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**THE EFFECT OF EARTH PULSE ON
LEARNING OF DECLARATIVE KNOWLEDGE**

A Thesis in

Instructional Systems

by

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ABSTRACT

The purpose of this double-blind, bio-medical research study was to investigate the effect of EarthPulse, a brainwave entrainment and pulsed electromagnetic field (PEMF) device, on learning of declarative knowledge. Currently, PEMF research explores physiological and psychological effects but a gap exists in the potential effects of PEMF on learning.

The study explored whether a relationship existed between receiving a thirty minute EarthPulse treatment on the “Entrain Up” setting and learning of declarative knowledge; whether the relationship remained over time; whether EarthPulse had an effect on sleep; and whether EarthPulse had an effect on attrition.

Ninety-eight, randomly assigned, undergraduate students participated in this double-blind, experimental design study, of which 87 remained after attrition. After receiving a thirty minute EarthPulse or placebo treatment, experimental and control groups read identical passages and completed identical instruments to test learning and retention of declarative knowledge. Participants completed the same test in two intervals: an immediate (learning) and delayed (retention) posttest.

Assumptions for normality and reliability were met. One-way ANOVA revealed no statistically significant effects on learning or retention at the 0.05 level. However, Chi square analysis revealed those who received the EarthPulse treatment were significantly less likely to fall asleep than those who received the control treatment ($p=0.022$) and very closely approached significance for attrition ($p=0.051$).

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CHAPTER 1:

INTRODUCTION

The world is increasingly becoming a land of electronic devices and communication where electromagnetic frequencies are emitted far above the natural dominant frequency of the Earth (7.8 Hz). To make technologies possible, many devices emit pulsed electromagnetic frequencies. As technologies evolve, it will become increasingly important to research how technological advancements are influencing our current lives and development. The implications of such exposure may have effects on a variety of levels, including environmental, cultural, physiological, psychological, and spiritual. This study focuses specifically on cognition and uses a device that aims to decrease the effects of overexposure to high levels of pulsed electromagnetic fields.

The questions in this study are not raised to deter technological advancement, but rather to challenge thinking, increase awareness, and decrease ignorance towards the long-term implications of automatically adopting and excessively utilizing emerging technologies.

Purpose and Background

The purpose of this study was to explore the effect of EarthPulse on learning of declarative knowledge. Learning of declarative knowledge relies upon the mental processing of information that takes place in the brain. As the brain processes information, electrical frequencies, referred to as brainwaves, are emitted. EarthPulse purports to change these electrical frequencies in the brain through entrainment by using non-invasive, pulsed electromagnetic technology.

EarthPulse was solely used on the “Entrain Up” (EU) setting for this study. The EU setting is designed to first eliminate a person’s electromagnetic anomalies and then stimulate an attention state where no anomalies exist to inhibit attention; thereby, the brain is left in this increased attentive state. This study explored the effect of this increased level of attention on learning of declarative knowledge.

Research Questions

Based on the purpose of this study, the following research questions were proposed.

Question 1

RQ 1: Does EarthPulse effect learning of declarative knowledge?

Question 2

RQ 2: Does EarthPulse effect the retention of knowledge over time?

Question 3

RQ 3: Does EarthPulse effect sleep?

Question 4

RQ 4: Does EarthPulse effect attrition?

Research Hypotheses

In direct relation to the proposed research questions, the following hypotheses were developed.

Hypothesis 1

Ho 1: There is no significant difference between the experimental and the control group in the learning of declarative knowledge.

Hypothesis 2

Ho 2: There is no significant difference between the experimental and the control group in the retention of declarative knowledge.

Hypothesis 3

Ho 3: There is no significant difference between the experimental and the control group in falling asleep.

Hypothesis 4

Ho 4: There is no significant difference between the experimental and the control group for attrition.

Key Terms and Definitions

To maintain focus and consistency, the working definitions for the key terms and concepts as they are used to answer the research questions in this study are provided in this section.

Learning. Learning, for the purpose of this study, is defined as knowledge demonstrated as the score on the immediate posttest. The score is the result of taking the declarative knowledge testing portion of the human gall bladder instrument immediately after reading the accompanying instructional script. The terms “learning score” and “immediate posttest” may be used interchangeably.

Retention. Retention is defined as the score on the delayed posttest administration of the human gall bladder instrument given two weeks after the learning phase and without re-reading the instructional script. The terms “retention score” and “delayed posttest” results may be used interchangeably.

Declarative knowledge. Declarative knowledge is factual information, and has been described as “knowing what” (Alexander, Schallert, & Hare, 1991), a passive type of knowledge, a knowledge base, or ‘knowing that’ based on nouns and factual information (Bruning, Schraw, & Ronning, 1999; Rabinowitz & Goldberg, 1995).

EarthPulse. EarthPulse is a pulsed electromagnetic field device that proposes to use entrainment to align brainwave frequencies (EarthPulse, 2005). Currently, it is sold primarily as an athletic performance and sleep enhancement tool. Additionally, repeated users report increases in alertness and attention, which may result in increased learning and retention.

Brainwave entrainment or adaptation. Brainwave entrainment is the process of adaptation and alignment of the brain to an external physiological stimulus. Therefore, in this study, the term adaptation may be used interchangeably with entrainment.

Electromagnetic field. Electromagnetic fields are the interaction of electric and magnetic forces (Beams, 2002).

Pulsed electromagnetic field. Pulsed electromagnetic fields (PEMF) are electromagnetic fields emitted at a pulsed rate (Beams, 2002).

DC Magnet. Direct current electromagnetic field emitted at a pulsed-rate and operates at a non- alternating current flow without changing the pole orientation (i.e. remains North or South on opposing surfaces).

Example: Air-Core Magnet in EarthPulse.

AC Magnet. Alternating current electromagnetic field emitted and energizes at a constant rate and the pole-orientation changes based on current flow (i.e. alternates between North and South on both surfaces).

CHAPTER 2: LITERATURE REVIEW

This chapter presents a review of the literature that pertains directly to this study's research purpose and question. It is divided into three main sections: declarative knowledge; information processing; and EarthPulse technology. The EarthPulse technology section briefly presents the concepts of brainwave entrainment, electromagnetic fields, brainwaves, and brainwave activity as they directly relate to the technology behind EarthPulse and the research questions of this study. Based upon the presented literature, the chapter concludes with an argument justifying this study.

Declarative Knowledge

A commonly accepted definition for declarative knowledge is that it is made of factual information and described as "knowing what" (Alexander et al., 1991) which leads to its reference as the foundation level of knowledge. It may also be referred to as a passive type of knowledge, a knowledge base, or 'knowing that' based on nouns and factual information (Bruning et al., 1999; Rabinowitz &

Goldberg, 1995). Declarative knowledge is formed by a semantic net linking propositions, images, and/or sequences by association (Anderson, 1982, 1983a). Propositions are the smallest units of knowledge which have meaning and specify relationships between things and their properties (Clark & Clark, 1977; Kintsch, 1974). Propositions are important elements of meaning in much of cognition. In general, what ends up in long-term memory are macropropositions, summaries of more detailed information that has been experienced and preserve meaning of the experience.

Once a macroproposition structure is formed, subsequent exposure to some part of the macrostructure activates other parts of the macrostructure (van Dijk & Kintsch, 1983). Information is connected by association in memory (Anderson, 1983b). Anderson (1983b) states, "Information is represented in long-term memory as a network of associations among concepts. Information is retrieved by spreading activation from concepts in working memory through the network structure" (p.25). Spread of activation occurs by linking propositional networks that share common elements (Hayes-Roth & Thorndyke, 1979).

According to Anderson & Bower (1973), all knowledge is represented in propositional form. Propositions are composed of relations, agents, modifiers, and objects that constrain each other to add or infer meaning (Anderson & Bower, 1973). Propositions also express relationships among concepts, ideas which can be used to classify or understand objects or events in the world and in isolation

have no meaning. When reading, macropropositions of text are integrated with prior knowledge to create new knowledge.

Declarative knowledge is anything but passive in terms of the cognitive functions necessary for its representation. In the declarative stage, the learner produces a crude approximation of the information by using general-purpose problem solving strategies to interpret facts about the skill (Anderson, 1982). Anderson (1982) further proposes that during this time, performance is slow, errors are likely, and working memory load is high because facts about the skill must be actively rehearsed.

For the brain to learn new declarative knowledge and recall stored declarative knowledge, an organization of connected associative networks is stimulated through spread of activation (Anderson, 1983b; Anderson & Bower, 1973; Collins & Loftus, 1975; Norman & Rumelhart, 1975). Associate networks contain concepts represented as nodes interconnected by associative links. Nodes represent concepts themselves and links represent connections between concepts. Nodes are organized in a pattern based upon connections. Therefore, nodes that are most closely associated to each other should be connected more closely. Nodes either indirectly connected, or that have no connection, should be more distant from each other. Spread of activation occurs when one node in a network is activated and this activation spreads to other nodes. This activation spreads automatically and continues as far as the capacity of short-term memory allows

based upon retrieval cues and alternative routes (Anderson, 1983b). Network organization and the spread of activation are also influenced by the strength of association between concepts. One is more likely to recall those concepts which are most strongly associated with the activated concept.

Declarative knowledge is housed in long-term memory (Anderson, 1983). Learning is the creation of connections and changing the strength of connections already in long-term memory (Bechtel & Abrahamsen, 1991; Martindale, 1991). Elaborate processing leads to the connection of the new concept in short-term memory to prior concepts in long-term memory and follows with inclusion of the concept into the network. When the appropriate links within the network are followed, learning and recall of declarative knowledge are accomplished.

Learning is explicit if the learner intends to acquire a specific set of target knowledge through conscious thought and is assessed directly (Frensch, 1998; Prawat, 1989). The instructional task in this study focuses on explicit learning through declarative knowledge. According to Squire's taxonomy for memory and learning, explicit learning involves the acquisition and use of declarative knowledge, which are facts and events (Squire, 1995).

Declarative knowledge may be assessed in a variety of ways. In this study, declarative knowledge is assessed through text comprehension as participants read a learning instrument and are tested on what they read.

According to Kintsch (1974), text comprehension requires one to maintain access to large amounts of information in working memory and simultaneously access long-term memory to form meaningful connections. Memory remains active in reading as working memory communicates with long-term memory to expand the knowledge base. As an individual reads text, sensory registers are activated. New information presented to working memory relies upon access to information previously stored in long-term memory for establishing contextual connections between the new information being presented in working memory and the information from long-term memory (Ericsson & Kintsch, 1995). Based on this theory, previous knowledge is a key factor in text comprehension as it is predicated on accessibility of information from long-term memory to working memory.

Memory is required for learning. If information is not remembered, learning will not take place. Therefore, information processing is necessary for learning of declarative knowledge.

Information Processing

The conceptualization of information processing as an active human memory system is influenced by Broadbent's multistage memory model (Broadbent, 1958). The process begins when a stimulus activates sensory registers that send messages to the brain. Once a stimulus is sensed, the executive control processes are activated. The executive control process begins by filtering through data in short term storage memory on a preliminary basis, which requires one half to two seconds, deciding what information consciously receives attention for further processing. Limited data is filtered forward to short-term working memory for approximately twenty seconds. Data that are remembered become coded into long-term memory and part of the knowledge system. Incoming data that are lost between short term and long-term memory is lost from the system.

Broadbent's information processing model has influenced current memory models. Cognitive theorists have built on Broadbent's model and evolved the concept of short-term memory to working memory (Baddeley, 1986). According to Baddeley (1986), the standard definition for working memory is, "the temporary storage of information that is being processed in any range of cognitive tasks" (p.34). Working memory (G. A. Miller, Galanter, & Pribram, 1960)

controls attention through the central executive and two subsystems: the phonological loop and the visuospatial sketchpad (Baddeley & Hitch, 1974).

The following diagram is an original image to represent how the theories of declarative knowledge and information processing connect in this study (Anderson, 1982, 1983a, 1983b; Baddeley, 1996, 2000, 2001a, 2001b, 2002; Baddeley & Hitch, 1974; Broadbent, 1958; Case, 1985; Collins & Loftus, 1975; Daneman & Carpenter, 1983; Jerslid, 1927; Norman & Rumelhart, 1975; Robbins et al., 1996; Spector & Biederman, 1976; Tulving, 1985).

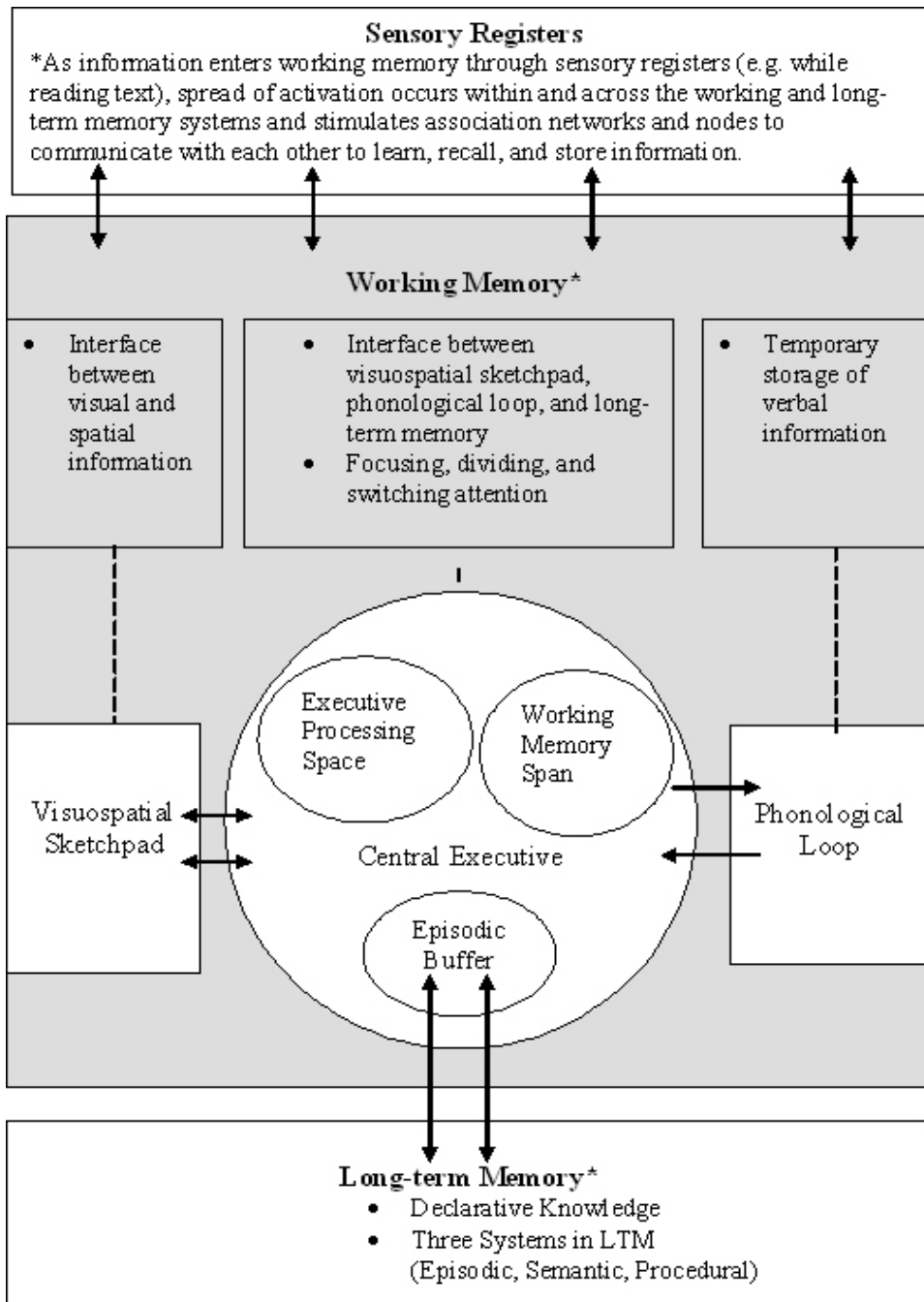


Figure 2.1. Declarative knowledge and information processing connections

Working memory contains the visuospatial sketchpad, phonological loop, and central executive. The visuospatial sketchpad provides the interface between visual and spatial information that is accessed either through sensory registers or long-term memory.

The phonological loop is an active system in working memory for the temporary storage of verbal information, which is approximately two seconds unless refreshed and rehearsed. Additionally, the phonological loop may play a role in switching attention (Allport, Styles, & Hsieh, 1994; Baddeley, Chincotta, & Adlam, 2001). The phonological loop was formerly referred to as the articulatory loop but was changed to emphasize the fact that this subsystem is not limited to the previously viewed articulatory component (Baddeley, 2002).

In working memory, the central executive is a system that handles general cognitive processing resources for focusing (Robbins et al., 1996), dividing (Baddeley, 1996), and switching attention (Jerslid, 1927; Spector & Biederman, 1976). The central executive also decides when and how the subsystems function, communicate with each other, and communicate with long-term memory (Baddeley, 1996).

It is further proposed that the central executive is connected with three additional capacities: working memory span, executive processing space, and the episodic buffer. The capacity for working memory to simultaneously process and store information is moderated through working memory span (Daneman &

Carpenter, 1980, 1983). Another capacity of the central executive is executive processing space, which is related to short-term storage. Executive processing space, a theory explaining attention span, explores the amount of information one can consciously attend to and have active at once in short-term memory while working towards a cognitive goal (Case, 1985). Meanwhile, retrieval from long-term memory to working memory takes place through conscious awareness in the episodic buffer of the central executive (Baddeley, 2000, 2001a, 2001b, 2002). The episodic buffer is proposed to integrate information from long-term memory and the subsystems into working memory through active maintenance and manipulation.

Based on the concept that working memory, specifically the central executive, controls attention, the average human's working memory can consciously focus attention on 7, plus or minus 2, bits, or chunks, of data at a time, (G. A. Miller, 1956; G. A. Miller & Selfridge, 1950). Chunking information in a meaningful fashion increases the likelihood that the information will be passed forward in the executive control process to long-term memory for storage and retrieval.

Another capacity of working memory is to filter information by associating, sorting, and organizing it into meaningful codes based upon prior knowledge. The encoded information is then moved from working memory,

stored into long-term memory, and transformed into part of one's knowledge base.

Long-term memory is vast and much more durable than working memory. It is often referred to as "permanent" memory. Ten seconds is the estimated time required for storage of a new retrievable connection to long-term memory (Simon, 1973). Storage in long-term memory is assumed to be primarily associative, connecting different items to one another and to new attributes of the current context. As in working memory, the chunking of information is important in long-term memory (G. A. Miller, 1956). More familiar and experienced concepts are stored over time as one chunk, rather than individual chunks. Scarcity of retrieval cues connected to the desired context hinders retrieval from long-term memory.

Long-term memory is composed of three systems (Tulving, 1985). According to Tulving, the three major long-term memory systems are episodic, semantic, and procedural. Each system serves a different purpose. Episodic memory includes personal, or autobiographical, information pertaining to events experienced by the individual and are typically connected to a time and place. Semantic memory includes general knowledge, such as concepts and definitions, and enables the construction of mental models of the world by the individual. Tulving (1985) states that procedural memory "enables the organism to respond adaptively to the environment" (p.387).

Long-term memory may be assessed through retention testing, as in the second phase of this study. Retention testing aims to assess, through retrieval and recall measures, whether information has been stored as part of a long-term memory knowledge system. Information that was not filtered through short-term memory becomes lost data and is therefore not encoded or stored. (Broadbent, 1958). Having an awareness of metacognition and the information processing system may assist one in building a knowledge base and minimizing lost data.

Now that an overview of declarative knowledge and information processing has been presented, the next section highlights essential concepts of EarthPulse related to this study.

EarthPulse Technology

EarthPulse is a brainwave entrainment, pulsed electromagnetic field therapy device that proposes to use entrainment to align brainwave frequencies (EarthPulse, 2005). EarthPulse is a registered device. It is important to note that what EarthPulse refers to as brainwave entrainment, educators may refer to as the process of adaptation and alignment of the brain to an external physiological stimulus.

Electromagnetic fields are the interaction of electric and magnetic forces (Beams, 2002). When electromagnetic fields are emitted at a pulsed rate they are termed pulsed electromagnetic fields.

The following provides an overview of brainwave entrainment, electromagnetic fields and brainwaves, and brainwave activity as they directly relate to the technology behind EarthPulse and this study.

Brainwave Entrainment

EarthPulse purports to use “non-contact methods” to balance energy fields through sound wave frequencies that match human brainwave frequencies to entrain the brain (EarthPulse, 2005).

The following briefly highlights sound waves and then moves into brainwave entrainment. Sound waves are examples of rhythm. Each cycle of a wave, as expressed in Hz, is a single pulse of sound. Although the average human ear hears electromagnetic sounds between 16 Hz – 20,000 Hz, the body perceives electromagnetics lower than 16 Hz as rhythmic frequencies (R. A. Miller & Miller, 2003). Therefore, it is presumable that electromagnetic devices that produce waves below 16 Hz may be used to entrain the brain even through they may not be audible.

According to Miller & Miller (2003), entrainment is the process of synchronization, where vibrations of one object will cause the vibrations of another object to oscillate at the same rate, including internal and external rhythms. Brainwave entrainment technology adapts brainwaves to various brainwave patterns and mental states through an external stimulus (TransparentCorporation, 2004).

EarthPulse uses the brainwave frequency ranges identified in Table 2.1 as the basis for the device (EarthPulse, 2005).

Table 2.1.

EarthPulse Brainwave Frequency Range

Total Range: 0.5 - 15 Hz	
0.5 - 3 Hz	Delta rhythm
3 - 7 Hz	Theta rhythm
7 - 12 Hz	Alpha rhythm
12 - 15 Hz	Beta rhythm

This study explores EarthPulse exclusively on the “Entrain Up” (EU) setting. According to EarthPulse inventor, Paul Becker (personal communication, January 26, 2006b),

“The entrainment process in the EU setting occurs by first stepping down the frequency in 1/10 Hz steps from 9.6 Hz (mid alpha) to .5 Hz (low delta). This gradual stepping down process during the first 30% of the program should entrain participants into a very relaxed or sleep state.

When the device reaches .5 Hz, the device then steps up the frequency for the remaining 70% of the program in 1/10 Hz increments to 14.1 Hz (low beta) entraining the participants to an alert, active thought process state

and then goes to the off position. The speed at which the device steps up and down is a function of whether the device is set for 30 or 60 minutes. Exposing a person to all of these frequencies in small 1/10 Hz steps, supplements the effect of the natural electromagnetic fields of the same frequency range found in the environment which help keep biological entities on our planet 'grounded'. This supplementation of natural electromagnetic fields has the effect of cleaning the neurological system of electromagnetic anomalies that may be affecting optimum mental performance."

Becker (personal communication, January 26, 2006b) also states, "The goal of the EU setting is to eliminate electromagnetic anomalies that a person has accumulated throughout daily living and leave the person in a high attentive, alert state with fewer, if any, anomalies to detract attention and mental performance."

If the EU setting of EarthPulse is to leave a person in a highly attentive, alert state, the question arises whether the EU setting would have a significant effect on learning and retention. Additionally, the question arises whether the EU setting would have an effect on sleep. Furthermore, if the EU setting is to affect a person by minimizing anomalies and increasing alertness, a fourth question arises whether a person exposed to EU would be significantly more likely to return for

retention testing in two weeks. These statements contribute to the argument justifying this study and the research questions.

The following section provides a brief overview of electromagnetic fields and brainwaves in relation to EarthPulse and this study.

Electromagnetic Fields and Brainwaves

EarthPulse operates on four proposals of L.B. Hainsworth (1983) that connect electromagnetic fields (EMF) with brainwave frequencies. The first proposal states that frequencies of human brainwaves, especially that of the body's dominant wave, the alpha rhythm, evolved in response to the naturally occurring rhythmic signals known as "Schumann resonances" (SR), (Hainsworth, 1983, 1987; Schumann & Konig, 1954). SR signals are extremely low frequency (ELF) electromagnetic waves that circulate the electrical cavity between the negatively charged Earth and the positively charged ionosphere. SR signals are caused by trapped solar particles and pulses of electromagnetic energy caused by thousands of lightning strikes occurring simultaneously around the Earth. SR signals operate at an inconsistent amplitude (R. A. Miller & Miller, 2003). The lower layer of the ionosphere is roughly 40-50 miles from the surface of the Earth and is known to reflect radio waves (R. A. Miller & Miller, 2003).

Secondly, Hainsworth proposes that human beings contain, generate, use, and respond to the electrical signals of the SR and other ELFs (Hainsworth, 1983,

1987). Liquid crystals in the human body may operate as an antennae for detecting and decoding global and local ELF signals (Beal, 1996). This leads to Hainsworth's third proposal, that the human body responds to auditory and visual signals in the range of 3-30 Hz (Hainsworth, 1983). This corresponds to the notion that we are intimately connected to the world of sound vibration (Leonard, 1978), some of which is not "heard" if it falls below the 3Hz threshold.

The Effects of Electromagnetic Signals on the Nervous System

The fourth proposal of Hainsworth is that electromagnetic signals may have biological effects, including on the central nervous system, although this response may not be universal (Hainsworth, 1983, 1987). SR signals help to keep the brain "grounded." Without adequate SR exposure, our neurological system is free to "entrain" to higher frequencies (R. A. Miller & Miller, 2003). The brain is a massive source of ELF signals that get transmitted through the body by way of the nervous system (R. A. Miller & Miller, 2003). Therefore, the nervous system may be viewed as a network of unceasing electrical activity (Leonard, 1978). The electrical activity within the brain can travel into space at the speed of light and is organized into pulsing waves that may be sensed on the surface of the scalp through EEG recordings (Leonard, 1978). EEG technology, first recorded in 1954 by Hans Berger, a German psychiatrist, provides a record of rhythmic fluctuations in potential voltage of electronic current flowing through the nerves in parts of the

head. Although there may not be consensus on where the voltage comes from, the frequencies have been correlated with states of consciousness (R. O. Becker & Selden, 1985).

The Effects of Electromagnetic Fields on Memory and Cognition

Research from the U.S. Navy's Pensacola lab reveals a decrease in test scores of short-term memory and the ability to add numbers after exposure for 24 hours to a 1 Gauss magnetic field at 45 and 60 Hz frequencies, the frequency found near some high voltage power lines, as the control group remained normal (Gibson & Moroney, 1974). The researchers concluded that information processing may be slowed with exposure to 45 and 60 Hz magnetic field frequencies (R. O. Becker & Selden, 1985). However, it is not known what the effect would be on information processing with exposure to a lower Hz range. At a distance of 2 inches away, the EarthPulse magnet vertically emits a range from 0.05-1 Gauss (P. F. Becker, 2006a). According to Becker (2006a), at 2 inches away from the magnet, the net magnetic field is approximately 1 Gauss as it touches the back surface of the brain and fades to less than 0.05 Gauss as it touches the frontal lobe. These Gauss levels fall well below the national safety standards (EarthPulse, 2005).

EarthPulse supplements ELF's, including the SR waves at 1.5 Hz (delta), 7.8 Hz (alpha), and 14.1 Hz (beta). It is believed that the dominant average

frequency that the Earth had remained constant at 7.8 Hz (alpha) for thousands, perhaps millions, of years (Hainsworth, 1983; R. A. Miller & Miller, 2003) but is now increasing. The suggestion that this average may currently be rising is leading to increased interest in potential implications (R. O. Becker, 1990; R. O. Becker & Selden, 1985; Hainsworth, 1983, 1987; R. A. Miller & Miller, 2003). 14.1 Hz is the average of the second Schumann frequency mode (Hainsworth, 1983). Recently, it has been proposed that the 1.5 Hz frequency also contains a fairly strong Schumann Resonance signal, which is included in the settings of EarthPulse (EarthPulse, 2005).

When Schumann waves and brainwaves are recorded, the results are displayed in sharp direct current (DC) spikes, representing the flow of electrons. Therefore, EarthPulse includes pulsed electromagnetic field (PEMF) supplementation as its method for brainwave entrainment. The pulsing action turns the DC magnet on, then off, repeatedly over and over to stimulate the naturally occurring action of the SR and brainwaves, as the human body is also comprised of DC currents (R. O. Becker, 1990; R. O. Becker & Selden, 1985).

The goal of EarthPulse is to return the brainwave rhythms to patterns compatible with natural conditions. This goal aligns with the premise that human beings are fundamentally electromagnetic, not merely chemical, and that the ELF of SR signals are intimately linked with human brainwaves and performance (R.

O. Becker & Selden, 1985; Hainsworth, 1983, 1987; R. A. Miller & Miller, 2003).

Brainwave activity is briefly presented in the next section as it relates to the purpose of this study, which was to explore the effects of EarthPulse's ELF EMF on learning.

Brainwave Activity

Learning declarative knowledge relies upon cognition, which involves the mental processing of information in the brain. As the brain processes information, electrical frequencies referred to as brainwaves are emitted.

Currently, four widely accepted brainwaves may be reliably monitored: delta, theta, alpha, and beta. Brainwaves are measured according to frequency and amplitude. Frequency is expressed in Hertz (Hz), the cycles per second of an electrical signal or event, and is the speed of the electrical pulses in the brain. Amplitude refers to the strength of the wave. Since the brainwaves slightly overlap each other, different theories exist on the exact Hz of each wave. Table 2.2 incorporates four similar viewpoints on brainwaves into one summative illustration. For consistency in this study, the researcher relied upon the brainwave descriptions proposed by Wise (2002, 2004), whose work directly builds upon the research of Cade & Coxhead (1979) and the Hz parameters established by EarthPulse (2005).

Table 2.2.

Summary of the Four Brainwave States and Frequencies

Brainwave	Explanation	Frequency & Resource
Delta	Unconscious state. Deep, peaceful sleep state. Strengthens intuition, empathetic attunement, instinctual insight, healing/regeneration, and possibly extrasensory perception. When present in combination with other waves in a waking state, it acts as a radar seeking out information, reaching to understand the deepest unconscious level things we can't understand through thought process.	0 - 4 Hz (Miller & Miller, 2003) 0.5 - 4 Hz (Wise, 2002, 2004; Cade & Coxhead, 1979) 0.5 - 3 Hz (EarthPulse, 2005)
Theta	Subconscious state. Dreaming, REM sleep. Provides the experience of deep meditation. Deep cognition/thought (gateway to enhanced learning, memory). Contains the storehouse of creative inspiration, vivid imagery flashes, spiritual and mystical connections. Thoughts withdrawn from external world and focused on internally originating signals (mindscape). Awakens intuition and possibly extrasensory perception. Provides peak in the peak experience, and ah-ha moments when appropriately combined with the other brainwaves.	4 - 8 Hz (Wise, 2002, 2004) 4 - 7 Hz (Miller & Miller, 2003; (Cade & Coxhead, 1979) 3 - 7 Hz (EarthPulse, 2005)
Alpha	Conscious state. Stronger, easier, more sustained concentration and attention, relaxed, calmness, detached external awareness, increased inner awareness, visualization, sensory imagery, mental coordination, and light imagining. Gateway to meditation. Bridge between the conscious and subconscious state. Mind/body integration and learning. Environmental synchronization.	8 - 14 Hz (Wise, 2002, 2004) 8 - 12 Hz: Adults (Cade & Coxhead, 1979) 7 -14 Hz: Children (Cade & Coxhead, 1979) 7 - 12 Hz (Miller & Miller, 2003) 7 - 12 Hz (EarthPulse, 2005)
Beta	Conscious state. Normal waking state. Active external awareness and cognitive thought process. Necessary for functioning in the outside world.	14 - 38 Hz (Wise, 2002, 2004) 13 - 30 Hz (Cade & Coxhead, 1979) 12 - 25 Hz (Miller & Miller, 2003) 12 - 15 Hz (EarthPulse, 2005)

References: (Cade & Coxhead, 1979; EarthPulse, 2005; R. A. Miller & Miller, 2003; Wise, 2002, 2004)

It is also important to note that at any given time, a person has a combination of all the brainwaves present, and this combination is flexible. When a person is said to be in one given brainwave state, it is because that specific brainwave is most prominent (i.e. the highest amplitude) at that time. The combination of highly reduced beta, high alpha, mid-low theta, low delta brainwaves is an optimum combination state for attention, concentration, meditation, and imagery (Cade & Coxhead, 1979; Wise, 2002, 2004), which will from this point forward be referred to as the attention state for simplification. One way the attention state may be attained is through adaptation, also referred to as brainwave entrainment, using a pulsed electromagnetic device designed to match the frequencies of the brain, such as EarthPulse. The attention state is a very lucid state of consciousness where a heightened state of internal and external awareness exists. The attention state has implications theorized to effect learning. According to the working memory model, attention is necessary for information processing to occur (Baddeley, 2002). Therefore, if a person increases concentration and imagery while in the attention state, it raises the question of whether learning of declarative knowledge may improve.

Argument Justifying the Study

Because attention, concentration and relaxation are increased in the alpha (conscious) state (9-14 Hz) (Cade & Coxhead, 1979; Wise, 2002, 2004), and since attention is controlled by the central executive in working memory as part of information processing (Baddeley, 2002), which may be connected to learning, if the brain is left in this increased attentive state through the EU setting, EarthPulse may have a positive effect on learning.

The next section presents the research design methods and procedures utilized for this study.

CHAPTER 3:

METHODS AND PROCEDURES

The purpose of this chapter is to describe the methods and procedures used in this study. Described in this chapter are the research design framework, independent variable, dependent variables, testing instrument, population selection, data collection, data analysis, and threats to internal validity.

Research Design Overview

This study used a one-variable, posttest only, experimental design. As Gall, Gall & Borg (2003) state, this experiment “involves the manipulation of a single treatment variable followed by observing the effects of this manipulation on one or more dependent variables” (p.366). The true experiment included the random assignment of participants into two treatment groups according to the design identified in Table 3.1.

Table 3.1.

Experimental Design of Study

	Independent Variable	Dependent Variables
Experimental Group	EarthPulse Entrain Up setting for 30 minutes (magnet is active)	E1. Declarative Knowledge Test: learning score (immediate posttest) E2. Declarative Knowledge Test: retention score (delayed posttest) (2 weeks later)
Control Group	Placebo EarthPulse treatment for 30 minutes (magnet is disabled)	C1. Declarative Knowledge Test: learning score (immediate posttest) C2. Declarative Knowledge Test: retention score (delayed posttest) (2 weeks later)

The experimental group received the EarthPulse Entrain Up (EU) treatment for thirty minutes and the control group received a placebo EarthPulse EU treatment for thirty minutes. Whether the device was experimental or placebo, all devices visually appeared to work in the same way to all participants. Each device was turned on at the onset of the experiment. The placebo devices

contained non-working magnets, which was an unobservable factor. All devices were certified by staff of the Penn State Materials Research Laboratory for safety and to verify whether or not it was an experimental or placebo magnet.

Immediately following the treatment, the testing instrument was administered to both treatment groups to attain the learning score. Since the immediate posttest identified the learning of declarative knowledge, from this point forward the term “learning score” may be used to represent an immediate posttest result. For the learning score, both groups completed the same instrument (see Appendix A) pertaining to the human gall bladder through the following process: read the five page instructional script, turn in the script to a research assistant, and then complete the declarative knowledge testing portion of the instrument.

Two weeks later, the same participants returned to the testing site to complete only the testing portion of the same instrument to attain the retention score. They were not given the opportunity to re-read the script prior to testing. Since the delayed posttest identified the retention of declarative knowledge over the two week time period, from this point forward the term “retention score” may be used to represent a delayed posttest result. The research and participants were notified of which group was experimental vs. control after all data was collected.

The following section more completely describes the independent and dependent variables involved in the experiment.

Independent Variable

In this study, the independent variable was exposure to EarthPulse. As presented in Chapter 2, EarthPulse is designed to use “non-contact methods” of pulsed electromagnetic fields to balance energy fields through sound wave frequencies that match human brainwave frequencies to entrain the brain (EarthPulse, 2005). This study specifically focuses on the Entrain Up (EU) setting of EarthPulse. The EU setting is designed to provide natural supplementation of pulsed electromagnetic fields ranging from 0.5 – 14.1 Hz through a gradual step down, step up process. The inventor of EarthPulse proposes the EU sequence may improve mental performance by cleaning the neurological system of electromagnetic anomalies (P. F. Becker, 2006b).

The study contained two treatment groups: experimental and control. The experimental group received EarthPulse on the EU setting, which may also be referred to as the intervention (Gall, Gall, & Borg, 2003). The control group received EarthPulse on the placebo EU setting. Both groups began reading an instructional script on the human gall bladder approximately 5 minutes after receiving the respective treatments. The participants took as much time as needed to finish reading the script.

Dependent Variables

The dependent variables were two test scores reported from the declarative knowledge test. The first score represented the learning score. The second score represented the retention score. The effect of the independent variable was determined by comparing scores on the dependent variables for the control and experimental treatments (Gall et al., 2003). The following describes the instrument used to test declarative knowledge in this study.

Declarative Knowledge Instrument

The instrument in this study was a paper-based test designed to measure learning of declarative knowledge by testing participants on factual information pertaining to the human gall bladder (see Appendix A). For this study, the researcher designed and piloted a modified version of Birdwell's learning instrument (see Appendix B). The original version of the instrument, which was used for this study, was developed in 2004 (Birdwell, 2005a).

This instrument was administered individually by the researcher or assistants through paper and pencil. The participant was first given a copy of the five page gall bladder instructional script and asked to read it completely. After reading the script, the participant was asked to turn in the script and were then given a copy of the 30-item, multiple choice test to complete. The test questions were based on factual information presented in the script pertaining to the human

gall bladder. The participants were not permitted to look at the script or talk while taking the test.

Retention was tested by giving the same participants an identical 30-item, multiple choice test two weeks following the learning test. Prior to retention testing, the participants were not permitted to re-read the script.

Population Selection

For recruitment of participants, the researcher contacted several undergraduate professors at The Pennsylvania State University. It was deemed appropriate to have participants from various majors as the declarative knowledge test was based on general knowledge, not discipline specific. The test was solely based on information contained within the instructional unit (Appendix A).

The researcher requested the opportunity for students to receive extra or class credit for their participation in this study. Three professors participated and offered their students credit for participating in both phases of the study.

All three professors asked the researcher to present the opportunity to at least two sections of their classes. The researcher went in person to each of the classes to present the opportunity. At the presentation, the researcher read the students an overview of the study and distributed a copy of the overview to each student. Interested students were asked to sign-up to reserve a time slot for both

phases of the study. Recruitment was followed up with an email to all registered participants to remind them of their assigned time slot.

With approval from the participants' professors, each participant was awarded either class or extra credit points for completing both the learning and retention tests. The total number of points awarded for participation was dependent upon the professor's discretion. One professor awarded 5 points for participation while another professor awarded two points for participation plus the option for an additional point after writing a reflective paper based on the experience as a research participant.

The third professor offered participants the opportunity to replace another class project by writing a reflective paper based on their experience as a research participant. The researcher does not know what percentage of the overall grade the points represented. Each professor awarded points based on the student's completion of both tests, not on actual test performance or scores.

Ninety-eight undergraduate students from The Pennsylvania State University without pacemakers or a history of seizures or epilepsy participated in the first phase of study. Eighty-seven of the original 98 participants returned two weeks later for the retention testing, as will be presented in Chapters 4 and 5. The attrition rate was not uniform across groups ($n=98$; $sig. = .051$) or by gender ($n=98$; $sig. = .050$), leaving 47 participants in the experimental group and 40 in the control group.

Data Collection

Data for this study were collected during the spring semester of the 2005-2006 academic school year. Data collection for both phases of this study took place in the same facility of Pennsylvania State University.

Data collection was conducted by the researcher and seven assistants. Each assistant was properly trained on the data collection procedures by the researcher prior to beginning data collection. Training included reading the assistant training materials (Appendix C) and the participant overview (Appendix D), both of which the assistants were asked to retain as job aids. The researcher was present during all data collection procedures in the event that questions or concerns arose.

Recruitment Procedures

1. The researcher contacted several Penn State undergraduate professors and asked for permission to present this study to their students. Three professors agreed.
2. The researcher presented the study to all students in each of the respective classes.
3. Interested participants were asked to register for one time slot. There were eight time slots available, each with twenty-two openings.

Participants selected a time that best suited their availability for the learning and corresponding retention phases.

Learning Testing Procedures

1. Prior to the first day of data collection, the researcher emailed the participants the date, time, and location for their learning phase registration. Data collection for the learning phase, which included registration, treatment, and testing, took approximately 1 hour and 30 minutes.
2. Participants arrived at the testing site, signed in, and read the participant overview.
3. All participants signed the approved screening and informed consent forms. All human subject paperwork and procedures were completed and administered as required by the Institutional Review Board of The Pennsylvania State University prior to beginning the data collection.
4. Participants were randomly assigned to one of two treatment rooms, experimental or control, and then asked to report to the respective room. One room contained ten stations; the other room contained twelve stations. The difference in number was solely based on availability of space in the rooms. Data collection for the entire study took place in the same building, only different rooms. The

experimental and control groups were in two separate rooms located on two different floors for the treatment. Wireless antennas were disconnected in both rooms.

5. Participants were asked to fully turn off all cell phones.
6. Each participant laid down at one station in the treatment area which included an identical yoga mat and pillow. Each mat was placed a minimum of three feet apart from the next mat. The three feet distance was used to meet the magnet separation distance suggested by EarthPulse to control for horizontal cross-over effects (P. F. Becker, 2006b). This is where the experimental group and control group received different treatments.
 - a. For the experimental group (half of the study participants): A standard 2 inch pillow was placed between the participants head and the EarthPulse Air-Core magnet. The magnet was placed near the upper part of the neck. EarthPulse was turned onto the EU setting for 30 minutes and the lights were turned down to barely light the room. A dim amount of light was used for safety purposes.
 - b. For the control group (half of the study participants): A standard 2 inch pillow was placed between the participants head and the placebo Air-core magnet. The placebo magnet

was disabled and placed near the upper part of the neck. The placebo EarthPulse was turned onto the EU setting for 30 minutes, but because it was disabled, no magnetic field was generated. Again, the lights were turned down to barely light the room. A dim amount of light was used for safety purposes.

7. Participants were asked to lay still for thirty minutes, and were told that it was acceptable if they fell asleep.
8. After 29 minutes, the researcher or assistants slowly began to turn up the lights, having them fully on by the 30 minute mark.
9. After the thirty minutes, the lights were turned completely on. Each group of participants went out into the adjacent hallway on their respective floor where they were asked to sit at a table to complete the test.
10. Participants were asked to read over a script on the human gall bladder. Reading of the script took the participants approximately 20 minutes.
11. After reading the script, the participants were asked to raise their hand, turn in the script, and were given the gall bladder test. Completion of the learning test took approximately 20 minutes.

12. Upon completion, each participant submitted the finished test to a research assistant. No scripts or testing materials were distributed for the participants to take outside of the testing site.
13. After the participants completed the test, they were verbally reminded that the retention phase would take place in two weeks. They were also reminded that they needed to attend the retention phase to receive credit from their professors.
14. The participants were thanked for their time and asked not to study more on the gall bladder during the two-week period before the retention test (unless required for other University coursework).
15. Participants were individually dismissed from the testing site once they submitted the finished test and received the previous instructions from the research assistant.

Prior to the retention phase, a reminder email was sent to each participant including the date, time, and location for the retest. The purpose of the retention phase was to identify whether any effects on learning of declarative knowledge were retained over time. Testing for the retention phase took approximately 30 minutes. The following describes the procedures used during the retention testing.

Retention Testing Procedures

1. Participants returned two weeks after their original day of testing (i.e. the learning phase). Participants arrived at the testing site and signed in. Since it was not necessary to separate the participants for this phase, all participants reported to one room, regardless of whether they were originally in the experimental or control group. Data collection for this phase took place in the same building as the learning phase.
2. When all participants for a given time slot had arrived (a maximum of twenty-two participants at one given session), the researcher verbally presented an overview of the testing procedures for this phase. To correspond with the learning procedures, there were eight corresponding time slots for retention testing. Participants were automatically signed up for the time slot that mirrored two weeks after the learning test.
3. The declarative knowledge test was distributed. All participants took this portion of the test in the same room, regardless of their treatment group from the learning phase. Completion of the retention test took approximately 20 minutes.
4. Upon completion, each subject returned the test to the research assistant.

5. As per the request of the Penn State Institutional Review Board, the participants were reminded that a debriefing statement (Appendix E) would be sent through email identifying which treatment group they were in.
6. Each participant was thanked for participating in the study and dismissed from the testing site.
7. A debriefing statement was emailed by the researcher to all participants and research assistants after all of the data were collected from the retention phase. The statement identified whether the participant received the experimental or the control treatment.

Data Analysis

Following data collection, each declarative knowledge test was individually scored by the researcher according to the instrument's answer key (see Appendix A) to produce a final score for the learning and retention testing phases. Once all of the scores were calculated, scores were entered by the researcher into the Statistical Package for the Social Sciences (SPSS) version 13.0 for reliability, descriptive and inferential data analysis.

Reliability of Declarative Knowledge Test

Test scores were analyzed for item-reliability using Cronbach alpha. The researcher used the SPSS v. 13 program which provides individual item-analysis results including overall Cronbach alpha values for internal consistency.

To establish score reliability, the instrument was piloted and revised several times prior to the study. The original 33 question instrument (see Appendix B) score had a Cronbach alpha at 0.747 (Birdwell, 2005a) when given to graduate level personnel at the Army War College. The instrument was revised to 31 items, included an "I don't know" option to each question, was piloted on 21 Penn State undergraduates in December 2005 and had a Cronbach alpha of 0.753.

From this data, the instrument was revised to exclude all “I don’t know” options, was piloted on 34 Penn State Altoona undergraduates in January 2006 and had a Cronbach Alpha of 0.632. Based on this data, additional revisions were made. The final instrument was cut down to 30 questions with four multiple choice items by excluding all “None of the above” options, was piloted on 33 Penn State undergraduate students in March 2006 and had an original Cronbach alpha of 0.650.

The Cronbach alpha of the final instrument used for the study (see Appendix A) was calculated according to the scores of the 87 participants that participated in both phases of the study. The Cronbach alpha was 0.676 on the immediate test and 0.609 on the retest, which is “acceptable” for a new instrument in its first generation (Black, 1999; Sax, 1997).

Descriptive Analysis

Descriptive analysis was conducted to provide a profile of the participants. The demographics collected included the participant’s gender, year in school, major, and the credit class of recruitment (the course from which the participants were recruited and received the extra or class credit points). The participants were also asked whether or not they thought they fell asleep during the treatment phase of the study. These results were also analyzed through descriptive analysis.

Descriptive analysis focused primarily on frequencies, percentages, means, standard deviations, and the use of various procedures to check statistical assumptions. Statistical assumptions were checked primarily using box-plots, skewness values, and with the Shapiro-Wilks test.

Inferential Analysis

Data from the learning and retention scores were analyzed using the inferential statistics measures to identify where statistically significant differences existed. To address the research questions and hypotheses, normality, reliability, one-way analysis of variance tests and Chi square tests were conducted.

One-way Analysis of Variance

Research questions one and two, and the corresponding hypotheses, were analyzed using one-way analysis of variance to examine whether differences existed between groups on the learning test and whether these differences remained over time. Table 3.2 summarizes the procedures used for checking basic assumptions for the inferential statistical tests and for examining the internal consistency of the scores generated from the learning or retention instrument.

Table 3.2.

Summary of Procedures for Checking Statistical Assumptions and Reliability

Assumption	Procedure Used	Guidelines	Was the Assumption Met?
Normality Assumption	Skewness, Box-plot, Shapiro-Wilk's test	Skewness: -1.0 to +1.0 Box-plots: minor and major outliers Shapiro-Wilk: $p > 0.05$	Yes
Equal Variance	Levene's test	$p > 0.05$	Yes
Internal consistency	Cronbach alpha	0.6 or higher based on (Black & Sax)	Yes

Table 3.3 summarizes the inferential statistics used for each hypothesis and includes the independent variable, dependent variable, and the data analysis technique used for each hypothesis.

Table 3.3.

Summary of Statistical Procedures for Hypotheses

Hypothesis	Independent variable and type of data	Dependent variable and type of data	Data analysis technique & n
Ho 1: There is no significant difference between the experimental and the control group in the <i>learning</i> of declarative knowledge.	Group with 2 treatment levels - EarthPulse (experimental) - Placebo (control) Nominal Data	Learning test score (range from 0-30) Interval Data (normality assumption checked) (Cronbach alpha computed) (Equal variance checked)	One-way analysis of variance n = 98 and n = 87
Ho 2: There is no significant difference between the experimental and the control group in the <i>retention</i> of declarative knowledge.	Group with 2 treatment levels - EarthPulse (experimental) - Placebo (control) Nominal Data	Retention test score (range from 0-30) Interval Data (normality assumption checked) (Cronbach alpha computed) (Equal variance checked)	One-way analysis of variance n = 87
Ho 3: There is no significant difference between the experimental and the control group in falling asleep.	Group with 2 treatment levels - EarthPulse (experimental) - Placebo (control) Falling Asleep Report - Yes - No Nominal Data	Not Applicable	Chi square n = 98
Ho 4: There is no significant difference between the experimental and the control group in attrition.	Group with 2 treatment levels - EarthPulse (experimental) - Placebo (control) Attrition Report Nominal Data	Not Applicable	Chi square n = 98

Threats to Internal Validity

Confounding variables may affect research findings and lead to erroneous interpretations that could threaten the internal validity of the study. Major types of confounding variables include maturation, history, testing, instrumentation, regression to the mean, selection, attrition, diffusion of the treatment, and sequence effects (Cook & Campbell, 1979; Graziano & Raulin, 1997). The following summarizes how the researcher addressed these potentially confounding variables in this study.

Maturation was not viewed as a major threat because the testing took place over a short time frame. History was not viewed as a major threat because the time frame of testing was only two weeks and the researcher was not aware of any intra or inter-historical events during that time that would have had a major influence on results. Since testing for the learning and retention phases occurred within a limited time frame of two weeks between the two tests, there may be a potential threat for the immediate test to have some influence on the scores of the retention test. The researcher was not able to identify any literature stating an appropriate time frame necessary to eliminate the threat of internal validity between immediate and delayed testing for retention of declarative knowledge. Therefore, the researcher selected the two week time period for this study.

Due to the fact that there was no difference in the testing instrument from the learning phase to the retention phase, instrumentation was not considered a threat. Random assignment was used to assign participants to treatment levels, and it is assumed through this process that regression to the mean and selection were not threats to internal validity.

Of the original 98 participants that completed the learning phase, eleven participants dropped out over time. There was no difference in the learning scores ($p=0.551$) between the original 98 participants that completed only the learning phase and the 87 participants that completed both the learning and retention phase. The potential threat of attrition was addressed through data analysis for research questions one and two. Once evidence of attrition was analyzed and determined to be minimal, data analysis were performed using data from the final 87 participants for research questions one and two.

Table 3.4 summarizes the attrition information regarding the original 98 study participants who completed only the learning phase and the 87 study participants who completed both the learning and retention phases. Of the eleven participants who dropped out, nine of them were from the control group and two of them were from the experimental group. The experimental group had 2 males drop out. The control group had 6 males and 3 females drop out. Analysis of these attrition statistics are presented in Chapter 4 and discussed in Chapter 5.

Table 3.4.

Summary of Attrition Information

	Started study in Learning Phase (n)	Finished both Learning & Retention Phase (n)	Difference (n)	Attrition %
Treatment				
Experimental Group	49	47	2	4.081
Control Group	49	40	9	18.367
Fall Asleep				
Experimental Fall Asleep	13	13	0	0.000
Control Fall Asleep	24	19	5	20.833
Experimental No Sleep	36	34	2	2.778
Control No Sleep	25	21	4	16.000
Gender				
Experimental Male	16	14	2	12.500
Control Male	28	22	6	21.429
Experimental Female	33	33	0	0.000
Control Female	21	18	3	14.286

CHAPTER 4:

RESULTS

This chapter summarizes the data analysis results. The results include a profile of the participants and test scores by treatment group using descriptive statistics, an examination of the statistical assumptions, and findings for the research hypotheses.

Participants Profile

Table 4.1 summarizes the background information for the 87 participants that completed both phases of the study by treatment group. The variable class for recruitment indicates the undergraduate class where the students were presented information requesting their voluntary participation in the study. The Communications 400 class included one foreign exchange student, who is listed under the senior and higher group. The variable, fall asleep indicates whether the participants reported they did or did not fall asleep during the 30 minute EarthPulse treatment.

Table 4.1.

Background Information for the Participants by Treatment Group After Attrition

Variable	Experimental Group		Control Group		Total (n= 87)	
	n	%	n	%	n	%
Gender						
Male	14	29.8	22	55.0	36	41.4
Female	33	70.2	18	45.0	51	58.6
Total	47	100.0	40	100.0	87	100.0
Undergrad Year in School						
Freshman	10	21.3	14	35.0	24	27.6
Sophomore	7	14.9	7	17.5	14	16.1
Junior	13	27.7	12	30.0	25	28.7
Senior/+	17	36.2	7	17.5	24	27.6
Total	47	100.0	40	100.0	87	100.0
Major*						
Sci, Eng, IST	13	27.7	8	20.0	21	24.1
HHD	12	25.5	14	35.0	26	29.9
Bus, Edu, Com, LA	18	38.3	16	40.0	34	39.1
All others	4	8.5	2	5.0	6	6.9
Total	47	100.0	40	100.0	87	100.0
Recruitment Class						
Edpsy 010	15	31.9	21	52.5	36	41.4
STS 100	13	27.7	7	17.5	20	23.0
STS 101	6	12.8	4	10.0	10	11.5
STS 200	9	19.1	4	10.0	13	14.9
COMM 404	4	8.5	4	10.0	8	9.2
Total	47	100.0	40	100.0	87	100
Fall Asleep During Treatment						
Yes	13	27.7	19	47.5	32	36.8
No	34	72.3	21	52.5	55	63.2
Total	47	100.0	40	100.0	87	100.0
* MAJOR KEY	Edu = Education		IST = Information Systems Technology			
Sci = Science	Com = Communications		HHD = Health & Human Development			
Eng = English	LA = Language Arts					
Bus = Business						

Test Scores Summarized by Treatment Group

Descriptive statistics were used to examine the central tendency (mean) and the variability (standard deviation) of test scores of the treatment groups.

Table 4.2 summarizes the means and standard deviations for the declarative knowledge tests by treatment group.

Table. 4.2.

Summary of Means and Standard Deviations for the Declarative Knowledge Tests by Treatment Group

Test	Treatment Group	Mean Test Score Points	Standard Deviation	Range	
				Low	High
Learning	Experimental n = 47	19.340	4.213	10	26
	Control n = 40	19.425	4.025	12	30
	Total n = 87	19.379	4.104	10	30
Retention	Experimental n = 47	15.575	3.734	8	25
	Control n = 40	15.875	4.058	6	27
	Total n = 87	15.713	3.867	6	27

Note: mean values on the learning and retention tests for declarative knowledge could have ranged from a low of 0 points to a high of 30 points.

Checking of Statistical Assumptions

Before analyzing the data for the study's hypotheses, the researcher examined whether the assumption for a normal distribution of the interval/ratio variable(s) was met. The researcher used multiple indicators to assess normality (Field, 2005). The Shapiro-Wilk (S-W) test for normality was calculated ($n=87$), and the researcher used significance above the 0.05 level to indicate normality (Gall et al., 2003; Huck, 2004; Tabachnick & Fidell, 2007). In addition, the researcher examined the skewness values for the interval/ratio variable(s) across each level of the treatment variable. Huck (2004, p.34) suggests "skewness is not considered to be too extreme if the coefficient of skewness assumes a value anywhere between -1.0 and +1.0". Table 4.3 summarizes the Shapiro-Wilk test significance level and skewness values for normality by testing phase and treatment group.

Table 4.3.

Summary of Shapiro-Wilks (S-W) Test and Skewness Values by Testing

Phase and Treatment Group

Testing by Treatment Group (n=87)	Sig. level for S-W test	Skewness value
Learning Test		
Experimental	.045	-.497
Control	.645	.380
Overall	.334	-.125
Retention Test		
Experimental	.124	.237
Control	.789	.216
Overall	.373	.232

In the learning phase, the experimental group had a S-W test significance level of 0.045 with a skewness value of -0.497. The control group had a S-W test significance level of 0.645 with a skewness value of 0.380.

In the retention phase, the experimental group had a S-W test significance level of 0.124 with a skewness value of 0.237. The control group had a S-W test significance level of 0.789 with a skewness value of 0.216.

The overall S-W test significance level for the learning phase was 0.334 with a skewness value of -0.125. The overall S-W test significance level for the retention phase was 0.373 with a skewness value of 0.232.

Field's (2005) suggestion to examine multiple indicators for normality was used by the researcher to determine whether the normality assumption was met. Using the S-W test significance values for normality, the only value that fell slightly below the 0.05 alpha level guideline was the experimental group during the learning phase (sig = 0.045). All other S-W test significance values exceeded 0.05. Using the skewness value guidelines of Huck (2004), the assumption of normality was met as all skewness values fell between -1.0 and +1.0.

The researcher further examined the data using box and whisker plots to identify potential outliers (see Appendix F). There were no minor or major outliers identified for the learning test between groups by treatment level (n=87). For the retention test, one minor outlier (more than 1.5 IQR from the median) was identified for both the treatment and control group.

According to the 87 participants that completed both phases of the study, the assumption for equal variance was analyzed and met using a Levene's test. The p value was greater than .05 for both tests (learning test: $p = .626$; retention test: $p = .585$).

Therefore, based upon an extensive examination of the dependent variables, the researcher judged the distribution could be considered normal for both learning and retention.

Reliability/ Internal Consistency Assumption

Testing for item-reliability of the test scores was conducted using Cronbach alpha. When an instrument is initially developed, it is acceptable and realistic to have an alpha score of 0.6 and to improve the instrument over time to an alpha level of 0.7 or above (Black, 1999; Sax, 1997). Since this study utilized a first generation test, the acceptable level for reliability is approximately 0.6 or higher. The Cronbach alpha value for the learning test score was 0.659. The Cronbach alpha value for the retention test score was 0.609. Therefore, both declarative knowledge test scores obtained for the gall bladder declarative knowledge test met the “acceptable” minimum level of reliability based on Black (1999) and Sax (1997).

Results for Hypotheses

The inferential test results for the hypotheses are presented in this section. An a priori alpha level of 0.05 was used for statistical significance.

Hypothesis 1 Findings: Learning Differences

Ho 1: There is no significant difference between the experimental and the control group in the learning of declarative knowledge.

A one-way analysis of variance was used to examine the first hypothesis. The results of the analysis (Table 4.4) indicate that no significant difference existed ($n=87$, $sig. = 0.924$) in the learning of declarative knowledge between the experimental group (mean = 19.340, SD = 4.213) and the control group (mean = 19.425, SD = 4.025).

Additionally, when the results were calculated according to the original 98 participants, no significant difference existed in learning of declarative knowledge ($n=98$, $sig= 0.708$) between the experimental group (mean = 19.347, SD = 4.226) and the control group (mean = 19.041, SD = 3.840).

Hypothesis 2 Findings: Retention Differences

Ho 2: There is no significant difference between the experimental and the control groups in the retention of declarative knowledge.

A one-way analysis of variance was also used to examine the second hypothesis. The results of the analysis (Table 4.4) indicate the null hypothesis was not rejected. No significant difference ($n=87$, $\text{sig} = 0.720$) existed in the retention of declarative knowledge between the experimental group (mean = 15.575, SD = 3.734) and the control group (mean = 15.875, SD = 4.058).

Table 4.4.

Analysis of Variance Results for Learning and Retention

Dep. Variable and Source	df	Sum of Squares	Mean Square	F	Sig.
Learning Score (n=87)					
Group	1	0.155	0.155	0.009	0.924
Error	85	1448.328	17.039		
Total	87	34133.000			
Retention Score					
Group	1	1.952	1.952	0.129	0.720
Error	85	1283.864	15.104		
Total	87	22765.000			

Hypothesis 3 Findings: Sleep Differences

Ho 3: There is no significant difference between the experimental and the control group in falling asleep.

Research hypothesis three was rejected by using Chi square analysis. A significant difference was found between those who reported falling asleep and those who did not fall asleep between receiving the EarthPulse treatment and the control treatment.

Through Chi-square analysis, it was possible to analyze how many participants reported they fell asleep during the treatments. Since participants were asked to report whether or not they fell asleep after the initial EarthPulse treatment, data from the original 98 participants were analyzed. Out of the 49 people in the experimental group, 13 reported they thought they fell asleep and 36 reported they did not think they fell asleep. Out of 49 people in the control group, 24 reported they thought they fell asleep and 25 reported they did not think they fell asleep. Those in the control group were significantly ($n = 98$, $p = 0.022$) more likely to report having fallen asleep than those in the experimental group. Therefore, those in the experimental group were more likely to not fall asleep.

Table 4.5 summarizes participants who reported falling asleep or not falling asleep based on treatment group.

Table 4.5

Falling Asleep by Treatment Group

	EarthPulse (Experimental) Group		Control Group	
	n	%	n	%
Yes = Slept	13	26.5	24	48.9
No = Did not sleep	36	73.4	25	51.0
Significance	(n = 98, p = 0.022)			

There was no significant difference in the scores of those who fell asleep as compared to those that did not fall asleep on the learning score (fall asleep, 18.84, did not sleep = 19.69, $p=0.651$) or the recall score (15.56= fall asleep, did not sleep = 15.80, $p = 0.833$). Additionally, there was no statistical interaction between treatment group and status of falling asleep on learning ($F = .113$, $df = 1.83$, $p =0.738$).

Hypothesis 4 Findings: Attrition Differences

Ho 4: There is no significant difference between the experimental and the control group in attrition.

Research hypothesis three was barely accepted by using Chi square analysis, as the difference in attrition rates for the EarthPulse and control treatments approached statistical significance.

The difference that was exhibited between those in the control group versus the experimental group regarding attrition, as summarized in Table 3.4, approached statistical significance at the .05 level using Chi square analysis.

Since attrition focuses on those participants in the first phase compared to those who returned for the second phase, the original 98 participants were used for data analysis. The participants in the experimental group approached significance in returning for retention testing ($n = 98, p=0.051$), as noted in Table 4.6.

Table 4.6.

Attrition Rate by Treatment Group

	EarthPulse (Experimental) Group		Control Group	
	n	%	n	%
Did not return	2	4.1	9	18.4
Returned	47	95.9	40	81.6
Significance	(n = 98, p = 0.51)			

This approaching significance result is reported because it is important to look near and beyond the .05 significance level to identify emerging patterns and areas for future research (Huck, 2004).

Although the difference in the number of participants across treatment groups that dropped out of the study approached significance, there was not a significant difference between the learning and retention scores of these groups.

Although gender is not explored in this study, the following results support the suggestion for future research between gender, cognitive function and pulsed electromagnetic fields, as mentioned in Chapter 5. Despite random assignment, the control group contained significantly more males (n=28) than the

experimental group (n=16) for the initial test (Chi square = 5.66, p= 0.01). In the retention test, the control group (n=22) contained significantly more males when compared to the experimental group (n=14) (Chi square = 5.66, p= 0.01). Additionally, males were significantly more likely to drop out of the study than females (n=98, p=0.050).

CHAPTER 5:

SUMMARY AND DISCUSSION

This chapter begins by presenting an overview of the study. Next, a discussion of findings, limitations, and suggestions for future research are presented, followed by a conclusive summary and closing comments.

Study Overview

As presented in Chapter 1, the purpose of this study was to empirically investigate the effect of EarthPulse on learning of declarative knowledge. Furthermore, the study examined whether any other observable effect existed over time.

A total of 98 participants began this one-variable, posttest only, experimental design study. After attrition, 87 participants remained in both the learning and retention phases of the study. The study utilized an immediate posttest and delayed posttest design through random assignment. An immediate posttest was conducted directly following the learning phase and was represented by a learning score. A delayed posttest was conducted two weeks later and was represented by a retention score.

Two treatment groups, experimental and control, existed in this study. The experimental group received the EarthPulse “Entrain Up” treatment for 30 minutes. The control group received the placebo treatment for 30 minutes. Immediately following the treatment, both groups read a script on the human gall bladder, returned the script, and then completed the accompanying 30-item, multiple choice declarative knowledge test for the learning score. Two weeks later, the 87 participants returned to the same site to retake the declarative knowledge testing instrument. These participants were not given the opportunity to receive the treatments or read the gall bladder script again prior to retesting.

Data were analyzed using SPSS version 13.0. The Shapiro-Wilk and skewness tests were run to determine if the normality assumption was met. The assumption for equal variance was analyzed using Levene’s test. To determine if the item-reliability assumption was met, the Cronbach alpha values were identified for the learning and retention tests.

Research question one asked whether EarthPulse had an effect on learning of declarative knowledge, and the corresponding hypothesis proposed no significant difference to exist between the experimental and the control groups in the learning of declarative knowledge. Research question two asked whether EarthPulse have an effect on retention of declarative knowledge, and the corresponding hypothesis proposed no significant difference to exist between the

experimental and the control groups in the retention of declarative knowledge. A one-way analysis of variance was used to test these research hypotheses.

Research question three asked whether EarthPulse had an effect on sleep and the corresponding hypothesis proposed there would be no effect between the experimental and control group on sleep. Research question four asked whether EarthPulse had an effect on attrition. The corresponding hypothesis proposed there would be no effect between the experimental and control group on attrition. To explore research hypotheses three and four, Chi-square tests were conducted.

The assumptions for normality, equal variance, and item-reliability were met. Research hypothesis 1 was not rejected as there was no statistically significant difference between the experimental and the control group in the learning of declarative knowledge. Research hypothesis 2 also was not rejected as there was no statistically significant difference between the experimental and the control groups in the retention of declarative knowledge over time.

Research hypothesis three was rejected since effects of EarthPulse on sleep were observed. A significant difference ($n=98$, $sig. =0.022$) existed between the experimental and control group regarding those who fell asleep. Although research hypothesis four was rejected, the difference between the rates at which the participants in the control group and the participants in the experimental group returned for retention testing very closely approached significance ($n = 98$, $p=0.051$).

Discussion

This study was based on the following premises: first, that attention, concentration and relaxation increase in the alpha (conscious) state from 8-14 Hz (Cade & Coxhead, 1979; Wise, 2002, 2004); second, that attention is controlled by the central executive in working memory as part of information processing (Baddeley, 2002), which may be connected to learning. Therefore, it was proposed that there might be a positive effect on learning if the brain was left in an increased attentive state through the EU (alpha dominant) setting of EarthPulse.

Data revealed a significant difference between the control group and the EarthPulse treatment group in relation to falling asleep. Those in the control group were significantly more likely to fall asleep than those in the EarthPulse group. Although not confirmed in this study, it may be that those in the control group were more likely to experience a decrease or loss in attention, concentration, and alertness by moving from the alpha (conscious) state into the theta (subconscious) and delta (unconscious) states. Stated conversely, it may be that those exposed to EarthPulse on the EU setting were more likely to not fall asleep; therefore, they retained attention during the treatment. This is an important finding because it signifies that EarthPulse did have a significant effect. The goal of the EarthPulse EU setting was to stimulate an alert and attentive state, which is supported from the results of the study.

Another interesting finding is the difference between treatment groups in terms of those who returned for the retention phase. If the $p = 0.051$ level, this score just barely fell below the desired level of significance ($p = 0.050$). Therefore, it is worth noting that there may have been an effect that made subjects more likely to return for the retention phase.

The data did not reveal increases in learning or retention. The following discussion points surfaced as possible explanations of these results, which did not support the rationale for the study.

In Chapter 2, it was presented that information processing may be slowed with exposure to 45 and 60 Hz magnetic field frequencies (R. O. Becker & Selden, 1985). However, the effects of exposure to dramatically lower Hz frequencies, such as those of EarthPulse on the EU setting (0.5 – 14.1 Hz), were not researched. The results of this study indicate that information processing for learning and retention of declarative knowledge did not increase or decrease with a single, 30 minute exposure to rotating frequencies from 0.5 – 14.1 Hz. The EarthPulse manual (2005) suggests to use the device for seven days to get the most out of the investment. Therefore, perhaps the single, 30 minute exposure was not long enough to entrain the brain to cognitive functions necessary to achieve learning improvement results.

This study solely focused on declarative knowledge. Perhaps EarthPulse would have had an effect if a different learning task was selected. Perhaps the

effect on learning of declarative knowledge was so slight that it was not observable given the limited exposure and given time frame for this type of learning.

Since all participants were undergraduate students of Penn State, perhaps this population has learned over time how to naturally put themselves into the state mimicked by the EU setting. In general, those who attend Penn State were above average high school students and exhibit strong cognitive abilities, which may be evidence of them having attained the ability to enter appropriate mental states when faced with a learning task.

Since the participants were only graded on attendance and not performance, there may have been low cause for performance anxiety. In being asked to complete a low anxiety task, perhaps the participants were attentive, yet calm, which would mimic the primary state (alpha) evoked by the EU setting. All participants were college undergraduates completing the study for extra or class credit. They received credit for participating, regardless of how they performed on the tests. Therefore, this raised the possibility that participants may have performed below their ability. The participants may have lacked motivation to put forth their best effort since they were not directly affected by their performance on the test.

Task difficulty may have been an issue in this study. The test was a 30 question, four-item, multiple choice test. The average learning score was

approximately 19 points and the average retention score was approximately 16 points. On a 30 question, four-item, multiple-choice test, random guessing of answers would produce a score of 7.5, almost half of the retention score mean.

Task relevance may have been an issue in this study. The instrument selected for this research study focused on the human gall bladder. Although the instrument contained all of the necessary information for the participant's to complete the test and was designed to be motivating because the subjects may, some day, experience the health problems discussed, perhaps the content of the test played a role in how well the participants scored. If the participants found the content boring, irrelevant, or unmotivating, perhaps they performed lower than they would on a test with content of higher personal value or to which they have previous knowledge (Ericsson & Kintsch, 1995).

The instrument used for this study was a first generation instrument. The Cronbach alpha level ranged between 0.7 and 0.6, which is acceptable for a newly developed instrument, but it is desirable to have a level of 0.8 and above.

The pulsed electromagnetic fields produced by EarthPulse were to have a balancing effect on the brainwaves and electromagnetic field of the entire body (EarthPulse, 2005). Therefore, another area for discussion is the placement of the magnet along the spine. In this study, the magnet was placed near the top of the spine. It would be interesting to explore whether placing the magnet at the base of

the spine would have a different effect on cognitive function than placing it near the top of the spine.

Although this is not likely given the significant effect on sleeping and the approaching significant effect on attrition, perhaps EarthPulse did not have any effect that might affect learning.

Vc

Limitations of the Study

The research questions in this study were satisfactorily answered. Additionally, no difficulties were encountered with the sampling procedures, data collection, data analysis, and overall execution of this study. However, the following may be considered limitations.

1. Because the brainwaves of the participants were not recorded, measurements of participants' brainwaves were not collected.
2. Because this study is limited to the 98 original and 87 final undergraduate participants from Penn State University, the findings of this study may be generalizable to this population.
3. Because participants were only exposed to the EarthPulse "Entrain Up" setting for one session of thirty minutes and this was their first and only exposure to the device, perhaps they were not given adequate

time and exposure for entrainment to occur and have a significant effect on learning and retention.

4. Because the EU setting was selected for this study because it purports to possibly eliminate electromagnetic anomalies, which may increase mental performance (P. F. Becker, 2006b), this study does not provide information on possible effects associated with other settings.
5. Because participants were only exposed to one, 30 question, four-item, multiple-choice, first generation instrument to test declarative knowledge, perhaps different results would be revealed by using an instrument with higher reliability or multiple instruments.
6. Because all participants were undergraduate college students working on a “low stake” task where attendance was the important factor, not the performance outcome, generalizability of the results is limited to this particular group working on tasks perceived to be of similar levels of importance and difficulty.
7. Because the participants were asked to report whether or not they fell asleep, the data collected for this finding may be a subjective measure.
8. Because the EarthPulse Air-Core Magnet was solely placed at the top of the spine, the results of this study do not investigate effects of EarthPulse when the Air-Core Magnet is placed at other parts of the spine or body.

Future Research

The discussion points and limitations presented above reveal opportunities for future research with EarthPulse.

1. It would be informative to include EEG recordings (Houck, 1994) of the participants' brainwaves at various stages of data collection for neurofeedback, biofeedback and cognitive research and development.
2. To challenge the significant effects found in this study, perhaps future research could utilize less subjective means, such as EEG machines, to measure whether or not participants fall asleep and their level of consciousness.
3. Future research could compare and combine other treatments prior to or during the EarthPulse treatment.
4. Future research should investigate the effects of EarthPulse with longer exposure sessions over extended timeframes.
5. Another idea for future research would be to test EarthPulse on its other settings and to conduct comparative analysis of cognitive results.
6. This study focused on declarative knowledge. It would be interesting to explore the effect of EarthPulse on other cognitive

functions, such as timed speed tasks (Van Meter, 1990), to identify whether differences exist.

7. In order to further analyze the effects on cognition, research may be expanded to explore diverse participants, such as various IQ levels, academic backgrounds, professional disciplines, and psychological groupings.
8. It would also be interesting to incorporate a research design which places emphasis on the participant's testing performance (i.e. final test score) to analyze whether the results of EarthPulse are effected by motivation or performance anxiety.
9. Additionally, it would be of value to explore the effects of using lower and higher task difficulty instruments.
10. Task relevance may also be an area of consideration for future research.
11. In future research, the EarthPulse Air-Core Magnet might be placed at various parts of the spine (i.e. the base of the spine vs. the top or middle of the spine) to identify whether effects are observed.
12. Exploring the cognitive effects of using the EarthPulse Solid-Core Magnet (a higher Gauss) compared to the Air-Core Magnet (a lower Gauss) might be of value.

13. Despite random assignment, the control groups in the learning and retention phases contained significantly more males than females. Since gender was not a focus of this study, an area for future research may involve exploring effects and gender

Summary and Closing Comments

The findings of this study suggest that EarthPulse did have an effect on cognition and warrants future research. This study was exploratory in nature and revealed that EarthPulse on the EU setting had a significant effect ($p=0.022$) on sleep and very closely approached significance ($p=0.051$) for attrition.

The theoretical assumptions and methods employed in this study might best be used as a gateway for future research opportunities on cognitive functions and pulsed electromagnetic fields. Further experimental research may be built on the discussion, limitations, and future research ideas presented in this study to enhance exploration and research design, as this specific design did not reveal significant effects on learning and retention of declarative knowledge.

In today's society, technologies are emerging at an ever increasing rate. A collective responsibility exists between consumers and researchers to question and explore the effects of varying levels of pulsed electromagnetic fields on all platforms of development: body, mind, spirit... and beyond.

APPENDIX A:

GALL BLADDER INSTRUMENT REVISED BY MCKINNEY

NOTE: The following script is modified from David M. Birdwell's document titled Script A: Traditional Education named from Appendix A of his dissertation at The Pennsylvania State University, titled Applying Keller's ARC Motivation Model to Improve Case Study Learning in Distance Education at the United States Army War College, in progress at the present time (2005). Birdwell granted permission to use his instrument (Birdwell, 2005c) and approved McKinney's revised version (Birdwell, 2005b).

The script was revised in the following ways:

1. David Birdwell's name is deleted to generalize the facilitation.
2. References to the electronic version of the test are excluded to correspond with this hand held version of the same instruction delivered in person.
3. The treatment has been reworded, where appropriate, to generalize the participating audience.
4. Meet recommendations of my own dissertation committee.

In summary, changes have been made accordingly so the instrument may be given in hard copy format to individual participants in a general population of college students, rather than electronically to the US Army War College, as noted in the original script.

INSTRUCTIONS

Version 030806

Please take your time and put forth your best effort in completing this test as your active participation is very important to the quality of the results.

To ensure that the responses you make are included in the results, it is extremely important that you follow the directions exactly.

Once you have read this instruction, please raise your hand to turn in this packet and receive your quiz. Be sure to record your start and stop times.

Following reading the script, you will be asked to complete a short test. Answer the test questions based **only** on the information provided in this packet.

You may not use this instruction to complete the test.

Thank you for volunteering and your cooperation.

Introduction

Hello. Welcome to this instructional segment on gall bladder disease.

Imagine that in this exercise you have been diagnosed with gall bladder disease and your physician has recommended that you submit to surgical removal of your gall bladder. However, before that treatment option can be performed, US law requires that you be advised of the nature of your disease, the treatment options available to you, and the risks associated with each of those treatment options. Lastly, you will be asked to provide to your physician your “informed consent” to the proposed treatment.

The following instruction presents the facts, current situation, treatment options, risks, and recommendations pertaining to gall bladder disease. The instruction is designed to assist you in reaching a truly informed consent decision regarding your plan of treatment. At the end, you will be asked to complete a short test to assess your knowledge the information presented on gall bladders and gall bladder disease.

2. Facts

Health care providers use a convenient method to describe the origin or location of pain in the body: Four sections or "quadrants" of the body are produced by drawing two imaginary lines through a body, one dividing a body down the middle and one running across our chest from right to left, just below

the lower portion of our rib cage. Always making reference to the patient's right or left, gall bladder pain almost always appears in the right upper quadrant (RUQ), inside and just below the right breast.

The gall bladder is a small pear-shaped organ, technically classified as a cyst, situated underneath and behind your liver on the upper, right-hand side of your abdomen. Its purpose is to store a digestive fluid called “bile” until it is needed by your digestive system and to then provide bile in a concentrated form on demand. Bile is a digestive enzyme produced by the liver consisting primarily of bile acids and cholesterol, and it contains bile salts, electrolytes, bilirubin, and other lipids. In what can become an important ratio, these bile acids are supposed to keep the cholesterol and electrolytes dissolved and in solution. Cholesterol, although implicated in heart disease, is a key constituent of cell membranes and hormones and is absolutely necessary for life. The liver produces about seventy percent of the total cholesterol in the bloodstream. Bile salts stimulate the large intestine to secrete water and other salts, which help move the intestinal contents along and out of the body.

Bile serves to assist in the digestion of fats and certain vitamins and minerals. An elaborate duct system called the “biliary tree” carries bile from your liver to the duodenum, the name we use for the first part of your small intestine,

right where your small intestine connects to your stomach. The gall bladder lays just underneath the liver and is connected here to tubes or ducts that carry bile from the liver to the small intestine. This network of tubes is called the biliary tree because it resembles a tree with many smaller branches at the top all joining to form a trunk toward the bottom. Along the way, this biliary tree is joined by the pancreatic duct, which carries pancreatic enzymes produced in the pancreas to the duodenum and is the name for the first part of the small intestine. There, a constrictive opening called the Sphincter of Oddi opens to regulate the flow of bile. The Sphincter of Oddi is normally closed to keep churned food from exiting the stomach and entering the duodenum through the biliary tree.

Bile is continually secreted by the liver and flows from the upper-most ducts of the biliary tree down through the right and left hepatic ducts into a large duct called the Common Hepatic Duct. The gall bladder is connected to the Common Hepatic Duct, by the cystic duct. When we travel farther down the biliary tree, we refer to this same duct as the Common Bile Duct and it ultimately connects to the small intestine here.

Now, most of the 400 to 800 milliliters of bile produced daily in the healthy adult human flows directly into the duodenum, but a small portion of that amount makes its way into the gall bladder through the cystic duct. There, in the

gall bladder, bile is stored and water is removed; in fact, so much water is removed that bile stored in the gall bladder can be up to five times more concentrated than when it entered.

When a person consumes fats and certain vitamins and chemicals, they are initially churned in the stomach and then arrive at the start of the small intestine in the duodenum. When the small intestine detects the presence of fats and certain vitamins and minerals, it secretes a trigger hormone called cholecystokinin into the circulatory system. Every organ in the body except the gall bladder ignores this hormone. Cholecystokinin causes the gall bladder to constrict and results in emptying its contents fairly quickly. When the gall bladder constricts and empties its contents into the cystic duct, the contents immediately flow into the Common Bile Duct.

3. Current Situation

Your doctor has determined that your gall bladder is diseased, as most likely evidenced by the presence of “choleliths” or gallstones. That word comes from the Latin “chole” meaning bile, and “lithos” meaning “stone.” These choleliths show-up on an ultrasound scan, a computerized tomography (also called a “CT scan”), or a specific x-ray called a cholecystograph that your physician ordered. Each of these tests can help detect the presence and the

location of choleliths or gallstones, which is especially important since gallstones can block a section of the biliary tree.

Although the exact process leading to the formation of gallstones is still under investigation, certain factors are known to contribute to the disease. Bacteria and inflammation appear to play a major role in the development of gallstones. Gallstones also result from an imbalance of bile composition. Certain bile acids hold a solution of cholesterol and bilirubin, a pigment, in bile. When the ratio of bile acids to cholesterol is not sufficient to keep the cholesterol in proportion, cholesterol and bilirubin precipitate out of the bile, like a thick ugly rain. That solid cholesterol can then congeal and clump to form a kind of sludge. That sludge can congeal into gravel, and that gravel can eventually form stones, which themselves eventually can harden with sharp, rough edges. Although sharp pain can come from an obstruction anywhere in the common bile duct, when the gall bladder constricts around a hard stone with sharp edges, it creates a type of excruciating pain that many patients describe in vivid detail.

These various conditions are all connected: the presence of gallstones seems to make the gall bladder more prone to inflammation and infection, and these conditions seem to lead to more stone formation. Also, chronic inflammation and irritation of the gall bladder can, in turn, encourage tumor

formation to some degree. The pain produced by gallstones is called biliary colic; the inflammation of the gallbladder is called cholecystitis.

You should know that the formation of gallstones is not uncommon in this country; in fact, more than six hundred thousand gall bladder operations were performed in the U.S. last year alone. In this country, females are three times more likely to develop gallstones than are males, and the incidence of gallstones in obese people and in persons over the age of sixty is also notably higher than in the general population. Although genetic linkages are difficult to establish because genetic predispositions vary greatly, there are certain Native American tribes in the southwest area of the U.S. where the incidence of gallstones approaches 100 percent.

But the presence of gallstones does not, in and of itself, indicate a need for any medical treatment. In fact, many people have gallstones with no symptoms whatsoever. These so called, "silent stones" create no problems for their hosts. Just to underscore how common gallstone formation is in this country; eighty percent of all people carrying gallstones do not know that they have them.

4. Treatment Options

There are several treatment options available to patients with gall bladder disease. However, the only current medical remedy for gallstones lodged in the biliary tree, acute sterile inflammation of the gall bladder, acute infections of the gall bladder that do not respond to antibiotics, and benign and malignant tumors of the gall bladder is surgical removal through a procedure known as a cholecystectomy.

There are two ways to remove the gall bladder. In the first procedure, three or four small incisions are made in the abdominal wall through which surgical tools and fiber-optic devices are inserted that allow the surgeon to see the gall bladder and to remove it. This process is called a laparoscopic cholecystectomy and is, in general, the preferred way to remove the gall bladder; with smaller incisions, the patient's recovery time is much faster.

The other method used to remove a gall bladder is called an "open" cholecystectomy. Here, the surgeon makes a seven or eight inch laceration in the patient's upper right quadrant to expose the gall bladder and remove it. Sometimes, a cholecystectomy begins using a laparoscopic procedure, but for patient safety, the surgeon opts to switch to an open procedure. Inadvertent damage to a nearby organ or common bile duct, or the discovery of a gallstone

lodged anywhere in the biliary tree might be a cause for such a change in procedure. Additionally, adhesions from previous surgeries, unexpected hemorrhage, and severe infection or inflammation can all make it necessary to stop an attempted laparoscopic removal and use the open procedure.

Among surgeons, the major controversy over the laparoscopic procedure concerns the relative merits of laser light versus electrocautery. The laser offers better precision; electrocautery seems to be better at controlling bleeding and allows for a slightly quicker operation (about 40 minutes as compared with about 90 minutes for the laser procedure), although these figures vary from surgeon to surgeon.

Physicians may opt to use non-invasive procedures to treat the symptoms of gallbladder disease. In some cases, patients may be given an oral drug, such as Ursodiol, to dissolve gallstones. This is called oral dissolution therapy. The drawback to such a treatment is that it can take several months to dissolve stones, and patients will be required to take these drugs on a permanent basis.

Alternatively, physicians may use a sonic device called a lithotripter, a device that pulverizes gallstones using sound waves from a spark-gap device. In lithotripsy therapy the patient is placed in a water bath (or a large bag containing water is placed next to the patient's skin) and the sound is focused on the gall bladder.

The limitation of this procedure is that it only works on stones that are hard and rigid enough to be shattered by the shock waves. Additionally, the lithotripter may, in some cases, cause inadvertent damage to organs located near the gall bladder, a primary risk of this procedure. But a key point to remember is that neither treatment does anything to correct the situation which created the gallstones in the first place. Lastly, some experimentation is being done injecting a drug such as methyl-*tert*-butyl ether, through the abdominal wall, directly into the gallbladder itself where the drug acts to dissolve the stones directly. This “contact dissolution therapy” is still experimental and carries with it the additional risk of creating a wound in the gallbladder itself through which biliary enzymes can spill.

Sometimes a gallstone can become lodged in a segment of the biliary tree. The body does not tolerate blockage of any of its ducts very well, and that is true here, too. A gallbladder attack accompanied by a yellowing of the skin and eyes indicates a blockage of the flow of bile; as it backs up, the white of the eyes, in particular, will yellow. A newer treatment option that is popular with some health care providers can sometimes be used to clear a blockage of stones at the Sphincter of Oddi itself, is called an Endoscopic Sphincterotomy. Here a narrow, but hollow, steerable tube is inserted through the throat and stomach to the

duodenum, where the Sphincter of Oddi is in view. There a small knife-like device is used to lance through the sphincter to open it and allow the stones to spill into the duodenum. Regardless of the corrective procedure used, such blockage cannot be allowed to continue, and some action must be taken to clear it. If the obstruction also blocks the pancreatic duct, a life-threatening situation exists and the blockage must be cleared as soon as possible.

5. Risks

Although surgical removal of the gall bladder is a very safe procedure, the death rate associated with cholecystectomies is 1.2 percent. In otherwise healthy patients, and even patients with cancer, cholecystectomy can offer a mortality rate which approaches zero and a complete relief of all symptoms which approaches ninety percent. A primary risk in surgically removing the gall bladder is damage to the liver or Common Bile Duct. Additional risks include those related to anesthesiology and those risks related to any type of major surgery. Further complications from the operation may include bleeding, leakage of bile, and infections.

As with any procedure in which anesthesia is used, death from reaction to the anesthetic drugs, error on the part of the anesthetist, or machine failure is a remote possibility. Additionally, there is a chance of stroke, kidney failure,

pneumonia, and blood clots in the legs, which may cause swelling, pain, or death. For reasons that are not clearly understood, mortality rates from this procedure are roughly quadrupled if common bile duct exploration for stones is combined with gall bladder removal. This may be due to duct damage that is not visible to the surgeon.

6. Recommendations

You must be comfortable with the treatment recommended by your physician. You may choose to schedule another conference session with your doctor, or you may choose to get a second opinion. Regardless, your comfort level should include a reasonable range of expectations from a level of discomfort following the trauma associated with any surgery, to a continued level of discomfort following any non-surgical procedure.

Some symptomatic gall bladder patients just “want the pain to go away,” but such a position ignores the basic tenets of informed consent. Expected here is a level of understanding of the benefits and risks associated with a given recommendation, and an understanding that any recommended treatment is just a plan; once the treatment begins, a modification to that plan may be necessary to ensure the safety of the patient.

Patient expectations for the results of this surgical procedure must include acknowledgment of a reasonable risk of a large scar and a longer-than-planned-for recovery period. The procedure selected influences the length of recovery. Furthermore, since there is no medical cure for a gallstone diseased gall bladder, any procedure other than its surgical removal will include the possibility of gallstone re-appearance, even if they disappear temporarily.

7. Conclusion

Thank you for your attention during this instructional session. The goal here is to teach you enough information to make an informed and quality decision concerning your own health care options. Truly, there is no more personal decision than one you make concerning your own health care. Ultimately, the choice of any given procedure is up to you; by being better informed, the hope is that you will make a better decision.

TEST - Version 030806

Study ID-Group #: _____ Date/Time: _____

Major: _____ Gender (circle one): Male Female

Credit Class: _____ Year: (circle one): Fr. Soph. Jr. Sr.

Other: _____

Please Read Carefully

Directions:

This examination tests the knowledge of what you have learned **directly** from the provided instruction on gall bladder disease. You have an unlimited amount of time to answer these questions; however, you should be able to finish the test within 30 minutes.

For each item, select the single best answer and darken the corresponding circle on your answer sheet. Be sure to answer every item. See the example below.

Before starting, write down the **START TIME** as indicated by any clock. When you finish the test, write down the **FINISH TIME** on the last page.

Example: Where is the gall bladder typically located?

-
- A. Lower-right abdominal quadrant
 - B. Upper-right abdominal quadrant
 - C. Lower-left abdominal quadrant
 - D. Upper-left abdominal quadrant
-

START TIME: _____

Please read thoroughly and mark your single best guess answer.

Facts on the Gall Bladder

1. The gall bladder is a:
 - A. Sphincter
 - B. Duct
 - C. Cyst
 - D. Cholelith

2. Bile is an enzyme composed primarily of:
 - A. Biliary acids and cholecystokinin
 - B. Cholecystokinin and cholesterol
 - C. Pancreatic enzymes and cholecystokinin
 - D. Bile acids and cholesterol

3. Bile is produced in the:
 - A. Pancreas
 - B. Duodenum
 - C. Gall bladder
 - D. Liver

4. What is the purpose of bile?
- A. Regulates production of pancreatic enzymes
 - B. Assists in the digestion of fats, certain vitamins and minerals
 - C. Regulates the production of cholecystokinin
 - D. Assists in the digestion of sugars and proteins
5. What is the purpose of the Sphincter of Oddi?
- A. Prohibits bile and pancreatic enzymes from flowing into the liver
 - B. Regulates the flow of bile into the Common Bile Duct
 - C. Regulates the flow of bile into the duodenum
 - D. Regulates the flow of pancreatic enzymes into the Common Bile Duct
6. The biliary tree contains ducts that carry bile from the:
- A. Gall bladder to the pancreas
 - B. Gall bladder to the liver
 - C. Liver to the duodenum
 - D. Pancreas to the duodenum
7. The purpose of the gall bladder is to:
- A. Manufacture bile
 - B. Store and provide a source of concentrated bile
 - C. Manufacture cholecystokinin
 - D. Store and provide a source of concentrated cholecystokinin

8. How does the gall bladder function?
- A. Provides a constant, steady flow of cholecystokinin
 - B. Provides a constant, steady flow of bile
 - C. Slowly collects cholecystokinin, removes water, and empties fairly quickly
 - D. Slowly collects bile, removes water, and empties fairly quickly
9. What is cholecystokinin?
- A. Digestive hormone that aids in the digestion of sugars and proteins
 - B. Digestive hormone that aids in the digestion of fats and certain vitamins
 - C. Trigger hormone that causes pancreas to constrict
 - D. Trigger hormone that causes gall bladder to constrict

Current situation

10. To what does the term “cholelith” refer?
- A. An enzyme that aids in the digestion of fats
 - B. A diseased gall bladder
 - C. A gallstone
 - D. A primary component of gallstones
11. After the gall bladder empties its contents into the cystic duct, the contents immediately flow into the:
- A. Common Bile Duct
 - B. Sphincter of Oddi
 - C. Duodenum
 - D. Pancreatic duct

12. What triggers the release of cholecystokinin?
- A. Presence of gallstones
 - B. Sudden release of concentrated bile
 - C. Presence of fats, certain vitamins and minerals
 - D. Sudden release of bilirubin
13. Gallstones are composed primarily of:
- A. Cholecystokinin and cholesterol
 - B. Cholesterol and bilirubin
 - C. Cholecystokinin and bilirubin
 - D. Biliary acids and cholesterol
14. Which of the following statements is true in terms of gall bladder disease and gallstones?
- A. Inflammation can encourage tumor formation
 - B. A blockage in the cystic duct causes gallstones
 - C. Gallstones must be surgically removed
 - D. Bacteria cause an imbalance in bile composition
15. In which of the following populations is gall bladder disease more common?
- A. Males
 - B. Obese
 - C. Malnourished
 - D. African Americans

16. What organ secretes cholecystokinin?
- A. Liver
 - B. Pancreas
 - C. Gall bladder
 - D. Small intestine
17. What causes a gall bladder patient to experience sudden pain?
- A. Obstruction of the Sphincter of Oddi
 - B. Obstruction of the Common Bile Duct
 - C. Constriction of the gall bladder around a stone
 - D. Constriction of the Sphincter of Oddi around a stone
18. What is a known factor that contributes to the formation of gallstones?
- A. An imbalance in the bile composition
 - B. An obstruction of the duodenum
 - C. An obstruction of the small intestine
 - D. A “no-fat” diet

Treatment options

19. What is the procedure to surgically remove the gall bladder using fiber-optic devices and several small incisions?
- A. Laparoscopic cholecystectomy
 - B. Open cholecystectomy
 - C. Dissolution therapy
 - D. Lithotripsy therapy

20. If a gallstone becomes lodged in the biliary tree so as to obstruct it, what treatment is almost always recommended?
- A. Cholecystectomy
 - B. Dissolution therapy
 - C. Lithotripsy therapy
 - D. Aggressive antibiotic treatment
21. Which medical treatment option is most commonly suggested for acute sterile inflammation of the gall bladder?
- A. Cholecystectomy
 - B. Dissolution therapy
 - C. Lithotripsy therapy
 - D. Aggressive antibiotic treatment
22. Which treatment option involves the use of sound waves to “break-up” gallstones?
- A. Laparoscopic cholecystectomy
 - B. Open cholecystectomy
 - C. Dissolution therapy
 - D. Lithotripsy therapy
23. Which treatment option(s) involves the regular ingestion of pharmaceuticals to re-suspend gallstones?
- A. Laparoscopic cholecystectomy
 - B. Open cholecystectomy
 - C. Dissolution therapy
 - D. Lithotripsy therapy

Risks

24. The following is NOT a risk associated with anesthesia:

- A. Pneumonia
- B. Kidney failure
- C. Infection
- D. Stroke

25. Blood clots may cause all of the following, EXCEPT:

- A. Swelling
- B. Bleeding
- C. Death
- D. Pain

26. A primary risk in surgically removing the gall bladder is:

- A. Over production of bile in the liver
- B. Post operative herniation into the small intestine
- C. Perforation of the stomach and intestines
- D. Damage to the liver or Common Bile Duct

27. What is a primary surgical risk associated with lithotripsy?

- A. Recurrent stones
- B. Inadvertent damage to nearby organs
- C. Infection of the gall bladder
- D. Blockage of the duodenum

28. What would make a surgeon switch from a laparoscopic to an open cholecystectomy?
- A. Recurrent stones
 - B. Gallstones lodged in biliary tree
 - C. Infection of the gall bladder
 - D. Blockage of the duodenum

Recommended treatment

29. If your doctor recommends a treatment OTHER than surgical removal of the gall bladder, which of the following is a possible result?
- A. Gallstones to reappear even if they disappear temporarily
 - B. The liver will begin to over produce bile
 - C. A higher risk of pneumonia
 - D. A higher risk of blood clots
30. When the gall bladder is surgically removed, recovery time is determined in part by the?
- A. Number of stones to remove
 - B. Procedure performed
 - C. Severity of infection
 - D. Size of gallstones

FINISH TIME: _____

THANK YOU.

SCORING

FOR TEST Version 030806

1. C
2. D
3. D
4. B
5. C
6. C
7. B
8. D
9. D
10. C
11. A
12. C
13. B
14. A
15. B
16. D
17. C
18. A
19. A
20. A
21. A
22. D
23. C
24. C
25. B
26. D
27. B
28. B
29. A
30. B

APPENDIX B:

GALL BLADDER INSTRUMENT DEVELOPED BY BIRDWELL

Script A: Traditional Education

(Version 62204)

NOTE: Birdwell's original version of the following script was designed in 2004 for computer or web-based training. Consequently, references to screens, graphics and buttons are included in his original script. The following script may still be a work in progress for Birdwell.

1. Introduction

Hello. My name is David Birdwell and I want to welcome you to this Informed Consent Instructional Segment on gall bladder disease. Imagine that in this exercise you have been diagnosed with gall bladder disease and your physician has recommended that you submit to surgical removal of your gall bladder. However, before that treatment option can be performed, US law requires that you be advised of the nature of your disease, the treatment options available to you, and the risks associated with each of those treatment options. Lastly, you

will be asked to provide to your physician your “informed consent” to the proposed treatment.<*Words: “Informed Consent” on the screen.*>

This instructional segment is designed to teach you what you need to know to be able to render truly **informed** consent. The instruction is divided into five main areas; it also contains a short introduction and conclusion. Those options are indicated along the top of the screen in front of you. To view a segment, you simply click on the appropriate button with your mouse. I recommend that you select the options in sequence from left to right, but the choice is up to you. At the end, you will be asked to complete a short exam designed to verify two specific objectives: First, I need to assess your knowledge about gall bladders and gall bladder disease, and secondly, I need to evaluate your ability to actually use this information to render an informed decision about this health care procedure.

I encourage you to begin by clicking on the button labeled “Facts.”

2. Facts

The gall bladder is a small, pear-shaped organ, [M1]technically classified as a cyst, situated underneath and behind your liver on the upper, right-hand side of your abdomen. Its purpose is to store a digestive fluid called “bile” until it is need by your digestive system, and to provide bile in a concentrated form on demand. <*Words on screen: Stores and Concentrates Bile*> Bile is a digestive

enzyme that consists primarily of bile acids and cholesterol, although it also contains bile salts, electrolytes, bilirubin, and other lipids. In what can become an important ratio, these bile acids are supposed to keep the cholesterol and electrolytes dissolved and in solution. Cholesterol, although implicated in heart disease, is a key constituent of cell membranes and hormones, and is absolutely necessary for life. The liver produces about seventy percent of the total cholesterol in the bloodstream. Bile salts stimulate the large intestine to secrete water and other salts, which help move the intestinal contents along and out of the body.

Bile serves to assist in the digestion of fats and certain vitamins and minerals. An elaborate duct system called the “biliary tree” carries bile from your liver, [M2] where all of your bile is made, to the duodenum, the name we use for the first part of your small intestine, right where your small intestine connects to your stomach. Look at this drawing <*Drawing #1*> which correctly depicts the gall bladder and its location in your body. If you look closely here, <*Drawing #2*> you can see the gall bladder itself just underneath the liver. Now, the gall bladder is connected here <*Drawing #3*> to tubes or ducts that carry bile from the liver to the small intestine. [M3]This network of tubes is called the biliary tree because it resembles a tree with many smaller branches at the top all joining to form a trunk toward the bottom. Along the way, this biliary tree is joined by the pancreatic duct, which carries pancreatic enzymes produced in the pancreas to the

duodenum, our name for the first part of the small intestine. There, a constrictive opening called the Sphincter of Oddi, *<Words on screen: Sphincter of Oddi>* opens to allow these various enzymes to flow into the duodenum. Normally, the Sphincter of Oddi is closed to keep churned food exiting the stomach and entering the duodenum from entering the biliary tree.

Bile is continually secreted by the liver, and flows from the upper-most ducts of the biliary tree, down through the right and left hepatic ducts into a large duct called the Common Hepatic Duct. The gall bladder is connected to the Common Hepatic Duct by the cystic duct. *<Words on screen: Cystic Duct>* When we travel farther down the biliary tree, we refer to this same duct as the Common Bile Duct and it ultimately connects to the small intestine here.

<Drawing #4 >

Now, most of the 400 to 800 milliliters of bile produced daily in a healthy adult human flows directly into the duodenum, but a small portion of that amount makes its way into the gall bladder through the cystic duct. There, in the gall bladder, bile is stored and water is removed; in fact, so much water is removed that bile stored in the gall bladder can be up to five times more concentrated than when it entered.

When a person consumes fats and certain vitamins and chemicals, they are initially churned in the stomach and then arrive at the start of the small intestine in a part of that organ known as the duodenum. When the small intestine detects the

presence of fats and certain vitamins and chemicals, it secretes a trigger enzyme called cholecystokinin <*Word on Screen: “Cholecystokinin”*> into the circulatory system. Every organ in the body, except the gall bladder, ignores this enzyme. Cholecystokinin causes the gall bladder to constrict, and in so doing, the gall bladder empties its contents fairly quickly.

3. Current Situation

Your doctor has determined that your gall bladder is diseased, most likely as evidenced by the presence of “choleliths” <*Word on screen: “cholelith”*> or gallstones. [M4] That word comes from the Latin “chole” meaning bile, and “lithos” meaning “stone” - literally giving us “bile stone.” These choleliths showed-up either on an ultrasound scan, a computerized tomography (also called a “CT scan”), or a specific x-ray called a cholecystograph that your physician ordered. Each of these can help detect the presence and the location of choleliths or gallstones, which is especially important since gallstones can block a section of the biliary tree. No one knows for certain the exact process leading to the formation of gallstones, but we do know that there are certain factors which contribute to the disease. Bacteria and inflammation appear to play a role. Also, and this is important, certain bile acids hold cholesterol and a pigment called bilirubin <*Words on screen: “Cholesterol and Bilirubin”*> in solution in bile itself; when the ratio of bile acids to cholesterol is not sufficient to keep the

cholesterol in solution, cholesterol and this pigment bilirubin will precipitate out of the bile, like a thick ugly rain. That solid cholesterol can then congeal and clump to form a kind of sludge. That sludge can congeal into gravel, and that gravel can eventually form stones, which themselves eventually can harden with sharp, rough edges. Although sharp pain can come from an obstruction anywhere in the common bile duct, when the gall bladder constricts around a hard stone with sharp edges, it creates the type of pain many patients describe in vivid detail using a variety of colorful and descriptive terms.

These various conditions are all connected: The presence of gall stones seems to make the gall bladder more prone to inflammation and infection, and these conditions seem to lead to more stone formation. Also, chronic inflammation and irritation of the gall bladder can, in turn, encourage tumor formation to some degree. The pain produced by gallstones is called biliary colic; inflammation of the gallbladder is called cholecystitis <***Words on screen: “Biliary Colic” and “Cholecystitis”***>.

You should know that the formation of gallstones is not uncommon in this country; in fact, more than six hundred thousand gall bladder operations were performed in the U.S. last year alone. In this country, females are three times more likely to develop gall stones than are males, and the incidence of gall stones in obese people and in persons over the age of sixty is also notably higher than in the general population. Although genetic linkages are difficult to establish

because genetic predispositions vary greatly, there are certain Native American tribes in the southwest area of the U.S. where the incidence of gall stones approaches 100 percent.

But the presence of gallstones does not, in and of itself, indicate a need for any medical treatment. In fact, many people have gallstones with no symptoms whatsoever. These so called, “silent stones” <*Words on screen: “Silent Stones”*> create no problems for their hosts. Just to underscore how common gall stone formation is in this country, eighty percent of all people carrying gallstones do not know that they have them.

4. Treatment Options

There are several treatment options available to patients with gall bladder disease, but the only cure for gallstones, acute sterile inflammation of the gall bladder, acute infections of the gall bladder that do not respond to antibiotics, and benign and malignant tumors of the gall bladder, remains surgical removal in a procedure known as a cholecystectomy. <*Words on screen: “Gall Stones”, “Acute Inflammation,” “Acute Infection,” and “Tumors” – then “Cholecystectomy”*> There are two ways to remove the gall bladder: In the first procedure, three or four small incisions are made in the abdominal wall through which surgical tools and fiber-optic devices are inserted that allow the surgeon to see the gall bladder and to remove it. This process is called a laparoscopic

cholecystectomy <*Words on screen: “Laparoscopic Cholecystectomy”*> and is, in general, the preferred way to remove the gall bladder; with smaller incisions, the patient’s recovery time is much faster. The other method used to remove a gall bladder is called an “open” cholecystectomy. <*Words on screen: “Open Cholecystectomy”*> Here, the surgeon makes a seven or eight inch laceration in the patient’s upper right quadrant to expose the gall bladder and remove it. Sometimes, a cholecystectomy begins using a laparoscopic procedure, but for patient safety, the surgeon opts to switch to an open procedure. Inadvertent damage to a nearby organ or common bile duct, or the discovery of a gallstone lodged anywhere in the biliary tree might be a cause for such a change in procedure. Additionally, adhesions from previous surgeries, unexpected hemorrhage, and severe infection or inflammation can all make it necessary to stop an attempted laparoscopic removal and use the open procedure.

Among surgeons, the major controversy over the laparoscopic procedure concerns the relative merits of laser light versus electrocautery. The laser offers better precision; electrocautery seems to be better at controlling bleeding and allows for a slightly quicker operation (about 40 minutes as compared with about 90 minutes for the laser procedure), although these figures vary from surgeon to surgeon.

Physicians may opt to use non-invasive procedures to treat the symptoms of gallbladder disease. In some cases, patients may be given an oral drug such as

ursodiol <**Word on screen: “Ursodiol”**> to dissolve gallstones. This is called oral dissolution therapy. <**Words on screen: “Oral Dissolution Therapy”**> The drawback to such a treatment is that it can take several months to dissolve stones, and that patients will be required to take these drugs on a permanent basis.

Alternatively, physicians may use a sonic device called a lithotripter, <**Word on screen: “Lithotripter”**> a device that pulverizes gallstones using sound waves from a spark-gap device. Here, the patient is placed in a water bath (or a large bag containing water is placed next to the patient’s skin) and the sound is focused on the gall bladder. The limitation of this procedure is that it only works on stones that are hard and rigid enough to be shattered by the shock waves. Additionally, the lithotripter may, in some cases, cause inadvertent damage to organs located near the gall bladder. But a key point to remember is that neither treatment does anything to correct the situation which created the gallstones in the first place.

Lastly, some experimentation is being done injecting a drug such as methyl-*tert*-butyl ether, through the abdominal wall, directly into the gallbladder itself where the drug acts to dissolve the stones directly. This “contact dissolution therapy” <**Words on screen: “Contact Dissolution Therapy”**> is still experimental and carries with it the additional risk of creating a wound in the gallbladder itself through which biliary enzymes can spill.

Sometimes a gallstone can become lodged in a segment of the biliary tree. The body does not tolerate blockage of any of its ducts very well, and that is true

here, too. A gallbladder attack accompanied by a yellowing of the skin and eyes indicates a blockage of the flow of bile; as it backs up, the white of the eyes, in particular, will yellow. A newer treatment option that is popular with some health care providers can sometimes be used to clear a blockage of stones at the Sphincter of Oddi itself, is called an Endoscopic Sphincterotomy. <Words on screen: “Endoscopic Sphincterotomy”> Here a narrow but hollow, steerable tube is inserted through the throat and stomach to the duodenum, where the Sphincter of Oddi is in view. There a small knife-like device is used to lance through the sphincter to open it and allow the stones to spill into the duodenum. Regardless of the corrective procedure used, such a blockage cannot be allowed to continue, and some action must be taken to clear it. If the obstruction also blocks the pancreatic duct, a life-threatening situation exists and the blockage must be cleared as soon as possible. We saw this exact situation played-out in real life in the medical condition that afflicted Attorney General John Ashcroft, in the spring of 2004.

5. Risks

Although surgical removal of the gall bladder is a very safe procedure, the death rate associated with cholecystectomies is 1.2 percent. In otherwise healthy patients, and even patients with cancer, cholecystectomy can offer a mortality rate which approaches zero, and a complete relief of all symptoms which approaches ninety percent. Complications from the operation include bleeding, leakage of

bile, and infections. <Words on screen: “Bleeding,” “Leakage of Bile,” “Infections,” “Stroke,” “Kidney Failure,” “Pneumonia,” and “Blood Clots”>

The risks here include those related to anesthesiology and those risks related to any type of major surgery.

As with any procedure in which anesthesia is used, death from reaction to the anesthetic drugs, error on the part of the anesthetist, or machine failure is a remote possibility. Additionally, there is a chance of stroke, kidney failure, pneumonia, and blood clots in the legs. For reasons that are not clearly understood, mortality rates from this procedure are roughly quadrupled if common bile duct exploration for stones is combined with gall bladder removal. This may be due to duct damage that is not visible to the surgeon.

6. Recommendations

You must be comfortable with the treatment recommended by your physician. You may choose to schedule another conference session with your doctor, or you may choose to get a second opinion. Regardless, your comfort level should include a reasonable range of expectations from a level of discomfort following the trauma associated with any surgery, to a continued level of discomfort following any non-surgical procedure. Some symptomatic gall bladder patients just “want the pain to go away,” but such a position ignores the basic tenets of informed consent. Expected here is a level of understanding of the

benefits and risks associated with a given recommendation, and an understanding that any recommended treatment is just a plan; once the treatment begins, a modification to that plan may be necessary to ensure the safety of the patient. For example, if during a laparoscopic cholecystectomy, the surgeon discovers a stone lodged in the common bile duct, or if the common bile duct itself is diseased or damaged, the patient's needs are best served by switching the operation to an open cholecystectomy. Patient expectations for the results of this surgical procedure must include acknowledgment of a reasonable risk of a large scar and a longer-than-planned-for recovery period. Furthermore, since there is no medical cure for a gallstone diseased gall bladder, any procedure other than its removal will include a patient's expectation of the re-appearance of gallstones.

7. Conclusion

Thank you for your attention during this instructional session. The goal here is to teach you enough information to make an informed and quality decision concerning your own health care options. Truly, there is no more personal decision than one you make concerning your own health care. Ultimately, the choice of any given procedure is up to you; by being better informed, my hope is that you will make a better decision. *<Words on screen: "Please Click on Close this Session when you are ready.">* Please close this session by clicking on the "Close this Session" button on your screen. Thank you, again, for your attention.

Informed Consent Assessment Device

Initial Evaluation: Version #414

NOTE: Birdwell's original test contains two parts. Only the first part of this test was used for this study. The following tests may still be a work in progress based upon feedback from this study and additional research.

Name: _____ Date: _____

Remember that you are a patient who has recently been diagnosed with gall bladder disease. Your doctor has recommended that you submit to surgical removal of your gall bladder, and soon, you must decide whether to give your "informed consent."

This is an examination to see what you have learned about disease of the gall bladder, treatment options available to you, and the risks associated with those options. This exam will test your knowledge of what you have learned, and your ability to actually use that knowledge to make an informed consent decision. The test will conclude with several short examples of patients with gall bladder disease and you will be given the opportunity to decide whether you consent to

the proposed treatment, based on your knowledge of various treatment options.

This is the only test you will be given on this material.

There are two parts to this test. The first part contains 31 items, and a second part which contains 4 short, practical application questions. You have an unlimited amount of time to answer these questions, however, you should be able to finish the test within 30 minutes.

For each item, select the answer which best completes the statement or answers the question, and darken the circle next to the letter. Be sure to answer every item. See the example below. Before starting, write down the **START TIME** as indicated by any clock. When you finish the test, write down the **FINISH TIME** on the last page.

Multiple-choice

Example: Where is the gall bladder typically located?

- A. Lower-right abdominal quadrant
 - B. Upper-right abdominal quadrant
 - C. Lower-left abdominal quadrant
 - D. Upper-left abdominal quadrant
-

PART ONE

Facts about Gall Bladders

1. You have learned a great deal about the gall bladder and its function. Specifically, what is the gall bladder?
 - A. A sphincter
 - B. A duct
 - C. A cyst
 - D. A cholelith
 - E. None of the above

2. Much of the instruction you have just completed concerns a substance called “bile.” What is bile?
 - A. An enzyme composed primarily of pancreatic enzymes and cholecystokinin
 - B. An enzyme composed primarily of cholecystokinin and cholesterol
 - C. An enzyme composed primarily of biliary acids and cholesterol
 - D. An enzyme composed primarily of biliary acids and cholecystokinin
 - E. None of the above

3. Where is bile produced?
 - A. In the pancreas
 - B. In the duodenum
 - C. In the gall bladder
 - D. In the liver
 - E. None of the above

4. What is the purpose of bile?

- A. Regulates production of pancreatic enzymes
- B. Assists in the digestion of certain vitamins and fats
- C. Regulates the production of cholecystokinin
- D. Assists in the digestion of sugars and proteins
- E. None of the above

5. What the purpose of the Sphincter of Oddi?

- A. Prohibits bile and pancreatic enzymes from flowing into the liver
- B. Regulates the flow of bile into the Common Bile Duct
- C. Regulates the flow of bile into the duodenum
- D. Regulates the flow of pancreatic enzymes into the Common Bile Duct
- E. None of the above

6. What is the biliary tree?

- A. Ducts that carry bile from the gall bladder to the pancreas
- B. Ducts that carry bile from the gall bladder to the liver
- C. Ducts that carry bile from the liver to the duodenum
- D. Ducts that carry bile from the pancreas to the duodenum
- E. All of the above

7. What is the purpose of the gall bladder?

- A. To manufacture bile
- B. To store and provide a source of concentrated bile
- C. To manufacture cholecystokinin
- D. To store and provide a source of concentrated cholecystokinin
- E. None of the above

8. How does the gall bladder function?

- A. Provides a constant, steady flow of cholecystokinin
- B. Provides a constant, steady flow of bile
- C. Slowly collects cholecystokinin, extrudes water, evacuates fairly quickly
- D. Slowly collects bile, extrudes water, evacuates fairly quickly
- E. None of the above

9. What is cholecystokinin?

- A. Digestive enzyme that aids in the digestion of sugars and proteins
- B. Digestive enzyme that aids in the digestion of fats and certain vitamins
- C. Trigger enzyme that causes pancreas to constrict
- D. Trigger enzyme that causes gall bladder to constrict
- E. None of the above

Current Situation

10. To what does the term “cholelith” refer?

- A. An enzyme that aids in the digestion of fats
- B. A diseased gall bladder
- C. A gallstone
- D. A primary component of gallstones
- E. None of the above

11. What causes gall stones?

- A. An imbalance in the bile composition
- B. An obstruction of the duodenum
- C. A “no-fat” diet
- D. Answers “A” and “B”
- E. None of the above

12. What are gall stones composed of?

- A. Primarily cholecystokinin and cholesterol
- B. Primarily cholesterol and bilirubin
- C. Primarily cholecystokinin and bilirubin
- D. Primarily biliary acids and cholesterol
- E. None of the above

13. Which of the following statements is true?

- A. Gall stones are evidence of gall bladder disease
- B. Bacteria cause gall bladder disease
- C. An imbalance in the bile composition causes gall stones
- D. Answers "A" and "C"
- E. All of the above

14. Is there a genetic link to gall bladder disease?

- A. Gall bladder disease is more common in females
- B. Gall bladder disease is more common in the elderly and the obese.
- C. Gall bladder disease is more common in some Native American Indians.
- D. Verifiable genetic linkage is difficult to establish as most genetic predispositions vary greatly
- E. All of the above

15. What organ secretes cholecystokinin?

- A. The liver
- B. The pancreas
- C. The gall bladder
- D. The small intestine
- E. None of the above

16. What triggers the release of cholecystokinin?

- A. The presence of gall stones
- B. The sudden release of concentrated bile
- C. The presence of fats and certain chemicals
- D. The sudden release of bilirubin
- E. All of the above

17. What causes a gall bladder patient to experience sudden pain?

- A. Obstruction of the Sphincter of Oddi
- B. Obstruction of the Common Bile Duct
- C. Constriction of the gall bladder around a stone
- D. Answers "A" and "B"
- E. All of the above

18. When the gall bladder constricts and empties its contents into the cystic duct, into what duct or duct structure do those contents immediately flow?

- A. The Common Bile Duct
- B. The Sphincter of Oddi
- C. The duodenum
- D. The pancreatic duct
- E. None of the above

Treatment Options

19. There are two ways to surgically remove the gall bladder. One method uses a large skin incision, and the other method uses scopes and smaller incisions. What is the term used to describe the procedure using fiber-optic devices and several small incisions?
- A. Open cholecystectomy
 - B. Dissolution therapy
 - C. Lithotripsy
 - D. Aggressive antibiotic treatment
 - E. None of the above
20. If a gall stone becomes lodged in the biliary tree so as to obstruct it, what treatment is almost always recommended?
- A. Surgery
 - B. Lithotripsy
 - C. Dissolution therapy
 - D. Aggressive antibiotic treatment
 - E. None of the above
21. Which treatment option always cures gall bladder disease?
- A. Open cholecystectomy
 - B. Dissolution therapy
 - C. Lithotripsy
 - D. Aggressive antibiotic treatment
 - E. None of the above

22. Which treatment option involves the use of sound waves to “break-up” gall stones?

- A. Laparoscopic cholecystectomy
- B. Dissolution therapy
- C. Lithotripsy
- D. Aggressive antibiotic treatment
- E. None of the above

23. Which treatment option(s) involves the regular ingestion of pharmaceuticals to re-suspend gall stones?

- A. Open cholecystectomy
- B. Dissolution therapy
- C. Lithotripsy
- D. Aggressive antibiotic treatment
- E. Answers “B” and “D”

24. Which treatment option involves the surgical removal of the gall bladder?

- A. Cholecystectomy
- B. Dissolution therapy
- C. Lithotripsy
- D. Aggressive antibiotic treatment
- E. None of the above

Risks

25. Although surgical removal of the gall bladder is a very safe procedure, there are identifiable risks; the risks here include those related to anesthesia and those related to any type of major surgery. Risks associated with anesthesia include:

- A. Stroke
- B. Kidney failure
- C. Pneumonia
- D. Blood clots in the legs
- E. All of the above

26. Blood clots in the legs can show up a few days after surgery. Blood clots:

- A. Can cause the leg to swell and hurt
- B. Can become dislodged and travel to the liver
- C. Can cause death
- D. Answers "A" and "C"

27. Risks common to any type of surgery include:

- A. Infection, deep or at the skin level
- B. Bleeding, either during or after the operation
- C. Skin scars
- D. Answers "A" and "B"
- E. All of the above

28. Risks which may accompany surgical removal of the gall bladder include:
- A. Damage to the liver or Common Bile Duct
 - B. Post operative herniation into the small intestine
 - C. Perforation of the stomach and intestines
 - D. Answers "A" and "C"
 - E. All of the above
29. What is the primary surgical risk associated with lithotripsy?
- A. Recurrent stones
 - B. Inadvertent damage to nearby organs
 - C. Infection of the gall bladder
 - D. Blockage of the duodenum
 - E. None of the above
30. What risk is inherent with either an open or a laparoscopic cholecystectomy?
- A. Recurrent stones
 - B. Inadvertent damage to nearby organs
 - C. Infection of the gall bladder
 - D. Blockage of the duodenum
 - E. None of the above

Recommended Treatment

31. If your doctor recommends and you agree to a treatment other than surgical removal of the gall bladder, which of the following is true?
- A. You should expect gall stones to reappear even if they disappear
 - B. You will assume a higher risk of pneumonia
 - C. You will assume a higher risk of blood clots
 - D. Answers "B" and "C"
 - E. All of the above
32. If you agree to surgical removal of your gall bladder, which of the following will determine the length of your recovery?
- A. The number of recurrent stones
 - B. The procedure performed
 - C. Infection of the gall bladder
 - D. Answers "B" and "C"
 - E. None of the above
33. If you reject all treatment options provided by your health care provider, which of the following may you expect?
- A. The severe pain you experience during attacks will increase
 - B. The risk of blockage of the duodenum will increase
 - C. The risk of infection of the gall bladder will increase
 - D. Answers "A" and "C"
 - E. None of the above

End of Part One; please turn the page and continue with Part Two.

PART TWO

Directions:

The following four scenarios are designed to test your ability to actually use the information you have learned about the gall bladder to make decisions concerning patients who have gall bladder disease. Read each patient profile and then indicate the treatment option you feel is appropriate for that specific patient. Please take time to write a few words describing why you feel that way.

Patient Scenario One:

This 75 year old white male attended family reunion and ate three pieces of chocolate pie. Developed acute attack of RUQ (Right Upper Quadrant), colicky-type pain which subsided within a few hours. No previous similar episode. No previous Hx (history) of ulcer or gallstones. No family Hx of gallstones. Health generally good, except he had CAB (Coronary Artery Bypass) 3 years ago. CBC (Complete Blood Count) showed transient increase in WBC (White Blood Cells) up to 11,000 mm³ (cells per cubic millimeter), and decrease back to 7,500 mm³ within 24 hours. Sonogram of gall bladder showed one stone shadow measuring 1.5cm diameter in fundus (part of a hollow organ opposite its opening) of gall bladder. No further colicky pain after 24 hours.

Rx (treatment): Recommend patient for (please indicate your choice or choices, and briefly state why):

- Surgery
- Lithotripsy
- Dissolution therapy
- Aggressive antibiotic treatment
- Wait, take no action now

Patient Scenario Two:

This 46 year old Latin American female mother of 5 children with family Hx of gall stones: both parents and her maternal grandmother. Complained of chronic Hx of “indigestion” with frequent attacks after meals. Present attack followed eating a “bowl of chili.” No cardiac Hx. Normal EKG (electrocardiogram). Negative UGI (Upper gastrointestinal x-ray series). Negative chest x-ray. No pulmonary Hx. Sonogram of gall bladder shows multiple small gall stones and dilated common bile duct suggesting stone obstruction of duct. Serum bilirubin of 4.6, urine bilirubin (urobilinogen) up. Liver enzyme levels climbing. Tenderness to palpations (feeling) of URQ abdomen. WBC 13,000 mm³. Segmented cells shift to left (increase in newly-formed cells). Pulse count 85. Bowel sounds sluggish.

Rx (treatment): Recommend patient for (please indicate your choice or choices, and briefly state why):

- Surgery
- Lithotripsy
- Dissolution therapy
- Aggressive antibiotic treatment
- Wait, take no action now

Patient Scenario Three:

This 26 year old white female with 2 children, most recent child born 6 weeks ago. Sonogram shows 2 gall stones in fundus of gall bladder, each 1 cm in size. Pt(patient) is obese, and is of short stature. Pt had toxemia of pregnancy with second child and is moderately hypertensive (high blood pressure). She has had 2 episodes of stone colic, one 6 months ago, during last pregnancy, but no sonograms were done then because of transient nature of attack and her obesity. Any surgery now would cause major disruption of her family life because of her need for childcare and no immediate presence of other family members. Pt has had a major problem in controlling BP (blood pressure), her weight, and emotional problems. She has a food preference for fatty foods, but denies loudly that she overeats; states that she, “must have a glandular problem.” She has had previous psychiatric care. Thyroid function tests normal. No evidence of elevated WBC. No jaundice. One older sister has had gall bladder surgery, as has her mother. Mild tenderness in RUQ, but “less than yesterday,” she states. Sluggish bowel sounds.

Rx (treatment): Recommend patient for (please indicate your choice or choices, and briefly state why):\

- Surgery
 - Lithotripsy
 - Dissolution therapy
 - Aggressive antibiotic treatment
 - Wait, take no action now
-
-

Patient Scenario Four:

This 56-year-old Native American male presented himself for treatment of chronic “indigestion.” Pt states that indigestion has worsened consistently over the past six months and that he frequently suffers from painful “stomach aches.” Pt is 5’ 10” tall, and weighs 175 pounds. Sonogram shows many small to medium sized stones (1-2 cm) in the gall bladder. EKG reveals arrhythmia (irregular heartbeat) and Pt is hypertensive (has high blood pressure). Pt has had a significant problem in controlling BP (blood pressure). No evidence of elevated WBC. No jaundice. One younger sister has had gall bladder surgery. Pt currently experiencing tenderness in RUQ. Sluggish bowel sounds.

Rx (treatment): Recommend patient for (please indicate your choice or choices, and briefly state why):

- Surgery
- Lithotripsy
- Dissolution therapy
- Aggressive antibiotic treatment
- Wait, take no action now

FINISH TIME: _____

SCORING

For Version #414

1. C
2. C
3. D
4. B
5. C
6. C
7. B
8. D
9. D
10. C
11. A
12. B
13. E
14. E
15. D
16. C
17. E
18. A
19. E
20. A
21. A
22. C
23. B
24. A
25. E
26. D
27. E
28. D
29. B
30. B
31. A
32. B
33. A

APPENDIX C:

ASSISTANT TRAINING MATERIALS

Thank you for assisting in this research study. Your involvement will take place during the Spring 2006 semester, and will be kept as minimal as possible. Training for the data collection will take a maximum of thirty minutes and will be conducted prior to actual data collection. A review of data collection procedures will take place prior to each day of data collection, as necessary.

Your involvement in the data collection phase of this study may take different forms. Some assistants will be asked to assist in the EarthPulse phase and/or to help in the logistics of running the data collection. All participants are important and will be asked to help in keeping the study running as smoothly and timely as possible.

General Rules During Data Collection

1. Inclusion criteria for participants in this study are the following: a current Penn State undergraduate student, 18 years of age or older, not pregnant, does not have a pacemaker and/or no history of seizures or epilepsy.
2. Each participant will be assigned a code for their identity. This code is to be retained by the participant throughout the study.
3. No food or drink in the testing areas.
4. When positioning the participant in the EarthPulse session, make sure the magnet is placed under the pillow and at the upper area of the participant's neck so that a pressure point on the neck is not created from the magnet. The North "N" side of the magnet is to be pointed upward. The participant may feel the magnet, but should not have pain or pressure from its placement. If they do feel pain or pressure, please position the pillow and magnet to relieve this discomfort at any time during the session.
5. Participants and assistants are to remain quiet during the 30 minute EarthPulse exposure period. This is very important, as the room should be quiet and dimly lit for this 30 minute EarthPulse treatment. If participants are noisy, please go ask them to be quiet and relax for the 30 minutes.

Questions & Contact Information

If you have any questions throughout this study, please contact me directly at hem127@psu.edu, h_mckinney@hotmail.com or (home phone #). Additionally, if you have questions during the data collection sessions, please ask Dr. Catherine Augustine or me for clarification. I sincerely thank you for your time and assistance in this study. Your efforts are necessary to help this study run in an efficient and effective manner. You are an important asset to this study and this experience.

Sincerely,

Heather E. McKinney
Ph.D. Candidate
The Pennsylvania State University

APPENDIX D:

PARTICIPANT OVERVIEW

The following is to be read by the participants and the assistants involved with the study prior to data collection. Each participant and assistant is to receive a copy.

1. Thank you for coming today.
2. Introduction of researcher and assistants.
3. Reminder of inclusions/exclusions: EarthPulse mimics the NATURALLY low frequencies of the Earth, operating at frequencies (.5-14 Hz) that are a fraction of household appliances, power lines, and cell phones (60 Hz) and especially GHz wireless networks. EarthPulse has not yet been tested on pregnancy, those with pacemakers or a history of seizures of epilepsy. Therefore, to be safe, we ask that you participate in this study only if you meet all of the following inclusion criteria:
 - a. Current Penn State undergraduate student
 - b. 18 years of age or older
 - c. Not pregnant
 - d. Not have a pacemaker
 - e. No history of seizure or epilepsy.
4. No food or drink is allowed in the testing areas. Please keep these items in the hall, rooms not used for testing, or dispose of them appropriately before entering the testing site.
5. The purpose of this project is to explore the effectiveness of EarthPulse on learning and retention of factual information.
6. During the testing, you will be asked to do the following:
 - a. Show up to a predetermined site at a specified time.

- b. Individually sign in at the testing site, read the participant overview, and complete the informed consent and screening form on site. Two copies will be signed so you keep one copy, and the researcher keeps one copy. The researcher will also sign the informed consent forms.
- c. Assemble into one or two rooms, depending upon participant group size, testing site size, and the number of devices lent by EarthPulse Technologies. Group size may be anywhere from 5-30 students. However, the participants will be spaced at least 3 feet apart. This space should provide added comfort and relaxation for you. Therefore, multiple devices will be used at once with multiple participants.
- d. You will be guided to one yoga mat by an assistant. The mat will already be prepared for you with a pillow for under your head. A magnet has been placed below each pillow.
- e. Lay down for 30 minutes in a quiet, darkened room on a padded yoga mat with a pillow under the head. It is ok if you fall asleep during the 30 minute EarthPulse session.
- f. Half of the group will be receive the EarthPulse session while the other half will be receive the placebo session for the 30 minutes. This is determined by random assignment.
- g. The two groups (experimental and control) will be randomly assigned.
- h. The experimental group will receive the EarthPulse treatment.
- i. The control group will receive a placebo treatment.
- j. In both groups, the EarthPulse control box will be positioned next to you and turned on by an assistant prior to lying down.
- k. In both groups, the magnet will be attached to the EarthPulse control box and placed under your pillow, placing the magnet in the upper neck area. The pillow should cause you to not feel any pressure from the magnet. EarthPulse is a non-contact device; therefore, the magnet should not be touching the skin. Touching the skin may create a pressure point and minimize the effectiveness of the device. Assistants will be available to help correctly position the pillow and magnet, if necessary.
- l. After 30 minutes, the lights are turned on.
- m. Next, you will complete a learning test on part of the human anatomy. It will take approximately 40 minutes to read the background information and answer the corresponding questions, consisting of multiple-choice and possibly a few short answer items. Please try and answer all questions to the best of your

ability. All of the information you need to complete the test is provided in the background information given to you.

- n. Once you have completed the test, you will be asked to return in two weeks to repeat the test to complete your full participation requirement. Please do not do additional reading or preparation pertaining to the contents of the learning test over the next two weeks (unless required for another course).
 - o. Then you will sign out and be dismissed from the site.
 - p. An email message will be sent to the participants to remind them of the day, time, location and details of the second meeting.
 - q. In approximately two weeks, you will be asked to return to a predetermined site at Penn State, University Park for approximately 30 minutes for the follow-up testing session.
 - r. You will sign in at the testing site.
 - s. You will be asked to go to the testing area.
 - t. You will be given only the testing portion of the learning test again, and will NOT receive the EarthPulse treatment or control, and will NOT be asked to read the background script again.
7. Upon completion of the test, you will receive a debrief statement, sign-out, and will have completed the full participation requirements. At this point your name will be submitted for complete extra credit.

Thank you for your patience, cooperation, and involvement with this study.

Sincerely,

Heather E. McKinney
Ph.D. Candidate
The Pennsylvania State University

APPENDIX E:

DEBRIEF STATEMENT

The purpose of this study is to explore the effects of EarthPulse on the Entrain Up setting on learning and retention. The goal of the Entrain Up setting is to leave the mind in a relaxed, attentive state.

Through random assignment, half of the group participants received the EarthPulse session and half of the group received a placebo session during the 30 minute laying down period.

You were in the following group:

 1 EarthPulse session

This experimental group did receive the EarthPulse session. This group was in Room 304 of the Keller Bldg at Penn State in State College, PA. After you went up the elevators, you turned right and went into a room monitored by one of my committee members. Her name was Dr. Catherine Augustine and she has long hair. She was assisted by other IRB qualified assistants. This is the same room that all of the RETEST sessions took place. This group was just as important as the other group in making this experimental study complete.

 2 Placebo session

This control group did not receive the EarthPulse session. This group was in Room 409 of the Keller Bldg at Penn State in State College, PA. After you went up the elevators, you turned left and went into a room where I monitored the session. My mom was assisting me for this group, as she also has met the IRB assistant qualifications. This group was just as important as the other group in making this experimental study complete.

All participants received and read the same Gall Bladder script and completed the same learning test at the initial and retention phases.

Scores from the tests will be analyzed to see if a difference exists between those who received the EarthPulse session and those who received the placebo treatment.

Thank you for your participation and for making this study possible. If you have questions regarding this study, you may email me at hem127@psu.edu.

Sincerely,

Heather E. McKinney
Ph.D. Candidate
The Pennsylvania State University

APPENDIX F:

**BOX-PLOTS FOR LEARNING AND RETENTION SCORES BY
TREATMENT**

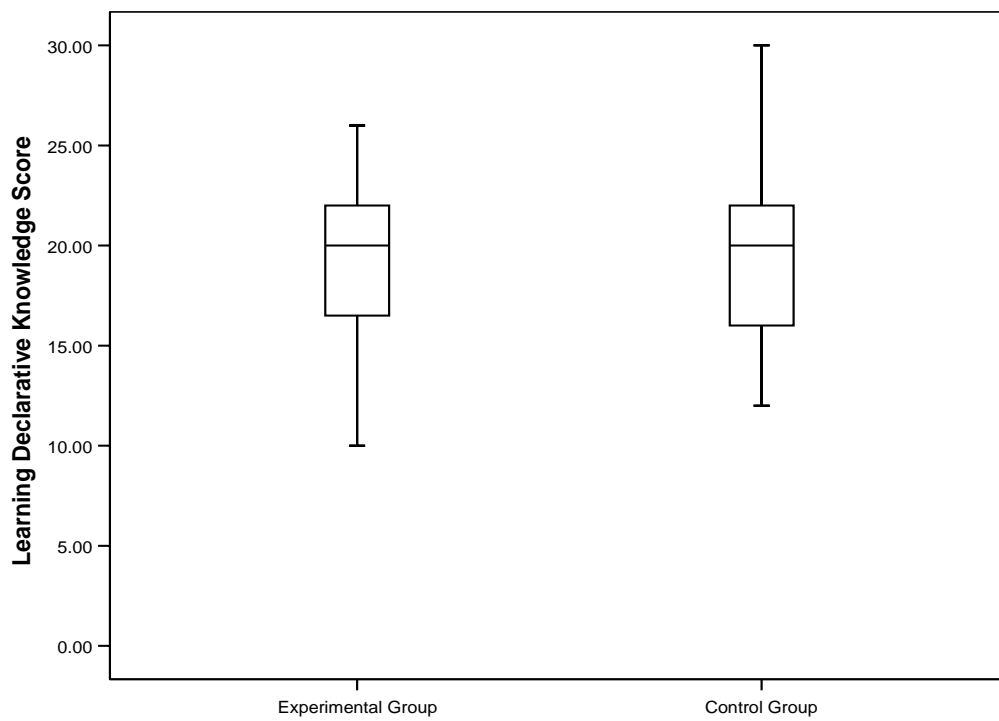


Figure . Learning declarative knowledge by treatment level

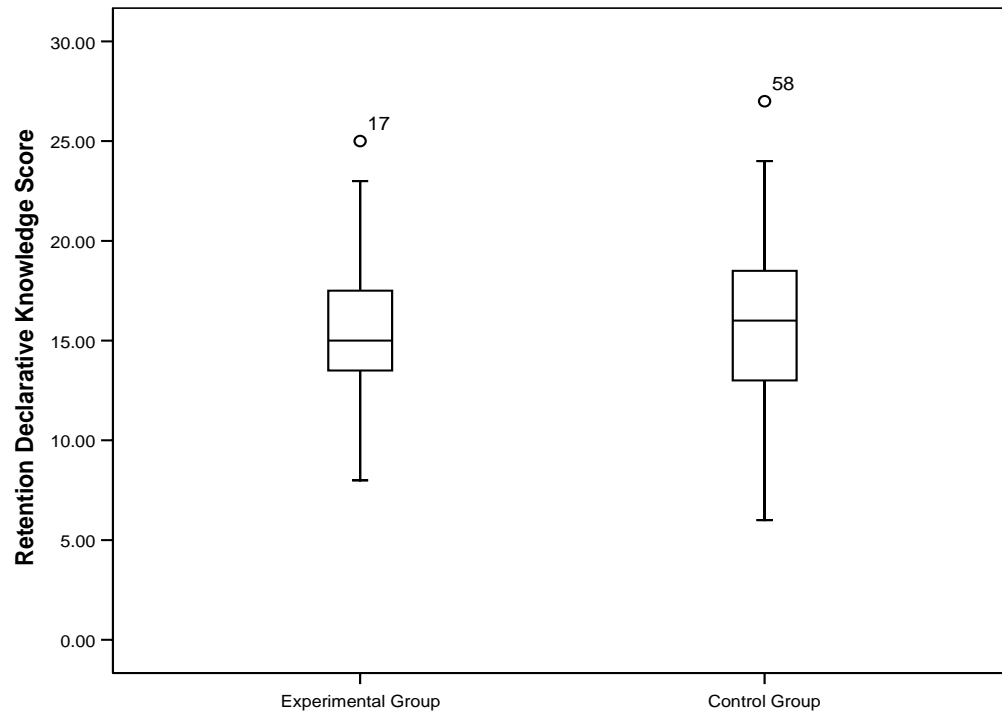


Figure . Retention declarative knowledge by treatment level

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