

Official Title: Feasibility of Delivering a Digital Behavioral Intervention to Increase Diet Quality Among Women Receiving WIC Benefits

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## ***Protocol***

### ***Population***

We will enroll mothers aged  $\geq 18$  years who have a child 2 years old or younger and who are currently enrolled in WIC in North Carolina. Caregivers must have a smartphone (i.e., a cell phone that can send and receive text messages and access the internet), be willing to send and receive study-related text messages, have an email address they check regularly, have regular access to the internet, and be comfortable reading and writing in English.

### ***Recruitment***

The target enrollment is 50 participants in accordance with published guidance for pilot studies and to allow for drop-outs<sup>1</sup>. We partnered with two different entities for participant recruitment, using different strategies. The first is a private, non-profit health system that operates Federally qualified community health centers in North Carolina that also administer WIC benefits. During WIC encounters, WIC nutritionists (n=2) will upload the name, phone number and email address of WIC beneficiaries who are interested in joining the pilot into a secure online Duke Box folder. Research assistants will upload this information into REDCap (Research Electronic Data Capture), a secure, web-based software platform designed to support data capture and management for research studies<sup>2,3</sup>. The second recruitment entity is the WIC office from the 2nd most populated county in North Carolina. This county WIC office will include flyers in mailings sent to all new WIC recipients. These flyers will provide information about the pilot study and will include a QR code that caregivers can scan to take them directly to the screener.

Additionally, the Nutrition Services Branch within the North Carolina Division of Public Health, which implements the WIC program for North Carolina, will alert all WIC directors in the state of the pilot study via email. The email will include the flyer with the QR code for WIC directors to distribute throughout their WIC clinics as they see fit. We will also utilize social media platforms, such as Facebook, and Duke University websites to distribute information about the study and aid in recruitment. Interested caregivers can also find a link to the screener from a study-specific website, <https://healthyrootsstudy.com>. This website contains study and contact information for the research team.

### ***Screening, baseline assessments, and enrollment***

All study related processes will be completed electronically to aid in the dissemination potential. Surveys are administered through REDCap, allowing caregivers to self-guide themselves through each one. The system incorporates functions such as scheduling surveys and tracking completion. If surveys are not complete, the system will automatically send reminders, via SMS text message and email, for up to 7 days.

The first survey is the eligibility screener which includes questions regarding eligibility criteria, as described above. As soon as contact information is entered into REDCap by the research

assistant the system will automatically email a link to the online screener and send a SMS text the following day if not complete. Interested caregivers will also be able to access the screener by scanning the QR code on the flyer or clicking on the screener link found on the study website and Facebook page. If the caregiver is eligible, they will confirm their contact information and be directed to an online consent form (see Figure 2 for study flow). Once the consent form is electronically signed, caregivers will be directed to complete an online baseline survey.

Upon completion of the baseline survey, participants will be asked via email to complete two 24-hour dietary recall assessments administered through the Automated Self-Administered 24-Hour Dietary Assessment Tool (ASA24)<sup>4</sup>. The ASA24 is a freely available, web-based, self-administered tool developed by the National Cancer Institute and provides comprehensive nutrient data on all foods and beverages consumed during the previous 24-hour period. Caregivers will be asked to complete two separate 24-hour dietary recalls (1 week and 1 weekend day) within two weeks of each other. When both ASA24s are complete caregivers will be enrolled in the intervention.

Once the participant is enrolled, they will begin receiving SMS text messages. The first text message will include a web link to a study-specific YouTube channel that includes an orientation video. This 2-minute orientation video informs participants of what to expect including surveys they have to complete and incentives for completing those surveys. They are presented with the study schedule and contact information for the study team and encouraged to reach out with any questions or concerns. Subsequently, participants will receive their first goal, followed by a new goal every 2 weeks until the end of the study for a total of 6 goals. During each 2-week goal cycle, participants will receive 3 tips per week related to that goal. At the end of each week, they will receive a tracking message related to their assigned goal. If they respond, they will receive feedback on their progress. If they do not respond they will receive an automated reminder. If still no response, they will receive a reminder to track next time as well as a tip. After 12 weeks, participants will be asked to complete two more ASA24s and a satisfaction survey. Participants will receive a gift card after completion of each ASA24 (n=4) for a maximum amount of \$55.

#### ***Data collection and outcome assessments***

Self-reported sociodemographic characteristics, including education, age, BMI (kg/m<sup>2</sup>), marital status, employment, depression, race, and ethnicity will be collected prior to enrollment through REDCap online surveys (Table 2). REDCap will also be used to capture intervention retention defined as responding to weekly tracking surveys. REDCap will also be used to capture post-intervention satisfaction survey. Research staff will follow up with phone calls and text messages for those who do not complete the satisfaction survey.

**Table 2:** Schedule of Assessments

| <b>Measure</b>               | <b>Screening</b> | <b>Baseline</b> | <b>12 weeks</b> |
|------------------------------|------------------|-----------------|-----------------|
| Inclusion/exclusion criteria | X                |                 |                 |
| Informed consent             | X                |                 |                 |
| Sociodemographics            |                  | X               |                 |
| Food insecurity <sup>1</sup> |                  | X               |                 |
| WIC shopping habits          |                  | X               | X               |
| Depression <sup>2</sup>      |                  | X               |                 |

|                                      |  |   |   |
|--------------------------------------|--|---|---|
| Everyday Discrimination <sup>3</sup> |  | X |   |
| ASA24 Dietary Tracking               |  | X | X |
| Satisfaction Survey                  |  |   | X |

<sup>1</sup>2-item screen for food insecurity<sup>5</sup>

<sup>2</sup>Personal Health Questionnaire Depression Scale (PHQ-8)<sup>6</sup>

<sup>3</sup>Expanded Everyday Discrimination Scale<sup>7</sup>

## References

1. Lancaster GA, Dodd S, Williamson PR. Design and analysis of pilot studies: recommendations for good practice. *Journal of evaluation in clinical practice*. 2004;10(2):307-312. doi:10.1111/j.2002.384.doc.x
2. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. *Journal of biomedical informatics*. 2009;42(2):377-381. doi:10.1016/j.jbi.2008.08.010
3. Patridge EF, Bardyn TP. Research electronic data capture (REDCap). *Journal of the Medical Library Association: JMLA*. 2018;106(1):142. doi:10.5195/jmla.2018.319
4. Subar AF, Kirkpatrick SI, Mittl B, et al. The Automated Self-Administered 24-hour dietary recall (ASA24): a resource for researchers, clinicians, and educators from the National Cancer Institute. *Journal of the Academy of Nutrition and Dietetics*. 2012;112(8):1134-1137. doi:10.1016/j.jand.2012.04.016
5. Hager ER, Quigg AM, Black MM, et al. Development and validity of a 2-item screen to identify families at risk for food insecurity. *Pediatrics*. 2010;126(1):e26-e32. doi:10.1542/peds.2009-3146
6. Kroenke K, Strine TW, Spitzer RL, Williams JB, Berry JT, Mokdad AH. The PHQ-8 as a measure of current depression in the general population. *Journal of affective disorders*. 2009;114(1-3):163-173. doi:10.1016/j.jad.2008.06.026
7. Williams DR, Yu Y, Jackson JS, Anderson NB. Racial differences in physical and mental health: Socio-economic status, stress and discrimination. *Journal of health psychology*. 1997;2(3):335-351. doi:10.1177/135910539700200305