A tablet-computer clinical intervention to support antiretroviral adherence: initial results of the MedCHEC randomized trial

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Background

- Tablet computers are in our homes, in our workplaces, and increasingly, in healthcare settings
- They are convenient, familiar to patients, and relatively inexpensive
- Audio computer-assisted self-interview (aCASI) can be used to assess patients in routine care, including adherence behaviors (McInnes 2013, Kozak 2012)
Background

- Tablet computer assessment of HIV adherence behaviors could improve patient outcomes
  - Improve clinician information – consistent, customizable, and less patient response bias
  - Educate and motivate patients
- Randomized trial of aCASI tablet computer assessment has not been conducted in HIV care settings
- Delivery of computer-assisted adherence assessments to providers did not improve antiretroviral (ARV) adherence (Wilson et al 2010)
Medication for Chronic HIV Education and Collaboration - *MedCHEC*

![Diagram of MedCHEC]

- **MedCHEC**
  - **Doctor** information/communication
  - **Patient** education/motivation
  - **Clinic** linkage to adherence care

**Adherence Care Manager (pharmacist or nurse)**
Research Hypotheses

- Compared to control, patients assigned to the MedCHEC intervention will
  - have better antiretroviral adherence
  - be more accurately assessed for ARV nonadherence by their providers
  - receive better adherence counseling
  - achieve better viral suppression (secondary hypothesis)
Compared to control, patients assigned to the MedCHEC intervention will

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- receive better adherence counseling
- achieve better viral suppression (secondary hypothesis)
Methods

- Adult HIV+ patients in care at 3 urban U.S. ID clinics
  - English language and adequate cognitive function
  - VA Boston, VA Greater Los Angeles, and Boston Medical Center
  - On, or starting antiretrovirals
- Outcome assessments at 6 months (initial effect) and 12 months (sustained effect)
- Adherence measured with electronic monitoring devices (MEMS), and computed Doses Taken, and Doses on Time
- Mixed random/fixed-effects models of adherence over time as function of baseline adherence, intervention arm, covariates
Outcomes Measurement

Assessments

Potential Clinic Visits

Initial MEMS Adherence

6-month

Sustained MEMS Adherence

12-month

Days Post-Randomization
MedCHEC Study

Enrollment & Baseline Assessments
- Informed consent & enrollment data
- Baseline Assessment
- HIV clinical care visit

Randomization
n=255

Intervention: at each clinic visit...
- Standard adherence information
- Patient uses MedCHEC tablet
- MedCHEC reports to doctor & patient
- Linkage to Adherence Care Manager directly facilitated if problems

Intervention Clinic Visits every 1-6 months

Control: at each clinic visit...
- Standard adherence information
- Adherence Care Manager available

Control Clinic Visits every 1-6 months

MEMS Monitoring

6 Month Assessment

12 Month Assessment
Enrollment and Progress (CONSORT)

349 Screened

297 Enrolled

255 Randomized

242 6-month Follow-up

238 12-month Follow-up

52 Voluntarily Declined or Excluded

42 Failed Protocol, Withdrawn, Lost to Follow-up

13 Withdrawn, Lost to Follow-up, Lost Cap

4 Withdrawn, Lost to Follow-up, Lost Cap
# Randomized Participants (n=255)

<table>
<thead>
<tr>
<th></th>
<th>Intervention (n=128)</th>
<th>Control (n=127)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Age (years)</td>
<td>52.3 (9.9)</td>
<td>51.1 (9.7)</td>
</tr>
<tr>
<td>Male Sex</td>
<td>101 (78.9)</td>
<td>106 (83.5)</td>
</tr>
<tr>
<td>Black</td>
<td>71 (55.5)</td>
<td>82 (64.6)</td>
</tr>
<tr>
<td>White</td>
<td>41 (32.0)</td>
<td>30 (23.6)</td>
</tr>
<tr>
<td>Other</td>
<td>16 (12.5)</td>
<td>15 (11.8)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>16 (12.5)</td>
<td>10 (7.9)</td>
</tr>
<tr>
<td>IVDU</td>
<td>29 (22.8)</td>
<td>31 (24.4)</td>
</tr>
<tr>
<td>MSM</td>
<td>43 (33.6)</td>
<td>38 (29.9)</td>
</tr>
<tr>
<td>Heterosexual</td>
<td>46 (35.9)</td>
<td>43 (33.9)</td>
</tr>
<tr>
<td>Other/Unknown</td>
<td>10 (7.8)</td>
<td>15 (11.8)</td>
</tr>
<tr>
<td>Mean Comorbidities</td>
<td>2.1 (1.9)</td>
<td>2.0 (2.1)</td>
</tr>
<tr>
<td>Viral Load &lt;75</td>
<td>92 (80.7)</td>
<td>86 (76.1)</td>
</tr>
<tr>
<td>Viral Load ≥75</td>
<td>22 (19.3)</td>
<td>27 (23.9)</td>
</tr>
<tr>
<td>CD4 0-200</td>
<td>15 (12.5)</td>
<td>18 (15.9)</td>
</tr>
<tr>
<td>CD4 201-500</td>
<td>58 (48.3)</td>
<td>51 (45.1)</td>
</tr>
<tr>
<td>CD4 ≥501</td>
<td>47 (39.2)</td>
<td>44 (38.9)</td>
</tr>
<tr>
<td>Single Pill ARV Regimen</td>
<td>28 (21.9)</td>
<td>34 (26.8)</td>
</tr>
<tr>
<td>Multi-pill Regimen</td>
<td>100 (78.1)</td>
<td>93 (73.2)</td>
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</tbody>
</table>
## Effects of MedCHEC on ARV Adherence

<table>
<thead>
<tr>
<th></th>
<th>Mean Difference over Time</th>
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</thead>
<tbody>
<tr>
<td></td>
<td><strong>Initial Adherence (2-6 mos)</strong></td>
</tr>
<tr>
<td>% Difference (95% CI)</td>
<td>11.4% (2.9%, 19.8%)</td>
</tr>
<tr>
<td>p value</td>
<td>0.008</td>
</tr>
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</thead>
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<tr>
<td>Doses Taken</td>
<td>11.4% (2.9%, 19.8%)</td>
<td>0.008</td>
</tr>
<tr>
<td></td>
<td>0.5% (-12.4%, 13.4%)</td>
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## Effects of MedCHEC on ARV Adherence

### Mean Difference over Time

<table>
<thead>
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<th>Initial Adherence (2-6 mos)</th>
<th>Sustained Adherence (6-12 mos)</th>
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<td>p value</td>
<td>% Difference (95% CI)</td>
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<tr>
<td>Doses Taken</td>
<td>11.4% (2.9%, 19.8%)</td>
<td>0.008</td>
</tr>
<tr>
<td>Doses on Time</td>
<td>8.5% (2.0%, 15.1%)</td>
<td>0.011</td>
</tr>
</tbody>
</table>
ARV Adherence: Doses Taken

Adherence Percentage

Days Post-Randomization

- Control
- Intervention

Initial MEMS Adherence
6-month
Sustained MEMS Adherence
12-month
Doses Taken, by baseline adherence status

**Initial MEMS Adherence**
- Ctl Poor
- Ctl Mod
- Ctl Good

**Sustained MEMS Adherence**
- Intv Poor
- Intv Mod
- Intv Good

**Adherence Percentage**
- Days Post-Randomization

- Initial MEMS Adherence: 0 - 6 months
- Sustained MEMS Adherence: 6 - 12 months

12-month

6-month
**Doses on Time,* by baseline adherence status**

*Adherent if dose taken within +/-2 hours of correct time*
Conclusions

- MedCHEC (tablet computer patient assessment, information feedback to doctors, and linkage to adherence care manager) led to significant initial ARV adherence improvement in doses taken, and doses taken on time.
- Initial improvements in adherence were not sustained.
- Future analyses will look at effects of the intervention on accuracy of doctors’ adherence assessment, receipt of adherence counseling, and viral load.
Questions
ARV Adherence: Doses on Time*

*Adherent if dose taken within +/-2 hours of correct time
Collaborative Provider-Patient Adherence Framework