

Back in Business: Final Paper

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The Need

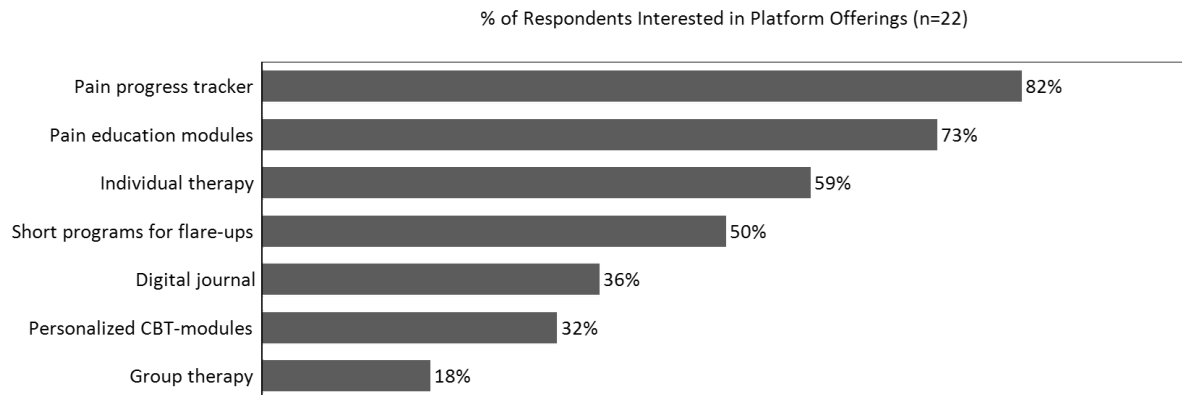
- We learned the important role psychology plays in pain processing in subacute to chronic lumbar disc herniation pain
- If we can help with psychological processing part, we can help allow the disc time to go through the natural resorption/healing process
- In our interviews with patients/the survey of patients we learned that many patients feel that current treatment for back is inadequate.
 - This unfortunately leads many patients to receive unneeded surgeries due to intolerable pain.
 - Despite pain psychology being a very effective solution, many patients are unfamiliar with it.
 - Of the few who are familiar with it, many did not find it very helpful often due to lack of education around proper implementation and a related lower level of adherence; they would have loved better instruction around those techniques.
- In our interviews with providers, we learned that many patients received surgery without a clear need often due to intolerable pain and frustration around navigating alternative options.
 - Many find pain psychology interventions useful for their patients but significantly underutilized (difficulty in scaling these solutions in easily accessible ways).
- Our need statement focuses on increasing the tolerability of pain to prevent invasive surgeries:
 - A way to **increase the tolerability*** of pain in **patients with subacute or chronic lumbar radiculopathy due to lumbar disc herniation** in order to **reduce the number of patients who undergo discectomy and spinal fusion surgery.**

*function of duration & severity, as well as psychological pain processing

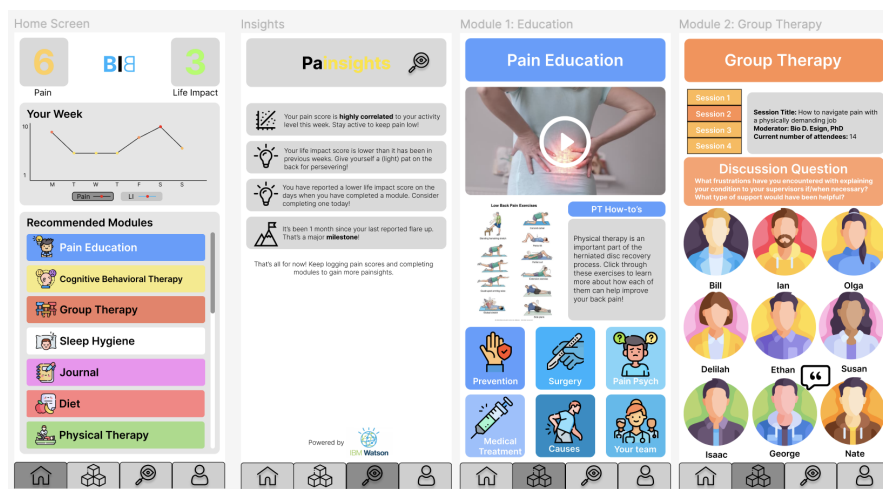
Our Solution

Our solution is Endura Health, a pain psychology platform based on the biopsychosocial model that helps patients **better understand, manage, and recover from their chronic pain in a streamlined, clinically-backed approach.** The platform includes a

number of features, including on-demand CBT-based modules, individual and group virtual therapy, pain progress tracking, and short-form programming for pain flare-ups, all designed to help users return to their normal life faster. These features are informed both by clinically-proven therapies as well as patient input, gathered through interviews and a survey. Below are the survey responses on which features patients want most, which informs the user experience outlined below.



This platform can be accessed from users' computers or phones, allowing users to engage with the content at home on their own time. Additionally, the platform provides personalized recommendations based on each individual patient's pain journey. Based on patient interviews, we know patients don't experience pain in the same way or on the same timeline, so we want to ensure our offering is tailored to each patient based on data (e.g., wearable data, self-reported pain and functional scores, module feedback). We believe a personalized experience will improve patient engagement and, therefore, improve patient outcomes.



The user experience will focus first on pain education as a significant portion of patients are unaware of the psychological factors contributing to their pain and that pain psychology is an evidence-based treatment for chronic pain. As users understand the importance of psychology in the pain they experience, the platform will introduce personalized recommendations on CBT-modules and talk therapy options. Talk therapy will be important as research indicates clinician-driven treatment results in better engagement than module-only treatment¹. Users will be prompted to complete recurring, quick pain and functional score reports that will inform their recommendations and help visualize the progress made. The visualizations above reflect initial wireframes for the user experience.

Through this platform, we believe we can address a number of key criteria that are important to patients, providers, and payers:

- **Efficacy:** Reduce proportion of patients who undergo discectomy or lumbar fusion by 10-15%
- **Efficacy:** Improve functional scores of patients after 6-8 weeks by clinically meaningful amounts
- **Cost:** Does not exceed the overall cost of similarly efficacious therapies
- **Usability:** Does not add complexity to the cycle of care relative to gains in efficacy

Business Model and Commercial Pathway

Our pain psychology platform, Endura Health, follows a subscription and service business model focused on using physical therapists and, eventually primary care providers and pain management doctors, as a key sales channel. Patient interviews support this approach as PTs are often one of the most influential providers in a patient's treatment decision (~80% of respondents have seen a PT, ~83% of those respondents ranked PTs as one of their top 3 most influential providers). Similarly, reimbursement policies often require patients to see a physical therapist before receiving additional care, placing PTs in a key gatekeeper role that intersects with the patient journey often as patients near the subacute phase.

Given PTs' role both as a gatekeeper and as a trusted provider for patients, we believe gaining referrals through PTs facilitates both stronger traction and long-term engagement. In terms of value proposition for physical therapists, referring patients to this product drives improved patient outcomes, particularly given initial research indicates PT or exercises are shown to have better outcomes when combined with CBT, and offers potential revenue through a new remote-monitoring CPT code (discussed further in the payments/reimbursement section below)².

To start, we propose going direct-to-consumer to get initial outcomes data and demonstrate traction. With initial outcomes data, we will pursue partnerships with large physical therapy networks known for investing in holistic care like Physical Rehabilitation Network (200 outpatient PT clinics, 17 states) and Dignity Health Physical Therapy (1,900 rehabilitation centers, 40 states) and begin driving users to the platform through PT referrals. Through this channel, we will become the premier pain management platform recommended by physical therapists. We will bolster these strategic partnerships through initial pilots with employers and potentially health plans, driving further evidence of impact and gaining additional sales channels.

At scale, we believe coverage by employers and health plans as well as access to those lives under coverage coupled with the PT referrals will drive long-term growth and success. For employers, we believe our solution will drive reduced employee absenteeism due to chronic pain as well as lower worker's compensation as employees experience less pain and can return to their daily lives, including work. From a health plan perspective, we believe our solution will reduce pain intensity and improve functional scores, resulting in a reduced need for costly treatments like surgery. We anticipate a per employee (or member) per month pricing structure for both approaches (more detail provided in the Payments & Reimbursement section).

IP Assessment

After a review of existing similar services and patents for adjacent technologies to Endura Health, it does not appear that the technology involved in the generation of our solution is patentable.

It is commonplace for data technology companies such as IBM, Google, and Spotify to patent the methods that are used in their recommendation algorithms, and there have been many successful patents generated that involve methods of determining a certain user experience based on inputs about the user. Additionally, there have been several patents awarded in the pain management space that use patient information as well as physiological data to generate a therapeutic regimen that may include thermoceuticals, electroceuticals, ultrasound, neurostimulation, and other forms of therapy. Specific patents around the tailored delivery of psychological therapies were not found, however a service called Pain EASE³ was found that includes a self-test that determines a pain management plan, which involves the use of modules to learn pain management techniques and additionally allows users to track pain level, sleep, and steps walked each day. Based on this service being in the public domain, it does not appear that the technology we intend to develop satisfies the novelty requirement under US Patent Law.

To this end, we will need to establish other methods besides patent protection in order to build a competitive barrier and distinguish ourselves from competition. The following is a non-exhaustive list of how we intend to accomplish this:

- **Regulatory Advantage:** We intend to operate as a medical device company and initially gain Class I authorization by satisfying General Controls in order to get our product on the market, then gain Class II clearance through the use of clinical data. This gives us the advantage of being able to make stronger claims about our service than other companies who have not gained regulatory clearance for their claims.
- **Reimbursement Advantage:** Somewhat tied to the regulatory advantage, we will also be navigating the reimbursement pathway and gaining knowledge of how to operate and gain CMS approval for reimbursing our service. This will allow us to navigate this space better than our competitors and potentially be the first service of our kind to qualify for reimbursement.
- **Personnel Advantage:** We would plan to bring and consult with various licensed pain management specialists, pain psychologists, and physical therapists in order to build out the modules and teletherapy services that power our service. Gaining the support of these Key Opinion Leaders and backing the content with their stamp of approval will give us an edge over other services that may not be backed up with as much clinical support.
- **Operational Advantage:** Finally, because this project uses the Biodesign process, follows a needs-driven approach to problem solving, and will implement the strategies that are taught by Biodesign, we believe that we will have an operational advantage over competitors who are not following a similar framework.

Market

Market Size

We performed a bottom-up market sizing based on an estimated annual recurring revenue of \$500 per patient via our first direct-to-consumer sales channel (see Payments & Reimbursement section). There are approximately 200 million people in the United States over the age of 18. The incidence of lumbar radiculopathy related to lumbar disc herniation is approximately 1%, or 2 million cases each year⁴. 30% of these patients (600,000) will fail to experience symptom relief after six weeks⁴, thus reaching subacute to chronic stages of pain. This is the target population for our intervention. At an estimated cost of \$500 per patient (about half the cost of a single steroid injection⁵), this creates a **serviceable available market of \$300 million**.

Given the generalizability of our solution to multiple etiologies of chronic pain, we estimated our total available market based upon the total population of patients with chronic pain in the United States. The CDC estimated that in 2021, 51.6 million U.S. adults experienced chronic pain⁶. This gives us a **total available market of \$25.8 billion**.

Competitive Landscape

Indirect Competitors: non pain psych focused solutions for MSK pain

Included because payers and employers are already paying for highly effective, holistic solutions for MSK pain, and may be less willing to pay for a more limited solution without established efficacy.

Vori Health⁷

Vori Health is a virtual-first, value-based care delivery innovator that offers full-service care for MSK patients to reduce areas of high spend (e.g. surgeries, ED visits, admissions). They offer full service physical medicine and rehabilitation medical care, (virtual or in-person) physical therapy, prescriptions, imaging & lab ordering, health coaching, nutritional guidance, community support and premium instructional content. They partner with self-funded employers, forward-thinking health plans in value-based arrangements, as well as primary care and surgical practices to drive appropriate, evidence-based care and faster, cost-effective recoveries.

Sword Health⁸

Sword Health provides virtual physical therapy enhanced by digital tools. They provide sensors, a tablet, and a telemedicine physical therapist. The information from sessions goes to a physical therapist who adjusts sessions from the data and coaches 1:1 over text and interspersed face-to-face telemedicine visits. Services are sold to employers who offer them to employees as a benefit.

Hinge Health⁹

Hinge Health offers a virtual physical therapy program designed to address chronic MSK pain in short, 15-minute sessions. Patients receive sensors for feedback on virtual physical therapy similar to Sword. Patients also receive Enso TENS units. They provide 1-on-1 health coaching to provide motivation and support via text, email, or call. It also incorporates interactive education to teach patients how to manage their specific conditions, treatment options, and more. Hinge targets patients who are overserved by surgery as the solution to address their chronic pain. One of Hinge's selling points is that 90% of their users claim they are less likely to pursue a surgical solution. They also target employers.

Direct Competitors: pain psychology solutions

While there are other direct competitors, Curable is the leading player, so we have focused our analysis on them.

Curable¹⁰

Curable is an online pain psychology program, where users interact with a virtual pain coach called Clara. Through a series of questions during the set-up process Clara gets insight into patients' pain and its causes. She then sends lessons and exercises that aim to help patients reverse the cycle of pain. Lessons or exercises last anywhere from 5 to 20 minutes, and the app uses the mind-body approach or emotional awareness and expressive therapy (EAET). They also offer guided meditations, visualizations, CBT techniques, and expressive writing exercises, each of which has been proven in studies to reduce pain. They offer a freemium model, with the pay version priced at \$22/mo. They also partner with employers and payers.

Regulation

FDA Regulation of Mobile Applications for Chronic Pain Management

The FDA classifies mobile health applications as medical devices if they are intended to be used for medical purposes, such as diagnosing, treating, or managing disease. However, not all behavioral health apps, such as our chronic pain management system for lumbar disc herniation patients, fall under the FDA's regulatory purview. Some apps may be considered wellness or lifestyle apps and may not require FDA approval. The determination of whether an app is subject to FDA regulations depends on its intended use and functionality.

The lower risk category of applications is wellness products, which generally aim to promote "general wellness" or healthy lifestyle choices without making specific treatment or diagnostic claims related to a disease or medical condition¹¹. Examples of wellness products in the context of behavioral health apps for chronic pain management might include general relaxation or stress reduction apps that do not claim to diagnose or treat specific medical conditions, educational and informational apps, and apps that monitor physical activity or sleep patterns to support well-being. Such products can typically be considered class I medical devices that are subject to general controls, including compliance with labeling, good manufacturing practices, and adverse event reporting.

The higher risk category of chronic pain management applications is medical products that make specific treatment claims, provide medical advice, or are intended to help diagnose or manage a specific condition. These devices are often subject to regulation as class II medical devices, cleared through either the 510(k) or De novo pathway.

Devices in this category may include features such as biofeedback mechanisms to assist users in managing pain perception and response, guiding users through cognitive behavioral therapy techniques for chronic pain management, or using virtual reality or augmented reality for pain distraction or relaxation during chronic pain episodes.

There are existing products on the market that have taken either approach. In the lower risk, class I category are products from companies like Kaia Health (self-management of back pain through physical exercise, behavioral exercise and education¹²), Curable, and Upside Health. In the higher risk, class II category are products from companies like Pear Therapeutics (Somryst - 510(k) cleared app for treating chronic insomnia with CBT) and AppliedVR (RelieVRx - De novo cleared VR system using CBT to treat chronic lower back pain). During the COVID-19 pandemic, the FDA implemented an emergency policy that enabled devices that otherwise may have fallen into the latter category to enter the market without seeking FDA marketing authorization in order to help quell the mental health crisis¹³. This relaxed regulatory approach is now being reversed, and companies entering the market now must more carefully consider what claims to make around their technology.

Our Strategy

Our strategy is to start with a product offering that would be sold direct-to-consumer either without FDA oversight or as a class I general wellness product. Once we have gained traction through this channel, we will then move towards developing a class II medical device indicated for use in chronic pain due to lumbar disc herniation through a 510(k) submission.

Payments & Reimbursement

Like many digital health companies, we would pursue a multi-pronged payment & reimbursement strategy. The goal is to seek reimbursement through Medicare/Medicaid as well as private insurers for as many users as possible, while still allowing customers to purchase services directly and employers to cover services as an employee benefit. This multi-pronged approach allows us to reach the maximum number of users and go to market as quickly as possible. We will provide an overview of each element of this payment / reimbursement strategy.

Direct to Consumer

We would offer two price & service tiers for customers willing to pay out of pocket. The first tier would include access to all recorded sessions/modules, (including the symptom tracking that powers module recommendations), anonymous group therapy, and monthly check-ins from a care navigator. This tier would be priced in line with

comparable products in the mental health space such as Real and Curable, approximately \$165 per year, or \$24 per month. In the second tier, users would also have the option to connect with a licensed therapist for 1:1 therapy. These live CBT therapy sessions would be charged on a per session basis, in line with the market rate of \$75-150 per session. Both tiers are eligible under FSA/HSA under merchant category code 8099.

Employer-Provided Benefit

Once we have demonstrated sufficient traction and efficacy in our direct to consumer pipeline, we will be able to approach large employers to offer our product as an employer-provided benefit. This is a common model for digital health players and enables a means to scale before insurance reimbursement is figured out. Chronic pain, especially from herniated discs, causes significant losses in employee productivity, so we believe this would be a compelling solution to employers. In such arrangements, employers typically pay on a per user per month basis. As a next step, we would need to explore how to price appropriately in this B2B2C arrangement relative to our direct to consumer model described above.

Insurance Reimbursement

The ultimate goal is insurance reimbursement from private insurers as well as medicare/medicaid. Our direct to consumer and employer-provided benefit models described above would generate the data we would need to convince payers of the value of our product. There is clear precedent for reimbursement of our second tier of service involving 1:1 live therapy. Through December 2024 and as a result of the Public Health Emergency, virtual therapy sessions lasting 60 minutes can be covered under CPT code 90837. According to CMS, in 2023 the Medicare reimbursement rate for this code is \$147.07. We will need to stay on the lookout for how the reimbursement environment for teletherapy evolves past 2024. For our lower tier of service including recorded sessions/modules and anonymous group therapy, we would explore utilization of a relatively new Level II HCPCS code (A9291) designed to cover digital therapeutics classified under prescription digital behavioral therapy. The process for using this code and the path to reimbursement remains unclear, and would require further research. Similarly, CPT Code 989X6 is a relatively new code that offers an estimated reimbursement of \$55.72 per 30 days for remote monitoring of adherence to CBT therapy, which could be utilized by the PTs in our referral network. Further research is required to determine PT eligibility for this reimbursement, but this approach offers a potential reimbursement mechanism to further incentivize PT referrals.

Next Steps

Operating Plan

Below is an operating plan that gives an overview of the milestones needed to drive towards launching the platform. Key value-driving milestones are marked with an asterisk. Importantly, there are 2 phases of the platform. One is an app that includes modules but not the 1:1 therapy aspects, which would require a Class I registration with the FDA. After gathering data from users, a clinical trial and pilot study with employers can help prepare for Class II 510(k) submission. These submissions and initial release, along with the pilot study, are important value-driving milestones. With strong data from each of these, a wider group of payers can be targeted in order for them to cover this.

* = value-driving milestone

Year	2023		2024				2025				2026+		
Quarter:	3	4	1	2	3	4	1	2	3	4	1	2	
<i>1. Proof of concept</i>	█												
customer feedback to source necessary features	█	█											
Creation of modules		█	█										
initial app development		█	█	█									
User Testing and Launch of App*				█	█								
redevelopment based on user feedback					█	█							
Registration with FDA			█										
clinical trial planning				█	█	█							
Clinical trial*							█						
<i>2. Product Development Progress</i>								█					
Finalize modules and UI								█					
<i>3. FDA Submission</i>							█						
Develop necessary							█	█					

management	1	1	1	1	2	2	2	2	2	2	2	2
admin	0	0	0	0	0	1	1	1	1	1	1	1

Above is a staffing plan that would allow us to meet the milestones outlined in the operating plan. Importantly, for functions such as marketing, clinical, and regulatory, we expect to be using consultants and thus do not have full-time staff listed in the table. We would expect 25 hours per quarter, on average, for each of these positions.

Funding Requirements Estimate

Amount	Who it is from	What it will be used for	Justification
\$1.2M	Bootstrapping, Friends and Family	Initial app development and releasing version 1 of the app	Comparable companies, specifically Seven Starling ¹⁴
\$3M	Angels, VCs	Clinical trial preparation and execution, FDA Approval (Class II)	Comparable companies, specifically Safe Space ¹⁴
\$7M	VCs	Employer Pilot, Securing payers and launching platform	Comparable companies, specifically Seven Starling ¹⁴

Funding lines up with the value-creating milestones highlighted in the operating plan. Amounts were based on similar companies funding expenditure.

Highest Priority Near-term Initiatives

- **Solution:** Further explore patient perceptions of pain psychology and the desired features / user experience in the platform. Also establish connections with pain psychologists to build out modules and ensure product alignment with clinically validated approaches that best supports patients through their pain journey.
- **Business model & commercial pathway:** Validate physical therapist interest in this solution and explore potential pilot opportunities with large physical therapy networks, employers, and payers. Refine initial D2C approach, particularly in driving sign-up and sufficient engagement, to ensure proper compliance to drive target outcomes.

- **IP:** Confirm proposed intellectual property strategy (not to pursue patent protection on governing technology) with a patent lawyer who specializes in software and preferably in digital health applications.
- **Market & competitive landscape:** Investigate more deeply the exact customer segments each competitor has gone after. For example, while we know that certain competitors have targeted employers more than payers, try to identify their customers with more granularity i.e. are they targeting employers in a certain geographic region or with certain demographics of employees. Are they targeting payers in certain regions or of certain sizes i.e. with a particular number of covered lives. This deeper dive will help us better understand which specific customer segments may be less served by current solutions. We can then speak to these customers to better understand their unique needs and discuss the possibility of piloting solutions with them.
- **Regulation:** We will seek to register our product as a Class I medical device once we have established the appropriate quality control infrastructure within our company. Until that point there are no pertinent regulatory objectives.
- **Payments & reimbursement:** Investigate whether we could utilize new CPT code 989X6 (remote monitoring of adherence to CBT therapy) for subscription reimbursement for patients brought to the platform through our PT referral network. Also further investigate usage of code A9291 (digital therapeutics) for subscription reimbursement.

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