

Improving Symptom Control in Pediatric Cancer Patients with SSPedi and SPARK

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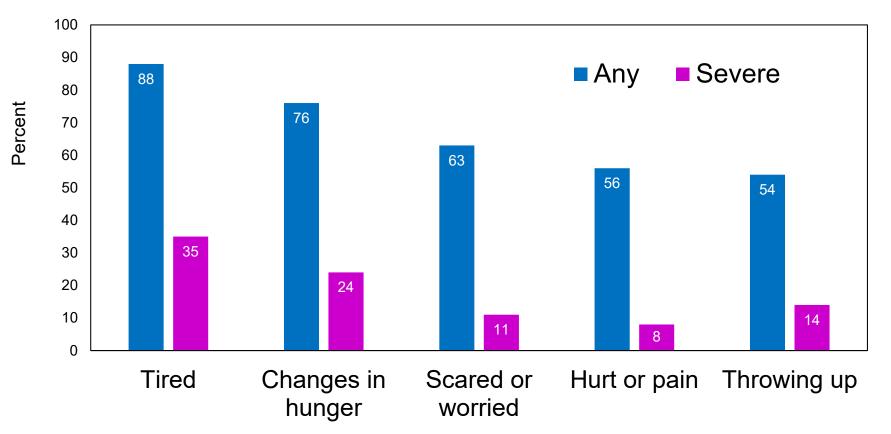
> NIH Pragmatic Trials Collaboratory Grand Rounds February 7, 2025



SickKids The hospital for sick children

Symptom Control is Poor

New diagnosis 8-18 years self-report (N=213)





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Supportive care 2030 movement: towards unifying ambitions for global excellence in supportive cancer care—an international Delphi study



Routine screening and actions

Routine collection of patient-reported outcomes measuresused to inform timely, individualized care for all people affected by cancer...

Evidence-based guidelines driven care

Supportive care is accessible to all people affected by cancer informed by evidence-based guidelines that are promoted and supported by the local and global community.



eClin Med 2024

Healthier Children. A Better World.

Check for updates

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Care	Pathway	/S
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spark Guidelines	Pow to use guidelines	Care Pathway	See Scores	Login
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Kapiolani Care Pathways				
Anger Care Pathway	s	park%	Ve	ersion date: KAP-23-May-202
Anxiety Care Pathway			Mucositis Care Pathway	
Appetite Alteration Care Pathway				
Body Image Care Pathway			Prevention Promote good oral hygiene including brushing at least tw and gentle flossing	rice daily
Cognition Alteration Care Pathway			Encourage follow up with family dentist for evaluation as possible after diagnosis	soon as
Constipation Care Pathway			For patients at high risk of mucositis, use normal saline ris cryotherapy where feasible	nses and
Depression Care Pathway				
Diarrhea Care Pathway			Assessment	
Fatigue Care Pathway			Evaluate oral mucous membranes routinely	
		Assessment	Assess routinely using <u>SSPedi</u>	
Mucositis Care Pathway			ther Moderate Bother	Severe Bother
Nausea and Vomiting Care Pathway		(SSPedi so a little		(SSPedi score = a lot or extremely)
Pain Care Pathway				
Peripheral Neuropathy Care Pathway			Treatment	
Taste Alteration Care Pathway			Optimize oral hygiene as tolerated ize nutrition including the use of enteral feeds or parentera engage dietitian	al nutrition and
			Follow pain care pathway	





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spark ※	SPARK links the detection of symptoms related to cancer tre supportive care for kids	atment with the best Cogin EN		ar Erin testpa ur patient Eri		res from SSPedi, a	validated symptom	screening tool, o	on Friday Fel	ruary 12, 202	1:	
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	SPARK has two parts SSPedi (track symptoms) and clinical practice guidelines (tre	at symptoms)		00	Headache			0	0	0	0	0
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			SPA	ARK Research	n Team							

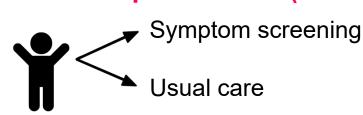




Randomized Controlled Trials

Individual patient RCT (N=345)







Cluster RCT (N=445)













Methods – Cluster RCT

Sites: 20 US sites

Years: July 2021 to August 2023

Unit of Randomization: Sites





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Site Name	Site Principal Investigator
Blank Children's Hospital	Wendy Woods-Swafford MD, MPH
Children's Hospital Colorado	Jenna Demedis MD, MS
Children's Hospital New Orleans	Lolie Yu MD, MPH
Children's Hospital of Richmond	Daniel Cannone DO
Children's Hospital Los Angeles	David Freyer DO, MS
	Etan Orgel MD, MS
Columbia University	Melissa Beauchemin PhD
Connecticut Children's	Andrea Orsey MD, MSCE
Driscoll Children's Hospital	Farha Sherani MD
Kapi'olani Medical Center for Women &	Wade Kyono MD
Children	
Lucile Packard Children's Hospital	Catherine Aftandilian MD
	Christina Baggott PhD
MD Anderson Cancer Center	Michael Roth MD
Nemours Children's Hospital, Delaware	Emi Caywood MD
Nemours Children's Hospital, Florida	Vibhuti Agarwal MD
	Ramamoorthy Nagasubramanian MD
Nemours Jacksonville	Scott Bradfield MD
Phoenix Children's	Alexandra Walsh MD
Roswell Park Oishei Children's	Kara Kelly MD
University of Iowa	David Dickens MD
UT Health San Antonio	Allison Grimes MD, MSCI
Vanderbilt University Medical Center	Adam Esbenshade MD, MSCI
Washington University in St. Louis	Allison King MD, PhD

Procedures







Contracts and IRB - agree to intervention or control groups

Randomize – stratify:

- No. patients
- Private insurance

Include: New diagnosis cancer Plan any treatment English/Spanish 8-18 years





Intervention Sites

Control Sites

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Adapt 14 care pathways symptom management

Usual Care



Patient reminders – email or text

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Symptom screening 3 times weekly x 8 weeks



Email to HCPs ≥ 1 severely bothersome symptom





Outcomes

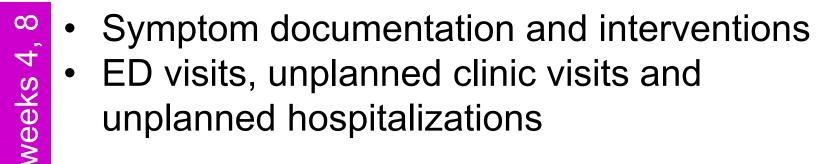
Review

Chart

Primary: Total SSPedi score (0-60) at 8 weeks

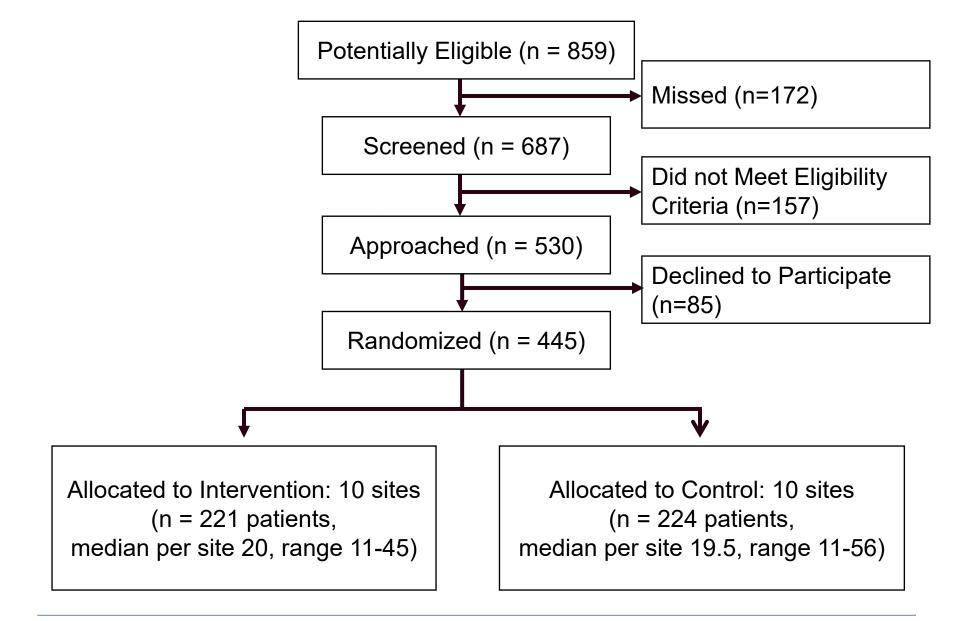
Secondary:

- Individual SSPedi symptoms
- PedsQL domain scores
- PROMIS Fatigue











Baseline Characteristics

Characteristic	Symptom Screening	Usual Care
	n=221	n=224
Male, n (%)	133 (60.2)	129 (57.6)
Age Group in Years, n (%)		
8-10	33 (14.9)	37 (16.5)
11-14	77 (34.8)	85 (37.9)
15-18	111 (50.2)	102 (45.5)
Race, n (%)		
American Indian or Alaska Native	2 (0.9)	4 (1.8)
Asian	13 (5.9)	7 (3.1)
Black or African American	13 (5.9)	14 (6.2)
Native Hawaiian or Other Pacific Islander	14 (6.3)	1 (0.4)
White	113 (51.1)	145 (64.7)
Ethnicity, n (%)		
Hispanic or Latino	85 (38.5)	63 (28.1)
Not Hispanic or Latino	123 (55.7)	139 (62.1)

Some Study Metrics

- R01 scores Feb 2020
- Completed accrual about 1 year early
- Only one patient came off study early
- Week 4 and week 8 PROs:
 - Missing 3.5% and 5.3%
 - 70 obtained remotely
- Intervention: median # SSPedi 20 (IQR 13 to 24)
 - Median minutes 1.0 (IQR 0.7 to 1.7)



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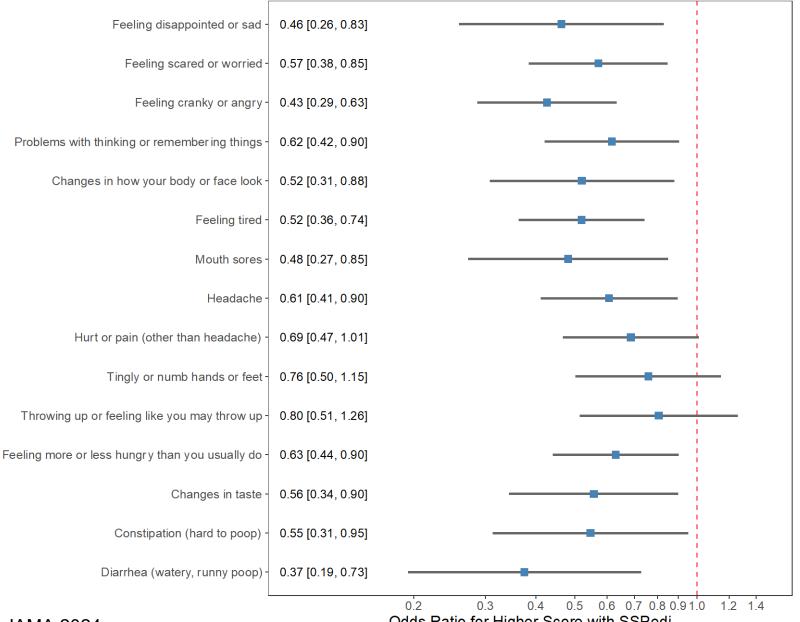
Primary Outcome – Week 8 Total SSPedi Score

Baseline Mean (SD)		Week 8 Mean (SD)		Treatment Effect Estimate Mean Difference (95% CI)	
SPARK	Usual Care	SPARK	Usual Care	Unadjusted	Adjusted
11.8 (8.2)	13.5 (8.2)	7.9 (7.2)	11.4 (8.7)	-3.7 (-6.3, -1.1)	-3.8 (-6.4, -1.2)



Less symptoms

More symptoms



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Odds Ratio for Higher Score with SSPedi

Chart Review

Symptom-specific intervention (provision clearly for symptom) more common in symptom screening group for six symptoms:

- Hurt or pain
- Changes in hunger
- Constipation
- Peripheral neuropathy
- Disappointed or sad
- Nausea and vomiting



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Healthcare Encounters

	Symptom Screening Mean (SD)	Usual Care Mean (SD)	Rate Ratio (95% CI)	P Value Adjusted
ED Visits	0.77 (1.12)	0.45 (0.81)	1.72 (1.03, 2.87)	0.0374
Unplanned Clinic Visits	0.40 (1.09)	0.24 (0.58)	1.01 (0.41, 2.50)	0.9865
Unplanned Admissions	0.65 (0.93)	0.43 (0.81)	1.40 (0.96, 2.03)	0.0803



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Logistic Regression ED Visits Among SPARK Group Only

	Est (SE)	P Value
Any Intervention		
Headache	0.987 (0.313)	0.002
Pain	0.812 (0.267)	0.002
Peripheral neuropathy	0.926 (0.001)	<0.001
Symptom-Specific Intervention		
Pain	1.066 (0.327)	0.001
Nausea and vomiting	0.291 (0.001)	<0.001



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Baseline SSPedi

- Care pathways implemented upon randomization and thus, in place at baseline
- Thus, baseline impact of care pathways without symptom screening

	Baseline Mean (SD)		Week 8 Mean (SD)		Effect Estimate rence (95% CI)
SPARK	Usual Care	SPARK	Usual Care	Unadjusted	Adjusted
11.8 (8.2)	13.5 (8.2)	7.9 (7.2)	11.4 (8.7)	-3.7 (-6.3, -1.1)	-3.8 (-6.4, -1.2)



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Conclusions

- Symptom screening improves symptom control
- Care pathway has independent effect on improving symptoms
- Symptom screening associated with increased ED visits – likely due to identification of symptoms requiring medical attention
- Strong support for integrating symptom screening into routine care





Methods – Inpatient RCT

Sites: 8 Canadian sites

Years: July 2018 to September 2023

Unit of Randomization: Patients





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SickKids The hospital for sick children



Site Name	Site Principal Investigator		
BC Children's Hospital Vancouver	Dr. David Dix		
Children's Hospital London Health	Dr. Serina Patel		
Sciences Centre			
Children's Hospital of Eastern Ontario	Dr. Donna Johnston		
Cancer Care Manitoba	Dr. Magimairajan Issai Vanan		
IWK Health Centre	Dr. Ketan Kulkarni		
McMaster Children's Hospital	Dr. Paul Gibson		
Stollery Children's Hospital Alberta	Dr. Sarah McKillop		
The Hospital for Sick Children	Dr. Lillian Sung and Dr. Lee		
	Dupuis		





Procedures





Include: cancer 8-18 years, English In hospital/clinic daily x 5 days Randomize – stratify:

- Age (8-10, 11-14, 15-18)
- Current HCT (yes/no)





Intervention





Daily symptom screening x 5 days

Usual Care



Reports provided to bedside nurse and HCP



Email to HCPs \geq 1 severely bothersome symptom on days 1 and 3





Outcomes

Primary: Total SSPedi score (0-60) on day 5

Secondary:

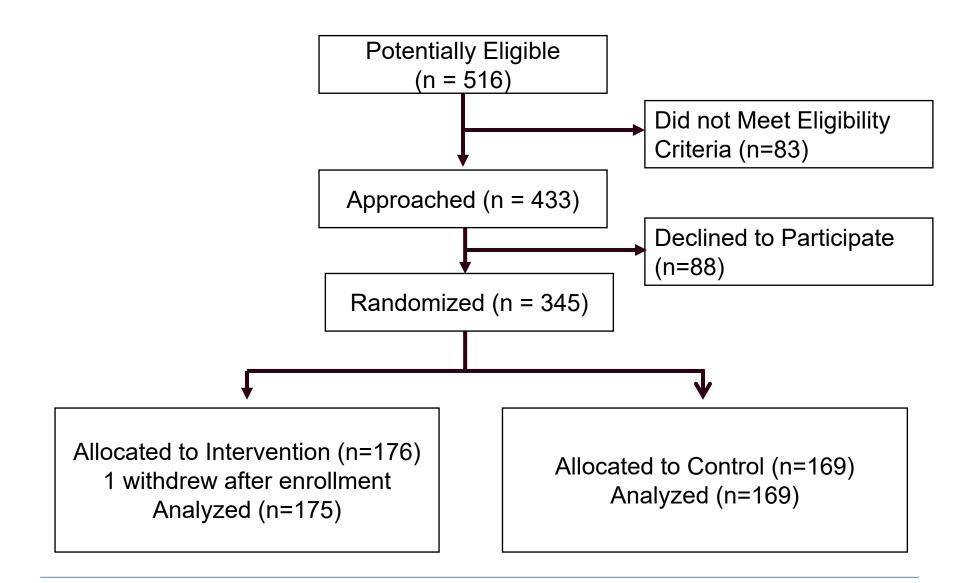
- Individual SSPedi symptoms
- PedsQL domain scores
- Faces pain scale-revised



Symptom documentation and interventions







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Baseline Characteristics

Characteristics	Symptom Screening	Usual Care
	n=176	n=169
Sex, n (%)		
Male	100 (56.8)	95 (56.2)
Female	76 (43.2)	74 (43.8)
Median Age in Years (range)	13.9 (8.0-18.4)	13.6 (8.0-18.8)
Age Group in Years, n (%)		
8-10	45 (25.6)	42 (24.9)
11-14	69 (39.2)	70 (41.4)
15-18	62 (35.2)	57 (33.7)
НСТ	19 (10.8)	14 (8.3)



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SickKids The hospital for sick children

Some Study Metrics

- Accrual impacted by COVID19 pandemic
- Missing day 5 PROs 3.8%
- Timing day 5 PRO:
 - Day 5 (n=321)
 - Day 4 (n=5)
 - Day 6 (n=6)



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Primary Outcome – Day 5 Total SSPedi Score

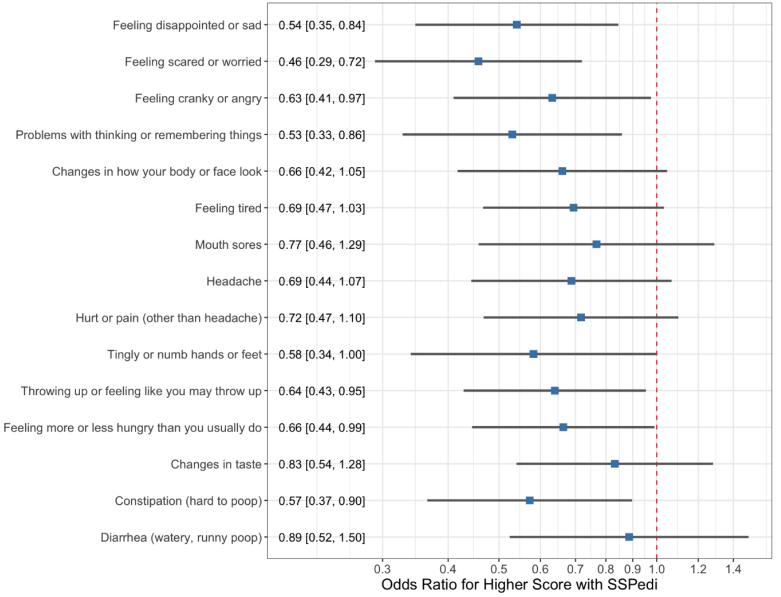
Baseline Mean (SD)		Day 5 Mean (SD)		Treatment Effect Estimate Mean Difference (95% CI)	
SPARK	Usual Care	SPARK	Usual Care	Unadjusted	Adjusted
13.2 (8.0)	13.1 (8.2)	10.2 (7.4)	12.7 (8.3)	-2.5 (-4.2, -0.8)	-2.5 (-3.8, -1.2)



Less symptoms

More symptoms

ORs for Individual SSPedi Symptoms



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Chart Review

Symptoms documented or treated more often in symptom screening for five symptoms:

- Hurt or pain
- Changes in hunger
- Constipation
- Feeling cranky or angry
- Peripheral neuropathy



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Conclusions

- Symptom screening improves symptom control
- Strong support for integrating symptom screening into routine care





Clinical Implementation

SSPedi incorporated into Epic Foundation

SickKids implementing via Remote Care Management for outpatients





SickKids The hospital for sick children

Site Pls and CRAs

SPARK Investigators

Lee Dupuis **Allison Grimes** George Tomlinson **Dilip Soman** Susan Kuczynski Tina Baggott Lisa Klesges Melissa Beauchemin

Sung Team **Emily Vettese** Sadie Cook Nicole Crellin-Parsons

POGO Paula Robinson Priya Patel





















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The Garron Family Cancer Centre



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