D-CRSE: Diminishing Chemotherapy Related Side Effects through Patient Education

Shelby Labe*, Hannah Dailey MS*, Gavin Jones*, Joanna Bhasker*, Rhea Kanwar, Sonia Hafiz, Junjia Zhu PhD, Daniella Mikhail, Monali Vasekar MD
Penn State Hershey Medical Center, Hershey, PA 17033

BACKGROUND & HYPOTHESIS

BACKGROUND:

- The diagnosis of cancer is a life-altering event an overwhelming for patients and their families
- Patients often turn to easily accessible but disreputable resources, such as the internet, to learn more
- There is a lack of patient education materials regarding cytotoxic chemotherapy side effects, research-supported treatments, and the utilization of complementary and alternative medicine
- We believe that an educational brochure about these topics would be beneficial to our patient population at Penn State

HYPOTHESIS:

Providing patients with comprehensible information about chemotherapy, side effects, and treatments will help them:

- Better understand how to address issues themselves
- Know when to contact their medical oncologist
- Understand when to go to the Emergency Department
- *Improve their quality of life*

PATIENT ELIGIBILITY, TRIAL DESIGN, & METHODS

METHODS:

- Baseline Visit: Consent, receive the brochure, and complete the following questionnaires:
- The Patient Education Material Assessment Tool (PEMAT), Emotional Thermometer Scales (ETS), and Memorial Symptom Assessment Scale (MSAS)
  - PEMAT: evaluates if a teaching material is understandable and promotes action, which will help determine if the brochure itself is an effective education tool.
  - ETS: evaluates mental health, specifically measuring distress, anxiety, depression, and anger
  - MSAS: evaluates a diverse group of symptoms commonly seen with chemotherapy
- Week 6 and Week 12: Repeat PEMAT, ETS, and MSAS
- All 3 surveys take about 12 minutes to complete on average
- Surveys are a surrogate for effectiveness of the educational brochure

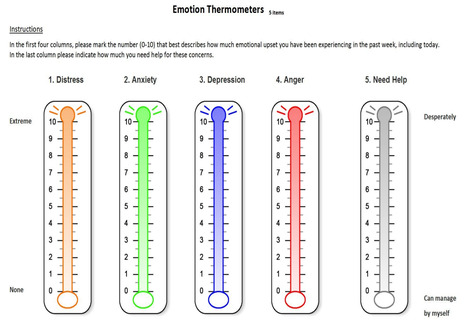
ELIGIBILITY:

- Breast or gastrointestinal (GI) cancer, any stage
- Cytotoxic chemotherapy treatment naïve
- Newly begun cytotoxic chemotherapy within the last 6 weeks
- Age >18 years old
- ECOG 0-3
- understand and read English or Spanish

TRIAL DESIGN:

- Patients enrolled on a rolling basis
- 60 target accrual
- Anticipated 10-15% dropout rate

DURING THE PAST WEEK Did you have any of the following symptoms?	DID NOT HAVE	IF YES How OFTEN did you have it?				IF YES How SEVERE was it usually				IF YES How much did it DISTRESS or BOTHER you?				
		Rarely	Occasionally	Frequently	Almost Constantly	Slight	Moderate	Severe	Very Severe	Not at all	A Little Bit	Somewhat	Quite a Bit	Very Much
Difficulty concentrating		1	2	3	4	1	2	3	4	0	1	2	3	4
Pain		1	2	3	4	1	2	3	4	0	1	2	3	4
Lack of energy		1	2	3	4	1	2	3	4	0	1	2	3	4
Cough		1	2	3	4	1	2	3	4	0	1	2	3	4
Feeling nervous		1	2	3	4	1	2	3	4	0	1	2	3	4
Dry mouth		1	2	3	4	1	2	3	4	0	1	2	3	4
Nausea		1	2	3	4	1	2	3	4	0	1	2	3	4
Feeling drowsy		1	2	3	4	1	2	3	4	0	1	2	3	4



Sample of MSAS (left) and ETS (right)

DATA ANALYSIS & RESULTS

Table 1. Patient Characteristics and Chemotherapy Regimen

Chemotherapy Naïve patients (n=32)	
Mean age (SD)	54.9 (14.9)
Median age	55
Female (%)	27 (84)
Female with breast cancer (%)	26 (97)
Male (%)	5 (16)
Male with GI cancer (%)	5 (100)
GI Cancer (%)	6 (19)
Breast Cancer (%)	26 (81)
Family history of cancer treated with chemotherapy (%)	12 (38)
Location/type of cancer	
Rectosigmoid (%)	2 (25)
Colon (%)	2 (25)
Rectal (%)	1 (13)
Ileum (%)	1 (13)
Invasive Lobular Carcinoma (%)	20 (77)
Invasive Ductal Carcinoma (%)	2 (8)
Invasive Metaplastic (%)	2 (8)
Ductal Carcinomas in situ (%)	2 (8)
Molecular characteristics	
ER positive (%)	16 (62)
PR positive (%)	13 (50)
HER2 positive (%)	6 (23)
Chemotherapy regimen	
Adriamycin and Cytoxan (AC-T)	5
Docetaxel, carboplatin, Trastuzumab and pertuzumab (TCHP)	1
Trastuzumab and paclitaxel (TH)	2
Docetaxel and Cyclophosphamide (TC)	5
Docetaxel, Trastuzumab and Pertuzumab (THP)	3
Pembrolizumab, Paclitaxel/Carboplatin, Gemcitabine/Nabpaclitaxel	2
Carboplatin-Paclitaxel	1
FOLFOX	5
Nab paclitaxel	2
ECOG performance scores of participants	
0 (%)	25 (78)
1 (%)	2 (6)
2 (%)	3 (9)

Table 2. Selected patient first impressions to educational brochure

Notable first impressions to chemotherapy educational brochure:

"The content is presented in a straightforward way. It is clear and organized. I like that it gives me all the information. I like to be aware of all the things that could happen to me and I feel more comfortable using this instead of google because I know it was made by medical professionals. I really like that it says what to do to avoid problems, and even more than that, I like that it explains why."

"This would have been perfect for when I started treatment!"

"I like that all this information is in one place. The content looks very applicable and helpful. I am excited to mark-up the pages!"

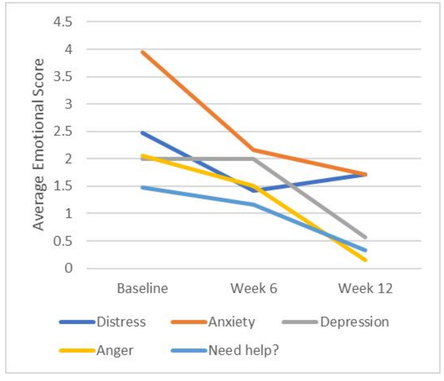


Figure 1. Line plot of the mean emotional thermometer scores completed at baseline, week 6, and week 12

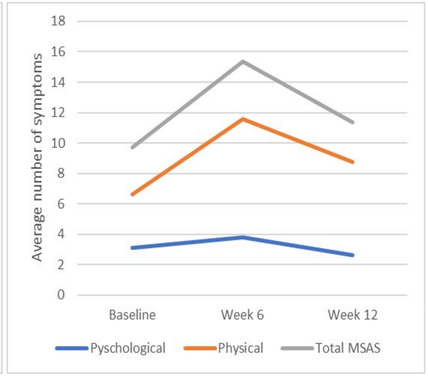


Figure 2. Line plot of the mean psychological symptoms, physical symptoms, and total MSAS completed at baseline, week 6, and week 12

Table 3. Summary of Preliminary results and P-values

	Results	n	P-value
ETS: baseline vs. 6-weeks	decreased from 2.4 to 1.7	12	0.046
ETS: baseline vs. 12-weeks	decreased from 1.35 to 0.73	8	0.063
Total MSAS: baseline vs. 12-weeks	increased from 9.7 to 11.4	8	0.01
Psychological MSAS: baseline vs. 12-weeks	decreased from 3.1 to 2.6	8	0.78
Physical MSAS: baseline vs. 12-weeks	increased from 6.6 to 8.6	8	0.004

DATA ANALYSIS PLAN:

- Trial in progress: 32 total patients accrued and 12 completed the study
- Outcome variables will be from PEMAT, ETS, and MSAS
  - For some of the measurement scales, not all the single items will be analyzed, sub-scales will be calculated and analyzed instead
- Paired-sample tests will be used to compare the difference between visit 2 and/or 3's data and the baseline measurements
- Linear mixed-effect models for repeated measures will be used to examine the overall pattern by using data from all three time points
- Secondary outcome: Drop-out rate after baseline visit
  - The point estimate and the 95% confidence interval (CI) for the patient dropout rate will be reported
  - This will help us better plan the next level of this study in the future.
- All tests will be two-sided and the statistical significance level to be used is 0.05
- Due to the exploratory nature of this study, we do not plan to do adjustments for multiple testing

CONCLUSIONS

- Comparing the mean ETS at the at the start of chemotherapy to the scores at 6 weeks shows a significant decrease in patient reports of negative emotions (p-value 0.046)
- MSAS data from baseline to week 12 demonstrates that despite a significant increase in physical symptoms (p-value 0.004) there was not a significant change in psychological symptoms (p-value 0.78)
- It is possible that the brochure helps improve quality of life and psychological symptoms, while the physical toxicities should be expected as a result of the cytotoxic treatment
- We are interested to see how these analyses may change over time once we have completed our study
- If this intervention is found to be impactful, educational brochures can be further utilized by other Penn State disease teams and departments, or by other institutions across the country

REFERENCES

Arthurs G, Simpson J, Brown A, Kyaw O, Shyrier S, Concert CM. The effectiveness of therapeutic patient education on adherence to oral anti-cancer medicines in adult cancer patients in ambulatory care settings: a systematic review. JBI Database of Systematic Reviews and Implementation Reports. 2015;13(5):244-292. doi:10.11124/01938924-201513050-00014.
Bashir NY, Moore JE, Buckland D, et al. Are patient education materials about cancer screening more effective when co-created with patients? A qualitative interview study and randomized controlled trial. Current Oncology. 2019;26(2). doi:10.3747/co.26.4621.
Gansler T, Strollo S, Fallon E, Leach C. Use of complementary/integrative methods: cancer survivors' misconceptions about recurrence prevention. Journal of Cancer Survivorship. 2019;13(3):418-428. doi:10.1007/s11764-019-00762-0.
Greenlee H, DuPont-Reyes M, Balneaves L, et al. Clinical practice guidelines on the evidence-based use of integrative therapies during and after breast cancer treatment. CA Cancer J. Clin. 2017 May 6; 67(3): 194-232. Doi:10.3322/caac.21397. Epub 2017 Apr 24.
Habimana O, Mukeshimana V, Ahishakiye A, et al. Standardization of Education of Patients With Cancer in a Low- and Middle-Income Country: A Quality Improvement Project Using the Cancer and You Booklet. Journal of Global Oncology. 2019;(5):1-6. doi:10.1200/jgo.19.00118.
Howell D, Harth T, Brown J, Bennett C, Boyko S. Self-management interventions for cancer survivors: a systematic review. Supportive Care in Cancer. 2017:1323-1355. doi:10.1007/s00520-016-3500-z.
Kaupp K, Scott S, Minard LV, Lambourne T. Optimizing patient education of oncology medications: A quantitative analysis of the patient perspective. Journal of Oncology Pharmacy Practice. 2019;25(6):1445-1455. doi:10.1177/1078155219843675.
Portenoy R, Thaler H, Kornblith A, et al. The Memorial Symptom Assessment Scale: an instrument for the evaluation of symptom prevalence, characteristics and distress. European Journal of Cancer. 1994;30(9):1326-1336. doi:10.1016/0959-8049(94)90182-1.
Shoemaker SJ, Wolf MS, Brach C. Development of the Patient Education Materials Assessment Tool (PEMAT): A new measure of understandability and actionability for print and audiovisual patient information. Patient Education and Counseling. 2014;96(3):395-403. doi:10.1016/j.pec.2014.05.027.
Smith PJ, Clavarino AM, Long JE, Steadman KJ. The Use of a Brochure to Enable CAM-with-Chemotherapy Patient Education. Journal of Cancer Education. 2016;32(4):814-819. doi:10.1007/s13187-016-1011-8.
Smith PJ, Clavarino AM, Long JE, Anstey CM, Steadman KJ. Complementary and alternative medicine use by patients receiving curative-intent chemotherapy. Asia-Pacific Journal of Clinical Oncology. 2016;12(3):265-274. doi:10.1111/ajco.12490.

email: SLabe1@pennstatehealth.psu.edu