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Osteopathic Medicine Supportive Care in Pediatric Oncology - A Pilot Study

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The authors have no conflict of interest.

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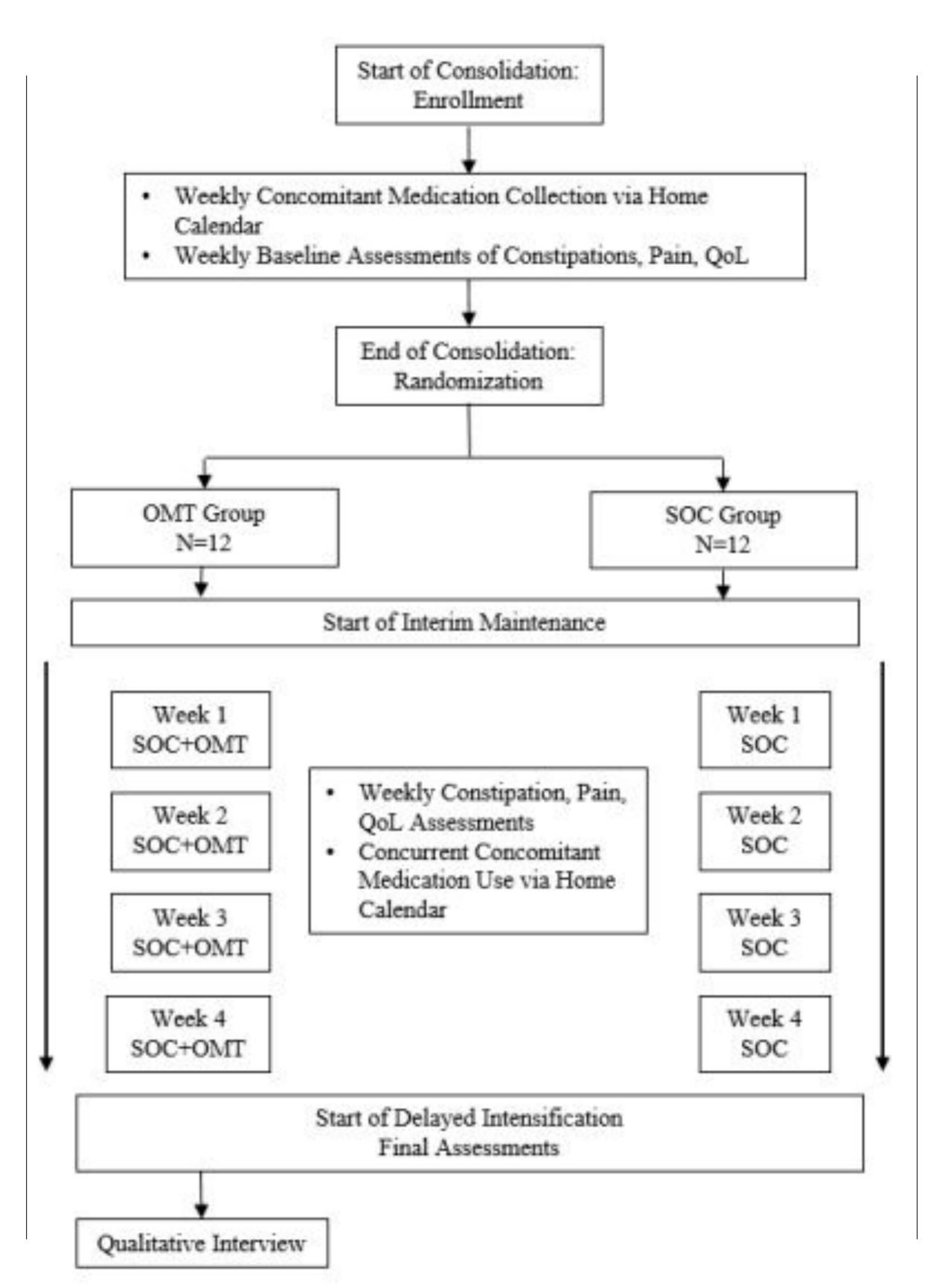
Background:

Chemotherapeutic agents, such as vincristine, are well known antineoplastic and cytotoxic drugs, affecting patients broadly during treatment of cancer. Well known side effects, such as constipation and neuropathic pain, affect the quality of life of these patients recovering from cancer as well as its treatment. An option that alleviates troublesome side effects while still allowing the treatment to work would assist patients with wellbeing and comfort.

Osteopathic manipulative treatments (OMT) are often utilized for various ailments in both pediatric and adult populations. A previous pilot study investigated the safety and feasibility of OMT in pediatric oncology patients and reported no serious adverse events attributed to OMT intervention. We hypothesized that OMT intervention during cancer therapy will improve constipation and neuropathic pain for children with leukemia undergoing chemotherapy.

Objectives:

The main objective of this study is to investigate the efficacy of osteopathic medicine on constipation and neuropathic pain as side effects of chemotherapy in pediatric oncology outpatient clinics.



Research Design:

This is a single institutional, randomized control trial, investigating patients aged ≥2 -21 years receiving chemotherapy for leukemia at Riley Children's Hospital. Patients will be enrolled and sign informed consent after an explanation of OMT with a previously published script and education video. Subjects will then complete 4 weeks of consolidation during which all participants will utilize the standard of care (SOC) chemotherapy treatment.

During consolidation, no OMT treatments will be used, only home calendars and validated clinical reporting tools. Afterwards they will be randomized to either OMT plus standard of care, or standard of care alone, for a total of 4 OMT treatments during interim maintenance if on the former arm. Osteopathic treatments will include muscle energy, myofascial release, balanced ligamentous tension, visceral inhibition, and counterstain in a specific order, and last no longer than 20 minutes each at the Riley Outpatient Center. Feedback will be elicited with use of the FACES pain scale before and after each OMT treatment and the PedsQL3.0 measuring quality of life before OMT treatments.

Throughout the entirety of the study, patients and caregivers will be given a calendar to record home as needed medication administration and a Bristol stool chart with which to track bowel movements in order to reduce recall bias. A qualitative interview for patients and caregivers will follow the final OMT treatment for patients randomized to the OMT arm. The interviews will be conducted independently.

Conclusion/ Future Directions:

The aim of the present study is to examine the direct association between OMT treatment and chemotherapy side effects of constipation and neuropathic pain in pediatric oncology patients through the Bristol stool chart and FACES scale. Results of this study will begin to answer the questions of which OMT work for specific chemotherapy induced side effects in children. Multicenter randomized trials of adequate sample size are needed to evaluate the efficacy of OMT in the treatment of chemotherapy induced side effects. Future studies should focus on utilizing OMT as an adjunctive supportive care option of pediatric patients.

Directions: Please fill out the calendar with your symptoms throughout the week. Frepresents pain. Place the Fon the figure to show where you felt pain on that day. Represents constipation. Place Represents on the figure when you have constipation.

MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY
ω	$ \omega\rangle$			
SATURDAY	SUNDAY			
	\bigcap	Name		
(1) N		Week	day Date (Month / Day /	Year)
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