypnotised is indicative of mental health difficulty. It has demonstrated good total score internal consistency of (α=.81) (Spanos et al., 1987). Within the present study, the total score demonstrated poor internal consistency of (α =.22). This will be returned to in the discussion.

Suggestibility

A bespoke "experience of hypnosis" questionnaire was designed to capture suggestibility during the group-session. Due to group-session time constraints, a brief measure was derived from the standardised measure of the Harvard groups scale of hypnotic susceptibility, form A (Shor & Orne, 1962). Four suggestibility tasks were chosen based upon administration-ease and which captured different aspects of hypnotic suggestion. These were: eye closure (suggestion that one felt unable to open eyes once closed), hands clasped tight (suggestion that one unable to pull hands apart once hands clasped together), arm heaviness (suggestion that arm feeling heavier), and change in leg temperature (suggestion that leg alternating between cold and hot temperatures). Self-rated perceptions from 0-10 (0= no response, 10= maximum response) of how much participants felt they responded to each task were made. Within the present study, the scale demonstrated high internal consistency of (α =.88).

2.3. Feedback questionnaire

This was an eleven-item questionnaire designed to collect participant feedback on their study experience. Questions covered programme likes/dislikes, satisfaction, ease-of-use, potential improvements, how helpful hypnosis was experienced and how futures with migraines/TTHs were envisaged. Questions consisted of Likert scale items (e.g., "please rate how satisfied you were with the overall programme from 0: "not at all" to 10: "extremely;" and open-ended questions (e.g. "what did you like most about the programme and why"). This was administered at study-completion to the intervention group.

2.4 Patient and Public Involvement and intervention development

The intervention was developed by the lead researcher. Initial consultation was held with a migraine-experiencer regarding the wording and suitability of the hypnosis script and group PowerPoint content. Additionally, following the 39 screening videocalls with

migraine/TTH experiencers, a high level of distress due to the severity and chronicity of migraine/TTHs was heard. It was also apparent, the extent that many felt disempowered, held reduced hope, and felt entrenched within what some perceived to be an at times 'unhelpful' medicalised health system. This was often reported because of experiences of visiting multiple specialists over many years, being prescribed several medications with perceived minimal changes to symptoms. Therefore, revisions were made to the group session presentation and hypnosis script that emphasised self-expertise and empowerment (whilst encouraged to work within the medical system). These were ratified in amendments to the study Ethics approval (Appendix E).

2.5 Procedure

From study-advertisements, individuals were invited to contact the lead-researcher to discuss study eligibility via videocall. During the call, diagnosis confirmation was obtained, requests to view diagnosis letters made, eligibility questions asked, and the HS-Q completed. Those who met criteria provided online consent via Qualtrics. Individuals were informed they would be on a waitlist until numbers had been recruited to fulfil the first cohort (N=18).

Once this was reached, participants were emailed to complete baseline questionnaires and the headache diary. Upon completion, diaries were checked to ensure at least one migraine was registered. Participants were randomised to group via a blocked 1:1 design method, using a computerised random generator (sealedenvelope.com). The same process occurred with the second cohort once the fulfilment number (N=17) was reached (two-days after first cohort establishment).

Participants randomised to the hypnosis group were emailed confirmation of the group-session date. To aid familiarity, the day before the session, a two-minute video modelling the hypnosis induction was emailed to intervention participants along with the

session PowerPoint slides (Appendix F). Participants were asked to prepare two scenarios: their most typical situation within which migraine/TTH triggers occurred, and what their 'preferred-future' looked like if increased control of migraines/TTHs was gained. Participants were asked to visualise these in vivid detail.

The video group-session was subsequently held. The first-cohort intervention group session contained eight participants, and the second-cohort, seven. These were held two-days apart. The group was led by the primary researcher (a qualified hypnotherapist and trainee clinical psychologist) who was joined by a project supervisor (a qualified clinical psychologist and hypnotherapist). Their role was to support anyone who experienced distress, in a breakout-room.

The session contained introductions, confidentiality-discussions, information about hypnosis and its common misconceptions (to foster positive attitudes towards hypnosis). Hypnosis' theoretical underpinnings, evidence base, and hypothesised psycho-social factors that contribute to migraines/TTHs were presented. General lifestyle factors and migraine/TTH triggers were discussed with participant self-expertise and knowledge emphasised. Theories of pain, placebo, expectancy, self-efficacy and ILOC were provided to increase expectancy for the positive impact of hypnosis on migraines/TTH symptom reduction.

A 15-minute hypnosis 'taster' session was held (Appendix G). Its rationale was predicated upon response expectancy theory (Kirsch, 1985) which maintains prior intervention experience enhances expectancy for improved outcomes. The administrator modelled the induction and invited questions regarding what hypnosis would 'feel or look like,' to clarify uncertainties that may have interfered with hypnosis. The 'taster' session consisted of induction, suggestions for relaxation and being a good responder to hypnosis and

administration of the suggestibility tasks, before guided to emerge from hypnosis. Suggestibility ratings were recorded and feedback on individual experiences sought.

A five-minute comfort break was held before the 20-minute hypnosis session for migraines/TTH (Appendix H). This consisted of induction, suggestions, visualisation of how one responds to triggers and what preferred futures with increased control over migraines/TTH looked like. Suggestions emphasised self-expertise, empowerment, self-efficacy, ILOC, expectancy for improvement of self-control over migraine/TTH symptoms, and the additive benefit of daily self-hypnosis.

Debriefing was held before self-hypnosis instructions were provided including instruction to listen at times that best suited people over the next 14-days. Participants were emailed the self-hypnosis recording and informed they would be contacted by the researcher in the next two-days to answer any queries.

2.6 Hypnosis intervention

The main hypnosis script was informed by the induction of Kirsch et al. (1993), followed by bespoke suggestions for relaxation. Based on Jensen and Patterson's (2008) contention that chronic-pain suggestions should address the complexity of psychosocial factors associated with conditions of longer chronicity, these addressed symptoms in two ways. The first acknowledged broad lifestyle factors that contribute to stress. Therefore, suggestions were given to pace activity in non "all-or-nothing" fashion, communicate assertively with family members and work colleagues, exercise and eat in balanced manners and adopt kinder self-talk during difficulties.

Secondly, suggestions were provided to address early warning signs and responses to migraine/TTH triggers. These were predicated on enhancing ILOC and self-efficacy (e.g. "every day I now feel more relaxed, strong, confident, more capable to take charge and

control over pain and discomfort in my life"). As summarised in Table 3, visualisation techniques were utilised, and participants were asked to imagine turning into miniature versions of themselves and travel to the source of discomfort in their body and push constricted blood vessels apart to bring relief to the source of pain. Participants were asked to visualise their early warning signs of migraines/TTH emerging and utilise this principle. They were encouraged to adopt externalising principles and imagine they can control and shrink headaches by following this procedure. They were asked to visualise their preferred future where they experienced increased control of migraines/TTHs. Additionally, the script included post-hypnotic suggestions to clench one's hand when triggers emerged and implement this procedure. Further positive suggestions (e.g., you will feel healthy, comfortable, confident) and negative suggestions (e.g., you feel very little stress, pain) were incorporated. The effects were suggested to occur during, and after the group session, and be enhanced for every day of self-hypnosis completed. Following Kirsch et al. (1995), permissive suggestions tailored to automatic, non-volitional responses to enhance response-expectancy were included. Traditional direct pain-relief suggestions (e.g., the affected body part becomes de-tensed with the arrival of a cooling sensation) were also included.

Table 3: Intervention summary

Intervention aspect	**Rationale**
Deconstruct misconceptions of hypnosis	Foster positive attitudes to hypnosis
Psychoeducation about general lifestyle factors that may contribute to migraines/TTHs	Enhance individual self-expertise of awareness of own migraine/TTH triggers
Psychoeducation on hypnosis's efficacy for pain conditions and migraines/TTH's	Foster expectancy for deriving benefit form hypnosis
Taster hypnosis session	Enhance response expectancy for positive outcome via direct experience of physiological changes within hypnosis e.g. relaxation, apparent automatic body movements
Main migraine/TTH group session	

Provide suggestions of coping with life, people, job, friends with more confidence so that can take control over general lifestyle factors that may contribute to stress and triggers of migraines/TTH	Develop self-efficacy, belief, confidence in one's own ability to manage difficult situations more helpfully.
Externalisation of migraines/TTHs Suggestions of given tool to shrink migraine (visualising shrinking self to miniature size and pushing apart constricted blood vessels inside one's own body)	Migraines/TTH something the individual can take control over (problem not located within individual). Increase ILOC, self-empowerment
Imagination/visualisation	Imagined direct experience of taking increased control over migraines/TTHs and experience of a future where migraines/TTH are around less. Act as if changes already occurred.
14-days of home self-hypnosis	Enhance ILOC, self-efficacy, self-empowerment via creating habit and change by self

2.7 Ethical considerations

Study ethical approval was provided by the Salomons Ethics panel, Canterbury Christ Church University. Additionally, the British Psychological Society's (2014) Code of Human Research Ethics was followed. Several participant-safety discussions were held with a consultant neuropsychiatrist. From these conversations it was deemed negligible predictable risks to participants with migraines/TTHs were likely, however the study was in line with similar established protocols and was supported by the systematic review of Hauser et al. (2019) which concluded hypnosis to be a safe procedure with minimal risks. Nevertheless, participants were encouraged to contact GP or emergency services should they feel distress following self-hypnosis and were asked to email the lead-researcher should any questions or uncertainties arise.

2.8 Analysis plan

Statistical analysis of outcome measures was conducted using SPSS version 24. An intention-to-treat analysis was applied whereby all participants were analysed according to their allocated group at randomisation, irrespective of whether they completed the intervention. Analysis of covariance (ANCOVA) was used to examine between-group differences. The independent variable was group (wait-list control versus hypnosis). ANCOVA was chosen due to its increased power to detect between-group differences compared to ANOVA, as it avoids post-hoc comparisons, therefore reducing Type II error risk. The covariate was the baseline score on the respective outcome measures, and the dependent variable was the outcome measure at respective time-points (i.e., post-intervention or follow-up). There was a different ANCOVA for each primary and secondary outcome measure at post-intervention (Appendix J) and four-week follow-up (Appendix K).

Given there were some violations of normality, significant ANCOVA findings were checked by using the more robust Mann-Whitney U test to compare the two groups' change scores from baseline to respective timepoints. In all cases, these supported ANCOVA findings, suggesting the normality violations were not problematic. Effect sizes were calculated utilising Cohen's d statistic and confidence intervals (95%) were reported. Additionally, because this was a pilot study, and not fully powered to detect effects, trends were reported within the results section.

Moderation and mediation hypotheses were tested using Hayes (2013) bootstrapping technique, utilised via the PROCESS macro for SPSS (Appendix L). The bootstrapping method was chosen due to its increased statistical power through use of random re-sampling methods (Hayes, 2013).

2.9 Qualitative feedback analysis

Quantitative data from the feedback questionnaire questions were averaged and reported for the first four items. The seven open-ended questions were explored using content analysis. Categories were established and frequencies tabulated. Reliability was assessed via inter-rater agreement, with 25% of participants randomly sampled for dual rating.

3. Results

3.1 Baseline data

Baseline data for outcome measures across all time-points is presented in Table 6. No significant between group differences were observed between the hypnosis intervention and waitlist-controls across all baseline outcome measures ($p > .05$). Collectively, this suggests effective randomisation (Appendix I). Baseline scores on the DASS indicated the sample scored within the mild to moderate ranges of respective total and subscale measures, except for the wait-list control group who scored in the non-clinical band for anxiety (this remained non-significantly different to the intervention group score).

3.2 Attrition and missing data

Three of the 35 randomised participants withdrew from the study prior to intervention. These participants (11.7%) did not complete post-intervention or four-week follow-up measures. Two participants completed all measures at post-intervention and follow-up, but not the headache diary at four-week follow-up. As this was a pilot study with small participation numbers, the attrition numbers were too small to complete a statistical analysis to compare those who left the study with those who remained. The two participants with missing data at follow-up were excluded for analysis at follow-up time point only for mean headache scores, headache frequency and medication use. Their scores on all other measures were included.

3.3 Intervention effects

Intervention effects are visually depicted in Figure 2 and descriptive statistics are provided within Table 6 for all outcomes at all time-points. The primary outcome was mean daily headache rating. As can be seen from Table 7, no significant group differences at post-intervention were observed for any measures. However, as shown in Figure 2, the primary outcome of mean daily headache rating showed a trend in favour of the hypnosis group at post-intervention. Furthermore, this became significant at follow-up, with a significant effect of intervention on mean daily headache rating, controlling for baseline mean daily headache rating ($F (1, 29) = 4.53$, $p = .043$). This was supported by the non-parametric Mann Whitney U test finding of a significantly greater decrease in mean daily headache rating for the hypnosis group than waitlist controls ($U = 61.00$, $Z = -2.07$, $p = .038$). This test was used due to the deviations from normality, and as a follow-up to ensure findings were consistent with the significant ANCOVA findings. The effect size for the between group difference at follow-up was in the medium range ($d=.46$).

Similarly, as see in Table 7, there was a non-significant difference in total number of non-medication use days at post-intervention, but this became significant at follow-up, with a significant effect of intervention on total number of non-medication use days, controlling for baseline non-medication use days ($F (1, 29) = 5.20$, $p = .032$). This was supported by the non-parametric Mann Whitney U test finding of a significantly greater decrease in total non-medication use days for the hypnosis group than waitlist controls ($U = 46.00$, $Z = -2.80$, $p = .005$). The effect size for the between-group difference at follow-up was in the medium range ($d=.52$).

As can be seen from Table 7, there were no other significant differences between the intervention group and waitlist-control group at post-intervention and at four-week follow up. However, as this was a pilot study, it was not fully powered, so these may represent Type II errors. It is worth noting that as observed in Figure 2 there were non-significant trends

approaching significance in favour of the hypnosis group at follow-up for decreased migraine/TTH frequency (p=.056) and DASS anxiety score (p=.088). This was reflected in the mean anxiety score shifting from the clinical to non-significant range for the hypnosis group. Regarding clinical significance for headache activity, Blanchard and Schwarz (1988) specify a 50% or more reduction in headache activity, without associated increase in medication use functions as a marker of clinical significance. Within this study, seven out of 17 of the hypnosis group compared with four out of 18 of the waitlist-control group met these criteria.

3.4 Mediators

A mediation analysis was performed to examine if changes in expectancy statistically-mediated the intervention effect on mean daily headaches. This was calculated at the follow-up time-point to allow temporal precedence between proposed mediator and outcome. The change in mediator was measured from baseline to post-intervention and the primary outcome was measured at follow-up, with baseline levels of the primary outcome measure controlled for. As can be seen from Table 4, the hypothesised mediator did not have significant indirect effects, meaning there was no evidence for mediation.

Table 4: Total, direct and indirect effects for bootstrapped-mediation-analysis, with group (hypnosis vs. control) the independent variable, mean daily headache rating at follow-up the dependent variable, mean daily headache rating at baseline the co-variate, and change in expectancy from baseline to post-intervention as proposed mediator.

	Effect	95% CI
Total effect	0.2356	(0.0085, 0.4626) *
Direct effect	0.2342	(-0.0011, 0.4695)
Indirect (mediation) effect	0.0014	(-0.0636, 0.0472)

* p<.05

3.5 Moderators

Similarly, as seen in Table 5, there was no significant moderation of the treatment effect by baseline expectancy, attitudes to hypnosis, treatment credibility or suggestibility. This is perhaps unsurprising, given that in the main analysis, they did not significantly change between assessed time-points (see Table 7).

Table 5: Bootstrapped moderation analyses, with each row representing a separate analysis. The R^2 change, F and p values refer to the change in model fit when a 'moderator X group' interaction term was added to the regression model. In all cases, the dependent variable was mean daily headache rating at follow-up and additional predictors were group (hypnosis vs. control), baseline mean daily headache rating, and the moderator.

Moderator	R^2 change	F (1, 25)	p value
Expectancy	.0007	.0587	.8106
Attitudes to hypnosis	.0023	.2127	.6486
Treatment credibility	.0171	1.6139	.2156

A different analysis was conducted to examine suggestibility as these ratings were only taken for the hypnosis group. In this regression analysis, at the first step, baseline mean daily headache ratings were the predictor, follow-up mean daily ratings, the dependent variable and in the second step, suggestibility was added as an additional predictor. The additional predictor did not increase the explained variance (r2 change = .383, F=1.722 p= .220). Therefore, there was no evidence high suggestibility levels predicted outcomes, however, given the small sample size, it is possible this is a type II error.

3.6 Participant Safety

Thirty four out of 35 participants reported no adverse experiences. One participant in the control group during hypnosis (after the trial-end), reported racing thoughts. This

appeared to be temporary and was managed by the second group-facilitator. The participant was contacted the next day and did not report any lasting effects.

Table 6: Descriptive statistics for intention-to-treat analysis at each time-point

	Mean hypnosis group baseline (SD)	Median Hypnosis group baseline (IQR)	Mean control group baseline (SD)	Median control group baseline (IQR)	Mean hypnosis group post intervention (SD)	Median hypnosis group post intervention (IQR)	Mean control group post intervention (SD)	Median control group post intervention (IQR)	Mean hypnosis group follow up (SD)	Median hypnosis group follow up (IQR)	Mean control group follow up (SD)	Median control group follow up (IQR)
Mean daily headache rating (/5)	.60 (.51)	.44 (.65)	.60 (.56)	.46 (.59)	.40 (.35)	.30 (.52)	.56 (.54)	.35 (.68)	.32 (.32)	.22 (.26)	.56 (.64)	.30 (.64)
Mean total headache frequency	11 (5.73)	11 (6.5)	11.24 (7.56)	9 (8.50)	7.38 (5.04)	6 (5)	9.40 (7.40)	5 (10)	6.08 (5.63)	4 (4)	8.53 (5.03)	7 (6)
Total non-medication use days (/14)	7.46 (5.47)	10 (12)	7.94 (4.52)	8 (6)	9.69 (5.01)	12 (8)	7.65 (5.33)	10 (12)	9.85 (4.93)	11 (6)	7.24 (5.12)	9 (11)
DASS Anxiety (/42)	10.92 (10.15)	8 (18)	7.06 (6.90)	6 (5)	6.15 (6.80)	4 (11)	7.06 (8.00)	4 (8)	6.00 (6.83)	4 (11)	7.76 (8.60)	4 (10)
DASS Depression (/42)	12(11.49)	6 (18)	10.94 (10.32)	8 (11)	8.92 (9.26)	6 (11)	9.76 (11.00)	6 (12)	9.08 (9.37)	6 (12)	9.65 (10.78)	6 (12)
DASS Total (126)	40.13(27.25)	32 (49)	35.17 (22.00)	32 (27)	28.67 (22.09)	20 (26)	32.12 (24.94)	22 (28)	28.67 (22.14)	20 (26)	32.71 (25.18)	22 (30)
WEMWBS Total (/70)	44.77 (10.40)	47 (13)	43.65 (8.87)	43 (10)	45.92 (13.36)	43 (19)	46.29 (10.56)	46 (11)	45.92 (13.36)	43 (19)	46.29 (10.56)	46 (11)
Self-efficacy (HMSES)	105.69 (10.44)	108 (16)	105.00 (9.86)	105 (13)	109.31 (14.10)	110 (24)	107 (10.36)	107 (16)	110.08 (14.912)	113 (24)	106.94 (10.33)	107 (16)
Internal Locus of control (ILOC)	35.69 (11.51)	36 (18.50)	36.29 (8.14)	37 (8)	38.23 (9.55)	40 (14)	37.76 (6.21)	39 (8)	38.23 (9.55)	40 (14)	37.76 (6.21)	39 (8)

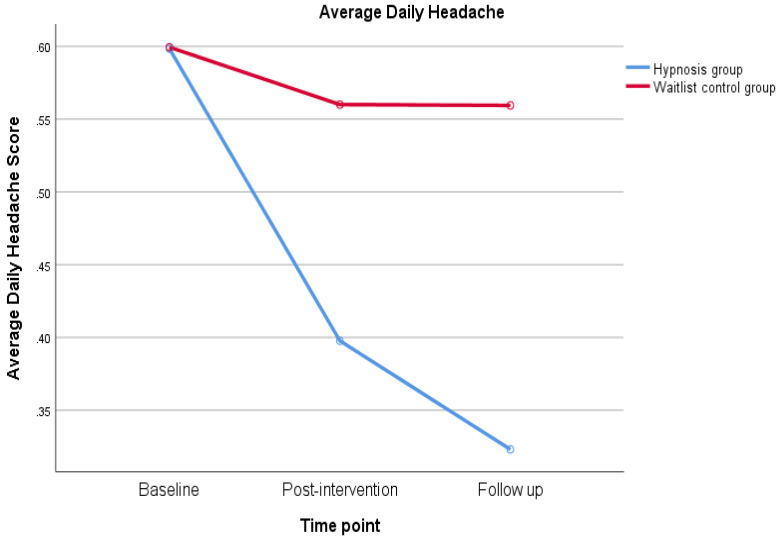
Table 7: Group comparison by outcome measure using ANCOVA, with baseline level of outcome as covariate

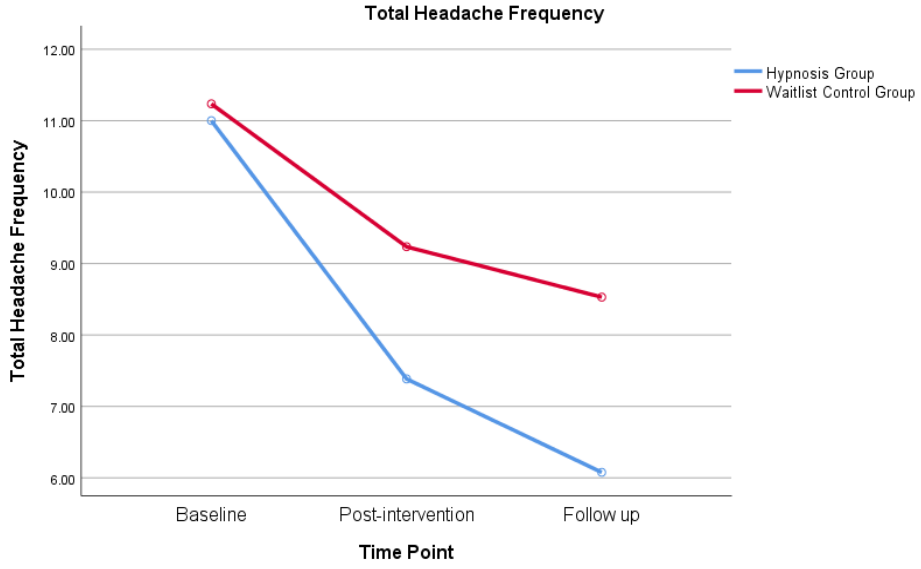
	Between group comparison post-intervention	P value	Effect size^ (95% C.I.)	Between group comparison at follow up	P value	Effect size^ (95% C.I.)
Mean daily headache (/5)	F (1, 29) = 1.306	.262	.35 (-.38,1.07)	F (1,27) = 4.530	.043*	.46 (-.30, 1.21)
Total headache frequency	F (1, 29) = 1.052	.314	.32 (-.41, 1.04)	F (1,27) = 3.978	.056	.46 (-.29, 1.22)
Total non-medication use days (/14)	F (1, 29) = 2.973	.105	.39 (-.33, 1.12)	F (1,27) = 5.119	.032*	.52 (-.24, 1.27)
DASS Anxiety (/42)	F (1, 29) =1.999	.168	.12 (-.6, .85)	F (1, 29) =3.13	.088	.22 (-.5, .95)
DASS Depression (/42)	F (1, 29) = .099	.755	.08 (-.64, .81)	F (1,29) = .047	.829	.06 (-.67, .78)
DASS Total (/126)	F (1,29) = .950	.338	.15 (-.58, .87)	F (1,29) = 1.113	.300	.17 (-.55, .89)
WEMWBS Total (/70)	F (1,29) = .725	.401	.03 (-.69, .75)	F (1,29) = .725	.401	.03 (-.69, .75)
Self-efficacy (HMSES)	F (1,29) = .020	.889	-.19 (-.91, .53)	F (1,29) = .003	.954	-.01 (-.73, .72)
Internal Locus of control	F (1,29) = .001	.970	-.06 (-.78, .66)	F (1, 29) =.001	.970	-.06 (-.78, .66)

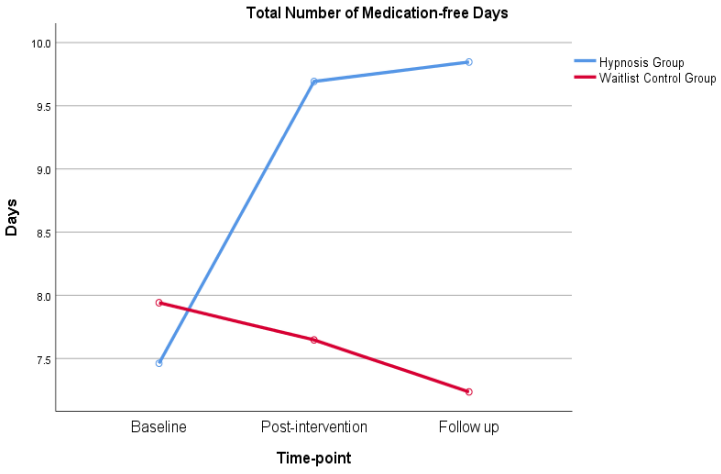
*= $p<.05$

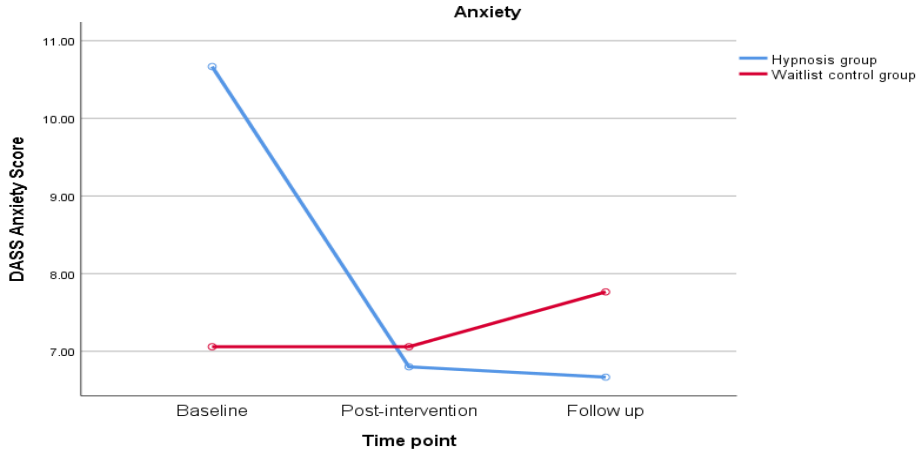
^ = The effect sizes are Cohen's d for the group differences at the respective time-points and do not control for baseline levels.

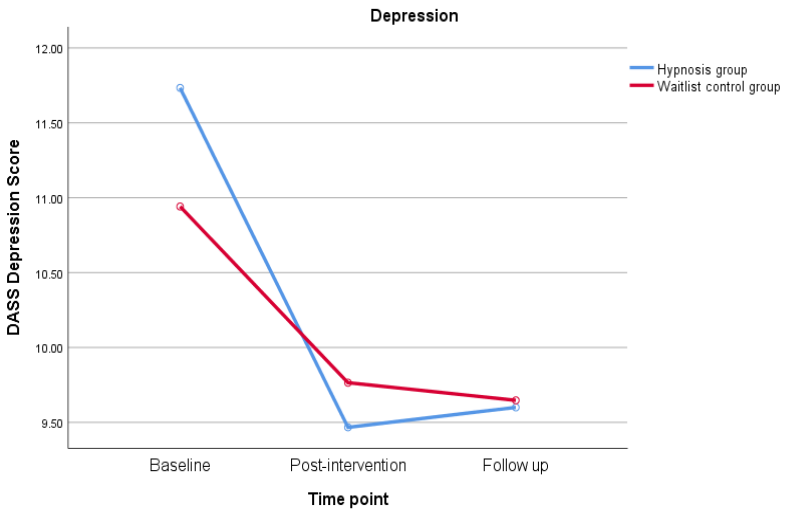
Figure 2: Graphs showing mean outcome scores by group across time-points

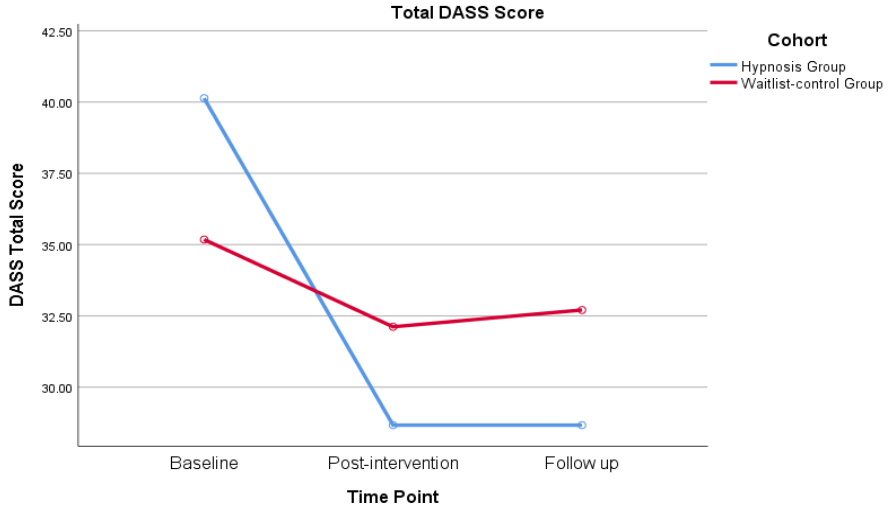


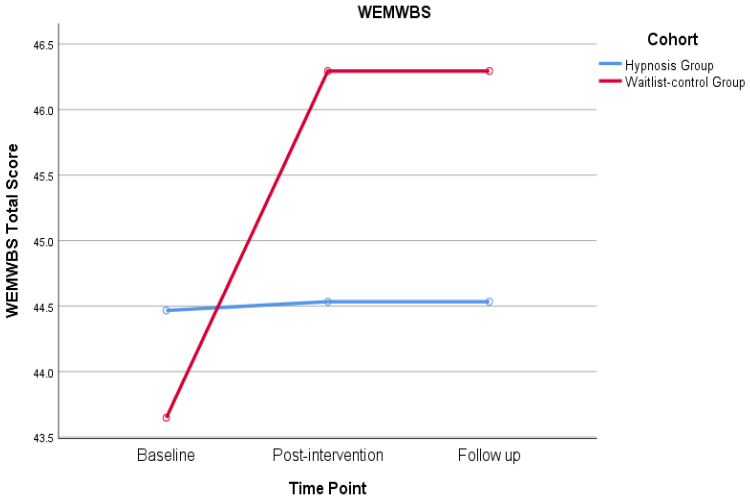


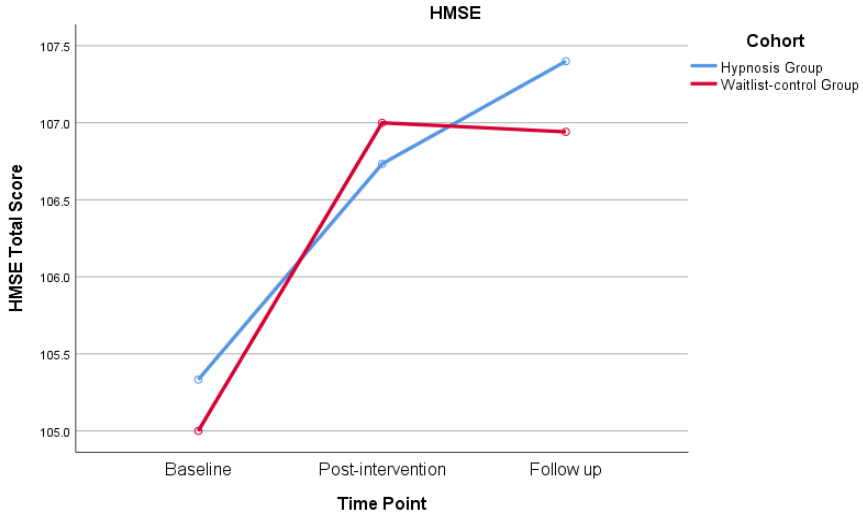


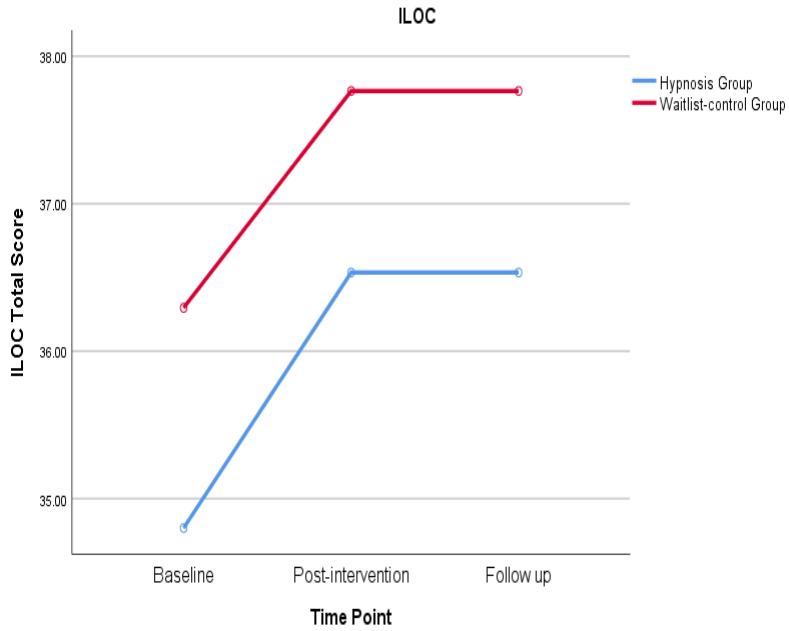



Depression
DASS Depression Score
12.00
11.50
11.00
10.50
10.00
9.50
Baseline
Post-intervention
Follow up
Time point
Hypnosis group
Waitlist control group


Total DASS Score
DASS Total Score
42.50
40.00
37.50
35.00
32.50
30.00
Baseline
Post-intervention
Follow up
Time Point
Cohort
Hypnosis Group
Waitlist-control Group


WEMWBS
WEMWBS Total Score
46.5
46.0
45.5
45.0
44.5
44.0
43.5
Baseline
Post-intervention
Follow up
Time Point
Cohort
Hypnosis Group
Waitlist-control Group


HMSE
HMSE Total Score
107.5
107.0
106.5
106.0
105.5
105.0
Baseline
Post-intervention
Follow up
Time Point
Cohort
Hypnosis Group
Waitlist-control Group



3.7 Feedback

Of the 17 participants allocated to the hypnosis group, 12 (70.6%) completed the feedback questionnaire. The open-ended questions are summarised in Table 8, describing the content analysis. The quantitative questions were on a 10-point scale from 1 (not at all) to 10 (extremely) and answers were averaged. Broadly, respondents were satisfied with the intervention with a mean rating of 8.2/10, experienced it easy to use (8/10) and found hypnosis moderately helpful (6.3/10). Adherence to self-hypnosis was high with an average 12.4 out of 14-days completed.

Table 8: Content analysis categories and frequencies generated from open-ended feedback questions

Question	Category	Number of participants	Example quote
What did you like least about the programme and why	Nothing identified	6	'nothing'
	Questionnaire and diary completion	5	'filling in the survey and spreadsheets but it's essential - hard sometimes with a bad head'
	Minimal change in symptoms	1	'migraines did not decrease'
What did you like most about the programme and why			
	Relaxing/ soothing	3	'It was very relaxing'
	Programme administrator	2	'Administrator was very helpful and patient'
	Giving time to self	2	'Having 20 mins each day to relax and focus felt a positive approach to my migraines'
	Gaining a tool	2	'Another tool to help with migraine'
	Group session	1	'I liked the initial group session.'
	Self-hypnosis	1	'Following the self-hypnosis each day'
	Ease of use	1	'Ease of use'
Was there anything that was a barrier to using the programme?			
	Nothing identified	8	'No'
	Work	2	'Work was incredibly busy, and it was also around Christmas time, so I didn't feel I had as much time.'

	Kids, busy home life	1	‘No - only kids in the house - so weekends were hard/when I had a migraine’
	Ongoing health difficulties	1	‘Ongoing health issues’
	Making time/prioritising	2	‘I didn't prioritise it and also didn't have it saved somewhere convenient to access.’
Was there anything that helped you to continue using the programme?			
	Desire for change and self-time	1	desire for change and having time to myself
	Positive impact it had on thinking	1	‘The positive impact it had on my thoughts and attitude towards controlling migraines.’
	Check-ins from administrator	1	‘Regular check ins and reminders’
	Self determination	2	‘Just determination to continue doing it - so grateful for anything that reduces or improves migraine.’
	Having self- hypnosis stored on phone	2	‘Having the recording on phone’
	Potential to reduce medication	1	‘Knowing that it could potentially reduce my massive amount of medication I have taken over many years.’
	Nothing identified	4	‘No’
What may have improved the programme			
	Self-management of storing recording in more accessible place	1	‘Probably more for me, but it would have been helpful for me to store the recording somewhere more convenient and separate to work-related information’

	Having programme and questions tailored more to migraines and not TTH	1	‘I think that the questionnaires and programme was probably more suited to tension headaches as I don’t believe stress is a significant factor in my migraines as I’ve had them since birth’.
	Interaction with group participants	1	‘It would be nice to check in with other participants too’
	Face-to-face check in	1	‘Maybe a face to face check in part way through the course’
	Improved method to record headaches/medication	2	‘maybe an app to help collect data real time but appreciate this is a job to develop one’
	Nothing identified	2	‘N/a’
Do you feel different to life with migraines/TTH than you did prior to the study?			
	Have more control	3	‘I do feel different. I have never done anything like this before. I feel more in control after a decade. I control the early onset of the pain which in turn does not develop into an attack. I would not have thought it was possible’.
	No change/little change	2	‘not really.’
	More empowered	1	‘I feel I can take more empowerment over the situation’
	Migraines no longer stop me from doing things	1	‘I am now not thinking about not doing things just incase a migraine attack happens’
	Now have extra coping tool/better coping tool to stop migraines	3	‘Yes, feel like I have an extra and very effective coping mechanism thank you sincerely.’
	More aware of triggers	1	‘This study has highlighted to me by keeping the headache diary that the source of my headaches is largely lack of sleep - which

			was hugely helpful in terms of knowing how to help with my headaches.'
How do you feel about your future living with migraines/TTH?			
	More positive/optimistic	4	'I feel very positive and will continue with the self-hypnosis. I've been in plenty of situations since starting the study where it has really helped'
	Have extra tool to cope	2	'Feel like I now have a new tool to help with managing my headaches in the future - with using hypnosis'
	More aware of triggers	1	'I feel like I now have a new tool to help with managing my headaches in the future - with using hypnosis; and also of being more aware of my headache triggers'
	Feel able to wean off medication	1	'Will attempt to wean off prophylactic medication on completion of the study'
	Not positive/hopeful/worried	3	'Not hopeful at all. I have tried and failed many treatments.'

Answers provided to the open-ended questions were explored using content analysis via the generated categories seen in Table 8. Inter-rater reliability was 100% agreement, but was perhaps not a surprise, given that for several questions, there was only one category per participant due to minimal answer overlap.

For the question 'what did you least like about the programme and why,' most respondents (six) could not identify any aspects, while five disliked the questionnaire and headache diary completion. One respondent disliked lack of symptom-change. Asked 'what liked most about the programme,' three reported feeling relaxed/soothed, two the administrator, two gaining a new tool to use, two giving time to their selves. Asked what barriers participants found to using the programme, the majority (eight) could not identify any aspect, two reported making time/prioritising the programme, while another two found work as a barrier. Asked if there was anything that helped participants use the programme, the largest single response (four) was 'nothing identified.' Two responded 'self-determination,' and another two reported having the self-hypnosis recording stored on their phone as helpful. Asked 'what may have improved the programme,' two reported an improved method to record headaches, another two reported 'nothing identified.' Other answers included group participant interaction, additional face-to-face check-ins, and having the programme/questionnaires better tailored to migraines rather than TTHs. Asked if people now felt different to life with migraines/TTH than before the intervention, three responded they felt more in control, another three reported they had another coping tool to manage migraines/TTH. One respondent provided a powerful response: "I do feel different. I have never done anything like this before. I feel more in control after a decade. I control the early onset of the pain which in turn does not develop into an attack. I would not have thought it was possible". Two respondents reported no change to symptoms. The final question asked 'how do you feel about your future living with migraines/TTH. The largest single response

(four) was ‘more positive/optimistic’. Three reported they were ‘not hopeful/optimistic’ or ‘worried’. One respondent said they were more aware of their triggers, while another said they intended to wean off prophylactic medication.

Broad positives included: increased control/empowerment, having a coping-tool, increased trigger awareness and stopping development into attacks, giving time to self, ability to relax and feeling positive/optimistic about the future. Broad negatives and suggested improvements included: no symptom changes, improved means of headache recording, feeling the programme was better TTH-suited, and that some were less optimistic.

4. Discussion

4.1 Overview

The present study developed and conducted a pilot RCT of an intervention consisting of single session online group hypnosis plus 14-days of self-hypnosis. It was designed to reduce migraine/TTH symptoms via enhancement of self-efficacy, ILOC and expectancy. To the author’s knowledge, this is the first intervention which has combined online group hypnosis with a pre-specified period of self-hypnosis for migraines/TTHs. Alongside Flynn’s (2019) RCT comparing self-hypnosis with waitlist-controls, it is one of the few RCTs of hypnosis for migraine/TTH research since the mid-1990’s.

As a pilot RCT, the study was designed to estimate effect sizes for a full-scale trial and was not fully powered to test the hypotheses. Nevertheless, in line with study hypotheses, results showed participants who received the hypnosis intervention reported significantly reduced mean daily headache scores at follow-up compared to waitlist-controls. Similarly, a statistically significant increase in the total number of medication-free-days was observed for the hypnosis group compared with waitlist-controls at follow-up. Interestingly, although there was a trend for the same effect on both measures at post-intervention, neither achieved

significance at this time-point. Thus, there was a suggestion these effects increased as time elapsed after the intervention. Similar findings were seen within Kirsch et al.'s (1995) meta-analysis of hypnosis plus CBT for obesity. Here it was exhibited that treatment effects were moderated by length of follow-up, with increased effects demonstrated over duration post-intervention ($r = .59$, $p < .02$). One implication of this is that in a full scale RCT it may be worth delaying the post-intervention time-point or designating the follow-up time-point as the primary time-point, rather than post-intervention.

Contrary to the secondary hypotheses, there were no significant improvements in total DASS score, depression, wellbeing, headache management self-efficacy, or ILOC. Similarly, expectancy, attitudes to hypnosis and suggestibility did not moderate outcomes, while changes in expectancy did not mediate the effects of the hypnosis intervention. Nevertheless, it is possible some of these were Type II errors, given this was a pilot study. Additionally, the attitudes to hypnosis scale demonstrated poor internal consistency and it is possible this contributed to the absence of moderation. Future research may look to re-evaluate the use of this measure (or develop a more reliable instrument), given its last validation in 1987. Despite non-significant findings, it is worth noting that trends toward decreased headache frequency ($p = 0.56$) and anxiety ($p = 0.88$) were observed for the hypnosis group compared with waitlist-controls at four-week follow-up.

Collectively, these findings suggest a brief online group plus 14-days of self-hypnosis intervention may be effective for migraine/TTH symptom and medication-use reduction, with significant differences potentially becoming more evident over longer time-periods post-intervention. They also suggest sufficient basis to warrant further evaluation in a fully powered RCT and the obtained effect size estimates could be used in the power calculation.

The study findings support those of previous studies suggesting hypnosis can be used to reduce migraine/TTH symptoms (e.g., Flynn, 2019; Nolan, 1995). Similar to Nolan et al.'s (1993) findings they support hypnosis being delivered effectively in a group format and replicates the findings of Hasan et al. (2019) that hypnosis can be successfully delivered online. Additionally, like Flynn (2019), findings suggest participants partaking in self-hypnosis may derive significantly improved outcomes than waitlist-controls. Moreover, while Richardson and Richardson (2012) have suggested web-based interventions are prone to high attrition, the rates in this study were low.

Although changes in self-efficacy and ILOC measures were not observed, it is possible these measures were less sensitive to change over the study measurement period. It is possible that if a later follow-up period was measured (e.g., 6-months) that changes may become more apparent over time once individuals experiences further migraine/TTH symptom decrease. This contention is supported by the qualitative feedback answers where a large proportion of responses reflected themes of increased empowerment, control, and acquisition of tools to utilise for migraine/TTH symptom reductions.

There was also a failure to find a mediating effect of post-intervention expectancy changes. While due to the small sample size, it is possible this was due to a Type II error, it is also possible that the timing of post-intervention expectancy assessment was too long (14-days) from the baseline expectancy measure to accurately capture change. Similarly, the specificity of expectancy question asked, could have been better worded to incorporate time and context specific parameters within which the participant might conceptualise likely migraine/TTH symptom improvement to occur.

Overall, the study findings support running a fully powered trial. Assuming this trial confirms the beneficial effects of this intervention that are suggested here, then the below implications are likely to apply.

4.2 Clinical and research implications

Blanchard and Schwarz's (1988) marker of clinical significance (headache symptoms reduced > 50% and no increase in medication use) was approximated for nearly half of the participants who experienced the intervention (7/15). Importantly, it also demonstrated significant effects from a small sample size that were obtained from the low resource-dependent nature of a single session of group hypnosis plus self-hypnosis. Clinically, the significant findings for a small sample size are encouraging. Importantly, the potential to deliver an intervention that is effective, in an online group-format offers several advantages. These include time and cost savings, but also, the possibility of offering an intervention that would not need to be delivered over the multiple sessions required for the only other NICE guidance recommended non-medication-based intervention of acupuncture (NICE, 2015). This is something that is instead maintained by the individual via self-hypnosis in a self-empowering manner.

Additionally, participation would not be constrained by geographical limitations and proximity to services. Given expanding health service waitlists, and in the current context of Covid-19, the further exploration of the significant quantitative and qualitative beneficial findings of this intervention would seem valuable to potentially maximise treatment reach.

Additionally, although the measures did not reflect significant changes in self-efficacy or ILOC, significant reductions in medication use were observed. Whether the self-hypnosis or suggestions for increased control (as reflected in some of the qualitative feedback) may be more meaningfully reflected in this 'real-world' change of significant medication-use

reduction remains uncertain. It does however reflect the possibility of a potential intervention that for some may reduce medication/s used (as reflected in the multiple medication-types used by study participants). Considering the brief nature of the present intervention, and the minimal adverse effects shown, it would seem practical to offer hypnosis as an early intervention (before alternatively embarking on long term medication use).

Of interest, within the study there was a long chronicity of time-period since diagnosis (average 15.8 years within this study) and high proportion of participants with chronic migraine (20%). This raises the question whether there is a differential response for those who feel more strongly governed by their chronicity and perceived entrenchment of symptoms compared with more recently diagnosed individuals. Further research which explores whether migraine/TTH experiencers respond differently to hypnosis on this basis will be of benefit (e.g. by stratifying a fully powered trial sample by migraine/TTH chronicity and examining if these moderate outcomes). Additionally, as discussed, research that explores longer periods of follow-up will be of benefit. Given that trends for improvement increased from post-intervention to follow-up and group differences tended to increase over time, this will be important to examine.

4.3 Limitations

Within the present study, the variation in medication type used prevented medication type and dosage comparisons between time-points. While this speaks to wider issues of poly-pharmacy prescription within migraine/TTH populations (Muhit & Rahman, 2010), in future studies it would be beneficial to request participants remain on the same medications throughout study duration to derive a more direct measure of comparison between measurement periods.

As this was a pilot study, the sample size was small. Given the downward trends observed over time in migraine/TTH symptoms, it is possible that other significant results may have been observed, had a larger sample been utilised (e.g., migraine/TTH frequency, total DASS and anxiety scores). Additionally, it should be noted that the present study used a passive control group. As future studies are designed with larger samples, the use of an active comparison group to ensure hypnosis specific, as opposed to generic factors are responsible for improved outcomes will be important to explore.

Furthermore, the disproportionate number of females of white ethnicity within the sample make it difficult to generalise findings to populations that are ethnically diverse and male. This is important given that there is some evidence for differential pain responses according to ethnicity (Fabian et al., 2011). Therefore, future studies would benefit from seeking to recruit from non-white and male populations to ensure a more representative sample of the general population.

Further study limitations lay in the time constraints imposed by the nature of the single group session delivery. Subsequently, it was not possible to capture suggestibility via standardised measures, and a bespoke measure was created to capture this. It is therefore possible suggestibility was not adequately measured, and this might explain why it was not observed to be associated with outcomes. Additionally, in developing the intervention content and hypnosis protocol, particular challenges lay in ensuring a maximal number of people benefited from the same group intervention. This was of relevance for bringing participants' individual triggers to the fore, utilising imagery and metaphors neutral enough to be accepted by as any people as possible. These generalisations may have limited individual responses to the present intervention. This will be helpful to explore regarding further individualisation of protocol whilst maintaining generalisability of effects.

Additionally, as described above, expectancy was shown not to mediate outcomes. It should be noted that the development of Section A research questions regarding response expectancies were developed after the present intervention began. Therefore, the timing of measure and question asked to capture response expectancy may hopefully be better designed so that future studies improve specificity of post intervention expectancy measurement closer to the timing of intervention, while also ensuring the response expectancy question is as time and place specific as possible. This is important given the possible mediatory role played by response expectancies for hypnosis interventions.

5. Conclusion

Significant difference in mean daily headache rating and number of medication-free days were observed for the hypnosis group compared with waitlist-controls at follow-up. However, the small sample size and disproportionately white, female sample limits generalisability. Nevertheless, finding significant differences with a small sample size suggests further large-scale research is warranted. If further supported, hypnosis may not only provide increased benefits of widening treatment access through a brief intervention, but individuals may also develop less medication-needs. It is possible also that self-empowerment via continued use of self-hypnosis and self-generative improvements from further reductions in migraines/TTHs may be observed. The potential for the intervention to be delivered in a brief, cost, and resource-efficient manner, that is not only relatively safe, but empowers individuals within an at times medicalised health system may be of immense benefit.

References

Adachi, T., Fujino, F., Nakae, A., Mashimo, T., Sasaki1, J. (2014) A Meta-Analysis of Hypnosis for Chronic Pain Problems: A Comparison Between Hypnosis, Standard Care, and Other Psychological Interventions. *International Journal of Clinical and Experimental Hypnosis, 62*:1, 1-28, DOI: 10.1080/00207144.2013.841471

Anderson, J., Basker, M., Dalton, R. (1975). Migraine and hypnotherapy. *International Journal of Clinical and Experimental Hypnosis*, *23*(1), 48-58. https://doi.org/10.1080/00207147508416172

Andrasik, F., Lipchik, G., McCrory, D., Whitrock, D. (2005). Outcome measurement in behavioral research: Headache parameters and psychosocial outcome. *Headache, 45,* 429-437. https://doi.org/10.1111/j.1526-4610.2005.05094.x

Andreychuk, T., Skriver, C. (1975). Hypnosis and biofeedback in the treatment of migraine headache. *International Journal of Clinical and Experimental Hypnosis*, *23*(3), 172-183. https://doi.org/10.1080/00207147508415942

Barnett, J, Shale, A. (2012). The integration of Complementary and Alternative Medicine (CAM) into the practice of psychology: A vision for the future. *Professional Psychology: Research and Practice, 43*(6), 576-585. doi.org/10.1037/a0028919

Blanchard, E., Andrasik, F., Neff, D., Jurish, E., O'Keefe, M. (1981). Social validation of the headache diary. *Behavior Therapy, 12*(5), 711-715. doi.org/10.1016/S0005-7894(81)80142-6

Borsook, D., Dodick, D. (2015). Taking the headache out of migraine. *Neurology. Clinical practice*, *5*(4), 317–325. doi:10.1212/CPJ.0000000000000171

Børte, S., Zwart, J., Stensland, S., Hagen, K., Winsvold, B. (2019). Parental migraine in relation to migraine in offspring: Family linkage analyses from the HUNT Study. *Cephalalgia*, *39*(7), 854-862. https://doi.org/10.1177/0333102419828989

Browne, R. (1995). On the use of a pilot sample for sample size determination. *Statistical Medicine, 14, 1933-1940.* doi.org/10.1002/sim.4780141709

Buse, D., Loder, E., Gorman, J., Stewart, W., Reed, M., Fanning, K., Serrano, D., Lipton, R. (2013). Sex differences in the prevalence, symptoms, and associated features of migraine, probable migraine and other severe headache: results of the American Migraine Prevalence and Prevention (AMPP) Study. *Headache*, *53*(8), 1278–1299. https://doi.org/10.1111/head.12150

Chaibi, A., Tuchin, P., Russell, M. (2011). Manual therapies for migraine: A systematic review. *The Journal of Headache and Pain*, *12*(2), 127–133. doi:10.1007/s10194-011-0296-6

Chapman, C. (2004). Pain perception, affective mechanisms, and conscious experience. *Pain: psychological perspectives*, 59-85. New Jersey.

Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I., Petticrew, M. (2008). Developing and evaluating complex interventions: the new Medical Research Council guidance. *British Medical Journal*, *337*. doi: https://doi.org/10.1136/bmj.a1655

Devilly, G., Borkovec, T. (2000). Psychometric properties of the Credibility/Expectancy Questionnaire *Journal of Behavior Therapy and Experimental Psychiatry 31*(2):73-86.
doi: 10.1016/S0005-7916(00)00012-4

Ebied, A., Nguyen, D., Dang, T. (2020). Evaluation of occipital nerve blocks for acute pain relief of migraines. *The Journal of Clinical Pharmacology*, *60*(3), 378-383. https://doi.org/10.1002/jcph.1528

Elkins, G., Jensen, M., Patterson, D. (2007). Hypnotherapy for the management of chronic pain. *International Journal of Clinical and Experimental Hypnosis*, *55*(3), 275-287. https://doi.org/10.1080/00207140701338621

Fabian, L., McGuire, L., Goodin, B., Edwards, R. (2011). Ethnicity, Catastrophizing, and Qualities of the Pain Experience, *Pain Medicine, 12,* (2), 314-321. https://doi.org/10.1111/j.1526-4637.2010.01015.x

Flynn, N. (2018). Systematic review of the effectiveness of hypnosis for the management of headache. *International Journal of Clinical and Experimental Hypnosis. 66*(4), 343-352.
doi.org/10.1080/00207144.2018.1494432

Flynn, N. (2019). Effect of an online hypnosis intervention in reducing migraine symptoms: A randomized controlled trial. *International Journal of Clinical and Experimental Hypnosis*, *67*(3), 313-335. https://doi.org/10.1080/00207144.2019.1612674

French, D., Holroyd. K., Pinell, C., Malinoski. P., O'Donnell, F., Hill, K. (2000). Perceived Self-efficacy and Headache-Related Disability. *Headache, 40* 647-656.
doi/abs/10.1111/j.1526-4610.1985.hed2507380.x

Friedman, H., Taub, H. (1984). Brief psychological training procedures in migraine treatment. *American Journal of Clinical Hypnosis, 26*(3), 187-200. https://doi.org/10.1080/00029157.1984.10404162

Gerson, C., Gerson, J., Gerson, M. (2013). Group hypnotherapy for irritable bowel syndrome with long-term follow-up. *International Journal of Clinical and Experimental Hypnosis*, *61*(1), 38-54. https://doi.org/10.1080/00207144.2012.700620

Goadsby, P. (2007). Recent advances in understanding migraine mechanisms, molecules and therapeutics. *Trends in molecular medicine*, *13*(1), 39-44. https://doi.org/10.1016/j.molmed.2006.11.005

Hammond, D. (2007). Review of the efficacy of clinical hypnosis with headaches and migraines. *Intl. Journal of Clinical and Experimental Hypnosis, 55*(2), 207-219. https://doi.org/10.1080/00207140601177921

Hammond, D. (2013) A Review of the History of Hypnosis Through the Late 19th Century, *American Journal of Clinical Hypnosis, 56*:2, 174-191.

doi: 10.1080/00029157.2013.826172

Hasan, S., Pearson, J., Morris, J., Whorwell, P. (2019). Skype hypnotherapy for irritable bowel syndrome: effectiveness and comparison with face-to-face treatment. *International Journal of Clinical and Experimental Hypnosis, 67*(1), 69-80. https://doi.org/10.1080/00207144.2019.1553766

Häuser, W., Hagl, M., Schmierer, A., Hansen, E. (2016). The efficacy, safety and applications of medical hypnosis: a systematic review of meta-analyses. *Deutsches Ärzteblatt International*, *113*(17), 289.

doi: 10.3238/arztebl.2016.0289

Hayes, A. (2009). Beyond Baron and Kenny: Statistical mediation analysis in the new millennium. *Communication Monographs. 76* (4): 408–420. doi:10.1080/03637750903310360.

Headache Classification Committee of the International Headache Society (IHS) (2013). The International Classification of Headache Disorders, 3rd edition (beta version). *Cephalalgia: an international journal of headache*, *33*(9), 629–808. https://doi.org/10.1177/0333102413485658

Holroyd, K., Labus, J., Carlson, B. (2009). Moderation and mediation in the psychological and drug treatment of chronic tension-type headache: the role of disorder severity and psychiatric comorbidity. *Pain*, *143*(3), 213–222. https://doi.org/10.1016/j.pain.2009.02.019

Hudzinski L., Levenson, H. (1985). Biofeedback Behavioral Treatment of Headache With Locus of Control Pain Analysis: a 20 month retrospective study. *Headache, 25*(7) 380-86. doi.org/10.1111/j.1526-4610.1985.hed2507380.x

Henry, J., Crawford, J. (2005). The short-form version of the depression anxiety stress scales (DASS-21): Construct validity and normative data in a large non-clinical sample. *British Journal of Clinical Psychology*, *44*(2), 227-239. Doi: 10.1348/014466505X29657

James, F., Large, R., Beale, I. Self-hypnosis in chronic pain. A multiple baseline study of five highly hypnotisable subjects. (1989) *The Clinical Journal of Pain*, 5(2):161-168. DOI: 10.1097/00002508-198906000-00006.

Jensen, M., Patterson, R. (2006). Hypnotic treatment of chronic pain. *Journal of behavioral medicine*, *29*(1), 95-124.
doi: 10.1007/s10865-005-9031-6

Jensen, M., Adachi, T., Tomé-Pires, C., Lee, J., Osman Z., Miró J. (2015). Mechanisms of Hypnosis: Toward the Development of a Biopsychosocial Model, *International Journal of Clinical and Experimental Hypnosis, 63*:1, 34-75
DOI: 10.1080/00207144.2014.961875

Julious, S. (2005). Sample size of 12 per group rule of thumb for a pilot study. *Pharmaceutical Stat, 4,* 287-291.
https://doi.org/10.1002/pst.185

Kihlstrom, J. (1985). Hypnosis. *Annual Review of Psychology, 36*:385-418.
https://doi.org/10.1146/annurev.ps.36.020185.002125

Kirsch, I. (1985). Response expectancy as a determinant of experience and behavior. *American Psychologist, 40,* 1189-1202.
DOI:10.1037/0003-066X.40.11.1189

Kirsch, I., Lynn, S., Rhue, J. (1993). *Introduction to clinical hypnosis.* In J. W. Rhue, S. J. Lynn, & I. Kirsch (Eds.), *Handbook of clinical hypnosis* (p. 3–22). American Psychological Association.
https://doi.org/10.1037/10274-001

Kirsch, I., Montgomery, G., Saperstein, G. (1995). Hypnosis as an adjunct to cognitive-behavioural psychotherapy: a meta-analysis. *Journal of consulting and clinical psychology 63*(2), 214-20.
https://doi.org/10.1037/0022-006X.63.2.214

Kirsch, I. (Ed.). (1999). How expectancies shape experience. Washington, DC, US: American Psychological Association. doi.org/10.1037/10332-000

Kroenke, K., Strine, T., Spitzer, R., Williams, J., Berry, J., Mokdad, A. (2009). The PHQ-8 as a measure of current depression in the general population. *Journal of Affective Disorders 114(1*-3),163-73.
doi: 10.1016/j.jad.2008.06.026

Landry, M., Lifshitz, M, Raz, A. (2017). Brain correlates of hypnosis: A systematic review and meta-analytic exploration, *Neuroscience & Biobehavioral Reviews, 81*, 75-98. https://doi.org/10.1016/j.neubiorev.2017.02.020

Lainez, M., Dominiquez, M., Rejaz, J., Palacios, G., Arriaza, E., Garcia-Garcia, Madrigal, M. (2005). Development and validation of the Migraine Screen Questionnaire (MS-Q). *Headache The Journal of Head and Face Pain 10*(39), 38-52.
doi.org/10.1111/j.1526-4610.2005.00265.x

Leonardi, M., Steiner, T., Scher, A., Lipton, R. (2005). The global burden of migraine: measuring disability in headache disorders with WHO's Classification of Functioning, Disability and Health (ICF). *The journal of headache and pain*, *6*(6), 429-440.
DOI 10.1007/s10194-005-0252-4

Llaneza-Ramos, M. (1989). Hypnotherapy in the treatment of chronic headaches. *Philippine Journal of Psychology, 22,* 17–25.

Lovibond, P., Lovibond, S. (1995). The structure of negative emotional states: Comparison of the depression anxiety stress scales (DASS) with the beck depression and anxiety inventories. *Behaviour Research and Therapy*, *33*(3), 335-343. https://doi.org/10.1016/0005-7967(94)00075-U

Lynn, S., Shindler, K., Meyer, E. (2003). Hypnotic suggestibility, psychopathology, and treatment outcome. *Sleep and Hypnosis 5*: 2-10.
doi.org/10.1007/BF01172965

Lynn S, Kirsch I, Hallquist M. Social cognitive theories of hypnosis. (2008). In: Nash JA, Barnier A, editors. *The oxford handbook of hypnosis: Theory, research, and practice.* 111-139. Oxford, UK: Oxford University Press.

Lynn, S., Kirsch I., Terhune, D., Green, J. (2020). Myths and misconceptions about hypnosis and suggestion: Separating fact and fiction. *Applied Cognitive psychology 34*: 1253-1264.

DOI: 10.1002/acp.3730

Martin, N., Holroyd, K. & Penzien, D. (1990). The Headache-Specific Locus of Control Scale: Adaptation to Recurrent Headaches. *Headache The Journal of Head and Face Pain*, *30*(11): 729-34.

doi.org/10.1111/j.1526-4610.1990.hed3011729.x

Martin, P., Aiello, R., Gilson, K., Meadows, G., Milgrom, J., Reece, J. (2015). Cognitive behavior therapy for comorbid migraine and/or tension-type headache and major depressive disorder: an exploratory randomized controlled trial. *Behaviour research and therapy*, *73*, 8-18.

https://doi.org/10.1016/j.brat.2015.07.005

Melis, P., Rooimans, W., Spierings, E., Hoogduin, C. (1991). Treatment of chronic tension-type headache with hypnotherapy: A single-blind time-controlled study. *Headache: The Journal of Head and Face Pain*, *31*(10), 686-689.

https://doi.org/10.1111/j.1526-4610.1991.hed3110686.x

Milling, L., Shores, J., Coursen, E., Menario, D., Farris, C. (2007). Response expectancies, treatment credibility, and hypnotic suggestibility: mediator and moderator effects in hypnotic and cognitive-behavioral pain interventions. *Annals of behavioral medicine*, *33*(2), 167-178.

https://doi.org/10.1007/BF02879898

Milling, L. (2014). Hypnosis in the treatment of headache pain: A methodological review. *Psychology of Consciousness: Theory, Research, and Practice*, *1*(4), 431-444. doi.org/10.1037/cns0000031

Milling, L., Valentine, K., McCarley, H., LoStimolo, L. (2018) A Meta-Analysis of Hypnotic Interventions for Depression Symptoms: High Hopes for Hypnosis? *American Journal of Clinical Hypnosis, 61*:3, 227-243. DOI: 10.1080/00029157.2018.1489777

Montgomery, G., Duhamel, K., Redd, W. (2000). A meta-analysis of hypnotically induced analgesia. *International Journal of Clinical and Experimental Hypnosis, 48*, 138–153. https://doi.org/10.1080/00207140008410045

Montgomery, G., Hallquist, M., Schnur, J., Silverstein, D., Bovbjerg, D. (2010). Mediators of a brief hypnosis intervention to control side effects in breast surgery patients: Response expectancies and emotional distress. *Journal of Consulting and Clinical Psychology, 78*(1), 80–88. https://doi.org/10.1037/a0017392

Moser G. (2013). Long-Term Success of GUT-Directed Group Hypnosis for Patients With Refractory Irritable Bowel Syndrome: A Randomized Controlled Trial. *American Journal of Gastroenterology*, *108(4)*, 602-609. doi.org10.1038/ajg.2013.19

Muhit, M., Rahman, M. (2010). Reducing Polypharmacy in Migraine: An Overview. *Journal of Pharmacy Research*, *3*(9), 2248-2250.

National Institute of Health and Care Excellence (2015). Headaches in over 12s: diagnosis and management. CG150. Retrieved from https://www.nice.org.uk/guidance/cg150

National Institute of Health and Care Excellence (2017). Irritable bowel syndrome in adults: diagnosis and management. CG61. Retrieved from

https://www.nice.org.uk/guidance/cg61/chapter/1-Recommendations#psychological-interventions

National Institute of Health and Care Excellence (2021). Chronic pain (primary and secondary) in over 16s: assessment of all chronic pain and management of chronic primary pain. NG193. Retrieved from https://www.nice.org.uk/guidance/ng193

Nicholson, R., Hursey, K., Nash, J. (2005). Moderators and mediators of behavioral treatment for headache. *Headache: The Journal of Head and Face Pain*, *45*(5), 513-519. https://doi.org/10.1111/j.1526-4610.2005.05103.x

Patterson, D., Jensen, M. (2003). Hypnosis and clinical pain. *Psychological bulletin*, *129*(4), 495. https://doi.org/10.1037/0033-2909.129.4.495

Penzien, D., Andrasik, F., Friedenberg, B., Houle, T., Lake A., Lipchik, G., Holroyd, K., Lipton, R. (2005). Guidelines for Trials of Behavioral Treatments for Recurrent Headache, First Edition: American Headache Society Behavioral Clinical Trials Workgroup. *Headache the Journal of Head and Face Pain 45*(2), 110-132. doi.org/10.1111/j.1526-4610.2005.4502004.x

Ramondo, N., Gilles, E., Gignac, C., Pestell F., Byrne, S. (2021). Clinical Hypnosis as an Adjunct to Cognitive Behavior Therapy: An Updated Meta-Analysis, *International Journal of Clinical and Experimental Hypnosis, 69*:2, 169-202. DOI: 10.1080/00207144.2021.1877549

Shariff, F., Carter, J., Dow, C., Polley, M., Salinas, M., Ridge, D. (2009). Mind and body management strategies for chronic pain and rheumatoid arthritis. *Qualitative Health Research*, *19*(8), 1037-1049. https://doi.org/10.1177/1049732309341189

Shor, R., Orne, E. (1962). Harvard group scale of hypnotic susceptibility, form A. *International Journal of Clinical and Experimental Hypnosis*. https://doi.org/10.1037/t02246-000

Spanos, N. (1986). Hypnotic behavior: A social-psychological interpretation of amnesia, analgesia, and "trance logic." *Behavioral and Brain Sciences 9*(3), 449-467. doi.org/10.1017/S0140525X00046537

Spanos P., Brett, P., Menary E. & Cross W. (1987) A Measure of Attitudes toward Hypnosis: Relationships with Absorption and Hypnotic Susceptibility, *American Journal of Clinical Hypnosis, 30*:2, 139-150. doi.org/10.1080/00029157.1987.10404174

Spanos, N. (1993). Hypnotic suggestion and placebo for the treatment of chronic headache in a university volunteer sample. *Cognitive Therapy and Research, 17(*92), 191-205. doi.org/10.1007/BF01172965

Staats, P., Hekmat, H., Staats, A. (2004). The psychological behaviorism theory of pain and the placebo: its principles and results of research application. *Advanced Psychosomatic Medicine*,*25*:28-40. doi: 10.1159/000079056

Tennant, R., Hiller, L., Fishwick, R., Platt, S., Joseph, S., Weich, S., Parkinson, J., Secker, J. (2007). The Warwick-Edinburgh Mental Well-being Scale (WEMWBS): development and UK validation. *Health Quality Life Outcomes, 5:63*, 1-13. doi:10.1186/1477-7525-5-63

Thompson, T., Terhune, D., Oram, C., Sharangparni, J., Rouf, R., Solmi, M., Stubbs, B. (2019). The effectiveness of hypnosis for pain relief: A systematic review and meta-analysis of 85 controlled experimental trials. *Neuroscience & Biobehavioral Reviews*, *99*, 298-310.

https://doi.org/10.1016/j.neubiorev.2019.02.013

Thompson-Hollands, J., Bentley, K., Gallagher, M., Boswell, J., Barlow, D. (2014). Credibility and outcome expectancy in the unified protocol: Relationship to outcomes. *Journal of Experimental Psychopathology*, *5*(1), 72-82. https://doi.org/10.5127/jep.033712

Valentine, K., Milling, L., Clark, L., Moriarty, C. (2019) The Efficacy of Hypnosis as a Treatment for Anxiety: A Meta-Analysis, *International Journal of Clinical and Experimental Hypnosis*, *67*:3, 336-363. DOI: 10.1080/00207144.2019.1613863

van der Meer, H., Visscher, C., Engelbert, R., Mulleners, W., Nijhuis–van der Sanden, M., Speksnijder, C. (2017). Development and psychometric validation of the headache screening questionnaire–Dutch Version. *Musculoskeletal Science and Practice*, *31*, 52-61. https://doi.org/10.1016/j.msksp.2017.07.001

van der Meer, H., Visscher, C., Vredeveld, T., Nijhuis van der Sanden, M., Engelbert, R., Speksnijder, C. (2019). The diagnostic accuracy of headache measurement instruments: A systematic review and meta-analysis focusing on headaches associated with musculoskeletal symptoms. *Cephalalgia*, *39*(10), 1313-1332. DOI: 10.1177/0333102419840777

Westra, H., Constantino, M., Aviram, A. (2011). The impact of alliance ruptures on client outcome expectations in cognitive behavioral therapy. *Psychotherapy Research*, *21*(4), 472-481. https://doi.org/10.1080/10503307.2011.581708

Whitehead, A., Julious, S., Cooper, C., Campbell, M. (2016). Estimating the sample size for a pilot randomised trial to minimise the overall trial sample size for the external pilot

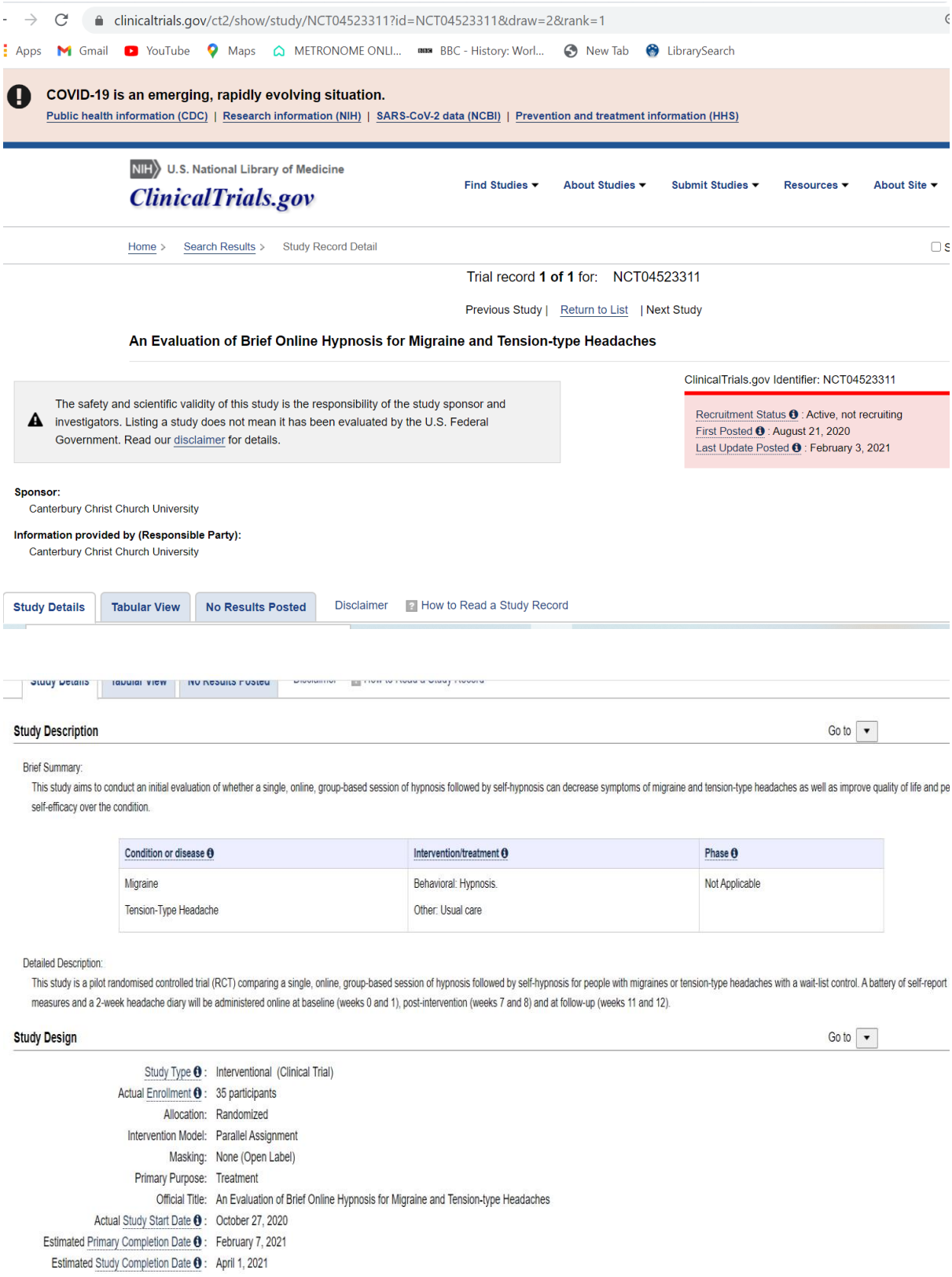
and main trial for a continuous outcome variable. *Statistical Methods in Medical Research*, *25*(3), 1057–1073. https://doi.org/10.1177/0962280215588241

Zitman, F., Van Dyck, R., Spinhoven, P., Linssen, A. (1992). Hypnosis and autogenic training in the treatment of tension headaches: a two-phase constructive design study with follow-up. *Journal of psychosomatic Research*, *36*(3), 219-228. https://doi.org/10.1016/0022-3999(92)90086-H

Major Research Project (MRP) Section C: Appendices of Supporting Material

Appendix (FOR SECTION B)

Appendix A: Trial Registration



clinicaltrials.gov/ct2/show/study/NCT04523311?id=NCT04523311&draw=2&rank=1

Apps Gmail YouTube Maps METRONOME ONLI... BBC - History: Worl... New Tab LibrarySearch

COVID-19 is an emerging, rapidly evolving situation.

Public health information (CDC) | Research information (NIH) | SARS-CoV-2 data (NCBI) | Prevention and treatment information (HHS)

U.S. National Library of Medicine
ClinicalTrials.gov

Find Studies | About Studies | Submit Studies | Resources | About Site

Home > Search Results > Study Record Detail

Trial record **1 of 1** for: NCT04523311

Previous Study | Return to List | Next Study

An Evaluation of Brief Online Hypnosis for Migraine and Tension-type Headaches

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT04523311

Recruitment Status : Active, not recruiting
First Posted : August 21, 2020
Last Update Posted : February 3, 2021

Sponsor:
Canterbury Christ Church University

Information provided by (Responsible Party):
Canterbury Christ Church University

Study Details | Tabular View | No Results Posted | Disclaimer | How to Read a Study Record

Study Description Go to

Brief Summary:
This study aims to conduct an initial evaluation of whether a single, online, group-based session of hypnosis followed by self-hypnosis can decrease symptoms of migraine and tension-type headaches as well as improve quality of life and pe self-efficacy over the condition.

Condition or disease	Intervention/treatment	Phase
Migraine	Behavioral: Hypnosis.	Not Applicable
Tension-Type Headache	Other: Usual care	

Detailed Description:
This study is a pilot randomised controlled trial (RCT) comparing a single, online, group-based session of hypnosis followed by self-hypnosis for people with migraines or tension-type headaches with a wait-list control. A battery of self-report measures and a 2-week headache diary will be administered online at baseline (weeks 0 and 1), post-intervention (weeks 7 and 8) and at follow-up (weeks 11 and 12).

Study Design Go to

Study Type : Interventional (Clinical Trial)
Actual Enrollment : 35 participants
Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: None (Open Label)
Primary Purpose: Treatment
Official Title: An Evaluation of Brief Online Hypnosis for Migraine and Tension-type Headaches
Actual Study Start Date : October 27, 2020
Estimated Primary Completion Date : February 7, 2021
Estimated Study Completion Date : April 1, 2021

Appendix B: Study recruitment advert and information-sheet

Hypnosis and migraine/tension-type headache study

- Do you experience migraine or tension-type headaches?
- Would you be interested in a free online and self-hypnosis course for migraine and tension-type headaches?
- Are you interested in taking part in research to explore if hypnosis is helpful for migraine/headache symptom relief and an improved quality of life?

Can I take part?

- You are a U.K. resident aged between 18-80.
- You have a diagnosis of migraine or tension-type headache from your G.P. or neurologist.
- You have had at least one headache every 2 weeks over the last 3 months.
- You have a laptop/tablet and internet access.

What is involved?

- One evening online group session, followed by listening to a guided self-hypnosis mp3 at home for 20 minutes daily for a 2-week period.
- The completion of a daily headache diary and some questionnaires.

For more information on suitability of study please use the link below and contact:

Paul Davies, Trainee Clinical Psychologist at:

p.davies253@canterbury.ac.uk or 07784 1924 47

https://cccusocialsciences.az1.qualtrics.com/jfe/form/SV_9L8c10hdJJYe3uR

This research has been approved by the Salomons Institute for Applied Psychology Ethics committee, Canterbury Christchurch University.

INFORMATION SHEET

PROJECT TITLE
An Evaluation of Brief Online Hypnosis for Migraine and Tension-type Headaches

INVITATION
We would like to invite you to consider taking part in a research study on the effect of group and self-hypnosis in the relief of migraine and tension-type headache symptoms. This is being run by Paul Davies, a clinical psychology doctorate student at the Salomons, Canterbury Christ Church University clinical psychology programme. This study is supervised by Dr Fergal Jones, also from this university, and Dr Rob Agnew. This project has been approved by the Salomons Research Ethics Committee.

WHO CAN TAKE PART?
This study is open to adults aged 18-80, who are resident in the U.K. and who have received a diagnosis of migraine or tension-type headache from a GP or specialist doctor. If you have a letter confirming this diagnosis and are happy to provide a copy to the research team, then please do so (but this will not be essential). You will also need to have experienced migraines/tension-type headaches once every two weeks for the last three-month period. Other than migraines or tension-type headaches, you'll need to be physically and mentally well and not have diagnoses of epilepsy, psychosis, personality disorder, medication-overuse headache and/or receiving psychiatric medication. You'll also need to be able to understand written and spoken English and have internet access via a laptop/tablet.

WHAT WILL HAPPEN
In this study, you will be invited to take part in an online group hypnosis session which includes the provision of background information about migraine and tension-type headache early warning signs, and what hypnosis is, followed by a 30-minute group hypnosis session. You will then be provided with a recording of guided self-hypnosis alongside guidance and instructions on how to follow this at home on your own. You will be asked to listen to this recording daily over the next fourteen days at home. Ongoing contact with the researcher via email will be provided for follow up questions should any further support be required during this process.

If you consent to take part in the study, there may be a waiting period until a sufficient number of people are recruited to the study before we can start the research. Once this number of people has been reached, you will be contacted and asked to complete the initial questionnaires and headache diary to be recorded for two weeks.

Once completed you will then be allocated to either an immediate or delayed intervention group. The reason that there are 2 groups is so we can measure whether it is the effect of hypnosis that improved migraine/tension-type headache symptoms alone rather than just improving over time. After allocation to immediate or delayed intervention group you will receive notification of this. Please note there may then be an approximate 1 to 5 week wait until the group hypnosis delivery.

Please be aware that if sufficient numbers of people are not recruited, then it is possible the study may not go ahead; however we do not expect this to be the case. You will be contacted regularly to update you regarding progress in relation to recruitment of sufficient numbers for the study to begin.

You will also be asked to complete several questionnaires and complete a daily migraine/headache diary for 14 days prior to the group hypnosis session. These will be repeated 2 weeks later (after the hypnosis is finished) and again 4 weeks after that, to see how long any benefits of the hypnosis last.

HOW MUCH TIME WILL IT INVOLVE?
The study typically takes 2-5 minutes per day to complete the migraine/headache diary during the pre-trial period. Then 2 hours in the group session, followed by 20 minutes self-hypnosis per day for 2 weeks and the recording of daily symptoms (approximately 5 minutes per day) upon completion of the trial and again 4 weeks later. In addition, on three occasions you'll be asked to complete a batch of questionnaires. We estimate these will take about 25 minutes to complete on each occasion.

DO I HAVE TO TAKE PART?
Your participation in this study is voluntary and you have the right to withdraw at any stage. You may decide to stop being a part of the study at any time without explanation. You have the right to ask that any data you have supplied to that point be withdrawn/destroyed. You will be able to omit or decline to answer or respond to any question that is asked of you.

You will be able to have your questions about the procedures answered (unless answering these questions would interfere with the study's outcome). If you have any questions as a result of reading this information sheet, you can ask the researcher before the study begins.

BENEFITS AND RISKS
It is possible that the hypnosis may reduce your migraine/tension-type headaches. However, as this research is breaking new ground, we cannot guarantee that.

We believe the study to be low risk and hypnosis is considered a generally safe procedure. However, as with any relaxation-based technique, it is possible that some individuals may experience unpleasant responses/emotions. You'll be able to talk about these with the researcher and withdraw from the study at any time.

Should your migraine/tension-type headache symptoms worsen significantly during the study, you are advised to consult with your GP/neurologist/specialist.

CONFIDENTIALITY/ANONYMITY
We will store the data you provide us with securely and confidentially.

Limits of confidentiality: In the unlikely event that during the study we become concerned for your safety or the safety of someone else, we may need to break confidentiality to liaise

with the appropriate services to ensure your and/or their well-being. We would try to talk to you about this first.

When your role with this project is complete, your data will be anonymised. From that time, there will be no record that links the data collected from you with any personal data from which you could be identified (e.g., your name, address, email, etc.). Up until the point at which your data have been anonymised, you can decide to withdraw your data from inclusion in the study. Once anonymised, this data may be made available to researchers via accessible data stores and possibly used for novel purposes. The data will be retained for 10 years after the study is complete.

FOR FURTHER INFORMATION

Paul Davies will be glad to answer your questions about this study at any time. You may contact him at p.davies253@canterbury.ac.uk or 07784192447.
Participants who wish to be updated on study findings will be provided summaries via their email addresses.

IF YOU HAVE A CONCERN OR COMPLAINT

If you have concerns or complaints that you do not feel can be addressed by the researcher, please contact Prof. Margie Callanan, Director of Salomons Institute of Applied Psychology (margie.callanan@salamons.ac.uk).

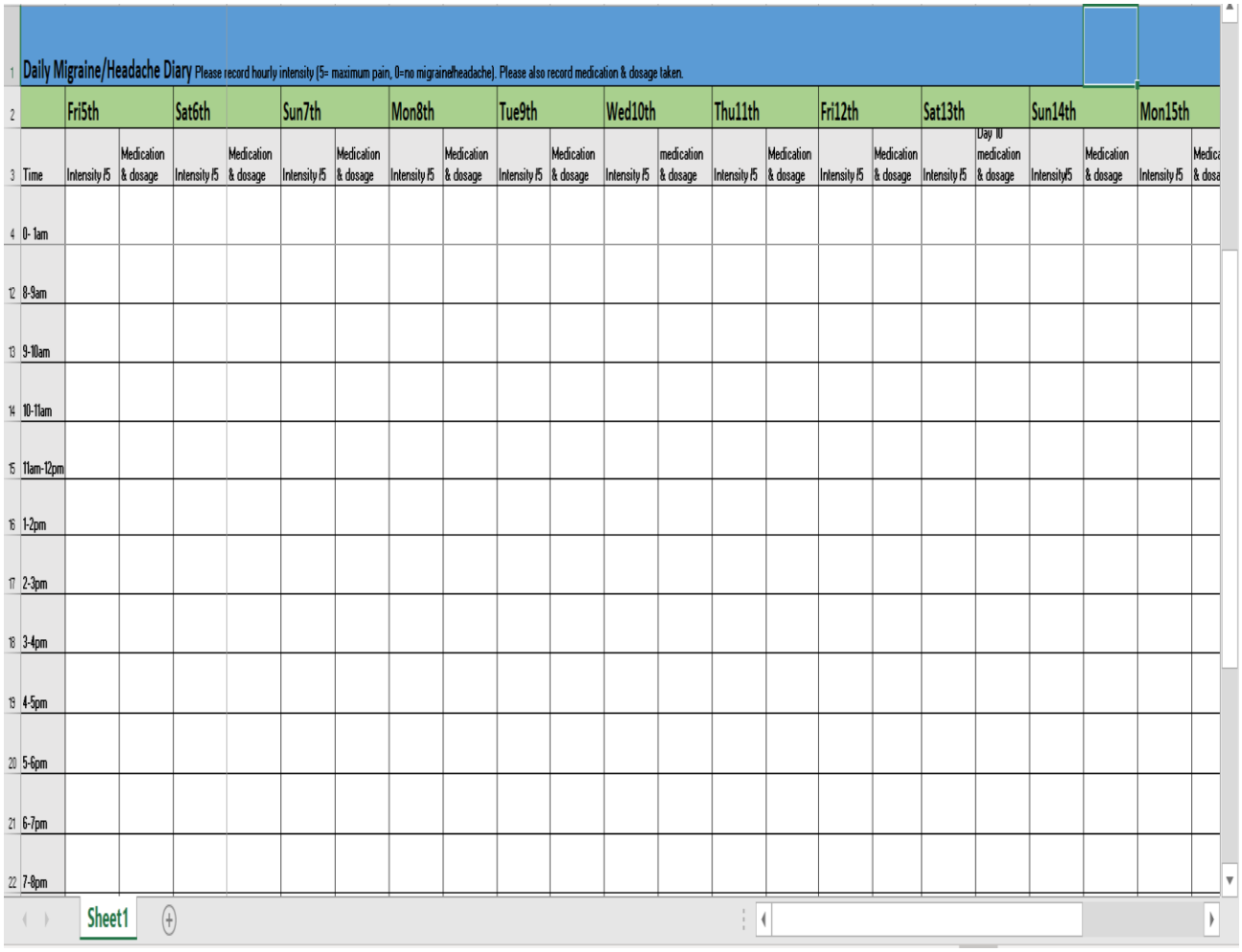
www.canterbury.ac.uk/appliedpsychology

Appendix C: The Headache Screening Questionnaire (HS-Q)

This has been removed from the electronic copy

Appendix D: Measures

Mean Daily Headache Rating Diary



Daily Migraine/Headache Diary Please record hourly intensity (5= maximum pain, 0=no migraine/headache). Please also record medication & dosage taken.

	Fri5th		Sat6th		Sun7th		Mon8th		Tue9th		Wed10th		Thu11th		Fri12th		Sat13th		Sun14th		Mon15th	
Time	Intensity /5	Medication & dosage	Intensity /5	Medication & dosage	Intensity /5	Medication & dosage	Intensity /5	Medication & dosage	Intensity /5	Medication & dosage	Intensity /5	medication & dosage	Intensity /5	Medication & dosage	Intensity /5	Medication & dosage	Intensity /5	Day 10 medication & dosage	Intensity/5	Medication & dosage	Intensity /5	Medica & dosa
0- 1am																						
8-9am																						
9-10am																						
10-11am																						
11am-12pm																						
1-2pm																						
2-3pm																						
3-4pm																						
4-5pm																						
5-6pm																						
6-7pm																						
7-8pm																						

Sheet1

Depression Anxiety Stress Scale-21

This has been removed from the electronic copy

The Warwick–Edinburgh Mental Well-being Scale (WEMWBS)

This has been removed from the electronic copy

The Headache Specific Locus of Control Scale

This has been removed from the electronic copy

The Headache Management Self-efficacy Scale (HMSE)

This has been removed from the electronic copy

Credibility/expectancy of change questionnaire

This has been removed from the electronic copy

Attitudes towards hypnosis scale

This has been removed from the electronic copy

Experience of hypnosis suggestibility questionnaire

From the preceding exercise, how much from 0-10 (0= no response, 10= maximum response) did you experience each of the following:

1. That you felt unable to open your eyelids when asked to do so.

   1 2 3 4 5 6 7 8 9 10

2. That you felt unable to unclasp your hands when asked to do so.

   1 2 3 4 5 6 7 8 9 10

3. That you felt your arm becoming heavier when asked to do so.

   1 2 3 4 5 6 7 8 9 10

4. That you felt your legs becoming colder and/or warmer when asked to do so.

   1 2 3 4 5 6 7 8 9 10

Appendix E: Ethics approval document

This has been removed from the electronic copy

Appendix F: PowerPoint intervention presentation

Hypnosis for migraine/tension-headache relief

The programme involves:

A BACKGROUND TO HYPNOSIS, MIGRAINES/TENSION-HEADACHES, CONTRIBUTING LIFESTYLE FACTORS, PERSONAL TRIGGERS, HOW HYPNOSIS IS USED TO HELP.

A SINGLE GROUP HYPNOSIS SESSION TODAY

FOLLOWED BY 14 DAYS OF SELF-HYPNOSIS AT HOME.

A REMINDER, YOU ARE FREE TO WITHDRAW AT ANY STAGE.

PLEASE RESPECT EACH OTHERS' PRIVACY AND KEEP WHAT IS DISCUSSED HERE CONFIDENTIAL.

Housekeeping

- Your safety is paramount: hypnosis is a safe procedure, it is entirely under your control to exit at any time (and nothing like stage hypnosis), we will discuss this further.
- Please respect the confidentiality of what may be discussed here today by others' in the group.
- Should you feel discomfort at any stage, please notify the therapist, and the co-therapist will join you in an online break-out room to support you in your well-being.

The migraine/tension-type headache experience

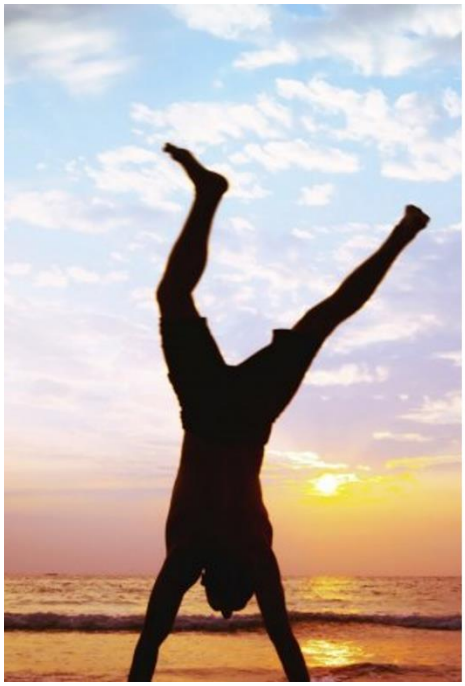
- We want to acknowledge:
  - How unique the experience of migraine and tension-type headaches are for each person.
  - The degree of physical and psychological distress they can cause.
  - Their wide-ranging impact on our lives: from work, to family relationships, to friendships and our ability to socialise and do many other day-to-day activities.
- Each person's experience is individual, and **you are very much the expert of your own experience.**
- Despite this, people can sometimes feel disempowered within any health system: due to its size and limited resources (e.g. not feeling our experiences or insights are always fully understood).
- Under-acknowledgement of our self-expertise and ability to contribute to change can sometimes lead to feeling reduced power, hope and sense of internal control of our own lives and future.
- Over time this can impact how we feel and affects our quality of self-talk and optimism for recovery.

What is hypnosis & how can it help?

- It is a safe technique that integrates psychological principles of attention, expectancy, optimism, hope and beliefs to create change in how we feel and think.
- It does so by pairing a relaxed physical state with suggestions.
- Relaxation quietens our self-critical voice (self-talk), and helps us accept suggestions more readily that then impact our physical body rapidly and beneficially.
- It demonstrates what we say to ourselves (suggestion) can have a rapid impact upon how we feel emotionally and physically. It illustrates a powerful integration of body and mind.
- By visualising a desired outcome, we can more deeply absorb this experience as if it was real.
- We can then imagine how we might like to respond situations such as when we experience a migraine/tension-headache.
- **It can empower us to feel we have an increased sense of control when migraines and tension headaches emerge.**

Hypnosis' positive impact upon physical conditions

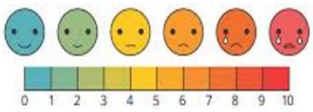
- Hypnosis can work very well to integrate our mind's suggestions/self-instructions to work in unison with our body.
- This is demonstrated with its effectiveness in treating physical conditions (via the process of suggestion/self-talk):
- Irritable bowel syndrome (Lee et al., 2014) This a NICE guidance recommended treatment.
- Skin conditions like eczema and warts (Shenfelt, 2000).
- Hypnosis has been proven to play an important role in the effective management of chronic physical pain (Elkins et al., 2007) and chemotherapy pain management.
- *"hypnosis interventions consistently produce significant decreases in pain associated with a variety of chronic-pain problems".*
- During dental extraction (Gokli et al., 1994), and historically in battlefield surgery where anaesthetics were unavailable.



Hypnosis and its impact on migraines/tension-headaches

- Much research shows hypnosis has a positive impact on the experience of migraines/tension-headaches (e.g. Flynn, 2019, Milling, 2014).
- It can lower how often, how strongly and how long these are experienced for.
- It can also improve our quality of life and increase our sense of control over our individual situation's.

The migraine/tension headache



- Migraines and tension-headaches can be distressing conditions.
- We are not certain of their exact cause however the pain experienced is real and can vary significantly between people.
- Pain is a subjective experience. There are no actual pain receptors in the brain- but the pain experience is a multi-faceted one.
  - E.g. we experience falling over differently if we are pushed during football compared with a stranger pushing us when out walking the dog. The same event has occurred, but the pain differs due to the context.
- There are many other factors which shape how we experience migraines/tension-headaches.

The onion metaphor of the migraine/tension-headache

- We can think of the migraine/tension headache a little like an onion.
- Although it is a single thing, it is made of many different layers.
- These layers shape, interact and influence the intensity and severity of the experience.

The layers of the migraine/headache 'onion'

Beliefs of our ability to manage migraines/ headaches (e.g. life with migraines and this pain may never change).

Lifestyle factors like sufficient sleep, water, balanced diet, exercise and regular, paced activity.

Management of stress at home, work & with family: do others/we always respond un/helpfully?

Communication with others: can we express how we are feeling before and during moments of stress?

Pacing of activity: do we race to complete all on good days but avoid 100%l when in discomfort? N.B. acknowledging there are times when discomfort is too much for any activity to be possible.

Awareness of what triggers our migraine/tension-headaches (You are your own expert)

- These vary between people, and may include:
- Emotional factors (stress, tension, anxiety)
- Physical factors (fatigue, poor sleep, muscle tension)
- Dietary factors (individual responses to certain foods)
- Environmental/Sensory factors (bright lights/noises)
- Hormonal factors (timing of menstrual cycles)
- Medicines (reactions to certain medications)
- *How we identify and respond to these can help how we experience migraines/tension-headaches.*

Belief, expectancy, placebo, imagination and its use within hypnosis

The beliefs we hold, and the responses we expect, greatly influence therapy outcomes. Kirsch (1999) has suggested that what we imagine and expect from hypnosis, we tend to experience.

The placebo effect plays a powerful part in treatment outcomes. In a wide range of trials, people given placebos will get better despite there being no active treatment (Colloca, 2019). Inert creams have brought instant physical pain relief (Price, 1999) and inert pills have reduced subjective migraine pain (Kam-Hansen et al., 2014): (Vice-versa with Nocebo findings). This highlights the power of our beliefs in influencing our experiences.

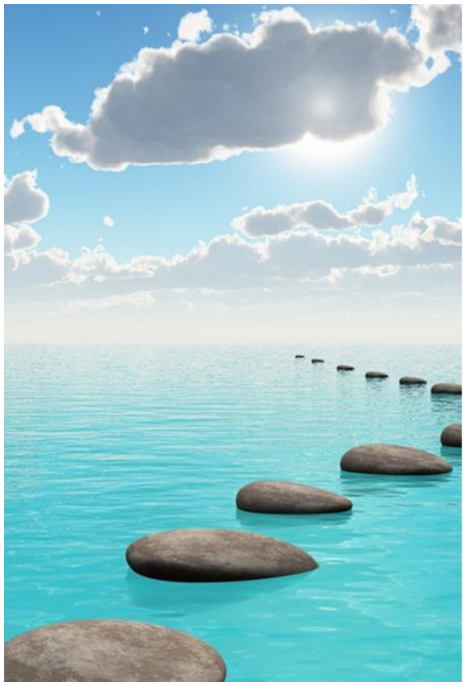
Similarly, our expectations influence outcomes. In Hou et al's (2015) study of several hundred people who experienced a mild traumatic brain injury, irrespective of injury severity, outcomes were associated with expectancy of improvement.

This highlights that our beliefs and expectations influence our subsequent experiences. We will use hypnosis to utilise belief and expectancy to improve our sense of control and self-efficacy in relation to our experience of migraines and headaches in a way that empowers us to have more control over them, rather than vice-versa.

This change will be reinforced via the habit formation achieved through the repeated imaginal absorption of the suggestions contained within the self-hypnosis over the next 14 days. Lets begin!

How hypnosis will be used

- 1. To address the general lifestyle factors/triggers that make up the layers of the 'onion' of the migraine/tension-headache and how we manage these.
- 2. To address how we respond to and manage the migraine/tension-headache once triggered and we are aware of its onset and directly experiencing it.
- We will experience hypnosis first in the group session, followed by you then listening to the recording individually over the next 14 days.
- This is the phase that then helps you take charge of the migraines/tension-headaches as you are the driver of action.
- In so doing, you are regaining increased control over your life.



Background information to the hypnosis procedure

- Hypnosis is generally a very safe procedure. During any form of relaxation, emotional responses may be experienced. Although uncommon, if this occurred you will come out of hypnosis, and be guided by a facilitator to a breakout-room, where you will be supported to slowly relax and return to baseline.
- It is not possible to be 'stuck' in hypnosis. You also have complete control to emerge from it at will.
- You will not do anything you do not want to do. You will only respond to suggestions you agree with.
- Hypnosis is very much about you taking control as it is you who is giving permission to agree/disagree with the suggestions.

Hypnosis Induction

- Once we begin the hypnosis procedure, you will remain seated comfortably with your feet flat on the ground and hands on your lap.
- We enter the process of hypnosis through what we call induction.
- This involves being asked to open your eyes, and gently gaze towards the ceiling with your vision focused on the tip of your nose.
- I will ask you to imagine that as you do this, and hold your gaze, that your eyelids feel heavier and heavier- like thick, concrete shutters.
- When you are ready, you will allow them to close firmly shut.
- Let's practice this together. I will model this procedure first, and then I will ask you to follow this once I have done it.

Hypnosis deepening, suggestion & emergence

- Following induction, we deepen the hypnosis through relaxation and use of imagery.
- A series of suggestions will then be provided to increase relief from and control over migraine/tension-headaches.
- Should there be distractions/noises around you, this is ok and normal. It is asked that you simply return to the sound of my voice and this will allow you to relax even further.
- We will then be gently guided to emerge from hypnosis.
- Once completed we will take a few minutes to unwind, have a stretch and glass of water before information is provided on the self-hypnosis component of the programme.

Hypnosis induction and practice

- Induction
- Relaxation
- Practical eyelids feeling heavy task
- Practical limbs feeling heavy task
- Practical hands feeling clasped shut task
- Emergence
- Debrief
- Questions and answers

Hypnosis session for migraine and headache management

- Induction
- Relaxation
- Suggestion
- Emergence
- Debrief
- Questions and answers

Completing self-hypnosis at home

- Over the next 14 days it is asked you complete self-hypnosis daily at home with this pre-recorded MP3 which is the same as you have listened to today.
- It will be helpful for you to choose a time of day to listen to the recording at the same time
- This will be helpful if it is done in a chair, in a space that as free of distractions as is possible. If you share your home with others, you might ask that they give you space at this time also.
- You will repeat the same procedure as today. This includes the induction process of focusing your gaze at the ceiling, which then helps guide you in to the hypnosis process.
- As stated earlier, there are no risks to self during the process at home- no one has ever been stuck/or 'trapped' in hypnosis. You can simply think of it as a process that allows your body to relax deeply that then enables helpful suggestions about control of migraines to be received easier by yourself.
- As mentioned, should you experience a strong emotional response, then we would ask that you open your eyes, get up and stretch and then take part in an activity that will be calming for you e.g. having a cup of tea, speaking with a friend, taking a bath.
- While such events are uncommon, it is normal following an emotional response for ourselves to soon return to baseline emotion. If for whatever reason this did not occur we would ask for you to make contact with your GP, or in extreme situations A and E. You can also email me.

Ongoing Support

- I will have a follow up email/call with everyone here, to hear any questions you may have within the next 2 days, to check if you have any questions or have any troubleshooting queries.
- You can contact me at any time at p.davies253@canterbury.ac.uk to discuss any questions you may have about the hypnosis process and procedure.

Appendix G: Hypnosis Taster session Script

Hypnosis taster and practical session

Take a moment to make yourself comfortable and prepare to begin to relax. Rest your feet flat on the floor and place your hands on your lap. Close your eyes and focus on the sound of my voice. The key to deep relaxation is to apply gentle attention. You will find that you can relax surprisingly deeply simply by focusing on the idea of letting go. Don't try too hard- be relaxed about relaxing. Allow yourself to enjoy feelings of relaxation in an easy and gentle way. If your mind wanders, that's normal- it really doesn't matter- just acknowledge this before gently returning to the sound of my voice. Don't try to force yourself to concentrate or block out distracting sounds or noises from your mind. Simply take a position of non-worry- any sounds or noises you hear will help you to deepen your journey into hypnosis. Your role is to remain as comfortable and as open as possible- You will be aware of my words and you will only accept suggestions which you choose to accept. So, as you rest there with your eyes closed, know that in a few moments you can ease into a wonderful state of deep hypnotic relaxation, where you find positive thoughts and feelings flow easily and naturally, where your imagination becomes stronger and more vivid- focused on the ideas and suggestions you will hear of deep relaxation that you then take into your daily life.

INDUCTION

Now just follow my words and you'll discover that you respond fantastically well to hypnosis. In a few moments, I will ask you to open your eyes and look up at your ceiling overhead. Fixing your eyes on one point will make them strain and feel very tired. You can help by imagining your eyelids feel increasingly heavy and telling yourself they want to close. When your eyelids close, let yourself relax and continue relaxing. Now turn your gaze up behind your shut eyelids, and very slowly open your eyes again. Open your eyes slowly and imagine that you're staring into a fixed point in the ceiling overhead. Stare deeper and deeper and imagine you can feel it sinking deep into your eyes. Now in a moment I'm going to begin counting from 5 all the way down to zero. As I count, count down with me in your mind. Imagine with each number we count that your eyelids feel heavier, more tired, more sleepy- like they are made out of heavy, thick lead. Let them close when they want to- don't resist- let them close as soon as they want to. Beginning now-5, 4, 3, 2, 1 zero. Let them close all the way down. Let them relax so completely that it feels as if the muscles of the eye have forgotten to work. It feels as if they are sealing comfortably shut, as heavy as lead. Indeed raise your gaze behind your tightly shut eyes. The more you imagine opening them, the tighter sealed they become.

SLEEP NOW.

Relax them completely, let go. Relax your eyes, relax your face, relax your body, relax your mind. SLEEP NOW.

Now take a deep breath and send a wave of pleasant relaxation through your body and through your mind. As you do so, let go and relax completely, and utterly, surrender to the process and let go.

Take a breath and let yourself relax as deep as you can right now- feel the feelings in your body- and allow yourself to move gently on and become relaxed and indifferent towards external things for a while and focus on accepting the here and now…. for your experience of time may seem to pass quickly in hypnosis or indeed to seem sped up and slowed down at the same time…. just forget about everything else for a while and listen to my words… Keep your eyes closed and go deeper into

hypnosis….. send a wave of relaxation from the top of your head right down through your body all the way down into your fingers and into the soles of your feet….. sleep now sleep now sleep now

…….

Eyes closed shut exercise

Now imagine your eyelids are so heavy that they are sealed shut permanently - locked heavily shut- your eyelids feel so heavily shut, the more you try to think about them being lifted, the more they're sealing shut now. As you exhale, make an effort and try to gently push against that heaviness and try to get those eyelids wide open- in fact- isn't it interesting- you notice that the more you try, the more they are closing- closing closing- relaxing and sealing heavily shut-now as you inhale, let go completely and find the eyelids growing twice as heavy, sealing shut- locking shut -twice as tightly- as you exhale, try again, and make a bigger effort you find the eyelids are closing closing further down, down – relaxing, and sealing heavily shut- the more you try to get them open, the more they are closing heavily shut -and relax completely- good now stop trying- let go and relax completely- and go deeper into hypnosis -you may have noticed when you imagine your eyelids are sealed shut they actually feel too heavy to open- now forget about the eyes locking shut and just go deeper into hypnosis.

Hand clasping exercise (participant is asked to imagine experience of hands clasping together tightly).

Now shift your attention to your hands- put your hands together- interlock your fingers and raise your arms straight in front of you and clasp your hands together -interlock the fingers tightly- press the palms of the hands together as if they are stuck fast with glue- the more you squeeze and tighten those fingers the more the hands become stuck together -imagine the hands are merging into one solid block of iron -the fingers intertwine together - the hands are so tightly clasped stuck together that it feels like too much effort to make them separate now- as you continue to imagine your hands stuck together let the belief that they're stuck fast dominate your mind -as you exhale - slowly make an effort and try to get those hands apart and find them sticking tighter together- the more you try to make them separate the more they are stuck fast together with your fingers locked together- as you breathe in, the hands lock tighter still -as you breathe out try again and find the more you try to make an effort the more the hands are locking tighter and tighter together they remain stuck together until I say the word relax in a few moments time……. relax now…….. quit trying…… let go completely and go deep into hypnosis……. your hands now relax and you're free to pull them apart easily relax your hands and place them on your lap…… perhaps you noticed how imagining your hands sticking together made them actually feel stuck together…….. isn't that interesting??r now forget about their hands locking together for a while and just go deeper into nicest

Arm heaviness exercise (participant is asked to imagine experience of arms beginning to feel heavy).

Now, focus on your arms please……. raise your right arm and straighten it out in front of you and raise it above your head and leave it suspended there for a moment….. with your palm facing down…… in a moment your arm will begin growing heavier and heavier…… so much so that it feels like sinking down all by itself to rest by your side or on your lap……. Indeed, your arm seems to grow 2 times heavier……you're responding well….. just let it grow heavy and it will want to sink down at its own rate…….. if you imagine your arm feeling heavy your arm will begin feeling heavy…..

imagining a feeling or movement tends to make it happen in our body…. Isn't that interesting?? keep your attention resting on the arm from deep in the shoulder all the way down to your finger tips……. now imagine your arm is growing even heavier and heavier…… your arms feel heavier and heavier….. the arm is growing heavier and heavier…….. its now sinking down down down…. the arm feels weary, tired and heavy more tired and heavy with each moment passes the hand and wrist are loose relaxed and heavy……. pulling the arm continuously down as if they have the weight of a cannonball on the end of the arm….note that as every tiny sensation, every feeling in the arm as it grows heavier and heavier….. the more you think about that arm…. the heavier it's becoming….. the more it wants to sink gently down, down, down as almost as if you can picture a heavy blanket of lead over the arm….. a heavy weight pushing it down pressing it down drawing it down more and more – im now going to count form 10……. 10 heavier and heavier 9.. down down…. 8 heavier and heavier and heavier 7,6 sinking down down, down 543 sinking all the way down to one all the way down ……zero…. its all the way down… right down let go completely and go deeper and hypnosis good now forget about all those feelings of happiness and just gently rest both your hands in a comfortable position you're learning how to use the power of your mind by letting yourself imagine feelings that inevitably move the muscles of the limbs this is the basis of hypnotic suggestion you're now learning to understand suggestion an learning how to respond more powerfully to suggestion when you choose to let it happen

Leg cooling/warmth exercise (participant is asked to imagine experience of legs beginning to change in temperatures from warm to cool).

Now I want you to bring your attention to your right leg and what I want you to imagine is you can start to feel a little sensation throughout your right leg of temperature and the temperature is beginning to cool and it cools down as colder and colder you can start to feel your right leg feel very different to your left leg becoming colder and colder and then what you notice is suddenly a very chilly indeed and you can notice how to cooling sensation is running from the top of your leg all the way to the bottom and you go deeper and hypnosis and as you do notice your leg is feeling colder and colder and colder again two times colder three times cold so cold it all the sudden it seems to feel too cold and as you do and you notice you realise you have control and when I say it begins to feel warmer you notice your leg the temperatures rolling all the way down as if it was sitting by a warm campfire and you can feel the heat coming off their campfire onto your leg and your legs slowly raising temperature 1 degree two degree more become so warm you feel a pleasant tingling sensation going all over that Ryan leg isn't it interesting how you can feel that warmth rising from the bottom and as he do I want you to slowly bring your attention away from your leg and realises returning back to not wanted the normal temperature before and you bring your attention to yourself and your body and you realise what a wonderful candidate you are hypnosis because ultimately you are responsive to these suggestions and you will enjoy the remainder of the evening .

EMERGENCE

And slowly we will soon return fully back to the room around us. You notice the sounds around you. Feel the sensations of the seat and floor against your body. More and more you are feeling awake and alert, and I ask that you now gently bring yourself fully in to the room around you. Slowly moving your fingers, toes and body, taking this relaxing feeling forward into the day ahead of you.

Appendix H: Main group hypnosis script

Now, take a moment to make yourself comfortable and prepare to begin to relax. Rest your feet flat on the floor and place your hands on your lap. Close your eyes and focus on the sound of my voice.

Now turn your gaze upwards behind your shut eyelids, and very slowly open your eyes again. Open your eyes slowly and focus on a fixed point in the ceiling above. Stare deeper and deeper and imagine you can feel the hypnosis sinking deep into your eyes. Now in a moment I'm going to begin counting from 5 all the way down to zero. Let your eyes close when they want to- don't resist- let them close as soon as they become too heavy to stay open. 5, 4, 3, 2, 1 zero. Let them close all the way down. Let them relax so completely that it feels as if the muscles of the eyes have forgotten to work. It feels as if they are sealing comfortably shut, as heavy as lead. Indeed, raise your gaze behind your tightly shut eyes. The more you imagine opening them, the tighter sealed they feel and become.

SLEEP NOW.

Relax them completely, let go. Relax your eyes, relax your face, relax your body, relax your mind. SLEEP NOW. And, just utterly and completely, give yourself permission to surrender to the process and let go.

DEEPENER

Now, focus your attention all the way down upon the soles of your feet. You're now going to relax a few levels deeper, relaxing through each part of your body. Imagine you're beside a beautiful blue clear lake and it's the middle of summer, with a cool breeze cooling your body temperature perfectly. With your attention focused on your feet, you take a small step into the water, now imagine that a calming blue sensation is spreading over the soles, up and around your toes, just as the summer water waves lap gently over your feet. Imagine the peaceful and gentle waves and picture it beginning to spread calm and soothing energy upward throughout your body (pause 5-10 secs).

Now imagine that feeling rising from your feet, dissolving every last ounce of tension from the muscles as it does so. Now flowing all the way over the ankles and up through the legs, send that feeling up through the calves and the shins, up into the knees. Let the knees relax completely. Now imagine that feeling rising up through the thighs towards the hips. Imagine both legs relaxing completely (as if they were made of thousands of loose rubber bands). Let go of every last ounce of tension in the left leg and the right leg, in both legs at once. Deep breath in and let go…..(pause)

Now imagine that feeling spreading up into your stomach, into the waist, up through the top half of your body. Now imagine that feeling spreading up into the chest and shoulders, filling the whole trunk of the body. Imagine relaxation spreading deep inside the body, right into the internal organs, soothing and healing as it revitalises your body and mind. (pause)

Now send that feeling up into the neck and the shoulders, feel the calm cooling blue spreading over the shoulders and down into the arms. Let the arms turn loose, completely limp and heavy, right down into the very tips of the fingers. Rest your mind on the top half of the body and feel the natural movements of your breathing- gentle deep breath in, and let go (pause)

Continue to relax the body so deeply that you can feel your breathing changing all on its own, becoming more slow and gentle. Let your breathing find its own rhythm and pattern. Now imagine that sense of relaxation spreading from the base of the spine all the way up through your back, right up to the base of your neck. Let the sensation flow over the back of the head, over the scalp and

down over the forehead, feeling it as a cooling sensation as it does. Relax all the muscles in the eyes and around the eyes.

Let the feeling spread down into the cheeks and down into the jaw. Send the relaxation feelings into the mouth, soften all the muscles in the mouth, let the tongue rest broad, flat, heavy and silent. Let the tongue relax completely. Relax all the muscles of the face completely, let them drop, soften and ease into a completely relaxed expression. Notice how that feels, how the facial expression now feels more peaceful. You now let go, release and are as deeply relaxed as you could ever possibly imagine. Surrender- let go

SUGGESTIONS

You are now growing so deeply relaxed- that the words I say take root permanently, like the seeding of an acorn it begins to grow there powerfully and effectively into the roots and trunk of a tree of great internal strength. These suggestions that I will suggest to you will begin to support you shaping a greater influence over the way you want to think, over the way you want to feel, and how you want to act in your life generally, and for when migraines and headaches emerge. These powerful changes will remain deep in the core of your being long after we finish our session tonight. They will continue to multiply in their impact as you complete your daily self-hypnosis-and will grow this powerful influence just as strongly, just as surely- when you are back at work, or back around others, and back at home. You're now feeling so very deeply relaxed, that every single suggestion is being absorbed so very deeply- and these words will help change your life, exactly as you want it to be. Breathe deeply in and release, let go, relax. Repeat.

You are becoming aware of your ability to create change and manage in day-to-day situations exactly as you would like to. You are becoming more confident in your ability to relax and take control of how you feel in your mind, your body and your life. More confident in your ability to cope with stressful situations. You feel more able to share how you feel with others, more able to choose to eat healthily, exercise and be kind to yourself. You notice more that you have control over how well you can sleep, relax, de-stress and be kind to yourself. More and more you are able to pace your activity in a steady fashion, so that you are not over-exerting yourself when feeling well, or doing anything less than you may be able when you are feeling unwell. Even on a difficult day, you are still able to do something, no matter how small it is- even if it is to remind yourself you are doing all you can. With each extra little thing you do, you are further re-taking control and ownership of the life you want to create for yourself. Take a deep breath in, release, relax, let go.

More and more you are developing a deeper awareness of your early signs and triggers of physical discomfort and stress related to migraines and headaches. The more you are aware of this, the more you notice you are able to take control over these situations as they emerge: to notice them and take increased charge and diminish their influence in your life. Every time you have this thought brought to your conscious awareness, it is just like you shrink the size and power of the migraine and headache in half so they begin to recede. The power of your belief and thought reduces them in half again every time you bring these thoughts to your awareness. With each step taken in this direction the more you are becoming calm, relaxed, and most importantly, empowered. By doing more, you are becoming more in control of the first signs of physical tension. You are noticing your patterns of thought- adopting more and more a balanced position and way of thinking. Your self-talk is kinder and more and more you value who you are as a special and unique individual. As you do, you become more relaxed and at ease. Indeed, you can visualise and imagine how you respond when the first signs of physical tension emerge and realise with each step you take towards the vision of life you wish to adopt.

So, I ask now that you can bring to mind that image of your typical triggers or emergent situation when migraine or headache is around. Now I want you to imagine that you are there now. You take a deep breath and slowly exhale. As you do, you silently say to yourself: 'I have this'- 'I take back

more control', no matter how strongly migraine or headache is around, I have power and I have strength. Right now, gently clench your right fist tight. This is your cue, your reminder that you have this inner strength to remind migraine and headache you are here and you have ownership of you. Every time you bring this thought to mind, it shrinks the size and presence of migraine in half, and half again. Gently clench and unclench your fist. Each time you do this, it has the effect of shrinking the power of migraine and headache. Repeat this again. Migraine begins to retreat and starts to shrink in your presence once more- indeed, every time you do this in the real world, you can instantly recapture this feeling of strength and control- each time the migraine and headache begins the process of slow retreat and shrinking in its attempts to control your way of living and life. Now gently relax and release that fist, take a deep breath in and release, let go, repeat.

Now with whatever residual presence of migraine and headache is left, I want you to notice where you feel its presence- whether it be in your head or your body- and the general tension, pressing or pulsation you normally feel. Wherever you notice this, I want you to now imagine that you can transport yourself there instantly as a miniature traveller inside your body- each time you clench your right fist you imagine shrinking down into a tiny yet powerful version of yourself- so tiny that you can imagine travelling instantly through the blood vessels of your body to the point of tension- you can imagine with the onset of the migraine and headache- go there now- shrink down to miniature size and travel to the place of your discomfort. Once arrived you use your inner strength to push and gently massage those pressured blood vessels apart- easing and releasing tension-you allow the flow of oxygenated blood to your body, to your limbs, to your face- you allow the flow of healing thought and calming energy to where your body needs it- you allow the **flow of healing where your body needs it. Breathe in, slowly exhale and say to yourself: I take back more control.**

Indeed,as you say this- You remember that pain is an experience processed within the brain and not the body. Made of many layers, this is something you now have increased control over. You realise you have control over this with the power of your beliefs for change.

As you take increased ownership over migraines and headaches, you know you can release a further soothing blue cool wave of energy to be released through your body and area of pain as you wish. Now imagine that whenever you experience the onset of your migraine or headache (or indeed its continued presence), you have the ability to travel inwardly through your body, and release areas of tension to lower the feeling of discomfort instantly and release the blue, soothing waves of pain relief to wherever you direct it in your body. You can instantly visualise this and direct this to lower the sensation in your body. Imagine now directing this release whenever you need it. Feel how good it feels to have this instant control. Really experience that instant cool relief. Let your smile widen as you now know you are beginning to equip yourself with the necessary tools to take direct control over your level of pain experienced. Whenever you experience this discomfort in the real world, you can instantly retake control by clenching your right fist and visualising this process- of travelling to the point of discomfort in your body and using and relaxing the body as needed. Breathe out, release, relax, saying to yourself I take back control and power over my life and my pain.

Now, I want you to bring to mind your preferred future. Visualise and imagine this. What does it look like- what are you doing more of- with others, by yourself? How do you feel? What emotions are you feeling? Happiness? Laugher? Warmth? love? Now, imagine stepping into your life in the future- a future where you have increased control over your migraine, over your headaches. How is life different- what do you notice that is different about you? What do you say to yourself differently- what do you do differently? How do you act different- how do you respond differently to migraine- to headaches? Feel it believe it- let this experience sink deep into your body and mind. Feel how amazing this feels- let your smile emerge and widen. Deep breath in- release and exhale- say to yourself I take back control.

You now know that you can enter situations with this control – any time you can clench your fist- take a deep breath- and visualise travelling to the seat of pain in your body and release it- and even when migraines are still present- you can speak to them and you- by reminding them that you have control. This becomes a more automatic process and with a calm relaxed self-assured confidence knowing you can and do handle these situations better and better every time-

Now- listen to these words: every day I now feel more relaxed, strong, confident, more capable to take charge and control over pain and discomfort in my life. Repeat 3 times as they create a more powerful, beneficial and lasting transformation in your life. Picture yourself in the situation you want to deal with, as if it's happening right now, and imagine yourself repeating the suggestion with me

Every day in every way I feel more relaxed, in control, calm and confident that I can reduce the discomfort of my symptoms. I have control and take charge of them.

Know that you are making this change- growing- becoming empowered- you are creating amazing life changes! You realise your beliefs dictate your present and future and our ability to imagine what is possible- to imagine and feel the life we want to live! Indeed, every day that you listen to the self-hypnosis on your own- you create incremental, automatic and exponential change for the life you are creating exactly as you want it to be. Take this amazing feeling of growing inner strength and empowerment in relation to migraines, headaches and your wonderful, special life ahead of you!

EMERGENCE

And now I will count from 5 all the way down to zero. As I count down with each number you will slowly begin to feel more aware of your surroundings in a calm, refreshed and pleasant manner. 5 aware of your physical sensation of your body contacting the seat and floor around you. 4 aware of the sounds of the outside world and room around you. 3 smelling the room, 2 slowly beginning to feel the light of the room around you and beginning to feel your eyelids flutter ready to open. 1 open your eyes back into the room, calm and relaxed. Zero, peaceful, calm and ready to take these positive suggestions into the day and evening ahead

Appendix I: Comparison of baseline measures between participants allocated to the hypnosis intervention compared to the waitlist control condition

Test Statistics[a]

	TOTAL_MIG_FREQ_0	DASS_DEP_TOT_0	DASS_ANX_TOT_0	DASS_TOT_0	WEM_TOT_0	ILC_0	HMSE_TOTAL_0	AV DAY MIG_0
Mann-Whitney U	115.000	149.500	131.500	152.000	122.000	136.000	150.500	135.500
Wilcoxon W	268.000	302.500	302.500	323.000	293.000	289.000	321.500	306.500
Z	-.759	-.116	-.716	-.033	-1.025	-.562	-.083	-.578
Asymp. Sig. (2-tailed)	.448	.907	.474	.974	.305	.574	.934	.563
Exact Sig. [2*(1-tailed Sig.)]	.465[b]	.909[b]	.483[b]	.987[b]	.318[b]	.590[b]	.935[b]	.568[b]

a. Grouping Variable: Cohort

b. Not corrected for ties.

Appendix J: Post-intervention measures between group differences

Mean daily headache

Between-Subjects Factors

		Value Label	N
Cohort	1	Intervention_cohort	15
	2	Control_cohort	17

Tests of Between-Subjects Effects

Dependent Variable: AV_DAY_MIG_1

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	8.408[a]	2	4.204	50.269	.000
Intercept	.020	1	.020	.241	.627
AVDAYM_0	8.386	1	8.386	100.280	.000
COHORT	.109	1	.109	1.306	.262
Error	2.425	29	.084		
Total	21.761	32			
Corrected Total	10.833	31			

a. R Squared = .776 (Adjusted R Squared = .761)

Total Headache frequency

Between-Subjects Factors

		Value Label	N
Cohort	1	Intervention_cohort	15
	2	Control_cohort	17

Tests of Between-Subjects Effects

Dependent Variable: TOTAL_MIG_FREQ_1

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	1086.964[a]	2	543.482	41.503	.000
Intercept	4.196	1	4.196	.320	.576
TOTAL_MIG_FREQ_0	1086.237	1	1086.237	82.950	.000
COHORT	13.769	1	13.769	1.051	.314
Error	379.755	29	13.095		
Total	4113.000	32			
Corrected Total	1466.719	31			

a. R Squared = .741 (Adjusted R Squared = .723)

Total number of medication free days

Between-Subjects Factors

		Value Label	N
Cohort	1	Intervention_cohort	15
	2	Control_cohort	17

Tests of Between-Subjects Effects

Dependent Variable: NO_MEDS1

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	518.409[a]	2	259.204	20.345	.000
Intercept	53.822	1	53.822	4.225	.049
NO_MEDS0	495.749	1	495.749	38.912	.000
COHORT	35.590	1	35.590	2.793	.105
Error	369.466	29	12.740		
Total	3166.000	32			
Corrected Total	887.875	31			

a. R Squared = .584 (Adjusted R Squared = .555)

DASS Depression

Between-Subjects Factors

		Value Label	N
Cohort	1	Intervention_cohort	15
	2	Control_cohort	17

Tests of Between-Subjects Effects

Dependent Variable: DASS_DEP_TOTAL_1

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	1503.389[a]	2	751.694	13.726	.000
Intercept	60.010	1	60.010	1.096	.304
DASS_DEP_TOT_0	1502.681	1	1502.681	27.440	.000
COHORT	5.444	1	5.444	.099	.755
Error	1588.111	29	54.762		
Total	6056.000	32			
Corrected Total	3091.500	31			

a. R Squared = .486 (Adjusted R Squared = .451)

DASS Anxiety

Between-Subjects Factors

		Value Label	N
Cohort	1	Intervention_cohort	15
	2	Control_cohort	17

Tests of Between-Subjects Effects

Dependent Variable: DASS_ANX_TOTAL_1

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	895.005[a]	2	447.503	16.705	.000
Intercept	15.260	1	15.260	.570	.456
DASS_ANX_TOT_0	894.471	1	894.471	33.390	.000
COHORT	53.563	1	53.563	1.999	.168
Error	776.870	29	26.789		
Total	3212.000	32			
Corrected Total	1671.875	31			

a. R Squared = .535 (Adjusted R Squared = .503)

DASS Full Total

Between-Subjects Factors

		Value Label	N
Cohort	1	Intervention_cohort	15
	2	Control_cohort	17

Tests of Between-Subjects Effects

Dependent Variable: DASSFULL1

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	6810.339[a]	2	3405.169	9.807	.001
Intercept	509.301	1	509.301	1.467	.236
DASSFULL0	6715.437	1	6715.437	19.340	.000
COHORT	329.836	1	329.836	.950	.338
Error	10069.661	29	347.230		
Total	46648.000	32			
Corrected Total	16880.000	31			

a. R Squared = .403 (Adjusted R Squared = .362)

WEMWBS

Between-Subjects Factors

		Value Label	N
Cohort	1	Intervention_cohort	15
	2	Control_cohort	17

Tests of Between-Subjects Effects

Dependent Variable: WEM_TOT_1

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	2245.807[a]	2	1122.903	16.462	.000
Intercept	49.046	1	49.046	.719	.403
WEM_TOT_0	2221.101	1	2221.101	32.561	.000
COHORT	49.480	1	49.480	.725	.401
Error	1978.162	29	68.212		
Total	70381.000	32			
Corrected Total	4223.969	31			

a. R Squared = .532 (Adjusted R Squared = .499)

HMSE

Between-Subjects Factors

		Value Label	N
Cohort	1	Intervention_cohort	15
	2	Control_cohort	17

Tests of Between-Subjects Effects

Dependent Variable: HMSE_TOTAL_1

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	1687.707[a]	2	843.853	7.946	.002
Intercept	243.111	1	243.111	2.289	.141
HMSE_TOTAL_0	1687.140	1	1687.140	15.886	.000
COHORT	2.087	1	2.087	.020	.889
Error	3079.793	29	106.200		
Total	370280.000	32			
Corrected Total	4767.500	31			

a. R Squared = .354 (Adjusted R Squared = .309)

ILOC

Between-Subjects Factors

		Value Label	N
Cohort	1	Intervention_cohort	15
	2	Control_cohort	17

Tests of Between-Subjects Effects

Dependent Variable: ILC_TOTAL_1

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	1725.205[a]	2	862.603	68.786	.000
Intercept	163.026	1	163.026	13.000	.001
ILC_0	1713.123	1	1713.123	136.609	.000
COHORT	.018	1	.018	.001	.970
Error	363.670	29	12.540		
Total	46342.000	32			
Corrected Total	2088.875	31			

a. R Squared = .826 (Adjusted R Squared = .814)

Appendix K: Follow up measures between group differences

Average daily headache

Between-Subjects Factors

		Value Label	N
Cohort	1	Intervention_cohort	13
	2	Control_cohort	17

Tests of Between-Subjects Effects

Dependent Variable: Average daily headache

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	5.882[a]	2	2.941	32.595	.000
Intercept	.029	1	.029	.323	.575
AVDAYM_0	5.471	1	5.471	60.630	.000
COHORT	.409	1	.409	4.530	.043
Error	2.436	27	.090		
Total	14.584	30			
Corrected Total	8.318	29			

a. R Squared = .707 (Adjusted R Squared = .685)

Mean daily headache Mann Whitney test

Ranks

	Cohort	N	Mean Rank	Sum of Ranks
ADM0MT2	Intervention_cohort	13	19.31	251.00
	Control_cohort	17	12.59	214.00
	Total	30		

Test Statistics[a]

	ADM0MT2
Mann-Whitney U	61.000
Wilcoxon W	214.000
Z	-2.074
Asymp. Sig. (2-tailed)	.038
Exact Sig. [2*(1-tailed Sig.)]	.039[b]

a. Grouping Variable: Cohort

b. Not corrected for ties.

Total headache frequency

Between-Subjects Factors

		Value Label	N
Cohort	1	Intervention_cohort	13
	2	Control_cohort	17

Tests of Between-Subjects Effects

Dependent Variable: TOTAL_MIG_FREQ_2

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	564.095[a]	2	282.047	28.697	.000
Intercept	.690	1	.690	.070	.793
TOTAL_MIG_FREQ_0	519.786	1	519.786	52.885	.000
COHORT	39.101	1	39.101	3.978	.056
Error	265.372	27	9.829		
Total	2502.000	30			
Corrected Total	829.467	29			

a. R Squared = .680 (Adjusted R Squared = .656)

Total Number of medication free days

Between-Subjects Factors

		Value Label	N
Cohort	1	Intervention_ cohort	13
	2	Control_cohort	17

Tests of Between-Subjects Effects

Dependent Variable: NO_MEDS2

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	420.641[a]	2	210.321	16.686	.000
Intercept	69.012	1	69.012	5.475	.027
NO_MEDS0	370.426	1	370.426	29.388	.000
COHORT	64.527	1	64.527	5.119	.032
Error	340.326	27	12.605		

Total	2861.000	30			
Corrected Total	760.967	29			

a. R Squared = .553 (Adjusted R Squared = .520)

Total number of medication free days Mann Whitney test

Ranks

	Cohort	N	Mean Rank	Sum of Ranks
MED0M2	Intervention_cohort	13	10.54	137.00
	Control_cohort	17	19.29	328.00
	Total	30		

Test Statistics[a]

	NMED2M0
Mann-Whitney U	46.000
Wilcoxon W	199.000
Z	-2.796
Asymp. Sig. (2-tailed)	.005
Exact Sig. [2*(1-tailed Sig.)]	.006[b]

a. Grouping Variable: Cohort

b. Not corrected for ties.

DASS Depression

Between-Subjects Factors

		Value Label	N
Cohort	1	Intervention_cohort	15
	2	Control_cohort	17

Tests of Between-Subjects Effects

Dependent Variable: DASS_DEP_TOTAL_2

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	1458.167[a]	2	729.084	13.405	.000
Intercept	67.323	1	67.323	1.238	.275
DASS_DEP_TOT_0	1458.150	1	1458.150	26.809	.000
COHORT	2.570	1	2.570	.047	.829
Error	1577.333	29	54.391		
Total	6000.000	32			

Corrected Total		3035.500	31			

a. R Squared = .480 (Adjusted R Squared = .445)

DASS Anxiety

Between-Subjects Factors

		Value Label	N
Cohort	1	Intervention_cohort	15
	2	Control_cohort	17

Tests of Between-Subjects Effects

Dependent Variable: DASS_ANX_TOTAL_2

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	953.462[a]	2	476.731	15.490	.000
Intercept	19.193	1	19.193	.624	.436
DASS_ANX_TOT_0	943.854	1	943.854	30.667	.000
COHORT	96.218	1	96.218	3.126	.088
Error	892.538	29	30.777		
Total	3528.000	32			
Corrected Total	1846.000	31			

a. R Squared = .517 (Adjusted R Squared = .483)

DASS Total

Between-Subjects Factors

		Value Label	N
Cohort	1	Intervention_cohort	15
	2	Control_cohort	17

Tests of Between-Subjects Effects

Dependent Variable: DASSFULL2

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	6884.750[a]	2	3442.375	9.739	.001
Intercept	540.739	1	540.739	1.530	.226
DASSFULL0	6754.738	1	6754.738	19.111	.000
COHORT	393.537	1	393.537	1.113	.300
Error	10250.125	29	353.453		
Total	47516.000	32			
Corrected Total	17134.875	31			

a. R Squared = .402 (Adjusted R Squared = .361)

WEMWBS

Between-Subjects Factors

		Value Label	N
Cohort	1	Intervention_cohort	15
	2	Control_cohort	17

Tests of Between-Subjects Effects

Dependent Variable: WEM_TOT_2

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	2245.807[a]	2	1122.903	16.462	.000
Intercept	49.046	1	49.046	.719	.403
WEM_TOT_0	2221.101	1	2221.101	32.561	.000
COHORT	49.480	1	49.480	.725	.401
Error	1978.162	29	68.212		
Total	70381.000	32			
Corrected Total	4223.969	31			

a. R Squared = .532 (Adjusted R Squared = .499)

HMSE

Between-Subjects Factors

		Value Label	N
Cohort	1	Intervention_cohort	15
	2	Control_cohort	17

Tests of Between-Subjects Effects

Dependent Variable: HMSE_TOTAL_2

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	1734.240[a]	2	867.120	8.159	.002
Intercept	231.217	1	231.217	2.176	.151
HMSE_TOTAL_0	1732.563	1	1732.563	16.303	.000
COHORT	.352	1	.352	.003	.954
Error	3081.978	29	106.275		
Total	372255.000	32			

Corrected Total	4816.219	31			

a. R Squared = .360 (Adjusted R Squared = .316)

ILOC

Between-Subjects Factors

		Value Label	N
Cohort	1	Intervention_cohort	15
	2	Control_cohort	17

Tests of Between-Subjects Effects

Dependent Variable: ILC_TOTAL_2

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	1725.205[a]	2	862.603	68.786	.000
Intercept	163.026	1	163.026	13.000	.001
ILC_0	1713.123	1	1713.123	136.609	.000
COHORT	.018	1	.018	.001	.970
Error	363.670	29	12.540		
Total	46342.000	32			
Corrected Total	2088.875	31			

a. R Squared = .826 (Adjusted R Squared = .814)

Appendix L: Mediation and moderation effects

Mediation by changes in expectancy

```
Sample
Size:  30

**************************************************************************
OUTCOME VARIABLE:
 EXP_T1M0

Model Summary
          R       R-sq        MSE          F        df1        df2          p
      .1948      .0379    23.6371      .5323     2.0000    27.0000      .5933

Model
             coeff         se          t          p       LLCI       ULCI
constant    3.2794     3.1130     1.0534      .3015    -3.1082     9.6669
COHORT     -1.6252     1.7913     -.9073      .3723    -5.3007     2.0503
AVDAYM_0     .8350     1.6964      .4922      .6265    -2.6458     4.3158

Standardized coefficients
             coeff
COHORT      -.3398
AVDAYM_0     .0929

**************************************************************************
OUTCOME VARIABLE:
 AVDAYM_2

Model Summary
          R       R-sq        MSE          F        df1        df2          p
      .8409      .7072      .0937    20.9309     3.0000    26.0000      .0000

Model
             coeff         se          t          p       LLCI       ULCI
constant    -.3981      .2000    -1.9910      .0571     -.8092      .0129
COHORT       .2342      .1145     2.0458      .0510     -.0011      .4695
EXP_T1M0    -.0008      .0121     -.0696      .9451     -.0257      .0241
AVDAYM_0     .8168      .1073     7.6142      .0000      .5963     1.0373

Standardized coefficients
             coeff
COHORT       .4373
EXP_T1M0    -.0075
AVDAYM_0     .8117

************************* TOTAL EFFECT MODEL ****************************
OUTCOME VARIABLE:
 AVDAYM_2

Model Summary
          R       R-sq        MSE          F        df1        df2          p
      .8409      .7071      .0902    32.5953     2.0000    27.0000      .0000

Model
             coeff         se          t          p       LLCI       ULCI
constant    -.4009      .1923    -2.0844      .0467     -.7955     -.0062
COHORT       .2356      .1107     2.1284      .0426      .0085      .4626
AVDAYM_0     .8161      .1048     7.7865      .0000      .6011     1.0312

Standardized coefficients
             coeff
COHORT       .4398
AVDAYM_0     .8110

************** TOTAL, DIRECT, AND INDIRECT EFFECTS OF X ON Y **************

Total effect of X on Y
     Effect         se          t          p       LLCI       ULCI       c_ps
      .2356      .1107     2.1284      .0426      .0085      .4626      .4398

Direct effect of X on Y
```

```
     Effect         se          t          p       LLCI       ULCI      c'_ps
      .2342      .1145     2.0458      .0510     -.0011      .4695      .4373

Indirect effect(s) of X on Y:
            Effect     BootSE   BootLLCI   BootULCI
EXP_T1M0      .0014      .0271     -.0636      .0472

Partially standardized indirect effect(s) of X on Y:
            Effect     BootSE   BootLLCI   BootULCI
EXP_T1M0      .0026      .0551     -.1250      .1083
```

Moderation effects

Attitudes to hypnosis

```
Model  : 1
    Y  : AVDAYM_2
    X  : COHORT
    W  : ATH_T_0

Covariates:  AVDAYM_0

Sample Size:  30

**************************************************************************
OUTCOME VARIABLE:
 AVDAYM_2

Model Summary
          R       R-sq        MSE          F        df1        df2          p
      .8575      .7352      .0881    17.3556     4.0000    25.0000      .0000

Model
             coeff         se          t          p       LLCI       ULCI
constant     1.0760     1.8997      .5664      .5762    -2.8367     4.9886
COHORT       -.2176     1.0474     -.2077      .8371    -2.3748     1.9396
ATH_T_0      -.0328      .0409     -.8017      .4303     -.1170      .0514
Int_1         .0103      .0222      .4612      .6486     -.0355      .0560
AVDAYM_0      .8540      .1070     7.9792      .0000      .6336     1.0745

Product terms key:
 Int_1    :        COHORT   x        ATH_T_0

Test(s) of highest order unconditional interaction(s):
       R2-chng          F        df1        df2          p
X*W      .0023      .2127     1.0000    25.0000      .6486
```

Expectancy

```
Model  : 1
    Y  : AVDAYM_2
    X  : COHORT
    W  : EXPEC_0

Covariates:
 AVDAYM_0

Sample
Size:  30

**************************************************************************
OUTCOME VARIABLE:
```

```
 AVDAYM_2

Model Summary
          R       R-sq        MSE          F        df1        df2          p
      .8421      .7091      .0968    15.2340     4.0000    25.0000      .0000

Model
             coeff         se          t          p       LLCI       ULCI
constant     -.4590      .5051     -.9088      .3722    -1.4992      .5812
COHORT        .3041      .3037     1.0011      .3264     -.3215      .9296
EXPEC_0       .0114      .0888      .1280      .8992     -.1714      .1942
Int_1        -.0134      .0552     -.2422      .8106     -.1271      .1003
AVDAYM_0      .8158      .1110     7.3524      .0000      .5872     1.0443

Product terms key:
 Int_1    :        COHORT   x        EXPEC_0

Test(s) of highest order unconditional interaction(s):
       R2-chng          F        df1        df2          p
X*W      .0007      .0587     1.0000    25.0000      .8106
```

Treatment Credibility

```
Model  : 1
    Y  : AVDAYM_2
    X  : COHORT
    W  : TC__TOT0

Covariates:
 AVDAYM_0

Sample
Size:  30

**************************************************************************
OUTCOME VARIABLE:
 AVDAYM_2

Model Summary
          R       R-sq        MSE          F        df1        df2          p
      .8569      .7343      .0884    17.2759     4.0000    25.0000      .0000

Model
             coeff         se          t          p       LLCI       ULCI
constant    -1.0629      .7087    -1.4997      .1462    -2.5226      .3968
COHORT        .7960      .4377     1.8188      .0809     -.1054     1.6974
TC__TOT0      .1021      .1111      .9188      .3670     -.1267      .3309
Int_1        -.0862      .0679    -1.2704      .2156     -.2261      .0536
AVDAYM_0      .8291      .1055     7.8595      .0000      .6118     1.0464

Product terms key:
 Int_1    :        COHORT   x        TC__TOT0

Test(s) of highest order unconditional interaction(s):
       R2-chng          F        df1        df2          p
X*W      .0171     1.6139     1.0000    25.0000      .2156

********************** ANALYSIS NOTES AND ERRORS ************************

Level of confidence for all confidence intervals in output:
  95.0000
```

Appendix M: Feedback summary to participants

Thank you very much for your interest in the hypnosis for migraine and tension-type headaches study.

Development

The hypnosis intervention was developed by the lead researcher in consultation with project supervisors and feedback from migraine experiencers.

Study

Participants were allocated into one of two groups at random. One group took part in the group hypnosis session, followed by self-hypnosis immediately. The other group were offered group hypnosis followed by self-hypnosis two months later. This helped us to know whether the hypnosis was effective in reducing migraine and tension-type headache symptoms. The study ran from December 2020 until February 2021.

There has been little research into hypnosis for migraines and tension-type headaches over the last 25 years, and the study hoped to assess the potential value of hypnosis in this area.

Content within the group hypnosis session covered general information about migraines and tension-type headaches, their theorised causes, and factors that may lead to their triggers, and how we may be able to respond to these helpfully. The group hypnosis session was followed by 14-days of self-hypnosis at home.

Results

Our analysis of the headache diaries showed that the hypnosis intervention had an overall effect of reducing migraine and tension-type headache symptoms for participants. We also saw that the hypnosis intervention led to an increased number of medication-free days experienced by participants.

The feedback we received from participants varied. For some, it produced reduced symptoms and an increased sense of control in managing triggers and migraine and tension-type headache symptoms. For these people, this increased hope and optimism for a future of increased control, while for a smaller number, no change in symptoms were experienced.

What does this tell us?

We found that hypnosis may potentially help some people with migraines and tension-type headaches. However, to be certain of this, further research needs to be completed to hopefully repeat these findings with a larger group of people.

APPENDIX N: Author guideline notes for the International Journal of Clinical and Experimental Hypnosis

The International Journal of Clinical and Experimental Hypnosis covers topics relevant to the research-informed practice of experimental and clinical hypnosis. The journal's emphasis is to cover empirical research, clinical trials evaluating hypnosis intervention efficacy, mechanisms of hypnosis and systematic reviews, meta-analysis, and theoretical papers within the field of hypnosis.

As this journal requires a word count of 3,500, this thesis will be reduced in words accordingly.

More detailed criteria can be viewed at:

https://www.tandfonline.com/action/authorSubmission?show=instructions&journalCode=nhyp20

APPENDIX O: End of study letter to Ethics Panel

Dear Salomons Ethics Committee,

Re: A pilot randomised controlled trial of an intervention comprising a single online group hypnosis session followed by self-hypnosis for migraines and tension-type headaches

Study

Participants with diagnoses of migraine or tension-type headache (N=35) were randomised into a waitlist-control (N=18) or intervention group (N=17). The intervention group took part in a single online group hypnosis session, followed by 14-days of self-hypnosis. The waitlist-control group were offered group hypnosis followed by self-hypnosis two-months later upon study-completion. The study ran from December 2020 until February 2021.

There has been little research into hypnosis for migraines and tension-type headaches over the last 25-years, and the study hoped to re-assess the potential value of hypnosis in this area.

Content within the group hypnosis session covered general information about migraines and tension-type headaches, their theorised causes, and factors that may lead to their triggers and how people may be able to respond to these helpfully via methods that emphasised self-empowerment. The group hypnosis session was followed by 14-days of self-hypnosis at home, which was a recording of the main group session.

The primary hypothesis was that individuals in the intervention group would demonstrate significantly decreased migraine/tension-type headache mean daily headache ratings at post-intervention. Secondary hypotheses included: the primary hypothesis would also be significantly different between groups at four-week follow-up, intervention participants would demonstrate significantly increased medication-free-days at both time-points, decreased anxiety, depression, and total DASS scores, increased well-being, internal-locus-of-control and self-efficacy. Additionally, it was hypothesised that these outcomes would be moderated by expectancy, attitudes to hypnosis, suggestibility and mediated by post-intervention changes in expectancy.

Results

Our analysis of the headache diaries showed that the hypnosis intervention group demonstrated a non-significant trend towards lowered mean daily headache ratings at post-intervention, which was subsequently significantly different at four-week follow-up. This suggested at follow-up, the intervention had an overall effect of reducing migraine and tension-type headache symptoms for participants who received the hypnosis intervention at this time-point. We also saw that the hypnosis intervention led to an increase in the number of medication-free days experienced by participants and that there were non-significant trends towards reduced anxiety and frequency of migraine/tension-type headache symptoms, all at four-week follow-up. All other secondary measures and hypothesised moderators and mediators were non-significantly different at both time-points.

The feedback we received from participants varied. For some, it produced reduced symptoms and an increased sense of control in managing triggers and migraine and tension-type headache symptoms. For them, this increased hope and optimism for a future of increased

control, while for a smaller number, no change in symptoms were experienced. One respondent provided a powerful response: “I do feel different. I have never done anything like this before. I feel more in control after a decade. I control the early onset of the pain which in turn does not develop into an attack. I would not have thought it was possible”

All participants reported no significant harm or distress from the intervention. One participant in the control group during hypnosis (after the trial-end), reported racing thoughts. This appeared to be temporary and was managed by the second group-facilitator. The participant was contacted the next day and did not report any lasting effects.

What does this tell us?

We found that hypnosis may potentially help some people with migraines and tension-type headaches, in particular reducing their symptoms. However, to be certain of this, further research needs to be completed to hopefully repeat these findings with a larger group of people. The present study provides effect sizes, with which a more fully powered RCT can be designed.