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Adaptation of a health literacy screener for computerized, self-administered use by U.S. adults

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ABSTRACT

Objective: Health literacy is a critical health determinant, for which few computerized, self-administered assessments exist. This study adapted and tested the reliability of the Newest Vital Sign® (NVS) as a computerized, self-administered health literacy screener.

Methods: Phase one involved 33 participants to create response options for a computerized, self-administered NVS (C-NVS). Phase two was a randomized crossover trial to test the consistency of C-NVS and original, interviewer-administered NVS (I-NVS) scores in 89 participants.

Results: Linear mixed-effects regression model results showed a significant carryover effect ($p < .001$). Crossover trial data from time 1 showed that participants who initially received the C-NVS had significantly higher average scores ($M = 5.7, SD = 0.6$) than participants who received the I-NVS ($M = 4.5, SD = 1.5; t(87) = 5.25, p < .001$). Exploratory analysis results showed that when the washout period was longer than 33 days (75th percentile) the carryover effect was not statistically significant ($p = .077$).

Conclusion and innovation: Findings suggest learning can occur when health literacy screeners are administered more than once in less than a month's time and computerized, self-administered health literacy screeners may produce ceiling effects. A universal precautions approach to health literacy therefore remains germane.

1. Introduction

Health literacy, the ability to access, process, and use health information and services, is vital to health and wellbeing [1-5]. Health literacy skills may include the ability to interpret a nutrition label, locate and understand information in healthcare documents, and follow medication instructions [1,3]. Approximately 80 million U.S. adults (36%) have limited health literacy [6]. Individuals who are older, have less education, have lower income, identify as an ethnic minority, and/or live in a rural area are at the highest risk of limited health literacy [6,7]. Limited health literacy is related to an array of adverse health outcomes including missed prescription refills and provider visits, increased hospitalizations, and poorer overall health among U.S. adults [8]. These findings underscore the need to better understand and address health literacy, especially for vulnerable populations in healthcare settings [5].

In a technology-focused society that is continuously innovating, computerized health literacy assessment may have benefits for

clinicians, patients, and researchers. According to the World Health Organization (2018), digital technologies such as computerized assessments are predicted to have a positive impact on healthcare access. That is, technology may help to optimize the use of computerized resources in healthcare leading to greater health information accessibility [9]. Healthcare organizations are rapidly transitioning to using eHealth systems to communicate health information and provide health services. Relatedly, telehealth visits are becoming increasingly prevalent, which may make patients more responsible for accessing and comprehending the health information provided to them online [10]. This rapid technological transition has, however, given rise to disparities in access to and use of health information and services thereby perpetuating persistent health inequities [9-11]. Consequently, it is imperative that patient health literacy continue to be both assessed and addressed through eHealth systems. On the assessment end, this may involve adapting existing health literacy assessments to be computerized and self-administered as part of eHealth systems.

The Newest Vital Sign® (NVS) is an interviewer-administered, health

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literacy screener that is widely utilized in clinical practice [12-14]. The original NVS was developed in English and Spanish by Weiss and colleagues (2005) and is valid, reliable, and quickly administered—taking an average of 2–3 min for patients to complete [14-16]. The NVS has been adapted and determined to be reliable for use in other countries such as China [17], Italy [18], and the United Kingdom [19]. Yet, few studies have adapted the NVS for computerized, self-administration to accommodate the fast-changing technological advancements in health-care delivery and health services research.

Mansfield and colleagues (2018) did conduct a randomized cross-over trial to assess the reliability of a computerized, self-administered adaptation of the NVS in Canada [20]. Their study's results demonstrated that participants' health literacy scores were similar between the new, computerized and original, interviewer-administered versions of the NVS, suggesting that the computerized, Canadian NVS is reliable. Still, the NVS has not yet been adapted for computerized, self-administration in the United States. This study, therefore, sought to adapt and examine the reliability of the NVS as a computerized, self-administered health literacy screening tool.

2. Methods

2.1. Overarching study design

This study's two-phase design followed that of the previous study conducted by Mansfield and colleagues (2018) to adapt and test the reliability of the NVS in French and as a computerized, self-administered tool for Canadian adults [20]. The first phase of this study, conducted from June to October 2020, involved administering the original, interviewer-based NVS (I-NVS) to determine the distractor response options that would be used in the study's second phase with the computerized-based NVS adaption (C-NVS). The second study phase, conducted from October 2020 to August 2021, used a randomized cross-over trial design with a two-to-nine-week washout period (median = 24 days). Because of safety concerns related to the COVID-19 pandemic, both study phases were conducted through telephone and videoconference. Some evidence exists to support the validity of the NVS when administered remotely via telephone or videoconference versus in-person [21]. The first author's Institutional Review Board approved this study's protocol.

2.2. Phase 1 instruments

2.2.1. I-NVS

The original NVS is a validated six-question tool that utilizes an ice cream nutrition label (Fig. 1) and is read aloud by an interviewer to assess a participant's health literacy and numeracy skills [14]. Correct responses are scored with one point, and incorrect responses receive a score of zero. A score of four to six indicates adequate health literacy, while anything below indicates limited health literacy. A score of zero or one indicates likely limited health literacy and a score of two or three indicates possible limited health literacy [13,14]. For the purposes of this study, the I-NVS questions were read aloud by a research team member over the telephone or on videoconference while the participant viewed the ice cream nutrition label. Research team members recorded and scored their responses.

2.2.2. Demographic and health questionnaire

In phase one, participants also completed a verbally administered demographic and health questionnaire. This questionnaire included items adapted from the National Health Interview Survey regarding participants' age, sex, Hispanic or Latin ethnicity, race, health insurance coverage, marital status, and employment. Additional questionnaire items were included regarding participants' health status and quality of life from the 36-item Short Form Health Survey (SF-36) [22], as well as impacts of the COVID-19 pandemic across personal and social life

Nutrition Facts			
Serving Size		½ cup	
Servings per container		4	
Amount per serving			
Calories	250	Fat Cal	120
		%DV	
Total Fat	13g		20%
Sat Fat	9g		40%
Cholesterol	28mg		12%
Sodium	55mg		2%
Total Carbohydrate	30g		12%
Dietary Fiber	2g		
Sugars	23g		
Protein	4g		8%

*Percentage Daily Values (DV) are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

Ingredients: Cream, Skim Milk, Liquid Sugar, Water, Egg Yolks, Brown Sugar, Milkfat, Peanut Oil, Sugar, Butter, Salt, Carrageenan, Vanilla Extract.

Fig. 1. Newest vital sign ice cream nutrition label. This is the ice cream label used as part of the Newest Vital Sign.

domains from the Epidemic – Pandemic Impacts Inventory Survey [23].

2.3. Phase 1 sample

2.3.1. Phase 1 recruitment

Patients who were 18 years or older and had one or more visit(s) at one of two federally qualified health centers in Northern Arizona during the past 12 months were randomly sampled by each health center using simple random sampling. For the patients sampled, recruitment initially occurred by mail with an invitation letter sent containing information about the study. Patients at one of the two federally qualified health centers were also contacted via telephone one to four weeks after the recruitment letters were sent if they had not already called the study team about participating. All individuals enrolled in the study provided verbal informed consent.

2.3.2. Phase 1 participants

Thirty-three individuals were enrolled in the study's first phase, and 31 participants provided complete I-NVS data. Because the purpose of the study's first phase was to generate distractor response options for the C-NVS, individuals were recruited and enrolled in the study's first phase until no new incorrect responses, which could serve as possible distractor response options, were being given by phase one participants to the I-NVS. The mean participant age was 55 years. Thirty-two percent of phase one participants identified as American Indian or Alaska Native. Approximately 6 % of phase one participants identified as Hispanic. Over half (54.8%) of phase one participants had public health insurance. Table 2 displays all phase one participant demographic characteristics.

2.4. Phase 1 data collection

Data were collected and managed using REDCap (Research Computerized Data Capture) tools hosted at Northern Arizona University [24]. REDCap is a secure, web-based software platform designed to support data capture for research studies, providing (1) an intuitive interface for validated data capture; (2) audit trails for tracking data manipulation and export procedures; (3) automated export procedures for seamless data downloads to common statistical packages; and (4) procedures for data integration and interoperability with external sources. All five research team members involved in data collection for the study underwent training on collecting data in REDCap, including administering the NVS, for phases one and two.

The first study phase involved determining the C-NVS distractor response options based on the participant interviews conducted using the I-NVS. The I-NVS was verbally administered by telephone or videoconference to allow participants the ability to freely respond. Participants were timed by the research member administering the survey using the research team member's telephone timer to determine the average amount of time that the I-NVS took participants to complete. Responses from the first phase were compiled, and the research team met to collectively determine the distractor response options for the C-NVS according to the incorrect responses most frequently given to the I-NVS items. For example, in response to the first NVS item ("If you eat the entire container, how many calories will you eat?"), some phase one participants said 250 cal as their response (the correct response is 1000 cal). Because this was the most frequent incorrect response to this NVS item, it was used as a distractor response option for this item in the C-NVS. For NVS questions that did not have many incorrect responses given, such as question six, the study team included distractor options from the electronic NVS created by Mansfield and colleagues (2018). Participants received a \$20 payment for completing the study's first phase.

2.5. Phase 2 instruments

For the C-NVS, a Microsoft PowerPoint© with the nutrition label from the I-NVS utilized pre-recorded narration and programmed buttons to capture participants' answers. The first slide of the PowerPoint© was an instructional slide that walked participants through how to answer the C-NVS questions. As the participant proceeded through each slide, they would hear the narration of the questions from the original I-NVS and see the nutrition facts label and the available answer options for each question. Table 1 shows the questions with the response options that were utilized within the PowerPoint©. Participants would complete the C-NVS on their own via PowerPoint© or via Zoom's shared screen feature if they did not feel confident in the navigation of the PowerPoint©. If completed on their own, they would save their work and then send it back to the research team via email and the research team would enter their responses into REDCap. Only five participants elected to complete the C-NVS via Zoom with a research team member. This was typically because they did not have familiarity with REDCap and were uncomfortable completing the survey on their own. An example of a C-NVS item and the text of the pre-recorded narration for that item is shown in Fig. 2. Phase two participants additionally completed the same demographic and health questionnaire completed by participants in the study's first phase.

2.6. Phase 2 sample

2.6.1. Phase 2 recruitment

Phase two recruitment strategies, participant eligibility criteria, and informed consent procedures were identical to phase one of the study. To ensure we met the requisite sample size needed for phase two, we additionally recruited individuals through word-of-mouth referrals (snowball sampling) and by posting flyers in the community. Eighteen

Table 1

Computerized NVS (C-NVS) questions and response options.

Question (Same Questions were used for the I-NVS)	Response Options
1. If you eat the entire container, how many calories will you eat?	A. 250 Calories (Distractor) B. 500 Calories (Distractor) C. 750 Calories (Distractor) D. 1000 Calories E. I don't know
2. If you are allowed to eat 60 g of carbohydrates as a snack, how much ice cream could you have?	A. 1/2 cup (1 serving) B. 1 cup (2 servings) C. 2 cups (4 servings) (Distractor) D. I don't know
3. Your doctor advises you to reduce the amount of saturated fat in your diet. You usually have 42 g of saturated fat each day, which includes one serving of ice cream. If you stop eating ice cream, how many grams of saturated fat would you be consuming each day?	A. 0 g (Distractor) B. 9 g (Distractor) C. 33 g D. 39 g (Distractor) E. I don't know
4. If you usually eat 2500 cal in a day, what percentage of your daily value of calories will you be eating if you eat one serving?	A. 5% (Distractor) B. 10% C. 25% (Distractor) D. I don't know
5. Pretend that you are allergic to the following substances: Penicillin, peanuts, latex gloves, and bee stings. Is it safe for you to eat this ice cream?	A. Yes B. No C. I don't know
6. Why not?	A. Contains peanut or peanut oil B. Comes from bees (Distractor) C. Contains egg (Distractor) D. Contains macadamia nuts (Distractor) E. I don't know

Question 6 was only asked if participants responded "No" to question 5. Distractor is indicated for the incorrect response options for the C-NVS.

individuals who were enrolled in phase two of the study were recruited through word-of-mouth referrals and one individual who was enrolled in phase two of the study was recruited as a result of seeing a flyer.

2.6.2. Phase 2 sample size calculation

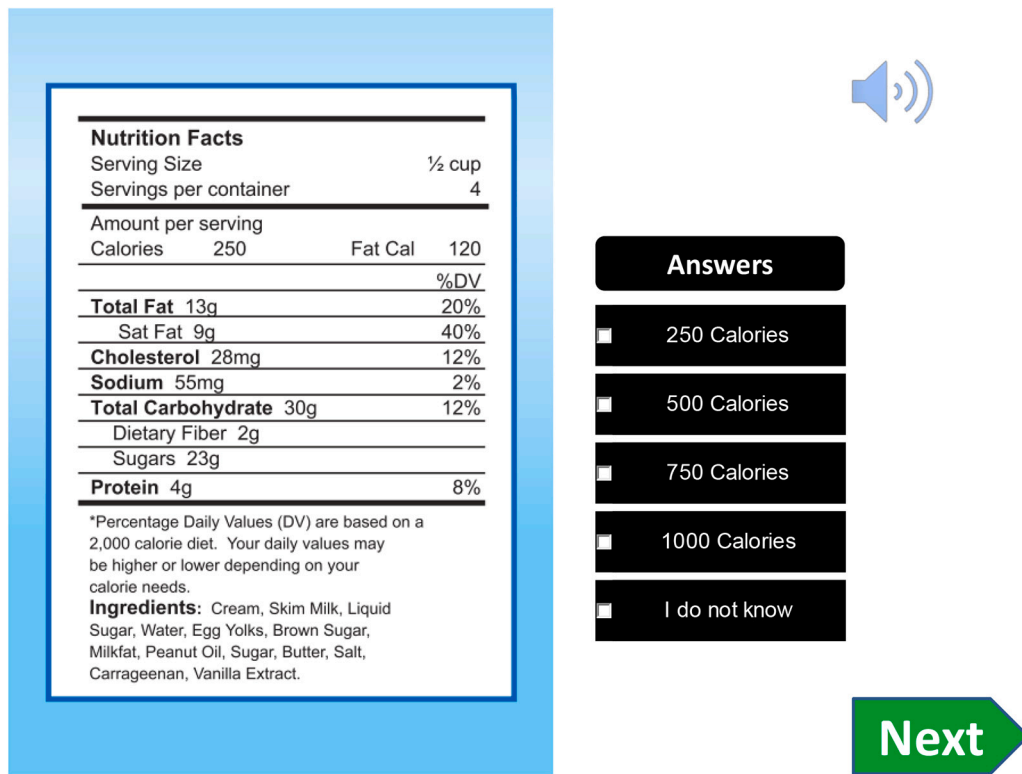
Based on prior research by Mansfield and colleagues (2018), a sample size calculation was conducted for a paired, two-sided *t*-test with an effect size (Cohen's *d*) of 0.35, $\alpha = 0.05$, and power > 0.90 [20]. This calculation showed that 90 participants would be needed to complete both the I-NVS and C-NVS. We aimed to recruit 110 participants, expecting that 20% of participants would not complete both the I-NVS and C-NVS in the study's second phase.

2.6.3. Phase two participants

Ninety-two individuals were enrolled in the study's second phase. Of the study's phase 2 participants, 89 had complete data for the I-NVS and C-NVS during period one (first NVS administration) of phase two. There were no statistically significant differences between participants assigned to the I-NVS or C-NVS in terms of their demographic characteristics. In phase two, the mean participant age was similar to phase one (phase 2 $M = 53.1$ years). Twenty percent of participants in phase two identified as American Indian or Alaska Native. Approximately 8 % of phase two participants identified as Hispanic or Latin. Nearly half (44.7%) of phase two participants had public health insurance. Table 2 displays all phase two participant demographic characteristics.

2.7. Phase 2 data collection

Similar to phase one, phase two data were collected and managed using REDCap (Research Computerized Data Capture) tools hosted at Northern Arizona University [24]. Simple random assignment was used to assign participants to first complete either the I-NVS or adapted C-



Nutrition Facts
 Serving Size ½ cup
 Servings per container 4

Amount per serving

Calories	250	Fat Cal	120
----------	-----	---------	-----

		%DV
Total Fat	13g	20%
Sat Fat	9g	40%
Cholesterol	28mg	12%
Sodium	55mg	2%
Total Carbohydrate	30g	12%
Dietary Fiber	2g	
Sugars	23g	
Protein	4g	8%

*Percentage Daily Values (DV) are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

Ingredients: Cream, Skim Milk, Liquid Sugar, Water, Egg Yolks, Brown Sugar, Milkfat, Peanut Oil, Sugar, Butter, Salt, Carrageenan, Vanilla Extract.

Answers

- 250 Calories
- 500 Calories
- 750 Calories
- 1000 Calories
- I do not know

Next

Voice Over Provided: “This Nutrition Facts label is on the back of the pint of ice cream. If you eat the entire container of ice cream how many calories will you eat?
 250 calories?
 500 calories?
 750 calories?
 1000 calories?
 I don’t know?”

Fig. 2. Example of computerized newest vital sign item with response options and pre-recorded narration as text.

Voice Over Provided: “This Nutrition Facts label is on the back of the pint of ice cream.

If you eat the entire container of ice cream how many calories will you eat?

250 cal?

500 cal?

750 cal?

1000 cal?

I don't know?”

This figure displays the first item of the computerized, self-administered Newest Vital Sign and the voice over provided with the item.

NVS. Upon completion of the first version of the NVS, a date two to nine weeks from that day was set to complete the second NVS version. The time to complete each NVS by participants was recorded in the same way that it was for phase one. Participants completing the C-NVS were instructed to do so on their own, without assistance. Participants who provided data for period one received \$20 and an additional \$25 for providing data in period two during the study's second phase.

2.8. Phase 2 analysis

Descriptive statistics such as means, standard deviations, frequencies, and relative frequencies were initially computed for all variables of interest and to characterize the study sample. We computed two-sample *t*-tests and chi-square tests to examine differences in the demographic characteristics of participants initially assigned to the C-NVS versus I-NVS in phase two. Per guidance on the appropriate analysis of data from crossover trials [25], we first assessed whether there was a carryover effect from period one to two by fitting a linear mixed effects random intercept regression model with participants' health literacy

score as the outcome variable and looking at period, treatment, and the interaction between period and treatment as the independent variables. Because the interaction effect between period and treatment was statistically significant ($p < .001$), we primarily examined period one data to determine differences in participants' scores on the I-NVS versus the C-NVS. We additionally conducted an exploratory, sensitivity analysis to examine the extent to which carryover effects varied by washout period length. If the carryover effect was not significant, we fit an exploratory linear mixed effects model within the subgroup with adequate washout period length, removing the interaction term to test for differences in NVS scores by version over both periods. We used an alpha value of 0.05 to determine statistical significance, and all hypothesis tests were two-sided. Data were analyzed with Stata 17 [26].

3. Results

3.1. Phase 1 results

Thirty-one participants completed the verbally administered I-NVS.

Table 2
Participant demographic characteristics.

	Phase 1 (n = 31)	Phase 2 (n = 89)
Age, years	<i>M (SD)</i>	
	55.3 (17.2)	53.1 (18.5)
Sex	<i>n (%)</i>	
Male	15 (48.4)	37 (41.6)
Female	16 (51.6)	52 (58.4)
Race	<i>n (%)</i>	
American Indian or Alaskan Native	10 (32.3)	18 (20.2)
Black or African American	0	1 (1.1)
Native Hawaiian or Other Pacific Islander	2 (6.5)	0
White or Caucasian	19 (61.3)	73 (82.0)
Ethnicity	<i>n (%)</i>	
Hispanic, Latino, or Spanish	2 (6.5)	7 (7.9)
Not Hispanic, Latino, or Spanish	28 (93.6)	82 (92.1)
Employed	<i>n (%)</i>	
Yes	19 (62.3)	43 (48.3)
No	12 (38.7)	46 (51.7)
Insurance Coverage	<i>n (%)</i>	
Private Insurance	14 (45.2)	40 (52.6)
Public Insurance	17 (54.8)	34 (44.7)
No Health Insurance	0	2 (2.3)
Recruited From	<i>n (%)</i>	
Federally Qualified Health Center	31 (100)	70 (37.8)
Word of Mouth or Flyer	0	19 (21.4)
Children ages <18 years	<i>n (%)</i>	
Yes	7 (22.6)	17 (19.1)
No	24 (77.4)	72 (80.9)
Marital Status	<i>n (%)</i>	
Married or Living with Partner	20 (64.5)	35 (39.3)
Divorced	6 (19.4)	8 (9.0)
Widowed	1 (3.2)	4 (4.5)
Single	4 (12.9)	40 (44.9)

Question one elicited seven different responses. Twenty-two participants answered correctly with “1000 cal.” One participant answered that they did not know. The incorrect responses included 250 cal ($n = 4$), 10,000 cal ($n = 1$), 900 cal ($n = 1$), 800 cal ($n = 1$), and 480 cal ($n = 1$). Question two revealed 11 different responses. Any participant who said one cup (two servings) or any amount up to one cup or half the container, was correct ($n = 26$). Two participants answered that they did not know. The incorrect responses included: 24% ($n = 1$), 150 g ($n = 1$), and 2 cups ($n = 1$). Question three had nine different responses. Fifteen participants answered correctly with 33 g. Three participants answered that they did not know. The incorrect responses included: 9 g ($n = 5$), 0 g ($n = 2$), 36 g ($n = 2$), 37 g ($n = 1$), 35 g ($n = 1$), 24 g ($n = 1$), and 2 g ($n = 1$). Question four had nine different responses. Twenty participants answered correctly with 10%. One participant answered that they did not know. The incorrect responses were as follows: 25% ($n = 4$), 250 g ($n = 1$), 250 cal ($n = 1$), 150 cal ($n = 1$), 6.25% ($n = 1$), 5% ($n = 1$), and 4.8% ($n = 1$). Question five required a “yes” or “no” response. Twenty participants answered correctly with a “no” response. Eleven participants answered incorrectly with a “yes” response. The final question of the I-NVS was only asked if patients answered question five correctly (“no”). Of the twenty participants who were asked question six, 19 participants answered correctly with “peanut oil”. The participant who answered incorrectly stated “honey.”

3.2. Phase 2 results

Table 3 displays the frequencies and percentages of total scores and health literacy categories for participants assigned to the I-NVS or C-NVS during period one. Among participants in period one, none who were assigned to the C-NVS had limited (likely or possible) health literacy while 10 (24.4%) who were assigned to the I-NVS had limited (likely or possible) health literacy. For those with limited health literacy in the I-NVS condition during period one, only two participants had likely limited health literacy (score = 1). Participants in the C-NVS condition

Table 3
Phase 2 NVS total scores and health literacy levels at first NVS administration (N = 89).

	Received the I-NVS First Total = 41 <i>n (%)</i>	Received the C-NVS First Total = 48 <i>n (%)</i>
NVS Total Score		
Score = 0	0	0
Score = 1	2 (4.9)	0
Score = 2	3 (7.3)	0
Score = 3	5 (12.2)	0
Score = 4	8 (19.5)	4 (8.3)
Score = 5	9 (22.0)	5 (10.4)
Score = 6	14 (34.2)	39 (81.3)
Health Literacy Level		
Likely Limited or Possible Limited		
Health Literacy	10 (24.4)	0
Adequate Healthy Literacy	31 (75.6)	48 (100)

NVS, Newest Vital Sign. For the NVS, a score of zero or one indicates likely limited health literacy, and a score of two or three indicates possible limited health literacy. An NVS score of 4–6 indicates adequate health literacy.

had significantly higher NVS scores ($M = 5.7, SD = 0.6$) than those in the I-NVS condition ($M = 4.5, SD = 1.5$) during period one (Table 4; $t(87) = 5.25, p < .001$). In addition, the amount of time to complete the C-NVS ($M = 6:43, SD = 2:49$) was significantly higher than the time taken to complete the I-NVS ($M = 3:21, SD = 1:23$) during period one ($t(86) = 7.28, p < .001$).

Results from the sensitivity analysis exploring carryover effects by washout period length showed that for those participants with a washout period >16 days (25th percentile), the carryover effect remained statistically significant ($p = .004$). We additionally examined the carryover effect in participants with a washout period length >24 days (the median) and found that the carryover effect among these participants was still statistically significant ($p = .028$). Last, we examined the carryover effect in participants with a washout period greater than the 33 days (75th percentile) and found that the carryover effect among these participants was not statistically significant ($p = .077$). Among the sample subgroup that had a washout period greater than the 75th percentile ($n = 20$), results showed that over both periods the NVS total did not differ significantly by version ($p = .14$, mean difference = -0.73), but that their I-NVS scores were still lower than their C-NVS scores.

4. Discussion and conclusion

To our knowledge, this was one of the first studies to adapt and test the reliability of the NVS for computerized, self-administration in the United States. Although we followed a similar protocol to other cross-over trial studies that have sought to adapt the NVS in other countries [13,20], we found a statistically significant carryover effect among participants in this trial. That is, participants' average NVS scores significantly improved between period one and period two, regardless of whether they were initially assigned to first complete the I-NVS or the C-NVS in phase two of this study. When we examined the data only from period one, we additionally found that participants assigned to the C-

Table 4
Phase 2 NVS mean scores at first NVS administration (N = 89).

	Mean Score (SD)	Mean Time (SD)
Interviewer Administration ($n = 41$)	4.5 (1.5)	3:21 (1:23)
Computerized, Self-Administration ($n = 48$)	5.7 (0.6)	6:43 (2:49)

Independent, two-sided *t*-test results for NVS scores by version were as follows: $t(87) = 5.25, p < .001$. Independent, two-sided *t*-test results for time it took participants to complete the NVS by version were as follows: $t(86) = 7.28, p < .001$. NVS, Newest Vital Sign; SD, standard deviation.

NVS scored significantly higher than participants assigned to the I-NVS. The C-NVS also took participants significantly longer, slightly more than double the time, to complete than the I-NVS.

Because learning likely contributed to the carryover effect found, we explored the effect that washout period length had. When limiting the sample to those participants who had a washout period longer than 16 days (25th percentile) or 24 days (median), we still found a statistically significant carryover effect. It was only when we limited the sample to those participants who had a washout period longer than 33 days (75th percentile) that the carryover effect was no longer statistically significant, suggesting that a washout period of at least five rather than two weeks may be needed in future crossover trials similar in nature. Even so, among this subgroup, their I-NVS scores were still lower than their C-NVS scores. Because of this, it may be necessary to change the response option format of computerized, self-administered NVS assessments so it more closely matches the I-NVS. In other words, having multiple choice response options rather than one response option entered by the individual may limit response variability and lead to ceiling effects in NVS scores.

4.1. Limitations

This study had limitations. Because of COVID-19 pandemic-related safety concerns, we administered the I-NVS and C-NVS by telephone or videoconference instead of in-person as was originally planned. Though we still verbally administered the I-NVS, as would be done in-person, the psychometric properties of the NVS administered verbally by telephone or videoconference among U.S. adults have not been well-established [13]. Similarly, we included voice over narration for the C-NVS; however, the other study that adapted and tested this type of NVS assessment did so in-person rather than by videoconference [20]. Along these lines, self-selection bias was likely an issue due to recruitment coinciding with the pandemic. That is, individuals who were better resourced and less burdened by the pandemic may have been more likely to enroll in this study, particularly during phase two that began approximately six months into the pandemic [27]. Nevertheless, we did have approximately 31% and 20% of participants identify as American Indian or Alaska Native in phase one and phase two, respectively, which we believe is a strength of this study and is fairly representative of the racial/ethnic composition of adults in Northern Arizona [28]. In addition, development of the distractor response options based on the incorrect responses of individuals recruited during the first six months of the pandemic may have not posed enough difficulty for the possibly better-resourced participants recruited for phase two of this study. Indeed, the mean NVS scores of participants in phase two were higher than those found in the original study of the NVS by Weiss and colleagues (2005), as well as the latter study by Mansfield and colleagues (2018) [14,20]. Although participants who completed the C-NVS in phase two were asked to do so without assistance, they may have sought help online or from other individuals. Another limitation of our measures was that we did not ask participants about their level of educational attainment, which may be correlated with their health literacy level. Last, the washout period for phase two participants varied widely (two to nine weeks) in part due to the pandemic and contributing to carryover effects. Nevertheless, based on our sensitivity analysis, we found that a washout period of more than one month (> 33 days) may reduce the risk of carryover effects in similar future research.

4.2. Innovation

This study is innovative insofar as it provides a starting point for the further development of a reliable computerized and self-administered version of the NVS health literacy screener that can be integrated into broader healthcare delivery and research innovations. Because health literacy is a determinant of health [5] [29], a reliable computerized and self-administered health literacy screening tool for U.S. adults is needed

particularly in the context of more widespread telehealth, electronic health record, and patient portal information systems. Moreover, capturing health literacy information from more individuals in this manner will enable researchers to understand healthcare inequities and the drivers of these inequities to a greater extent.

This work can also be used to inform innovative mobile health (mHealth) applications with health literacy assessment embedded for the purposes of tailoring the application and/or understanding the effectiveness for certain population segments with different health literacy levels. As concluded by Welch and colleagues (2011), over a decade ago, health literacy assessment using a tool like the NVS is often feasible in clinical practice; however, clear guidelines do not exist on how this information should be used by clinicians in their education, counseling, and general communication with patients and their families [16]. Therefore, determining ways that information from the NVS and other health literacy assessments can be efficiently linked to health record systems and facilitate clinician prompts, as well as increased usage of universal precaution techniques (e.g., pictograms, teach-back) could further hold great value for practice [30].

4.3. Conclusion

This study was one of the first to adapt and examine the reliability of the NVS as a computerized, self-administered tool among U.S. adults. Due to a significant carryover effect, only data from period one of the phase two crossover trial were examined showing higher average scores on the C-NVS compared to the I-NVS, as well as longer completion times for the C-NVS versus the I-NVS. Future crossover trials may need to employ a longer washout period of five or more weeks to ensure that learning does not lead to carryover effects. Establishing a reliable C-NVS tool is important to advancing population health, given the increase in telehealth practice, other healthcare innovations, and the need to assess health literacy in research.

CRediT authorship contribution statement

Olivia J. Lindly: Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Software, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Taylor A. Wahl:** Writing – review & editing, Writing – original draft, Supervision, Resources, Project administration, Methodology, Investigation, Data curation. **Noa M. Stotts:** Writing – review & editing, Writing – original draft, Methodology, Formal analysis, Data curation. **Amy M. Shui:** Writing – review & editing, Writing – original draft, Methodology, Formal analysis.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

Olivia Lindly reports financial support was provided by Southwest Health Equity Research Collaborative at Northern Arizona University (U54MD012388), which is sponsored by the National Institute on Minority Health and Health Disparities.

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References

- [1] Berkman N, Davis T, McCormack L. Health literacy: what is it? *J Health Commun* 2010;15(sup2):9–19. <https://doi.org/10.1080/10810730.2010.499985>.
- [2] K. Sørensen et al., “Health literacy and public health: a systematic review and integration of definitions and models,” *BMC Public Health*, vol. 12, p. 80, Jan. 2012, doi: <https://doi.org/10.1186/1471-2458-12-80>.
- [3] Nutbeam D. Defining, measuring and improving health literacy. *Health Eval Promot* 2015;42(4):450–6. <https://doi.org/10.7143/jhep.42.450>.
- [4] Nutbeam D. The evolving concept of health literacy. *Soc Sci Med* 2008;67(12):2072–8. <https://doi.org/10.1016/j.socscimed.2008.09.050>.
- [5] Nutbeam D, Lloyd JE. Understanding and responding to health literacy as a social determinant of health. *Annu Rev Public Health* 2021;42(1):159–73. <https://doi.org/10.1146/annurev-publhealth-090419-102529>.
- [6] Kutner M, Greenberg E, Jin Y, Paulsen C. *The health literacy of America’s adults: Results from the 2003 National Assessment of adult literacy (NCES 2006–483)*. Washington, DC: U.S. Department of Education, National Center for Education Statistics; 2006.
- [7] Cheng C, Beauchamp A, Elsworth GR, Osborne RH. Applying the electronic health literacy lens: systematic review of electronic health interventions targeted at socially disadvantaged groups. *J Med Internet Res* 2020;22(8). <https://doi.org/10.2196/18476>. pp. e18476–e18476.
- [8] Berkman N, Sheridan S, Donahue K, Halpern D, Crotty K. Low health literacy and health outcomes: an updated systematic review. *Ann Intern Med* 2011;155:97–107. <https://doi.org/10.1059/0003-4819-155-2-201107190-00005>.
- [9] *World Health Organization. Digital Health. 2018.*
- [10] M. Mackert, A. Mabry-Flynn, S. Champlin, E. E. Donovan, and K. Pounders, “Health literacy and health information technology adoption: the potential for a new digital divide,” *J Med Internet Res*, vol. 18, no. 10, pp. e264–e264, Oct. 2016, doi: <https://doi.org/10.2196/jmir.6349>.
- [11] Magnani JW, et al. Health literacy and cardiovascular disease: fundamental relevance to primary and secondary prevention: a scientific statement from the American Heart Association. *Circulation* 2018;138(2):e48–74. <https://doi.org/10.1161/CIR.0000000000000579>.
- [12] Shealy KM, Threatt TB. Utilization of the newest vital sign (NVS) in practice in the United States. *Health Commun* 2016;31(6):679–87. <https://doi.org/10.1080/10410236.2014.990079>.
- [13] Weiss BD. The newest vital sign: frequently asked questions. *Health Lit Res Pract* 2018;2(3):e125–7. <https://doi.org/10.3928/24748307-20180530-02>.
- [14] Weiss BD, et al. Quick assessment of literacy in primary care: the newest vital sign. *Ann Fam Med* 2005;3(6):514–22. <https://doi.org/10.1370/afm.405>.
- [15] Haun J, Valerio M, McCormack L, Sorensen K, Paasche-Orlow M. Health literacy measurement: an inventory and descriptive summary of 51 instruments. *J Health Commun* 2014;19. <https://doi.org/10.1080/10810730.2014.936571>.
- [16] Welch VL, VanGeest JB, Caskey R. Time, costs, and clinical utilization of screening for health literacy: a case study using the newest vital sign (NVS) instrument. *J Am Board Fam Med* 2011;24(3):281. <https://doi.org/10.3122/jabfm.2011.03.100212>.
- [17] Xue J, et al. Validation of a newly adapted Chinese version of the newest vital sign instrument. *PLoS One* 2018;13(1):e0190721. <https://doi.org/10.1371/journal.pone.0190721>.
- [18] Capecchi L, Guazzini A, Lorini C, Santomauro F, Bonaccorsi G. The first italian validation of the most widespread health literacy assessment tool: the newest vital sign. *Epidemiol Prev* 2015;39(4):124–8.
- [19] Rowlands G, Khazaeezadeh N, Oteng-Ntim E, Seed P, Barr S, Weiss BD. Development and validation of a measure of health literacy in the UK: the newest vital sign. *BMC Public Health* 2013;13(1):116. <https://doi.org/10.1186/1471-2458-13-116>.
- [20] Mansfield ED, Wahba R, Gillis DE, Weiss BD, L’Abbé M. Canadian adaptation of the newest vital sign©, a health literacy assessment tool. *Public Health Nutr* 2018;21(11):2038–45. <https://doi.org/10.1017/S1368980018000253>.
- [21] Russell AM, et al. Test-retest reliability of the newest vital sign health literacy instrument: in-person and remote administration. *Patient Educ Couns* 2019;102(4):749–52. <https://doi.org/10.1016/j.pec.2018.11.016>.
- [22] Ware JE, Sherbourne CD. The MOS 36-item short-form health survey (SF-36): I. Conceptual framework and item selection. *Med Care* 1992;30(6):473–83.
- [23] Grasso DJ, Briggs-Gowan MJ, Ford JD, Carter AS. *Epidemic – Pandemic Impacts Inventory (EPII)*. 2020. p. 6.
- [24] 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. *J Biomed Inform* 2009;42(2):377–81. <https://doi.org/10.1016/j.jbi.2008.08.010>.
- [25] Wellek S, Blettner M. On the proper use of the crossover design in clinical trials: part 18 of a series on evaluation of scientific publications. *Dtsch Arztebl Int* 2012;109(15):276–81. <https://doi.org/10.3238/arztebl.2012.0276>.
- [26] *StataCorp. Stata statistical software: Release 17*. College Station, TX: StataCorp LLC; 2021.
- [27] Hlatshwako TG, et al. Online health survey research during COVID-19. *Lancet Digit Health* 2021;3(2):e76–7. [https://doi.org/10.1016/S2589-7500\(21\)00002-9](https://doi.org/10.1016/S2589-7500(21)00002-9).
- [28] US Census Bureau. 2010 Census Population and Housing Tables (CPH-T-6.): American Indian and Alaska Native population by tribe in the United States and Puerto Rico: 2010. Accessed: Dec. 17, 2019. [Online]. Available: <https://www.census.gov/population/www/cen2010/cph-t/cph-t-6.html>.
- [29] World Health Organization. Health literacy development for the prevention and control of noncommunicable diseases: Volume 1. Overview. Geneva. Accessed: Dec. 04, 2023. [Online]. Available: <https://www.who.int/publications/i/item/9789240055339>; 2022.
- [30] Connelley R, Turner T. Health literacy and child health outcomes promoting effective health communication strategies to improve quality of care. In: *Springer briefs in public health*. Cham, Switzerland: Springer; 2017.