HHS Public Access

Author manuscript

Neuroimage. Author manuscript; available in PMC 2017 January 01.

Published in final edited form as:

Neuroimage. 2016 January 1; 124(0 0): 1232–1237. doi:10.1016/j.neuroimage.2015.04.018.

Pain and Interoception Imaging Network (PAIN): A multimodal, multisite, brain-imaging repository for chronic somatic and visceral pain disorders

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Abstract

The Pain and Interoceptive Imaging Network (PAIN) repository (painrepository.org) is a newly created NIH (NIDA/NCCAM) funded neuroimaging data repository that aims to accelerate scientific discovery regarding brain mechanisms in pain and to provide more rapid benefits to pain patients through the harmonization of efforts and data sharing. The PAIN Repository consists of two components, an *Archived Repository* and a *Standardized Repository*. Similar to other 'open' imaging repositories, neuroimaging researchers can deposit any dataset of chronic pain patients and healthy controls into the *Archived Repository*. Scans in the Archived Repository can be very diverse in terms of scanning procedures and clinical metadata, complicating the merging of datasets for analyses. The *Standardized Repository* overcomes these limitations through the use of standardized scanning protocols along with a standardized set of clinical metadata, allowing an unprecedented ability to perform pooled analyses. The *Archived Repository* currently includes 741 scans and is rapidly growing. The *Standardized Repository* currently includes 433 scans. Pain conditions currently represented in the PAIN repository include: irritable bowel syndrome, vulvodynia, migraine, chronic back pain, and inflammatory bowel disease. Both the PAIN

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Archived and *Standardized* Repositories promise to be important resources in the field of chronic pain research. The enhanced ability of the Standardized Repository to combine imaging, clinical and other biological datasets from multiple sites in particular, make it a unique resource for significant scientific discoveries.

Keywords

chronic pain; neuroimaging data repository; archived repository; standardized repository; large biological datasets; multiple sites

Introduction

Chronic pain remains one of the most prevalent and challenging health problems. As central factors play a prominent role in the development and maintenance of chronic pain, structural and functional brain imaging has become a primary tool for discovery of the pathophysiologic mechanisms of chronic pain and evaluation of novel treatments. Despite the remarkable progress achieved with these approaches in relatively small samples, further advances in the field require much larger datasets obtained in phenotyped populations, which allow for data driven analysis approaches. Individual investigators can seldom amass large enough datasets for these types of analysis and multisite cooperative studies are limited in number and scope. It has become clear that the sample sizes needed to test many important hypotheses about pain will not be obtainable by any single site or laboratory. To this end, the Pain and Interoception Imaging Network (PAIN) Repositories (PAINRepository.org) were developed to expand pain research opportunities for individual users, facilitate collaborations between sites in the design and analysis of data, and aid in the development of competitive grant proposals. Currently, the PAIN Repository system includes two repositories open to contributing pain investigators, the *Archived* and *Standardized Repositories*. In addition, PAIN administers several collaboration specific repositories. All the PAIN repositories use the same general infrastructure but data sharing and user agreements are repository specific.

The PAIN repositories are multimodal, containing three types of MRI data: high quality structural, diffusion tensor, and functional imaging during resting state and pain tasks. The three primary data types (excluding the pain tasks) are obtainable with almost any high-resolution scanner and are relatively context independent, provided standardized acquisition protocols are followed. The current PAIN *Archived and Standardized Repositories* developed from the infrastructure of the Multidisciplinary Approaches to Pelvic Pain Neuroimaging Network, a research consortium funded by the US National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) to study pelvic pain, for which the Oppenheimer Family Center for Neurobiology of Stress serves as the Neuroimaging Core (Landis et al., 2014). Preliminary funding to establish the PAIN *Archived and Standardized Repositories* was provided by the US National Center for Complementary and Alternative Medicine (NCCAM) and the National Institute on Drug Abuse (NIDA).

To address known limitations of open access databases without standardization, the PAIN general repository includes two imaging databases: the PAIN *Standardized Repository* and

the PAIN *Archived Repository*. The *Standardized Repository* is the primary repository. It was designed to enable discovery of mechanisms and biomarkers related to chronic pain and its treatment, and correlation of brain biomarkers with a limited, standardized set of clinical metadata (i.e., data describing subject characteristics). The *Standardized Repository* contains scans from multiple sites and different scanners that have been collected with pre-tested protocols that enable combined multisite analyses. Scans in the *Standardized Repository* undergo quality control to assure consistency across sites.

The PAIN *Archived Repository* is a repository in which contributors can deposit any structural, DTI, resting state or evoked fMRI scans from pain patients or healthy controls which do not conform to the guidelines for scans in the *Standardized Repository*. Scans in the *Archived Repository* have minimal clinical information and can be very diverse in terms of scanning procedures. The *Archived Repository* is seen as a resource to deposit and access data from already completed studies, older datasets, or those with limited subject data available. Evoked pain studies can also be placed in the PAIN *Archived Repository*.

PAIN Repository Infrastructure and Function

The PAIN repository infrastructure and function is depicted in Figure 1. All uploaded clinical, behavioral and image data are integrated into the central data repository at PAIN. The image archiving system enforces data de-identification rules, automatically organizes images into similar collections, which can then be processed with an appropriate quality assessment pipeline workflow. The repository database employs an identity management system to ensure accurate linking of all data elements including images and metadata, and provenance information (e.g., site name, specific scanner). Database schemas are provided for the collection and transfer of all metadata to ensure consistency and compatibility of all variables. This database structure allows PAIN staff to efficiently respond to data queries and generate specific data sets.

The PAIN web portal provides a single interface supporting searching, retrieval, management and aggregation of imaging and metadata. The design of the data management architecture ensures: 1) protection of subject privacy through integrated data de-identification components; 2) strict access controls to ensure data are only accessible to authorized individuals; 3) ease of use through a platform-independent, user-friendly interface; and, 4) automated capture of acquisition protocol specifications and metadata. When members upload data some of the data/metadata may be susceptible to human errors (e.g., mixing data identification indices) therefore, PAIN integrates data inspection code into the upload process to alert users of possible errors.

The main database components are: 1) simple and advanced query interfaces for searching the contents of the repository using demographic, subject, study, keyword, and other metadata; 2) a collections interface for forming logical collections of data and downloading them; 3) and an archiving interface for de-identifying and transmitting data to the Repository.

The PAIN Repositories physically reside in a secured data center at the Oppenheimer Center for Neurobiology of Stress at the University of California, Los Angeles (UCLA). Hardware

consists of scalable, secure, Intel-based servers running Redhat Enterprise Linux. Following best practices for data integrity, the repository uses redundant arrays of independent drives, distributed file systems, and backup to both local and remote long-term storage tape. Use of internal private networking, the NSA Security Enhanced Linuxprogram, and physical separation between the data storage and Internet-accessible hosts ensure security.

Quality Control

All scans in the PAIN *Standardized Repository* are assessed for protocol adherence, basic quality and compatibility with the repository standards using automated algorithms and visual review. Contributors are notified as soon as possible if scans do not meet the agreed upon acquisition parameters so that adjustments can be made in data acquisition or the data can be targeted to the *Archived Repository* as an alternative. Scans in the *Archived Repository* will only undergo data integrity and validity checks to assure that the images are complete and readable upon receipt in the Repository.

Standardized MRI acquisition protocols for imaging data included in the *PAIN Standardized Repository*

In an effort to ensure valid multisite dataset across scanners and sites, PAIN has developed standardized acquisition protocols for structural, functional and diffusion tensor imaging acquisition. The sequences were selected based on previous multisite, multimodal imaging research initiatives (Glover et al., 2012; Jack et al., 2008), physicist recommendations, and our own experience with multisite studies to enable implementation of compatible sequences on GE, Philips and Siemens devices. The recommended scanning protocols include a tri-planar scout localizer, sagittal MPRAGE, axial resting state fMRI, and axial DTI.

The structural sequence included in the *Standardized Repository* MRI protocol originates from the sequences developed by The Alzheimer's Disease Neuroimaging Initiative (ADNI) (Jack et al., 2008). The sequence has been updated to make slice thickness equal to the acquisition matrix resulting in isotropic $1mm^3$ voxels. A corresponding increase in the number of slices from 176 to 240 allows for ample field of view.

The resting state fMRI sequence proceeds from the sequence developed by the Functional Biomedical Informatics Research Network (fBIRN) for multisite, standardized acquisition across brands and models (Glover et al., 2012). The singular update to the sequence involves reducing the slice gap from 1mm to 0.5mm due to improved acquisition capabilities in 3T scanners.

The DTI sequence included in the PAIN Repository MRI protocol is derived from a common q-ball imaging protocol involving 64 directions at equidistant angles on a sphere in q-space. The number of directions were chosen based on a balance between total acquisition time, the need for high angular resolution data for use in probabilistic tractography techniques, and commonly used gradient schemes from MR system manufacturers. The 2mm isotropic resolution and 64 directional encoding scheme is also commonly used in studies involving structural connectivity analysis.

An MRI acquisition manual that covers site qualification, pre-scan procedures, scan protocols and subject scan procedures is available for download at PainRepository.org. The manual also includes information on subject positioning, minimizing movement artifact, and subject instructions as well as procedures for uploading and downloading scans and metadata.

Pain Standardized Repository Metadata

A concise common data set appropriate for subjects with chronic pain and healthy controls was chosen to allow for analysis of relevant phenotype variables with the neuroimaging data. Measures were chosen based on reliability, validity and availability of translated questionnaires. To determine psychosocial status we include specific measures of symptom severity (Zalon, 2006), mood symptoms (Watson et al., 1988; Zigmond and Snaith, 1983), widespread symptoms (Kroenke et al., 2002), pain catastrophizing (Robinson et al., 1997), personality (Goldberg et al., 2006), childhood adversity (Bremner et al., 2007), and socioeconomic status (MacArthur, 2007). Table 1 contains description of basic demographic data and the questionnaires used to assess these constructs. All questionnaires and forms to assess basic demographic/descriptive variables are readily available for download on the website.

Data requirements for the *Archived Repository*

The *Archived Repository* is available to house scans from studies with diverse protocols. In addition to structural, DTI and resting state functional scans, this repository contains evoked pain studies and other imaging modalities (e.g. arterial spin labeling). The requirement for subject metadata is minimal: age, sex, handedness, collection site, date, patient group or primary diagnosis, and description of the study design the main requirements.

PAIN Membership

Membership to the *Archived Repository* is open to any pain investigator who is willing to contribute a minimum of one dataset and accept the membership agreement. PAIN aims to promote scientific collaborations between participating members by creating the opportunity for collaborative analysis of existing datasets. All contributing investigators are encouraged to provide the complete study methods accompanying the datasets they upload to the PAIN *Archived* Repository, but direct communication between the contributing investigators and those utilizing the *Archived* data is expected. The contributing investigator will be notified of any request to utilize the data they have placed in the repository.

Membership to the *Standardized Repository* is open to any investigator who is willing to contribute a minimum of 20 structural, DTI and/or resting state imaging scans per year, which have been acquired using PAIN protocols, together with the recommended clinical metadata. The registration process is the same as with the Archived Repository, beginning with the completion of the online registration form found at PAINRepository.org. Sites that express interest in participating receive an initial inquiry to determine personnel in key roles, scanner hardware and software brand, model and version, and current scanning practices. The PAIN staff then set up accounts for access and data transfer. PAIN staff can also assist

in integrating the prescribed procedures into a site's study to ensure that collected data will fit into the *Standardized Repository* database schema. Initial scan qualification consists of a human test scan, protocol printout or exam card, and optional functional and structural phantoms to determine parameter compliance and correct scanning practices. Sites are required to provide documentation from their respective Ethics/Institutional Review Boards for each dataset included in the repository. All members may not be able to continue to provide 20 scans per year to the Standardized Repository. If requested the Executive Committee, on a case-by-case basis, can authorize contributors to maintain access to repository data based on their overall contributions, participation in PAIN collaborations, or other pertinent considerations.

Uploading Data to PAIN

The repository infrastructure consists of a web-based front-end for data upload and download, reference documentation, and blog communication. Each member site has access to view data availability, upload scans, review reports, request data and discuss projects. Images in nonstandard image formats or custom DICOM version will be flagged and processed to match the specifications of other images. Metadata corresponding to each scanning session must be uploaded at the same time using the data schema provided by PAIN. Interfaces for batch uploading and/or direct data entry through web-based forms will be available. At the time of upload, contributors are asked to upload papers previously published on the dataset, the study protocol scanning parameters file, and the timing file for task-based imaging. When any data set is uploaded, the Principal Investigator or authorized proxy must accept the Data Sharing Agreement. The preferred format for all scans uploaded to the *PAIN Standardized Repository* is DICOM format. Data must be anonymized or encoded before uploading. PAIN staff can assist in anonymizing data when necessary.

All data transfer to the PAIN Repository occurs via Hypertext Transport Protocol over Transport Layer Security (HTTPS), the standard for all secure web transaction. Data is stored on encrypted, secure servers in a dedicated datacenter on a private network behind the UCLA Medical Center firewall. The servers utilize all security best-practices, including role-based access control, automatic security updates, and thorough review by UCLA Medical Center security compliance personnel. A secure network file transfer program is recommended to upload data sets larger than 1 Gigabyte and support for this data transfer with be provided. Metadata is submitted in text or Excel file format. The PAIN Repository will provide feedback to member sites for every upload via direct email with regard to scan and metadata compatibility and suggest corrections if needed.

Data Access Policy

Access to the PAIN Repositories is currently restricted to contributing members. The access and publication policy for the repository follows closely that which was utilized by NIH consortium studies (Bagarinao et al., 2014; Clemens et al., 2014; Landis et al., 2014) with an emphasis on fostering collaboration, making the most efficient and productive use of repository data, and providing fair and timely access to all members. Briefly, members submit analysis proposals in writing to the Executive Committee (EC), which are checked for overlap with other ongoing or proposed analyses. When approved the requested dataset

is bundled and sent to the member. In cases in which multiple members request datasets for overlapping analyses the EC will discuss the issues with the parties involved in order to reach an equitable division of data or collaborative approach.

Downloading data from PAIN

Upon approval of the data request, the PAIN staff will make a link available to download the bundled imaging and metadata package. By default, the data will be available for download as a complete set of DICOM or NIFTI files. Each dataset will include associated metadata. The download package will be in a compressed format to ensure data integrity. The Repository provides various incremental and distributed transfer methods (e.g., GLOBUS to handle large data requests and interrupted connections).

Sociology and governance of PAIN

The governance plan for the PAIN Repositories is based on similar plans from NIH consortium projects, multisite imaging studies, and discussion with other imaging repositories. The PAIN staff is responsible for maintaining the hardware, website, data transfer protocols, backup systems, reporting, administration and organization of the repository with input from EC members. The EC has a rotating membership (2 year terms) made up of 8 individuals representing members of the Repositories. Chairpersonship of this committee and ultimate financial responsibility for PAIN is based at the Oppenheimer Center for Neurobiology of Stress at UCLA. The EC oversees publication and access policy, minimal scan contributions for full membership and execution of a fair priority access system based on timing of proposals. PAIN does not have specific requirements regarding authorship beyond requiring proper recognition in the manuscript that the data were obtained from the PAIN repository and references to previously published articles using the same datasets. A quarterly newsletter containing news relevant to pain researchers is sent to all PAIN members.

Confidentiality and Subject Protection Issues

The PAIN Repositories only contain de-identified data. The PAIN has approval from the UCLA Office for the Protection of Research Subjects to maintain the databases. All uploaded datasets need to have received approval from their local IRB or Ethics Board for collection and for de-identified data sharing such as the transfer to the repository. To date, approval for de-identified imaging data sharing has not been a barrier for participation in the repositories.

Available PAIN Data and Current Statistics

Both databases are continually growing. Twelve sites from North America and Europe are either members in the PAIN *Standardized Repository*. Table 2 contains complete descriptions of scans uploaded to the *Standardized* and *Archived Repositories* as of January 21st, 2015. Currently the *Archived Repository* is comprised of 479 structural scans, 132 resting state scans and 130 DTI scans from subjects with irritable bowel syndrome (N=186), vulvodynia (N=86), chronic back, neck or shoulder pain (N=68), inflammatory bowel

disease (N=9), and healthy controls (N=392). The Standardized Repository contains 210 structural scans, 196 resting state scans, and 137 DTI scans from subjects with irritable bowel syndrome (N=285), vulvodynia (N=53), migraine (N=27), and healthy controls (N=178).

Long Term Plans for Managing and Maintaining PAIN

In addition to growing the size of the PAIN Repositories, future plans include several important expansions of the repository scope. Acquisition protocols are reassessed regularly to assess the need for updates or additions, such as the addition of a fast repetition time resting state protocol for those sites with appropriate scanner technology. 1) Subgroups of members with similar interests are planning on developing their own disease specific set of metadata that they feel will increase the opportunities for disease specific analyses. 2) PAIN is also expecting that biologic or 'omics' data will become both more important and more available to link brain mechanisms with peripheral pain mechanisms. To prepare for this challenge, the PAIN Repository metadata database has been set up to allow for storage of several other types of biologic data that may become useful in pain studies. These include genomics (DNA, RNA, miRNA) and microbiome data (16s RNA, metabolomics). Several of the initial members of the PAIN Repositories are already funded to collect some of this type of metadata and plan to include this in their data deposits. 3) Future interactions with other repositories to expand the scope of the imaging data available has been planned. Although initially data from the PAIN *Archived* and *Standardized Repositories* are reserved for contributing members, it is expected that the repositories will be opened for wider access to pain investigators at some point in the future.

Conclusion

The *Archived* and *Standardized* Repositories represent an ambitious initiative to facilitate brain research on one of our most common and challenging medical problems. PAIN has built an efficient and easily used infrastructure to enable a broad base of contributions from both primary research and clinical settings and large-scale collaborative studies. PAIN also provides data for preliminary analyses, independent replication, and novel exploration. The PAIN Repositories promise to be an important resource in the field of chronic pain research. The *Standardized Repository*, in particular, can aid in the testing of hypotheses that require large, high quality datasets typically unachievable by single laboratories, and in making more direct comparisons of imaging and behavioral variables across populations studies in different geographic sites. The Repositories also aim to serve as a hub for new collaborations among pain researchers and to be a critical resource for the next generation of 'big data' studies combining neuroimaging with advanced physiological, genetics and omics measures. The PAIN repositories will accelerate scientific discovery regarding brain mechanisms in pain through the harmonization of efforts and data sharing, providing more rapid benefits to pain patients.

Acknowledgments

This research was supported in part by grants from the National Institutes of Health: NCCAM/NIDA: R01 AT007137 (KT, BN), P30 DK041301, R01 DK048351 (EAM), R01 HD076756 (JSL).

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Highlights

- Pain and Interoception Imaging Network (PAIN) Repository consists of multimodal MRI
- PAIN pools MRI and metadata from patients with chronic pain and healthy controls
- PAIN consists of the *Archived and Standardized Repositories*
- The goal of PAIN is to accelerate scientific discovery regarding brain mechanisms in pain
- PAIN will harmonize efforts and data sharing in pain research

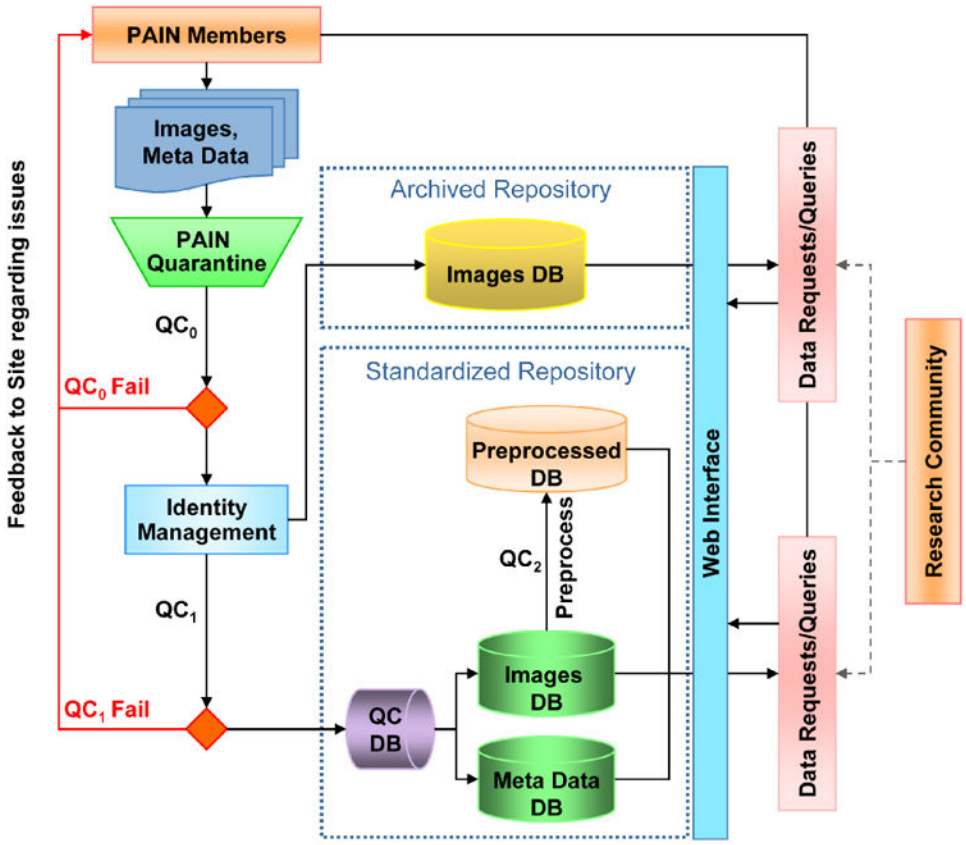

Figure 1. PAIN repository infrastructure and function

The figure shows the operating structure of the PAIN Repository. Data are initially quarantined before quality control. Initial quality control (QC_0) is performed to check for valid image files, correct formats and inclusion of relevant metadata. Data that passes QC_0 is then assigned a repository-specific identifier and is organized into the appropriate repository.

Standardized Repository: QC_1 = checks for parameter compliance, image and metadata matching, assessment of modality-specific criteria and completeness of metadata. QC_2 =determines level of usability within the overall repository.

Abbreviations: QC, quality control; DB, database

Table 1
Basic Demographic Data and Questionnaires

Demographic Information		**Item Details**		
Sex				
Age				
Residence		Country		
Race (from NIH categories)[1]		African Asian Pacific Islander White Other		
Primary pain problem (how recruited?)				
Education Level		Years of education		
Estimate of pain chronicity		'At what age did you first begin to have any persistent pain problem?'		
Body Mass		Height, Weight		
Current medications list (categories)		Antidepressants Narcotics Anxiolytics Pentanoids (i.e gabapentin, pregabalin) Other Centrally Acting Medication		
Handedness		Right, Left, Ambidextrous		
FEMALES ONLY: Menopausal State		Pre-menopausal, Peri-menopausal, Post-menopausal		
FEMALES ONLY: First day of last menstrual period ON DAY OF SCAN				
Psychosocial Status	**Scale**	**Number of Items**	**Time Period**	**Translations**
Pain/Symptom Severity	Brief Pain Inventory (BPI)	15 items	Past week	Widely translated
Anxiety/Depression Symptoms	Hospital Anxiety and Depression Scales (HADS)	7 items each	Past week	Widely translated
Widespread symptoms	Patient Health Questionnaire (PHQ-15)	15 items	Past 4 weeks	Widely translated
Pain Catastrophizing	Coping Strategies Questionnaire - Catastrophizing scale (CSQ-C)	6 items	Usual	Widely translated
Personality	IPIP Neuroticism and Extroversion scales (IPIP-NEO)	10 items each	Usual	Some translations available
Childhood adversity[2]	Early Trauma Inventory-Self Report (ETISR)	29 items	Before 18 years old	No translations
Social economic status	SES Ladder (SES-L)	1 item	Current	Some translations available
Day of Scan Acute Measures	**Scale**	**Number of Items**	**Time Period**	**Translations**
Mood	Positive and Negative Affect Scales (PANAS-SF)	10 items each	Current	Some translations available
Current Pain Severity	BPI Item #6	1 item	Current	Widely translated

Table 2
Description of Scans from the Standardized and Archived Repositories

Pain Archived Repository			
Pain Condition	**Structural**	**RS**	**DTI**
Chronic Back, Neck or Shoulder Pain	34	34	0
Irritable Bowel Syndrome	121	26	39
Vulvodynia, Vestibulodynia	53	0	33
Inflammatory Bowel Disease – Crohn's	2	0	0
Inflammatory Bowel Disease - Ulcerative Colitis	7	0	0
Healthy Control	262	72	58
Total	**479**	**132**	**130**
PAIN Standardized Repository			
Pain Condition	**Structural**	**RS**	**DTI**
Irritable Bowel Syndrome	90	104	91
Migraine	9	9	9
Vulvodynia, Vestibulodynia	10	33	10
Healthy Control	101	50	27
Total	**210**	**196**	**137**