



STUDY MATTERS

April 11, 2024

Wake NCORP Website: <https://wakencorp.phs.wakehealth.edu/>

Congratulations to Dr. Kate Weaver!

Dr. Kate Weaver was selected by the NCI Director, Dr. Rathmell, to present the results of her R01-funded Automated Heart-Health Assessment for Cancer Survivors (AH-HA) study (WF-1804CD) at the March NCI Board of Scientific Advisors meeting. The presentation, part of a new program to present highlights of the NCI extramural grants portfolio, spotlighted the work of the NCI Community Oncology Research Program (NCORP) and opportunities in cancer care delivery research. Presentation available at: <https://videocast.nih.gov/watch=54423> at the 1:03 mark.

WF NCORP RB Annual Meeting Travel Awards

We will be presenting travel awards to sites with the most enrollment to WF-1805CD HN-STAR, WF-1806 M&M, WF-1901 IMPACTS and WF-2201 HYPOGRYPHE **between February 1 and September 15, 2024.**

- Awards will be given to 2 sites for each study.
- Travel awards assist with travel to our 2024 Wake Forest NCORP RB Annual Meeting in Myrtle Beach, SC, October 21-23.
- **Awards are worth up to \$1,000 each** to cover travel and hotel expenses at The Grande Dunes Marriott Resort.



****NEW STUDY NOW OPEN****

WF-2202 - SHINE- Optimizing Psychosocial Intervention for Breast Cancer-related Sexual Morbidity: The Sexual Health and Intimacy Education Trial



Brief Summary

The SHINE trial is designed to develop an internet-delivered sexual health program that can help breast cancer survivors with sexual concerns by studying four different cores (i.e., Sexual Health Essentials, Health Care Discussions, Partner Conversations, and Intimacy Insights) in different combinations. This study is a factorial study and seeks to identify which combination of these four intervention core components produces the greatest benefit with the least intervention burden over a 24-week period.

Study Population

Adult women, status post treatment of Stage 0-III breast cancer, who are currently in an intimate relationship and are experiencing sexual concerns. 320 participants will be randomized (20 randomized into each of the 16 conditions).

Protocol documents are now available on CTSU. Please note that patient surveys are not posted to CTSU, as these are to be directly entered into the REDCap Database.

Introductory webinar and slides are now posted on our website

Click on the link below and open "Site Calls and Webinars"

<https://wakencorp.phs.wakehealth.edu/study/wf2202-shine/>

If your site is interested in participating in this study, please email NCORP@wakehealth.edu with Subject: WF-2202 SHINE

*****Save the Date*****

Wake Forest NCORP Research Base Quarterly Call

Wednesday, April 24, 2024 at 3 PM ET

**Updates to this meeting will not occur automatically.
Please check email reminders and Study Matters for schedule changes**

Upcoming Site Calls

****Please note that your calendar may not update automatically if changes are made. Please check these emails and our website for meeting updates.****

You can also join site calls from our [Wake NCORP website](#). Click the call in the "Upcoming Events" section on the Home page or through the Calendar. You must be a registered user to join from the website.

If you are having trouble joining a call or have any other issues please email NCORP@wakehealth.edu

WF-1806 - M&M- Myopenia and Mechanisms of Chemotherapy Toxicity in Older Adults with Colorectal Cancer
April 23, 2:30-3:00 PM ET

WF-2201 - HYPOGRYPHE- Hypofractionated Radiotherapy vs Single Fraction Radiosurgery for Brain Metastasis Patients on Immunotherapy
May 14, 3:00 PM ET

Study Updates

WF-1804CD - AH-HA- Assessing Efficacy and Implementation of an EHR Tool to Assess Heart Health Among Survivors

AH-HA

Automated Heart-Health Application

****DATA UPDATE****

We are nearing the end of data collection! Please send and/or remind participants to complete the 1-Year surveys as soon as possible. Please also complete the 1-Year Medical Record Data Forms as soon as you can. We greatly appreciate all your help!

WF-1805CD - HN-STAR- Implementation and Effectiveness Trial of HN-STAR



Closing to Onboarding

We are anticipating closing this study to new practices soon. All site onboarding activities must be completed by May 1, 2024, as we hope to reach our patient enrollment goal and close the study by this Fall. Please reach out if you have any questions or need any assistance.

Sites with 10 Enrollments

We have had several sites reach the minimum goal of 10 enrollments, and more that are very close. If you haven't already, once your site has reached 10, please be sure to send your Designated Clinicians and Stakeholders their final survey in REDCap so that we can complete interviews.

Please complete the "DC Intro" section for each of your DCs that have enrolled patients and click the "Send Survey" button. For Intervention sites only, you will do the same thing for your Stakeholder(s) under the "SH-Email Trigger" section.

Remember that each site can continue to enroll up to 50 patients. Thanks so much to everyone for all your efforts!

WF-1806 - M&M- Myopenia and Mechanisms of Chemotherapy Toxicity in Older Adults with Colorectal Cancer



WF-1901 – IMPACTS - Internet-delivered Management of Pain Among Cancer Treatment Survivors



IMPACTS was featured in the NCI Clinical Trials Update for March!

Click the link [Clinical Trials Update from NCI, March 2024 \(govdelivery.com\)](https://govdelivery.com) to access the content.

NCI-Supported Clinical Trials That Are Recruiting Patients

Targeted Therapy for HER2+ Solid Tumors

This phase 2 clinical trial compares treatment with the targeted drugs neratinib and palbociclib versus neratinib alone for people with gynecologic or other solid tumors with high levels of HER2. Giving neratinib with palbociclib may shrink or stabilize cancers that have too much HER2.

Treating Urinary Incontinence in Men with Prostate Cancer

This phase 2 trial is testing a device that uses electrical signals to help strengthen the pelvic floor. Men treated for prostate cancer frequently develop urinary incontinence. Doctors want to see if the device will help improve the symptoms of urinary incontinence in men experiencing this side effect.

Testing an Internet Intervention to Help Cancer Patients Control Pain

This phase 3 clinical trial will test an internet-based program of coping skills for pain in adults with cancer. People undergoing adjuvant treatment or who have finished cancer treatment but are still having cancer-related pain will be randomly assigned to receive the internet-based program along with standard pain care, or standard pain care alone. Doctors want to see if the internet-based program reduces the pain and the amount of interference in daily life it causes.

WF-2201 - HYPOGRYPHE - Hypofractionated Radiotherapy vs Single Fraction Radiosurgery for Brain Metastasis Patients on Immunotherapy



NEW AMENDMENT ACTIVATION

HYPOGRYPHE (WF-2201) Amendment 4, Protocol Version Date 1/19/2024, Release Date: 04/10/2024.

The WF NCORP Research Base study entitled *Hypofractionated Radiotherapy vs Single Fraction Radiosurgery for Brain Metastasis Patients on Immunotherapy (HYPOGRYPHE)* has been amended. The amended protocol, related documents, and recruitment materials were released on April 10, 2024.

Changes with this amendment include:

- Allowing prior courses of SRS for brain metastases
- Offering central review prior to enrollment if a lesion is borderline for size criteria
- Allowing enrollment of patients with Small Cell Lung Cancer
- Clarifying that it is not necessary to wait for results of next generation sequencing prior to enrollment.
- Added new exclusion criteria to address patients with prior SRS for brain metastases who have a history of ARE and/or possible ARE or local failure at the time they are being evaluated for enrollment.
- Increased the allowable interval from the MRI used in treatment planning to start of SRS from 14 to 21 days
- Added a 5th factor as part of the minimization randomization process to incorporate prior courses of SRS for brain metastases (yes vs. no).
- Updated Section 7.1 (Schedule of Events)
- Updated CTSU language based on 01/25/2024 support logistical template language document.

WF-2201 Document Access:

- The protocol and participant directed documents are available on the [CTSU](#) website.
- The *Helpful Guide* and *Training resources* are available on the [WAKENCORP](#) website.

Sites interested in participating should contact NCORP@wakehealth.edu; Attn: WF-2201 and request a start-up packet. **Your site must be IROC certified to participate or be willing to become certified.** Refer to Sections 5.2, 6.2 & 6.6 of the protocol for the Protocol Specific Requirements and Site Registration and Credentialing Requirements for site participation.

Regulatory requirements to activate this study can be found in the protocol on the CTSU website.

If there are any questions regarding the WF-2201 activation, please contact NCORP@wakehealth.edu; Attn: WF-2201.

Wake Forest NCORP Research Base Website

Remember to update your profile to include any new studies you may be involved in

We use this information for targeting email communications and surveys.

<https://wakencorp.phs.wakehealth.edu/>

Registering for an account will allow you to:

- Join site calls and other meetings from the Upcoming Events or Calendar sections
- Access study training materials
- View previous study meetings
- Download important study documents including training videos, study guides, and neurocognitive CRFs

Once registered, you must update your user profile to sign up for study-specific mailing lists and meeting announcements, indicate your NCORP Community site, add your user roles, and update your GCP for database access.

If you have any questions or need assistance with registration, please email NCORP@wakehealth.edu

Accruals as of April 10, 2024

Open Studies	Name	Enrolled (Patients)	Change in Past 2 Weeks	Target (Patients)	Enrolled (Non-Patients)	Target (Non-Patients)
WF-1806	M&M	199	+3	300		
WF-1901	IMPACTS	155	+3	250	0	40
WF-1805CD	HN-STAR	245	+3	350	121	140
WF-2201	HYPOGRYPHE	3	--	244		
WF-2202	SHINE	5	+2	320		

Open Studies	Name	Enrolled Practice Groups	Change in Past 2 Weeks	Target Practice Groups	Enrolled CTEP IDs	Change in Past 2 Weeks	Max CTEP IDs
WF-2300CD	CONNECT Survey	126	--	200	256	--	600

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