Challenges in Health Literacy Research: Missouri Health Literacy and Diabetes Initiative

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Background

- Missouri Foundation For Health – American College of Physicians Foundation Partnership (2007)

- First large scale evaluation of ACP health literacy initiatives

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Study Objective

- To compare the fidelity and effectiveness of two viable approaches to the delivery of the ACPF Diabetes Guide and self-care strategy among patients receiving care in safety net clinics.

- Compare two common models
  - Re-deploy existing resources (no cost)
  - Outsource to external entity (at cost)

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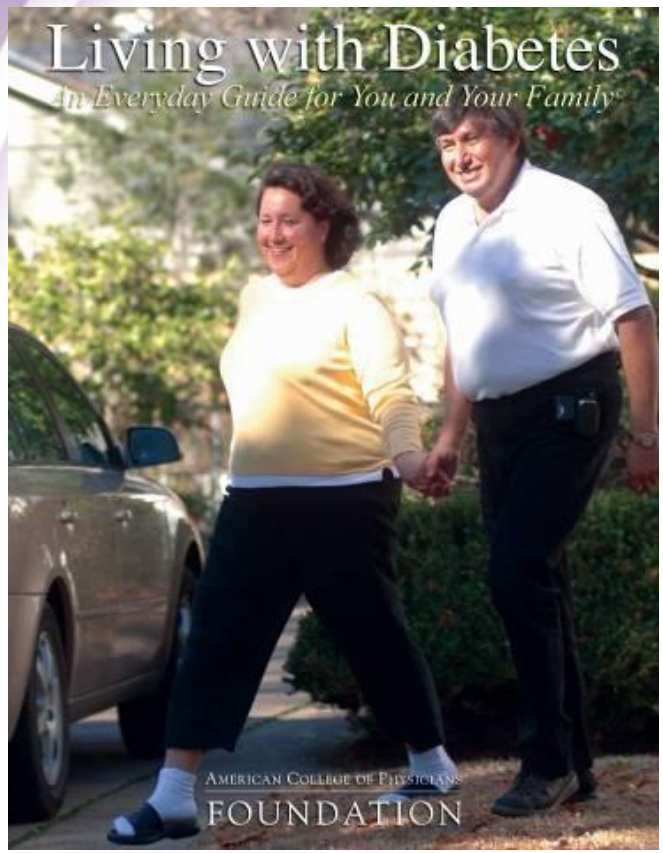
ACPF Diabetes Guide



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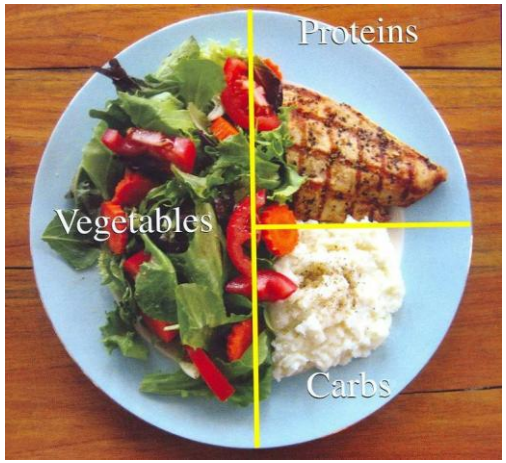
Living with Diabetes' Guide

- Developed in 2006
- Brief, plain language messages
- Patient narratives and testimonials
- Supportive pictures, graphics
- Non-linear approach to education



Focused on Doing

- Utilized **action plans** to help patients self-manage diabetes

What is an action plan?
A *specific, easy-to-achieve, short-term* activity a ***patient chooses*** in order to reach a long-term goal.

– **Long-term goal**: lose weight

– **Action plan**: I will walk around the block after dinner 3 times during the next 7 days.

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Methods: Overview

Design:	Clinic-randomized trial
Site:	3 Missouri sites (urban, mid-size, rural)
	3 clinics per site (N=9)
Inclusion:	Diabetes dx, > 25 old, English or Spanish speaking, HbA1c > 6.5%
Intervention:	**CARVE-IN** vs. **CARVE-OUT** vs. control
Outcomes:	**Fidelity**
	- receipt of services, satisfaction
	Effectiveness
	- diabetes knowledge, self-efficacy, health behaviors (i.e. physical activity, diet, medication adherence), HBA1C, cholesterol and blood pressure

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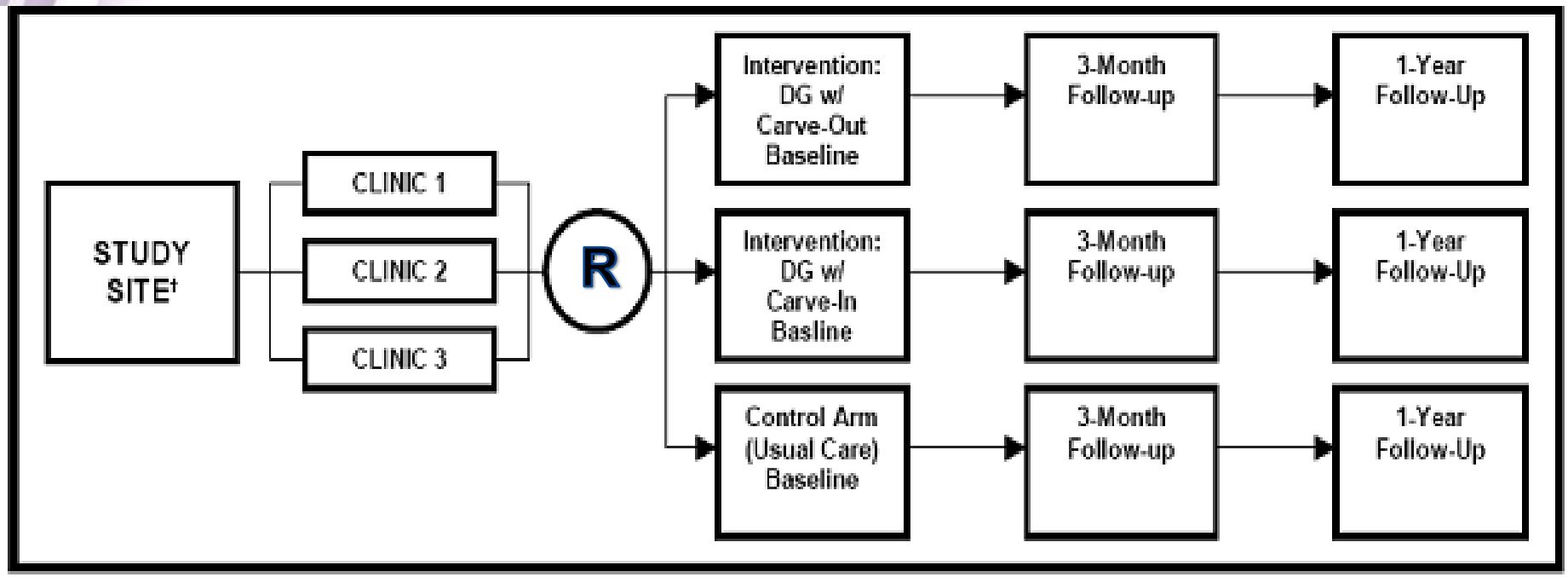
Study Design



DG = Diabetes Guide; R = Randomization; †Reflective of only one of the three sites in the study

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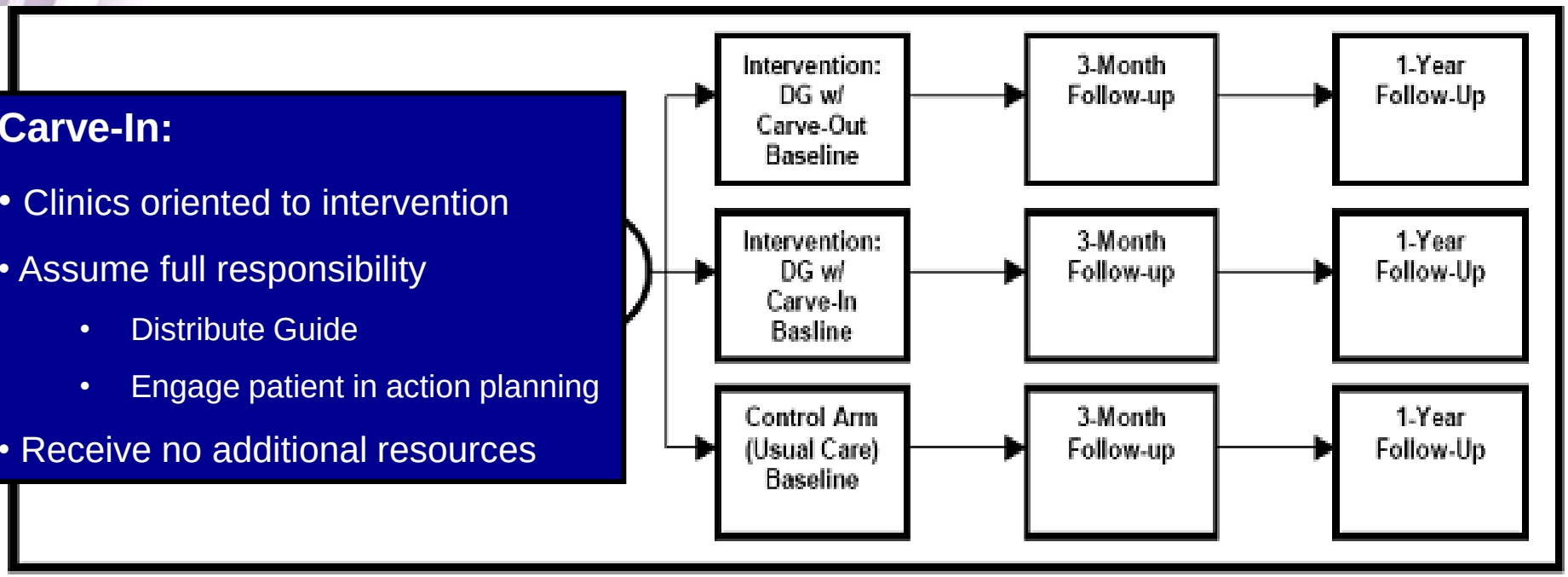
Study Design

Carve-In:

- Clinics oriented to intervention
- Assume full responsibility
  - Distribute Guide
  - Engage patient in action planning
- Receive no additional resources



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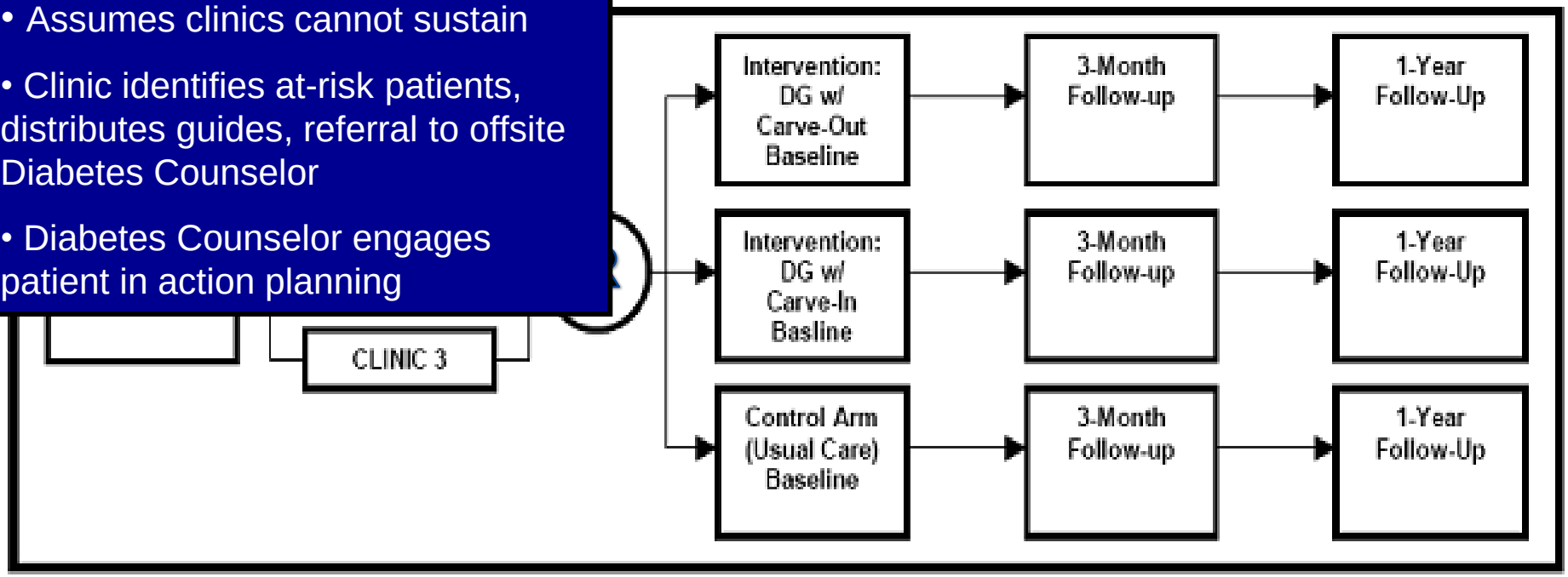
Study Design

Carve-Out:

- Assumes clinics cannot sustain
- Clinic identifies at-risk patients, distributes guides, referral to offsite Diabetes Counselor
- Diabetes Counselor engages patient in action planning



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Implementation Protocol

- Identify patients in need
- Distribute and introduce the Guide
- Briefly counsel and set an action plan
- Record information and track patients
- Follow-up on action plan progress
- Repeat process at a minimum number of intervals
- Trouble-shoot along the way

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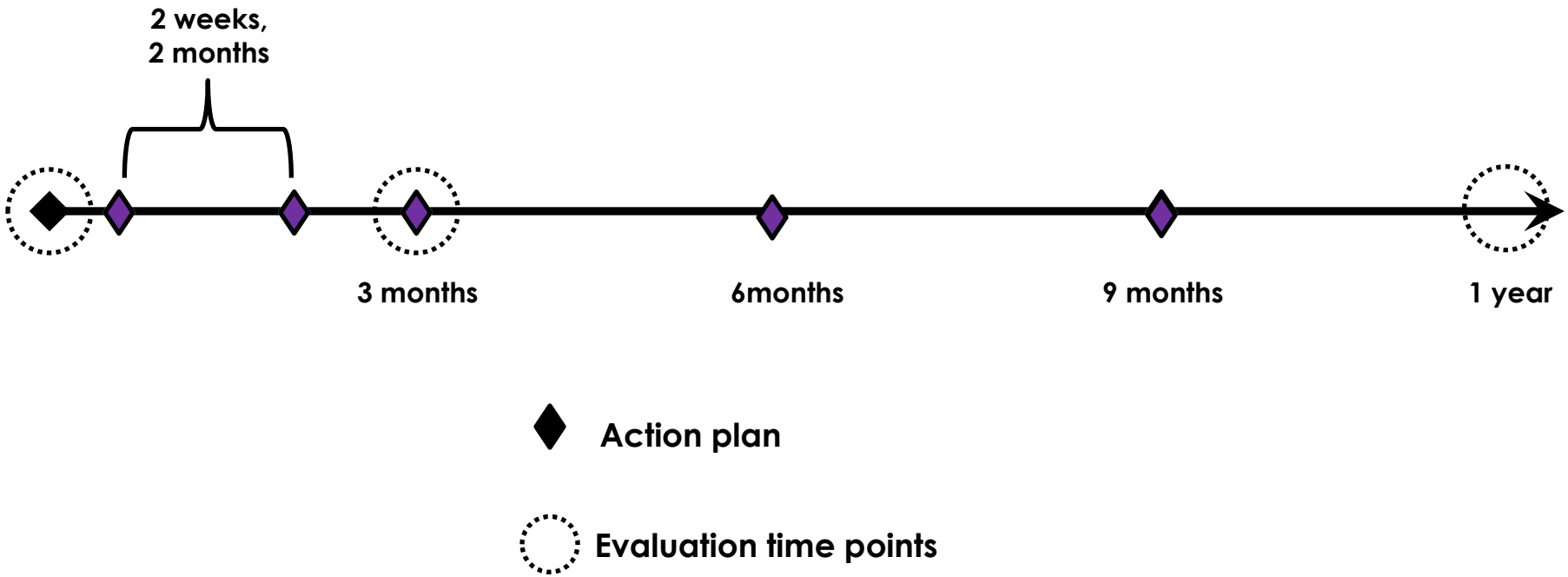
Intervention Touch-points



Results

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Intervention Fidelity

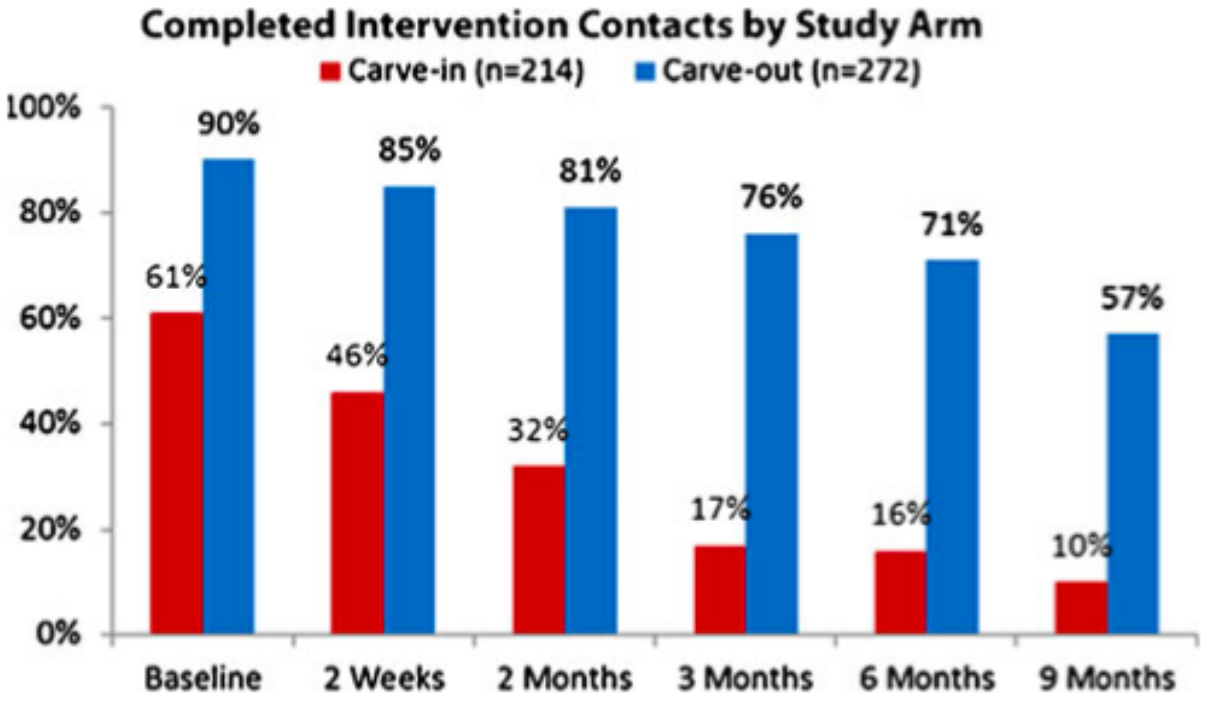

Figure 1. Completed intervention contacts by study arm.

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Intervention Fidelity

Table 3. Intervention Fidelity and Patient Satisfaction with Carve-In and Carve-Out Approaches

Outcome		Carve-In	Carve-Out	*P* Value
Number of Total Contacts	M (SD)	1.7 (2.0)	4.3 (2.2)	< 0.001
	β (95 % CI)	—	2.60 (1.11–4.09)	0.001
Over the past 12 months, has a nurse/diabetes educator *spoken with you about creating an action plan or setting a goal* to improve your diabetes?	%	45.7	78.7	< 0.001
	OR (95 % CI)	—	4.73 (2.37–9.45)	< 0.001
Over the past 12 months, did you *set an action plan or a goal* with the nurse/diabetes educator who contacted you?	%	31.7	68.4	< 0.001
	OR (95 % CI)	—	5.21 (2.13–12.78)	< 0.001
On a scale of 1 to 10, one being not helpful at all and 10 being extremely helpful, *how helpful was this process* of setting action plans to improving your health?	M (SD)	3.5 (0.3)	6.6 (0.3)	< 0.001
	β (95 % CI)	—	3.04 (2.20–3.89)	< 0.001
If given the opportunity, *would you like to continue* to set action plans with the nurse/diabetes educator?	%	62.2	75.5	0.02
	OR (95 % CI)	—	1.72 (1.02–2.89)	0.04

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Intervention Fidelity

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Intervention Fidelity:

Literacy Interactions

Table 5. Adjusted Estimates for Outcomes with Significant Literacy Level-Study Arm Interactions

Outcome	Literacy Level	Carve-In	Carve-Out
Intervention Fidelity and Patient Satisfaction			
Number of Total Contacts, M (SD)	Limited	2.40 (0.19)	4.29 (0.22)
	Adequate	1.49 (0.22)	4.40 (0.22)
Over the past 12 months, has a nurse/diabetes educator *spoken with you about creating an action plan or setting a goal* to improve your diabetes?, %	Limited	54.6 %	69.6 %
	Adequate	42.7 %	84.3 %
Over the past 12 months, did you *set an action plan or a goal* with the nurse/diabetes educator who contacted you?, %	Limited	48.6 %	66.8 %
	Adequate	36.7 %	82.1 %
On a scale of 1 to 10, one being not helpful at all and 10 being extremely helpful, *how helpful was this process* of setting action plans to improving your health?, M (SD)	Limited	4.08 (0.35)	6.34 (0.38)
	Adequate	3.32 (0.38)	6.80 (0.38)
If given the opportunity, *would you like to continue* to set action plans with the nurse/diabetes educator?, %	Limited	56.4 %	76.1 %
	Adequate	62.6 %	73.1 %
Knowledge			
Diabetes Knowledge at 12 months, M (SD)	Limited	4.26 (0.66)	4.74 (0.87)
	Adequate	5.99 (0.78)	5.89 (0.76)

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Effectiveness

Table 4. Effectiveness of Carve-In Versus Carve-Out Implementation Approaches

Outcome			Carve-In	Carve-Out	*P* Value
Diabetes Knowledge	3 months	M (SD)	5.5 (1.7)	5.5 (1.6)	0.90
		β (95 % CI)	—	**−0.17 (−0.20–−0.15)**	< 0.001
	12 months	M (SD)	5.4 (1.7)	5.4 (1.5)	0.92
		β (95 % CI)	—	**0.16 (0.03–0.29)**	0.01
Diabetes Self-Efficacy	3 months	M (SD)	82.2 (13.2)	87.8 (12.8)	0.66
		β (95 % CI)	—	−1.08 (−2.55–0.39)	0.15
	12 months	M (SD)	89.9 (12.2)	87.9 (13.8)	0.17
		β (95 % CI)	—	−3.14 (−6.41–0.12)	0.06
Health Behaviors					
Physical Activity	3 months	%	40.2	43.7	0.48
		OR (95 % CI)	—	1.04 (0.54–2.01)	0.90
	12 months	%	50.0	44.9	0.36
		OR (95 % CI)	—	**0.74 (0.68–0.81)**	< 0.001
Fruit Intake	3 months	%	15.1	14.4	0.84
		OR (95 % CI)	—	1.38 (0.65–2.92)	0.41
	12 months	%	26.0	**14.4**	0.01
		OR (95 % CI)	—	**0.47 (0.23–0.99)**	0.05
Vegetable Intake	3 months	%	21.6	19.8	0.66
		OR (95 % CI)	—	0.99 (0.62–1.58)	0.96
	12 months	%	17.7	15.6	0.60
		OR (95 % CI)	—	1.34 (0.78–2.29)	0.29
High R_x Adherence	3 months	%	45.4	46.0	0.92
		OR (95 % CI)	—	**0.75 (0.57–0.99)**	0.04
	12 months	%	50.0	45.2	0.39
		OR (95 % CI)	—	1.18 (0.86–1.62)	0.30
Intermediary Clinical Outcomes					
HbA1c	6 months	M (SD)	8.2 (1.6)	**7.4 (1.5)**	< 0.001
		β (95 % CI)	—	**−0.31 (−0.56–−0.06)**	0.02
Systolic Blood Pressure	6 months	M (SD)	136.6 (19.7)	132.6 (18.0)	0.08
		β (95 % CI)	—	**−3.65 (−6.39–−0.90)**	0.01
Diastolic Blood Pressure	6 months	M (SD)	78.9 (9.1)	78.7 (10.6)	0.86
		β (95 % CI)	—	−1.57 (−7.17–4.02)	0.58
LDL Cholesterol	6 months	M (SD)	95.3 (37.5)	87.0 (31.4)	0.11
		β (95 % CI)	—	**−7.96 (−10.08–−5.83)**	< 0.001

Bolded values reflect significant associations at p< 0.05

Challenges

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Challenges

- Preparation
  - Finding clinics to participate
  - Clinic variability

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Challenges

- Preparation
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  - Clinic variability
- Intervention
  - Lack of integrated EHR at sites

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Challenges

- Preparation
  - Finding clinics to participate
  - Clinic variability
- Intervention
  - Lack of integrated EHR at sites
- Analysis
  - Natural clinical data

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Take home message

- Strengths and challenges with both Carve-In and Carve-Out
  - Implementation differences
  - Patient preferences
  - Resource variability

- Use of EHR is promising

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Interview Battery

- Demographics
- Socioeconomic background
- Food security
- Medication trade-off
- Social support
- Cognitive processing (speed, working memory)
- Health literacy (S-TOFHLA)
- Baseline health (PROMIS, comorbidity, diabetes Hx)
- Diabetes knowledge
- Self-efficacy (communication, disease management)
- Physical activity (BRFSS)
- Nutrition (BRFSS)
- Medication discrepancies, understanding, and adherence
- Patient Assessment of Chronic Illness Care (PACIC)
- Diabetes distress
- **CLINICAL OUTCOMES : HBA1c, blood pressure, LDL**

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	Clerical	Medical Records	Nursing	Provider	Care Manager
1. Identify patients with an Hba1c >7					
2. Notify RA of eligible participants					
3. Give RA bi-weekly calendar every two weeks for patients with uncontrolled diabetes					
4. Distribute Diabetes Guide to patient					
5. Introduce DG and purpose					
6. Coach patient on the process of setting behavioral goals					
7. Set first Action Plan with patient					
8. Complete Action Plan Update Form and place in patient's medical chart					
9. Follow-up phone call with patient after 14 days					
10. Go to medical chart and complete next section of the Action Plan Update Form (14 days)					
11. Pull medical records of participants and give to RA					
12. Follow-up phone call with patient after 2 months					
13. Go to medical chart and complete next section of the Action Plan Update Form (2 months)					
14. Pull medical records of participants and give to RA					
15. Follow-up phone call with patient after 3 months					
16. Go to medical chart and complete next section of the Action Plan Update Form (3 months)					
17. Pull medical records of participants and give to RA					
18. Follow-up phone call with patient after 6 months					
19. Go to medical chart and complete next section of the Action Plan Update Form (6 months)					
20. Pull medical records of participants and give to RA					
21. Follow-up phone call with patient after 9 months					
22. Go to medical chart and complete next section of the Action Plan Update Form (9 months)					
23. Pull medical records of participants and give to RA					
24. Manage the tracking system including Action Plan modifications					

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TASK	Name	Position	How will this be Accomplished?
1. Identify patients with an HbaIc >/			
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4. Place emailed or faxed AP tracking sheets in patients' medical chart					

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