A Full Research Study Formally Analyzing an Objective, Functional Measurement of Pain with the use of a Validated Visual Analog Scale for Chronic Pain Patients for the Purposes of a Disability Determination Program.

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Abstract

The first part study determines if pain can be objectively measured through functional testing of chronic pain patients, using systolic blood pressure [SBP] as a proxy measure for pain. The second part study investigates what effect the validation of a visual analog scale [VAS], a 10-point pain measurement tool, would have when working with the chronic pain population. Neither of these theoretical processes has been done before the pilot project completed by this investigator last year, and no evidence was found of any prior investigations into these questions or ideas in multiple literature reviews.

There were two questions to be finalized in this case-control, full panel research study: can pain be objectively and functionally measured so as to be included within an evaluation such as in that of a disability determination process [DDP], or within a clinical setting? The unqualified answer to this, from this study, is a yes. Second, is it possible to validate a visual analog scale [VAS], a 10-point pain scale, for use with the chronic pain population, to improve their communication of pain? The validation process would make the pain ratings comparable both intra- and inter-personally, as well as converting the pain ratings from an ordinal to a cardinal scale. Could these results and changes then be use within a DDP, as well as in a clinical setting? The answer the validation question, from this research study, is also an unqualified yes.

This research study was designed to be the answer to these questions; there was positive proof of concept in a pilot project (Skenzich, published DDP Cycle 3, 2013). The results here now take the responses of the 251 "normal" subjects, 71 controls, and 50 narcotics users, a group sufficient to meet the "law of large numbers" and establish randomization within the panel, and guarantees the results to be stable long-term, and the results could be immediately be moved into advanced testing for process for inclusion as part of a DDP to effectively determine the individual's pain as a part of the disability process for either the Social Security Administration [SSA] or the Veteran's Administration [VA].

With these results, the DDP functional testing can now effectively determine at what level of pain the person is partially and at what level the person is permanently disabled when using the combined tools of the objective measured pain and the validated VAS tool.

Measuring pain is important, but considering pain as a primary disabling disorder is a secondary objective of this study. To show that pain can be measured functionally, repetitively, and transparently, and that the effect pain has on the life of the individual can be enumerated in a predictable manner is primary. This writer hopes to make it so that pain is not merely mentioned in a report as 'contributing to disability' but the effect of pain on the life of an individual applying for disability is front of mind for the adjudicator in the DDP process.

Background

"How we come to our knowledge of another person's pain is a nice study in communication. It has much in common with the sort of communication attempted by the painter, the poet and the musician – conveying the moods and feelings" (Parkhouse, J. & Holmes, C.M., 1963). Pain is a component of the human experience. Our pain response is a learned experience – one's expression and understanding of "greatest pain ever" changes over time; a broken arm as a teen may be a called a the worst possible pain at that point in life, but that pain will pale in comparison to the pain of child birth, or from a neurological injury (McNamara, Harmon, & Saunders, 2012). Although pain is described in many settings as only a symptom of a disorder or disease, it is a most personal experience that involves the bio-physical, psychological, social, and environmental factors of the person feeling it (Frampton & Hughes-Webb, 2011).

Pain is either acute or chronic: acute pain episodes stem from an injury or a surgical intervention and last no more than approximately 6 weeks (Choate, McDonald, & Scott, 2011). Chronic pain begins after 6 months, leaving a significant gap between the end of the acute pain period (Beard, & Aldington, 2012). The gap between end of acute and start of chronic pain allows for the variation in healing times before someone is diagnosed with a chronic condition (ibid; Choate, et al, 2011).

Chronic pain can be either the nociceptive (mechanical pain) or neuropathic (neural-based pain) variety. The difference is moot: both cause pain that is, at times, uncontrollable except with narcotics or electrical assistance (spinal cord stimulation, etc.). Both cause increased pain with movement: the nociceptive pain through the muscles and joints, (i.e., it hurts to move the knee mechanically); the neuropathic pain through neural networks that do not "fire" properly, causing pain signals to overwhelm the processes of movement direction (Arnstein, 2012). Both types of pain are present in studies of chronic pain patients (Majid, 2013). Both types of pain were present in this study's subjects.

Showing that pain can be measured functionally, repetitively, and transparently, and that the effect pain has on the life of the individual can be enumerated in a predictable manner is a primary focus of this study. Functional Capacity Evaluations [FCE] are an established means by which a physical testing of a patient is used to establish that individual patient's range of limitations from pain and joint disability, as well as listing areas of strength on which future planning may be done (Gouttebarge, Wind, Kuijer, Paul, Sluiter, & Frings-Dresen, 2010; Trippolini, Dijkstra, Jansen, Oesch, Geertzen, & Reneman, 2013; van der Meer, Trippolini, van der Palen, Verhoeven, & Reneman, 2013; Viikari Juntara, 2009). Within the FCE, the testing follows an proven protocol: a series of tasks of increasing difficulty; each task uses more muscles and greater muscle control than the previous; each successive task causes more pain and disability; continue with tasks until the testing subject reaches his/her maximum capacity of function or pain (Gouttebarge et al, 2010; Trippolini et al, 2013; & van der Meer et al, 2013). Four "all body" tasks standard in FCE are used in this study, sit, stand, walk, and step-up, with each task fulfilling the above requirements (Viikari Juntara, 2009).

Each person's physiological response to pain is identical, as multiple studies cited here will show, and as this study replicates: there is a predictable physiological process by which the body responds to all pain, in all situations, regardless if the pain is acute or chronic, nociceptive or neuropathic. There is not an individualistic response to pain; if there was, no pain killer, no

analgesic, no pain reductive process could work. There would be no study of pain because there would be nothing to study. Each person may claim an individualistic reaction to it, but the physiological response is the same within each person. Some may react dysfunctionally and go outside the approved medical community with what they claim is a goal of "pain reduction," but this is denial and part of their addictive process and is only mentioned here to eliminate that as a distraction.

In the first paper, Skenzich (2014) noted that pain should be considered by the DDP and Social Security as a separate disorder, as well as a symptom of other things, "because often there is no disorder ever fully diagnosed…all there is…is ever-present pain." Skenzich noted, from personal experience, that pain could be "all-encompassing, blinding…" and it was not any found disorder that caused her inability to work, inability to sit, inability to live a full life but the fact of the pain itself. That as a result of this study pain can now be accurately and repetitively measured, and the results can be compared intra-personally and inter-personally elevates pain from a mere symptom to disease status. Pain's effect on the function of the person, i.e., the resultant effect of the pain on the subject's life, is given but it is not the focus of this study. Chronic, intensive pain will necessarily interfere with a person's life's functions – but this study does not have any focus on that type of functionality. The functionality that is the focus of this study is the functions performed to achieve testing results, to achieve the measurements

The visual analog scale [VAS], a 10-point pain scale used to assist patients in communicating about their pain to others, has been around since the 1920's, but it was not widely in use until the 1950's (Hayes & Patterson, 1921; Freyd, 1923). The VAS is shown as a vertical line across a page, with numbers 0 through 10 showing with "No Pain" on the left end (zero) of the scale and "Worst Possible Pain" on the right end (ten) of the scale. The scale can also be displayed as a series of bricks laid end-to-end, which is called a Numeric Ratings Scale [NRS]; the VAS and NRS have been shown to be equivocal in research and clinical settings (Breivik, Björnsson, & Skovlund, 2000; Hollen, Gralla, Kris, McCoy, Donaldson, & Moinpour, 2005).

In clinical practice, the VAS has been validated multiple times for use exclusively with acute pain and post-surgical patient populations, with the first validations occurring more than 60 years ago (Bird & Dickson, 2001). The VAS in all of these settings was only treated as an ordinal scale, a ranking of from best to worst, with no comparability of results on scales (Kersten, Kucukdeveci, & Tennant, 2012). The VAS can have comparability between subjects, and becomes a cardinal scale, indicating equality of size and scale for each single numerical increase, only if the VAS is properly validated for each person/subject, and establishing of a "bottom" or valid zero point for each subject (ibid).

To further expand the possible base of knowledge on all areas of interest prior to the start of testing, experts in pain were contacted and provided input on their experiences working with the chronic pain population and attempting to monitor and communicate on the patient's pain. These expert discussions were with dozens of orthopedic surgeons, as well as accredited pain specialists in the area. All repeatedly said; unscientifically, anecdotally, and parenthetically, that their chronic pain patients "do not work like 'normal' patients do" in respect to pain communication. They repeatedly stated "a chronic pain patient, when given a 10-point pain scale, will invariably give a pain rating of 7 or higher."

The oddity of scaling was discussed at length with these experts, all of whom concurred with the observation, but without explanation on cause. The theory underlying this paper was presented, that the chronic pain patients cannot recall being without pain therefore only mark at the high end of the scale because that is what they feel on a daily basis, and the experts demurred, stating this was "possible" or "likely." This reinforced the goal for the VAS portion of this project: to validate the VAS for use with a chronic pain population so as to improving the communication about pain for this population. All of the experts for this study encouraged this VAS validation research as it would give them an evidenced-based means by which to better monitor their chronic pain population, a means of comparing episodes within one patient's care to other episodes, but also to compare episodes between patients (Kane et al, 2005; Nyman et al, 2007).

It is necessary to require validation of the visual analog scale [VAS] for each subject for the VAS to be used as a preference elicitation device, a device to obtain what a person likes or prefers more than something else (Kind, Dolan, Gudrex, & Williams, 1998; Nyman, Barleen, Dowd, Russell, Coons, & Sullivan, 2007). Though the validation process is typically specific to a Quality of Life [QoL] preference device, the validation process appears appropriate here due to the all-encompassing effect pain has on the patient's life (Rhudy & Meagher, 2003). Also, a simple pain scale, without any validation, and without an attempt to establish in the mind of the patient the "best" case and/or worst case pain situations prior to having them rate their current pain condition, sets a false precedent for how much weight the VAS instruments must bear (Williams, Oakley Davies, & Chadury, 2000).

When a valid zero is established for each subject, the result of each subject's VAS becomes comparable. Even though each subject has a different zero or "bottom," they are all still zero and zero equals zero, etc. If all scales start with the same base, and have the same scale, the same distance between each change in number, and all have the same terminus or top point, i.e., they alter from cardinal to ordinal in nature, then the results will be comparable, just as they are within the QoL scale findings (Kind et al, 1998; Nyman et al, 2007). With these VAS scales, when a patient rates a 4 today and a 7 tomorrow, an observer can know that there was a 30% change in pain from the first measure to the second. That has important usefulness in a Disability Determination Process [DDP].

Literature Review and Findings

For purposes of disability determination, the Social Security Administration's Disability Determination Process only recognizes pain as a component of another disabling process or disease. There is no rating for pain as a separate and distinct disease or disability process. For example, under section 1.02 Major Dysfunction of a Joint due to any cause "Characterized by gross anatomical deformity … *and chronic joint pain* and stiffness with signs of limitation of motion or other abnormal motion of the affected joint(s)" (emphasis mine, from www.ssa.gov/bluebook/1.00-Musculoskeletal-Adult). Within all categories in section A – adult disability categories, there are a total of eleven notations for pain such as that shown above, all a part of another disorder but never with pain as the primary. In no area and at no time has pain ever been measured, nor has pain been enumerated beyond simply stating its presence.

Three literature reviews were performed, one prior to starting the pilot study, one following completion of the testing but before the write up, with a gap of 9 months in between, and a third following completion of the full study but prior to write up. In each literature review,

first the terms pain (any kind), pain measurement (any kind of pain), and VAS were searched, together and separated were searched in all journals from 1994 to 2015 using PubMed. The searches returned 12,716 articles from 23 countries and 33 specialties or sub-specialties. A few of these articles "hinted" at attempts to objectively measure pain in their titles or abstracts, but these hints were not borne out upon reading the full text (Kramer, Haefeli,& Jutzeler, 2012). There were a large number of articles on use of Visual Analog Scales [VAS] and Numeric Ratings Scales [NRS] as a means of rating pain in multiple settings, but none showed validation of the instrument, i.e., establishing a bottom or a zero point for each subject, and none showed use with a chronic pain population. Subsequent searches found second publications of the original search items, but, again, none discussed validating the VAS, measurement of pain, or functional measurement of pain (i.e., none was applicable to the range of studies here).

This initial searches were then narrowed to look only for any attempts to objectively measure pain, with multiple exclusions (e.g., cancer, labor/labour, etc.), with 3,710 articles were returned. No articles showed any attempts at objective pain measurement of any kind of pain, but many used an unvalidated VAS to measure or monitor the subject's/patient's pain (the reasons for validation of VAS is discussed in the design and results sections) A few articles discussed the emotional or non-physiological aspects of pain, and to what affect these might alter the self-reports, but again, none validated the instrument to improve the potential inter-personal comparability (Ferreira-Valente, Pais-Ribeiro, & Jensen, 2011; Huber, Suman, Rendo, Biasi, Marcolongo, & Carli, 2007; Jensen Hjermstad, Fayers, Haugen, Caraceni, Hanks, Loge, Fainsinger, Aass, & Kaasa, 2011). One study created a method to normalize VAS pain reporting, to provide some standardized comparable responses between subjects, but again, this study did not validate their VAS (Kane, Bershadsky, Rockwood, Saleh, & Islam, 2005).

The initial literature review provided articles which showed an empirical basis for using a proxy for pain, and specifically using the left systolic blood pressure [SBP] as that proxy. Bruehl, Carlson, & McCubbin (1992) formally establishes using blood pressure as an indicator for pain. Bruehl's (1992) study was designed "to explore the relationship between pain sensitivity and blood pressure" in a normal population" (p 466). And Bruehl et al (1992) found"(t)he relationship between resting SBP and pain intensity…remained nearly unchanged over the … pain stimulation…(and) this relationship appears to be independent of the effects of coping styles and emotional state as assessed in this study" (ibid). The Bruehl et al (1992) result was cited in the study by Rhudy & Meagher (2003) in which negative affect (bad mental state) was measured as a means of effecting pain, with SBP again used as the proxy for pain. And Bruehl et al (1992) was cited in the empirically-based study done by Green, Wang, Owen, Xie, Bittar, Stein, Paterson, & Aziz (2006) where the brain was stimulated to find the link between pain and blood pressure; SBP was the link – and the greater the pain, the greater the effect on the SBP in every setting.

The empirical basis for SBP as proxy also gave direction to the confounder by being cited in a study that looked at the relationship between pulse, and exercise as possibly over-sensitizing a subject to pain. Koltyn, Garvin, Gardiner, & Nelson (1996) empirically looked at pain following strenuous aerobic exercise, how exercise altered both the subject's pain thresholds and pain perceptions (sensitivity). Koltyn et al (1996) defined exercise by the subjects as an increase in pulse rate over their resting heart rate and specified two levels of exercise: "exercise" was an increase in pulse by greater than 15% and "strenuous exercise" an increase in pulse by more than 20% (1996). This study found that the subject's pain thresholds were higher but pulse lower

following strenuous exercise but the strenuous exercise increased the subject's sensitivity to pain. In other words, if physical activity were high enough to raise the pulse rate by 20%, as would happen with exercise, the subject's would be more sensitive to pain (more aware of it) while simultaneously able to bear more pain (ibid).

Koltyn's et al (1996) definition of exercise was the motivation for selecting the conservative 10% increase in pulse rate as the indicator for the start of exercise for the present study: this is before where the subject's pain sensitivity could start to increase and before where the pain threshold could start to change. This exercise factor is a confounder of the exposure of interest, and therefore appropriate for inclusion in this paper.

Research Design, Recruitment, Methods

This case-control research study was designed to objectively measure pain, with the "test" being the objective measurement itself. In a case-control study, the subjects have an exposure or issue of interest, and the controls do not; the testing condition is that the subjects are different from the controls because of a factor, an element, an issue. In this case-control study, all subjects had chronic pain and none of the controls did. Controls were "normal people; the controls were different from the subjects both qualitatively and quantitatively on the basis of their pain. The highest pain level reported by any control after any task was a 1 on a standard unvalidated VAS of 0-10; all other reports were "zero" or "no pain." Therefore, no control's pain ever met criteria for chronic pain, as the pain was not present prior to the start of the testing, and only acute, discrete pain was exhibited by a small segment of the controls in the later tests, with the highest rating of pain being a 1. This confirmed them all as true controls, as being truly different from the subjects on the issue of interest: pain.

The core purpose of this case-control study was to look at the difference between the chronic pain patient's physical response to pain during the functional tests and the physical responses of the controls. Subjects and controls were asked to perform a series of functional tasks and their systolic blood pressure [SBP] and pulse were measured after each task. They were also asked to rate their pain after each task. By combining the FCE or functional tests with the use of the systolic blood pressure as a proxy for pain, the first, physical, hypothesis is formed. It is based on multiple prior studies, the seminal and/or leading work cited within the literature review, and thus this physical testing hypothesis needs little in the way of statistical testing to formally prove. The formal hypothesis, that the functional tests will cause pain to increase with each successive test in the subjects is already tested in the FCE studies; That pain will be reflected in increased SBP is shown in the cited studies for the inclusion of this factor; that there will not be a similar change in the controls (of increase in pain associated with FCE factor tests, or of SBP with pain in non-chronic pain subjects) has, again, was shown and proven in these other cited studies. All of these features are again replicated here, in this study, as noted in the results section. A second hypothesis is formed when adding the newly validated VAS to the physical testing result. This second hypothesis, that the physical testing result is strengthened by the validated VAS self-report of pain, i.e., the self-report supports the SBP result, and there is a relationship between the physical testing result and the self-reports of pain using the new VAS that is so resilient and durable that the results could be predictive.

Subjects were recruited through a large, multi-clinic orthopedic group in the Twin Cities Metropolitan area and Western Wisconsin, with patients self-referring upon seeing the informational sign-up sheets, and doctors referring patients who they believed fit the criteria

internally. Those who were doctor-referred had their case information forwarded to the primary investigator [PI] for review and inclusion as a subject or a control. Doctor-referrals were accurate for subject inclusion 92% of the time, with the remaining 8% being below standard on duration of time for chronicity of their pain (i.e., less than 6 consecutive, continuous months). These patients were not included as either subjects or controls to eliminate any potential overlap or confusion in testing.

Controls were recruited from the same clinics, and included many of the various clinic and clinical staff in their midst. Of the 71 controls, 33 were patient's family members (parents waiting on a child in therapy, significant other, etc.) while the balance were the clinic (both clerical and clinical) staff. The clinic staff, having all received care at the clinic, were within the patient population of the clinic and therefore eligible for participation in any part of the study; had any staff member been a chronic pain sufferer, they would have been screened for participation in the case portion of the study. The primary investigator, having been a former patient of the clinic (over 6 months since last clinical contact, no previous relationship with the supervising physician, no relationship with any of the board who approved the research request), was therefore appropriate for inclusion within the narcotics section of the study . By using clinic staff as controls, it increased their investment in the study process and the results – made them feel a part of it, and want to make things work well.

Patients were allowed to schedule their research "appointments" electronically, so that for the term of the study, the PI was listed in the electronic calendar. This made things move very smoothly, allowed the clinic to do the auto-generated no cost reminder calls, and even re-schedule an entire day's research due to a winter storm without any difficulty or inconvenience to the subjects, staff or PI. This assistance and ease of scheduling made this research move very well, and eliminated all of the problems present in the pilot project of 2013-14.

In addition to the 251 subjects who had chronic pain diagnoses (felt pain in the same area or system, all day, every day, for at least 6 consecutive, continuous months), there was a small sup-group recruited that was previously actively excluded: narcotic's users. Two sub-samples were found among this group: "users" or those who presented after administration, within the active period of the drug; and "rebounders" those who were no under the effects of the drug but were actively "detoxing" or their vital signs were "rebounding" from their previous narcotic's administration. When using a central nervous system depressant, the vital signs of the user tend to become depressed or chemically suppressed; when that chemical suppression is removed, the vital signs tend to rebound or become unnaturally elevated as they were previously unnaturally depressed.

The size of the study was determined to far exceed the requirements to meet the needs of the Law of Large Numbers [LLN] (Bernoulli, 1713). LLN specifies that the larger a sample gets, the closer the mean of that sample gets to that of the "true" population. The second "theorem" of LLN is that a large number of items, taken at random, from a population, will have the same characteristics as the population as a whole. By doing a sample size large than 50 (what some estimate is the bottom of the LLN scale), this sample becomes random and large enough to be generalizable to the public of chronic pain sufferers.

Despite a skewing upward from their normal blood pressure and pulse rates, the "rebounders" group tested statistically identically to the "normal" subject group of chronic pain patients in the full sample. For this reason, the "rebounders" results are merged into the full

sample's results in the final analyses, but were analyzed and presented separately in an appendix for the interest of the reader.

The narcotic's "users" groups also have altered responses, but the alteration is in both physiological response to pain, as well as their intellectual response to the pain. Their pain responses are present, but increase at a slower rate, and with lower total increase as compared to their normal or rebounding counterparts. These "user" subject's results will be kept and analyzed entirely separately of all other results for this reason. The "user" subjects are entirely separate and distinct sample and not a sub-sample of the main; they are a different testing group and their results are never to be merged with or into any other group's results.

In the pilot project, all subjects currently taking narcotic pain prescriptions were excluded from the sample, but were recruited in the small group here for purposes of complete coverage of this study result: some people will present at a DDP evaluation under the influence of a narcotic. With these results covering all such possible subjects, these results allow the DDP process to begin using this study result immediately, as all contingencies of patient presentation were considered within the sampling.

There were no breaks once the process started or between tasks (process started with forms); there was no beverage or food allowed in testing site; entire testing process took an average of 15.5 minutes, with 12.2 minutes for the short measurement and 17.5 minutes for the long measurement. All subjects were viewed as "non-obese," and had no difficulty completing the physical tasks.

Each person, regardless of which testing group they were in, completed a questionnaire which gathered information on exclusions, and demographics, as well as on items about which the data could be confounded or stratified. These possible confounders included: current medications; all of the various medical treatments attempted to control the painful condition; and what activities were avoided due to pain. Those items collected and used for stratification were the demographics. After all forms were reviewed for completion and exclusions, each person began by sitting quietly, and the remote blood pressure/pulse monitors were attached one to each wrist.

There were 4 testers, broken into teams of two, with each team simultaneously running up to 3 subjects through the study tasks at the same time. One of the team members was in charge of all paperwork and maintaining integrity of the sample data; the other was in charge of oversight and all peripherals, i.e., doing any validations on the blood pressure cuffs, changing the batteries, finding Kleenex tissues, etc. In the first two days of testing, where 78 and 54 subjects and controls were tested, respectively, with the inter-rater reliability was 99.997% and that .003% was due to handwriting, not any error in data interpretation or transposition. In all cases, the inter-rater reliability tested the administration of the validation process and the scoring of the of pain scores. There is no "rater reliability," per se, in the writing of participant blood pressure and pulse after each test – and the participants can see everything that is being written and were able to correct any errors of transposition, if any. Thus inter-rater reliability was only on the VAS portion; there was no potential on the FCE portion of the testing.

Each tester team was randomly assigned a subject or control participant: whichever team finished their person first started the next one waiting. On some days, there was a medical intern who assisted with some paperwork, but she had no effect on any study procedures (she collected completed questionnaires, putting aside any that the PI needed to look over or that had any

blanks the individual team would have to address, etc.) Her role was assistive and to streamline during times when a member of a team was unavoidably out of the room or someone had another obligation at the clinic to which they had to attend. Inter-rater reliability with this person on the team did not alter; it remained at 99.99%.

VAS Validation Process

Once all monitors were working, an initial reading for blood pressure and pulse were taken, and then the validation process of the VAS was completed on all subjects. To validate the VAS, a "zero" or "bottom" needed to be established for each subject. As controls did not have pain, they were not included in this part of the study, but completed a traditional unvalidated VAS for all of their "pain" readings.

The validation process for the VAS begins with each subject being directed to think about his/her pain, and directed to think specifically about the least amount of pain s/he remembers feeling. Standard biographical directive questioning was used; some of the prompts included:

"When you felt that little pain, on that day, what were you doing? What sort of day was it (inquire about weather, events, people, places – get very specific)? What were you doing that you think the pain was so low or so small?"

Some of the subjects had difficulty thinking about the least amount of pain, as evidenced by their visual expressions and statements of "I've never thought about that before!" Once a day and specific event and time are firmly in the subject's mind, the validation then continues;

"What time of year was it? What year was it?" "Ok, so it was the fall of 2012. So since fall 2012, you've not had another day as low in pain as that?"

The VAS is intended to be rescaled by the subjects by designating this level of pain as "zero." After the "zero" is firmly established in the mind of the subject, then came the difficult part for the subject: converting their existing "mental pain scale" to the new analog scale for the study. The conversion instructions to the subjects were:

"Earlier you said your current pain is a X. Now thinking of that time we just talked about, in fall of 2012, when you felt the least amount of pain? If that day is zero here (holding up VAS paper scale), how would you compare today's pain to THAT pain, to THAT day?"

"If that lowest pain is a zero, here (using visual aids, hold the zero as far to the subject's left as possible), how would you rate your current pain now? If your lowest pain is here (hold zero to left, 10 is far to right), and your pain today used to be here on that old scale, where would you put your pain in comparison to that zero?"

All subjects were able to understand the idea of this new VAS, how taking their own "zero" would alter their pain rating, though some struggled and took longer to convert; average time was 7.5 minutes, with entire validation process taking an average of 11.25 minutes.

In the pilot project, there was difficulty with this conversion task, and it was thought to be possibly related to reading skill or other educational abilities. For this reason, the PI had reading tests available for this study's subjects, but no such tests were administered or needed. The educational achievement of this group was far higher than that of the pilot, but there were still those who had not completed high school and those subjects had no difficulty with this mental conversion process.

Functional Testing Process

The functional testing began following validation. Each subject agreed to complete 4 tasks: 2 timed and 2 at a speed comfortable for the subject. After each task, the subject was asked to report their pain level using the validated VAS (subjects) or traditional VAS (controls) and their pulse and blood pressure was measured and recorded for each arm. Task 1 was to sit quietly for 3 minutes; task 2 was to stand quietly for 3 minutes (subjects could hold onto a wall but could not lean on it); task 3 was to walk the length of the room and back (approximately 120 feet total); task 4 was to do 10 step-ups (step up 6.5 inches with one foot, step up with other foot, then step down with original foot, step down with second foot = counted as 1 step-up).

All subjects and controls were told that they could stop at any time if their pain became too great, but no subjects or controls stopped or quit testing.. After each task, all subjects and controls had blood pressure and pulse recorded for each arm using automatic blood pressure cuffs on each wrist, and both subjects and controls were asked to rate their pain at the same time.

The automatic cuffs were verified as accurate by using a standard blood pressure cuff opposite every five groupings of subjects (about 35 measurements each cuff, each validation run), and batteries were changed on all cuffs every 20 groupings of subjects (about 105 individual measurements). The automatic cuffs, and the standard cuffs used to validate them were tested against each other immediately after use in a testing session, alternating between a subject, narcotics members, or control to remove any bias. No variation was ever found in any validation of the cuffs. No batteries ever ran down enough to be below a 50% charge, so there was no effect on results by this factor either.

The same sixteen blood pressure/pulse cuffs were used on all subjects and controls, with eight being designated as “primary “each testing day, and the others being available to swap out when it was time for new batteries, or calibrations needed to be done. All cuffs were used interchangeably: no two cuffs were always used together, no cuff was always a left or a right cuff; they were randomly placed on subject/control arms and used throughout the entire experiment in that manner.

Data analysis

Results of the Functional Testing of Subjects and Controls

The functional testing gives a six physical data points for each task: full blood pressure (systolic and diastolic blood pressures) and a pulse on each arm (used only for inclusion/exclusion on confounding indicator). There were five separate measures for each subject and control: start measure, once each at the conclusion of each task (sit, stand, walk, step-up. So for each subject and control there are thirty individual physical measures of body function in response to the function testing.

For the subjects, there was an average change of SBP from starting measure final measure at completion of step-up task of an average of 38.79 points, or an average of 68% change in SBP from the starting measurement. The controls, by comparison, had an average SBP change of only 7.44 points or an average of 7% change in SBP from the starting measurement. The controls were drawn from the same normal population as the subjects, with only 1 difference, the characteristic of interest, the subjects had chronic pain. Therefore it was the chronic pain that caused this difference in SBP within this testing, as the multiple prior studies stated it would do, and that the results, as measured by SBP, are meaningful.

Results of the validated VAS Reported Pain of Subjects and Controls

Subjects had an average change of reported pain from initial report to the final report of the step-up task of 5.2 points or over half of the total new scale, and the subjects had an average starting pain of 3.5, with an average ending point of 7.8. By comparison, in the 355 individual opportunities for controls to report pain, there were only 44 reports of pain and all of those were a "1," the lowest positive report of pain; all other reports were zero or "no pain." For controls, 12 of 71 subjects reported pain of 1 on two tasks (walk and step-up) with the other 20 reports from were one time only on either walk or step-up task. The wide differential in reporting, the difference in the type of pain experienced and the level of pain throughout further confirm that the subjects and controls did experience pain differently, and that this difference was based entirely upon the subject's status as chronic pain patients and the control's lack of pain diagnosis.

Joined Study Results

The important data for this case-control research study is the movement of physiometric measure in relation to the self-reported pain level: "If either the one moves but the other doesn't, the theory doesn't hold and there is nothing to report" (McDonald, p. W3, 2009). The data from the functional testing and VAS are of a mixed variety, with both quantitative-deductive and qualitative-inductive results to be presented and reported.

Qualitative results are inductive, and are used primarily to understand how people think and experience their lives, with the focus being more on the person rather result. Quantitative results are deductive, and are used primarily for description and prediction. Using quantitative data, it is the analysis of the variables mathematically or statistically, with the goal to generalize the results to a population. Any conflict that may arise between these two competing methods is resolved with a balanced, commonsense but pragmatic focus, using what works best for that research question, in that context. The researcher must focus on balancing the strengths of each focus to offset any potential weakness, making the results both complementary and complimentary (Johnson, no date). Linear regression was chosen to present all of the data, as this allowed the qualitative to be represented graphically, and the results to create images to better represent the results.

Linear regression is an approach for modeling the relationship between a scalar dependent variable y, the systolic blood pressure [SBP], and one or more explanatory, dependent variables x, the VAS self-report. Regression allows the inductive, qualitative, to be formally incorporated and included in a quantitative manner by the measure of the relationship. The measure of a relationship would be a correlation coefficient.

For linear regression, there are two measures of the correlation, the strength of the relationship and the percentage of the variation of the dependent variable that is explained with the independent variable: r and r^2. The r is the correlation coefficient; it is a number between -1 and +1, with 0 signifying no relationship, and the closer to the extremes showing a more perfect positive (increasing values of one variable correspond with increasing values of the other variable) or negative relationship (increasing values of the one variable are associated with decreasing values of the other variable). The r^2 represents the portion of variation in one variable that can be explained by the other variable: example $r=.95 = r^2 = .9025 = 90.25\%$ of the variability of *either variable* is explained by the other within this linear regression model.

As discussed in the background/literature review section, the physiometric measure of interest was the left systolic blood pressure [SBP], as this was hypothesized in a number of studies to be a good proxy measure for pain (Bruehl et al, 1992; Green et al, 2006; Rhudy & Meagher, 2003). Pulse was used as a confounder indicator; if the pulse increased more than 10% between the start and completion, then the physiometric results were viewed as possibly tainted by bias, and that the subjects could have been overly sensitized to pain, or the pain threshold could have altered as a result of the exercise, therefore the results should be viewed with as suspect due to these factors (Koltyn et al, 1996). No subject or rebounder reached the pulse rate sufficient to me included within Koltyn et al "exercise" or "strenuous exercise" groups, so there is no issue of sensation of pain within this group, and all subjects who reached the 10% threshold, the "confounders" were removed for the noted analysis. There were no narcotics users or rebounders who met the confound exclusion, but that was not unexpected.

Findings/Results

Group	Linear equation	Slope	Intercept	Correlation	r^2	p
Subjects	y = 9.20x + 103.81	9.20	103.81	.85	.73	5.34E-90
Rebounders	y = 9.43x = 111.05	9.43	111.05	.90	.81	6.28E-12
Subjects less confounders	y = 8.97x + 107.61	8.97	107.61	.94	.89	7.51E-22
Subjects & rebounders	y = 9.16x + 104.76	9.16	104.76	.85	.72	2.78E-97
S & R less confounders	y = 9.32x + 104.70	9.32	104.70	**.95**	.90	1.25E-129
Controls	y = 17.03x + 126.05	17.03	126.05	.37	.13	.000448
Narc Users	y = 9.84x + 95.84	9.84	95.84	.92	.84	3.83E-13

Table 1 – Linear Regression Equation Factors for all subjects, groups and combinations

Table 1, shows the linear regression equation, the factors of that equation, the measure of the strength of the relationship, r2, and the significance of the regression relationship, the p value. This table is for the regression on all tasks, which includes the "start" reading, which is the reading with all possible bias included (e.g., some study participants having a short wait before having this reading taken, and others having no wait, virtually taking off their coats and having the blood-pressure sensors strapped on). These equations were selected because of this bias: the results are startling positive in their correlation and by presenting those with the worst possible bias, with the most conservative confound measure, and the most conservative interpretation will only serve to highlight the strength and value of these results.

The table 1 snapshot, shows the following: that the relationship between the measured SBP pain readings were correlated to the self-reports of pain on the validated VAS from 85% of the time in the worst case measure, to a nearly perfect relationship of 95% correlation in the regression with all subjects and rebounders, less the confound. Table 1 also confirms that the controls were a separate and distinct group from the subjects, as the control slope is nearly twice that of any other equation, (17.03 vs 9.84 next highest), and the correlation is less than one-third that of the next least relationship, (37% vs 85% next highest).

All results/relationships were significant; in other words, all results are not being found by chance and that the characteristic being measured, pain and the self-reported pain using the validated VAS, is a part of the population (AHRQ Definitions of Statistical Significance, 2014).

The slope of a line shows the rate of change over time, or the rate of change across a set group of cells. Here in table 1, the slope is showing the rate of change of the subject's systolic blood pressure [SBP] from one task to the next, from one pain rating to the next. Across subgroups, the slopes are very similar in nature, with a difference of less than 7%. Even when looking at the per-task slopes in the appendices, the per task slopes remain very consistent and begin to show the future: a probability "calculator" based on the slope and the correlation to predict the subject's pain and rating, given a starting point. That is almost possible now, within this sample, with this data, because the results were so consistent in forming a clear line.

Narcotic's 'users" results were well within the range of the non-narcotic users, but their results did show a slower rate of increase in pain, and a lower result of pain from the testing. Despite this, their correlation remained a high 92%, and 84% of the variability within the factors is explainable by the other factor, i.e., the slower rate of change in the blood pressure is explained by the lower rate of change of the pain recognition as referenced in the self-report. The two results will vary together; as the subject becomes more cognizant of the pain, the pain ratings will increase and so too will the pain felt and measured by the SBP.

For this narcotic's "users" group, there is less predictability due to the smaller size, but the data are still sufficient to make determinations. These subjects are still having their pain validly measured, but DDP testers have to be very aware of what medications were taken, when, and in what dose, in proximity to their testing.

When looking at the same correlation, slope, and statistical significance data and information in the different breakouts as found visually in the appendices, there is no doubt about these results: pain can be consistently and objectively measured using systolic blood pressure [SBP] as a proxy for the physiological report; and when combined with the properly validated VAS scale for subject's/patient's self-report of pain, the resulting pain measurement has a 90% accuracy across time and subjects. The results from these tests were consistent across subjects, across testing periods, and across time showing their resistance to change and the authenticity and veracity of the measurement and correlation.

Discussion/Implications

With these full sample, fully generalizable results, the DDP process can immediately be moved into advanced testing for process for inclusion as part of a DDP to effectively determine the individual's pain as a part of the disability process for either the Social Security Administration [SSA] or the Veteran's Administration [VA].

In the short term, this new result can be used as a "liar's scale" to determine if a person presenting with pain as a major symptom is telling the truth or is faking, as the subjects/patients presenting with high pain have, consistently, high presenting systolic blood pressures. And having them do any task which they claim will increase their pain, including sitting for a period of five [5] minutes will confirm the presentation: if their systolic blood pressure does not increase during this wait/test time despite the subject's/patient's claim of increased pain, you will have valid proof of their lying about presenting symptoms during a DDP testing. If, on the other hand, their systolic blood pressure did show a positive increase, as reflected in these tests, then

you would be able to confirm the diagnosis of chronic pain for the subject/patient without much effort. Once the full functional testing process with validated VAS is implemented in DDP, you would have a valid liar's scale at every opportunity: each testing would prove the validity of the subject's/patient's claim of pain or disprove it, as no person without pain will have any change in systolic blood pressure, regardless of what they may claim in the self-report. And, with the validation, those who are true chronic pain sufferers have no difficulty in following the task; their only difficulty is in recalling a time with lowest pain to use as their "zero" point.

The DDP can train for this new DDP process quickly, as it requires no special equipment, only some new on the validation process of the VAS. That will be the important piece, as without the validated VAS, these results will not stand; the correlation shows that the validated VAS is as important to the process of the pain measurement as is the task determination or the measurement of the SBP. The SBP is part of the process; the validation is part of the process; the tasks are part of the process. Any one of these left out or not done properly or not done with full investment in the result will have the consequences of poor or no result, or, worse, inconsistencies across raters, across sites, and across DDP.

The next, last step, from this data, would be to establish a probability table or prediction calculator by which the slope of each equation (the rate of change of pain in the systolic blood pressure of the subject from one task to the next) is combined with the correlation (the relationship between the pain felt and measured, and the pain felt and reported) to give a table or form by which the testers can determine what an ending point could be, based on a person's starting point. That would be the only foreseeable study from this, going forward.

. The next publications for this study, in a standard publication, will be in a shorter format but will include the probability chart noted above, for use within a testing setting so that any tester could look at the VAS/systolic blood pressure combination and see on the chart what the likelihood of that correlated pairing would be. That process is at least 9 months of testing away at this point, but it could be added as an addendum to this paper once it is prepared. This would further improve the utility of this process.

References

Acute Pain Management Guideline Panel (1992). Acute pain management: Operative or medical procedures and trauma: Clinical practice guideline. *US Department of Health and Human Services.* Washington DC.

Agency for Healthcare Research and Quality [AHRQ] (2014). *Statistical significance definition.* Online source at effectivehealthcare.ahrq.gov/index.cfm/glossary-of-terms/

Arnstein, P. (2012) *MEDSURG Nursing. Nov/Dec 2012, 21*/6, 388-388

Beard, D.J., & Aldington, D. (2012). Chronic pain after trauma. *Trauma. Jan 2012 14*/1, 57-66.

Bernoulli, J. (1713). *Ars Conjectandi: Usum & Applicationem Praecedentis Doctrinae in Civilibus, Moralibus & Oeconomicis*, #4, (Translation Sheynin)

Bird, S., & Dickson, E. (2001). Clinically significant changes in pain along the visual analog scale. Annals of Emergency Medicine; 38: 639–643

Breivik E., Björnsson G. & Skovlund, E. (2000). A comparison of pain rating scales by sampling from clinical trial data. *Clinical Journal of Pain*; 16: 22–28.

Bruehl, S., Carlson, C.R., & McCubbin, J.A. (1992). The relationship between pain sensitivity and blood pressure in normotensives. *Pain, 48*; 463-467.

Choate, K., McDonald, W., & Scott, D. (2011). Pain management. *Australian Nursing Journal,* 18/11, 40-40

Choiniere, M., & Amsel, R. (1996). A visual analogue thermometer for measuring pain intensity. *Journal of Pain and Symptom Management, 11*; 299-311.

Ditto, B., Lavoie, K.L., Campbell, T., Gordon, J., Arsenault, A., & Bacon, S.L. (2010). Negative association between resting blood pressure and chest pain in people undergoing exercise stress testing for coronary artery disease. *Pain*, 149; 501-505.

Frampton, C.L., & Hughes-Webb, P. (2011). The measurement of pain. *Clinical Oncology. 23*; 381-386.

Ferreira-Valente, M.A., Pais-Ribeiro, J.L., & Jensen, M.P. (2011). Validity of four pain intensity rating scales. *Pain.152*; 2699-2404.

Freyd M. (1923). The graphic rating scale. *Journal of Educational Psychology*; 14: 83–102

Green, A.L., Wang, S., Owen, S.L.F., Xie, K., Bittar, R.G., Stein, J.F., Paterson, D.J., & Aziz, T.Z. (2006). Stimulating the human midbrain to reveal the link between pain and blood pressure. *Pain, 124*; 349-359.

Gouttebarge, V., Wind, H., Kuijer, P., Paul, F.M., Sluiter, J.K., & Frings-Dresen, M.H.W. (2010). How to assess physical work-ability with Functional Capacity Evaluation methods in a more specific and efficient way? *Work*, 37/1; 111-115.

Hayes M, & Patterson, D (1921). Experimental development of the graphic rating method. *Psychology Bull*; 18: 98

Hollen, P., Gralla, R., Kris, M., McCoy, S., Donaldson, G., & Moinpour, C. (2005). A comparison of visual analogue and numerical rating scale formats for the Lung Cancer Symptom Scale {LCSS): Does format affect patient ratings of symptoms and quality of life? *Quality of Life Resident*; 14: 837-847.

Huber, A., Suman, A.L., Rendo, C.A., Biasi, G., Marcolongo, R., & Carli, G. (2007). Dimensions of "unidimensional" ratings of pain and emotions in patients with chronic musculoskeletal pain. *Pain. 130*; 216-224.

Jaztrzab, G., Kerr, S., & Fairbrother, G. (2009). Misinterpretation of the Faces Pain Scale-Revised in adult clinical practice. *Acute Pain, 11*/2, pp 51-55

Jensen-Hjermstad, M., Fayers, P.M., Haugen, D.F., Caraceni, A., Hanks, G.W., Loge, J.H., Fainsinger, R., Aass, N., & Kaasa, S. (2011). Studies comparing numerical ratings scales, verbal ratings scales, and visual analogue scales for assessment of pain intensity in adults: A systematic literature review. *Journal of Pain and Symptom Management, 41*; 1073-1093.

Johnson, B. (no date). *Quantitative, Qualitative, and Mixed Research*. Sage Publication, publisher; New York, NY. Online only; there is no printed version.

Kane, R.L., Bershadsky, B., Rockwood, T., Saleh, K., & Islam, N.C. (2005). Visual analog scale reporting was standardized. *Journal of Clinical Epidemiology, 58.* 618-623.

Kersten, P., Kucukdeveci, A., & Tennant, A. (2012). The use of the visual analog scale (VAS) in rehabilitation outcomes. *Journal of Rehabilitation Medicine.* 44; 609-610.

Kind, P., Dolan, P., Gudrex, C., & Williams, A. (1998). Variations in population health status: results from a United Kingdom national questionnaire survey. *British Medical Journal, 316*; 736-741.

Koltyn, K.F., Garvin, A.W., Gardiner, R.L., & Nelson, T.F. (1996). Perception of pain following aerobic exercise. *Medicine and science in sports and exercise. 28*; 1418-21.

McDonald, J.H. (2009). *Handbook of Biological Statistics, 2nd Edition (Online Edition)*; Sparky House Publishing. Baltimore.

McNamara, M.C., Harmon, D., & Saunders, J. (2012). Effect of education on knowledge, skills, and attitudes around pain. *British Journal of Nursing, 21/*18, 958-964.

Majid, A. (2013). I can't cope with this back pain any longer. *Pulse, Feb 2013*, 54-55

Nyman, J.A., Barleen, N.A., Dowd, B.E., Russell, D.W., Coons, S.J., & Sullivan, P. (2007). Quality-of-life weights for the U.S. population: Self-reported health status and priority health conditions. *Medical Care, 45*; 1143-1153.

Parkhouse, J. & Holmes, C.M. (1963) Assessing post-operative pain relief. *Processes of the Royal Society of Medicine, 56*. 579-585.

Rhudy, J.L. & Meagher, M.W. (2003). Negative affect: Effects on an evaluative measure of human pain. *Pain. 104*; 617-626.

Skenzich, A.M. (2014). A proposal to measure chronic pain: From subjective or non-measurement to objective and scientific measurement of chronic pain for purposes of disability evaluation. Online by the Disability Determination Process Small Grant Program, Cycle 3, at http://ddp.policyresearchinc.org/completed-projects/

Trippolini, M.A., Dijkstra, P.U., Jansen, B., Oesch, P., Geertzen, J.H.B., & Reneman, M.F. (2013). Reliability of clinician rated physical effort determination during functional capacity evaluation in patients with chronic musculoskeletal pain. *Journal of Occupational Rehabilitation*, 24/2; 361-369.

van der Meer, S., Trippolini, M.A., van der Palen, J., Verhoeven, J. & Reneman, M.F. (2013). Which instruments can detect submaximal physical and functional capacity in patients with chronic nonspecific back pain? A systemic review. *Spine*, 38/25; E1608-E1615.

Viikari Juntara, E. (2009). Musculoskeletal pain at multiple sites and its effects on work ability in a general working population. *Occupational and environmental medicine*, 67/7; 449-455.

Williams, A.C., Oakley Davies, H.T., & Chadury, Y. (2000). Simple pain rating scales hide complex idiosyncratic meanings. *Pain*. 85: 457-463.

Appendix A
Subject and Control Demographic Information

Gender	128 – Men	123 – Female			
Marital	93 – Single	80 - Married	72 - Divorced	6 - Widowed	
Race	138 – White	68 – Black	24 – Latino	19 – Asian	2 - Aboriginal
Age	53 – under 30yrs	59 – 30's yos	58 – 40's yos	52 – 50s yos	29 – 60-65yos
Income	68 - $30'sK	102 -$40'sK	51 - $50's-75K	17 – over $75K	13 – under 20K
Education	8 – less 12yrs	77 – 12-14yrs	133 – 16yrs	21 – 16-22yrs	12 – over 22yrs

Table 1a – All Subject's Demographic Data, n = 251

Gender	37 – Men	34 - Female			
Marital	20 – Single	28 – Married	21 – Divorced	2 - Widowed	
Race	31 – White	24 – Black	10 – Latino	4 – Asian	2 - Aboriginal
Age	12 – under 30yrs	17 – 30's yos	19 – 40's yos	19 – 50's yos	5 – 60-65yos
Income	20 - $30'sK	31 - $40K	15 - $50's-75K	3 – over $75K	2 – under $20K
Education	2 – less 12yrs	17 – 12-14yrs	40 – 16yrs	9 – 16-22yrs	3 – over 22yrs

Table 1b – Control Group Demographic Data, n = 76

Gender	13 – Male	12 – Female			
Marital	9 – Single	7 – Married	7 – Divorced	2 - Widowed	
Race	12 – White	8 – Black	2 – Latino	2 – Asian	1 Aboriginal
Age	2 – under 30yrs	10 – 30's yos	7 – 40's yos	5 – 50's yos	1 – 60-65yos
Income	6 - $30's K	10 - $40's K	4 - $50's-75K	4 – over 75K	1 – under $20K
Education	0 – less 12yrs	8 – 12-14yrs	14 – 16yrs	2 – 16-22yrs	2 – over 22yrs

Table 1c – Narcotic "Rebounders" Group Demographic Data, n = 25

Gender	141 – Male	135 - Female			
Marital	102 – Single	87 – Married	79 – Divorced	8 - Widowed	
Race	150 – White	76 – Black	26 – Latino	21 – Asian	3 - Aboriginal
Age	55 – under 30yrs	69 – 30's yos	65 – 40's yos	57 – 50's yos	30 – 60-65yos
Income	75 - $30's K	111 - $40's K	55 - $50's-75K	21 – over $75K	14 – under $20
Education	9 – less 12yrs	84 – 12-14yrs	147 – 16yrs	23 – 16-22yrs	13 – over 22yrs

Table 1d – All Subjects and Rebounders, n = 276

Gender	33 – Male	31 – Female			
Marital	23 – Single	11 – Married	20 – Divorced	2 - Widowed	
Race	38 – White	17 – Black	6 – Latino	2 – Asian	1 - Aboriginal
Age	10 – under 30yrs	13 – 30's yos	15 – 40's yos	20 – 50's yos	6 – 60-65yos
Income	18 - $30's K	26 - $40's K	12 - $50's-75K	4 – over $75K	4– under $20K
Education	4 – less 12yrs	20 – 12-14yrs	34 – 16yrs	5 – 16-22yrs	1 – over 22yrs

Table 1e –Confounders Demographic Data, n = 62

Gender	12 – Male	13 – Female			
Marital	8 – Single	7 – Married	7 – Divorced	3 - Widowed	
Race	12 – White	9 – Black	2 – Latino	1 – Asian	1 - Aboriginal
Age	0 – under 30yrs	5 – 30's yos	8 – 40's yos	8 – 50's yos	4 – 60-64yos
Income	4 - $30's K	11 - $40's K	5 - $50's-75K	3 – over 75K	2 – under $20K
Education	2 – less 12yrs	7 – 12-14yrs	13 – 16yrs	1 – 16-22yrs	2 – over 22yrs

Table 1e – Narcotic "Users" Group Demographic Data, n = 25

Appendix B –
Linear Regression Equation Diagrams –
All Subjects, all tasks as compared to All subjects, less confounders, all tasks

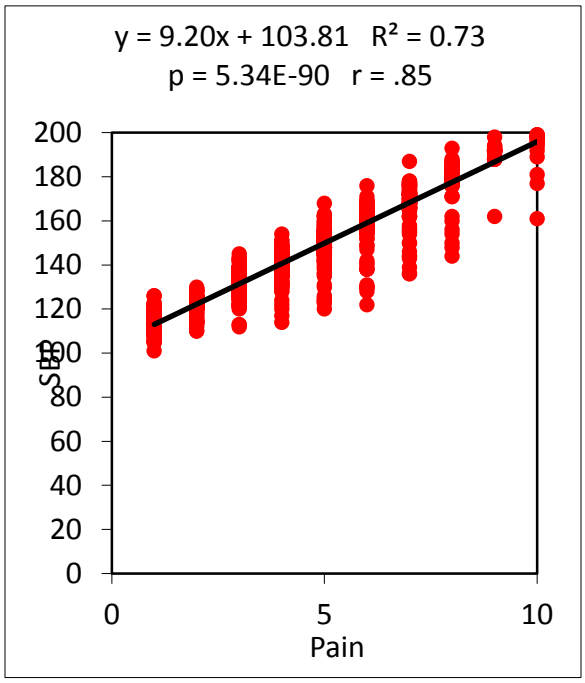

Diagram 1 – All subjects, regressed, all tasks

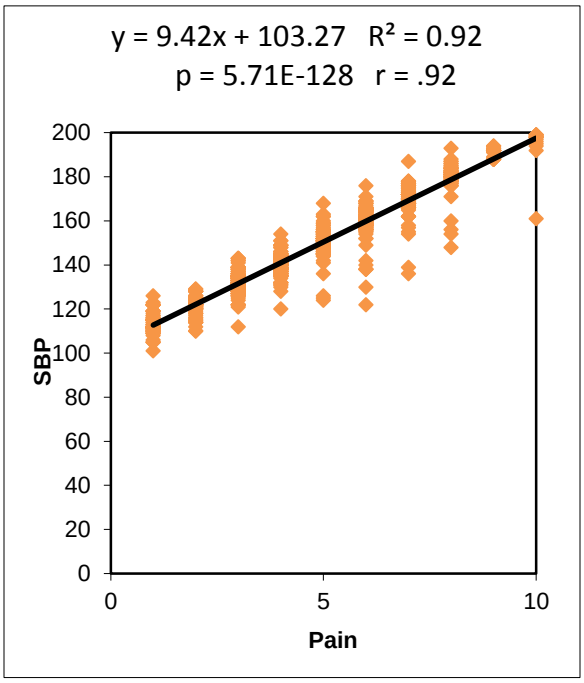

Diagram 1a – All subjects less confound

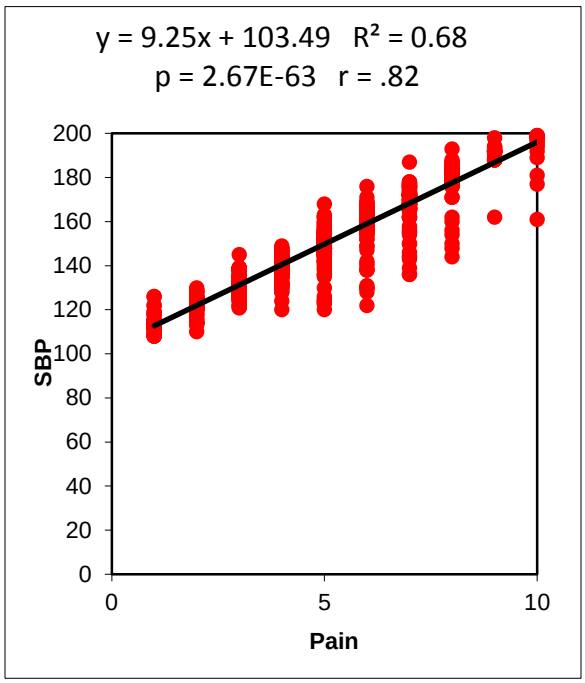

Diagram 2 - all subjects, regressed, no start task

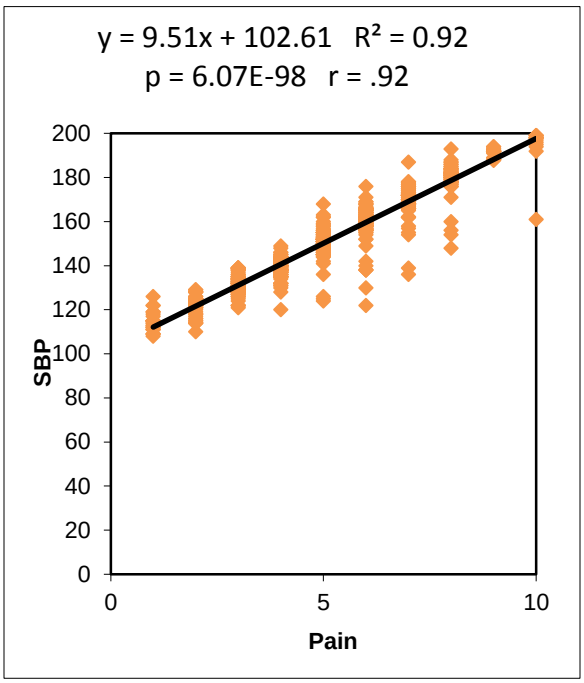

Diagram 2a – all subjects, less confound

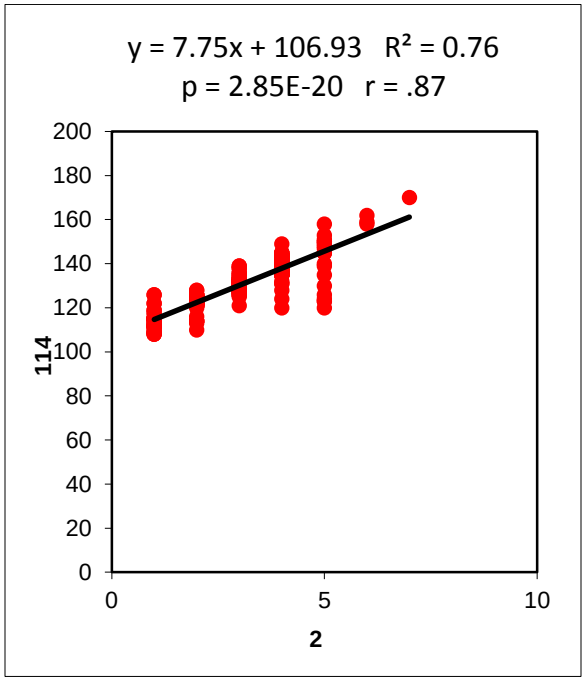

Diagram 3 – all subjects, sit task

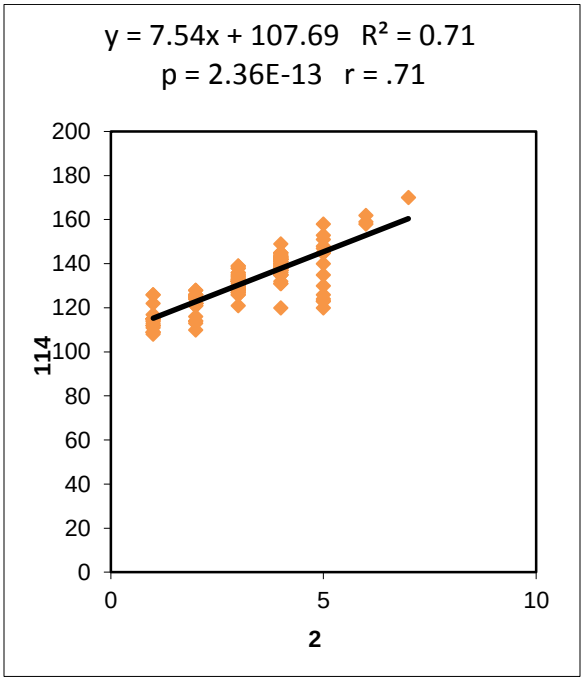

Diagram 3a – sit task, less confound

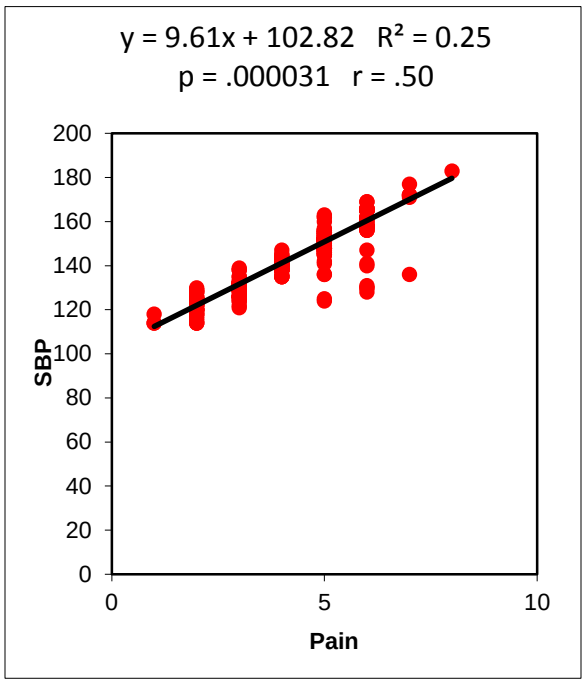

Diagram 4 – all subjects, stand task,

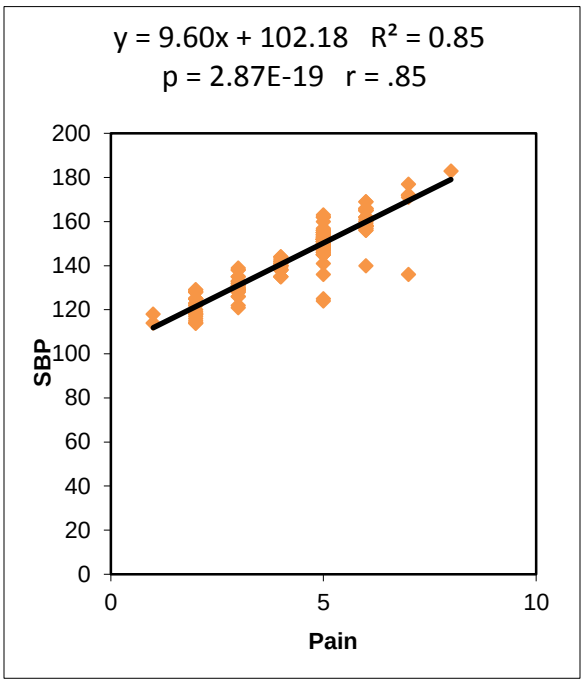

Diagram 4a – stand task, less confound

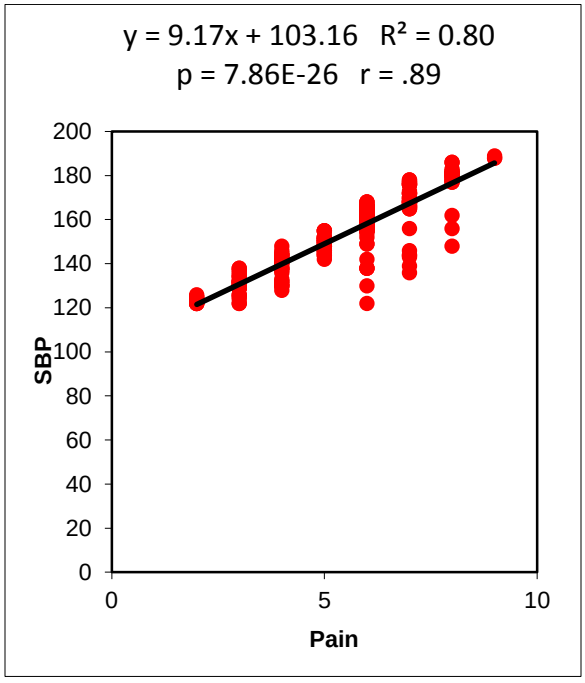

Diagram 5 – all subjects, walk task

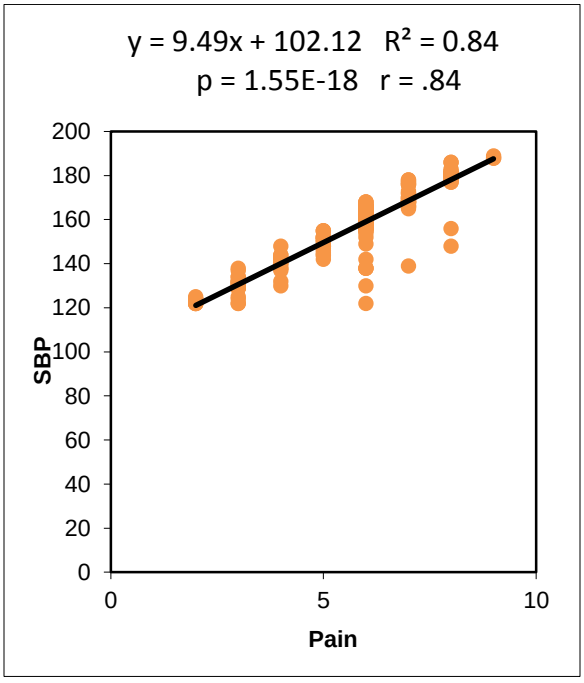

Diagram 5a – walk task, less confound

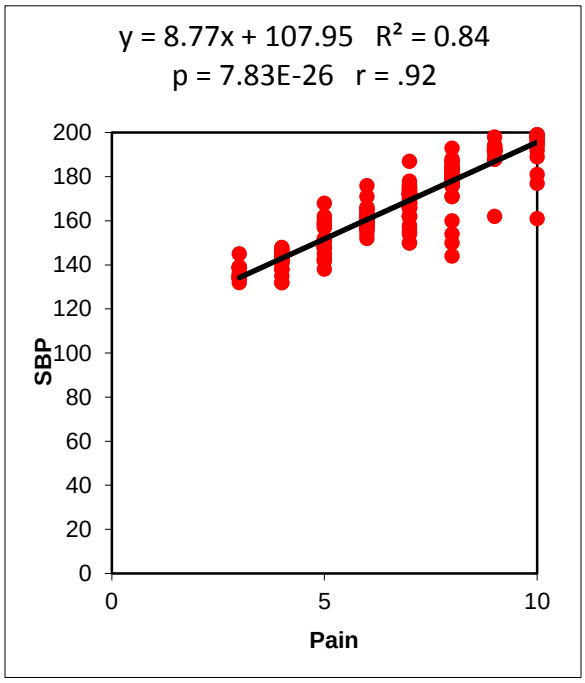

Diagram 6 – all subjects, step-up task

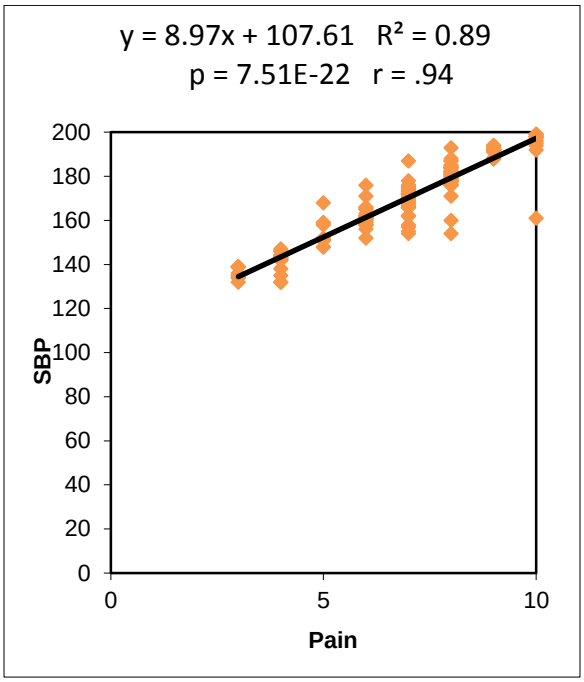

Diagram 6a – step-up task, less confound

Measure	Linear equation	Slope	Intercept	Correlation	r^2	p
All with start	y = 9.20x + 103.81	9.20	103.81	.85	.73	5.34E-90
No start	y = 9.252x + 103.49	9.25	103.49	.82	.92	2.67E-63
Sit	y = 7.75x + 106.93	7.75	106.93	.87	.76	2.85E-20
Stand	y = 9.61x + 102.82	9.61	102.82	.5	.25	.000031
Walk	y = 9.17x + 103.16	9.17	103.16	.89	.8	7.86E-26
Step-up	y = 8.77x + 107.95	8.77	107.95	.92	.84	7.83E-26

Table 3a – Linear regression table of all results for All Subjects, All Tasks

Measure	Linear equation	Slope	Intercept	Correlation	r^2	p
All with start	y = 9.42x + 103.27	9.42	103.27	.92	.92	5.71E-128
No start	y = 9.51x + 102.61	9.51	102.61	.92	.92	6.07E-98
Sit	y = 7.54x + 107.69	7.54	107.69	.71	.71	2.36E-13
Stand	y = 9.60x + 102.18	9.6	102.18	.85	.85	2.87E-19
Walk	y = 9.49x + 102.12	9.49	702.12	.84	.84	1.55E-18
Step-up	y = 8.97x + 107.61	8.97	107.61	.94	.89	7.51E-22

Table 3b - Linear regression table of all results for Subjects less the confounders, All tasks

Appendix C

Linear Regression Equation Diagrams –

Rebounders Group Regressions, All Tasks

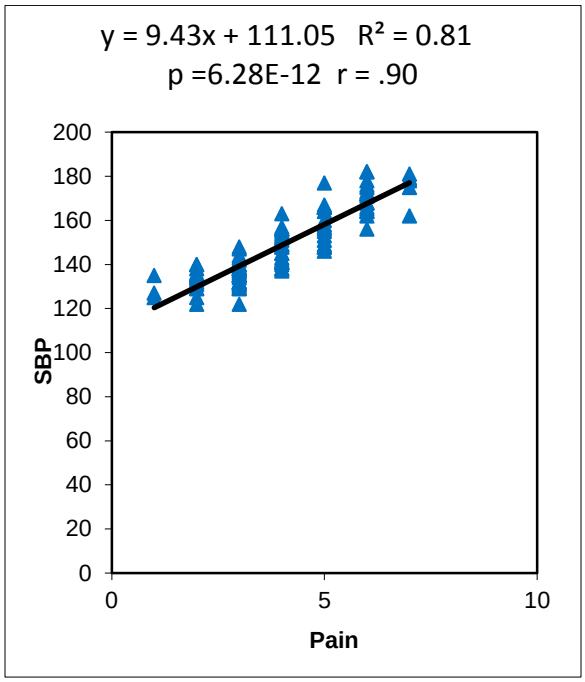

Diagram 7 – Rebounders, all tasks

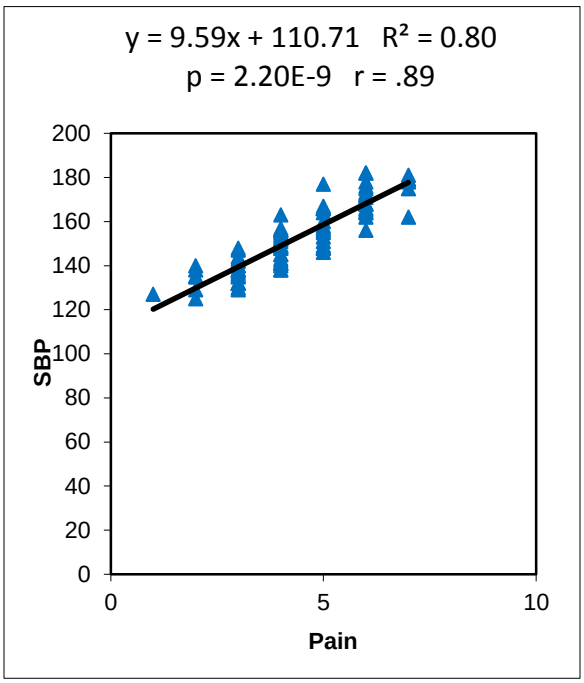

Diagram 8 – Rebounders, no start task

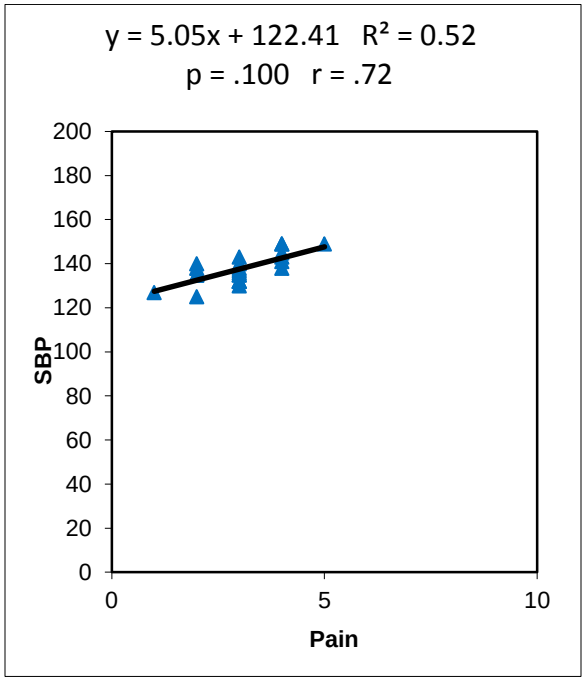

Diagram 9 – Rebounders, sit task

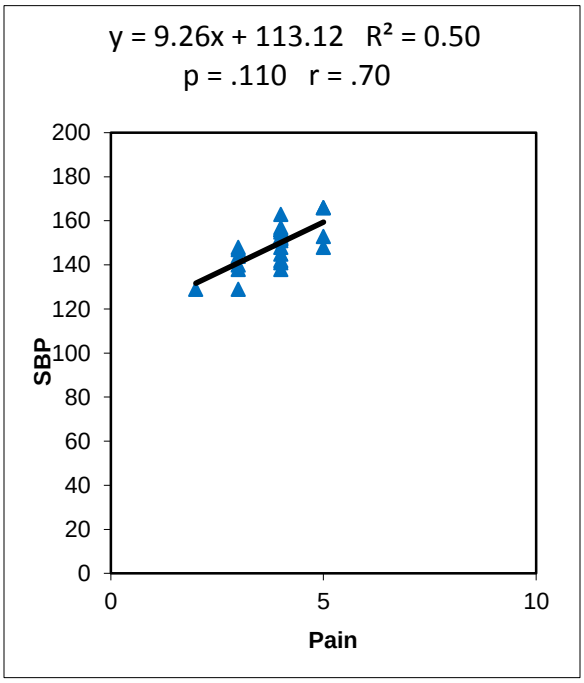

Diagram 10 – Rebounders, stand task

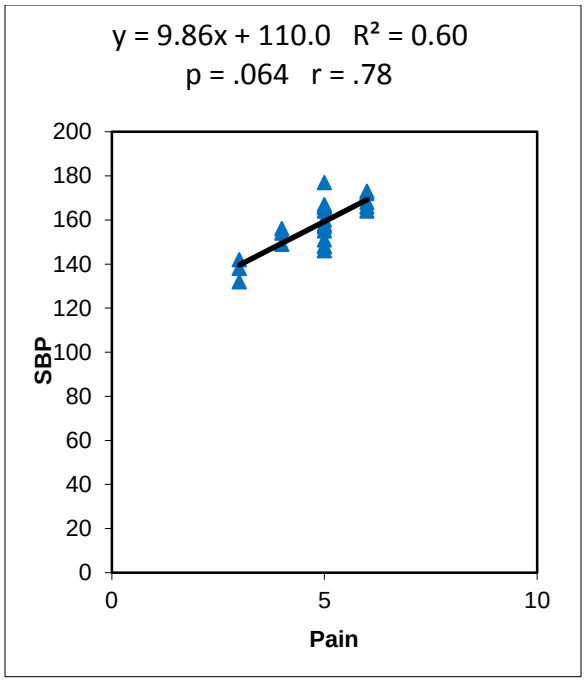

Diagram 11 – Rebounders, walk task

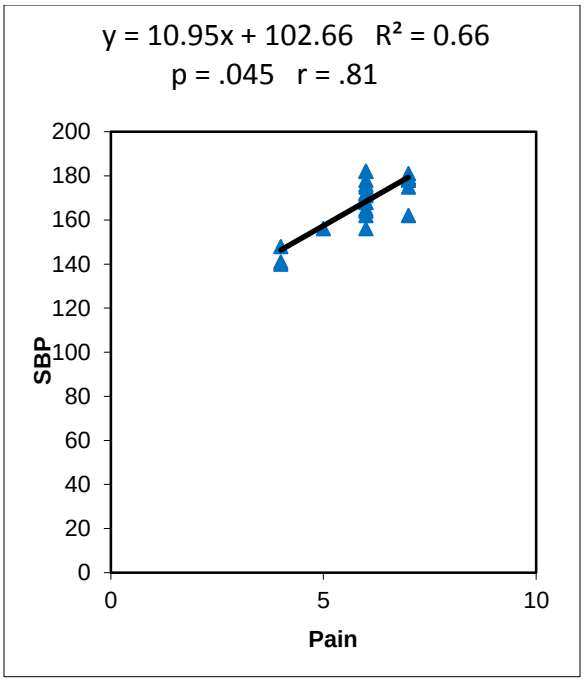

Diagram 12 – Rebounders, step-up task

Appendix D:
Linear Regression Equation Diagrams
Control Group, All Tasks

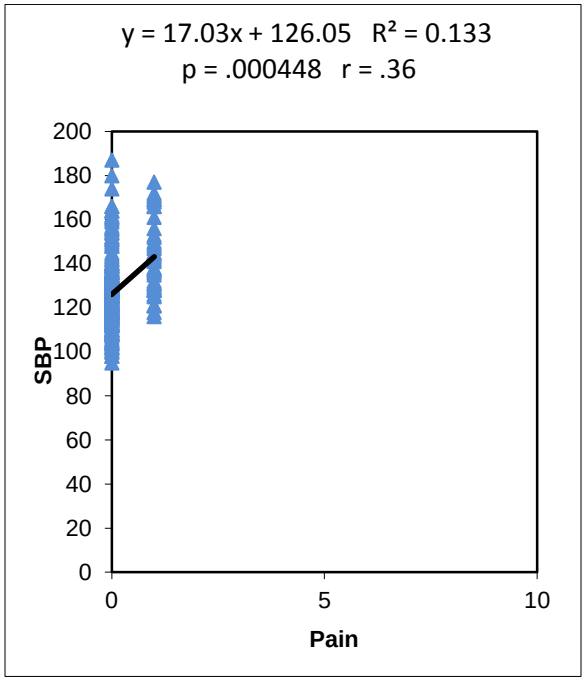

Diagram 13 – Controls, all tasks

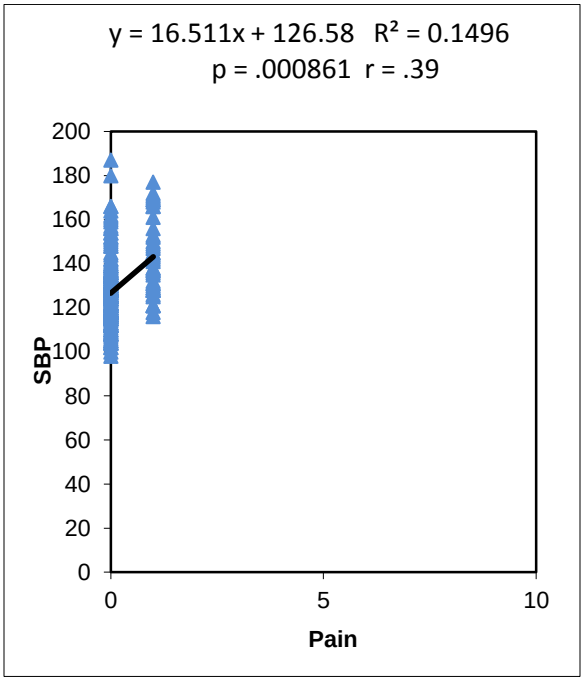

Diagram 14 – Controls, no start task

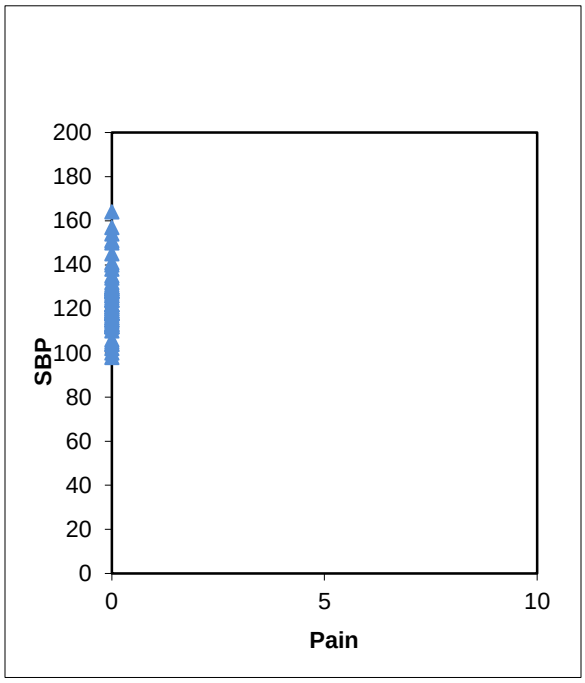

Diagram 15 – Controls, sit task

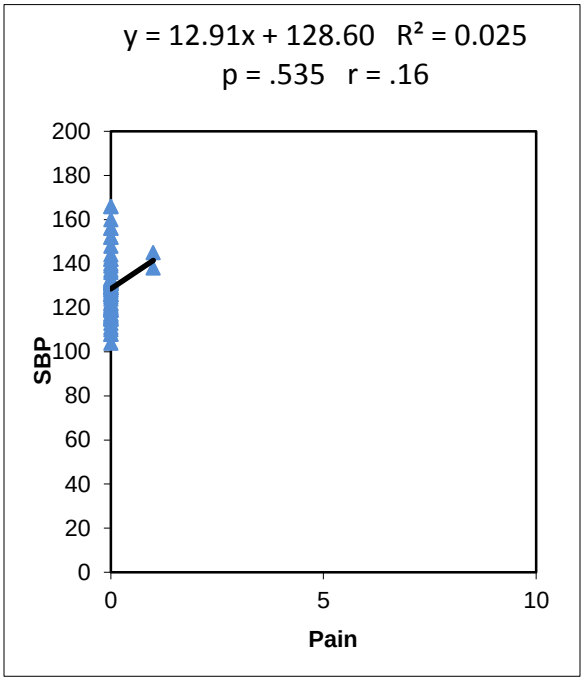

Diagram 16 – Controls, stand task

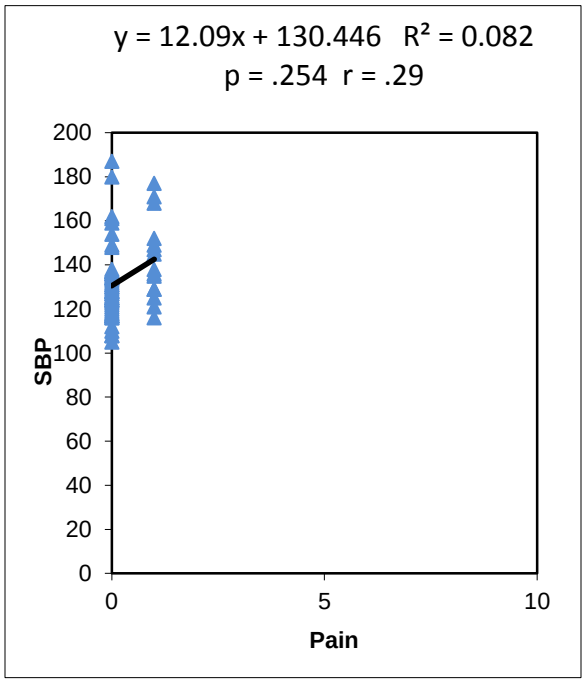

Diagram 17 – Controls, walk task

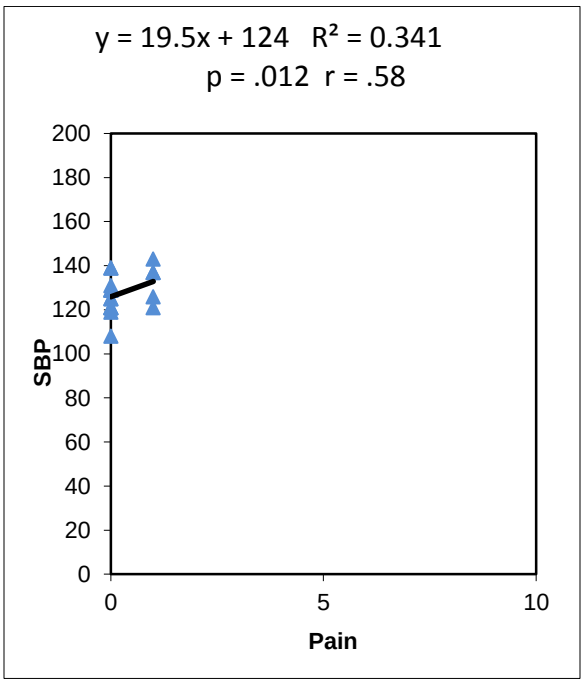

Diagram 18 – Controls, step-up task

Linear Regression Equation Diagrams
Subjects and Rebounders as compared to Subjects and Rebounders, less Confound, All Tasks

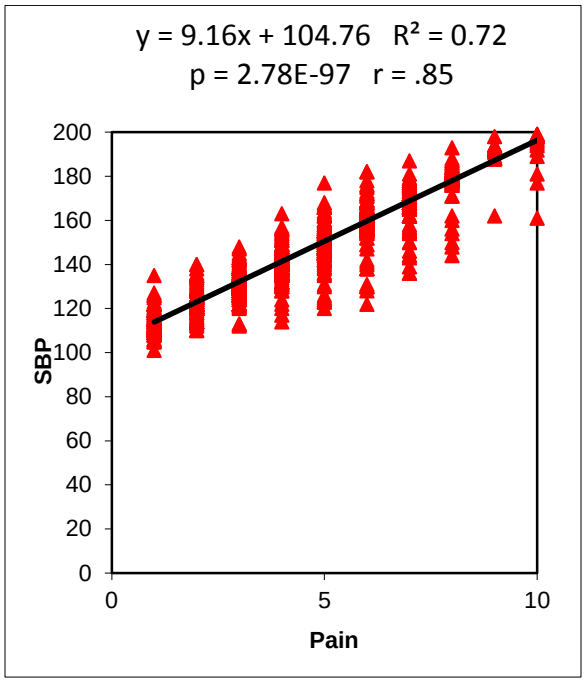

Diagram 19 – All Subjects, rebounders, all task

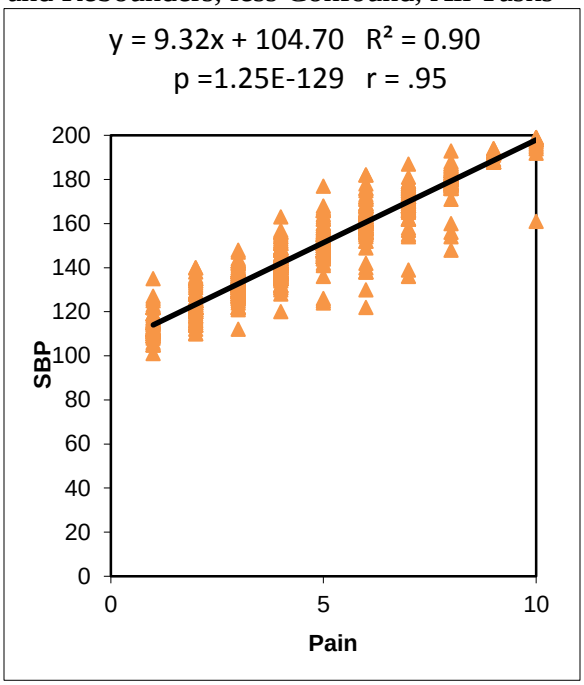

Diagram 19a – All subjects, rebounders, less confounds, all tasks

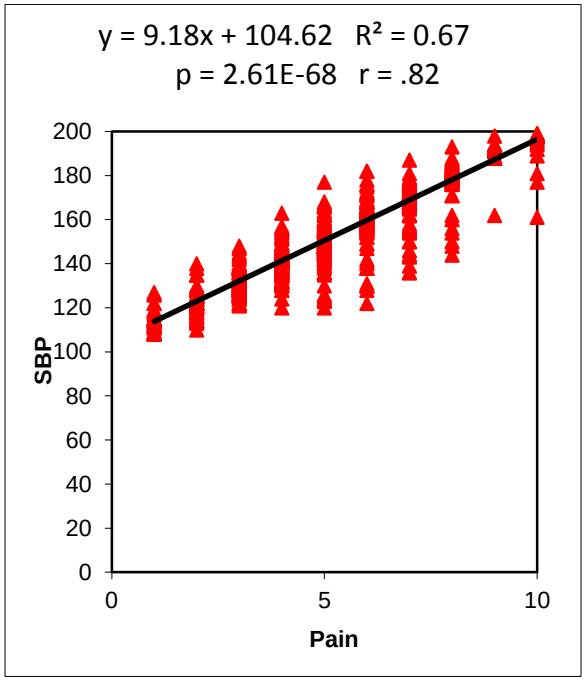

Diagram 20 – All subjects, rebounders, no start task

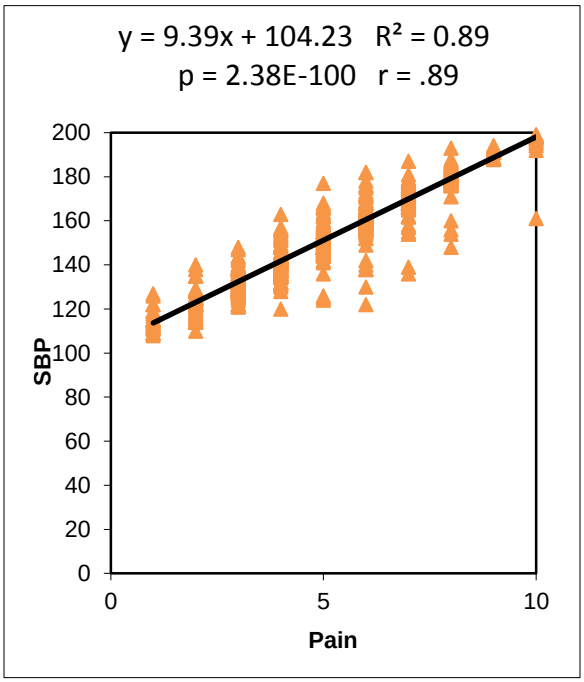

Diagram 20a – All subjects, rebounders, , less confound, no start task

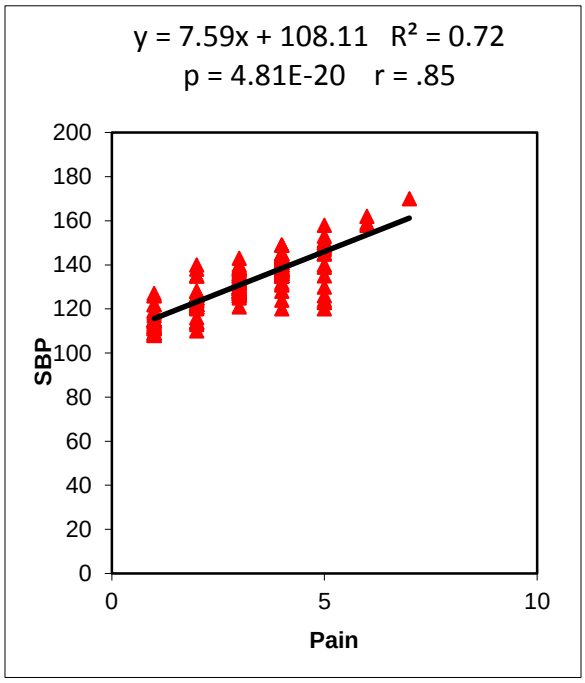

Diagram 21 – All subjects, rebounders, sit task

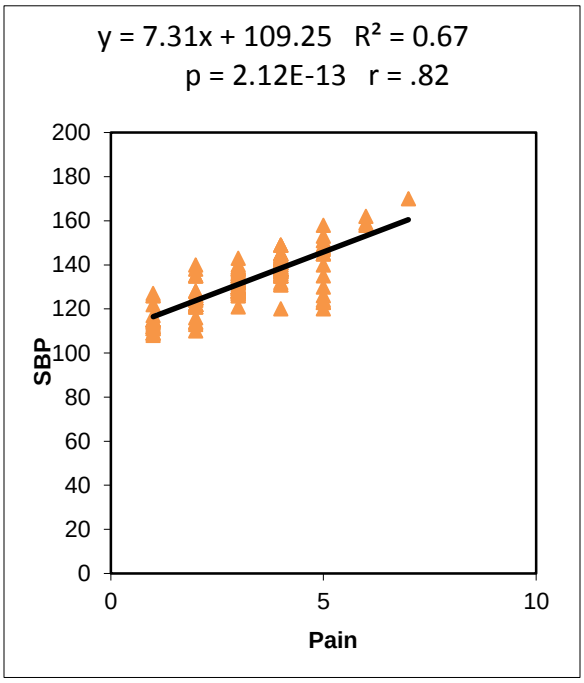

Diagram 21a – All subjects, rebounders, less confound, sit task

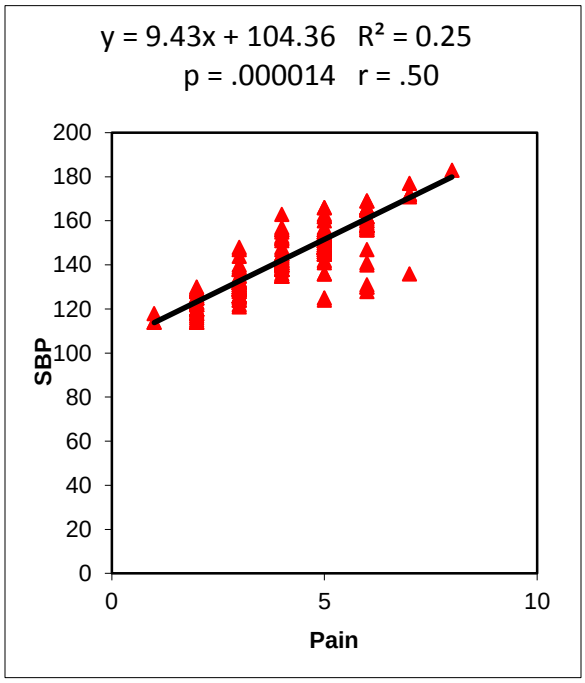

Diagram 22 – All subjects, rebounders, stand task

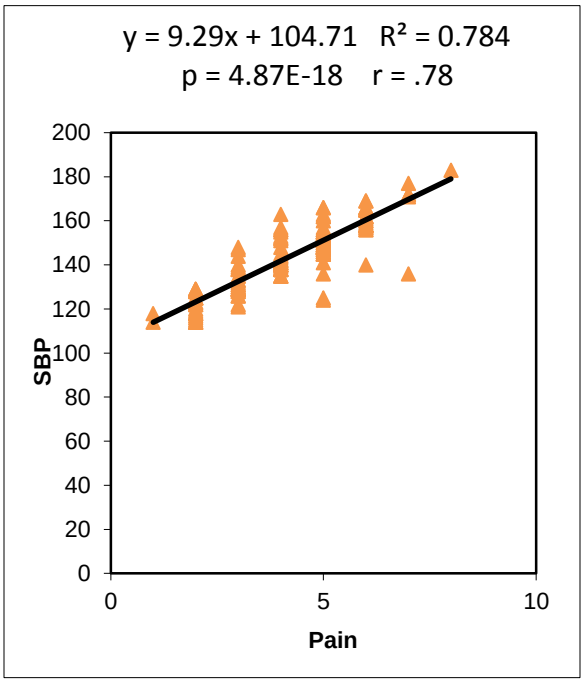

Diagram 22a – All subjects, rebounders, less confound, stand task

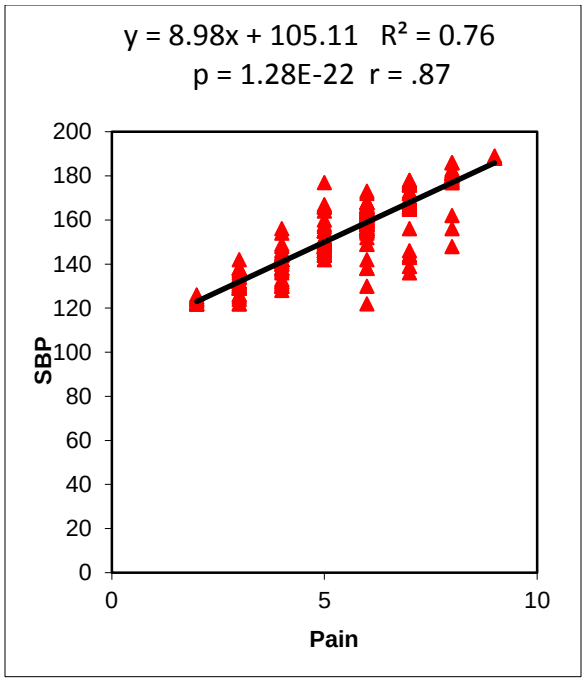

Diagram 23 – All subjects, rebounders, walk task

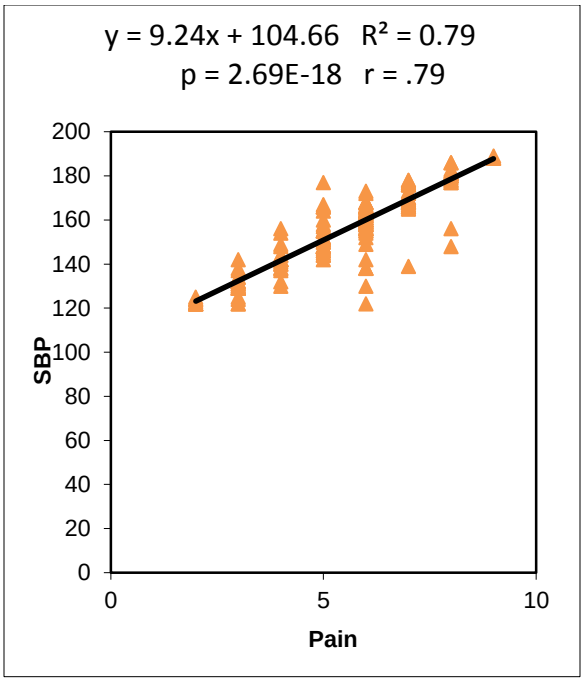

Diagram 23a – All Subjects, rebounders, less confound, walk task

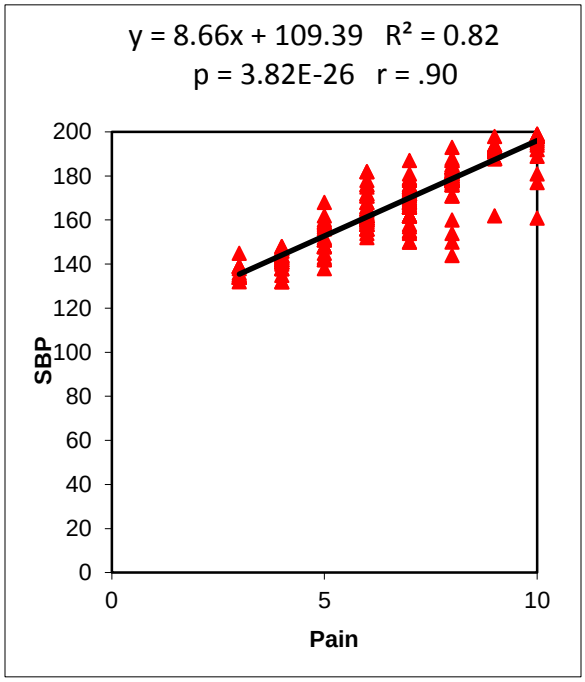

Diagram 24 – All subjects, rebounders, step-up task

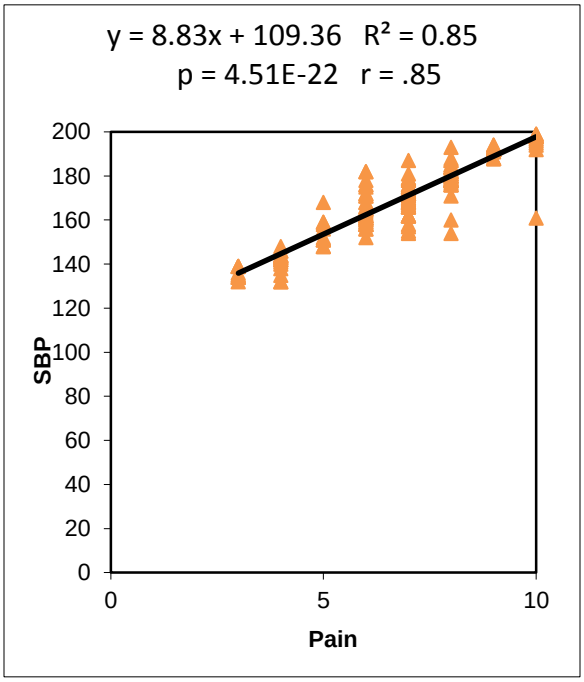

Diagram 24a – All subjects, rebounders, less confound, step-up task

	Linear equation	Slope	Intercept	Correlation	r^2	p
All with start	y = 9.16x + 104.76	9.16	104.76	.85	.75	2.78E-97
No start	y = 9.18x + 104.62	9.18	104.62	.82	.67	2.61E-68
Sit	y = 7.59x + 108.11	7.59	108.11	.85	.72	4.81E-20
Stand	y = 9.43x + 104.36	9.43	104.36	.5	.25	.000014
Walk	y = 8.98x + 105.11	8.98	105.11	.87	.76	1.28E-22
Step-up	y = 8.66x + 109.39	8.66	109.39	.9	.82	3.82E-26

Table 4a -- Linear regression table of all results for Subjects and rebounders, All Tasks

	Linear equation	Slope	Intercept	Correlation	r^2	p
All with start	y = 9.32x + 104.70	9.32	104.70	.95	.9	1.25E-129
No start	y = 9.39x + 104.23	9.39	104.23	.89	.89	2.38E-100
Sit	y = 7.31x + 109.25	7.31	109.25	.82	.67	2.12E-13
Stand	y = 9.29x + 104.71	9.29	104.71	.78	.78	4.87E-18
Walk	y = 9.24x + 104.66	9.24	104.66	.79	.79	2.69E-18
Step-up	y = 8.83x + 109.36	8.83	109.36	.85	.85	4.51E-22

Table 4b - - Linear regression table of all results for Subjects, rebounders. less the confounders, All Tasks

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Appendix F
Linear Regression Equation Diagrams
Narcotics "Users" group, All Tasks

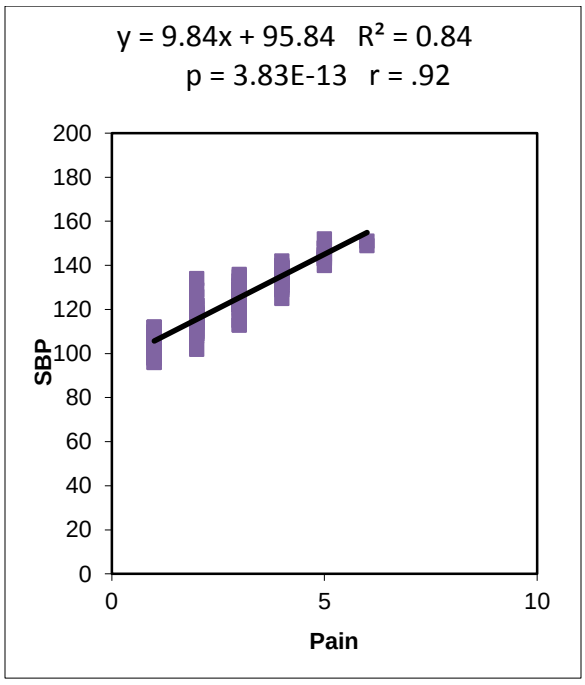

Diagram 25 – Narcotics "Users" – all tasks

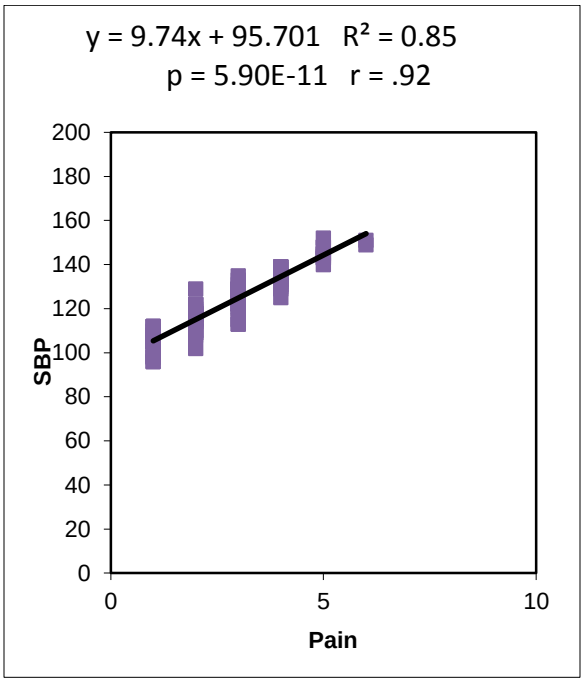

Diagram 26 – Narcotics "Users" – no start task

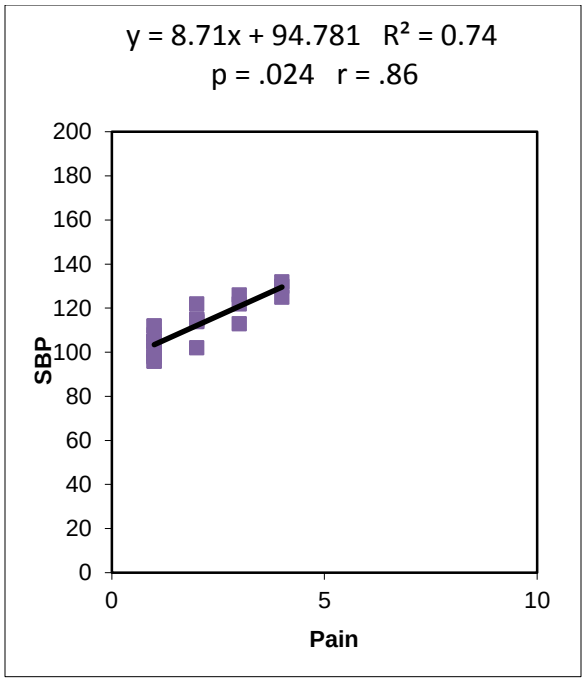

Diagram 27 – Narcotics "Users" – sit task

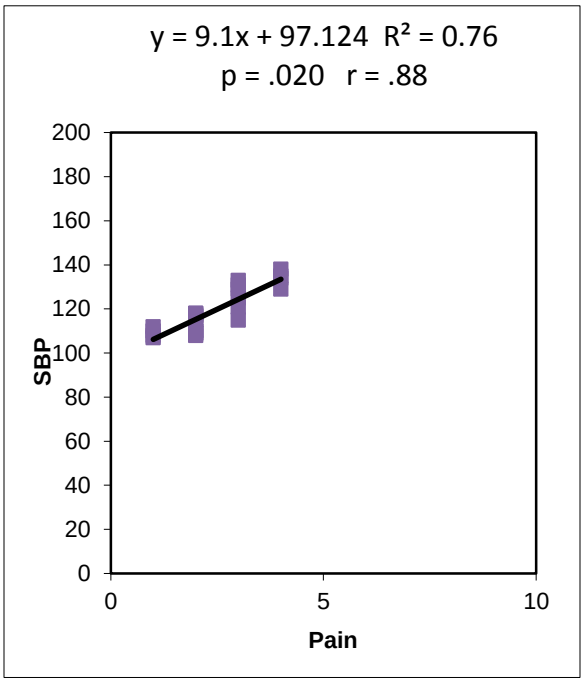

Diagram 28 – Narcotics "Users" – stand task

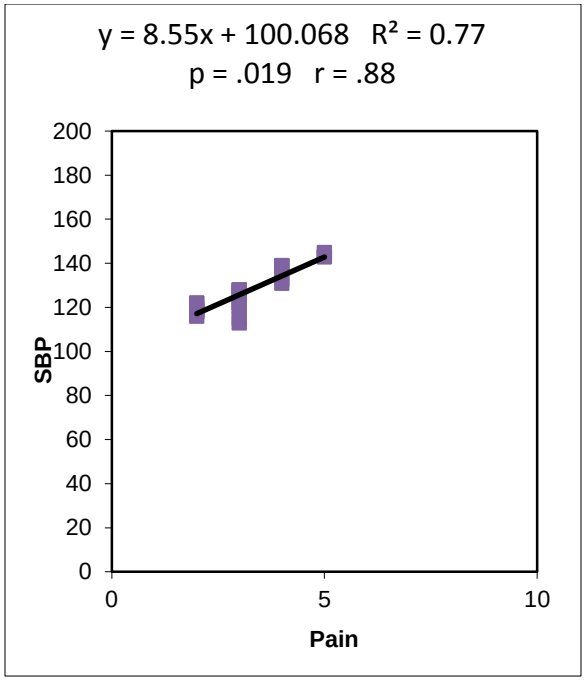

Diagram 29 – Narcotics "Users" – walk task

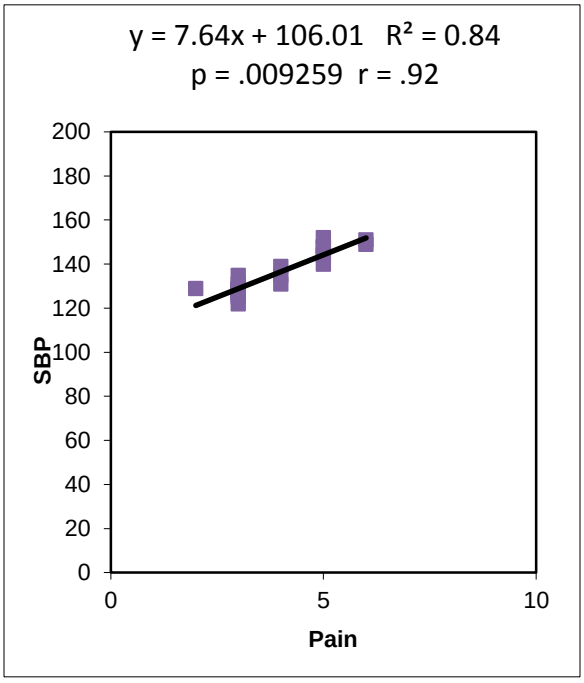

Diagram 30 – Narcotics "Users" – step-up task

Abbreviations and Definitions

Abbreviation	Definition
DDP	Disability Determination Process – the process by which the Social Security Administration concludes a person is disabled.
et al	Latin, means "and all others"
FCE	Functional Capacity Evaluations
ibid	Ibid is a contraction of ibidem, a Latin word meaning "the same place," and means "the same as previous" in citations
n	n indicates the number of things in the study. In this case, the n = 251 study subjects, or 25 "rebounders" or 276 "merged" subjects
NRS	Numeric Ratings Scale – is like a visual analog scale, but instead of a line with numbers from left to right, is a series of bricks laid end-to-end
p	The measure of statistical significance in a study. Must be less than at least .05
PI	Principle Investigator – the person who is running the study
QoL	Quality of Life
SSA	Social Security Administration
SBP	Systolic Blood Pressure – the upper or first measure of the blood pressure. This is the physical proxy for pain in this study. SBP increases as pain increases
VA	Veteran's Administration – The federal agency which manages and controls all funds and services for the country's veterans.
VAS	Visual Analog Scale – a 1-10 scale of measure where the person chooses the lower numbers for a better event/feeling, a higher number for a more intense/worse event/feeling. Low pain = 2; high pain = 8