



UNIVERSITI PUTRA MALAYSIA

**CLINICAL HYPNOSIS TO REDUCE CLINICAL AND PSYCHOLOGICAL
RISK FACTOR OF POST-SURGICAL PAIN IN PATIENTS UNDERGOING
TOTAL KNEE REPLACEMENT**

LEE JI KWAN

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By

LEE JI KWAN

**Thesis Submitted to the School of Graduate Studies, Universiti Putra Malaysia,
in Fulfilment of the Requirements for the Degree of Doctor of Philosophy**

January 2018

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Abstract of thesis presented to the Senate of Universiti Putra Malaysia
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January 2018

Chair: Zubaidah binti Jamil @ Osman, Psy.D.

Faculty: Medicine and Health Sciences

Purpose

There has been an increasing interest among clinicians and researchers to develop surgical care strategies to prevent chronic post-surgical pain (CPSP). The objective of this study was to examine the efficacy of clinical hypnosis to alleviate risk factors associated with CPSP in patients undergoing total knee replacement (TKR) surgery. The study hypothesized that participants randomly assigned to clinical hypnosis (HYP condition) would report significantly greater reductions in acute post-surgical pain (APSP) intensity, anxiety, depression, and pain catastrophizing than participants randomly assigned to the minimal-effect treatment (MET) or treatment as usual (TAU) control conditions.

Methodology

This was a single-blinded, open-label, three-arm, randomized, parallel-group controlled study. The study population included adult patients with knee injury that required TKR intervention. Individuals awaiting TKR in Hospital Kuala Lumpur (1) aged 18 and above, (2) able to converse in Malay, English, or Mandarin, and (3) able to provide informed consent were screened for eligibility to participate in the randomized-controlled trial (RCT) using the Depression Anxiety Stress Scale (DASS) and the Pain-Related Self-Statement (PRSS). Those diagnosed with (1) any psychiatric disorders, (2) terminal illnesses, and/ or (3) chronic pain conditions other than the reason for surgery were excluded. Upon screening, individuals with (1) an average pain score of $\geq 4/10$ in the past week and (2) reported moderate levels of anxiety, depression, and/or catastrophizing were enrolled into the RCT.

Randomization was done with replacement by matching randomly generated numbers with a pre-generated list.

Twenty-four ($N = 24$) participants were randomly assigned to receive (1) a pre-recorded hypnotic intervention with music (HYP; $n = 8$), (2) breathing relaxation training intervention with music (MET; $n = 8$), or (3) treatment as usual (TAU; $n = 8$). Immediate pain relief, 72-hour APSP intensity, and pain intensity at 1-, 3-, and 6-months were measured using a 0 - 10 Numerical Rating Scale (NRS). Psychological outcome variables were measured on discharge using the Hospital Anxiety Depression Scale (HADS) and Pain Catastrophizing Scale (PCS). The treatment effects were analyzed using Analysis of Variance (ANOVA) and Fisher's exact test performed with SPSS 21.

Results

For immediate pain relief effects of HYP, mixed ANOVA revealed that the Time (before, after) X Treatment (HYP, MET, TAU) interaction effect was medium but not statistically significant ($p = .418$, $\eta_p^2 = .08$). In addition, ANOVA showed that the treatment main effect on overall APSP intensity in the first 72 hours was medium but not statistically significant ($p = .316$, $\eta_p^2 = .10$). Similarly, the Time (1-, 3-, 6-months) X Treatment (HYP, MET, TAU) interaction effect on pain over the six months follow-up period resulted in a medium but not statistically significant effect ($p = .461$, $\eta_p^2 = .08$). ANOVA revealed large and statistically significant treatment main effects for anxiety ($p = .025$, $\eta_p^2 = .30$) and pain catastrophizing ($p = .043$, $\eta_p^2 = .26$). Post hoc analyses indicated that the HYP group (anxiety: $M = 3.13$, $SD = 3.40$; pain catastrophizing: $M = 5.00$, $SD = 4.84$) reported large and statistically significant decreases in anxiety ($p = .014$, $\eta_p^2 = .36$) and pain catastrophizing ($p = .013$, $\eta_p^2 = .36$) relative to TAU (anxiety: $M = 7.00$, $SD = 1.93$; pain catastrophizing: $M = 18.75$, $SD = 12.78$), while no statistically significant effect was found in the MET group (anxiety: $M = 7.88$, $SD = 4.42$; pain catastrophizing: $M = 16.75$, $SD = 13.24$), relative to TAU (anxiety: $p = .616$, $\eta_p^2 = .02$; pain catastrophizing: $p = .763$, $\eta_p^2 = .01$). The observed treatment main effect on depression was very weak ($p = .939$, $\eta_p^2 = .01$).

Conclusion

The current study shows that pre-recorded hypnosis is largely effective in reducing peri-surgical anxiety and pain catastrophizing. However, the alleviation of anxiety and pain catastrophizing did not result in statistically significantly better pain outcomes in the current sample, relative to treatment as usual. Further research is needed to clarify the mechanisms of risk factors in contributing to the development of CPSP, and identify more effective strategies for the prevention of CPSP.

Keywords: Clinical hypnosis, chronic post-surgical pain, peri-surgical care, randomized controlled trial, total knee replacement

Abstrak tesis yang dikemukakan kepada Senat Universiti Putra Malaysia
sebagai memenuhi keperluan untuk ijazah Doktor Falsafah

**HIPNOSIS KLINIKAL UNTUK MENGURANGKAN FAKTOR RISIKO
KLINIKAL AND PSIKOLOGIKAL YANG MENINGKATKAN SAKIT
SELEPAS PEMBEDAHAN DALAM PESAKIT YANG RAWATAN
MENERIMA PENGGANTIAN LUTUT TOTAL**

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Tujuan

Terdapat minat yang semakin meningkat dalam kalangan doktor dan ahli penyelidik untuk membangunkan strategi penjagaan pembedahan untuk mencegah kesakitan kronik selepas pembedahan (CPSP). Objektif kajian ini adalah untuk menilai keberkesanan hipnosis klinikal bagi mengurangkan faktor risiko yang berkaitan dengan CPSP dalam kalangan pesakit yang menjalani pembedahan penggantian lutut keseluruhan (TKR). Kajian ini mengandaikan bahawa peserta yang dibahagikan secara rawak kepada kumpulan hipnosis klinikal (HYP) akan melaporkan pengurangan dalam tahap kesakitan akut selepas pembedahan (APSP), tahap kecelaruan, kemurungan, dan *pain catastrophizing* yang lebih signifikan berbanding dengan peserta yang dibahagikan secara rawak kepada kumpulan rawatan kesan minimum (MET) ataupun rawatan seperti biasa (TAU).

Metodologi

Kajian ini merupakan sebuah kajian “*single blinded*”, berlabel terbuka dan merangkumi tiga kumpulan selari terkawal yang dibahagikan secara rawak. Populasi kajian ini melibatkan orang dewasa yang mengalami kecederaan lutut yang memerlukan TKR. Individu-individu yang sedang menunggu rawatan TKR di Hospital Kuala Lumpur yang (1) berumur 18 dan keatas, (2) boleh berbicara dalam Bahasa Melayu, Inggeris, atau Cina, dan (3) dapat memberi keizinan untuk menyertai kajian ini telah disaring untuk kelayakan bagi mengambil bahagian dalam Kajian Terkawal Rawak (RCT) dengan menggunakan *Depression Anxiety Stress Scale* (DASS) dan *Pain-Related Self-Statement* (PRSS). Individu yang telah diberi

diagnosis dengan (1) penyakit psikiatri, (2) penyakit terminal, dan/ atau (3) kesakitan kronik selain daripada tujuan pembedahan telah dikecualikan. Selepas penyelesaian saringan, individu yang (1) mengalami skor purata kesakitan $\geq 4/10$ pada minggu sebelumnya dan (2) melaporkan tahap kecelaruan, kemurungan, dan/ atau *pain catastrophizing* yang sederhana telah mengambil bahagian dalam RCT. Proses pembahagian secara rawak dijalankan dengan memadankan nombor yang diperoleh secara rawak dengan senarai nombor yang telah dijana secara rawak sebelum ini.

Dua-puluh empat peserta ($N = 24$) dibahagikan secara rawak untuk menerima (1) rakaman hipnosis dengan muzik (HYP; $n = 8$), (2) relaksasi dengan muzik (MET; $n = 8$), atau (3) rawatan seperti biasa (TAU; $n = 8$). Kesan dari segi kelegaan kesakitan segera, intensiti APSP dalam jangka masa 72-jam, dan intensiti kesakitan pada jangka masa 1-, 3-, 6-bulan selepas pembedahan diukur dengan skala 0 - 10 *Numerical Rating Scale* (NRS). Pembolehubah psikologi diukur dari masa discaj dengan menggunakan *Hospital Anxiety Depression Scale* (HADS) dan *Pain Catastrophizing Scale* (PCS). Efek rawatan dianalisa dengan menggunakan *Analysis of Variance* (ANOVA) dan *Fisher's exact test* dengan menggunakan SPSS 21.

Keputusan

Bagi kesan kelegaan kesakitan segera dari HYP, mixed ANOVA menunjukkan bahawa kesan interaksi Masa (sebelum, selepas) X Rawatan (HYP, MET, TAU) adalah sederhana, namun ia tidak mempunyai kesan yang signifikan ($p = .418$, $\eta_p^2 = .08$). Di samping itu, keputusan ANOVA menunjukkan bahawa kesan rawatan utama ke atas intensiti APSP dalam jangka masa 72 jam pertama adalah sederhana, namun tidak mempunyai efek signifikan ($p = .316$, $\eta_p^2 = .10$). Begitu juga dengan kesan interaksi Masa (1-, 3-, 6-bulan) X Rawatan (HYP, MET, TAU) terhadap kesakitan yang dilaporkan pada tempoh susulan 6 bulan di mana kesan adalah sederhana, namun tidak mempunyai efek signifikan ($p = .461$, $\eta_p^2 = .08$). ANOVA menunjukkan saiz efek utama rawatan yang besar dan signifikan ke atas kecelaruan ($p = .025$, $\eta_p^2 = .30$) and *pain catastrophizing* ($p = .043$, $\eta_p^2 = .26$). Analisa post hoc pula menunjukkan bahawa kumpulan HYP (kecelaruan: $M = 3.13$, $SD = 3.40$; *pain catastrophizing*: $M = 5.00$, $SD = 4.84$) melaporkan pengurangan saiz efek yang besar dan signifikan dari segi kecelaruan ($p = .014$, $\eta_p^2 = .36$) dan *pain catastrophizing* ($p = .013$, $\eta_p^2 = .36$) berbanding dengan TAU (kecelaruan: $M = 7.00$, $SD = 1.93$; *pain catastrophizing*: $M = 18.75$, $SD = 12.78$), manakala tiada kesan yang signifikan ditemui dalam kumpulan MET (kecelaruan: $M = 7.88$, $SD = 4.42$; *pain catastrophizing*: $M = 16.75$, $SD = 13.24$), berbanding dengan TAU (kecelaruan: $p = .616$, $\eta_p^2 = .02$; *pain catastrophizing*: $p = .763$, $\eta_p^2 = .01$). Efek utama rawatan ke atas kemurungan adalah sangat lemah ($p = .939$, $\eta_p^2 = .01$).

Kesimpulan

Kajian ini menunjukkan bahawa pra-rakaman hipnosis adalah sejenis rawatan yang berkesan bagi mengurangkan tahap kecelaruan dan *pain catastrophizing* sepanjang tempoh peri-pembedahan. Walau bagaimanapun, pengurangan tahap kecelaruan dan

pain catastrophizing tidak menunjukkan pesakit mendapat kelegaan sakit yang berbeza di kalangan sampel kajian ini, jika dibandingkan dengan kumpulan yang menerima rawatan seperti biasa. Kajian selanjutnya diperlukan untuk mengenalpasti mekanisme di mana faktor risiko menyumbang kepada CPSP, and cara-cara yang lebih efektif untuk mencegah CPSP.

Kata kunci: Hipnosis klinikal, kesakitan kronik pos-pemudahan, penjagaan peri-pembedahan, kajian rawak terkawal, rawatan penggantian lutut total



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This thesis was submitted to the Senate of Universiti Putra Malaysia and has been accepted as fulfilment of the requirement for the degree of Doctor of Philosophy. The members of the Supervisory Committee were as follows:

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LIST OF ABBREVIATIONS

ACC	Anterior Cingulate Cortex
ACT	Acceptance-Based Therapy
ANOVA	Analysis of variance
APA	American Psychological Association
APSP	Acute Post-Surgical Pain
BMA	British Medical Association
BPI	Brief Pain Inventory
CBT	Cognitive-Behavioral Therapy
CNS	Central Nervous System
CPSP	Chronic Post-Surgical Pain
DASS	Depression Anxiety Stress Scale
GA	General Anesthesia
HADS	Hospital Anxiety and Depression Scale
HSSS	Hospital for Special Surgery Scale
HYP	Clinical Hypnosis
IASP	International Association for the Study of Pain
KSS	Knee Society Score
MET	Minimal-Effect Treatment
MMPI	Minnesota Multiphasic Personality Inventory
MOH	Ministry of Health
NRS	Numerical Rating Scale
NSAIDs	Nonsteroidal Anti-Inflammatory Drugs
PCA	Patient-Controlled Analgesia
PCS	Pain Catastrophizing Scale
PFH	Pain Free Hospital
PPSP	Persistent Post-Surgical Pain
PRSS	Pain-Related Self-Statement
QALY	Quality-Adjusted Life Years
RA	Regional Anesthesia
rACC	Rostral Anterior Cingulate Cortex
rCBF	Regional Cerebral Blood Flow
RCT	Randomized Controlled Trial
SF-36	Short Form 36
TAU	Treatment as Usual
TKA	Total Knee Arthroplasty
TKR	Total Knee Replacement
VAS	Visual Analogue Scale
WOMAC	Western Ontario and McMaster Universities Arthritis Scales
χ^2	Chi-Square

CHAPTER 1

INTRODUCTION

1.1 Background

1.1.1 Total Knee Replacement

Total knee replacement (TKR), also known as total knee arthroplasty (TKA), is the replacement of the knee joint with a prosthesis. This reconstructive surgery is performed when damage that causes pain and dysfunction to the knee is irreversible, such as damage caused by primary arthrosis (e.g. osteoarthritis, ankylosing spondylitis, and rheumatoid arthritis) or other secondary causes (e.g. trauma and musculoskeletal injury) (Walker, 2012). From 1991 to 2010, the volume of primary TKR (knee replacement surgery for the first time, as opposed to revision surgery) performed annually in the United States had increased 162% (from 93,000 to 243,000 approximately), and has become one of the most frequently performed major surgeries (Cram et al., 2012). In Malaysia, TKR is also commonly performed for knees affected by osteoarthritis and rheumatoid arthritis (Ahmad Hafiz, Masbah, & Ruslan, 2011).

The clinical efficacy and cost-effectiveness of TKR is well established. A systematic review of 62 studies published from 1995 to 2003 that included pre- and post-surgery functional data, concluded that TKR had large beneficial effects on several widely accepted outcome measures such as the Knee Society Score (KSS), the Hospital for Special Surgery Scale (HSSS), the Western Ontario and McMaster Universities Arthritis Scales (WOMAC), and the Short Form 36 (SF-36) (Kane, Saleh, Wilt, Bershadsky, & Cross, 2003). A more recent systematic review which included 19 studies with at least three years of follow up that were published from year 2000 onwards also found that patients who underwent TKR showed marked improvements from baseline in the measures such as WOMAC, KSS, pain, and functioning (Shan, Shan, Suzuki, Nouh, & Saxena, 2015).

Annual report data from six countries (i.e., Australia, Denmark, Finland, New Zealand, Norway, & Sweden) indicated only a 6% revision rate after five years and a 12% revision rate after 10 years; these data indicate that the surgery can be viewed as highly successful (Labek, Thaler, Janda, Agreiter, & Stöckl, 2011). A cost-effectiveness analysis based on data from the United Kingdom suggested that TKR costs less than £6,000 per quality-adjusted life years (QALY) gained, and thus represent very good value for money to the national healthcare system (Dakin, Gray, Fitzpatrick, MacLennan, & Murray, 2012).

1.1.2 Chronic Post-Surgical Pain

With such strong evidence supporting the clinical benefits of TKR, it is likely that the volume and demand of this surgery will continue to increase in the years to come. Like any other surgery, however, chronic post-surgical pain (CPSP) can result from TKR (De Kock, 2009). Traditionally, CPSP has been defined as pain that: (1) develops after a surgical procedure, (2) persists for at least 2 months, (3) is not better explained by causes other than the surgery, and (4) is not merely a continuation of a preexisting problem (Macrae & Davies, 1999). Although this definition of CPSP is the most common found in the existing literature, it has also been criticized as overly simplistic (Gupta, Gandhi, Viscusi, 2011; Kehlet & Rathmell, 2010; Schug & Pogatzki-Zahn, 2011). Specifically, as opposed to chronic pain which has been traditionally defined as pain that persists beyond the time it takes for tissue to heal from an injury (usually 3 - 6 months post-injury), the timeframe of 2 months for CPSP may be insufficient to rule out post-surgical pain that could potentially resolve, such as pain due to an ongoing inflammatory response following surgery. Furthermore, the differentiation between a preexisting pain and a new pain is often difficult in practice. Hence, in the context of the current study, CPSP is defined as pain that persists for 6 months or longer following surgery.

Although acute pain following surgery is not unexpected, when it persists and becomes chronic, its implications and treatment become far more complicated (Katz & Seltzer, 2009). Like any chronic pain condition, CPSP not only interferes with individuals' biopsychosocial functioning, but also presents a major economic burden for the society (Blyth, Macfarlane, & Nicholas, 2007; Gupta, Gandhi, Viscusi, 2011). Chronic pain of any type can contribute to physical disability (Turner et al., 2004), significant emotional distress (Greenwood, Thurston, Rumble, Waters, & Keefe, 2003; Wegener, Castillo, Haythornthwaite, MacKenzie, & Bosse, 2011), family problems (Payne & Norfleet, 1986; Turk, Flor, & Rudy, 1987), occupational dysfunction (Blyth, March, Nicholas, & Cousins, 2003; Gheldof, Vinck, Vlaeyen, Hidding, & Crombez, 2005; Martel, Wideman, & Sullivan, 2012), challenges in activities of daily living (Amris, Wæhrens, Jespersen, Bliddal, & Danneskiold-Samsøe, 2011), and financial difficulties (Schofield et al., 2012).

On a societal level, chronic pain can result in significant costs due to the cost of care as well as loss of productivity (Phillips, 2006). Therefore, while a significant number of individuals are likely to benefit from TKR, the incidence of CPSP as well as the amount of burden and suffering associated with chronic pain may grow as the volume of TKR increases, especially if the risks of developing CPSP have not been adequately addressed. This view has been supported by many investigators and clinicians that highlighted the importance of prevention in dealing with CPSP (e.g. Burns & Moric, 2011; Gupta, Gandhi, Viscusi, 2011; Macrae, 2008; Niraj & Rowbotham, 2011; Schug & Pogatzki-Zahn, 2011).

1.2 Problem Statement

Despite the potential benefits of TKR in reducing pain and improving functioning, there is a 10% to 50% probability that individuals undergoing the surgery may develop CPSP (Kehlet, Jensen, & Woolf, 2006). One large scale survey conducted in England and Wales found that 20% of patients (n = 8010) who underwent TKR continued to experience persistent pain after one year (Baker, Van der Meulen, Lewsey, Gregg, 2007). A systematic review that examined the proportion of patients experiencing chronic pain after joint replacement also found that about 20% of patients have unfavourable long-term (up to five years) pain outcomes after TKR (Beswick, Wylde, Gooberman-Hill, Blom, & Dieppe, 2012). This estimation suggests that one out of five patients undergoing TKR continue suffer from pain and its negative consequences long after the surgery.

A number of biological, psychological, and social factors have been identified as predictors of post-surgical pain in TKR. On top of the emerging findings which indicated that pre-surgical psychological distress is associated with poor post-surgical outcomes in joint replacement surgery (Howard, Ellis, & Khaleel, 2010), previous research has also identified pain, depression, and anxiety during the pre-surgical period as significant predictors for pain at 6 months in patients who have undergone TKR (Judge et al., 2012). Notwithstanding the growing knowledge about its predictors, the prevention of CPSP leaves much room for improvement (Pogatzki-Zahn, Schnabel, & Zahn, 2012).

Many clinicians and researchers are now aware of the psychosocial aspects of pain and have moved towards a biopsychosocial approach to the management of chronic pain (Domenech, Sánchez-Zuriaga, Segura-Ortíz Espejo-Tort, & Lisón, 2011), but the use of psychosocial techniques to prevent CPSP is not yet part of the standard surgical care (Burns & Moric, 2011). Most of the proposed preventive measures have focused on the biomedical aspects of surgery, such as employing less invasive surgical techniques (e.g. laparoscopic surgery), use of preemptive analgesia, and use of multimodal analgesia (Bouman et al., 2014; Buvanendran, 2008; Buvanendran & Kroin, 2009; Kehlet et al., 2006; Pogatzki -Zahn et al., 2012). However, the previous findings also suggested that psychological factors such as depression, anxiety, and catastrophizing experienced by the patients before and after surgery may play important causal roles in the development of CPSP. Therefore, interventions that target these dimensions may also reduce the risk of developing CPSP.

Consistent with this idea, research indicates that a number of psychotherapeutic modalities such as Acceptance-Based Therapy (ACT; Fernández, Luciano, & Valdivia-Salas, 2012), Cognitive-Behavioral Therapy (CBT; Riddle et al., 2010), music therapy (Binns-Turner, Wilson, Pryor, Boyd, & Prickett, 2011; Nilsson, Rawal, Unestahl, Zetterberg, & Unosson, 2001; Nilsson, Rawal, Enqvist, & Unosson, 2003), and clinical hypnosis (Montgomery et al., 2007; Saadat et al., 2006) to be effective in alleviating surgical-related pain and distress. Apart from CBT which is usually

structured and conducted in a course of several sessions (Riddle et al., 2010), other psychological interventions are typically cost-effective and can be easily incorporated into daily practice.

For example, Fernández and colleague (2012) have showed that patients awaiting laparoscopic cholecystectomy who were given a 30-minute ACT session to address their perceptions regarding the surgery resulted in lesser demand of analgesics and earlier hospital discharge after the surgery. Patients undergoing mastectomy for breast cancer who listened to soft and comforting music throughout the peri-surgical period were found to have lower anxiety and pain scores, as well as lower blood pressure levels (Binns-Turner et al., 2011). Montgomery and colleagues (2007) demonstrated that patients who received a 15-minutes pre-surgery hypnosis session experienced significantly less post-surgical pain intensity, pain unpleasantness, nausea, fatigue, discomfort, and emotional distress after surgery as compared to those in the control group. As a group, these findings provided strong support for the role of simple and brief psychological interventions in the surgical setting.

Powell and colleagues (2016) published a Cochrane review that included 105 studies on psychological preparation for adults undergoing surgery under general anesthesia. The authors categorized the different psychological preparation methods into: (1) providing procedural information, (2) providing sensory information, (3) behavioral instruction, (4) cognitive interventions, (5) relaxation techniques, (6) hypnosis, and (7) emotion-focused interventions. Their findings suggest that the psychological preparation methods tend to have comparable effects, and were associated with lower post-surgical pain, shorter length of stay, and lower negative affect when compared with controls.

Despite the potential for psychological interventions to reduce the incidence and severity of CPSP, there is limited evidence from randomized clinical trial in that regard. By conceptually mapping the effects of CBT on reducing catastrophizing and catastrophizing on predicting pain through the calculation of effect sizes, Burns and Moric (2011) were able to estimate that treating patients with high catastrophizing with CBT may prevent 50% of them from developing CPSP, with a CBT effect size of Cohen's $d = 0.63$ on catastrophizing. Such promising estimations, albeit theoretically derived, indicate that testing of psychotherapeutic interventions to prevent CPSP is clearly warranted.

1.3 Significance of the Study

The current study was an attempt to incorporate clinical hypnosis, one of the oldest form psychotherapy that has a particular relevance to the field of anesthesia and surgery (Spiegel, 2006), to the surgical care setting to reduce the risk of CPSP. The treatment protocol developed in this study can be adopted as a routine care strategy to help manage pain and psychological distress in patient undergoing TKR, and can

perhaps be adapted into other surgical modalities. A comparison of predictors in two surgical models that differ considerably (i.e. TKR and breast surgery) suggested that anxiety, pain catastrophizing, and intense acute post-surgical pain (APSP) are predictors of CPSP in both types of surgery, and that psychological predictors may be consistent across multiple surgical model (Masselin-Dubois et al., 2013). The preventive treatment of CPSP, if successful, can reduce the cost and suffering brought about by chronic pain. Besides potentially mitigating the risk of CPSP, the intervention may help patients better cope with the surgical environment, which on its own can be meaningful to the patients.

Given that very few studies in Malaysia have examined hypnotic intervention for surgical care using RCT, the current study may set off a research line of hypnosis for clinical applications in the local context. Results of this study can serve as a reference for future studies that examine the effects of hypnosis or other psychological treatment in reducing post-surgical pain, depression, anxiety, and pain catastrophizing.

1.4 Objectives

The current study examined the efficacy of hypnosis as a potential preventive treatment for CPSP using a randomized controlled trial (RCT) design. As patients' pain intensity and psychological states prior to the surgery have been found to significantly predict post-surgical outcomes, it is likely that initiating hypnotic interventions during the pre-surgical (as opposed to only during the post-operative period) may yield the best outcomes.

1.4.1 General Objectives

The general objective of this study was to develop, implement, and evaluate a peri-surgical hypnotic intervention to alleviate the clinical and psychological risks of CPSP.

1.4.2 Specific Objectives

The specific objectives of the study include:

1. To describe the demographic background as well as the levels of pain, anxiety, depression, and pain catastrophizing of individuals going for TKR in the General Hospital of Kuala Lumpur (GHKL).

2. To develop a hypnotic intervention that can be incorporated into the peri-surgical care process.
3. To compare the hypnotic intervention against standard care (treatment-as-usual; TAU) and an intervention that controls for both time and therapist attention (minimal-effect treatment (MET)).
4. To determine the efficacy of peri-surgical hypnotic intervention in providing immediate pain relief by comparing against TAU and MET.
5. To determine the efficacy of peri-surgical hypnotic intervention in reducing pain intensity during the first 72-hour post-surgical period by comparing against TAU and MET.
6. To determine the efficacy of peri-surgical hypnotic intervention in reducing anxiety, depression, and pain catastrophizing during the peri-surgical period by comparing against TAU and MET.
7. To determine the efficacy of peri-surgical hypnotic intervention in reducing pain intensity during 1-month, 3-month, and 6-month follow up by comparing against TAU and MET.

1.5 Hypotheses

1. Peri-surgical hypnotic intervention provides significant pain reduction relative to TAU and MET within an hour after administration.
2. Peri-surgical hypnotic intervention significantly reduces pain intensity during the first 72 hours post-surgery as compared to TAU and MET.
3. Peri-surgical hypnotic intervention significantly reduces anxiety throughout the peri-surgical period as compared to TAU and MET.
4. Peri-surgical hypnotic intervention significantly reduces depression throughout the peri-surgical period as compared to TAU and MET.
5. Peri-surgical hypnotic intervention significantly reduces pain catastrophizing throughout the peri-surgical period as compared to TAU and MET.

6. Peri-surgical hypnotic intervention significantly reduces pain intensity at 1-month, 3-months, and 6-months follow up as compared to TAU and MET.
7. Peri-surgical hypnotic intervention significantly reduces the incidence of CPSP at 6-months follow up as compared to TAU and MET.

1.6 Operational Definitions

Risks of CPSP: Experiencing moderate pain intensity for more than a week together with moderate level(s) of anxiety, depression, and pain catastrophizing prior to surgery.

Clinical hypnosis: A psychotherapeutic approach characterized by the use of verbal suggestions to elicit cognitive, behavioural, and emotional changes in a subject.

Minimal-effect treatment: A control group used in clinical trials that resembles the target treatment but without the specific core components.

Treatment as usual: Standard care where no additional therapeutic intervention is given.

Immediate pain relief: The reduction in pain intensity immediately after the implementation of an intervention.

Acute post-surgical pain: The average pain intensity in the first 72 hours after surgery.

Chronic post-surgical pain: Pain that persists for 6 months or longer following surgery.

Peri-surgical: The period throughout the surgery, beginning from admission until discharge.

Anxiety: Fear-related experience as measured by standardized psychometric instruments.

Depression: Sadness-related experience as measured by standardized psychometric instruments.

Pain catastrophizing: The tendency to exaggerate the negativity of an actual or anticipated pain experience as measured by standardized psychometric instruments.



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