STUDY OF A TELE-PHARMACY INTERVENTION FOR CHRONIC DISEASES TO IMPROVE TREATMENT ADHERENCE

THE STIC2IT RANDOMIZED CONTROLLED TRIAL

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on behalf of:

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Medication non-adherence is extremely common

- One-half of patients with cardiometabolic conditions do not adhere to their prescribed medications
  - Leads to adverse clinical consequences and $100-$300 billion in preventable health spending each year in the U.S. alone

- Interventions to improve adherence have been modestly effective
  - Do not adequately address each individual’s unique adherence barriers
  - Imprecisely targeted to patients who do not need adherence assistance

- Even effective interventions are difficult to sustain
  - Often require new infrastructure and/or are expensive
OBJECTIVE

STIC2IT: Study of a Tele-pharmacy Intervention for Chronic diseases to(2) Improve Treatment adherence

- To evaluate the effect of a medication adherence intervention for diabetes, hypertension, and hyperlipidemia that was:

  - Targeted → FOCUSED ON PATIENTS MOST LIKELY TO BENEFIT
  - Multi-component → ADDRESSED MULTIPLE BARRIERS
  - Behaviorally-tailored → PERSONALIZED TO PATIENT NEED
  - Delivered by practice-embedded pharmacists → INTEGRATED INTO EXISTING CARE
  - Technologically-enabled → IMPROVED EFFICIENCY

ADULT PATIENTS OF A LARGE MULTI-SPECIALTY GROUP PRACTICE WITH DIABETES, HYPERTENSION OR HYPERLIPIDEMIA CONTACTED AND OFFERED:

▪ pharmacist telephone consultation (using brief negotiated interviewing)
▪ text messages (reminders or motivation)
▪ automated individual progress reports

RANDOMIZED PRACTICE SITES (N=14)

USUAL CARE

POOR DISEASE CONTROL (based on EHR data)

NON-ADHERENT (based on claims data)

INTERRUPTION

CONTUCTED AND OFFERED:

▪ pharmacist telephone consultation (using brief negotiated interviewing)
▪ text messages (reminders or motivation)
▪ automated individual progress reports

Content tailored to “patient activation” + adherence barriers

• ENROLLMENT: Aug 2015-July 2016
• END OF FOLLOW-UP: July 2017

clinicaltrials.gov NCT02512276
OUTCOMES

Outcomes assessed using routinely-collected data

- Outcomes assessed during the 12 months after randomization

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Data Source</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Medication adherence</td>
<td>Prescription health insurance data</td>
<td>Average adherence (“proportion of days covered”) for eligible medications at the time of randomization</td>
</tr>
<tr>
<td>Disease control</td>
<td>Electronic health record data</td>
<td>Proportion of patients meeting guideline targets for: (a) all eligible conditions and (b) at least 1 eligible condition</td>
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</tbody>
</table>

- Primary analyses conducted on an intention-to-treat basis
  - Powered for a 2.5% mean improvement in adherence assuming that <50% of patients would agree to a pharmacist consultation
RESULTS

Enrollment

ELIGIBLE SUBJECTS
(n=4078)

INTERVENTION
(n=2038)
Left practice (n=10)
MD declined (n=127)
Opted-out by pharmacist (n=97)

PROGRESS REPORTS
(n=1804, 89%)

USUAL CARE
(n=2040)

AS TREATED ANALYSIS

USUAL CARE
(n=2040)

PHARMACIST CONSULT
(n=1069, 52%)
Left practice (n=10)
MD declined (n=127)
Unreachable (n=268)
Refused (n=457)
No show (n=107)

PRIMARY ANALYSIS

TEXT MESSAGES
(n=194, 9.5%)

PILLBOXES
(n=137, 6.7%)

Clinical pharmacist telephone consultations lasted a mean of 24.9 minutes; 1050 (98.2%) patients completed at least 2 calls and 175 (16.4%) patients received 3 or more calls
## RESULTS

### Baseline characteristics

<table>
<thead>
<tr>
<th>CHARACTERISTIC</th>
<th>USUAL CARE (N=2040)</th>
<th>INTERVENTION (N=2038)</th>
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</thead>
<tbody>
<tr>
<td>Age, mean years*</td>
<td>60.4</td>
<td>59.2</td>
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<tr>
<td>Male sex</td>
<td>54.7%</td>
<td>55.0%</td>
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<tr>
<td>White race*</td>
<td>53.6%</td>
<td>60.6%</td>
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<tr>
<td>Qualifying conditions</td>
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<tr>
<td>Hyperlipidemia</td>
<td>72.0%</td>
<td>73.7%</td>
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<tr>
<td>Hypertension</td>
<td>25.9%</td>
<td>23.8%</td>
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<tr>
<td>Diabetes</td>
<td>12.1%</td>
<td>11.9%</td>
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<tr>
<td>Charlson comorbidity score, mean</td>
<td>0.90</td>
<td>0.74</td>
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<tr>
<td>Baseline disease control</td>
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<td>LDL cholesterol, mean mg/dL,</td>
<td>204.8</td>
<td>207.8</td>
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<td>Systolic blood pressure, mean mmHg</td>
<td>149.9</td>
<td>149.2</td>
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<tr>
<td>Hemoglobin A&lt;sub&gt;1c&lt;/sub&gt;, mean</td>
<td>9.8</td>
<td>9.5</td>
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<tr>
<td><strong>Baseline adherence, mean</strong></td>
<td><strong>57.0%</strong></td>
<td><strong>57.2%</strong></td>
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* Standardized mean difference for age and race/ethnicity were >0.1; there were no other significant differences
PRIMARY OUTCOME
Adherence

MONTHLY ADHERENCE

<table>
<thead>
<tr>
<th>Months after randomization</th>
<th>Intervention</th>
<th>Usual Care</th>
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<tbody>
<tr>
<td>1</td>
<td>46.2%</td>
<td>42.1%</td>
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INTENTION TO TREAT:
- HYPERLIPIDEMIA: 4.6% (p<0.001)
- HYPERTENSION: 8.5% (p<0.001)
- DIABETES: -0.2% (p=0.86)

AS TREATED:
- HYPERLIPIDEMIA: \(\uparrow 4.7\%\) (p<0.001)
- HYPERTENSION: \(\uparrow 10.4\%\) (p<0.001)

Median (IQR) time from randomization to pharmacist call (when it occurred): 22 (17 to 32) days
SUBGROUP ANALYSES

Adherence

OVERALL

≥ 65 years
< 65 years

Female
Male

White
Black
Other

Baseline adherence < 50%
Baseline adherence ≥ 50%

1 eligible condition
2 or 3 eligible conditions

Interaction p-value

p=0.19
p=0.03
p=0.56
p=0.44
p=0.77

Absolute difference in adherence (%)
SECONDARY OUTCOMES

Good disease control

Mean duration between randomization and outcome assessment: 229.2 days
The STIC2IT intervention improved adherence

- An intervention for patients with diabetes, hypertension, and hyperlipidemia with poor medication adherence and suboptimal disease control:

- Effect size was similar to those achieved by more labor intensive interventions
- Used highly-pragmatic research methods to facilitate the generalizability of the results
SUMMARY AND IMPLICATIONS

Intervention did not improve secondary clinical outcomes

Routinely-collected data used inaccurate?

Adherence improvement too small?

Patients may have required therapeutic intensification?

FUTURE INTERVENTIONS MAY NEED TO:

- Be more intensive while still pragmatic
- Focus on a more impactable patient population
- Simultaneously address adherence and other barriers to optimal disease control