Supermarket and Web-Based Intervention Targeting Nutrition

"SuperWIN"

A Randomized, Parallel Assignment, Active Control, Efficacy Trial

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Cincinnati Children's

Disclosures

Dr. Dylan L. Steen discloses the following relationships:

- Consultant: Sanofi
- CEO/Cofounder: High Enroll, LLC

SuperWIN received partial funding and other support (e.g., clinic space and equipment, study dietitians, and purchasing data) from The Kroger Company.

Background

2021 Dietary Guidance to Improve Cardiovascular Health: A Scientific Statement From the American Heart Association

Alice H. Lichtenstein, DSc, FAHA, Chair*; Lawrence J. Appel, MD, MPH, FAHA, Vice Chair*; Maya Vadiveloo, PhD, RD, FAHA, Vice Chair; Frank B. Hu, MD, PhD, FAHA; Penny M. Kris-Etherton, PhD, RD, FAHA; Casey M. Rebholz, PhD, MS, MNSP, MPH, FAHA; Frank M. Sacks, MD, FAHA; Anne N. Thorndike, MD, MPH, FAHA; Linda Van Horn, PhD, RD, FAHA; Judith Wylie-Rosett, PhD, RD, FAHA; on behalf of the American Heart Association Council on Lifestyle and Cardiometabolic Health; Council on Arteriosclerosis, Thrombosis and Vascular Biology; Council on Cardiovascular Radiology and Intervention; Council on Clinical Cardiology; and Stroke Council

- Guidelines continue to recommend heart-healthy dietary patterns, like the Dietary Approaches to Stop Hypertension (DASH) Diet.

- Public adherence to healthy dietary patterns remains low.

Innovation is needed….

versus

Background

AHA SCIENCE ADVISORY

Innovation to Create a Healthy and Sustainable Food System

A Science Advisory From the American Heart Association

2019 Advisory calls for "immediate action" for more sponsored research with retailers (e.g. supermarkets), research on online shopping to promote healthier purchases, and research on nutrition and health applications.

In a broader context, delivery of healthcare beyond hospitals and clinics in needed. Key elements:
- Access, Convenience, Engagement, and Effectiveness
- Testing Platforms and Rigorous Studies
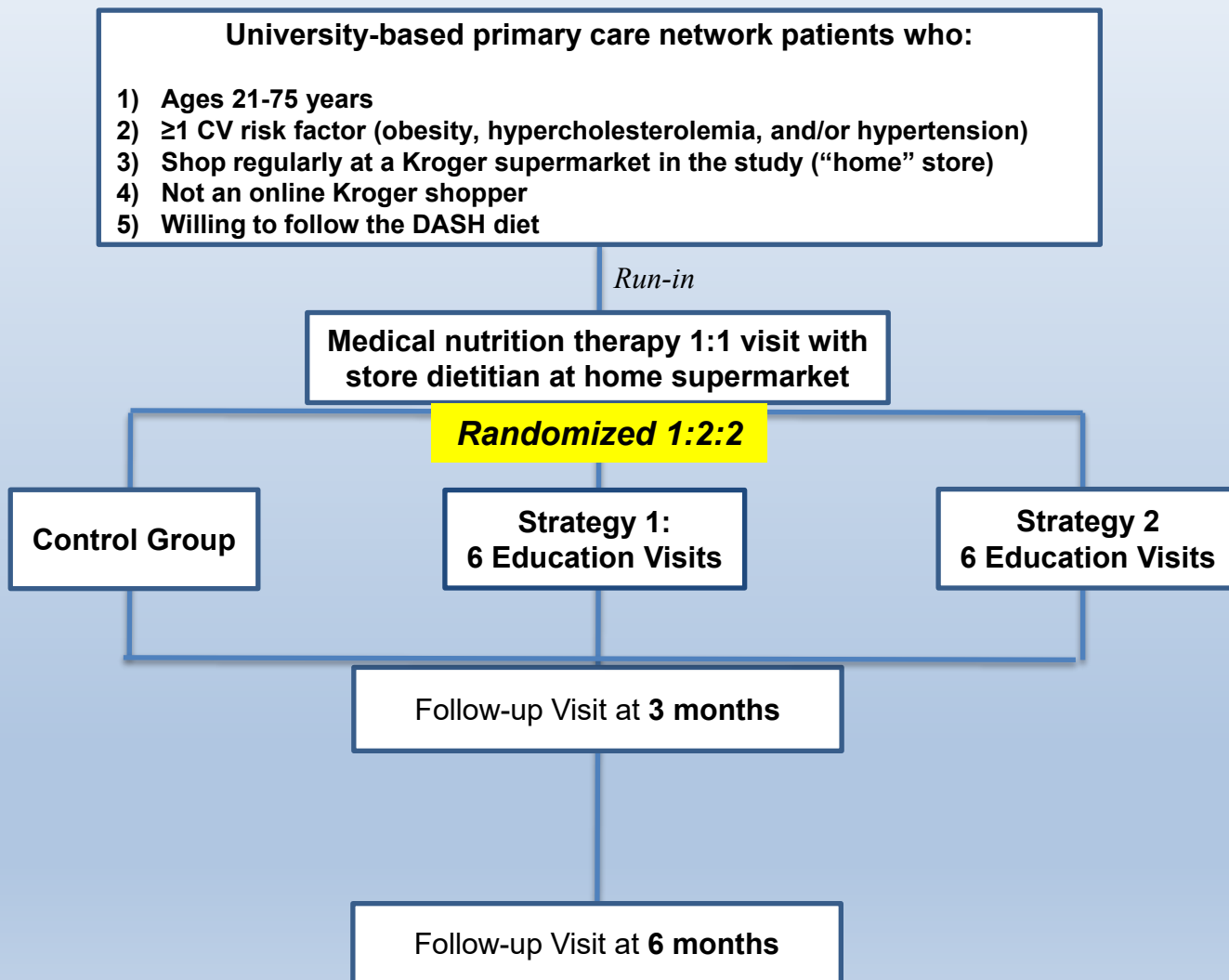- New Industry Partners
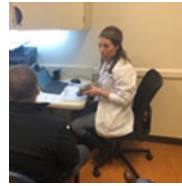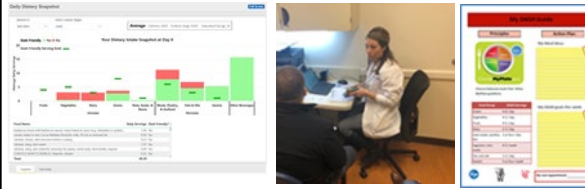
Hospitals

Clinics

SuperWIN Study Design

University-based primary care network patients who:

1) Ages 21-75 years
2) ≥1 CV risk factor (obesity, hypercholesterolemia, and/or hypertension)
3) Shop regularly at a Kroger supermarket in the study ("home" store)
4) Not an online Kroger shopper
5) Willing to follow the DASH diet

Run-in

Medical nutrition therapy 1:1 visit with store dietitian at home supermarket

Randomized 1:2:2

Control Group

**Strategy 1:
6 Education Visits**

**Strategy 2
6 Education Visits**

Follow-up Visit at **3 months**

Follow-up Visit at **6 months**

Couch SC, Helsley RN, Siegel FU, et al, Steen DL, AHJ, 2022

Dietary Education
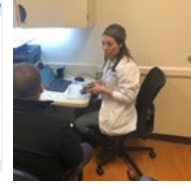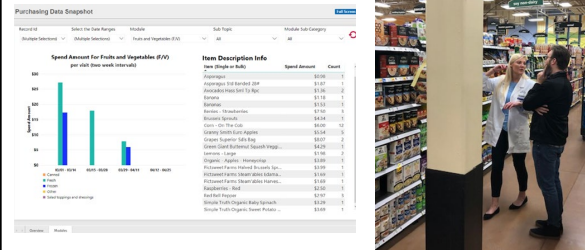
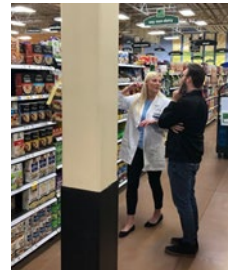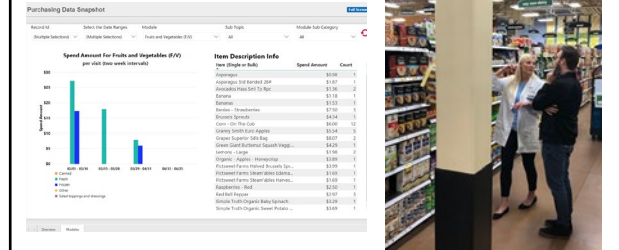| Control	Strategy 1	Strategy 2
Medical Nutrition Therapy (30min)	Medical Nutrition Therapy (30min)	Medical Nutrition Therapy (30min)
Randomized 1:2:2		
	Purchasing data-guided, "in the aisles" education (6 sessions- 60min each)	Purchasing data-guided, "in the aisles" education (6 sessions- 60min each)
		Stepwise introduction and training on technologies (e.g., online shopping)

Dietary Education

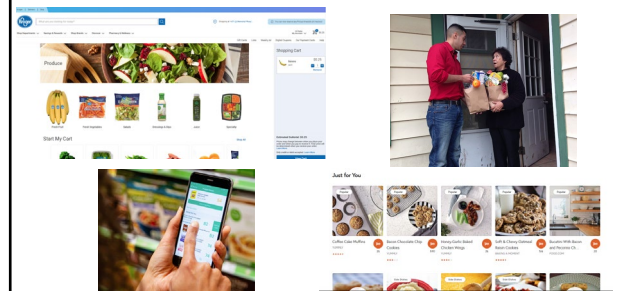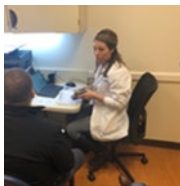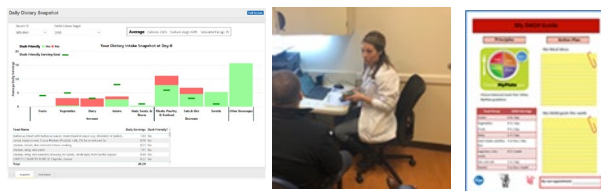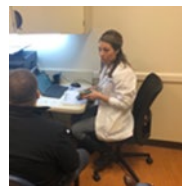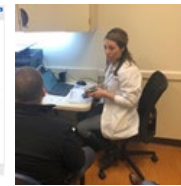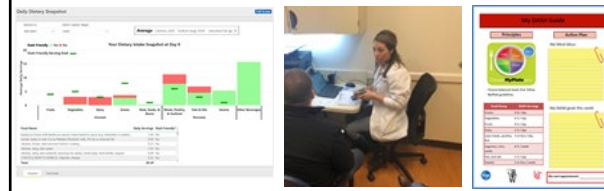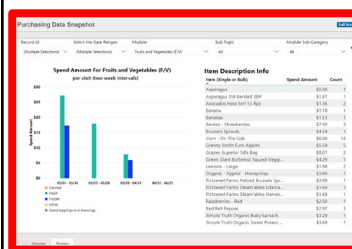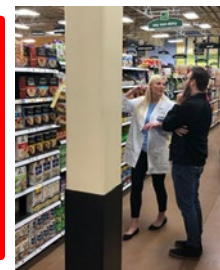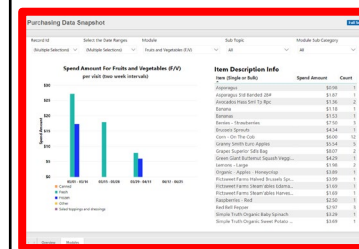| Control	Strategy 1	Strategy 2
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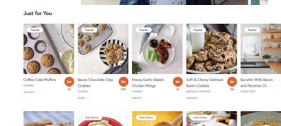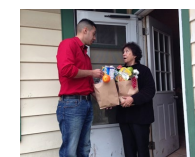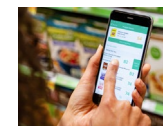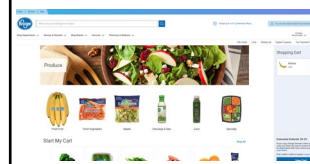
Individualized Purchase Review
(Both Strategies 1 and 2)

Example
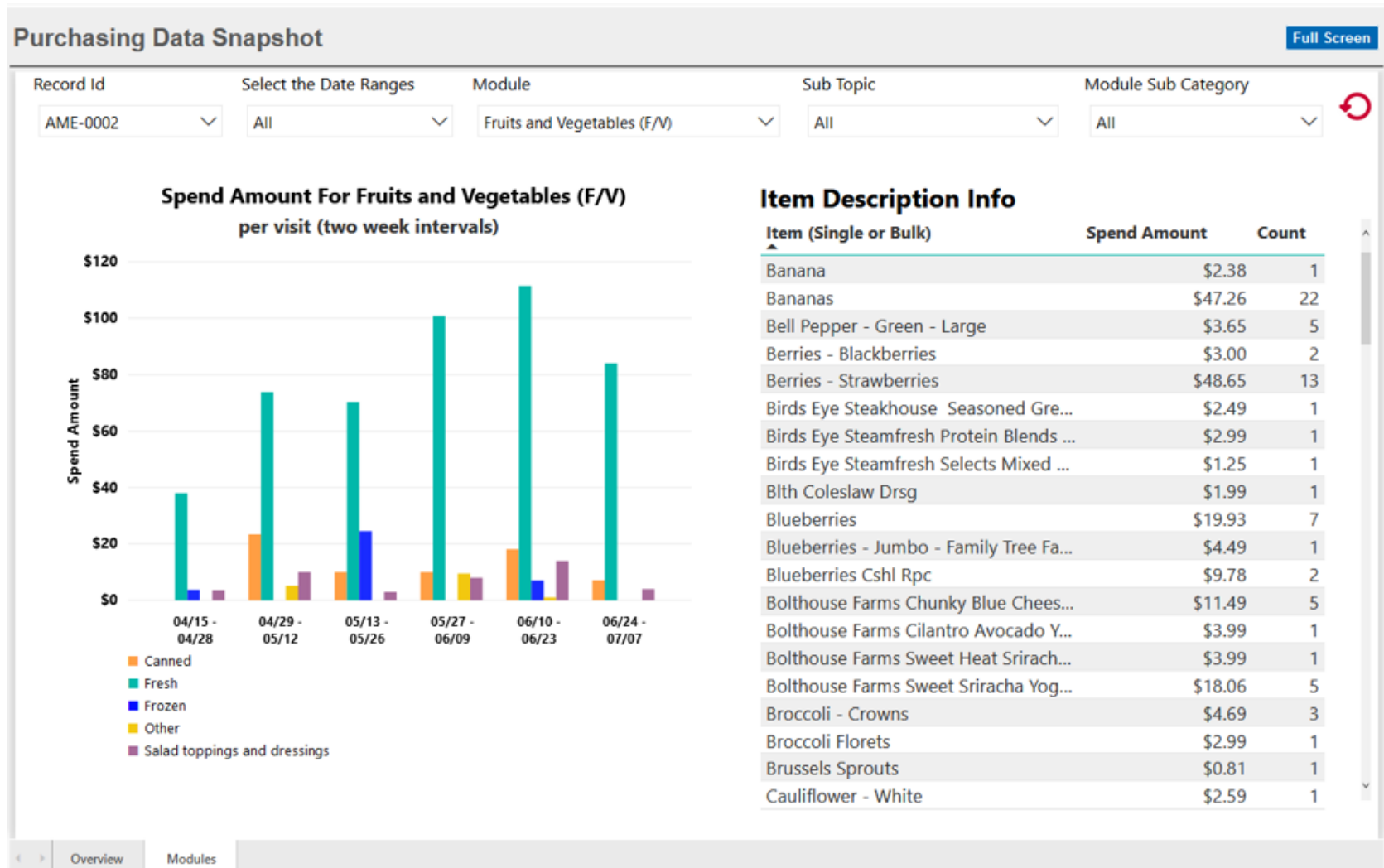
Hypothesis Testing

△ DASH score (baseline to 3 months):

1) Strategies 1 and 2 versus Control

if p <0.05, then

2) Strategy 2 versus Strategy 1

DASH score:

- Range 0-90.

- Higher is better.

- Calculated from raw dietary intake data.

SuperWIN Trial Profile

Screened by Phone and Entered Run-in (N=486)

Excluded During Run-in or In-Person Randomization Visit (N=219)
Top 5 reported reasons:
- Did not complete phone calls, surveys, and/or attend first study visit (N=44)
- Undefined participant choice (N=33)
- Did not meet BP, BMI, and/or other biometric eligibility criteria (N=30)
- Unwilling or unable to modify diet (N=23)
- Unwilling to be randomized to any of the 3 study groups (N=14)

Strategy 1 (N=107)

COVID Withdrawal (N=7)

Included in Analysis (N=100)

Strategy 2 (N=109)

COVID Withdrawal (N=8)

Included in Analysis (N=101)

Control (N=51)

COVID Withdrawal (N=5)

Included in Analysis (N=46)

Baseline Characteristics

Variable	Control (n=46)	Strategy 1 (n=100)	Strategy 2 (n=101)
Age - mean- yr	56.2 (11.4)	57.0 (10.7)	55.8 (11.0)
Female- N (%)	32 (69.6%)	68 (68.0%)	71 (70.3%)
Race- N (%)			
Black or African American	6 (13.0%)	23 (23.0%)	22 (21.8%)
White	36 (78.3%)	73 (73.0%)	72 (71.3%)
Married/Living with Partner- N (%)	30 (65.2%)	70 (70.0%)	60 (59.4%)
Employed full-time (40 or more hours per week)- N (%)	25 (54.3%)	60 (60.0%)	47 (46.5%)
Graduate degree - N (%)	14 (30.4%)	27 (27.0%)	32 (31.7%)
Annual household income $125,000 or more – N (%)	13 (28.3%)	37 (37.0%)	40 (39.6%)
Children living in the household – mean (SD)	0.33 (0.67)	0.43 (0.89)	0.42 (0.89)
Major challenge in sticking to a diet (top 3 reasons)- N (%)			
Busy schedule/Not enough time	6 (13.0%)	32 (32.0%)	18 (17.8%)
Diet too repetitive or strict	10 (21.7%)	16 (16.0%)	29 (28.7%)
Lack of cooking or meal planning skills	11 (23.9%)	18 (18.0%)	25 (24.8%)
Prior myocardial infarction or stroke - N (%)	5 (10.9%)	7 (7.0%)	5 (5.0%)
Treated with hypertension meds - N (%)	31 (67.4%)	77 (77.0%)	73 (72.3%)
Blood pressure- mean (SD) - mm Hg			
Systolic	130.0 (16.4)	129.8 (18.6)	128.4 (14.9)
Diastolic	85.7 (11.1)	82.1 (11.6)	83.4 (10.4)
Body mass index- mean (SD) - kg/m^2	33.8 (7.2)	34.0 (7.9)	32.9 (8.1)
Treatment with hypercholesterolemia medications - N (%)	20 (43.5%)	47 (47.0%)	37 (36.6%)
Non-HDL cholesterol – mean (SD)- mg/dl	107.0 (32.5)	115.2 (37.0)	112.5 (35.3)
Triglycerides[b]- mean (SD)- mg/dl	170.5 (84.1)	173.0 (95.3)	159.2 (96.2)

Impact of COVID-19 on SuperWIN

Strategy 1 and 2 Visit Completion Frequency:
Before and During the COVID-19 Pandemic

Results at 3 months

First Hypothesis:

Does a 6-Session Educational Intervention, Guided by Purchasing Data, Conducted in the Store by a RD Increase DASH Score (adherence)?

Overall Cohort	Control (N=46)	Strategy 1 (N=100)	Strategy 2 (N=101)	Strategies 1 and 2 vs. Control	P-value
At baseline	45.2 (42.0, 48.4)	44.4 (42.0, 46.8)	43.2 (40.8, 45.5)		
At 3 months	51.0 (47.6, 54.4)	53.1 (50.6, 55.5)	55.6 (53.2, 58.1)		
DASH Change	*5.8 (2.5, 9.2)*	*8.6 (6.4, 10.8)*	*12.4 (10.3, 14.6)*	*4.7 (0.9, 8.5)*	*0.02*
Data are reported as least-squares means (95%CI).					

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At baseline	45.2 (42.0, 48.4)	44.4 (42.0, 46.8)	43.2 (40.8, 45.5)		
At 3 months	51.0 (47.6, 54.4)	53.1 (50.6, 55.5)	55.6 (53.2, 58.1)		
DASH Change	*5.8 (2.5, 9.2)*	*8.6 (6.4, 10.8)*	*12.4 (10.3, 14.6)*	*4.7 (0.9, 8.5)*	*0.02*
Data are reported as least-squares mean (95%CI).					

Pre-COVID Subgroup*	(N=22)	(N=45)	(N=42)		
At baseline	45.1 (39.9, 50.4)	42.6 (38.6, 46.6)	42.7 (38.4, 47.0)		
At 3 months	48.9 (43.6, 54.2)	53.2 (49.2, 57.2)	56.4 (52.1, 60.7)		
DASH Change	*3.8 (-0.7, 8.2)*	*10.6 (7.5, 13.7)*	*13.7 (10.5, 16.9)*	*8.3 (3.4, 13.3)*	*0.001*

*Prespecified prior to database lock

Results at 3 months

Second Hypothesis:
Does the addition of online shopping and other technologies increase DASH Score (adherence)?

Overall Cohort	Control (N=46)	Strategy 1 (N=100)	Strategy 2 (N=101)	Strategy 2 vs. 1	P-value
At baseline	45.2 (42.0, 48.4)	44.4 (42.0, 46.8)	43.2 (40.8, 45.5)		
At 3 months	51.0 (47.6, 54.4)	53.1 (50.6, 55.5)	55.6 (53.2, 58.1)		
DASH Change	*5.8 (2.5, 9.2)*	*8.6 (6.4, 10.8)*	*12.4 (10.3, 14.6)*	*3.8 (0.8, 6.9)*	*0.01*
Data are reported as least-squares mean (95%CI).					

Results at 3 months

Second Hypothesis:
Does the addition of online shopping and other technologies increase DASH Score (adherence)?

Overall Cohort	Control (N=46)	Strategy 1 (N=100)	Strategy 2 (N=101)	Strategy 2 vs. 1	P-value
At baseline	45.2 (42.0, 48.4)	44.4 (42.0, 46.8)	43.2 (40.8, 45.5)		
At 3 months	51.0 (47.6, 54.4)	53.1 (50.6, 55.5)	55.6 (53.2, 58.1)		
DASH Change	**5.8** **(2.5, 9.2)**	**8.6** **(6.4, 10.8)**	**12.4** **(10.3, 14.6)**	*3.8* *(0.8, 6.9)*	*0.01*
Data are reported as least-squares mean (95%CI).					
Pre-COVID Subgroup	(N=22)	(N=45)	(N=42)		
At baseline	45.1 (39.9, 50.4)	42.6 (38.6, 46.6)	42.7 (38.4, 47.0)		
At 3 months	48.9 (43.6, 54.2)	53.2 (49.2, 57.2)	56.4 (52.1, 60.7)		
DASH Change	*3.8* *(-0.7, 8.2)*	*10.6* *(7.5, 13.7)*	*13.7* *(10.5, 16.9)*	*3.1* *(-1.3, 7.6)*	*0.17*

Secondary Results: DASH at 6 months

Does increased DASH adherence persist at 6 months?

Overall Cohort	Control (n=46)	Strategy 1 (n=100)	Strategy 2 (n=101)	Strategies 1 and 2 vs. Control	P-value	Strategy 2 vs. 1	P-value
At baseline	45.2 (42.0, 48.4)	44.4 (42.0, 46.8)	43.2 (40.8, 45.5)				
At 6 months	49.6 (46.3, 52.8)	51.0 (48.6, 53.5)	51.6 (49.2, 54.0)				
DASH Change	*4.4 (0.6, 8.1)*	*6.6 (4.0, 9.2)*	*8.4 (5.9, 11.0)*	*3.1 (-1.0, 7.3)*	*0.14*	*1.8 (-1.9, 5.5)*	*0.34*
Data are reported as least-squares mean (95%CI).							

Secondary Results: DASH at 6 months

Does increased DASH adherence persist at 6 months?

Overall Cohort	Control (n=46)	Strategy 1 (n=100)	Strategy 2 (n=101)	Strategies 1 and 2 vs. Control	P-value	Strategy 2 vs. 1	P-value
At baseline	45.2 (42.0, 48.4)	44.4 (42.0, 46.8)	43.2 (40.8, 45.5)				
At 6 months	49.6 (46.3, 52.8)	51.0 (48.6, 53.5)	51.6 (49.2, 54.0)				
DASH Change	*4.4 (0.6, 8.1)*	*6.6 (4.0, 9.2)*	*8.4 (5.9, 11.0)*	*3.1 (-1.0, 7.3)*	*0.14*	*1.8 (-1.9, 5.5)*	*0.34*
Data are reported as least-squares mean (95%CI).							

Pre-COVID Subgroup	(N=22)	(N=45)	(N=42)				
At baseline	45.1 (39.9, 50.4)	42.6 (38.6, 46.6)	42.7 (38.4, 47.0)				
At 6 months	49.8 (44.5, 55.1)	51.9 (47.8, 55.9)	53.1 (48.8, 57.5)				
DASH Change	**4.7 (-0.6, 10.0)**	**9.3 (5.5, 13.0)**	**10.4 (6.6, 14.3)**	*5.1 (-0.8, 11.1)*	*0.09*	*1.2 (-4.2, 6.6)*	*0.67*

Secondary Results: Biometrics at 3 months

Did changes in dietary impact improve other health measures?

	Control (n=46)	Strategy 1 (n=100)	Strategy 2 (n=101)	Strategies 1 and 2 vs. Control	P-value	Strategy 2 vs. 1	P-value
Systolic BP – mmHg							
At baseline	125.9 (119.1, 132.7)	125.6 (119.7, 131.5)	125.0 (119.0, 130.9)				
At 3 months	123.2 (116.2, 130.1)	118.9 (113.0, 124.9)	119.2 (113.3, 125.2)				
Change	***-2.8 (-7.1, 1.6)***	***-6.6 (-9.8, -3.4)***	***-5.7 (-8.7, -2.8)***	***-3.4 (-8.4, 1.6)***	***0.18***	***0.9 (-3.2, 5.0)***	***0.66***
Diastolic BP – mmHg							
At baseline	82.8 (78.2, 87.5)	79.2 (75.1, 83.2)	81.4 (77.3, 85.6)				
At 3 months	80.2 (75.5, 84.9)	76.7 (72.6, 80.9)	79.4 (75.1, 83.7)				
Change	***-2.6 (-5.5, 0.2)***	***-2.4 (-4.2, -0.6)***	***-2.0 (-3.9, -0.1)***	***0.4 (-2.7, 3.6)***	***0.79***	***0.4 (-2.1, 2.9)***	***0.76***
BMI - kg/m^2							
At baseline	37.9 (34.2, 41.7)	38.1 (34.8, 41.4)	37.1 (33.7, 40.5)				
At 3 months	37.7 (33.9, 41.4)	37.7 (34.3, 41.0)	36.3 (32.9, 39.8)				
Change	***-0.2 (-0.6, 0.1)***	***-0.4 (-0.7, -0.2)***	***-0.8 (-1.0, -0.5)***	***-0.4 (-0.8, 0.0)***	***0.08***	***-0.3 (-0.7, 0.0)***	***0.06***

Data are reported as least-squares mean (95%CI).

Summary

- SuperWIN demonstrated the efficacy of dietary interventions harnessing the store's physical environment, RDs, and purchasing data.

- SuperWIN demonstrated the efficacy of the online shopping tools and applications being rapidly adopted by the public.

- Pre-COVID metrics demonstrated near-perfect visit attendance suggesting the participants' experiences were optimized by using the stores at which they routinely shopped.

And finally…

- SuperWIN was made possible by a unique-to-date research collaboration between a diverse academic team and a large retailer.

- A new era of research collaborations between academia and retailers is needed to extend the reach of healthcare beyond traditional systems and to address many of the most pressing public health challenges.