Guided Imagery for Total Knee Replacement: A Randomized, Placebo-Controlled Pilot Study

Ann F. Jacobson, PhD, RN,¹ Wendy A. Umberger, PhD, RN,¹ Patrick A. Palmieri, PhD,²
Thomas S. Alexander, PhD,³ Rodney P. Myerscough, PhD,⁴ Claire B. Draucker, PhD, RN,⁵
Susann Steudte-Schmiedgen, PhD,⁶ and Clemens Kirschbaum, PhD⁶

Abstract

Objectives: To determine the effect of guided imagery (GI) on functional outcomes of total knee replacement (TKR), explore psychological and neuroimmune mediators, and assess feasibility of study implementation.

Design: Investigator-blinded, randomized, placebo-controlled pilot study.

Settings: Hospital, surgeon's office, participant's home.

Participants: 82 persons undergoing TKR.

Interventions: Audiorecordings of TKR-specific GI scripts or placebo-control audiorecordings of audiobook segments.

Outcome measures: Gait velocity and Western Ontario and McMaster Universities Arthritis Index (WOMAC) Function scale.

Results: Outcomes for 58 participants (29 receiving GI and 29 controls) were analyzed at 6 months after surgery. The most frequent reason for noncompletion was protocol-driven exclusion at 6 months for having the contralateral knee replaced before the study endpoint ($n=15$). With imaging ability as a moderator, gait velocity, but not WOMAC Function score, was significantly improved at 6 months in the GI group. Participants in the GI group, but not the control group, had lower WOMAC Pain scores at 3 weeks after surgery than at baseline. Hair cortisol concentration was significantly lower at 6 months after surgery than at baseline in the GI group but not the control group. GI group participants had lower treatment adherence but greater treatment credibility than the control group.

Conclusion: Randomized controlled trials of GI in the TKR population are feasible, but inclusion/exclusion criteria influence attrition. Further studies are needed to elaborate this study's findings, which suggest that guided imagery improves objective, but not patient-reported, outcomes of TKR. Hair cortisol concentration results suggest that engagement in a time-limited guided imagery intervention may contribute to stress reduction even after the intervention is terminated. Further investigation into optimal content and dosing of GI is needed.

Introduction

TOTAL KNEE REPLACEMENT (TKR), THE THIRD MOST frequently performed surgery in the United States,¹ is widely considered to have successful outcomes, marked by significant improvement of pre- and postoperative scores on pain and function measures.^{2–8} Nevertheless, a significant proportion of patients report continuing pain, functional limitations, and dissatisfaction up to 2 years after the surgery.^{8–15}

Complementary and alternative strategies that influence mind–body dimensions of the TKR experience may hold potential for improving outcomes in this population.^{16–23} Guided imagery (GI), the generation of self- or practitioner-guided positive sensory (e.g., taste, vision, smell) and affective (e.g., calm, happy) mental images to promote therapeutic outcomes, is a widely used mind–body intervention that may be effective in promoting clinical outcomes, including those of surgery.^{22–25} The goals of GI have been described as empowering patients,

¹Kent State University College of Nursing, Kent, OH.

²Center for the Treatment and Study of Traumatic Stress, Summa Health System, Akron, OH.

³Department of Immunology, Summa Health System, Akron, OH.

⁴Department of Psychiatry, Summa Health System, Akron, OH.

⁵Indiana University School of Nursing, Indianapolis, IN.

⁶Technische Universität Dresden, Dresden, Germany.

promoting healing changes in the body, reducing anxiety and stress, and evoking psychological and physiologic relaxation.^{20,22,25,26} In the context of surgery, GI involves patients imagining healing after surgery and being confident about the health care team.²⁵ Because preoperative psychological states influence postoperative TKR outcomes,^{27,28} complementary and alternative strategies that influence mind–body dimensions of the TKR experience may improve outcomes in this large population.

Despite the frequent claims of GI's effectiveness, critical gaps in the evidence base for its clinical application exist. Exploratory studies suggest a possible "responder" mechanism, in which variations in responses may be due to mechanisms that remain to be elucidated.^{29,30} Although the effectiveness of GI in reducing pain has been studied widely, most of the research has been done on acute pain induced in laboratory situations. Finally, studies of the use of GI for clinical conditions have produced inconsistent results, which may be due to methodologic flaws, such as absent or inappropriate controls; inadequate or absent theoretical frameworks; and variation in timing (frequency and duration), delivery (taped vs. in person), and type (distraction vs. attention-focused).^{31,32} Manipulation and fidelity checks have been absent from GI studies, and thus substantiation of treatment fidelity and whether participants actually used the intervention is lacking.^{33–41} Randomized controlled trials of GI's effects on salient patient outcomes, accounting for theoretically derived mediators and moderators, are needed.⁴² This exploratory pilot study was conducted to examine the effect of GI vs. placebo on functional outcomes of TKR and to identify possible psychological and physiologic variables associated with GI response in persons undergoing TKR.

Psychological Variables and TKR Outcomes

The association of preoperative psychological attributes with outcomes of total joint replacement surgery has been explored.^{15,27,43–49} For example, in a study of 102 patients undergoing total hip replacement, patients' perioperative emotional state was a stronger predictor of functional status 6 months after surgery than was degree of surgical trauma.⁴³ Moreover, in a study of 952 patients who underwent TKR, preoperative psychological distress was associated with greater postoperative pain for up to 2 years.⁴⁷ Three other studies of TKR outcomes found that negative preoperative emotional state and avoidant postoperative coping strategies were associated with poorer postoperative functional status.^{44,45,49} Furthermore, in a prospective study of 74 patients undergoing TKR, individual differences in psychosocial variables accounted for significant differences in functional outcomes. Specifically, expectancies about outcome (pessimism, chance of recovery, change in quality of life) and beliefs about efficacy (ability to cope and arthritis helplessness) accounted for more than 10% of the variance in physical health improvements from TKR. Thus, a mind–body intervention such as GI might have beneficial effects on TKR outcomes through improving patients' psychological states.⁴⁶

Catastrophizing is a cognitive and affective orientation to pain that has a negative influence on pain-related outcomes.^{50–52} In one recent investigation of 140 patients undergoing TKR, pain catastrophizing was the sole predictor of poor TKR outcome.⁵³ Catastrophizing may increase

macrophage activation and thus inflammation, as suggested by a study of laboratory-induced pain in 42 healthy volunteers.⁵¹ The fear-avoidance model of pain posits that catastrophizing leads to fear of movement (kinesophobia),⁵⁴ which may lead to avoidant coping⁴⁹ and negatively affect functional status and quality of life after TKR through reduced commitment to postoperative rehabilitation participation.⁵⁵ Incorporating imagery exercises in athletic training and stroke rehabilitation improves performance and recovery.^{56,57} In a study of 191 older adults with knee pain and osteoarthritis, the desire to improve their health and the expectation that exercise would accomplish this were the most significant motivators for participation in an exercise program.⁵⁸ Similarly, self-efficacy, or belief in the ability to perform a required behavior to produce an outcome, was a significant predictor of postoperative exercise in 50 patients who had had total knee or total hip replacements.⁵⁹ Imagining a desired future and the processes to attain it is hypothesized to increase motivation and effort.^{60,61} Imaging ability, the capacity to create vivid mental images (image generation) and become so absorbed in them as to experience them as if they were real (absorption), has been proposed to moderate the relationship between GI and outcomes.⁶²

Physiologic Variables and TKR Outcomes

The physiologic stress response, characterized by endocrine and neuroimmune mechanisms, may also influence TKR outcomes.^{63–68} The stress response is linked to sickness response and immune-mediated analgesia, physiologic processes that may mediate the effect of GI on TKR. The sickness response is initiated and perpetuated by stress, while innate immune-mediated analgesia is altered by stress. Recent studies suggest a common profile of psychological stressors associated with TKR surgery and the period leading up to it. In one of the authors' prior studies, participants described stressors of worry, pain, fear of anesthesia, complications, death, and loss of control,⁶⁹ concerns that are echoed in other studies examining the TKR experience from the patient's perspective.^{70–72} Such psychological stressors can elicit neuroimmune responses similar to those initiated by physical trauma and/or inflammation, although the physiologic mechanisms related to psychological stress are not as well understood.^{23,73,74} Hypothalamus-pituitary-adrenal (HPA) activation, prolonged sickness response, and dysregulation of immune-mediated analgesia can be modulated by GI, which decreases allostatic load and allows for normalization of endocrine and neuroimmune functions.^{75–79}

Materials and Methods

Study aims

The aims of this investigator-blinded, randomized, controlled pilot study were to (1) test the effect of GI on functional outcomes of TKR as moderated by imaging ability; (2) describe group and time differences of potential psychological, endocrine, and neuroimmune mediating and moderating variables; and (3) assess feasibility of study implementation.

Participants and setting

This project was approved by the Summa Health System and Kent State University institutional review boards.

Potential participants were recruited from patients of a single orthopedic surgeon during their preoperative office visit, between June 2011 and November 2012. The surgeon performs a high volume of joint replacement surgery at a single hospital using a standardized approach. Of the 239 patients who agreed to be approached about the study, 129 agreed to be screened for eligibility by telephone after their office visit. Inclusion criteria were as follows: scheduled for a single TKR; age 21 years or older; attendance at hospital-sponsored joint replacement class; and ability to speak, read, and write English. Exclusion criteria were the following: current or planned use of GI; body mass index of 40 kg/m² or higher; history of total joint replacement; current enrollment in another clinical study; diagnosis of rheumatoid arthritis; self-reported sensory, cognitive, neurologic, or motor impairment that would limit participation in study; history of psychosis; or comorbidities that would impair recovery, such as hemiparesis, peripheral neuropathy, lymphedema, or lower-extremity amputation. All criteria were assessed by self-report during a telephone screening interview, except for cognitive ability, which required a score of 21 or greater on the modified Telephone Interview of Cognitive Status.⁸⁰ Figure 1 summarizes the details of participant enrollment and study completion.

Procedures

Persons who fulfilled eligibility criteria met with study staff at the hospital on the day of their preadmission testing appointment (T1). Those who agreed to participate signed a consent form. After collection of baseline data (Table 1), participants were randomly assigned to the treatment or control group via receipt of sequentially numbered study packets of CDs stored in opaque nylon CD holders, so that neither the study staff member nor the participant was aware of treatment assignment. The allocation schedule was generated by permuted block randomization with random block sizes of 4, 6, and 8 to yield equal-sized groups for both arms of the clinical trial. After demonstrating use of equipment, the blinded study team member provided the participant with the study CDs, a CD player, headphones, a study journal, and written instructions for using the CDs at home.

Participants were instructed to listen to a CD every day for 2 weeks before and 3 weeks after surgery; they were told to miss no more than 2 days a week if possible. Data were collected at three time points after enrollment, culminating at 6 months postoperatively (Table 1). A research staff member not otherwise involved in the study called participants weekly during the intervention phase to answer questions and identify

FIG. 1. Flow diagram of participant enrollment and allocation. TKR, total knee replacement.

¹"Mixed" intervention: combination of experimental and control interventions at pre- and postop

TABLE 1. OVERVIEW OF STUDY MEASURES, DATA POINTS, AND PROCEDURES

Variable	Time			
	T1: Baseline (2–3 wk before surgery)	T2: day of surgery ^a	T3: 3 wk after surgery	T4: 6 mo after surgery
Treatment and control intervention	Preoperative CDs: one daily for 2 wk	Intraoperative CD: once on day of surgery	Postoperative CD: once daily for 3 wk	
Biomarkers				
Cytokines (IL-1 β , IL-6, TNF)	✓	✓	✓	
PHA (lymphocyte proliferation)	✓	✓	✓	
LPS (macrophage proliferation)	✓	✓	✓	
Hair cortisol	✓			✓
Self-report measures				
Imaging Ability Questionnaire ¹⁰¹	✓			
Pain Catastrophizing Scale ¹⁰²	✓	✓	✓	✓
Tampa Kinesophobia Scale ¹⁰³	✓	✓	✓	✓
TKR Outcome Expectancy ^b	✓	✓	✓	
Self-Efficacy for Rehabilitation Scale ¹⁰⁴	✓	✓	✓	
WOMAC ¹⁰⁵	✓	✓	✓	✓
SF-36 (Acute Version) ¹⁰⁶	✓	✓	✓	✓
Daily Pain VAS	✓	✓	✓	
CD Use Questionnaire ²	✓	✓	✓	✓
Functional measure				
Timed 10-m walk ¹⁰⁷	✓		✓	✓
Feasibility measures				
Expectancy/Treatment Credibility Check ⁹⁹	✓	✓	✓	
Fidelity Check ²	✓	✓	✓	

^aSelf-report measures were completed at home the day before surgery for T2.

^bTKR Outcome Expectancy (Appendix A), CD Use Questionnaire (Appendix B), and Fidelity Check (Appendix C) were developed for use in this study.

IL, interleukin; TNF, tumor necrosis factor; PHA, phytohemagglutinin; LPS, lipopolysaccharide; TKR, total knee replacement; WOMAC, Western Ontario and McMaster Universities Arthritis Index; SF-36, Short-Form 36; VAS, visual analog scale.

any problems with the protocol or intervention. Participants were provided with a phone number to call to report any issues with the study or equipment. Equipment issues were resolved within 1 day of occurrence (e.g., replacement of skipping CDs, battery replenishment). Participants were instructed not to disclose their treatment allocation to study personnel in order to preserve blinding. When blinding breaks occurred, subsequent data collection was assigned to a blinded staff member.

Guided imagery treatment

The GI intervention consisted of professionally produced 19- to 21-minute audiorecordings designed for this project to promote functional outcomes after TKR. Participants' concerns and hopes about TKR identified in a previous study⁶⁹ were incorporated into the scripts to facilitate mind-body connections to promote optimal TKR outcomes. Scripts for each of the pre-, intra-, and postoperative periods were developed and read by an experienced GI practitioner (Jane Pernotto Ehrman, MEd) and recorded with a soothing instrumental music background (Kohn SM. Music for Relaxation and Meditation #2 in D Flat. Unpublished manuscript).

Placebo control treatment

The placebo control treatment consisted of 17- to 21-minute commercially available audiorecordings (e.g., poetry, short

stories, essays), selected according to reports of preferences from a previous pilot study,⁸¹ that were copied onto individual study CDs following copyright clearance from the publisher.

Measures

Main outcome variables (function and gait velocity). TKR outcome variables were assessed with patient-reported outcome measures of functional status and a clinician-administered physical performance measure⁸² (walking velocity). Patient-reported outcome measures of functional status are important indicators of patients' perspectives after TKR⁷ and should include both general and disease-specific health assessments.^{47,83,84} This study used the Short Form-36, the most commonly used general health assessment, as well as the Western Ontario and McMaster Universities Arthritis Index (WOMAC), a measure specific to lower-extremity function. Although both of these instruments contain scales on physical function and pain, the disease-specific WOMAC is most sensitive to change after therapy or surgery for knee osteoarthritis,^{3,6,46,84–890} and thus was used as the primary measure of TKR outcome. The SF-36 Acute Version, which uses a 1-week recall period,^{90,91} was used as a secondary outcome measure. A physical performance measure, the Timed 10-Meter Walk, was used to objectively assess outcomes.⁸²

Psychological variables. Measures of a potential moderator (imaging ability) and mediators (optimism/pessimism, distress,

TABLE 2. PARTICIPANT CHARACTERISTICS BY TREATMENT GROUP (N=82)

Variable	Range	Mean	SD	Patients, n (%)	p-Value
Age (yr)	41–81	65.0	8.6		0.198
GI	47–81	66.1	8.2		
Control	41–78	63.7	8.8		
Imaging ability questionnaire score	11–121	68.7	22.0		0.648
GI	38–121	69.8	20.6		
Control	11–113	67.6	23.5		
Body mass index (kg/m ²)	22.7–40.1	31.6	5.0		0.188
GI	22.7–40.1	30.9	5.2		
Control	24.4–39.7	32.3	4.5		
Male				31 (37.8)	0.116
GI				19 (45.2)	
Control				12 (30)	
White				7 (93.9)	0.477
GI				40 (95.2)	
Control				37 (92.5)	

GI group: *n* = 42; control group: *n* = 40.
SD, standard deviation; GI, guided imagery.

self-efficacy for rehabilitation, outcome expectancy, pain catastrophizing, and fear of movement) were conducted using well-established and widely used self-report instruments (Table 1).

Physiologic variables. Lymphocyte and macrophage proliferation and cytokine levels were measured using flow

cytometry and multiplex methods. Whole blood was stimulated with phytohemagglutinin (a T-cell mitogen) or lipopolysaccharide (a B-cell and monocyte mitogen). T-cell activation was measured via flow cytometric measurement of the induced expression of the activation marker CD69. Monocyte function was measured by the lipopolysaccharide-induced release of cytokines using Luminex based assays (ThermoFisher Scientific, Waltham, MA). Background and stimulated values for CD69 expression and cytokine release were recorded.

Hair cortisol concentration (HCC) was obtained from hair strands of approximately 3 mm diameter cut from the posterior vertex area of the scalp at baseline and T4. HCC in the proximal 3-cm hair segment was measured to indicate integrated cortisol secretion over the 3-month period before hair sampling.⁹² HCCs were determined at the endocrine laboratory of C.K. using a commercially available luminescence assay (LIA IBL, Hamburg, Germany).

Feasibility and acceptability variables. Participants completed daily diaries during the intervention phase of the study to assess percentage of use of the assigned intervention as well as responses to it (Appendix C). Adherence scores were calculated for pre- and postoperative periods by dividing the total number of “yes” responses to each of the five questions, divided by the number of days in that period. Treatment credibility was assessed via the credibility scale of the Credibility/Expectancy Questionnaire.⁹³ The diary also solicited narrative comments about feasibility, acceptability, and benefit and burden of participation; results of the analysis of these qualitative data are reported elsewhere.⁹⁴ Blinding breaks were recorded if participants disclosed their treatment assignment to the study team member during data collection at T2–T4.

TABLE 3. MODEL SUMMARY FOR MODERATION EFFECT OF IMAGING ABILITY ON 6-MONTH POSTOPERATIVE GAIT VELOCITY

R	R ²	MSE	F	df1	df2	p-Value
6404	0.4101	3.4893	7.2988	4	42	0.0001
Model						
Variable	Coefficient	SEM	t	p-Value	LLCI	ULCI
Constant	1.1960	1.6828	0.7107	0.4812	−2.2000	−4.5920
Imaging ability	0.0399	0.0168	2.3793	0.0220	0.0061	0.0738
Group	3.5328	1.9143	1.8455	0.0720	−0.3304	7.3960
Group×imaging ability	−0.0655	0.0259	−2.5256	0.0154	−0.1178	−0.0132
Time to walk (T1)	0.4561	0.1246	3.6600	0.0007	0.2046	0.7076
Interaction: Group×Imaging Ability: R ² Increase Due to Interaction						
R ² change	F	df1	df2	p-Value		
0.0896	6.3789	1	42	0.0154		
Conditional Effect of Imaging Ability on Gait Velocity at Mean and ± SD on Imaging Ability						
Imaging ability	Effect	SEM	t	p-value	LLCI	ULCI
48.2	0.3757	0.8023	0.4682	0.6420	−1.2435	1.9948
70.3	−1.0702	0.5510	−1.9422	0.0588	−2.1823	0.0418
92.4	−2.5161	0.7868	−3.1979	0.0026	−4.1040	−0.9283

MSE, mean squared error; SEM, standard error of the mean; LLCI, lower limit confidence interval; ULCI, upper limit confidence interval.

FIG. 2. Moderating effect of imaging ability on gait velocity, controlling for baseline values.

Data analysis

Data were entered using the double-entry technique for accuracy⁹⁵ and analyzed with IBM SPSS Statistics (IBM, Armonk, NY). Frequencies, percentages, means, and standard deviations (SDs) were calculated to describe the sample. Tests of moderation for aim 1 were conducted with the PROCESS add-in for SPSS,⁹⁶ excluding cases as indicated in Figure 1. Differences between group means were analyzed with two-tailed *t* tests, and effect sizes were generated to address aim 2. For the HCC analysis, additional participants who reported receiving oral or parenteral steroids after

surgery were excluded. Means, SDs, percentages, and two-tailed *t* tests and effect sizes were conducted to address aim 3. The α level was set at 0.05.

Results

Sample

A total of 82 participants were recruited between June 2011 and November 2012 (Table 2). At the 6-month postoperative data collection point (T4), 29 participants per group had met criteria for complete analysis (Fig. 1).

Aim 1: effect of GI on 6-month postoperative function and gait velocity

SPSS PROCESS⁹⁶ was used to examine the effect of GI versus placebo, moderated by imaging ability, on the main outcome variables of gait velocity and knee function, controlling for baseline levels. (The effective sample sizes for these two analyses were reduced because of the exclusion of participants who received mixed interventions, had postponed surgery dates, underwent TKR on the contralateral knee during the study follow-up period, and/or had missing data on the variables included for analysis.) There was a significant group-by-imaging ability interaction on gait velocity (Table 3; Fig. 2) but not on knee function ($R^2=0.0822$; $F[4, 53] 1.1860$; $p=0.3277$).

Aim 2: group and time differences of potential mediating and moderating variables

Means and SDs according to treatment group and time were computed. Differences in mean scores from baseline (T1) for each time (T2–T4) in each treatment group were

TABLE 4. MEANS AND SDs OF PHYSIOLOGIC VARIABLES

Variable	Group	T1		T2			T3			T4		
		M	SD	M	SD	ES	M	SD	ES	M	SD	ES
IL unstimulated	Control	8.9	13.1	12.3	26.2	-0.17	15.3	29.7	-0.28			
	GI	6.8	11.7	3.8	3.2	0.10	8.7	9.7	-0.50			
IL-1S stimulated	Control	2094.4	1743.6	1778.0	1339.3	0.07	2268.8	1605.4	-0.01			
	GI	1983.9	1625.2	1619.0	1463.2	0.18	2047.6	1691.2	-0.21			
IL-6 unstimulated	Control	41.4	46.3	52.8	91.5	-0.08	45.9	66.6	-0.41			
	GI	37.8	59.0	18.3	10.0	0.33	34.4	34.0	-0.08			
IL-6 stimulated	Control	6844.5	3812.7	6274.1	3756.3	0.07	5358.8	3378.8	0.16			
	GI	6454.0	4231.1	5291.4	2899.4	0.48	5482.9	3157.9	0.15			
TNF unstimulated	Control	30.3	26.5	126.9	370.2	-0.33	55.5	119.9	-0.36			
	GI	40.4	75.9	25.3	24.1	0.03	53.6	100.8	-0.25			
TNF stimulated	Control	6409.6	4896.5	6022.7	3923.3	0.10	4650.9	2988.3	0.38			
	GI	6646.3	4797.8	4420.9*	3167.8	0.60	5722.9	3831.7	0.34			
CD69 unstimulated	Control	1.6	0.4	1.6	.3	0.13	1.6	0.4	0.01			
	GI	1.6	0.3	1.7	.3	-0.08	1.7	0.3	-0.11			
CD69 Stimulated	Control	60.6	22.5	59.9	21	-0.04	54.6	18.9	0.26			
	GI	61.0	22.4	62.1	15.4	0.08	47.7*	19.2	0.46			
Hair cortisol	Control	55.0	105.7							47.5	106.6	-0.05
	GI	141.3	383.2							17.6*	25.0	0.57

Means and SDs included all valid data for time point indicated (i.e., not missing, not excluded for reasons indicated in Fig. 1). Effect size calculated from pairwise valid data. Mean is statistically significantly different from T1 baseline.

* $p < 0.05$.

TABLE 5. MEANS AND SDs OF PSYCHOLOGICAL AND FUNCTIONAL VARIABLES

Variable	Group	T1		T2			T3			T4		
		M	SD	M	SD	ES	M	SD	ES	M	SD	ES
Pain catastrophizing	Control	12.1	10.8	10.6	7.9	0.16	5.6***	7.4	0.77	4.1***	6.5	0.72
	GI	10.7	8.9	8.7	7.7	0.19	5.4**	8.4	0.49	2.1***	3.4	0.98
Kinesophobia	Control	24.1	6.9	23.5	6.9	0.11	18.8***	5.8	1.06	20.0**	6.4	0.59
	GI	22.2	5.2	21.3	5.6	0.25	17.3***	5.6	1.04	16.8***	5.0	0.97
TKR outcome expectancy	Control	21.3	2.3	20.7	2.6	0.21	21.7	3.1	-0.10	21.1	3.0	-0.11
	GI	21.2	2.9	21.5	2.3	-0.09	21.7	2.9	-0.10	20.2	4.1	0.28
Self-efficacy for rehabilitation	Control	109.4	16.6	110.7	11.9	-0.11	112.5	10.1	-0.22			
	GI	110.1	16.6	110.7	11.9	-0.05	111.7	12.5	-0.10			
Helplessness	Control	12.9	3.0	12.9	3.4	0.01	10.7**	3.8	0.52	8.9***	3.7	0.89
	GI	12.1	3.3	11.1*	3.1	0.39	10.1**	3.4	0.55	8.0***	3.1	0.93
Pessimism	Control	25.5	3.6	25.4	3.8	0.08	25.3	4.3	0.12	26.1	3.4	-0.29
	GI	24.0	4.9	24.1	4.4	-0.01	24.8	3.9	-0.19	23.6	4.7	0.15
Worry	Control	39.3	14.0	38.9	12.7	0.05	36.3*	11.2	0.40	33.1***	9.9	0.67
	GI	38.8	11.7	37.7	13.6	0.24	37.0*	12.5	0.39	37.4	10.9	0.24
Negative affect	Control	15.0	4.5	16.3	5.7	-0.25	13.7	5.0	0.28	12.6*	3.7	0.42
	GI	17.1	6.6	16	5.3	0.20	14.1*	5.0	0.43	14.8	5.3	0.28
Positive affect	Control	36.6	6.5	34.7	6.5	0.30	34.9	7.4	0.22	38.1*	6.3	-0.41
	GI	33.1	7.7	34.3	6.2	-0.22	34.4	8.7	-0.19	35.6	7.1	-0.23
SF 36 Physical	Control	38.2	6.3	37.6	7.2	0.12	35.2	7.7	0.32	47.3***	7.5	-1.23
	GI	40.8	7.4	39.6	7.0	0.28	37.4*	8.2	0.41	50.4***	6.0	-1.04
SF 36 Mental	Control	55.0	8.6	53.0	8.0	0.31	53.4	9.7	0.16	57.1	6.4	-0.27
	GI	52.3	11.2	53.8	10.7	-0.27	52.8	14.3	-0.12	53.2	8.2	-0.10
Daily pain VAS	Control	—	—	1.9	1.7	—	3.4**	2.2	—	—	—	—
	GI			2.7	2.0		3.7	2.0				
WOMAC Pain	Control	8.2	3.4	8.2	3.8	0.00	7.1	2.9	0.26	3.5***	3.3	0.96
	GI	8.6	3.6	7.8	3.1	0.35	6.9**	2.8	0.47	2.7***	3.1	1.37
WOMAC Stiffness	Control	3.9	2.1	3.9	1.9	0.07	3.6	1.2	0.12	2.1***	1.9	0.73
	GI	3.9	1.7	3.7	1.7	0.16	3.8	1.3	0.06	1.9***	1.4	0.82
WOMAC Function	Control	28.7	10.2	28.4	13.4	0.03	21.3**	11.7	0.52	10.2***	10.5	1.36
	GI	26.3	11.5	24.0	10.8	0.25	19.6**	9.5	0.55	7.2***	7.1	1.44
WOMAC Total	Control	40.9	14.5	40.6	18.4	0.02	32.0**	14.8	0.45	15.8***	14.6	1.28
	GI	38.7	15.7	35.5	14.7	0.27	30.3**	12.5	0.51	11.8***	10.8	1.45
Timed Walk in Seconds	Control	10.0	2.5	—	—	—	17.8*	22.1	-0.37	8.5***	2.3	0.75
	GI	10.2	2.6				14.0***	3.2	-1.17	7.4***	2.2	1.07

Means and SDs included all valid data for time point indicated (i.e., not missing, not excluded for reasons indicated in Fig. 1). Effect size calculated from pairwise valid data. Mean is statistically significantly different from T1 baseline (T2 baseline for daily pain VAS).

* $p < 0.05$.

** $p < 0.01$.

*** $p < 0.001$.

ES, effect size.

TABLE 6. PERCENTAGE OF COMPLIANCE/FIDELITY DURING PREOPERATIVE PERIOD

Variable	Group	Patients (n)	Mean (%)	SD	t	p-Value
Listened to CD daily	Control	39	95.93	0.07313	2.368	0.021
	GI	41	90.36	0.13054		
Remained awake	Control	39	94.77	0.08722	1.478	0.144
	GI	41	90.95	0.13971		
Mind wandered	Control	39	38.26	0.28811	-2.491	0.015
	GI	40	54.89	0.30495		
Interrupted during CD	Control	39	9.12	0.18371	-0.154	0.878
	GI	39	9.66	0.12320		
Felt tuned in to content	Control	39	72.61	0.21178	-1.361	0.177
	GI	41	79.51	0.23996		

Differences in group size due to missing data.

TABLE 7. PERCENTAGE OF COMPLIANCE/FIDELITY DURING POSTOPERATIVE PERIOD

	Group	Patients (n)	Mean (%)	SD	t	p-Value
Listened to CD daily	Control	37	94.56	0.07956	2.147	0.036
	GI	35	89.44	0.11792		
Remained awake	Control	37	90.75	0.12358	1.568	0.123
	GI	35	84.17	0.21720		
Mind wandered	Control	37	40.91	0.27150	-1.654	0.103
	GI	33	52.58	0.31895		
Interrupted during CD	Control	37	11.83	0.13643	-0.660	0.511
	GI	33	14.61	0.21178		
Felt tuned in to content	Control	37	67.79	0.21749	-0.465	0.643
	GI	35	70.73	0.31212		

Differences in group size due to missing data.

analyzed with paired *t* tests, and effect sizes were calculated (Tables 4 and 5). The only variable with a statistically significant difference in mean score from T1 (baseline) to T2 (day before surgery) was arthritis-related helplessness, which decreased from 12.1 (SD, 3.3) to 11.1 (SD, 3.1) in the GI group. At T3 (3 weeks after surgery) and T4 (6 months after surgery), the means for pain catastrophizing, kinesophobia, and arthritis-related helplessness were significantly lower for both groups. Negative affect was lower after surgery for both groups, statistically significantly so at T3 for the GI group and T4 for the control group. Worry also decreased in both groups after surgery, although the difference was not statistically significant in the GI group at T4. Positive affect differed from baseline only in the control group at T4, where it was significantly higher.

Statistically significant differences and predominantly large effect sizes were obtained in both groups in differences from baseline at T4 (6 months after surgery) for functional measures (SF 36 Physical Component; WOMAC Pain, Stiffness, Function, and Total; and timed walking test). At T3 (3 weeks after surgery), control group participants had significantly higher mean daily pain visual analog scale (VAS) scores than in the preop period, whereas the GI group participants had significantly lower pain on the WOMAC than at T1 (baseline) (Table 5).

Cytokine levels did not differ from baseline for either group, with two exceptions in the GI group (Table 4). Tumor necrosis factor unstimulated was significantly lower at T2 and CD69 stimulated was significantly lower at T3. HCCs were significantly lower than baseline at 6 months after surgery in the GI group but was not statistically significantly different in the control group.

Aim 3: feasibility

To assess study feasibility, experiences with and adherence to treatment, treatment credibility, and implementation integrity were examined.

Experience with treatment. Tables 6 and 7 present the mean percentages of the participants' listening experiences (Appendix C). Persons in the GI group had significantly lower percentages of daily listening, and more instances of mind wandering, in both pre- and postoperative periods.

Treatment credibility. At both time points (T2 and T3), participants in the GI group had statistically significantly higher scores on the treatment credibility scale (Table 8).

Other reported implementation issues included possible diffusion of treatment (participants' affirmative response to question at T4 if they spoke to other study participants during the study), breaking of blinding during data collection, and minor issues with equipment (e.g., battery replacement) (Table 9).

Implementation integrity. The study experienced a 29% attrition rate (24 noncompleters) (Fig. 1). The most frequent reason for noncompletion was having the contralateral knee replaced before the study endpoint (*n* = 15). Other reported implementation issues included possible diffusion of treatment (participants' affirmative response to question at T4 if they spoke to other study participants during the study), breaking of blinding during data collection, and minor issues with equipment (e.g., battery replacement) (Table 9).

Discussion

Function and pain

Results of this study suggest that prerecorded GI may be a beneficial intervention for persons undergoing TKR, particularly those with high imaging ability. Specifically, regarding study aim 1, persons in the GI group had a faster gait velocity 6 months after surgery than did those in the control group, after adjustment for baseline values and moderated by imaging ability (Table 3, Figure 2). However, the effect of GI on the patient-reported outcome measure of

TABLE 8. MEAN TREATMENT CREDIBILITY SCORES BY GROUP (REPORTED AS *Z*-SCORES)

Variable	Group	Patients (n)	Mean (%)	SD	t	p-Value
T2 (1 d before surgery, following 2 wk of intervention)	Control	39	-1.5463	4.82130	-3.082	0.003
	GI	37	1.6299	4.11147		
T3 (3 wk after surgery, following 5 wk of intervention)	Control	39	-1.2632	5.83304	-2.099	0.039
	GI	37	1.3314	4.87213		

TABLE 9. FREQUENCY OF STUDY IMPLEMENTATION ISSUES (N=82)

Group	<i>Possible treatment diffusion</i>		<i>Blinding break</i>		<i>CD equipment issue</i>		<i>Surgery postponed</i>	
	<i>f</i>	<i>Patients (%)</i>	<i>f</i>	<i>Patients (%)</i>	<i>f</i>	<i>Patients (%)</i>	<i>f</i>	<i>Patients (%)</i>
GI (n=42)	2	4.8	11	26.2	5	11.9	3	7.1
Control (n=40)	1	2.5	7	17.5	5	12.5	0	0

knee function, moderated by imaging ability and adjusted for baseline, was not significant.

Persons receiving GI fared significantly better with postoperative pain scores than those receiving the control intervention: They had significantly lower WOMAC knee pain scores 3 weeks after surgery than at baseline, whereas the control group had significantly higher mean daily pain visual analog scale scores in the 3-week postoperative period compared with their 2-week mean daily pain (Table 6). Because pain in the perioperative period is a major concern of persons undergoing TKR,⁶⁹ further study on nonpharmacologic interventions, such as GI, to manage pain during this period is warranted.

In both groups, all functional measures improved significantly at 6 months after surgery, a finding that is consistent with other reports of TKR outcomes. Similarly, both groups also experienced significant reductions in pain catastrophizing, kinesophobia, and helplessness by the study endpoint, suggesting that TKR may also contribute to resolution of negative attitudes about pain and mobility. Further studies with sufficient power are needed to more fully examine these and other potential mediators and moderators.

Neuroimmune effects

Differences in unstimulated and stimulated cytokine levels from baseline values were largely insignificant, except that in the GI group, tumor necrosis factor stimulated at T2 and CD69 stimulated at T3 were significantly different (Table 4). These findings suggest that GI may reduce the inflammatory and proliferative capability of monocytes and T cells, respectively. If further studies confirm these findings, additional research is indicated to determine whether these effects reduce pain and improve function in persons undergoing TKR.

HCCs were significantly lower at T4 from baseline in the GI group, suggesting that this group, but not the control group, had significantly lower HPA activation from 3 to 6 months after surgery than during the 3 months before surgery. Although persons in the study stopped engaging in the intervention 3 weeks after surgery, participants in the GI group may have gained stress reduction techniques as a result of 5 weeks of GI intervention 6 months earlier. This explanation is compatible with previous reports of a “carryover” effect from a brief GI intervention,⁹⁷ which may lead to persistent effects of relaxation, enhanced pain management, and improved outlook and mood.⁹⁴ Our HCC data are in line with recent research suggesting that hair cortisol analysis is a useful tool to evaluate the effects of a stress-reduction intervention on long-term cortisol secretion.⁹⁸

Feasibility

The GI treatment was perceived as more credible than the placebo control intervention (Table 9). Treatment credibility is an important attribute for complementary therapies.⁹⁹ Never-

theless, the GI group experienced a higher dropout rate (Fig. 1), poorer adherence with the intervention, and more mind wandering (Tables 5 and 7) than did the control group. Reasons for this are unclear but may be due to the intervention not being a good fit with individuals’ preferences or to inappropriate intervention frequency or duration. Because prior studies of GI have used widely differing types and doses of the intervention, further studies are needed to identify optimal dosing.⁹⁴

Study integrity data (Table 9) demonstrate feasibility of implementation protocols. Participant retention was most adversely affected by protocol-driven exclusion of participants from end point analyses because of TKR performed on the contralateral knee (15 of the initial 82 participants). Although this study’s sampling strategy excluded individuals who had undergone a prior joint replacement surgery in order to achieve a more homogenous sample, future studies of functional outcomes of TKR should consider the implications of such exclusions because surgery on the contralateral knee is common and may confound results of studies examining outcomes.¹⁰⁰ Blinding breaks occurred at the highest rate, even though patients were instructed not to reveal their treatment assignment during interactions with study staff. The unblinded staff member was prevented from further interactions with participants to minimize influence of this occurrence.

Conclusions

In this study, GI was superior to a placebo-control intervention for gait velocity outcomes in participants with high imaging ability, confirming results of previous studies on the effect of GI imaging as a moderator. In addition, HCC results in GI participants suggest that they had lower HPA activation in this period than before surgery. Findings suggest that a randomized controlled trial of self-administered GI in the TKR population is feasible but that issues such as equipment and attrition should be addressed.

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Address correspondence to:
 Ann F. Jacobson, PhD, RN
 Kent State College of Nursing
 P.O. Box 5190
 Kent, OH 44242

E-mail: ajacobso@kent.edu

(Appendix follows →)

APPENDIX A. TOTAL KNEE REPLACEMENT OUTCOME EXPECTANCY INSTRUMENT

The statements listed below describe expectations for what you think the outcomes of your total knee replacement will be. Please rate how strongly you agree with each statement using the rating scale on the right.

<i>Circle the number that indicates how strongly you agree with each statement.</i>	<i>Strongly disagree</i>	<i>Disagree</i>	<i>Do not agree or disagree</i>	<i>Agree</i>	<i>Strongly agree</i>
When I have recovered from the surgery:					
1. My condition will be significantly improved.	1	2	3	4	5
2. I will continue to have pain.	1	2	3	4	5
3. I will be able to do things I used to do before my knee problems.	1	2	3	4	5
4. My life will be back to normal.	1	2	3	4	5
5. Going through the surgery will be worth it in the end.	1	2	3	4	5

APPENDIX B. GUIDED IMAGERY (CD/AUDIOBOOK) USE QUESTIONNAIRE

Please circle the number that best represents your reaction to the guided imagery (CD/audiobook) intervention you have taken part in:

<i>Question</i>	<i>Not at all</i>	<i>A little</i>	<i>A medium amount</i>	<i>A lot</i>
1. Using the guided imagery [listening to the audiobook] has been helpful.	1	2	3	4
2. I like the background music on the guided imagery [audiobook] CD.	1	2	3	4
3. I like the verbal content of the CD.	1	2	3	4
4. I would use guided imagery [an audiobook] again in the future.	1	2	3	4
5. I would recommend guided imagery [an audiobook] to a friend or family member.	1	2	3	4
6. I had difficulty creating images during the guided imagery [intervention].	1	2	3	4
7. My mind wandered during the imagery [intervention].	1	2	3	4
8. The images appeared real.	1	2	3	4
9. I felt relaxed after the imagery [intervention].	1	2	3	4
10. I had difficulty concentrating on the imagery [audiobook].	1	2	3	4
11. I enjoyed doing the guided imagery [intervention].	1	2	3	4

Items 1–5 adapted from:

Haase O, Schwenk W, Hermann C, Müller JM. Guided imagery and relaxation in conventional colorectal resections: a randomized, controlled, partially blinded trial. *Dis Colon Rectum* 2005;48:1955–1963 and Manyande A, Berg S, Gettins D, et al. Preoperative rehearsal of active coping imagery influences subjective and hormonal responses to abdominal surgery. *Psychosom Med* 1995;57:177–182.

Items 6–11 adapted from:

Kwekkeboom K, Huseby-Moore K, Ward S. Imaging ability and effective use of guided imagery. *Res Nurs Health* 1998;21:189–198.

APPENDIX C. QUESTIONS IN DIARY COMPLETED DURING INTERVENTION PHASE TO ASSESS FEASIBILITY/ACCEPTABILITY

<i>Item</i>	<i>Yes</i>	<i>No</i>
1. I listened to a CD today.		
2. I remained awake for the entire CD.		
3. My mind wandered during the CD.		
4. I was interrupted during the CD.		
5. I felt tuned in to the CD's content.		