

Online Supplementary Materials

Observational stepped-wedge analysis of a community health worker-led intervention for diabetes and hypertension in rural Mexico

Supplementary Table 1 Sensitivity analysis with exclusion of baseline measurements

Continuous Outcomes	Adjusted estimate (95% CI)	p-value
Diabetes, HbA1c (n=72 [474])	-0.30% (-0.86 to 0.26%)	0.30
Baseline A1c \geq 9% (n=36 [241])	-0.88% (-1.63 to -0.12%)	0.02
Baseline A1c < 9% (n=36 [233])	0.26% (-0.51 to 1.04%)	0.50
Hypertension, Systolic Blood Pressure (n=116 [759])	-2.8 mmHg (-7.1 to 1.4 mmHg)	0.19
Not Controlled at Baseline (n=47 [316])	-7.6 mmHg (-15.7 to 0.5 mmHg)	0.07
Controlled at Baseline ^a (n=62 [424])	-2.1 mmHg (-6.9 to 2.7 mmHg)	0.39
Hypertension, Diastolic Blood Pressure (n=116 [759])	-1.5 mmHg (-3.8 to 0.9 mmHg)	0.23
Not Controlled at Baseline (n=47 [316])	-3.4 mmHg (-7.7 to 0.8 mmHg)	0.11
Controlled at Baseline ^a (n=62 [424])	-1.0 mmHg (-3.8 to 1.8 mmHg)	0.49
Binary Outcomes	Adjusted OR (95% CI)	p-value
Diabetes (n=72 [474])	2.71 (0.68 – 10.93)	0.16
Not Controlled at Baseline (n=53 [363])	4.90 (0.81 - 29.84)	0.08
Controlled at Baseline ^b (n=15 [93])	0.88 (0.02 – 35.41)	0.94
Hypertension (n=116 [759])	2.65 (1.25 - 5.61)	0.01
Not Controlled at Baseline (n=47 [316])	4.83 (1.34 - 17.46)	0.02
Controlled at Baseline ^a (n=62 [424])	2.64 (0.96 – 7.28)	0.06

Primary and secondary outcomes with exclusion of baseline data for patients used to dichotomize based on disease control (n=number of individual patients [number of time points]). Analysis performed using individual-level mixed effects adjusting for time and cohort with clustering by individual and community. Continuous outcomes presented as adjusted difference in mean between exposed and unexposed with 95% confidence intervals (95% CI) and p-value. Binary outcomes presented as adjusted odds ratio (odds of control in exposed/odds of control in unexposed) with 95% CI and p-value. Two patients (one with diabetes, one with hypertension) in primary analysis not included because they contributed data only to the baseline time point. ^a Defined as blood pressure (in mm Hg) < 140/90, < 130/80 if concomitant diabetes, < 150/90 if age \geq 80 according to Mexican Ministry of Health guidelines.¹ ^b Defined as glycosylated haemoglobin (HbA1c) < 7%.

Supplementary Table 2 Sensitivity analysis of 2010/2014 vs 2017 hypertension guidelines

Continuous Outcomes	2010/2014 Guidelines			2017 Guidelines		
	n	Adjusted Estimate (mm Hg, 95% CI)	p-value	n	Adjusted Estimate (mm Hg, 95% CI)	p-value
Systolic Blood Pressure	117 [869]	-4.7 (-8.9 to -0.6)	0.03	117 [869]	-4.7 (-8.9 to -0.6)	0.03
Not Controlled at baseline	48 [364]	-12.4 (-22.9 to -2.0)	0.02	43 [332]	-9.3 (-17.1 to -1.5)	0.02
Controlled at baseline	62 [486]	-3.5 (-7.6 to 0.6)	0.09	67 [518]	-3.9 (-8.4 to 0.6)	0.09
Diastolic Blood Pressure	117 [869]	-2.2 (-4.5 to 0.1)	0.06	117 [869]	-2.2 (-4.5 to 0.1)	0.06
Not controlled at baseline	48 [364]	-4.6 (-8.5 to -0.7)	0.02	43 [332]	-4.5 (-8.6 to -0.4)	0.03
Controlled at baseline	62 [486]	-1.2 (-3.9 to 1.5)	0.39	67 [518]	-1.6 (-4.3 to 1.1)	0.24
Binary Outcomes	n	Adjusted OR (95% CI)	p-value	n	Adjusted OR (95% CI)	p-value
Hypertension	117 [869]	3.18 (1.55 to 6.55)	0.002	117 [869]	2.51 (1.19 to 5.31)	0.02
Not controlled at baseline	48 [364]	6.28 (1.79 to 22.06)	0.004	43 [332]	4.26 (1.31 to 13.89)	0.02
Controlled at baseline	62 [486]	2.65 (0.99 to 7.12)	0.053	67 [518]	3.66 (1.12 to 11.98)	0.03

Primary and secondary hypertension outcomes comparing 2010/2014 with 2017 Mexican Ministry of Health hypertension guidelines (n=number of individual patients [number of time points]). Analysis performed using individual-level mixed effects adjusting for time and cohort with clustering by individual and community. Continuous outcomes presented as adjusted difference in mean between exposed and unexposed with 95% confidence intervals (95% CI) and p-value. Binary outcomes presented as adjusted odds ratio (odds of control in exposed/odds of control in unexposed) with 95% CI and p-value. Seven patients with hypertension not included in stratified analysis due to missing baseline control data. 2010/2014 guidelines define blood pressure control (in mm Hg) as < 140/90, < 130/80 if concomitant diabetes, and < 150/90 if age ≥ 80.¹ 2017 guidelines define blood pressure control as < 140/90 if age < 60, < 140/80 if concomitant diabetes, and < 150/90 if age ≥ 60 (<140/90 if concomitant diabetes).²

Supplementary Table 3 Sensitivity analysis modeling community as a fixed effect

Continuous Outcomes	Adjusted estimate (95% CI)	p-value
Diabetes, HbA1c (n=73 [543])	-0.26% (-0.82 to 0.30%)	0.36
Baseline A1c \geq 9% (n=37 [278])	-0.96% (-1.70 to -0.21%)	0.01
Baseline A1c < 9% (n=32 [247])	0.17% (-0.58 to 0.92%)	0.66
Hypertension, Systolic Blood Pressure (n=117 [869])	-4.2 mmHg (-8.4 to -0.03 mmHg)	0.048
Not Controlled at Baseline (n=48 [364])	-8.9 mmHg (-16.4 to -1.3 mmHg)	0.02
Controlled at Baseline ^a (n=62 [486])	-1.9 mmHg (-6.5 to 2.7 mmHg)	0.42
Hypertension, Diastolic Blood Pressure (n=117 [869])	-1.9 mmHg (-4.2 to 0.4 mmHg)	0.11
Not Controlled at Baseline (n=48 [364])	-3.8 mmHg (-7.8 to 0.2 mmHg)	0.06
Controlled at Baseline ^a (n=62 [486])	-0.8 mmHg (-3.6 to 1.9 mmHg)	0.56
Binary Outcomes	Adjusted OR (95% CI)	p-value
Diabetes (n=73 [543])	2.08 (0.53 to 8.19)	0.30
Not Controlled at Baseline (n=54 [417])	3.97 (0.61 to 25.75)	0.15
Controlled at Baseline ^b (n=15 [108])	1.59 (0.06 to 42.08)	0.78
Hypertension (n=117 [869])	3.00 (1.43 to 6.32)	0.004
Not Controlled at Baseline (n=48 [364])	4.81 (1.30 to 17.73)	0.02
Controlled at Baseline ^a (n=62 [486])	2.25 (0.80 to 6.38)	0.13

Primary and secondary outcomes with community modeled as a fixed effect (n=number of individual patients [number of time points]). Analysis performed using individual-level mixed effects adjusting for time, cohort, and community with clustering by individual and community. Continuous outcomes presented as adjusted difference in mean between exposed and unexposed with 95% confidence intervals (95% CI) and p-value. Binary outcomes presented as adjusted odds ratio (odds of control in exposed/odds of control in unexposed) with 95% CI and p-value. Four patients with diabetes and seven patients with hypertension not included in stratified analysis due to missing baseline control data. ^a Defined as blood pressure (in mm Hg) < 140/90, < 130/80 if concomitant diabetes, < 150/90 if age \geq 80 according to Mexican Ministry of Health guidelines. ^b Defined as glycated haemoglobin (HbA1c) < 7%.

Supplementary Table 4 Sensitivity analysis adjusted for time as a random effect

Continuous Outcomes	Adjusted estimate (95% CI)	p-value
Diabetes, HbA1c (n=73 [543])	-0.35% (-0.90 to 0.20%)	0.21
Baseline A1c \geq 9% (n=37 [278])	-0.96% (-1.69 to -0.23%)	0.01
Baseline A1c < 9% (n=32 [247])	0.11% (-0.62 to 0.84%)	0.76
Hypertension, Systolic Blood Pressure (n=117 [869])	-6.0 mmHg (-11.2 to -0.4 mmHg)	0.04
Not Controlled at Baseline (n=48 [364])	-10.3 mmHg (-18.4 to -2.2 mmHg)	0.01
Controlled at Baseline ^a (n=62 [486])	-2.8 mmHg (-7.3 to 1.7 mmHg)	0.23
Hypertension, Diastolic Blood Pressure (n=117 [869])	-2.6 mmHg (-5.4 to 0.1 mmHg)	0.06
Not Controlled at Baseline (n=48 [364])	-4.6 mmHg (-8.8 to -0.5 mmHg)	0.03
Controlled at Baseline ^a (n=62 [486])	-1.2 mmHg (-3.9 to 1.5 mmHg)	0.39

Primary and secondary continuous outcomes with time modeled as a random effect to adjust for random secular trends by cluster (n=number of individual patients [number of time points]). Analysis performed using individual-level mixed effects adjusting for time and cohort with clustering by individual and community with random slopes for time. Continuous outcomes presented as adjusted difference in mean between exposed and unexposed with 95% confidence intervals (95% CI) and p-value. Seven patients with hypertension not included in stratified analysis due to missing baseline control data. ^a Defined as blood pressure (in mm Hg) < 140/90, < 130/80 if concomitant diabetes, < 150/90 if age \geq 80 according to Mexican Ministry of Health guidelines.¹

Supplementary Table 5 Sensitivity analysis excluding patients removed from treatment during study period

Continuous Outcomes	Adjusted estimate (95% CI)	p-value
Diabetes, HbA1c (n=72 [537])	-0.29% (-0.84 to 0.26%)	0.30
Baseline A1c \geq 9% (n=36 [272])	-0.88% (-1.61 to -0.15%)	0.02
Baseline A1c < 9% (n=32 [247])	0.11% (-0.62 to 0.84%)	0.76
Hypertension, Systolic Blood Pressure (n=106 [815])	-5.0 mmHg (-9.4 to -0.6 mmHg)	0.03
Not Controlled at Baseline (n=47 [361])	-9.8 mmHg (-17.3 to -2.3 mmHg)	0.01
Controlled at Baseline ^a (n=53 [436])	-3.7 mmHg (-8.6 to 1.2 mmHg)	0.14
Hypertension, Diastolic Blood Pressure (n=106 [815])	-2.8 mmHg (-5.2 to -0.4 mmHg)	0.02
Not Controlled at Baseline (n=47 [361])	-4.5 mmHg (-8.5 to -0.5 mmHg)	0.03
Controlled at Baseline ^a (n=53 [436])	-2.3 mmHg (-5.1 to 0.6 mmHg)	0.12
Binary Outcomes	Adjusted OR (95% CI)	p-value
Diabetes (n=72 [537])	2.50 (0.65 - 9.55)	0.18
Not Controlled at Baseline (n=53 [411])	4.81 (0.78 - 29.48)	0.09
Controlled at Baseline ^b (n=15 [108])	1.46 (0.06 - 37.26)	0.82
Hypertension (n=106 [815])	3.41 (1.61 - 7.20)	0.001
Not Controlled at Baseline (n=47 [361])	5.88 (1.67 - 20.71)	0.006
Controlled at Baseline ^a (n=53 [436])	2.98 (1.07 - 8.35)	0.04

Primary and secondary outcomes with exclusion of 11 patients who were removed from treatment by their provider (n=number of individual patients [number of time points]). Analysis performed using individual-level mixed effects adjusting for time and cohort with clustering by individual and community. Continuous outcomes presented as adjusted difference in mean between exposed and unexposed with 95% confidence intervals (95% CI) and p-value. Binary outcomes presented as adjusted odds ratio (odds of control in exposed/odds of control in unexposed) with 95% CI and p-value. Four patients with diabetes and six patients with hypertension not included in stratified analysis due to missing baseline control data. ^a Defined as blood pressure (in mm Hg) < 140/90, < 130/80 if concomitant diabetes, < 150/90 if age \geq 80 according to Mexican Ministry of Health guidelines.¹ ^b Defined as glycosylated haemoglobin (HbA1c) < 7%.

References

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