Personalized Patient Data and Behavioral Nudges to Improve Adherence to Chronic Cardiovascular Medications (The Nudge Study)

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Study objectives

- Conduct a pragmatic patient-level randomized intervention across 3 HCS to improve adherence to chronic CV medications.
  - Primary outcome: Medication adherence defined by the proportion of days covered (PDC) using pharmacy refill data.
  - Secondary outcomes:
    - Intermediate clinical measures (e.g., BP control)
    - CV clinical events (e.g., hospitalizations)
    - Healthcare utilization
    - Costs

Patient population

- Adult patients diagnosed with ≥ 1 condition of interest and prescribed ≥ 1 medication of interest

Condition	Classes of medications
Hypertension	Beta-blockers (B-blockers), Calcium Channel Blocker (CCB), Angiotensin converting enzyme inihibitors (ACEi), Angiotensin Receptor Blockers (ARB), Thiazide diuretic
Hyperlipidemia	HMG CoA reductase inhibitor (Statins)
Diabetes	Alpha-glucosidase inhibitors, Biguanides, DPP-4 inhibitors, Sodium glucose transport inhibitor, Meglitinides, Sulfonylureas, Thiazolidinediones, and statins
Coronary artery disease	PGY-2 inhibitor (Clopidogrel, Ticagrelor, Prasugrel, Ticlopidine), B-blockers, ACEi or ARB and statins
Atrial fibrillation	Direct oral anticoagulants, B-blockers, CCB

- English or Spanish-speaking

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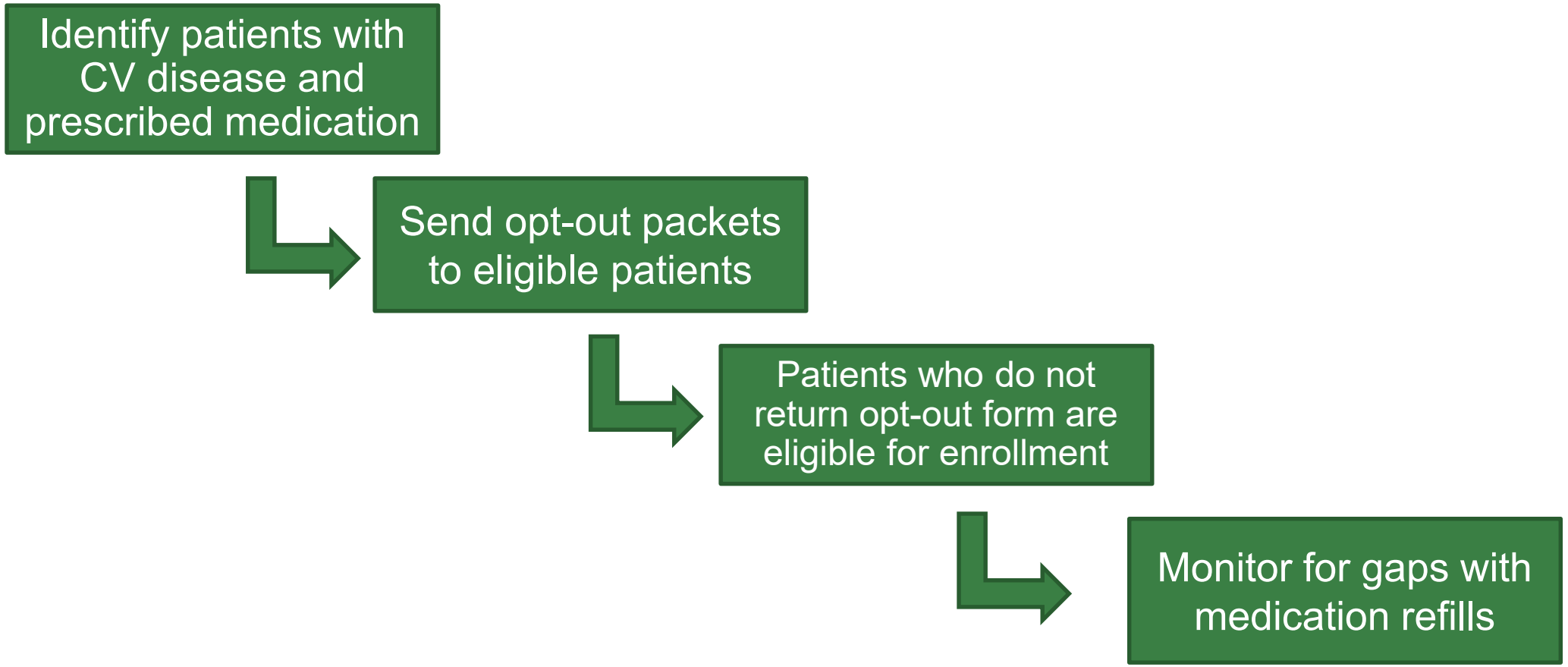
Opt-out study design



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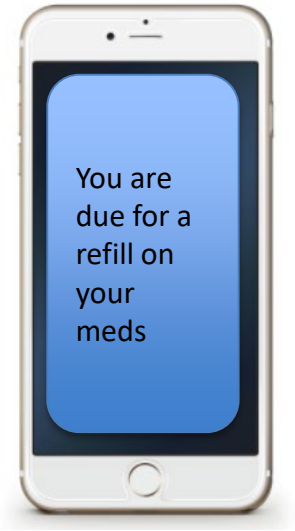
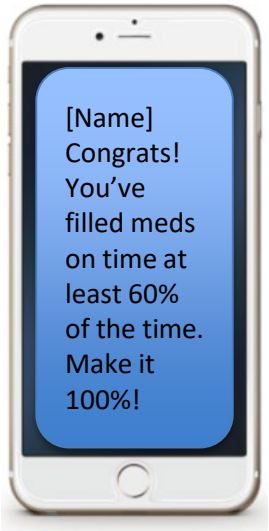
Intervention arms

7 day gap between medication refills

- Usual Care
- Generic Texts



- Optimized Texts



- Optimized Texts + AI Chat Bot

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Table 1: UG3 Milestone

CORE	UG3 MILESTONE
Stakeholder	Identify a stakeholder to serve on the steering committee and on each of the project cores
	Identify stakeholder to serve on Collaboratory Stakeholder Engagement and Healthcare Systems Interactions cores
	Review text messages for cultural appropriateness
	Assess ethical issues of behavioral nudge messages
	Review study protocol for patient acceptability
Data and Statistics	Draft data element definitions/specifications in collaboration with Collaboratory investigators and NIH staff
	Draft data management manual
	Test methods for subject identification
	Test data collection procedures
	Test data transfer procedures
	Test randomization procedures
	Assess statistical power and finalize analytic plan
Administrative	Obtain IRB approval at all sites
	Establish DUAs with all sites
	Collaborate with NIH Collaboratory Regulatory/Ethics core
	Obtain DSMB approval
	Establish sub-contracts
	Finalize budget
	Develop and test opt-out and consent procedures
	Submit IRB modifications following pilot study
Mobile Health	Develop text, IA Chart bot, and IVR components
	Translate messages to Spanish
	Test and refine messages in series of N of 1 trials
	Test text, IA chart bot, and IVR components in pilot study
Dissemination and Implementation	Draft implementation evaluation plan
	Draft cost analysis plan
	Test implementation and cost analysis procedures in pilot study
	Develop dissemination plan
Steering Committee	Draft study protocol
	Draft intervention manual
	Identify staff to participate in NIH Collaboratory cores
	Oversee pilot study at 3 clinical sites
	Revise study protocol and intervention manual following pilot study

Nudge study year 1 lessons learned

- Timeframe is short (~10 months to complete pilot)
- Contracting takes longer than anticipated
- Collaborative partnerships are key
- Teamwork and experienced project manager is key
- Pre-work prior to grant start date is helpful