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A Pilot Project to Develop a Tool to Assess Gain in Knowledge in Third Graders Participating in a Science Based Drug Prevention Education Curriculum

Miriam Dawn Butler
University of Missouri-St. Louis

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Miriam Butler RN, MSN, FNP-BC, NP-C

M.S.N., Family Nurse Practitioner, University of Missouri-St. Louis, 1997

B.S.N., University of Missouri-St. Louis, 1989

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Committee Chairperson

Nancy Magnuson, DSN

Advisory Committee

Kimberly Allen, PhD

Wilma J. Calvert, PhD

Sue Farberman, DNP

James Topolski, PhD

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Abstract

Drug use and abuse presents a significant problem to individuals, families, and law enforcement in communities across the United States. Methamphetamine is a particular concern in one rural eastern Missouri county. Much work being done in this county by multiple agencies to decrease methamphetamine production and use. Little attention, however, has been focused on prevention in the elementary schools. Substance use and experimentation may begin as early as 12 years old or even earlier. By initiating a proven drug prevention education curriculum before children begin to experiment with tobacco, alcohol and illicit drugs, drug use may be delayed or prevented.

Community Oriented Policing Services (COPS) grant funds have supported a collaborative initiative between the University of Missouri St Louis College of Nursing, Partners Responsible 4 Increasing Drug Education (PRIDE), the county Sheriff's Department, and the County Health Department. This community-based participatory action research process has focused on the implementation of the *Brain Power!* Junior Scientist Program developed by the National Institute on Drug Abuse. The purpose of this specific project was to create a pilot tool to evaluate the effectiveness of the *Brain Power!* program by determining gain in drug-related scientific knowledge after the presentation of six learning modules for third graders in a rural eastern Missouri county elementary school. Data from pre and post tests demonstrated a gain in knowledge of information covered in the modules for the third graders in this project. Project benefits, limitations, barriers, challenges and implications for future research and application to practice are discussed.

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Drug use, abuse and addiction have been a concern for communities across the United States for decades. From the opium wars in the mid-1800s to prohibition in the early 1900s to the drug wars of today, our knowledge of drugs and methods of controlling drug use continues to evolve. In the early 1970s drug prevention efforts were directed toward alcohol abuse. The National Institute on Drug Abuse (NIDA) was formed in 1974 and prevention efforts were expanded to include cocaine and heroin (Goode, 2012). Current concerns include the quality or purity of drugs making them more addictive and dangerous, their availability to a wider and younger audience and the abuse of prescription drugs. Individuals are often unaware of the significant negative effect these drugs can have on their health, productivity and quality of life even into the next generation (NIDA, 1997). Preventing drug use before it begins is a cost effective and common sense approach to promoting safe and healthy communities (NIDA, 2008). Targeting children before the age of first use may be our best opportunity at prevention, waiting until adolescence may be too late (Botvin, 2000).

The need for a sustainable, evidence based, drug prevention education program was identified in a school district in a rural eastern Missouri county. Working with various community partners in the county, faculty from the University of Missouri-St. Louis College of Nursing, were awarded a grant to implement a sustainable evidence based program Funding for the project was provided by U.S. Department of Justice, Office of Community Oriented Policing Services grant. This community-based participatory action research process allowed a team of university, school, and community organizations to perform a needs assessment and compare several drug

prevention education curriculums. The *Brain Power! Junior Scientist* program, developed by the National Institute on Drug Abuse was chosen.

For three decades NIDA has led in the development of addiction science research. The NIDA 2010 Strategic Plan attacks drug abuse and addiction from several directions. The strategic goal relating to prevention is to "prevent the initiation of drug use and the escalation to addiction in those who have already initiated use" (NIH, 2010, p. 10). The *Brain Power!* program was developed by NIDA as an "age appropriate exploration of the science behind drug abuse explaining effects of drugs on the body (www.drugabuse.gov/brain-power). NIDA has developed the *Brain Power!* program but recognizes the program is not being widely implemented with limited research supporting its effectiveness. Research is needed to identify factors relating to "adoption and long-term sustainability of evidence-based prevention initiatives in schools and other settings" (National Institutes of Health [NIH], 2010, p. 20) as well as its effectiveness in real world setting.

Project Purpose

The purpose of this project was to create a pilot tool to evaluate the effectiveness of the *Brain Power!* program by determining gain in drug-related scientific knowledge after the presentation of six learning modules for third graders in a rural eastern Missouri county elementary school. To date, the Holtz and Twombly (2007) article is the only published study evaluating the fourth and fifth grade six module curriculum of the *Brain Power!* program. Determining overall effectiveness of this drug prevention program requires multiple evaluation techniques such as assessing the effectiveness of the *Brain*

Power! program to support gain in knowledge prior to the recognized age of first use of harmful substances, including nicotine, inhalants and methamphetamine.

Comprehensive Review of the Literature

A review of the literature was helpful in identifying the significance of the problem, at the national, state and local level, characteristics of proven drug prevention education programs and the theory behind their development. Nationally, the use of illicit drugs has been declining but the misuse of prescription drugs and over the counter medications has increased (NIDA, 2010). Methamphetamine and heroin have been identified as a significant problem in this rural eastern Missouri county (Missouri State Highway Patrol, 2011, Department of Mental Health, 2011).

Health Consequences

The health consequences of tobacco, alcohol and drug use are significant. Even with first time use individuals can experience nausea, seizures, rapid heart rate, respiratory failure, elevated blood pressure, dizziness, tremors, psychosis, coma and death. Long term use can lead to weight gain or loss, high blood pressure, depressed immune system, liver disease, vitamin deficiency, impotence, central nervous system damage, memory loss, cancer, depression, paranoia, and psychosis (NIH, 2012). The National Institute on Drug Abuse (NIH, 2010) reports that methamphetamine use can lead to weight loss, memory loss, periodontal disease, anxiety, confusion, insomnia, mood disturbances, violent behavior, paranoia, hallucinations and delusions. Long term use of methamphetamine causes physical changes to the brain, some of which have been found to be irreversible even after two or more years of non-use and include psychosis, auditory and visual hallucinations, delusions and memory loss. The Drug Abuse Warning

Network (DAWN) reported 4.6 million drug-related emergency department visits in 2009 (NIH, 2011). The NIH (2008) ranks alcohol as the second most costly health concern, tobacco, sixth, and drug disorders the seventh most costly with a total cost estimate of $510.8 billion. In comparison, the annual cost to society for diabetes is $131.7 billion and for cancer, $171.6 billion (NIH, 2008).

Drug Use in America

Drug abuse is a top social problem contributing to significant health concerns, school failure, family discord, accidents, injury, violence, unplanned and unsafe sex, unplanned pregnancy, and suicide (NIH, 2012; Office of Juvenile Justice and Delinquency Prevention 1998). According to the 2010 Substance Abuse and Mental Health Services Administration (SAMHSA, 2010), 22.6 million Americans (8.9% of the population) aged 12 or older were current (past month) illicit drug users. The United States Department of Health and Human Services (HHS), Healthy People 2020 (2011), reports 22 million Americans were estimated to be struggling with drug abuse or addiction and 95% were unaware they had a problem. The National Institute on Drug Abuse (NIDA) reports 50% to 80% of child abuse and neglect is related to drug abuse, 31% of homeless persons use drugs and 60% of federal inmates are incarcerated for drug related crimes (NIH, 2012). While estimates of the cost of addiction and drug use vary, a report by the White House, Office of National Drug Control Policy (2012) estimated the 2007 cost to the country in healthcare, productivity, criminal justice system costs to be $193 billion, increasing at 5.3% annually. The White House Office of National Drug Control Policy (2012) estimated spending in fiscal year 2012 to be $10.1 billion for substance abuse prevention and treatment programs.

Drug Use in Missouri

Missouri rates of illicit drug use have declined but remain sizable. The Missouri Department of Mental Health (2011) reported nearly 10% of the state's population, including 43 thousand adolescents, experienced abuse or dependence of an illicit drug in the past year. The most common substance used by Missouri youth is alcohol. Current (past month) adolescent alcohol use is reported to be 14.7% although 38.1% of Missouri students reported lifetime use of alcohol, 7.3% reported past 30 day marijuana use, 9.2% reported lifetime use of an inhalant and approximately 2.5% report lifetime use each of speed/meth, cocaine and ecstasy (Department of Mental Health, 2011).

Drug Use in the County of Interest

The age of first use for alcohol, tobacco, marijuana and inhalants in this county according to the May 2012 Behavioral Health Profile for current substance users in grades six through 12, is 12 – 13 years old (Department of Mental Health, 2011). Investigators have found that early use contributes to later use and abuse and progression or escalation in the types of other drugs used (Anthony & Petronis, 1995, Collins, 2002; Kandel, Yamaguchi, & Chen, 1992). Donovan (2007) found the data to be consistent across states and regions.

The drug crisis has been prominent in federal, state and local news. This county in rural eastern Missouri and neighboring counties have drawn nationwide attention for the number of methamphetamine labs and related arrests in recent years, and led the country with 253 meth lab seizures in 2011 (Missouri State Highway Patrol, 2011), nearly twice as many as the next leading Missouri county. There were 144 adolescents under the age of 18 admitted to Alcohol and Drug Abuse (ADA) substance abuse treatment programs

from this county in 2010 (Department of Mental Health, 2011). There were 94 individuals, any age, admitted to ADA substance abuse treatment programs for methamphetamine use (Department of Mental Health, 2011).

Efforts to Control Methamphetamine Production

Local cities and counties have put laws in place to limit the availability of chemicals needed to produce methamphetamine (Bill No. 09-112 Ordinance No. 09-0422). Pseudoephedrine, one of the chemicals used in making methamphetamine, is only available by prescription in many communities in the area but remains available for purchase behind the counter in neighboring areas. Statewide tracking laws require a driver's license and signature for all pseudoephedrine purchases (Missouri Department of Health and Senior Services, n.d.). Methamphetamine production continues to place a heavy burden on law enforcement, the court and family welfare systems in the area. In the past several years, however, heroin related deaths and emergency rooms visits have also moved to the forefront in this county (Department of Mental Health, 2011).

Prevention Efforts

Adults who used drugs at an earlier age were more likely to be classified as drug dependent than those who initiated their drug use at a later age (Substance Abuse and Mental Health Services Administration, 2005; Vega, Aguilar-Gaxiola, & Andrade, 2002). Early users of cannabis, by age seventeen, had higher rates of other illicit substance abuse or dependency (Lynskey, 2003), and almost half of drug abusers also suffered from alcohol abuse at some point during their lifetime (Reiger et al.,1990, Staines, Magura, Foote, Deluca, & Kosanke, 2001). The gateway theory suggests that the use of drugs such as tobacco, alcohol, marijuana or inhalants may lead to the use of illicit drugs such as

cocaine, heroin and methamphetamine (Kandel & Yamaguchi, 1993). The American Academy of Child and Adolescent Psychiatry (2011) reports the average age for first use of marijuana is 14 and alcohol can be younger than 12. One report indicates that as many as one third of fifth graders had tried alcohol and as many as 18% of eighth graders and 24% of ninth graders report being heavy users of alcohol, defined as five or more times in the past 30 days (Silvia, Thorne, & Tashjian, 1997).

Prevention efforts targeted at gateway drug use in adolescents can prevent future illicit drug use (Botvin, 2000) and this may best be achieved by educating children on the effect of drugs before they reach the age of first use or experimentation around age twelve. A goal of Healthy People 2020 (2011) is to reduce substance abuse especially in children. Thirty seven states including Missouri mandate health education that includes tobacco, alcohol and drug abuse prevention education (National Association of State Boards of Education, 2008). Drug prevention education is extremely important given the effect drug use has on individuals, families and communities.

The area of prevention science continues to grow and develop. Over the past 20 years, programs which were thought to be effective, once studied, were found to have little or no effect in decreasing drug use in the target population, wasting millions of dollars. As evidence accumulated, standards have been identified as being necessary for a program's effectiveness. Organizations such as NIDA, the Office of Safe and Healthy Schools, the Office of Juvenile Justice and Delinquency Prevention (OJJDP), the Centers for Disease Control (CDC), Substance Abuse and Mental Health Services Administration (SAMHSA), Drug Strategies and Center for Substance Abuse Prevention (CSAP) have identified programs they deem effective in reducing drug use as well as other associated

issues such as violence, bullying, gangs, improved grades and graduation rates among others (U.S.Department of Health and Human Services, 2001). Some states such as New Jersey, New York and California, have listings of approved evidence based programs. The National Registry of Effective Programs and Practices (NREPP) supported by SAMHSA lists 269 interventions that are broken down according to age, race, location, gender, setting, design, outcome, and funding. There are over 200 programs identified in the literature.

One of the most well-known drug prevention education programs is Drug Abuse Resistance Education (DARE). The DARE program became government funded and supported in 1986 and was used in 80% of the school districts in the United Sates, taught to 36 million students a year (Hanson, 2007). The General Accounting Office (GAO) released a review of six long term studies of DARE, between three and 10 years, and found no significant differences in illicit drug use between students who received DARE and those students who did not (GAO, 2003). DARE was removed from the approved programs recommended by the Safe and Drug Free School, later renamed the Office of Safe and Healthy Students.

Prevention programs are categorized by their target such as school, family, or community. School programs are usually targeted to age and/or grade level and often begin around sixth, seventh or eighth grade. Programs for younger children are often family focused. Prevention programs are also targeted according to risk such as universal for all students, selective for those at risk or indicated for students already using substances. Multi component programs targeting a combination of students, families and communities have demonstrated the most success (Pentz, 1996; Pentz et al., 1989).

Healthy Alternatives for Little Ones

New developmentally appropriate programs have been developed for children as young as preschool and kindergarten. Drug Free and Safety Sure Kids has developed material such as coloring books, books and songs for children from kindergarten through sixth grade (www.nationalchildsafetycouncil.org). Healthy Alternatives for Little Ones (HALO) is an evidence based, developmentally appropriate health education program for three through six year olds. HALO is endorsed by the National Registry of Evidence-based Programs and Practices of SAMHSA. This program has 12 units that progress from supporting a positive self-image and self-esteem to social competencies, body organ structure and function and the harmful effects of drugs, healthy peer relationships and school success to healthy lifestyles choices. Parental involvement is supported with accompanying newsletters for each unit. Outcome surveys from 2008 support an increase in knowledge and skills including what is helpful and harmful, internal organs and their function, the program's definition of healthy and increased expression of feelings (haloforkids.org/research).

There is a large body of knowledge assessing many facets of drug abuse prevention education. One area that has been ignored, especially in the younger population, is the effect of gain in knowledge on the outcomes of prevention programs. A literature search revealed only two drug prevention programs, Botvin's Life Skills Training and *Brain Power!* with published studies assessing gain in knowledge.

Life Skills Training

Botvin's Life Skills Training is the only program approved by the endorsing organizations mentioned above and the only study found that assessed gain in knowledge

(Kreutter,Gewirtz, Davenny & Love, 1991). The Life Skills Training (LST) is a school based universal program for upper elementary and middle or junior high school students 11 to 14 years old. The SAMSHA National Registry reports that LST has been extensively evaluated since 1995 with over 30 studies and seven independent evaluations. According to Botvin and Kantor (2000) it is the "most extensively evaluated school-based prevention approach available" (p. 256). The Life Skills Training website (www.lifeskillstraining.com) reports LST is used in 50 states and 33 countries. The online resource fact sheet reports an:

- 87% reduction in tobacco use
- 60% reduction in alcohol use
- 75% reduction in marijuana use
- 66% reduction in poly-drug use
- 68% reduction in methamphetamine use

Duration of effect was reportedly six years (www.lifeskillstraining.com).

Kreutter et al., (1991) assessed the effect on knowledge as well as self-concept, passivity, and locus of control. The results of the study suggested a significant positive impact on knowledge. In this study of Life Skills Training, there was a statistically significant decrease in the number of incorrect items, indicating a significant gain in knowledge about drugs and alcohol (Kreutter, 1991).

A randomized control trial in rural Iowa found students were 21% less likely to have ever smoked cigarettes, 23% less likely to have ever used marijuana (Trudeau, Spoth, Lillehoj, Redmond & Wickrama, 2003). A randomized control trial in New York of six thousand predominantly white middle income seventh graders found the LST

group 19% less likely to smoke weekly, 21% less likely to smoke a pack-a-day and 16% less likely to have gotten drunk in the last month (Botvin, 1995). Long term effects were reported by Botvin and Kantor (2000) with significantly fewer students reporting past week, past month and heavy smoking, 47% fewer experimenters with marijuana and 51% fewer drinkers one year after the end of the intervention.

The LST program, however, can be expensive with supplies costing five dollars or more per student for student material. Training costs begin at $235 per person not including travel expenses. Training is not required but training is reported to increase the effectiveness (www.lifeskillstraining.com).

Keepin' it REAL

Keepin' it REAL is a drug resistance strategy developed some 20 years ago. Original research explored the social processes of substance use offers as well as the role of race and ethnicity (www.kir.psu.edu, 2013). The program consists of ten 45 minute lessons taught over 10 weeks by trained teachers. Booster sessions are presented the following year. The strategy promoted by KiR is summarized by the acronym REAL – **r**efuse offers to use drugs, **e**xplain why you don't want to use, **a**void situations where substances are used and **l**eave situations where substances are used. Keepin' it REAL has been instituted in 50 states as well as Canada, Mexico and the United Kingdom. This program identifies beer as the most frequently offered alcoholic beverage with 50% - 70% of sampled middle school adolescents having been offered alcohol or another drug and nearly two thirds accepting offers of alcohol (www.kir.psu.edu/research/findings.shtml). Participants reported lower alcohol, marijuana and cigarette use with effects lasting eight months for cigarettes and 14 months

for alcohol and marijuana (www.kir.psu.edu, 2013). Problems with skill based type programs such as KiR include insufficiently developed abstract reasoning at this age level, suggestions that use is normative, and role playing and modeling may be iatrogenic (Ringwalt et al, 2010).

Multiple studies have been completed since 1998 looking at ethnicity, culture, gender and effectiveness of KiR. Studies found the program to have positive results in reducing use and discontinuing use (Kulis, Nieri, Yabiku, Stromwall, & Marsiglia, 2007; Hecht, Graham & Elek, 2009). Although a study of fifth and seventh graders showed that the KiR program appeared no more effective than comparison school programs and when presented only in fifth grade, there was a greater increase in substance use than in the control group (Elek, 2010).

Brain Power! Junior Scientist Program

Prevention has figured prominently in the 2010 strategic priorities for NIDA over the next five years. Their goal is to prevent the initiation of drug use and in those who have already initiated use, the escalation to addiction (NIH, 2010). This is consistent with the goal of Healthy People 2020 to reduce substance abuse to protect the health, safety, and quality of life for all, especially children (HHS, Healthy People 2020, 2011).

The *Brain Power! Junior Scientist* program was developed by the National Institute on Drug Abuse (NIDA) as an "age appropriate exploration of the science behind drug abuse explaining effects of drugs on the body (www.drugabuse.gov/brain-power). The curriculum is broken down for kindergarten – first, second -third, fourth – fifth, and sixth – ninth grades. The curriculum is available free of charge from NIDA and materials can be copied and shared as needed. Each level consists of five – seven modules

requiring about 45 minutes per module to present. The curriculum can be integrated into the science curriculum as well as other subjects. Materials include a videotape or DVD to set the stage for the day's activities, a lesson plan, a list of learning objectives, teacher preparation, a step by step procedure guide and discussion questions. Related handouts, worksheets, playing cards and posters are also included for each level.

Holtz and Twombly in a 2007 study assessed for change in knowledge after exposure to the *Brain Power!* program in fourth and fifth graders. Also assessed in the instrument were attitudes about science, attitudes and intention to use drugs. The researchers found that the curriculum played a significant role in changing knowledge about drugs compared to the control group. Even when controlling for gender, race, grade and preexisting knowledge and attitudes about drugs, the curriculum is significantly and positively related to knowledge acquisition (Holtz, 2007). No other studies are currently available on the *Brain Power! Junior Scientist* program.

Evaluating a drug prevention program is a large undertaking requiring many people to assess and evaluate multiple aspects of the program. An earlier scholarly project was utilized to identify the needs and recommendations of faculty and staff in this school in order to implement an evidence-based drug prevention and health protective factors curriculum. This study laid the groundwork for this project (Mueller, 2011). A listening sessions were conducted and key themes emerged regarding the problem of methamphetamine, the danger of methamphetamine and other drugs, the need to educate parents and children, identification of risk factors, advantages of prevention education in general and the *Brain Power!* program specifically, its integration with school wide positive behavioral support (SWPBS) currently under implementation, and lastly, the

ability for faculty and staff to evaluate the program (Mueller, 2011). The decision was made by this school's administration to add the *Brain Power! Junior Scientist* curriculum due to no cost, early and comprehensive grade level curriculum and it because it fulfills some core curricular requirements for science.

Parental Participation

The *Brain Power!* program encourages and promotes parental participation and discussion, an important component of effective drug prevention education programs. Involving parents in the planning and implementation of a prevention program is essential to its success (Zavela, 2002). Over 60% of youths, age 12 through 17 had at least one conversation with at least one parent about the dangers of drug, tobacco, or alcohol use and in these students, current, past year and lifetime use were lower than among students who did not have this conversation (SAMHSA, 2005). Family dinners are important. As the frequency of family dinners increase (five – seven times per week), teens reported a decrease in drinking, smoking, and drug use, less stress, and an increased perception of parental disapproval of drug use (National Center on Addiction and Substance Abuse, 2012). Teens who have fewer than three family dinners per week are one and one half times more likely to have used marijuana or alcohol, are three times more likely to say it is okay to use marijuana or alcohol and twice as likely to say they expect to try drugs (National Center on Addiction and Substance Abuse, 2012). It is important for parents or caregivers to provide a safe and supportive environment to teach children about the dangers of drug use (Zavela, 2002). Parents must connect with their children and clearly communicate their expectations as well as the consequences of drug

use (Zavela, 2002). Some school based programs such as *Brain power!* incorporate families into the program, recognizing the importance of parent and family participation.

School Wide Positive Behavioral Support

School wide positive behavioral support (SWPBS) is a systems approach to establish evidence based social culture of behavioral supports that promote social competence, academic achievement and safety (Sugai & Horner, 2006; Greenberg et al, 2003) which, in turn, supports and promotes protective factors. The Search Institute, a research organization "dedicated to advancing the health of children, youth, families and communities" (Search Institute.org) identified forty developmental assets. In a 2003 survey of more than 148 thousand American students in grade six through 12, the fewer developmental assets identified increased the percent of high risk behavior such as problem alcohol use, violence and school difficulties more than tenfold (Search Institute, 2006). Catalano (1999) found similar results, with the number of risk factors declining as competencies increased related to 30 day past marijuana and alcohol use, and past year arrests. Academic success increased with number of competencies and those with higher social competence showed fewer risk factors (Catalano, 1999).

Health Protective Factors

Catalano (1999; Catalano, Berglund, Ryan, Lonczak, and Hawkins, 2004) evaluated 25 effective school based programs and found that three behaviors, competence, self-efficacy, and prosocial norms, were addressed in every program, however, the most effective programs addressed eight and several addressed 10 behaviors. Catalano (1999) found that addressing a minimum of five protective factors or

behaviors was necessary for a program to be effective. In addition to competency, self-efficacy and prosocial norms, the other most commonly identified behaviors include opportunities for prosocial involvement, recognition for positive behavior and bonding (Catalano, 1999, Catalano et al, 2004).

Utilizing Catalano's rubric (Catalano, 1999) for determining protective factors in prevention programs, seven were identified:

- **Shifting peer group perceptions** – seeks to influence perception in a prosocial direction.
- **Decision making** – cognitive skills training in making choices, problem solving, coping with goals and priorities.
- **Self-management** – understanding oneself and managing emotions, self-regulation.
- **Family home unit** – actively targets an activity or parent child relationship in the home.
- **Self-efficacy** – ability to achieve goals by one's own actions; goal setting, coping skills.
- **Cognitive competence** – (two parts, social and academic) interpreting social cues, problem solving and decision making, empathy, understanding, positive life attitude, logical, analytic thinking, abstract reasoning.
- **Behavioral competence** – nonverbal and verbal communication, taking action, and effective behavior choices.

Health protective factors are a necessary part of successful drug prevention education programs (Catalano, 1999). Development and identification of health protective factors associated with *Brain Power!* will be an important component in tool development and program evaluation. Gain in knowledge contributes to cognitive and behavioral competence and decision making. Normative education contributes to peer group perception and parental participation contributes to the family home unit. SWPBS also contribute to competence, self-efficacy, self-management and decision making. These factors will be important for tool development and program evaluation.

Theoretical Foundations

There is a great deal of confusion regarding the goal of drug prevention education programs. Some organizations consider experimentation with drugs by adolescents a normal part of growth and development and seek to delay as much as to avoid drug use. "Statistics on prevalence of drug use indicate that some experimentation with drugs, especially marijuana, cannot be considered abnormal behavior among younger Americans at this time" (U.S. Department of Agriculture, 1998, p. 3).The American Academy of Child and Adolescent Psychiatry (2010, p.1) writes "All alcohol use by teens should be regarded as dangerous not only because of the risk of alcoholism but because teen drinkers put themselves in harm's way." The goal of Healthy People 2020 (2011) related to tobacco is to decrease initiation and use by adolescents and adults.

The Gateway Drug Theory

The gateway drug theory suggests that the use of tobacco, alcohol, marijuana or inhalants leads to the use of illicit drugs such as cocaine, heroin and methamphetamine (Kandel and Yamguchi, 1993). Generally, research on adolescent drug use has shown

that alcohol and tobacco are used before marijuana which is used before hallucinogens, cocaine and heroin (Kandel and Yamaguchi, 1993). A great deal of research has taken place in the past decade looking at nicotine, marijuana and alcohols role as a gateway drug. Research is looking at the changes in brain biology caused by drug use and its influence on abuse and addiction (NIH, 2010). Levine et al. (2011) studied the physiologic effect of nicotine on brain cells in mice, with the resulting biologic model suggesting that nicotine may change and prime the brain DNA for an increased response to cocaine. Hall and Lynskey (2005, p. 42) found a "reasonably strong association between regular and early cannabis use and other illicit drug use". Botvin et al (2000) suggest that prevention efforts targeted at gateway drug use in adolescents can prevent future illicit drug use. Newer prevention efforts aim to educate children on the effect of drugs before they reach the age of first use or experimentation around age 12.

Normative Education

Normative education is another goal of the *Brain Power!* program and a recommended component of effective prevention programs. Students often think that more of their friends use drugs, approve of drug use, and use them more often or heavier use, than they actually are (Silvia, 1997). Informing students of actual peer use and attitudes helps to normalize their peer activities so that students understand that not everyone is "doing it", far fewer and to a lesser extent than they assume (Silvia et al., 1997). A study prepared for the U.S. Department of Education (Silvia et al., 1997, p. 20) "found that students believed that their peers approved of drugs more than they themselves did (and more than their peers reported) and also held inflated beliefs about

the amount of drugs their peers used". This overestimation and unrealistic view supports a willingness on the part of teens to try drugs.

Social Learning Theory

Banduras' Social Learning Theory (Bandura and Adams, 1977) proposes that individuals learn by observing others attitudes, behaviors, and outcomes. Self-efficacy is described by Bandura (1977) as one's belief in their ability to respond appropriately to a situation. Bandura also theorized that self-protective factors such as school and social connectedness, parental engagement, social and emotional competence, firmly established over time are not easily ignored by the individual (Bandura, Pastorelli, Barbaranelli, & Caprara, 1999).

Theory of Reasoned Action

The Theory of Reasoned Action (TRA) was derived from Social Learning Theory by Fishbein and Ajzen (1975) and proposes that individuals consider the consequences of a behavior before performing that behavior. This theory was used as the foundation for the *Brain Power!* program developed by the National Institute on Drug Abuse (NIH, 2007). TRA supports the idea that human behavior is guided by three kinds of beliefs: behavior beliefs, normative beliefs, and control beliefs (Ajzen & Fishbein, 1980). Behavior beliefs are related to the likely consequences of the behavior and development of a favorable or unfavorable attitude about the behavior. Normative beliefs are developed according to one's perceived social pressures and expectations of others such as peer pressure or parental expectations. Lastly, control beliefs are those factors that support or interfere with the performance of behaviors. Research around control beliefs

led to an expanded Theory of Planned Behavior. This theory emphasizes the role of intention while recognizing that an individual cannot control all of the factors that affect the performance of a behavior (Ajzen, 1991). Concerns with which factors can be controlled and how they relate to the behavior continue to be debated (Thompson & Spacapan, 1991). However, these beliefs are thought to influence behavioral intention, or how one intends to behave which in turn, influences actual behavior. Performance is proportional to the amount of control and self-efficacy is an important influence of intention (Ajzen, 1991).

The theory of reasoned action would support the theory that knowledge about drugs and their effects on the brain and body are expected to positively influence behavioral beliefs, attitudes and expectations about the consequences of drug use thereby delaying or avoiding the use of drugs. Knowledge is a positive influence on personal health decisions (Ryan, 2009). The *Brain Power!* program is also expected to influence normative beliefs and expectations by influencing the (peer) group as a whole and normalizing the beliefs regarding peer beliefs and actions. The addition of the PBSWS system, parental inclusion and overall enhanced health protective factors provide students with enhanced behavioral control.

Methods

Tool Development

This pilot project will utilize a quasi-experimental method without a control group and with unmatched pre and post-testing in order to initiate the development of a valid and reliable tool for future studies. The pre and post-test were derived from the

curriculum guide and the stated goals and outcomes for each module (Appendix A). There was at least one question for each module, seven questions total. Questions one through five were multiple-choice, worth one point each. Question six consisted of four parts, matching a drug to its description. Question seven consisted of four fill in the blank to describe nerve impulse transmission. Each answer is worth one point, for 13 total points. The language or word choices were taken directly from the curriculum.

The pre and post- test, along with the curriculum goals and objectives, were presented to four third grade teachers for comments and suggestions. Two third grade general curriculum teachers and two third grade science teachers were asked to review and comment on the test. Suggestions consisted of: eliminating obviously incorrect answer choices, keep answer choices consistent, reading level may be difficult for poor readers, do not mix types of questions, a picture may be helpful in question two. Revisions were made and the pre and post-test were then reviewed by the curriculum committee of another large neighboring school district. Suggestions were made regarding the addition of graphics to increase the appeal to third graders and vocabulary is appropriate as long as it is used when presenting the material. The pre and post-test were also reviewed by a curriculum expert at the University of Missouri-St. Louis College of Education who advised that a process question might helpful, but the test did cover the objectives, content and knowledge base of the material. This expert review lends content validity to the tool and led to the pre/post-test (Appendix B).

Data Collection

An IRB exemption was obtained through the University of Missouri St. Louis (Appendix C). The pretest was administered to two groups totaling 82 third graders on the first day prior to presentation of the curriculum. The test was distributed by the classroom teachers and the students were asked to complete the pretest and return it when finished. The posttest was completed in the same manner at the end of the Module 6. Completion of the pre and posttest took no more than 15 minutes. The data were collected within a three week timeline.

The evaluation tool was easily utilized by the instructors and completed by the students in a reasonable amount of time and without difficulty. Each student completed the pre and post-test with minimal assistance. This allowed the pre and post-test to be offered within the time period allowed for the first and last module and did not require additional time to be set aside for its completion.

Data Analysis

The data were analyzed using descriptive statistics. The initial data analysis was a comparison of gain in knowledge looking at mean, median and mode of the overall score as well as each question individually. Scores for individual questions offer some insight into needed revisions for clarity. Matched data were not obtained, limiting statistical inferences. This was a pilot test to assess the ability of the tool to assess gain in drug-related scientific knowledge from the *Brain Power!* program in third graders. This study was unable to determine reliability due to the limited data collected. Revisions and

additions are indicated and additional study will be needed to establish validity and reliability.

Data from the pre and post-test demonstrated a gain in knowledge regarding the information covered in each of the modules:

- The four steps of scientific process
- The four parts of the brain
- The cerebellum has a left and right hemisphere
- Drugs and medicine can be helpful or harmful
- Addiction
- Types of drugs such as cocaine, marijuana, alcohol and nicotine
- Parts of the nervous system such as neurotransmitter, synapse, receptor and neuron

Only one student did not complete the post test, yielding 82 pre and 81 post tests. The number correct increased at posttest for each question, as shown in Table 1. Mean pretest score increased from 4.46 to 7.65 at posttest. The median score increased from 4 to 8.

Table 1. Pre and Post Test Individual Question Scores

	Pretest	Posttest	
Question topic	# correct out of 82 (Percent scoring correctly)	# Correct out of 81 (Percent scoring correctly)	Percent Gain
Scientific Process	39 (47.6)	75 (92.6)	+ 45.0
Parts of the brain	57 (69.5)	81 (100)	+ 30.5
Largest part of brain/hemispheres	17 (20.7)	40 (49.4)	+ 28.7
Helpful /harmful drugs and medicine	64 (78)	74 (91.4)	+ 13.4
Addiction definition	27 (32.9)	33 (40.7)	+ 7.8
Cocaine	28 (34.1)	50 (61.7)	+ 27.6
Marijuana	20 (24.4)	47 (58)	+ 33.6
Alcohol	37 (45.1)	57 (70.4)	+ 25.3
Nicotine	22 (26.8)	55 (67.9)	+ 41.1
Neurotransmitter	10 (12.2)	19 (23.5)	+ 11.3
Synapse	14 (17.1)	23 (28.4)	+ 11.3
Receptor	19 (23.2)	28 (34.6)	+ 11.4
Neuron	14 (17.1)	36 (44.4)	+ 27.3

Improvement in posttest scores ranged from 7.8% for the definition of addiction to 45% for the definition of scientific process. This variability requires additional study to determine if it relates to presentation of the material, vocabulary, question format or some other variable. The data show greater gains in knowledge with definition questions, with the exception of addiction, and lesser gains in knowledge regarding neurotransmission

process. This could possibly be due to the mixed question format (multiple choice versus fill in the blank) or to an increased difficulty level of specific content. For future studies, reformatting the question or presenting questions pertaining to the same content in more than one format would provide insight into whether consideration for test construction is necessary.

Project Benefits

This project affords multiple benefits to all stakeholders. A proven cost effective evidence based drug prevention education program offers an additional opportunity to schools and communities to impact future drug use by preventing or delaying drug use. The *Brain Power!* program is free and requires minimal time investment for training and implementation. The program can be easily integrated into multiple subjects within the curriculum meeting the requirements for state health and drug prevention education guidelines. Targeting students before first use is cost effective (NIDA, 2008), since adults who use drugs at an earlier age are more likely to be classified as dependent then those who initiated drug use at a later age (SAMHSA, 2005; Vega et al., 2002). This tool will be used to assess the gain in drug-related scientific knowledge which is useful to understand the effectiveness of the 2nd and 3rd grade curriculum and guide the development of assessment tools for other grade levels.

The *Brain Power!* program includes key components that have been identified as necessary for a successful drug prevention program such as parental involvement, promotion of health protective factors and normative education. These components create an environment where children and families can succeed. Parents will be better informed

and able to provide a strong and consistent message regarding the use of drugs. Students will benefit from a better understanding of the effects of drugs and the attitudes of parents and peers on drug use. Multi-component programs such as *Brain Power!* generally demonstrate the most benefit (Pentz, 1996).

Limitations

The pre and post-test developed for third grade forms a foundation for future evaluation of gain in knowledge and provides insight into needed revisions and additions. The pre and post-test also provides a basis for tool development at other grade levels. A valid and reliable tool is necessary to ensure the effectiveness of the program for future implementation and allow that information to be communicated to others in a consistent and understandable manner.

The pre and post-test did not have a clearly defined area for students to place their name and no biographical data was collected. After the pre-tests were collected, it was realized that not every pre-test had a name. For that reason, matched data was unable to be collected limiting the statistical inferences that could be made. In the future, a cover page with name and demographics could be included which could then be removed while allowing for matched data collection and more detailed demographic data analysis. The lack of identifying data created a missed opportunity for data collection in the initial pre and post-test. Matched data would have allowed additional insight into the test scores. Identifying data and demographic information will be necessary and valuable for future analysis. The lack of identifying information was a limitation to the study. In future

studies class identification could be used to look at differences between classes and assist in establishing tool reliability.

Data collection on only one group is also a limitation of the study as factors other than information from the curriculum when presented could have contributed to the gain in knowledge. Efforts were made to determine if other drug prevention information had been available to the students during the year and none were identified. Differences between the groups may exist intentionally or unintentionally through teacher assignments or for some other reason that was not considered. A control group was not available for this project. Future studies would benefit from random assignment and a control group.

Barriers and Challenges

There was little or no resistance from the elementary school faculty and staff when the program design and implementation was introduced to the faculty. The classroom teachers were helpful in organizing the students and assisting with classroom activities. The students were interested and participative.

The length of time it would take for the students to complete the pre and post-test was a concern that was unfounded. Most students completed the test within fifteen minutes. Few students needed longer than the time allowed. No students displayed anxiety over the pre or post-test or the length of time allowed for the test.

Because the pre and post-test was completed at the end of the school year, additional follow up testing was not completed for this study. It would be of interest to have these same students complete the test four to six months later to compare test scores

as well. Also, a control group was not available for comparison for several reasons including timing; it was the end of the school year, and a control group from another third grade class in the district was not supported by the district at this time. A control group will be important for future studies.

Developing a valid and reliable tool that was comprehensive and reflective of the material that was covered in the curriculum while manageable for the students and those administering the pre and post-test was challenging. Input from educators was invaluable but limited from those unfamiliar with the curriculum. Variability in reading, comprehension and skill levels was not accounted for and variability for mainstreamed children with special needs was not considered.

Maintaining fidelity of the curriculum was challenging. The *Brain Power!* curriculum itself offers additional opportunities for inclusion in other areas of the students curriculum. There are additional learning tools that can be utilized such as playing cards, posters and optional activities. Program fidelity through consistency in curriculum presentation will be necessary for evaluating the effectiveness of the program in the future.

Applications for Practice

Drug use and addiction cause financial, social and emotional problems for individuals, families, and communities. The effects on health are considerable and can be irreversible. Even first time or one time use can be devastating. The impact of drug use on children and families is significant and often continues into future generations. Drug use and addiction creates a significant financial burden for families, business, social

welfare, criminal justice, healthcare and government. The SAMHSA (2008) estimates that $18 could be saved for every $1 invested in effective drug prevention education programs. Research has shown that drug prevention efforts directed at students at an early age, before first use are cost effective and just make sense (Lynskey, 2003; Lynskey et al., 2003).

Brain Power! is a cost effective program that currently has limited published data supporting its effectiveness. *Brain Power!* was developed by NIDA, a leader in drug use prevention, addiction and treatment research. Program materials are free and easily accessible online to schools across the country. A comprehensive and detailed age appropriate curriculum, teachers' guide, additional teaching tools and resources, parent newsletter, extension and additional activities and assessment guide make *Brain Power!* a user friendly, cost effective alternative to other drug prevention curriculums that require or recommend additional training for teachers and expensive student materials. *Brain Power!* like other proven effective drug prevention programs utilizes multiple avenues to support drug use avoidance including positive behavioral support, parental participation, and normative education all of which promote health protective factors through education and information.

The DNP prepared nurse practitioner must partner with opinion leaders, school board members, potential users and professional organizations to engage stakeholders to continue research, disseminate information, facilitate change, and assess process and outcomes. Partnering with the university and other organizations impacted by drug use such as businesses, healthcare organizations and law enforcement can distribute the burden of such an undertaking while allowing widespread benefit. Health care providers

from multiple settings including pediatricians, school and public health nurses, and emergency workers can share in the knowledge development and assist in implementation and evaluation of the process and outcomes as well.

There are individuals and groups within schools that would complement and support the efforts of a proven drug prevention education program. School nurses, teachers, administrators, parents and school organizations could benefit from, support and facilitate such a program with the assistance of a facilitator. Cooperation between individuals and groups will be necessary to coordinate the program. Dissemination of information surrounding the program is vital for the programs continuation and success. Sharing the purpose, goals and outcomes with stakeholders is vital.

Initially the *Brain Power!* program was presented by community educators and then student nurses. Supporting teachers will be necessary to promote ownership and control of the program by providing guidance and support when they assume implementation of the program. Fidelity of the curriculum must be emphasized not only while assessing its effectiveness but to maintain the effectiveness of the program. The training and implementation require a minimal investment of time and energy compared to some other programs but teachers will require support and guidance.

Currently, there is no dedicated funding for the *Brain Power!* program and while the cost is minimal compared to other programs a funding source for experiment supplies, copying, paper and time will need to be found. Government leaders at the local, state and national level must be made aware of the program, and the results of the research. Local business and organizational leaders must be made aware of potential impact on the

community and needs must be explicitly stated in order to obtain support and funding. DNP's could work with government leaders to write and implement policies to obtain necessary support and funding.

This project set up an assessment process that could be replicated for other grade levels. This is important since the initial success of the *Brain Power!* program has led to additional implementation at other grade levels with plans for continued expansion. Participation and support by individuals and organizations within the school and the district as well as from the community are vital for the success of the program. The purpose, goals and success of the program including study results must be shared not only within the school but with all stakeholders including community and government leaders. Results must be published and success of the program shared with NIDA. Ultimately, it is hoped that *Brain Power!* will be included on the SAMSHA list of proven drug prevention education programs.

Implications for Future Research

Translating research into widespread practice will allow the *Brain Power!* program to have an impact on public health, as well as family and individual health, immediately and far into the future. Establishing the evidence base for the effectiveness of the *Brain Power!* program is the first step in translating the drug prevention research into practice and allowing widespread use. Determining the effectiveness of the program is critical to its long term use and wide spread implementation. The effect of the intervention on reducing drug use may not be apparent or measurable for several years. Initiating drug prevention education at an early age, before first use, is a relatively novel

approach. Assessment of gain in knowledge is a first step in understanding the effectiveness of the curriculum. The Theory of Reasoned Action supports the basis of the program, that knowledge regarding the negative impact of drugs on the brain and body should influence attitudes and intentions regarding drug use and therefore result in avoidance or delay in drug use. Assessing attitudes about drug use will be helpful for future understanding of the effectiveness of the program and in several years, information on age at first use and drug use and abuse in these students will be most informative.

This process must be able to be replicated in future studies. The universality or extensiveness of the effects of the intervention on populations and risk groups must also be determined. Other settings must also be considered when applying this information to practice. This research is being carried out in a rural setting and may not translate well to an urban setting where organizations and systems may function differently. Studies will be needed to assess the impact of the *Brain Power!* program within different settings and organizations. Organizational adoption and implementation may be challenging until evidence is available to support the effectiveness of the intervention. Schools within the same district have demonstrated a reluctance to allow the intervention to be studied. A great deal of time and effort will be required to share research findings and information with individuals and committees within the organization who can facilitate change and adoption of this program. The DNP prepared nurse practitioner is well prepared to translate and replicate research in multiple settings and organizations and share this information with all stakeholders.

As noted above it will be necessary to maintain fidelity of the curriculum especially as the program is expanded within and outside of the school district.

Engagement and implementation figure prominently in the acceptance and success of the program. Studies to monitor program fidelity will be important when the program is implemented in other settings. Parental engagement, participation and understanding of the program also figure prominently in the acceptance and success of the program and provide an area for future study. Analysis of individual components of the program will help to determine those aspects that are most beneficial.

Analysis of long term effects of the program is necessary to determine the effect on initiation and substance use and abuse. Few programs demonstrate a long term effects for more than two years. A longitudinal study would be most beneficial in identifying long term effects of the *Brain Power!* program through age 17 as this appears to be the age of first use of methamphetamine.

An assessment of health protective factors supported by the *Brain Power!* program would also be informative. This could be done by an additional or survey or by adding assessment questions to the tool. Identifying the health protective factors supported by the program and evaluating their impact on the effect of the program could provide valuable information to support the development and continued success of the program.

DNP Education Influence on Personal APRN Practice

DNP education provides the opportunity for understanding the research process as well as the process of translating research into practice. The difficulty associated with translating an intervention into the practice setting reinforced the necessity of and opportunity for the DNP. Utilizing the evidence of proven drug prevention programs

provided an opportunity to assist in the implementation of a drug prevention education program and develop a tool for analysis in a real world setting. This provided an opportunity to understand practice and delivery approaches within an organization, particularly, the integration of nursing theory and practice within an organization that does not have a healthcare focus. While the success of this drug prevention program will have an impact on students' health and safety, the setting and the program are not exclusively health related. The DNP program provided an opportunity to see healthcare and health education in a more holistic and universal manner while affecting future outcomes. The opportunity to influence population health and future outcomes in a cost effective and efficient manner is an important role of DNP education.

DNP educational experience provided an opportunity to develop specialized knowledge in an area that has an impact on practice. The literature clearly demonstrates that drug use and abuse is a problem that has not been adequately addressed by healthcare providers. Children and families are seen by healthcare providers who have an opportunity to not only address the issue within their practice but to provide support and leadership to those organizations that have daily contact with children and families. Developing, implementing, maintaining, and evaluating a proven prevention program will require support and guidance from a variety of areas including education, law and healthcare. The unique skill set of the DNP will be invaluable not only in the implementation of such a program but in its continued evaluation and dissemination of findings.

Developing a pilot evaluation tool for the third grade required cooperation and input from educators and other experts in the field. The pilot project was useful to

understand the importance of considering all aspects of a project prior to implementation. The importance of understanding how other programs were implemented and evaluated was very helpful. Most importantly, the piloting a tool provides necessary information for future revisions and changes to make the program successful and allow the collection of appropriate data. The pre and post-test content and process will be revised because the pilot test provided valuable insight into the process as well as the need to incorporate additional questions regarding demographics and attitudes to maximize the information that can be gained from the pre and posttest. The results of this test and future test will provide the necessary information to determine the effectiveness of the *Brain Power!* drug prevention education program.

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Appendix A:

Brain Power! **Grades 2 and 3 Purpose, Goals, and Objectives**

Module	Purpose and Goals	Objectives
1	• Introduction to process of science • Illustrate how information is transmitted through the senses	• Experience process of science • Learn how to ask appropriate scientific questions • Learn how to develop investigations to answer questions • Discover how information is transmitted through the senses
2	• Provide an opportunity to visualize the brain • Make students aware that the brain has different parts that perform different functions • Understand the brain in the control center for the body	• Learn the brain has different parts • Know the different parts of the brain • Identify the function of each part
3	• The student will understand that messages travel from different parts of the body to the brain and how.	• Students simulate neurotransmission • Students discover how messages travel through the body • Students learn about the relationship between the brain and the rest of the nervous system
4	• The student will learn how different drugs affect the body.	• Explain how different drugs affect the body • Explain the difference between helpful and harmful drugs • Discuss drugs that can be helpful and harmful
5	• To explain the effect of tobacco and nicotine on the body	• Understand the effect of tobacco on the body • Understand the effect of nicotine on the body
6	• Review and summarize all previous information using the effects of cocaine, marijuana, alcohol and nicotine on the brain and nervous system	• Review information about cocaine, marijuana, alcohol and nicotine • Students will be able to explain how these drugs effect the brain and nervous system

Note: Adapted from "*Brain Power! The NIDA Junior Scientists Program, Grades 2 and 3 Teachers Guide"* by U.S. Department of Health and Human Services, National Institutes of Health, National Institute on Drug Abuse. Reprinted August, 2008, NIH Publication No. 08-4575.

Appendix B: Pre and Post-Test

1) The scientific process has four steps, they are:
    a) Eat, sleep, play and read
    b) Observe, hypothesize, experiment and conclude
    c) Read about, think about, decide what should work and then try it
    d) Speculate, investigate, experiment and decide
2) The brain has four parts, they are:
    a) Cerebral cortex, cerebellum, brain stem, limbic system
    b) Hearing, seeing, thinking, smelling
    c) Hippocampus, amygdala, limbic system, spinal cord
    d) Front, back, top and bottom
3) The largest part of the brain and is divided into the left and right hemisphere.
    a) Cerebellum
    b) Brain stem
    c) Cerebral cortex
    d) Limbic system
4) Drugs and medicines are very powerful and are:
    a) Only helpful
    b) Only harmful
    c) Can be helpful or harmful
5) Drug use can change structure and function of the brain and cause addiction which is:
    a) Using drugs even though they are causing problems for you
    b) Using more and more drugs
    c) Drugs cause you to say or do things you normally wouldn't say or do
    d) Wanting to use the drug more often even though you know you shouldn't
    e) All of the above

Match the drug with the description:

A. Cocaine
B. Marijuana
C. Alcohol
D. Nicotine

_____ Comes from tobacco leaves and causes a pleasurable feeling in the brain but also causes lung cancer, emphysema, heart disease and addiction.

_____ Made from the coca plant, quickly stimulates the brain and uses up neurotransmitters causing permanent changes to the brain. It also increases blood pressure and heart rate.

_____ Not harmful to adults in small amounts but can cause addiction and slow your thinking. Long term use can cause poor nutrition and damage to your liver, kidneys and heart.

_____ Made from the cannabis plant, it affects thinking, problem solving, sensory perception, movement, balance and memory.

Complete the sentence by filling in the correct term to explain how information is transmitted through the body.

Neurotransmitters synapse receptors neuron

David steps on a tack. (OUCH!) A signal travels along the _____

Releasing chemicals called_____ into the space between the axon and dendrites called _____.

The neurotransmitters fit into spaces called _____

allowing the message to travel on to the brain.

Appendix C: IRB Exemption

Office of Research Administration

One University Boulevard
St. Louis, Missouri 63121-4499
Telephone: 314-516-5899
Fax: 314-516-6759
E-mail: ora@umsl.edu

DATE:	February 22, 2013
TO:	Miriam Butler, MSN
FROM:	University of Missouri-St. Louis IRB
PROJECT TITLE:	[328426-3] A University/Community Partnership to Reduce Methamphetamine Use in Jefferson County, MO.
REFERENCE #:	
SUBMISSION TYPE:	Amendment/Modification
ACTION:	MODIFICATIONS APPROVED
DECISION DATE:	February 21, 2013
EXPIRATION DATE:	May 4, 2013
REVIEW TYPE:	Full Committee Review

This modification was approved by the University of Missouri-St. Louis IRB for the term of this protocol. The University of Missouri-St. Louis IRB must be notified in writing prior to major changes in the approved protocol. Examples of major changes are the addition of research sites or research instruments.

An annual report must be filed with the committee. This report should indicate the starting date of the project and the number of subjects since the start of project, or since last annual report.

Any consent or assent forms must be signed in duplicate and a copy provided to the subject. The principal investigator must retain the other copy of the signed consent form for at least three years following the completion of the research activity and they must be available for inspection if there is an official review of the UM-St. Louis human subjects research proceedings by the U.S. Department of Health and Human Services Office for Protection from Research Risks.

This action is officially recorded in the minutes of the committee.

If you have any questions, please contact Carl Bassi at 314-516-6029 or bassi@umsl.edu. Please include your project title and reference number in all correspondence with this committee.