

Lessons learned for preventing REDCap Pain: The Breakthrough Pain Action Plan Study

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This study has been reviewed by and approved by the Island Health Research & Ethics Board.

Outline

- Study Background
- Design and Development Phase
- Study Management
- REDCap Benefits & Lessons Learned

Study Background

What is breakthrough pain?

- Chronic pain patients experience pain “flares” on top of their baseline pain
- These flares can be:
 - Spontaneous - no particular reason
 - Incidental- related to activities or events

What are the concerns regarding drug use to manage pain flares?

- Takes time for the medication to “kick-in” & pain flare is often over by the time medication takes effect
- Most concern around `opioids’ such as morphine, Dilaudid, Percocet, Tylenol #3
- Frequent or regular use can lead to:
 - Side effects
 - Tolerance
 - Dependence



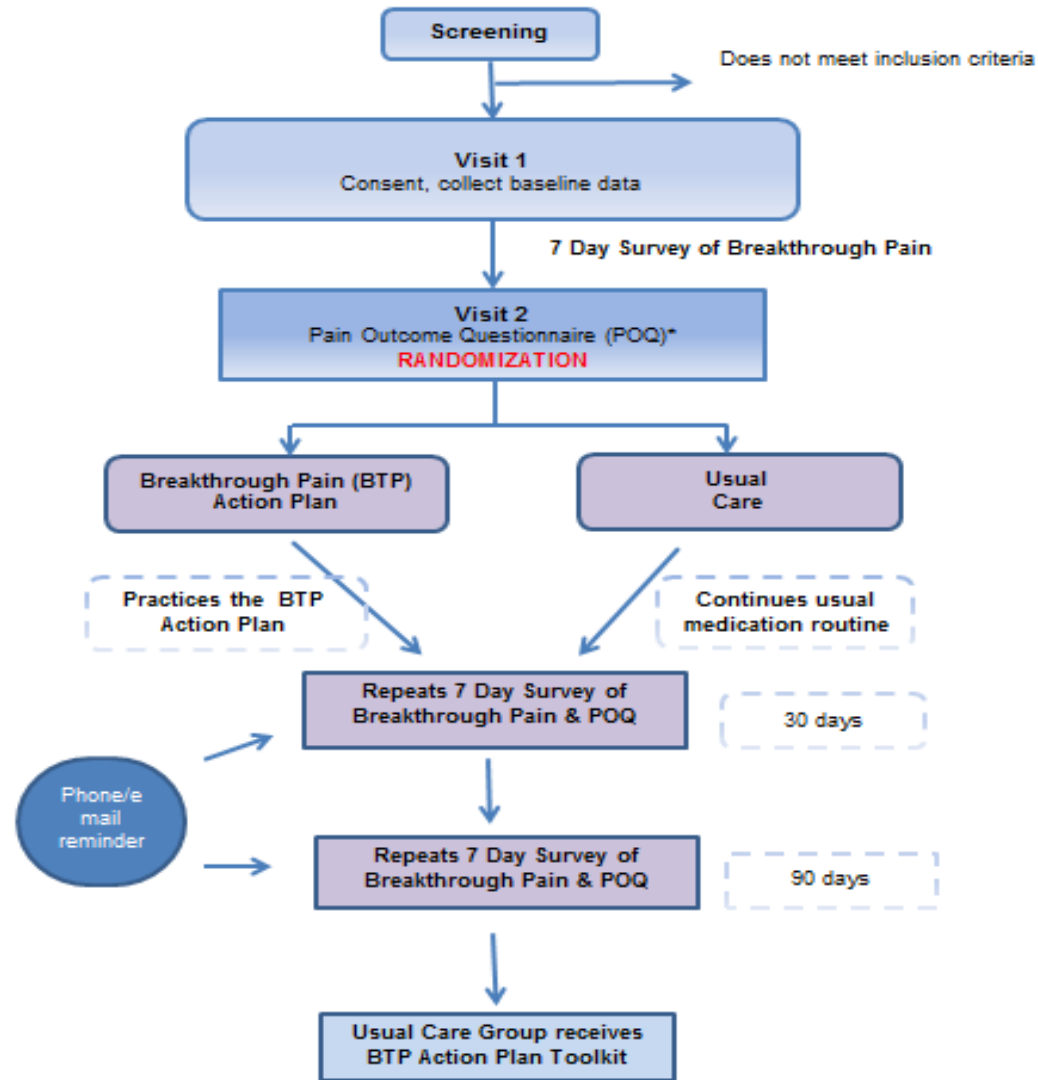
The research question



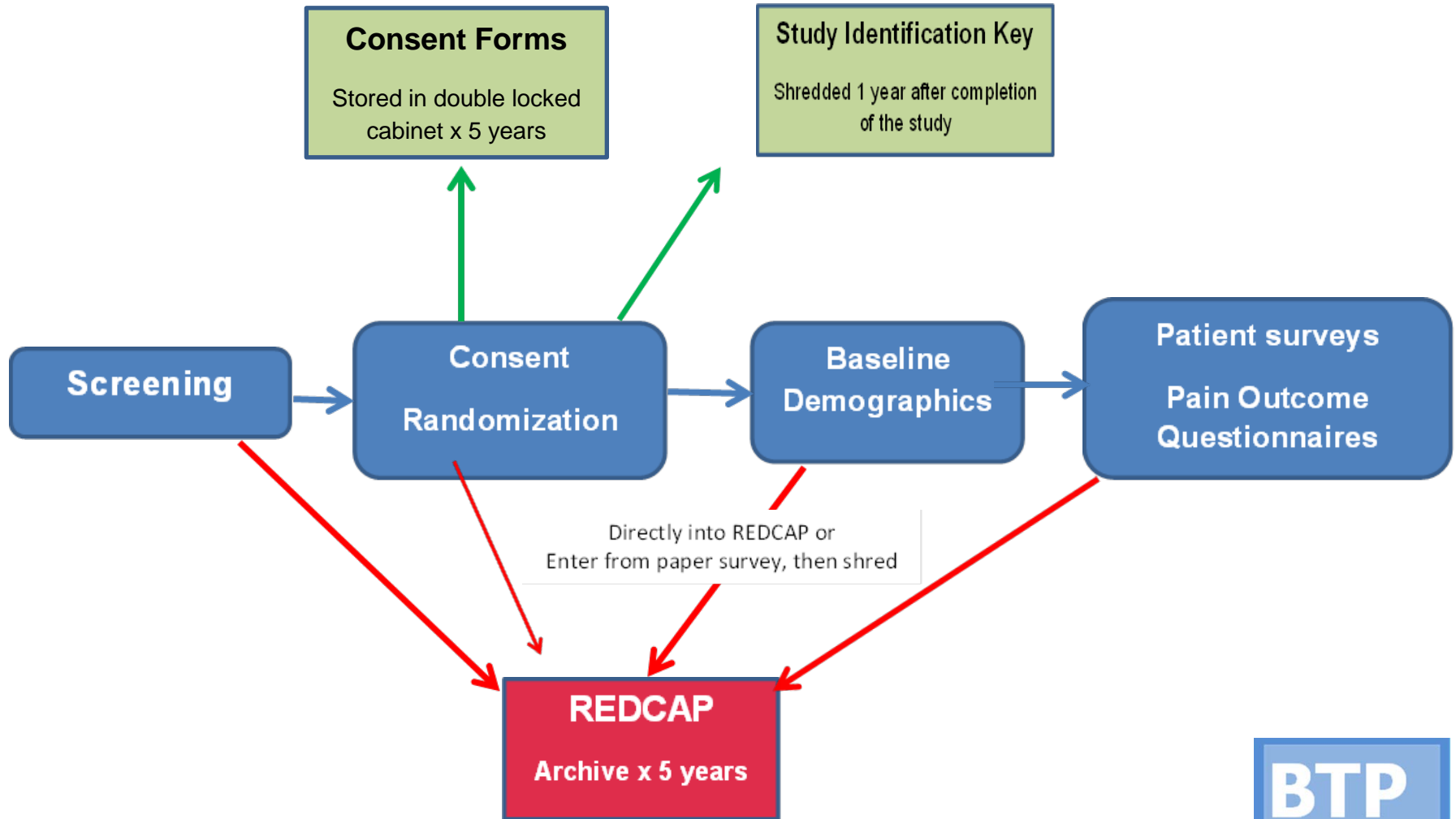
“Will a personalized non-drug
`Breakthrough Pain (BTP) Action Plan’
decrease the number of medication
doses required to manage pain flares
without decreasing overall pain
control?”

Design & Development Phase

Study Design



Data Flow & Storage



Development phase

- 2 hour hands-on REDCap tutorial with Victor
- Started by converting the ethics approved case report forms into REDCap
- Used study flow to set up Study Events in REDCap
- Easy to set up basic stuff – Victor assisted with the more complex forms and logic (eg., morphine equivalents and randomization)
- Entered data for several “test” patients and tested the email survey functionality
 - External emails only work in “Production”
- Continued to adjust even after first patient enrolled

Study Management

Study Management

1. Screening for inclusion
2. Participant management
3. Data collection and entry

1. Screening

- Originally planned to screen directly into REDCap but...
 - For eligible participants wanted background information around medications to assist in coaching participants how to enter their information into REDCap and develop their action plan
 - Record Status Dashboard seemed messy
- Solution: Hybrid system
 1. Screened on paper first – room for participant specific notes
 2. Entered in REDCap in batches – easy to tell who is active/eligible vs not eligible
 3. Mark ineligible participants yellow (incomplete)



Screening

Eligibility Screening

Adding new Participant ID Number 30

Event Name: **Screening**

Participant ID Number 30

Screening date 3.1 Today D-M-Y
* must provide value

Diagnosis chronic non-cancer pain for at least 6 months? Yes No
* must provide value Primary pain diagnosis must exclude headaches. reset

Taking on average at least 2 breakthrough immediate acting opioids per day Yes No
* must provide value reset

The participant demonstrates stable pain control by taking a stable regimen of regularly schedule pain medications that have not changed in the last month. This may include regular opioids, non-opioids and/or pain adjunctives. Yes No
* must provide value reset

Participant able to read and write English Yes No
* must provide value reset

Participant 19 years of age or older? Yes No
* must provide value reset

Participant willing to carry out requirements of study Yes No
* must provide value Up to 2 visits, 3 weeks of recording breakthrough pain and medication use and 3 questionnaires evaluating pain and function. reset

Has participant been hospitalized in the last year with depression, anxiety, psychosis, mania, schizophrenia or substance abuse disorder? Yes No
* must provide value Hospitalized with mental illnesses last year reset

Has the participant begun new medications or therapies in the last 3 months for depression, anxiety, psychosis, mania, schizophrenia or substance abuse disorder. Yes No
* must provide value New therapies for mental illnesses last 3 months reset

Participant is eligible

Form Status

Complete? Incomplete ▼

Lock this record for this form? 🔒 Lock
If locked, no user will be able to edit this record on this form until someone with Lock/Unlock privileges unlocks it.

Record Status Dashboard

Record Status Dashboard (all records)

Displayed below is a table listing all existing records/responses and their status for every data collection instrument (and if longitudinal, for every event). You may click any of the colored buttons in the table to open a new tab/window in your browser to view that record on that particular data collection instrument. Please note that if your form-level user privileges are restricted for certain data collection instruments, you will only be able to view those instruments, and if you belong to a Data Access Group, you will only be able to view records that belong to your group.

Legend for status icons:

- Incomplete Incomplete (no data saved) ?
- Unverified Partial Survey Response
- Complete Completed Survey Response

Displaying record "1" through "28" of 28 records

Displaying: [Instrument status only](#) | [Lock status only](#) | [All status types](#)

Enable floating table headers

Participant ID Number	Eligibility Screening	Baseline Data Consent/Demographics Baseline	Consent Form Consent/Demographics Baseline	Survey Of Breakthrough Pain Baseline Survey Baseline Day 1	Survey Of Breakthrough Pain Baseline Survey Baseline Day 2	Survey Of Breakthrough Pain Baseline Survey Baseline Day 3	Survey Of Breakthrough Pain Baseline Survey Baseline Day 4	Survey Of Breakthrough Pain Baseline Survey Baseline Day 5	Survey Of Breakthrough Pain Baseline Survey Baseline Day 6	Survey Of Breakthrough Pain Baseline Survey Baseline Day 7	Randomization 1 Week FU Assignment	Pain Outcome Questionnaire 1 Week FU Assignment	Withdrawal Form Withdrawal From Study	Survey Of Breakthrough Pain Survey Post Intervention Day 1	Pain Outcome Questionnaire Survey Post Intervention Day 1
1	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input checked="" type="radio"/>
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7	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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9	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
13	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
14	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
15	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>




2. Participant Management

Patient is eligible... now what?

A hybrid participant management system:

- “Add record” in **REDCap** (assigns Participant ID)
- Create a record of the participant (**Excel**)
 - Log dates for Visits 1 and 2
 - Pushes out dates for 30 and 90 day surveys and email and phone reminders
- Appointments for Visits 1, 2 and follow-up reminders (**Outlook**)
- Consent (paper and **REDCap**) and withdraw (**REDCap**)
- Randomize to intervention vs control (**REDCap**)
- View participants “at a glance” (**REDCap**)

Add Record to Create Participant ID



Logged in as **CMalmberg** | [Log out](#)

- My Projects
- Project Home
- Project Setup

Project status: **Production**

Data Collection

- Manage Survey Participants
- Record Status Dashboard
- Add / Edit Records

Applications

- Calendar
- Data Exports, Reports, and Stats
- Data Import Tool
- Logging
- Field Comment Log
- File Repository
- User Rights
- E-signature and Locking Mgmt
- Data Quality

Reports [Edit reports](#)

- 1) Eligible Patients

Help & Information

- Help & FAQ

BTP Action Plan Study

Add / Edit Records

You may view an existing record/response by selecting it from the drop-down lists below. To create a new record/response, click the button below.

Total records: 34	
Choose an existing Participant ID Number	<input type="text" value="-- select record --"/>
<input type="button" value="Add new record"/>	

Data Search	
Choose a field to search <small>(excludes multiple choice fields)</small>	<input type="text" value="-- select search field --"/>
Search query <small>Begin typing to search the project data, then click an item in the list to navigate to that record.</small>	<input type="text"/>



Consent Participant

Consent Form

 Editing existing Participant ID Number 38

Event Name: **Consent/Demographics Baseline**

Participant ID Number 38


Consent Date

* must provide value

  Today D-M-Y

Consent to participate

* must provide value



 Yes
 No

reset

Ensure consenting participants sign and date the form. Provide copy to participant.

Form Status

Complete?

Lock this record for this form?

If locked, no user will be able to edit this record on this form until someone with Lock/Unlock privileges unlocks it.

 Lock

Save Record

Save and Continue

-- Cancel --

Delete Record (All forms/events)

Additional delete options:

Delete data for THIS EVENT only

Randomize Participant

Randomization


 Editing existing Participant ID Number 2

Event Name: **1 Week FU Assignment**

Participant ID Number


Treatment Group assigned Randomly

* must provide value

 Already randomized
 Control
 Intervention

Form Status

Complete?

 Complete

Lock this record for this form?

If locked, no user will be able to edit this record on this form until someone with Lock/Unlock privileges unlocks it.

 Lock

Save Record

Save and Continue

Save and go to Next Form

-- Cancel --

Delete Record (All forms/events)


Withdraw Participants

Event Name: **Withdrawal From Study**


Participant ID Number

38

Withdrawal date

 D-M-Y


Method of request to withdraw



If request is by email, print and upload a copy.

Reason for Withdrawal

* must provide value



Permission to use existing information

* must provide value

Yes
 No

Withdrawal documentation




 [Upload document](#)

Form Status

Record Status Dashboard

BTP Action Plan Study

Record Status Dashboard (all records)

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Enable floating table headers

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1	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="radio"/>	<input checked="" type="checkbox"/>	
2	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="radio"/>	<input checked="" type="checkbox"/>	
3	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
4	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
5	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
6	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
7	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



3. Data Collection and Entry

Visit 1

- Enter Baseline Demographics into REDCap , then:
- For 7 Day Breakthrough Pain Survey customize – participant decides based on computer literacy:
 1. REDCap directly OR 2. Paper → REDCap

Visit 2

- Evaluate whether to continue electronically
- Completes POQ with patient in REDCap

Breakthrough Pain Surveys and POQ at Day 30 and 90

- Participant enters data into REDCap from email link OR
- Mailed in paper surveys are entered by study personnel.


Baseline Demographics

Baseline Data

➕ Adding new Participant ID Number 38

Event Name: **Consent/Demographics Baseline**

Participant ID Number 38

Date  D-M-Y
* must provide value date of data gathering

Age
* must provide value in full years

Phone number
* must provide value

Email of participant

Paper or Electronic surveys/questionnaires? ▼
* must provide value

Gender Male Female
* must provide value reset

Primary Pain diagnosis ▼
* must provide value

Has the participant received care at the Island Pain program or other specialty or comprehensive pain management program? Yes No
* must provide value Care in Specialized Pain Program reset

Has the participant been part of a specialty or comprehensive pain management program and attended Yes No

Participant Email Link to Survey

From: BTPActionPlanStudy@viha.ca [mailto:BTPActionPlanStudy@viha.ca]

Sent: July-24-15 7:01 AM

To:

Subject: Baseline Survey of Breakthrough Pain - Day 3 of 7

Dear Study Participant,

On behalf of the Breakthrough Pain Action Plan Study, thank you for taking the time to complete all the questionnaires and surveys. Your participation will help us gather more complete and accurate results for the study.

You may open the survey in your web browser by clicking the link below:

[Survey Of Breakthrough Pain Baseline](#)

If the link above does not work, try copying the link below into your web browser:

<https://redcap.viha.ca/redcap/surveys/?s=yIqDi5kB7M>

This link is unique to you and should not be forwarded to others.



Breakthrough Pain Episode Survey



Event Name: Survey Baseline Day 1	
Participant ID Number	38
Episode 1	
Date/time of breakthrough pain episode <i>* must provide value</i>	<input type="text" value="01-01-2016 15:49"/> <input type="button" value="Now"/> D-M-Y H:M
What were you doing when the pain flared? <i>* must provide value</i>	<input type="text" value="example"/> Expand
Did you use a non-drug intervention to manage the pain flare? <i>* must provide value</i>	<input checked="" type="radio"/> Yes <input type="radio"/> No reset
What non-drug intervention did you use to deal with the pain flare? <i>* must provide value</i>	<input type="text" value="heating pad"/>
Did you use breakthrough medication to manage the pain flare? <i>* must provide value</i>	<input checked="" type="radio"/> Yes <input type="radio"/> No reset
What type of breakthrough medication did you use?	<input type="checkbox"/> Plain acetaminophen (eg Plain Tylenol) <input checked="" type="checkbox"/> Anti-inflammatory (eg ibuprofen, naproxen) <input type="checkbox"/> Other medication (eg gabapentin) <input checked="" type="checkbox"/> Opioid or narcotic
What opioid or narcotic breakthrough medication did you use to manage the pain flare? <i>* must provide value</i>	<input type="text" value="hydromorphone"/>
How many doses of breakthrough medications did you use to manage the pain flare? Note: Number must have 1 decimal place - for example 1 tablet must be entered as 1.0 tablet <i>* must provide value</i>	<input type="text" value="1.0"/>
How many milligrams (mg) in each dose of breakthrough medication? Note: Number must have one decimal point-for example 2 mg must be entered as 2.0 mg <i>* must provide value</i>	<input type="text" value="1.0"/>



Pain Outcome Questionnaire

Pain Outcome Questionnaire

Invitation status: 



 Survey options 

 Editing existing Participant ID Number 38


Event Name: **1 Week FU Assignment**

Participant ID Number 38

Date Pain Outcome Questionnaire

  31 Today D-M-Y

What regularly scheduled opioid are you presently taking?


 

* must provide value


1. On a scale of 0 to 10, how would you rate your pain on average during the past week?

	0-No Pain	1	2	3	4	5	6	7	8	9	10-Worst Possible Pain
 * must provide value	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> reset

2. Does your pain interfere with your ability to walk?

	0- Not at all	1	2	3	4	5	6	7	8	9	10-All the time
 * must provide value	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> reset

3. Does your pain interfere with your ability to carry/handle everyday objects such as a bag of groceries or books?

	0-Not at all	1	2	3	4	5	6	7	8	9	10-All the time
 * must provide value	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> reset

4. Does your pain interfere with your ability to climb stairs?

10-All





of Breakthrough Pain

Participants can enter their own data in REDCap:

– Advantages :

- Daily surveys sent directly to participants with link
- Can set-up reminders if survey not done
- Participants enter directly into system
- Nice system of drop-downs; expansion of information

– Disadvantages:

- Participants have to be computer-savvy
- Participants must have a reliable computer system
- (Very) occasionally server is down

REDCap Benefits & Lessons Learned

Benefits of using REDCap

- Web-enabled database-capacity
- Support - IHA supported
- Victor likes it!
- Electronic data-gathering- eliminate steps, especially if participants can enter their own data
- Assists with participant management
- Ease of statistical analysis
- Data storage – in the REDCAP cloud



Lessons Learned for Preventing REDCap Pain!

1. Test, test, test, and when you think you are done testing → test some more
2. Coach participants how to enter information into REDCap
3. Anticipate challenges and be flexible
4. Customize and adapt the use of REDCap to make it suitable to the unique needs of your study.

Help Us Recruit!

- We are looking for eligible participants!
- Do you know someone with **chronic pain** who is:
 1. Taking a **short-acting opioid** or narcotic medication AND
 2. Using **2 or more** doses per day
- Please share our study information brochures with your patients and colleagues!



Thank you!

Please contact us if you have any questions...

Donna, Christine, Kelsey

 www.facebook.com/BTPactionplanstudy

Email: BTPActionPlanStudy@viha.ca.

Call: 1-250-519-5300-ext 16882

