Artificially intelligent text messaging technology to improve American Heart Association's Life's Essential 8 Health Behaviors

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Background

- At least 50% of the US population will develop two or more chronic medical conditions by age 45, with the prevalence increasing to >80% for those age 65 years and older.
- Patients experiencing health disparities are disproportionately affected by these CV conditions and suffer greater consequences from these conditions.
- The Nudge Study leveraged principles of behavioral economics to nudge people via text message to increase medication adherence.
  - 9,501 patients were enrolled across the three sites: Denver Health, Veteran's Affairs Eastern Colorado, and UCHealth.

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Study aims

To study effects of texts & an AI chatbot on control of AHA's Life's Essential 8 (LE8) lifestyle factors

Study objectives:

- **Aim 1 (Y1)**
  - Develop the data infrastructure
  - Create a text message and chatbot library through one-on-one interviews and focus group sessions with patients.
- **Aim 2 (Y1)**
  - Conduct a small, randomized pilot, enrolling 30 patients from each health care system.
- **Aim 3 (Y2-5)**
  - Conduct a pragmatic, patient-level randomized intervention.
  - The primary outcome will be change in LE8 health score.
    - Secondary outcomes include individual components of the LE8 lifestyle factors, Framingham risk score, self-efficacy, medication adherence, clinical outcomes (such as CV-related hospitalizations), and healthcare utilization.
- **Aim 4 (Y2-5)**
  - Evaluate the effectiveness of the intervention.

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Study setting

Denver Health

- Integrated HCS, safety net for the City and County of Denver, with 9 FQHCs
- ~ 60% of the patients seen are members of racial/ethnic minority groups and > 70% live below 200% of the federal poverty level
- Serves ~208,000 individuals/year; 15% of patients having hypertension, 6% hyperlipidemia, and 9% diabetes.

Salud Family Health Centers

- FQHC, 13 clinics
- Medical, dental, pharmacy and behavioral health care services, focused on low-income, medically underserved populations as well as the migrant and seasonal farmworker population.
- Serves ~85,000 patients/year, with a third of patients having chronic conditions

STRIDE Community Health Centers

- FQHC, 18 clinics
- Provides integrated services to low-income, uninsured, and underserved populations residing outside the City and County of Denver.
- Serves ~47,000 patients/year. High burden of CV disease, with 64.2% hypertension, 81%, hyperlipidemia, and 29.7% diabetes.

Patient population

Study inclusion

English/Spanish speaking primary care patients with:

1. A diagnosis of ≥1 of the following CV risk factors: hypertension, diabetes or hyperlipidemia, and
2. The risk factor is at poor or intermediate health levels as defined by LE8 (e.g., BP≥140/90 mm Hg), and
3. The patient exhibits poor adherence to prescribed medication to treat the CV risk factor as defined by a delay of ≥7 days in refilling the medication in the past 6 months.

Patients without an address and cell phone on file; patients <18 or ≥89 years of age; in hos pice or palliative care; enrolled in another clinical trial if denoted in the EHR will be excluded.

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Patient identification process

- Patients meeting inclusion criteria will be identified through EHR. Staff will mail each patient an opt out packet via USPS.
  - The packet included an introductory letter signed by the Site PI, "FAQ" about the study, an opt out form, a self-addressed stamped envelope
    - Patients that return opt out consent forms or have packets returned by USPS will be removed from the study
    - If patients do not return the opt out form within 2 weeks, they are considered enrolled and will be randomized to a study arm
- All enrolled patients have a secondary opportunity to opt out of the intervention by texting STOP after the first text message
- The Nudge study utilized this approach and we have consistently observed opt-out rates at or below 15% across our three health system partners.

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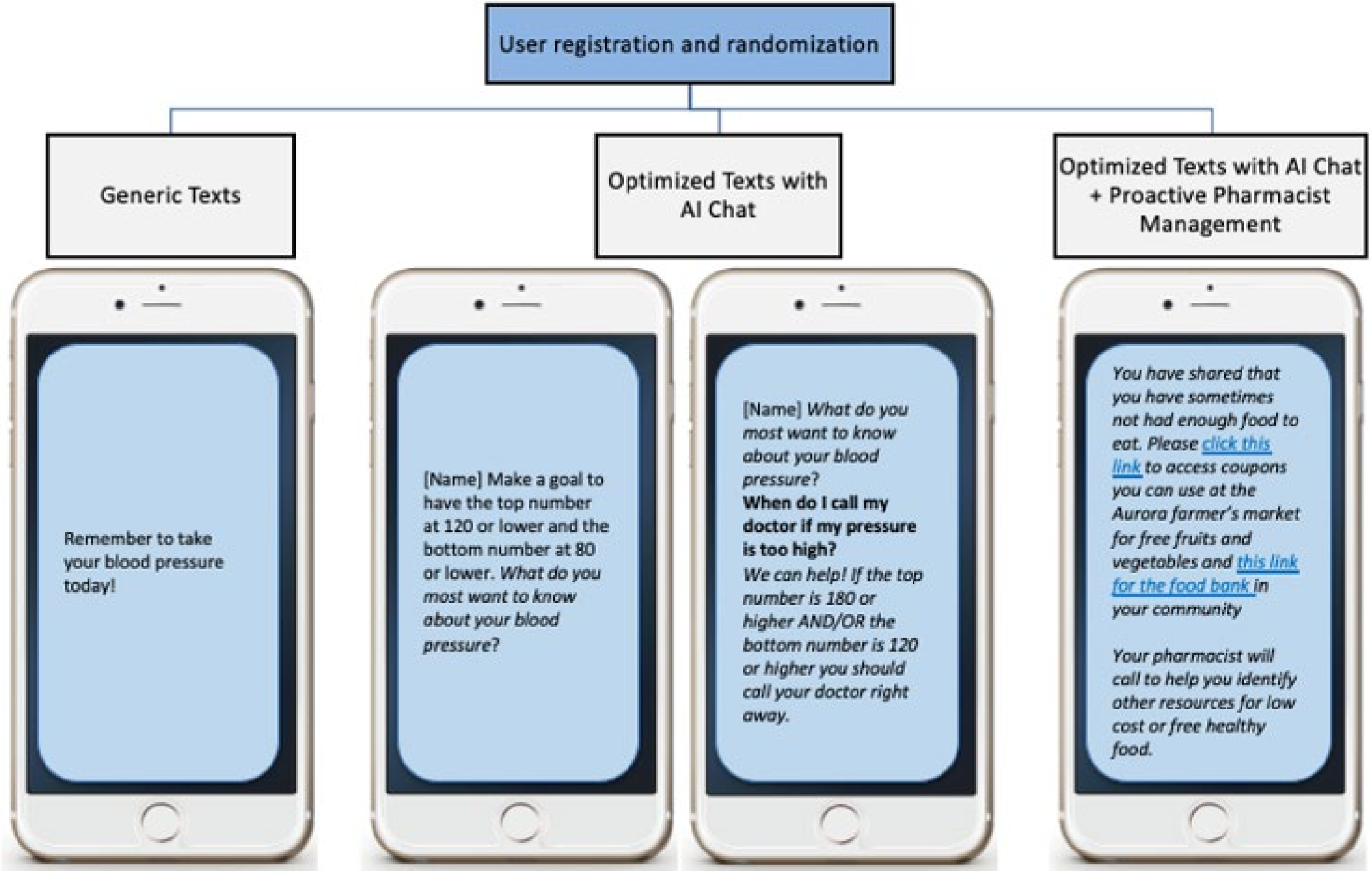
Study Arms


User registration and randomization
Generic Texts
Optimized Texts with AI Chat
Optimized Texts with AI Chat + Proactive Pharmacist Management
Remember to take your blood pressure today!
[Name] Make a goal to have the top number at 120 or lower and the bottom number at 80 or lower. What do you most want to know about your blood pressure?
[Name] What do you most want to know about your blood pressure?
When do I call my doctor if my pressure is too high?
We can help! If the top number is 180 or higher AND/OR the bottom number is 120 or higher you should call your doctor right away.
You have shared that you have sometimes not had enough food to eat. Please click this link to access coupons you can use at the Aurora farmer's market for free fruits and vegetables and this link for the food bank in your community
Your pharmacist will call to help you identify other resources for low cost or free healthy food.

Developing the message library

Nof1 interviews

10 patients per HCS offer feedback on messages and chatbots and identify resources to help overcome barriers to improved lifestyle factors.

Focus groups

6-8 providers per HCS and an additional group of community advocates to further refine content for the library of messages.

Nominal groups

6-8 patients per HCS meet to reach consensus on the text and chat bot message content, including readability, navigability, engagement and persuasiveness using a star rating system (0-5 stars).

Quantitative data: Sources for primary & secondary outcomes

Source	Data collected
EHR	Blood pressure, total cholesterol, blood sugar, weight
	ED visits and hospitalizations
	Routine clinical visits
EHR or Pharmacy records	Pharmacy refill data
Self-reported by patients via survey	Physical activity, health diet pattern, sleep, and smoking

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Community and Expert Advisory Panel

We are convening an Advisory Panel comprised of 1 patient, 1 provider or individual from leadership from each health care system, as well as 3-4 representatives of key community organizations.

Advisory Panel objectives:

- Identify resources available locally to address social determinants of health which we will be able to incorporate into our educational material for patients (e.g., food banks, transportation vouchers, access to goods such as medical supplies, access to information on financial assistance programs).
- Review ongoing text message development and adaptations needed to ensure sociocultural and linguistic relevance.
- Explore ethical considerations of using behavioral nudges and discuss strategies to address them to assure that the trial will be ethical from the perspectives of multiple stakeholders.

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Current status

- Obtaining IRB and regulatory approval
- Convening an Advisory Panel
- Building the technological infrastructure between sites
- Message library development
- Preparing for the study pilot

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Barriers Scorecard

Barrier	Level of Difficulty*				
	1	2	3	4	5
Enrollment and engagement of patients/subjects			X		
Engagement of clinicians and health systems				X	
Data collection and merging datasets		X **Data collection**	X Merging datasets		
Regulatory issues (IRBs and consent)		X			
Stability of control intervention	X				
Implementing/delivering intervention across healthcare organizations				X	

1 = little difficulty; 5 = extreme difficulty

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UG3 Data Sharing plan

Our current data sharing plan (summarized)

All data will be released in accordance with standard data sharing policies and procedures. Data will be made available to the broader scientific community after study results are published in peer-reviewed journals. Data will first be redacted to strip all direct and indirect identifiers utilizing the Safe Harbor method. Due to the small numbers of participants in the qualitative portions of our study, we will only include composite qualitative data.

Anticipated obstacles

While we hope to release data in a timely manner, the release of de-identified data from sites less familiar with research may be delayed.

What data you are planning to share from your project (individual-level data, group-level data, specific variables/outcomes, etc.)?

- Group-level qualitative data
- Technical and practical knowledge regarding the creation and implementation of the intervention
- Individual-level data will be shared in accordance with institutional policies and regulations
- Metadata (data collection instruments, protocols, message libraries, and data dictionaries)

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Questions

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