



## STUDY MATTERS

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May 9, 2024

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

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### 2024 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, WF-2201 HYPOGRYPHE, and WF-2202 SHINE **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.



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If you missed the Wake Forest NCORP Research Base Quarterly Call on 4/24/2024, you can watch the video on our website here:

<https://wakencorp.phs.wakehealth.edu/meetings-committees/ncorp-quarterly-calls/>

## WF-97116 REMEMBER Primary Paper Published in ASCO Journal of Clinical Oncology

Rapp SR, Dressler EV, Brown MA, et al. Phase III randomized, placebo-controlled clinical trial of Donepezil for treatment of cognitive impairment in breast cancer survivors after adjuvant chemotherapy (WF-97116). Journal of Clinical Oncology. 2024.

<https://doi.org/10.1200/JCO.23.01100>

Original Reports | Breast Cancer Check for updates

### Phase III Randomized, Placebo-Controlled Clinical Trial of Donepezil for Treatment of Cognitive Impairment in Breast Cancer Survivors After Adjuvant Chemotherapy (WF-97116)

Stephen R. Rapp, PhD<sup>1,2</sup>; Emily V. Dressler, PhD<sup>1</sup>; W. Mark Brown, MA<sup>1</sup>; James L. Wade III, MD, FACP, FASCO, FACCC<sup>1</sup>; Nguyet Le-Lindqwister, MD<sup>3</sup>; David King, MD<sup>3</sup>; Kendrith M. Rowland, MD<sup>3</sup>; Kathryn E. Weaver, PhD, MPH<sup>4</sup>; Heidi D. Klepin, MD<sup>5</sup>; Edward G. Shaw, MD, MA<sup>6</sup>; and Glenn J. Lesser, MD<sup>7</sup>

DOI: <https://doi.org/10.1200/JCO.23.01100>

**ABSTRACT**

**PURPOSE** To test efficacy of donepezil, a cognitive enhancer, to improve memory in breast cancer survivors who report cancer-related cognitive impairment 1-5 years postchemotherapy.

**PATIENTS AND METHODS** Adult female BCS exposed to ≥4 cycles of adjuvant chemotherapy 1-5 years before enrollment who reported cancer-related cognitive impairment were eligible. Participants, enrolled at sites affiliated with the Wake Forest NCI Community Oncology Research Program (NCORP) Research Base, were randomly assigned to receive 5 mg of donepezil once daily for 6 weeks titrated to 10 mg once daily for 18 weeks or placebo. Cognition and self-report cognitive

**ACCOMPANYING CONTENT**

Appendix  
Protocol

Accepted February 28, 2024  
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J Clin Oncol 00:1-12  
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### 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](mailto:NCORP@wakehealth.edu)

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

WF-1805CD - HN-STAR- Implementation and Effectiveness Trial of HN-STAR  
**May 15, 3:00 PM ET**

WF-2202 - Optimizing Psychosocial Intervention for Breast Cancer-related Sexual Morbidity: The Sexual Health and Intimacy Education (SHINE) Trial  
**June 12, 2:00 PM ET**

WF-1806 - M&M - Myopenia and Mechanisms of Chemotherapy Toxicity in Older Adults with Colorectal Cancer  
**June 25, 2:30 PM ET**

Please email [7NCORP@wakehealth.edu](mailto:7NCORP@wakehealth.edu) when shipping biospecimen samples to the NCORP Research Base Biospecimens lab (Studies WF-1806, WF-1901, and WF-2201). Include the FEDEX tracking number in your email so that misplaced samples can be tracked before they spoil. Please ship by "FedEx Priority Overnight" (please change this on the pre-printed shipping label if this is not selected).

## Study Updates

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



#### **Closed to Onboarding**

This study has closed to new practices. All site onboarding activities should have been 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-1901 – IMPACTS - Internet-delivered Management of Pain Among Cancer Treatment Survivors

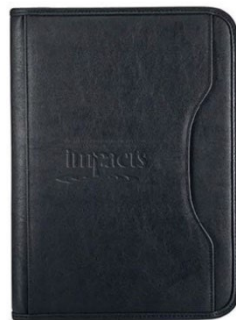


### **WF-1901 IMPACTS NEEDS YOUR HELP!** **We still need 25 patients by June 30, 2024!**

- Currently, there are 149 sites that have agreed to participant in the WF-1901 study, with 52 of them actively enrolling patients!
- With just one patient enrolled at each of these sites, our goal will be surpassed within the next two months.
- Each site that enrolls in **April-June** can choose from the following below as a “thank you” for helping to make this important trial a success!!

We are glad to organize refresher trainings for anyone excited to restart IMPACTS!

Wake Forest NCORP Research Base: [NCORP@wakehealth.edu](mailto:NCORP@wakehealth.edu)



Executive Padfolio /Organizer



Sweatshirt Blanket, 50" x 60"



20 oz/ Stainless Steel Tumbler



Messenger Bag with Shoulder Strap

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



***Based on your feedback, we have made several protocol changes to the HYPOGRYPHE Study...CHECK IT OUT!***

**NEW RECRUITMENT MATERIAL POSTED**

**HYPOGRYPHE (WF-2201) Hypofractionated Radiotherapy vs Single Fraction Radiosurgery for Brain Metastasis Patients on Immunotherapy Amendment 4, Protocol Version Date 01/19/2024 was posted on 05/08/2024.**

The following document was posted on CTSU on **May 8, 2024**.

- **Study Summary v4.15.2024**

**NEW SPANISH DOCUMENT POSTED**

**HYPOGRYPHE (WF-2201) Hypofractionated Radiotherapy vs Single Fraction Radiosurgery for Brain Metastasis Patients on Immunotherapy Amendment 4, Protocol Version Date 01/19/2024 was posted on 04/15/2024.**

The Spanish version of the following document was posted on CTSU on Monday, **April 15, 2024**.

- **Consent Form, (PVD 01/19/24): Spanish**

**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 5<sup>th</sup> 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](mailto: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](mailto: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](mailto:NCORP@wakehealth.edu)

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### Accruals as of May 8, 2024

Open Studies	Name	Enrolled (Patients)	Change in Past 2 Weeks	Target (Patients)	Enrolled (Non-Patients)	Target (Non-Patients)
WF-1806	M&M	206	+2	300		
WF-1901	IMPACTS	158	+2	250	0	40
WF-1805CD	HN-STAR	253	+5	350	123	140
WF-2201	HYPOGRYPHE	4	+1	244		
WF-2202	SHINE	37	+23	320		

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