Childhood Cancer Survivor Study
Concept Proposal and Analytic Plan

1. **Study Title:** Acceptability and Feasibility of mHealth-based Symptom Monitoring among Adult Survivors of Childhood Cancer with Chronic Pain

2. **Working Group:** Psychology

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4. **Background and Rationale:**

Chronic pain is defined as recurrent or persistent pain lasting three months of more.[1] The presence of chronic pain can be particularly challenging for childhood cancer survivors. Recent work from our team shows that 41% of adult survivors of childhood cancer experience chronic pain, with 32.3% of these survivors experiencing pain for over 10 years.[2] Moreover, 71% of survivors with chronic pain experienced moderate or greater pain interference – highlighting the daily impact of pain on survivors' lives.[2] Despite these clear indications that chronic pain is prevalent and burdensome among survivors many years after treatment, both chronic pain and survivors' daily pain and symptom experiences remain understudied and poorly understood.[2]

Experiences of pain are often captured using retrospective pain assessments which introduces potential recall bias into the results. To limit potential recall biases and improve the reliability and validity of pain reporting, ecological momentary assessment (EMA) can be used to examine patients' daily pain and symptom experiences.[3] More specifically, EMA involves the repeated assessment of pain and associated symptoms at least 1x/day over several days or weeks.[3] The use of EMA via mHealth technology is particularly favourable given the widespread use and availability of smartphones, and its ability to capture symptoms in real-time. However, previous EMA research within both cancer and chronic pain populations has shown evidence of low completion rates which may lead to less comprehensive data obtained, and in turn reduce the validity of findings and the strength of the conclusions that can be made.[2,4,5] Recent work from our team which used EMA over 14-days showed that elevated levels of average pain (≥5) and pain interference (≥5) were reported on 28.2% and 24.6% of completed daily assessments by childhood cancer survivors with chronic pain, respectively.[2] Moreover, for male but not female survivors, low sleep quality, elevated anxiety, and elevated depression predicted high pain intensity and pain interference the next day.[2] Although these findings provided initial insight into

the daily pain experiences of adult survivors of childhood cancer with chronic pain, the strength of the conclusions was limited by low EMA completion rates. Specifically, completion rates dropped from 53.9% in week 1 to 37.1% in week 2.[2] Therefore, an examination of the acceptability and feasibility of using EMA via smartphones and mHealth technology is essential to understanding factors which may be associated with completion rates among childhood cancer survivors with chronic pain. Such an investigation can also provide insight into not only the use of EMA among childhood cancer survivors but other cancer and chronic pain populations.

Despite this importance, little research has examined the feasibility and acceptability of EMA via mHealth technology among cancer populations, and no studies have examined the feasibility and acceptability of EMA among childhood cancer survivors with chronic pain.[6–8] Furthermore, many existing studies examining the acceptability of EMA have often failed to examine potential predictors of acceptability, including neurocognitive impairment or cognitive-affective factors such as current levels of depression and anxiety.[6] Previous research among individuals with neurocognitive impairment across a variety of neurological conditions suggests EMA as acceptable however, at a lower rate than those without cognitive impairment.[9] Given childhood cancer survivors are at risk for neurocognitive problems,[10,11] acceptability of the EMA platform may be impacted among those with increased cognitive impairment however, no studies to date have examined this. In terms of psychological difficulties experienced within our sample, 44% of survivors with chronic pain reported clinically significant depressive symptoms, 34% reported clinical levels of anxiety and 26% reported fear of recurrence. Moreover, higher levels of pain interference are associated with clinical levels of both depressive and anxiety symptoms or either depressive *or* anxiety symptoms, and fear of cancer recurrence.[2] These findings suggest that not only are elevated levels of pain interference common in adult survivors of childhood cancer but associated psychological difficulties are also present. Elevated levels of distress may impact EMA acceptability and feasibility via several potential avenues. For example, survivors with elevated depressive symptoms may perceive EMA studies as overwhelming and potentially intrusive as it might increase their psychological burden, fatigue, and awareness of mental state, which in turn could impact their engagement.[12] Participants with increased anxiety and fear of cancer recurrence might find EMA studies burdensome as they can evoke an increased awareness of their past cancer diagnosis and therefore subsequent anxiety. For example, approximately 10% of adolescent and young adult cancer survivors reported high levels of distress associated with completing daily surveys within an EMA study of fear of cancer recurrence.[8]

Sociodemographic factors such as older age have also been associated with higher EMA acceptability among those with chronic pain and within broader populations.[13,14] This has been hypothesized to result from fewer competing demands in the daily lives of older adults in contrast to younger patients who may need to balance responsibilities such as career obligations.[14] However, no studies have examined sociodemographic factors such as age in relation to the feasibility and acceptability of EMA among adult survivors of childhood cancer with chronic pain. Regarding pain experiences, previous research within non-cancer pain populations has shown strong acceptability of EMA across varying levels of pain intensity and pain-related disability.[15–17] However, no studies have examined varying levels of pain intensity and disability with regards to EMA acceptability among adult survivors of childhood cancer with chronic pain.

EMA has the potential to greatly advance our understanding of chronic pain in the context of childhood cancer survivorship. Prior to future EMA studies and the development or use of interventions that occur in real time (e.g., just in time adaptive interventions), it is essential that we first examine the acceptability and feasibility of this method to better understand EMA completion rates among survivors with chronic pain.

Exploring Aspects of Survivors Pain Ancillary Study

The Exploring Aspects of Survivors Pain (EASE) is an ancillary study to CCSS. The primary aims of EASE were to examine the prevalence and risk factors of chronic pain and pain interference among adult long-term survivors of childhood cancer. A random sample of survivors enrolled in CCSS (n=700) were recruited and invited to download Eureka – an mHealth app where all study activities were completed. After study eligibility was assessed and informed consent obtained, all participants completed baseline measures. A total of 38% of recruited survivors downloaded the mHealth app and 35% provided informed consent. The final study sample included 233 survivors. Of those, 96 survivors reported chronic pain via EMA, with acceptability data available from 73.

We are interested in examining the acceptability and feasibility of the EMA platform used in the EASE study. With the exception of demographic and treatment-related data, the proposed aims and associated analyses use data already collected as part of the EASE study. The adapted Acceptability E-scale, recruitment rate, retention rate, and associated measures that will be used to determine acceptability and feasibility in this sample are summarized below. Claire Galvin, MSc (PhD student in Clinical Psychology in the Behavioural Health Innovations (BHI) lab at Concordia University) will be leading this project under my supervision.

Thus far, three manuscripts have been published using data from EASE. The first was the primary study which examined the prevalence and risk factors for chronic pain and pain interference among survivors. This paper also included the EMA portion of the study described above and which examined the daily pain and symptoms experiences of survivors with chronic pain over the course of 2 weeks (see Alberts et al., 2024; PAIN). [2] The second study examined fear of cancer recurrence (see Pizzo et al., 2024; JAMA Open Network).[5] A third manuscript examining intolerance of uncertainty and its associations with pain and psychological symptoms and was recently published (see Alberts et al., 2025; Journal of Cancer Survivorship).[19]

5. Specific Aims:

1. Describe the acceptability and feasibility (i.e., recruitment rate, retention rate) of the mHealth-based EMA platform (EASE) to assess daily pain and associated symptoms among childhood cancer survivors with chronic pain.
    a. Hypothesis: Childhood cancer survivors with chronic pain will report a high level of acceptability with the EMA platform and the feasibility of its use will be high.

2. Examine whether the acceptability of the mHealth-based EMA platform (EASE) is associated with completion rates of the daily diary
    a. Hypothesis: Higher scores on the Acceptability E-scale will be associated with higher EMA completion rates.

3. Examine whether the acceptability of the mHealth-based EMA platform (EASE) is associated with socio-demographic factors (i.e., current age in survivors)

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    a. Hypothesis: Older age of participants will be associated with higher levels of acceptability with the EMA platform.

4. Examine whether the acceptability of the mHealth-based EMA platform (EASE) is associated with baseline cognitive impairment and cognitive-affective factors in

survivors, including elevated levels of anxiety, depression, and fear of cancer recurrence.
    a. Hypothesis: Lower levels of cognitive impairment, anxiety, depression and FCR at baseline will be associated with higher acceptability.

5. Examine whether the acceptability of the mHealth-based EMA platform is associated with baseline pain factors in survivors, including duration of chronic pain, pain intensity, and pain interference.
    a. Hypothesis: Shorter duration of chronic pain, lower pain intensity, and lower pain related disability will be associated with higher acceptability.

6. Analysis Framework:

Study population: Adult survivors of childhood cancer who took part in the EASE ancillary study. The final EASE sample included 233 survivors. Of those, 96 reported chronic pain, with 80 survivors participating in the EMA. Of those, 73 had EMA acceptability data available. Therefore, the final sample for this study is 73 participants.

Inclusion criteria

- Participant in the EASE study
- CCSS survivors ≥ 18 years of age
- Speak and read English
- Own a smartphone
- Access to data/Wi-Fi/Internet

EMA-study specific inclusion criteria:

- Meets above criteria
- Participant in the EASE study with chronic pain and acceptability data available

Outcomes of interest

- **Acceptability** was assessed using a modified version of the Acceptability E-Scale (see Appendix A). This modified version of the Acceptability E-Scale includes 14 items assessing acceptability of the Eureka app and the daily/weekly diaries (referred to as "trackers" in the survey), including two free-response questions designed to obtain qualitative feedback from those who were dissatisfied. Qualitative data is excluded from this study. Each quantitative item was rated on a 5-point Likert scale ranging from 1 to 5. An overall acceptability score was obtained by adding together the scores from all 12 Likert scale items, with higher scores reflecting higher levels of overall acceptability. In addition to the total score, each item was also examined individually. The Acceptability E-Scale has previously demonstrated strong psychometric properties and has been used to examine acceptability and usability of mHealth applications.[20]
- **Feasibility** will be assessed using recruitment rate (number of individuals consented to study/number of individuals approached for consent), and retention rate (number of individuals completing study/number of individuals consented; daily diaries completed/daily diaries sent)
- **Cognitive impairment** was assessed by the Childhood Cancer Survivor Study Neurocognitive Questionnaire (CCSS-NCQ). The CCSS-NCQ is a scale developed to

screen for impairment in long-term survivors of cancer [28,29]. The CCSS-NCQ demonstrates excellent reliability, as well as construct and discriminative validity.[21]

- **Fear of cancer recurrence** was assessed by the Fear of Cancer Recurrence Inventory-Short Form (FCRI-SF). The FCRI-SF has strong psychometric properties and contains 9-items that assess the severity of fear of cancer recurrence. Each item is rated on a scale ranging from 0 (not at all) to 4 (a great deal). A summed score is created ranging from 0 to 36, with higher scores indicating greater fear of cancer recurrence. Several cut-off scores for clinically significant fear of cancer recurrence have been proposed, including ≥13, ≥16, and ≥22. The FCRI-SF has been shown to be a reliable and effective scale for screening FCR in clinical settings.[22]
- **Depression** was assessed with the Patient Health Questionnaire-8 (PHQ-8). The PHQ-8 is composed of eight items rated on a 4-point Likert scale ranging from 0 (not at all) to 3 (nearly every day). The PHQ-8 assesses symptoms of depression within the last two weeks. Examples of items on the PHQ-8 include “Little interest or pleasure in doing things” and “Feeling, depressed, irritable or hopeless”. The PHQ-8 is a reliable and valid measure of depression with excellent psychometric properties. Higher scores on the PHQ-8 indicate more symptoms of depression and a total score of ≥10 represents the cut-point for moderate or clinically significant depression. The PHQ-8 is a reliable and valid measure with strong psychometric properties.[23]
- **Anxiety** was assessed with the Generalized Anxiety Disorder-7 (GAD-7). The GAD-7 is composed of seven items rated on a 4-point Likert scale ranging from 0 (not at all) to 3 (nearly every day). The GAD-7 assesses symptoms of anxiety within the last two weeks. Examples of items on the GAD-7 include “Feeling nervous, anxious, or on edge” and “Not able to stop or control worrying”. The GAD-7 has strong test-retest reliability, good internal consistency, and good convergent validity with alternative measures of anxiety. Higher scores on the GAD-7 represent more symptoms of anxiety and a total score of ≥10 represents the cut-point for moderate or clinically significant anxiety. The GAD-7 has demonstrated strong psychometric properties.[24]
- **Brief Pain Inventory Scale:** Pain interference and intensity was assessed using the Brief Pain Inventory (BPI). Two items were used to calculate pain intensity. These asked individuals to rate the intensity of their average pain and their worst pain within the past week using an 11-point Likert scale ranging from 0 (no pain) to10 (pain as bad as you can imagine). Pain interference includes seven items that assess the interference of pain in daily functioning. Each item (i.e., general activity, mood, walking ability, normal work, relations with others, sleep, enjoyment of life) are rated from a 0 (*does not interfere*) to 10 (*completely interfere*s). Participants indicate how much their pain has interfered with each activity during the past 24 hours. Scores are calculated as the mean of the seven interference items. Higher scores indicate greater interference. Pain interference was retained as a continuous variable for analyses. The BPI shows good internal consistency and convergent.[25]
- **Chronic Pain:** Chronic pain was assessed using two items derived from the definition of chronic pain developed by the International Association for the Study of Pain[1] and recommended for use in epidemiological studies of chronic pain.[26] The two items are 1) “Do you have any persistent or recurrent pain, more than aches and pains that are fleeting and minor?” and 2) “How long have you been experiencing pain?”.
- **Pain Catastrophizing**: Pain catastrophizing was assessed through the Pain Catastrophizing scale (PCS) .[27] Pain catastrophizing is rated using a 13-item scale with total scores ranging from 0 (*no catastrophizing*) to 52 (*severe catastrophizing*). It has reliable and valid psychometric properties.[27,28]

- **Demographic (from FU5 or most recent survey):** age at evaluation, sex, race/ethnicity, household income, education, employment, marital status, assistance with routine needs.
- **Treatment-related (from MRAF frozen data):** age at diagnosis, primary diagnosis, radiation (cranial and non-cranial), chemotherapy, major treatment-related surgery, amputation, relapse/subsequent neoplasm.

7. Statistical Analyses

Aim 1: Describe the acceptability and feasibility of the mHealth-based EMA platform to assess daily pain and associated symptoms among childhood cancer survivors with chronic pain.

- For aim 1, we will describe the mean, SD, and range obtained on the Acceptability E-scale (total score – total score calculated by summing all items, with higher scores indicating greater acceptability; percentage score - total score calculated by summing all items dividing by total possible score). Skewness and kurtosis will be examined for all individual items on the Acceptability E-Scale as well as means for each individual item. We will also calculate recruitment (number of individuals consented to study/number of individuals approached for consent) and retention rate (number of individuals completing study/number of individuals consented; daily diaries completed/daily diaries sent)

Aim 2: Examine the acceptability of the mHealth-based EMA platform (EASE) is associated with completion rates of the daily diary.

- To determine if acceptability is associated with completion rates, we will use a Pearson correlation to examine the association between the Acceptability E-scale total score and EMA completion rate.

Aim 3: Examine whether the acceptability of the mHealth-based EMA platform is associated with socio-demographic factors (i.e., current age) in survivors.

- To determine if acceptability is associated with age as a socio-demographic variable, we will calculate a linear regression model to assess the relationship between our Acceptability E-scale total score as dependent variable and age as the independent variable.

Aim 4: Examine whether the acceptability and feasibility of the mHealth-based EMA platform is associated with baseline cognitive impairment and cognitive-affective factors in survivors, including elevated levels of anxiety, depression, and fear of cancer recurrence.

- To determine if acceptability is associated with baseline cognitive affective factors, we will calculate a series of multivariable linear regression model to assess the relationship between our Acceptability E-scale total score as dependent variable and cognitive impairment (as measured by the NCI),
- anxiety (as measured by the GAD-7), depression (as measured by the PHQ-9) and fear of recurrence (as measured by the FRC-SF) as the independent variables. Model 1 will include anxiety, depression, and fear of cancer recurrence. Model 2 will examine cognitive impairment. Model 3 will combine all predictors.

Aim 5: Examine whether the acceptability and feasibility of the mHealth-based EMA platform is associated with baseline pain factors in survivors, including duration of chronic pain, pain intensity, pain interference, and pain catastrophizing.

- To determine if acceptability is associated with baseline pain factors, we will calculate a multivariable regression model to assess the relationship between our Acceptability E-scale total score as dependent variable and duration of pain (as measuring by Chronic Pain duration item), pain intensity and pain interference (as measured by the BPI), and pain catastrophizing (as measured by the PCS) as the independent variables.

Table 1. *Demographic and clinical characteristics of the study population*

Participant characteristic		
	M	*SD*
Age at study, years		
Age at diagnosis, years		
Time since diagnosis, years		
	n	%
Sex		
Male		
Female		
Race/Ethnicity		
White, non-Hispanic		
Black		
Other/Unknown		
Education		
Completed high school		
Post-high school training		
≥ College graduate		
Employment		
Full-time		
Part-time		
Not employed		
Marital status		
Married, living as married		
Single, widowed, divorced, separated		
Diagnosis		
Leukemia		
CNS tumor		
Lymphomas (Hodgkin, Non-Hodgkin)		
Wilms, neuroblastoma, soft-tissue sarcoma		
Bone cancer		
Radiation		
Cranial radiation		
≥20Gy		
<20Gy		
None		
Non-cranial radiation		
None		
Chemotherapy		
Antimetabolites		
Corticosteroids		
Anthracyclines		

Alkylating agents	
Other/none	
Surgery	
Amputation	
Limb sparing	
Other major therapeutic surgery	
None	
Prior Relapse/SMN	
Yes	
No	

Note. *CNS* = central nervous system; *SMN* = second malignant neoplasm

Table 2: *Descriptive Statistics Acceptability*

Acceptability E-Scale Daily/Weekly Tracker	*M*	*SD*	Range
How easy was the Daily/Weekly Tracker for you to use? (Usability)			
How understandable were the questions in the Daily/Weekly Trackers? (Usability)			
How much did you enjoy using the Daily/Weekly tracker? (Satisfaction)			
How helpful was the Daily/Weekly Trackers in tracking your pain? (Helpfulness)			
How helpful was the Daily/Weekly Trackers in tracking your mood? (Helpfulness)			
How helpful was the Daily/Weekly Trackers in tracking your sleep? (Helpfulness)			
Was the amount of time it took to complete the Daily/Weekly Trackers acceptable? (Usability)			
How would you rate your overall satisfaction with the Daily/Weekly Trackers? (Satisfaction)			
Acceptability E-Scale Eureka app	***M***	***SD***	**Range**
How easy was the Eureka app to use? (Usability)			
How much did you enjoy using the Eureka app? (Satisfaction)			
How would you rate your overall satisfaction with the Eurka app? (Satisfaction)			
Acceptability—Total Score			

Table 3. Linear Regression for age predicting acceptability

	B	95% CI for *B*		*SE B*	β	*R*	R^2	*p*
		LL	*UL*					
Predictor								
Age								

Note. *CI* = confidence interval; *LL* = lower limit; *UL* = upper limit.

***Table 4*. Multivariable regression for baseline cognitive-affective factors predicting acceptability**

	B	95% CI for *B*		*SE B*	β	*R*	R^2	*p*
		LL	*UL*					
Predictor								
Step 1								
Anxiety								
Depression								
Fear of Recurrence								
Neurocognitive impairment								

Note. *CI* = confidence interval; *LL* = lower limit; *UL* = upper limit.

***Table 5*. Multivariable regression for baseline pain factors predicting acceptability**

	B	95% CI for *B*		*SE B*	β	*R*	R^2	*p*
		LL	*UL*					
Predictor								
Step 1								
Duration of Pain								
Pain Intensity								
Pain Interference								
Pain Catastrophizing								

Note. *CI* = confidence interval; *LL* = lower limit; *UL* = upper limit.

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Appendix A: Acceptability E-Scale

Chronic Pain in Adult Survivors of Childhood Cancer: A Smartphone-Based Ecological Momentary Assessment Study

ACCEPTABILITY E-SCALE: PATIENTS **WITh** CHRONIC PAIN

We would like to ask you about your thoughts on using the Eureka app and Pain/Wellbeing Diary.

1. How easy was the Eureka app for you to use?

Very difficult				Very easy
1	2	3	4	5

2. How easy was the Daily/Weekly Tracker for you to use?

Very difficult				Very easy
1	2	3	4	5

3. How understandable were the questions in the Daily/Weekly Trackers?

Difficult to understand				Easy to understand
1	2	3	4	5

4. How much did you enjoy using the Eureka app?

Not at all				Very much
1	2	3	4	5

5. How much did you enjoy using the Daily/Weekly tracker?

Not at all				Very much
1	2	3	4	5

6. How helpful was the Daily/Weekly Trackers in tracking your pain?

Very unhelpful				Very helpful
1	2	3	4	5

ACCEPTABILITY E-SCALE: PATIENTS **WITh** CHRONIC PAIN

7. How helpful was the Daily/Weekly Trackers in tracking your mood?

Very unhelpful				Very helpful
1	2	3	4	5

8. How helpful was the Daily/Weekly Trackers in tracking your sleep?

Very unhelpful				Very helpful
1	2	3	4	5

9. Was the amount of time it took to complete the Daily/Weekly Trackers acceptable?

Very unacceptable				Very acceptable
1	2	3	4	5

10. How would you rate your overall satisfaction with the Daily/Weekly Trackers?

Very dissatisfied				Very satisfied
1	2	3	4	5

11. We're sorry that you were dissatisfied with the Daily/Weekly Trackers. Do you have any feedback for us to improve this feature?

12. How would you rate your overall satisfaction with the Eureka app?

Very dissatisfied				Very satisfied
1	2	3	4	5

13. We're sorry that you were dissatisfied with the Eureka app. Do you have any feedback for us to improve the experience?

14. How long would you be willing to use the Pain/Wellbeing Diary?

Same amount of time	4 weeks	6 weeks	8 weeks	Longer than 8 weeks