

Feasibility Study of 2MRx-CP Use by Patients with Chronic Pain

Phase II: Protocol & Statistical Analysis Plan

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Feasibility Study of 2MRx-CP Use by Patients with Chronic Pain: University of Washington Final Report

Study's Overview

Background

Feasibility studies are preliminary studies designed to evaluate the methods and procedures for use in randomized control trials (1-3). These studies aim to identify necessary adjustments that could increase the likelihood of success of larger-scale research (i.e., a well powered efficacy trial) (4). Recently published guidelines emerged to assist researchers on the planning and evaluation of feasibility studies and prevent common misuses (3), which were not available when the original proposal was approved by NIH's NCCIH.

The feasibility randomized control trial (RCT) aimed to test the 2MRx-CP app (i.e., 2Morrow Inc.'s Salty app), a behavioral health app targeted at delivering Acceptance and Commitment Therapy and Cognitive Behavioral Therapy strategies and activities to improve patient function and quality of life. A two-arm feasibility RCT study was conducted with adult patients recruited from primary care settings in rural and urban areas and active self-reported experience of chronic pain. The study aims have been refined and enhanced to align with the latest published guidelines for feasibility trials, while still addressing the original objectives.

Aims

Aim 1. To assess acceptability, appropriateness and feasibility of 2MRx-CP digital therapeutic as an intervention for primary care patients with chronic pain.

App Measure Selection: The preliminary usability and acceptance of the Salty app was measured to ensure alignment with the latest guidelines for feasibility trials while still addressing the core objective of evaluating the intervention for primary care patients with chronic pain. As part of this measurement selection, the mHealth App Usability Questionnaire (MAUQ) was used to measure preliminary usability, replacing the originally proposed Weiner and colleagues (2017, <https://implementationscience.biomedcentral.com/articles/10.1186/s13012-017-0635-3>) usability measure, due to its strong psychometric evidence and better alignment with construct definitions of evaluating a mobile app. Namely, the MAUQ provided a more robust evaluation of app usability, compared to the originally proposed measure. The MAUQ, the SaltyChP (i.e., a custom built measure developed by 2Morrow Inc. to help evaluate usability for product development and support marketability), and descriptives of app usage (i.e., total number of intervention arm patients that successfully engaged use of the app; days the app was used / proportion of days used that were possible; and, total number of badges earned out of the four that were possible) were used to evaluate preliminary usability and acceptance.

Aim 2. To assess feasibility of recruitment, study uptake, and completion of study assessments.

Feasibility Measure Selection: In alignment with standard measures used in feasibility randomized controlled trials, the following feasibility indicators were selected to assess recruitment procedures, retention, outcome measures' adequacy, and feasibility of implementing the intervention (i.e., Salty app):

1. Recruitment procedures: Ability to recruit a diverse sample of participants with various chronic pain diagnoses and exploring the reasons for ineligibility or study decline.
2. Retention: Will participants stay engaged in the study? Survey completion rates by arm and timepoint.
3. Outcomes measures adequacy: a) Are the measures acceptable, appropriate and relevant to the target population? b) Is there evidence of reliability and validity (including responsiveness to change) of measures in the target population?
4. Intervention implementation: a) Was the intervention delivered as intended? b) Were participants engaged with the program components?

Aim 3. To estimate the likely treatment efficacy effect size for a large RCT.

Measures for Preliminary Response to Intervention: Recently published guidelines discourage estimating effect sizes in feasibility studies due to small sample sizes and unrepresentative samples (3). This can lead to inaccurate estimates of parameters and their standard errors, resulting in misleading power calculations (3, 5). Instead, these guidelines recommend focusing on confidence intervals rather than point estimates of effect size (3). Aim 3 has been expanded to include exploring preliminary responses to the intervention and generating initial parameter estimates for sample size calculations. This refinement builds upon Aim 3 by incorporating additional aspects aligned with current best practices for feasibility studies. Initial parameter estimates for a sample size calculation were calculated to detect clinically meaningful differences with adequate power. Outcome measures included a pain interference measure (PROMIS Pain Interference Short Form 6b), depression symptoms (PHQ-9), anxiety symptoms (GAD-7), and a pain intensity rating.

Methods

Study Design

This study used a 2-arm, open, feasibility RCT with parallel design. We assessed participants at four timepoints, at baseline (T0), 1 month (T1), 3 months (T2) and 6 months (T3) post intervention.

Inclusion and Exclusion Criteria

Eligibility criteria included: 1) adult patients (i.e., aged ≥ 18 years) with chronic non-cancer related pain (i.e., pain experience was current and present for ≥ 3 months), 2) documentation of at least one International Classification of Diseases (ICD) code of a common pain related conditions (e.g., low back pain, musculoskeletal pain, fibromyalgia) based on published identified chronic pain conditions (6), 3) had at least two primary care visits within the last 12 months at the time of recruitment, 4) significant levels of self-reported pain interference (i.e., PROMIS Pain Interference Short Form 6b T-score of 55 or above), 5) daily smartphone access, 5) ability to download an app, 6) willingness to engage in a 3-month chronic pain self-management program administered via an app, 7) speak English, and 8) consent to randomization in the study.

Participants were excluded if: 1) their pain was related to cancer, 2) they had plans for surgery within the next 3 months, 3) they were pregnant, or 4) they were receiving hospice services.

Recruitment and Screening

Potential participants were identified using electronic health record (EHR) data extracted from three health systems, which included information from 60 primary care clinics in Washington and Idaho. These data were accessed through the Data QUEST Coordinating Center's EHR data repositories. From the generated potential participant lists, random cohorts were created for recruitment email blasts.

Patients were invited to participate via direct email. Each email contained a link to an interest survey with three options: 1) proceed to the study eligibility survey, 2) request a call back from a study coordinator for further discussion, or 3) opt out of the study. Patients who proceeded to the eligibility survey were informed at the end of the survey of their study eligibility. Those who were eligible were directed to an e-consent form. The e-consent form required patients to either 1) confirm that they wanted to participate in the study, 2) request a call to discuss the study with a study coordinator first, or 3) confirm that they were not interested in participating in the study. Patients who confirmed their interest in participating in the study were asked to sign the e-consent form. A study coordinator would then counter-sign the e-consent form. A study coordinator would follow up with any call requests and if needed assist with the consent over the phone.

Group Allocation

Participants were randomized using a stratified method based on healthcare system and age, aiming to distribute them equally across health systems while matching the national age distribution of individuals living with chronic pain. This stratified allocation was implemented in the REDCap randomization module. The intervention group received access to the 2Morrow Inc. digital behavioral health Salty app (2MRx-CP), while the control group received treatment as usual.

Upon randomization, the REDCap project was programmed to send automatic emails to participants with links to their baseline survey. Participants in both arms needed to complete the baseline survey within two weeks to be considered fully enrolled in the study. Participants in the intervention arm were emailed separate instructions about how to download and access the app and create a user profile. These participants were reminded up to three times (including two automatic email reminders and one phone call from a study coordinator) in the two-week enrollment window. Those that completed the baseline survey, but did not access the app, are included in the study. Participants in the intervention arm that encountered technical difficulties with the app were connected with the tech team at 2Morrow, Inc.

Intervention: The Salty Program, 2Morrow, Inc.

Data collection

Data was collected at baseline (T0), 1-month (T1), 3-month follow (T2), and at 6-month follow up (T3) via REDCap which is a secure, HIPAA-compliant web-based application used for data capture and management. Automatic survey invitation emails were programmed in REDCap to be emailed to participants at each study time point. In these automatic emails, participants were asked to complete surveys via a personalized REDCap survey link. They had two weeks to complete each survey. During the two-week data collection window, follow-up for participants who had not yet completed their surveys could include automatic REDCap email reminders (up to two) and a reminder call and/or email from the study team. Participants could return to their surveys using their personalized survey link at any time during the data collection window. Time spent completing surveys was not recorded. The surveys utilized REDCap enhanced radios and checkboxes for a better user experience across different devices (laptops, tablets, and mobile phones). Participants received a \$50 e-gift card for each survey they completed, up to \$200 total for the entire study. REDCap survey settings allowed participants to skip some questions. In accordance with IRB requirements, participants were not obligated to answer any questions they felt uncomfortable with; as a result, the REDCap survey was configured to allow optional responses. For the purposes of statistical analysis, only complete data sets were included for each outcome measure. Specifically, if a participant omitted any subscale items necessary to calculate a total score, their data were excluded from the summary statistics and analyses for that measure.

The data were extracted from REDCap at the completion of the study for data analyses. No identifiers were maintained, and data were stored using a password protected delimited file and stored in an access-controlled location on a secure HIPAA-compliant server at UW. 2Morrow gave UW usability data logged by their platform. UW linked the 2Morrow usability data to de-identified study identifiers, links to identifiers were then destroyed, and stored similarly to the REDCap derived data.

Outcome measures

(Appendix 1 includes a copy of all outcome measures)

Intervention and Control Group

1. Baseline survey, administered at T0, consisted of demographic questions (education, employment, marital status, income and insurance), social determinants of health questions (living situation, electricity, food, transportation), and the following tools:

- **Patient-Reported Outcomes Measurement Information System (PROMIS) Pain Interference Scale – Short Form 6b** is a six-item self-report questionnaire that assesses the impact of pain on various aspects of a person's life (e.g., social, cognitive, emotional, physical and recreational activities) over the last 7 days (7). Responses are scored using a 5-point ordinal rating scale from 1 to 5 (1=Not at all, 2=A little bit, 3=Somewhat, 4=Quite a bit, 5=Very much). Raw score totals are converted to T-score using the scoring manual (8). T-score of 50 is the mean for the U.S. general population with a standard deviation of 10; the higher the T-score, the worse the pain interference.
 - **Patient Health Questionnaire – 9 (PHQ-9)** is a 10-item self-report questionnaire used to assess depression symptoms consistent with criteria for Major Depressive Disorder over the last two weeks (9). The tool uses a 4-point rating scale (0=not at all, 1=several days, 2=more than half the days, 3=nearly every day) and has demonstrated strong psychometric properties including high levels of specificity and sensitivity of major depressive disorders (9, 10).
 - **Generalized Anxiety Disorder 7-item scale (GAD-7)** is a widely used self-reported questionnaire to measure the severity of generalized anxiety disorder symptoms over the past two weeks (11). Responses are scored from 0 to 3 (0= Not at all, 1= Several days, 2= More than half days, 4= Nearly every day). The tool has shown strong psychometric properties, including high evidence of internal consistency and reliability (12).
 - An additional set of 4 questions explored participants' recent primary care visits, engagement with the Salty app, and receipt of treatment for their pain in the last month.
2. Follow-up survey, administered at T1, T2, and T3, consisted of the following tools: PROMIS pain interference, PHQ-9, and GAD-7, and pain intensity.
 3. **The Health Care Utilization (HCRU)** (Administered at T2 and T3).

Intervention Group

1. **mHealth App Usability Questionnaire (MAUQ)**, administered at T2, is a 21-item survey that assesses mobile health (mHealth) app usability across three domains: ease of use and satisfaction (8 items), system information arrangement (6 items), and usefulness (7 items). It uses a 7-point Likert-type scale (1=strongly disagree to 7=strongly agree) and has established reliability and validity evidence (13).
2. **Salty Program for Chronic Pain Questionnaire (SaltyChP)** is a 6-item survey developed by 2Morrow, Inc., that explores specific aspects of the app (e.g., patients' satisfaction with various specific app features, patient ratings of helpfulness of the app for pain, likelihood to recommend the app to others) using Likert-type response scales. The survey includes two open-ended questions addressing what was helpful and what could be improved in the app. This survey was administered at both T2 and T3.

References

1. National Center for Complementary and Integrative Health. Pilot Studies: Common Uses and Misuses [Available from: <https://www.nccih.nih.gov/grants/pilot-studies-common-uses-and-misuses>].
2. Thabane L, Ma J, Chu R, Cheng J, Ismaila A, Rios LP, et al. A tutorial on pilot studies: the what, why and how. *BMC medical research methodology*. 2010;10:1-10.
3. Teresi JA, Yu X, Stewart AL, Hays RD. Guidelines for Designing and Evaluating Feasibility Pilot Studies. *Med Care*. 2022;60(1):95-103.
4. Leon AC, Davis LL, Kraemer HC. The role and interpretation of pilot studies in clinical research. *Journal of psychiatric research*. 2011;45(5):626-9.
5. Kraemer HC, Mintz J, Noda A, Tinklenberg J, Yesavage JA. Caution regarding the use of pilot studies to guide power calculations for study proposals. *Archives of general psychiatry*. 2006;63(5):484-9.
6. Mayhew M, DeBar LL, Deyo RA, Kerns RD, Goulet JL, Brandt CA, et al. Development and Assessment of a Crosswalk Between ICD-9-CM and ICD-10-CM to Identify Patients with Common Pain Conditions. *J Pain*. 2019;20(12):1429-45.
7. Amtmann D, Cook KF, Jensen MP, Chen W-H, Choi S, Revicki D, et al. Development of a PROMIS item bank to measure pain interference. *Pain*. 2010;150(1):173-82.
8. Health NIO. PAIN INTERFERENCE A brief guide to the PROMIS Pain Interference instruments. 2018.
9. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. *J Gen Intern Med*. 2001;16(9):606-13.
10. Manea L, Gilbody S, McMillan D. A diagnostic meta-analysis of the Patient Health Questionnaire-9 (PHQ-9) algorithm scoring method as a screen for depression. *General hospital psychiatry*. 2015;37(1):67-75.
11. Spitzer RL, Kroenke K, Williams JB, Löwe B. A brief measure for assessing generalized anxiety disorder: the GAD-7. *Archives of internal medicine*. 2006;166(10):1092-7.
12. Löwe B, Decker O, Müller S, Brähler E, Schellberg D, Herzog W, et al. Validation and standardization of the Generalized Anxiety Disorder Screener (GAD-7) in the general population. *Medical care*. 2008;46(3):266-74.
13. Zhou L, Bao J, Setiawan IMA, Saptono A, Parmanto B. The mHealth App Usability Questionnaire (MAUQ): Development and Validation Study. *JMIR Mhealth Uhealth*. 2019;7(4):e11500.
14. Rikard SM. Chronic pain among adults—United States, 2019–2021. *MMWR Morbidity and Mortality Weekly Report*. 2023;72.
15. Stantcheva S. How to run surveys: A guide to creating your own identifying variation and revealing the invisible. *Annual Review of Economics*. 2023;15(1):205-34.

Appendixes

Appendix 1. Outcome measures

Eligibility Survey

What is your age?	<input type="radio"/> Younger than 18 years old <input type="radio"/> 18-29 <input type="radio"/> 30-44 <input type="radio"/> 45-64 <input type="radio"/> 65 or older
What is your assigned sex at birth?	<input type="radio"/> Male <input type="radio"/> Female <input type="radio"/> Intersex
Which gender do you identify most with?	<input type="radio"/> Men <input type="radio"/> Women <input type="radio"/> Non-binary <input type="radio"/> Prefer to self-describe <input type="radio"/> Prefer not to answer
Please describe: -----	
Which of the following best describes you?	<input type="radio"/> American Indian or Alaskan Native <input type="radio"/> Asian American <input type="radio"/> Black or African American <input type="radio"/> Middle Eastern and/or North African decent <input type="radio"/> Native Hawaiian or Other Pacific Islander <input type="radio"/> White <input type="radio"/> Two or more races <input type="radio"/> Other <input type="radio"/> Prefer not to answer
Please specify: -----	
Are you of Hispanic or Latinx origin?	<input type="radio"/> Yes <input type="radio"/> No
How long have you been experiencing pain?	<input type="radio"/> Less than 3 months <input type="radio"/> 3 months to 1 year <input type="radio"/> 1 year-3 years <input type="radio"/> 3 or more years

In the past 7 days, how much did pain interfere with...	Not at all	A little bit	Somewhat	Quite a bit	Very much
your enjoyment of life?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
your ability to concentrate?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
your day-to-day activities?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
your enjoyment of recreational activities?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
doing your tasks away from home (e.g., getting groceries, running errands)?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How often did pain keep you from socializing with others?	<input type="radio"/> Never	<input type="radio"/> Rarely	<input type="radio"/> Sometimes	<input type="radio"/> Often	<input type="radio"/> Always

☐ 41.6

☐ 49.6

☐ 52.0

☐ 53.9

☐ 55.6

☐ 57.1

☐ 58.5

☐ 59.9

☐ 61.2

☐ 62.5

☐ 63.8

☐ 65.2

☐ 66.6

☐ 68.0

☐ 69.7

☐ 71.6

☐ 75.6

What number best describes your pain on average in the past 7 days?

No pain _____ Pain as bad as you can imagine

Do you have plans for inpatient surgery or surgery that requires hospitalization in the next three months?	<input type="radio"/> Yes <input type="radio"/> No
Are you pregnant?	<input type="radio"/> Yes <input type="radio"/> No
Are you currently being treated for cancer?	<input type="radio"/> Yes <input type="radio"/> No
Are you currently receiving hospice care?	<input type="radio"/> Yes <input type="radio"/> No

Do you have daily access to a smartphone and the Internet or a digital plan?	<input type="radio"/> Yes <input type="radio"/> No
It is easy for me to use mobile devices (e.g., mobile phone, tablets) to seek health information or services.	<input type="radio"/> Strongly disagree <input type="radio"/> Disagree <input type="radio"/> Somewhat disagree <input type="radio"/> Neutral <input type="radio"/> Somewhat agree <input type="radio"/> Agree <input type="radio"/> Strongly agree
I have the capability to use mobile devices to seek health information or services.	<input type="radio"/> Strongly disagree <input type="radio"/> Disagree <input type="radio"/> Somewhat disagree <input type="radio"/> Neutral <input type="radio"/> Somewhat agree <input type="radio"/> Agree <input type="radio"/> Strongly agree
I can use mobile devices to seek health information or services without much effort.	<input type="radio"/> Strongly disagree <input type="radio"/> Disagree <input type="radio"/> Somewhat disagree <input type="radio"/> Neutral <input type="radio"/> Somewhat agree <input type="radio"/> Agree <input type="radio"/> Strongly agree
How did you hear about our study?	<input type="radio"/> Phone calls <input type="radio"/> Mobile text messages (SMS) <input type="radio"/> Letter by mail <input type="radio"/> Email <input type="radio"/> Word-of-mouth (e.g., friends, colleagues, family) <input type="radio"/> Primary care providers <input type="radio"/> Other
Please describe	<div></div>

Baseline Survey (T0)

What is the highest level of education you have completed?

- ☐ 8th grade or less
- ☐ Some high school, but did not graduate
- ☐ High school graduate or GED
- ☐ Some college but did not complete degree
- ☐ 2-year college degree
- ☐ 4-year college degree
- ☐ More than 4-year college degree

What is your current employment status?

- ☐ Full-time employed
- ☐ Part-time employed
- ☐ Contract/temporary
- ☐ Voluntarily unemployed
- ☐ Involuntarily unemployed
- ☐ Unable to work due to disability
- ☐ Retired

What is your current marital status?

- ☐ Never Married
- ☐ Living with a partner
- ☐ Married or civil union
- ☐ Separated
- ☐ Divorced
- ☐ Widowed

What is your annual household income in the past 12 months?

- ☐ Less than \$35,000
- ☐ \$35,000 to \$49,999
- ☐ \$50,000 to \$75,000
- ☐ More than \$75,000
- ☐ Don't know

Which type of health insurance do you now have?

- ☐ Private insurance
- ☐ Indian Health Service
- ☐ Medicare
- ☐ Medicaid
- ☐ Other government program (e.g., Marketplace)
- ☐ Others
- ☐ None or self-pay to receive medical care

Please specify:

What is your living situation today?

- ☐ I have a steady place to live
- ☐ I have a place to live today, but I am worried about losing it in the future
- ☐ I do not have a steady place to live

In the past month, how often was the following true: "You worried that your food would run out before you got money to buy more."

- ☐ Often true
☐ Sometimes true
☐ Never true

In the past month, has the electric, gas oil, or water company shut off service or threatened to shut off service in your home?

- ☐ No
☐ Threatened to shut off service
☐ Already shut off service

In the past month, has lack of reliable transportation kept you from medical appointments, meetings, work, or from getting to things needed for daily living? (Check all that apply)

- ☐ No
☐ Yes, it has kept me from non-medical meetings/appointments, work, or getting things that I need
☐ Yes, it has kept me from medical appointments or getting medication

What types of treatment do you currently receive for pain? (Check all that apply)

- ☐ Medications
☐ Outpatient procedures (e.g., epidurals or other injections)
☐ Behavioral health service or therapy
☐ Physical therapy
☐ Massage
☐ Acupuncture
☐ Yoga
☐ Mindfulness
☐ Dietary changes
☐ Exercise
☐ Mobile apps (other than the 2Morrow chronic pain program)
☐ Others
☐ None

Please specify which medications:

Please specify which other treatments:

In the past 7 days, how much did pain interfere with...					
	Not at all	A little bit	Somewhat	Quite a bit	Very much
your enjoyment of life?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
your ability to concentrate?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
your day-to-day activities?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
your enjoyment of recreational activities?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
doing your tasks away from home (e.g., getting groceries, running errands)?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

	Never	Rarely	Sometimes	Often	Always
How often did pain keep you from socializing with others?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Over the last 2 weeks, how often have you been bothered by any of the following problems?

	Not at all	Several days	More than half the days	Nearly every day
Little interest or pleasure in doing things	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Feeling down, depressed, or hopeless	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Trouble falling or staying asleep, or sleeping too much	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Feeling tired or having little energy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Poor appetite or overeating	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Feeling bad about yourself - or that you are a failure or have let yourself or your family down	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Trouble concentrating on things, such as reading the newspaper or watching television	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Moving or speaking so slowly that other people could have noticed? Or the opposite - being so fidgety or restless that you have been moving around a lot more than usual	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Thoughts that you would be better off dead or of hurting yourself in some way	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

PHQ9 Score

.....

PHQ9 Q9 Alert Trigger

.....

	Not difficult at all	Somewhat difficult	Very difficult	Extremely difficult
If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Over the last 2 weeks, how often have you been bothered by any of the following problems?	Not at all	Several days	More than half the days	Nearly every day
Feeling nervous, anxious or on edge	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Not being able to stop or control worrying	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Worrying too much about different things	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Trouble relaxing	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Being so restless that it is hard to sit still	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Becoming easily annoyed or irritable	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Feeling afraid as if something awful might happen	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	Not difficult at all	Somewhat difficult	Very difficult	Extremely difficult
If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

What number best describes your pain on average in the past 7 days? (0 = No pain, 10 = pain as bad as you can imagine)

No pain _____ Pain as bad as you can imagine

1-Month, 3-Month and 6-Month Follow-up Survey

Includes the Salty for Chronic Pain Questionnaire for Intervention Arm

In the past 7 days, how much did pain interfere with...	Not at all	A little bit	Somewhat	Quite a bit	Very much
your enjoyment of life?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
your ability to concentrate?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
your day-to-day activities?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
your enjoyment of recreational activities?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
doing your tasks away from home (e.g., getting groceries, running errands)?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

	Never	Rarely	Sometimes	Often	Always
How often did pain keep you from socializing with others?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Over the last 2 weeks, how often have you been bothered by any of the following problems?

	Not at all	Several days	More than half the days	Nearly every day
Little interest or pleasure in doing things	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Feeling down, depressed, or hopeless	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Trouble falling or staying asleep, or sleeping too much	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Feeling tired or having little energy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Poor appetite or overeating	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Feeling bad about yourself - or that you are a failure or have let yourself or your family down	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Trouble concentrating on things, such as reading the newspaper or watching television	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Moving or speaking so slowly that other people could have noticed? Or the opposite - being so fidgety or restless that you have been moving around a lot more than usual	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Thoughts that you would be better off dead or of hurting yourself in some way	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

	Not difficult at all	Somewhat difficult	Very difficult	Extremely difficult
If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

PHQ9 Q9 Alert Trigger

PHQ9 Q9 Alert Trigger

PHQ9 Q9 Alert Trigger

Over the last 2 weeks, how often have you been bothered by any of the following problems?

	Not at all	Several days	More than half the days	Nearly every day
Feeling nervous, anxious or on edge	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Not being able to stop or control worrying	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Worrying too much about different things	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Trouble relaxing	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Being so restless that it is hard to sit still	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Becoming easily annoyed or irritable	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Feeling afraid as if something awful might happen	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

GAD7 Score Questions 1-7

	Not at all	Somewhat difficult	Very difficult	Extremely difficult
If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

GAD7 Score Total

What number best describes your pain on average in the past 7 days? (0 = No pain, 10 = pain as bad as you can imagine)

No pain _____ Pain as bad as you can imagine

Have you visited primary care for pain during the past month?	<input type="radio"/> Yes <input type="radio"/> No
Have you engaged with the content of the 2Morrow chronic pain app program during the past month?	<input type="radio"/> Yes <input type="radio"/> No

What types of treatment have you received for pain during the past month?

(Check all that apply)

- ☐ Medications
- ☐ Outpatient procedures (e.g., epidurals or other injections)
- ☐ Behavioral health service or therapy
- ☐ Physical therapy
- ☐ Massage
- ☐ Acupuncture
- ☐ Yoga
- ☐ Mindfulness
- ☐ Dietary changes
- ☐ Exercise
- ☐ Mobile apps (other than the 2Morrow chronic pain program)
- ☐ Others
- ☐ None

Please specify which medications

Please describe what other treatments you have received

The next questions relate to the Salty Program for Chronic Pain that you used while participating in this study.

	Not at all	Slightly	Moderately	Very	Extremely
The Salty Program helped me with my pain, for example, to better understand or manage my pain.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Was using the Salty program worth your time?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

What did you like or find most helpful about the Salty program?

What did you like or find most helpful about the Salty program?

What would you like to see improved or added to the Salty program?

How likely are you to recommend the Salty Program to others experiencing chronic pain?

- ☐ 0 - Not at all
- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ 5
- ☐ 6
- ☐ 7
- ☐ 8
- ☐ 9
- ☐ 10 - Extremely likely

Please rate how helpful the following features in the Salty Program were to you.

	Not at all	Slightly	Moderately	Very	Extremely
The lessons and content in the program	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Having the program divided into different topics ranging from physical, emotional, social aspects of pain	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Having content related to how pain may affect you physically	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Having content related to how pain may affect you emotionally	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Having content related to how pain may affect you socially	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How much you got to do each day	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Having to complete an entire section of lessons before moving to other topics or themes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Daily check-ins to track how things are going for you	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Viewing insights from daily tracking	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The option to connect with a coach	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Earning passport stamps	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Opportunity to receive a Fitbit	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Seeing Fitbit data in the app	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Length of the program (100 days)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Self-discovery surveys in the app to learn more about your mood, drinking, etc.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Videos that you watched	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

What other features were helpful to you?

Looking back to your use of the Salty program, what did you learn that may have changes the way you think about or manage your pain?

Health Care Resource Utilization (HCRU) Survey

During the past 3 months, did you receive any care, treatments, or tests for your chronic pain?

- ☐ No
☐ Unsure
☐ Yes
☐ Prefer not to say

This may include seeing or talking with a doctor or health professional, having laboratory tests, x-rays or other imaging, receiving treatment procedures, seeing an acupuncturist, massage or physical therapist, or some other care for your chronic pain.

In the past 3 months, do you think any of the following improved?

Satisfaction with my chronic pain care: _____
The communication with my providers about my pain and treatment: _____
Feeling more involved in my pain care: _____
Amount of pain care received (doctor visits, tests, procedures, etc): _____

Check all that apply

- ☐ More emergency room visits
☐ More urgent care visits
☐ More doctor visits (in person or virtually)
☐ More treatment procedures
☐ More tests
☐ More something else

Check all that apply

- ☐ Fewer emergency room visits
☐ Fewer urgent care visits
☐ Fewer doctor visits (in person or virtually)
☐ Fewer treatment procedures
☐ Fewer tests
☐ Fewer something else

mHealth App Usability Questionnaire

Ease of Use and Satisfaction							
	Strongly Disagree	Disagree	Somewhat Disagree	Neither Agree or Disagree	Somewhat Agree	Agree	Strongly Agree
The app was easy to use.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
It was easy for me to learn to use the app.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I like the interface of the app.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The information in the app was well organized, so I could easily find the information I needed.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I feel comfortable using this app in social settings.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The amount of time involved in using this app has been fitting for me.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I would use this app again.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Overall, I am satisfied with this app.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

System information arrangement							
	Strongly Disagree	Disagree	Somewhat Disagree	Neither Agree or Disagree	Somewhat Agree	Agree	Strongly Agree
Whenever I made a mistake using the app, I could recover easily and quickly.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
This mHealth app provided an acceptable way to receive health care services.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The app adequately acknowledged and provided information to let me know the progress of my action.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The navigation was consistent when moving between screens.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

The interface of the app allowed me to use all the functions (such as entering information, responding to reminders, viewing information) offered by the app.

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

This app has all the functions and capabilities I expect it to have.

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

Usefulness							
	Strongly Disagree	Disagree	Somewhat Disagree	Neither Agree or Disagree	Somewhat Agree	Agree	Strongly Agree
The app would be useful for my health and well-being.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The app improved my access to health care services.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The app helped me manage my health effectively.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The app made it convenient for me to communicate with my health care provider.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Using the app, I had many more opportunities to interact with my health care provider.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I felt confident that any information I sent to my provider using the app would be received.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I felt comfortable communicating with my health care provider using the app.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>