

Improving Data Collection and Behavior-Change Support via Veterans' Mobile Phones: One Solution for HSR&D

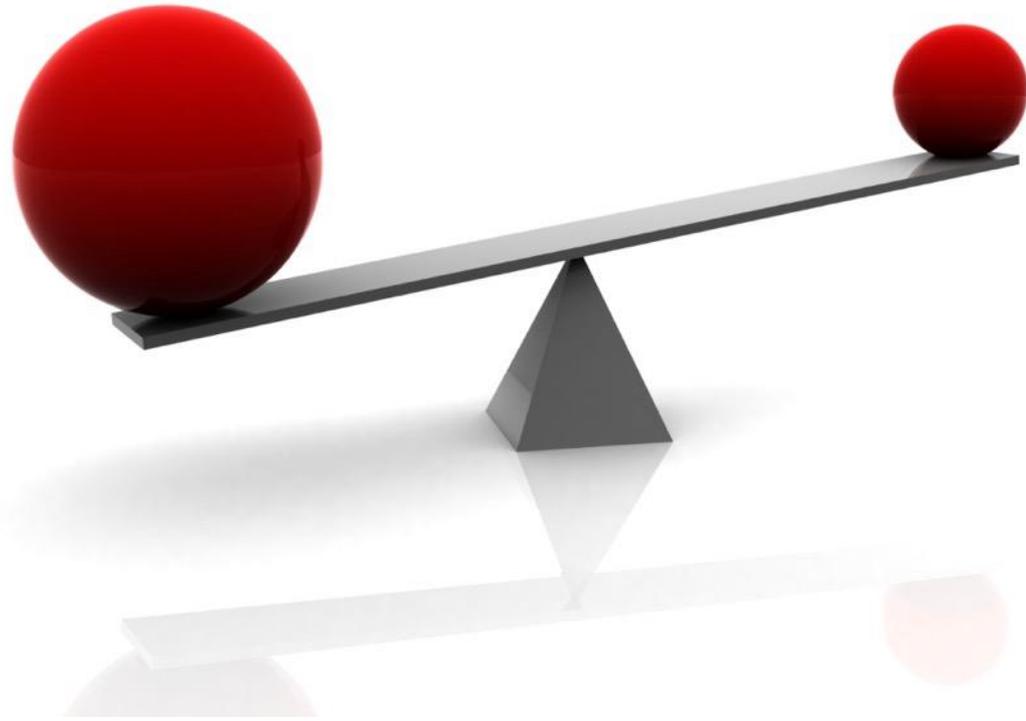
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Ann Arbor Center for Clinical Management Research



Many veterans need
more help than
clinicians can ever
realistically provide
during standard
encounters.



Rubenstein LV et al. Improving care for depression: there's no free lunch. *Annals of Internal Medicine* 2006;145:544-546.

Dobscha SK et al. Depression decision support in primary care: a cluster randomized trial. *Annals of Internal Medicine* 2006;145:477+.

Diabetes Self-Management Care via Cell Phone:
A Systematic Review

A review

The Effectiveness of Mobile-Health Technology-Based
Health Promotion and Disease Management Interventions: A
Systematic Review and Meta-Analysis

Health Promotion and Disease Management Interventions: A Systematic Review

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Global Burden of Cardiovascular Disease

Mobile Health Devices as Tools for Worldwide Cardiovascular Risk Reduction and Disease Management

John D. Piette, PhD; Justin List, MD; Gurpreet K. Rana, MLIS; Whitney Townsend, MLIS; Dana Striplin, MHSA; Michele Heisler, MD, MPA

The Effectiveness of Mobile-Health Technologies to Improve Health Care Service Delivery Processes: A Systematic Review and Meta-Analysis

Caroline Free^{1*}, Gemma Phillips², Louise Watson³, Leandro Galli⁴, Lambert Felix⁵, Phil Edwards³, Vikram Patel³, Andy Haines³

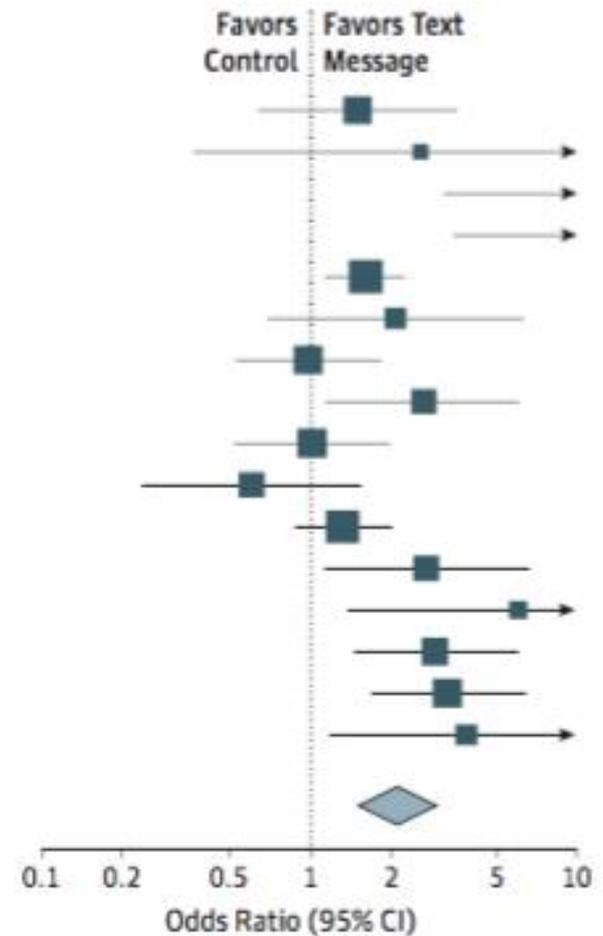
¹ Clinical Trials Unit, London School of Hygiene & Tropical Medicine, London, United Kingdom, ² Department of Health Services Research and Policy, London School of Hygiene & Tropical Medicine, London, United Kingdom, ³ Department of Population Health, London School of Hygiene & Tropical Medicine, London, United Kingdom, ⁴ Warwick University, Coventry, United Kingdom, ⁵ Department of Primary Care and Public Health, Imperial College, London, United Kingdom

The humble reminder



Figure 2. Meta-analysis of the Effect of a Mobile Telephone Text Message Intervention on Medication Adherence

| Source | Statistics for Each Study | | |
|---|---------------------------|----------------------|-----------------|
| | Odds Ratio | (95% CI) | P Value |
| Márquez Contreras et al, ⁴³ 2004 | 1.508 | (0.631-3.605) | .36 |
| da Costa et al, ²⁹ 2012 | 2.571 | (0.371-17.831) | .34 |
| Hardy et al, ³⁰ 2011 ^a | 21.131 | (3.161-141.237) | .002 |
| Khonsari et al, ³¹ 2015 ^a | 12.273 | (3.405-44.236) | <.001 |
| Lester et al, ³² 2010 | 1.612 | (1.144-2.271) | .006 |
| Lv et al, ²¹ 2012 | 2.074 | (0.686-6.251) | .20 |
| Lua and Neni, ³³ 2013 | 0.985 | (0.535-1.812) | .96 |
| Maduka and Tobin-West, ³⁴ 2013 | 2.644 | (1.135-6.160) | .02 |
| Mbuagbaw et al, ³⁵ 2012 | 1.026 | (0.519-2.026) | .94 |
| Park et al, ³⁶ 2014 | 0.610 | (0.236-1.585) | .31 |
| Pop-Eleches et al, ³⁷ 2011 | 1.330 | (0.882-2.005) | .17 |
| Quilici et al, ³⁸ 2013 | 2.705 | (1.109-6.596) | .03 |
| Strandbygaard et al, ³⁹ 2010 | 6.018 | (1.368-26.466) | .02 |
| Vervloet et al, ⁴⁰ 2012 | 2.959 | (1.448-6.046) | .003 |
| Wald et al, ⁴¹ 2014 | 3.267 | (1.686-6.331) | <.001 |
| Wang et al, ⁴² 2014 | 3.857 | (1.180-12.606) | .03 |
| Overall | 2.107 | (1.517-2.926) | <.001 |



Thakkar et al. Mobile telephone text messaging for medication adherence in chronic disease: A meta-analysis. JAMA Internal Medicine 2016;176(3):340-349.

Smoking cessation support delivered via mobile phone text messaging (txt2stop): a single-blind, randomised trial



Caroline Free, Rosemary Knight, Steven Robertson, Robyn Whittaker, Phil Edwards, Weiwei Zhou, Anthony Rodgers, John Cairns, Michael G Kenward, Ian Roberts

Summary

Background Smoking cessation programmes delivered via mobile phone text messaging show increases in self-reported quitting in the short term. We assessed the effect of an automated smoking cessation programme delivered via mobile phone text messaging on continuous abstinence, which was biochemically verified at 6 months.

Methods In this single-blind, randomised trial, undertaken in the UK, smokers willing to make a quit attempt were randomly allocated, using an independent telephone randomisation system, to a mobile phone text messaging smoking cessation programme (txt2stop), comprising motivational messages and behavioural-change support, or to a control group that received text messages unrelated to quitting. The system automatically generated intervention or control group texts according to the allocation. Outcome assessors were masked to treatment allocation. The primary outcome was self-reported continuous smoking abstinence, biochemically verified at 6 months. All analyses were by intention to treat. This study is registered, number ISRCTN 80978588.

Findings We assessed 11914 participants for eligibility. 5800 participants were randomised, of whom 2915 smokers were allocated to the txt2stop intervention and 2885 were allocated to the control group; eight were excluded because they were randomised more than once. Primary outcome data were available for 5524 (95%) participants. Biochemically verified continuous abstinence at 6 months was significantly increased in the txt2stop group (10.7% txt2stop vs 4.9% control, relative risk [RR] 2.20, 95% CI 1.80–2.68; $p < 0.0001$). Similar results were obtained when participants that were lost to follow-up were treated as smokers (268 [9%] of 2911 txt2stop vs 124 [4%] of 2881 control [RR 2.14, 95% CI 1.74–2.63; $p < 0.0001$]), and when they were excluded (268 [10%] of 2735 txt2stop vs 124 [4%] of 2789 control [2.20, 1.79–2.71; $p < 0.0001$]). No significant heterogeneity was shown in any of the prespecified subgroups.

Interpretation The txt2stop smoking cessation programme significantly improved smoking cessation rates at 6 months and should be considered for inclusion in smoking cessation services.

Funding UK Medical Research Council, Primary Care Research Networks.

Lancet 2011; 378: 49–55

Published Online
June 30, 2011
DOI:10.1016/S0140-6736(11)60701-0

See [Comment](#) page 6

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caroline.free@lshtm.ac.uk

| | Intervention (SE) | Control (SE) | Relative risk (95% CI) | p value |
|--|----------------------|-----------------|---------------------------|---------|
| Primary outcome | | | | |
| Biochemically verified continuous abstinence at 6 months | 10.7% (0.6) | 4.9% (0.4) | 2.20 (1.80–2.68) | <0.0001 |
| Secondary outcomes (4 weeks) | | | | |
| Self-reported no smoking in past 7 days | 28.7% (0.8) | 12.1% (0.6) | 2.37 (2.11–2.66) | <0.0001 |
| Secondary outcomes (6 months) | | | | |
| Self-reported 28-day continuous abstinence | 19.8% (0.8) | 13.5% (0.7) | 1.47 (1.30–1.66) | <0.0001 |
| Self-reported no smoking in past 7 days | 24.2% (0.8) | 18.3% (0.8) | 1.32 (1.19–1.47) | <0.0001 |
| Self-reported involvement in vehicle crashes | 4.5%(0.4) | 3.8% (0.4) | 1.16 (0.89–1.51) | 0.269 |
| Pain in thumb while texting | 4.5% (0.4) | 4.5% (0.4) | 1.00 (0.78–1.28) | 0.985 |

Data are percentage (SE) or relative risk (95% CI). Multiple imputation by chained equations (number of imputations=100).

Table 2: Primary and secondary outcomes

Special devices



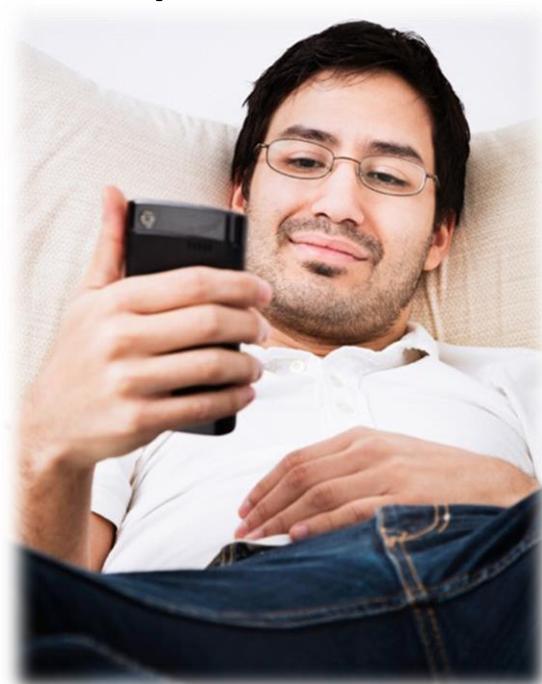
Automated calls (IVR)



Text messages (SMS)



Smartphones



An Examination of 26,168 Hamilton Depression Rating Scale Scores Administered via Interactive Voice Response Across 17 Randomized Clinical Trials

Heidi K. Moore, PhD, James C. Mundt, PhD,* Jack G. Modell, MD,† Heidi E. Rodrigues, BS,‡¶
David J. DeBroda, MD,§ James J. Jefferson, MD,* and John H. Greist, MD**

Feasibility and validation of a computer-automated Columbia-Suicide severity rating scale using interactive voice response technology[☆]

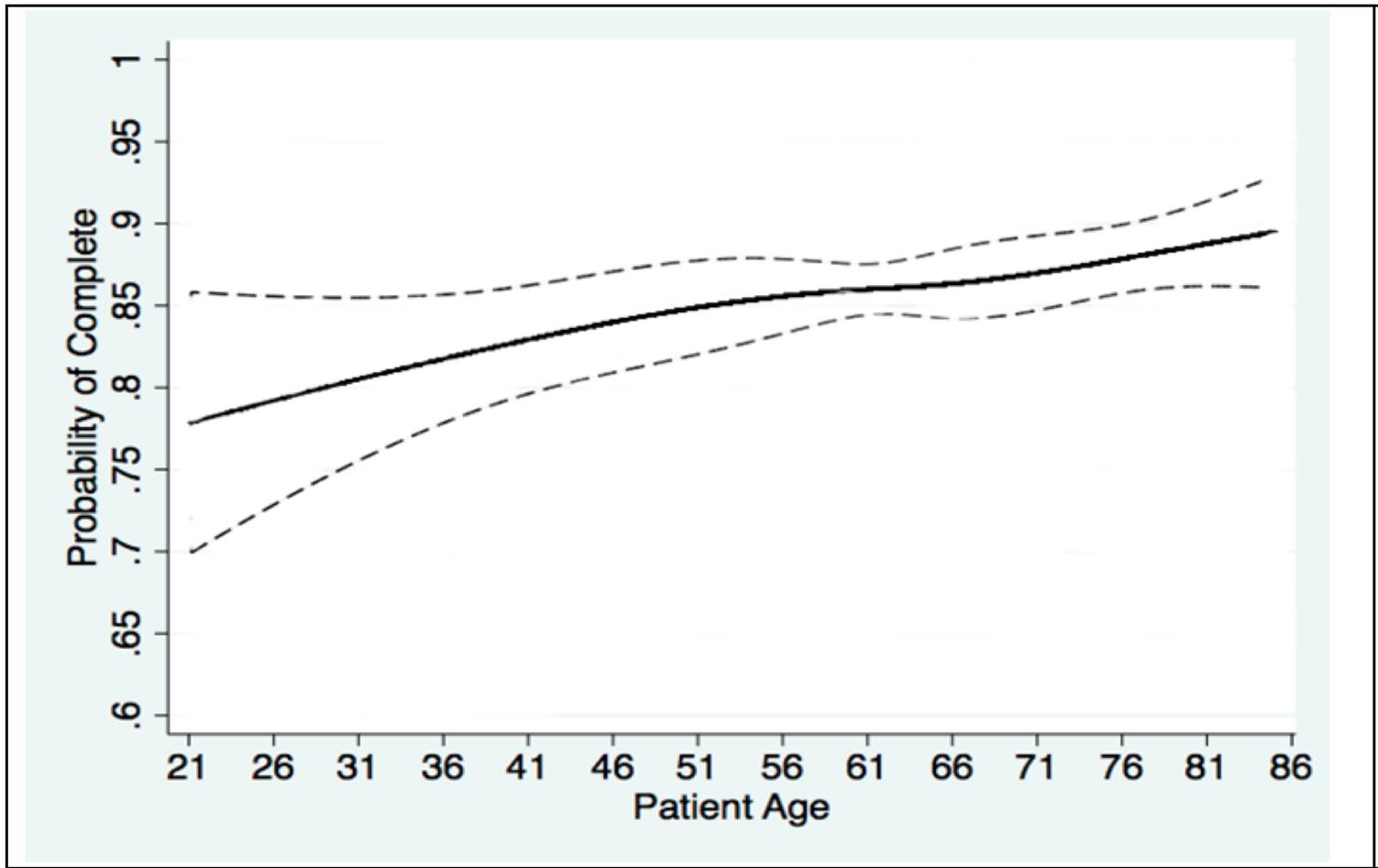
James C. Mundt^a, John H. Greist^{a,b,*}, Alan J. Gelenberg^{a,b}, David J. Katzelnick^{a,b},
James W. Jefferson^{a,b}, Jack G. Modell^c

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Patient Engagement Rates are High for 2000+ Patients with a Variety of Chronic Diseases



Piette JD, Rosland Am, Marinec NS, Striplin D, Bernstein SJ, Silveira MJ. Engagement in automated patient monitoring and self-management support calls: experience with a thousand chronically-ill patients. Medical Care 2013.



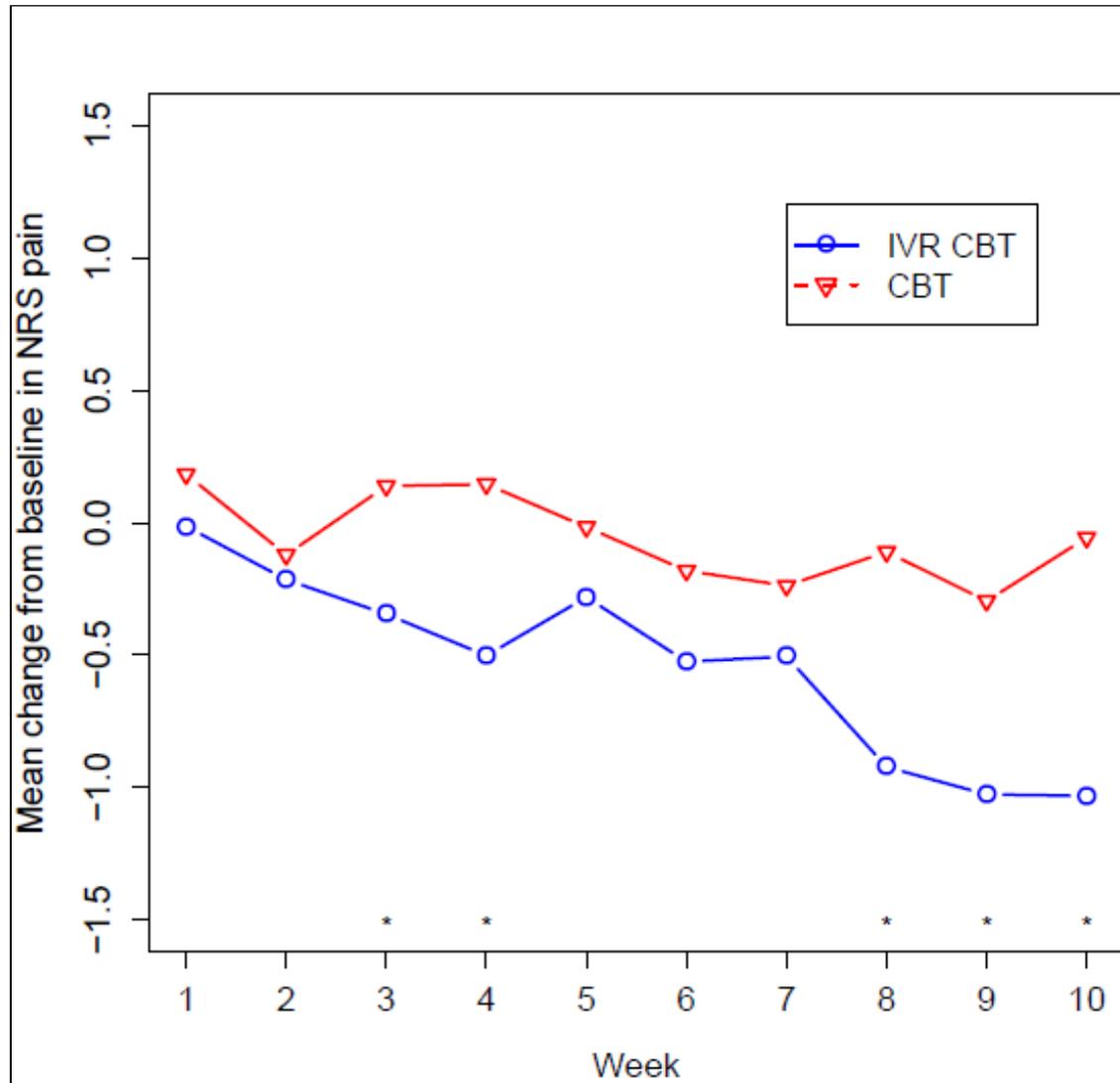
Randomized non-inferiority trial of IVR-based CBT versus face to face CBT for chronic low back pain



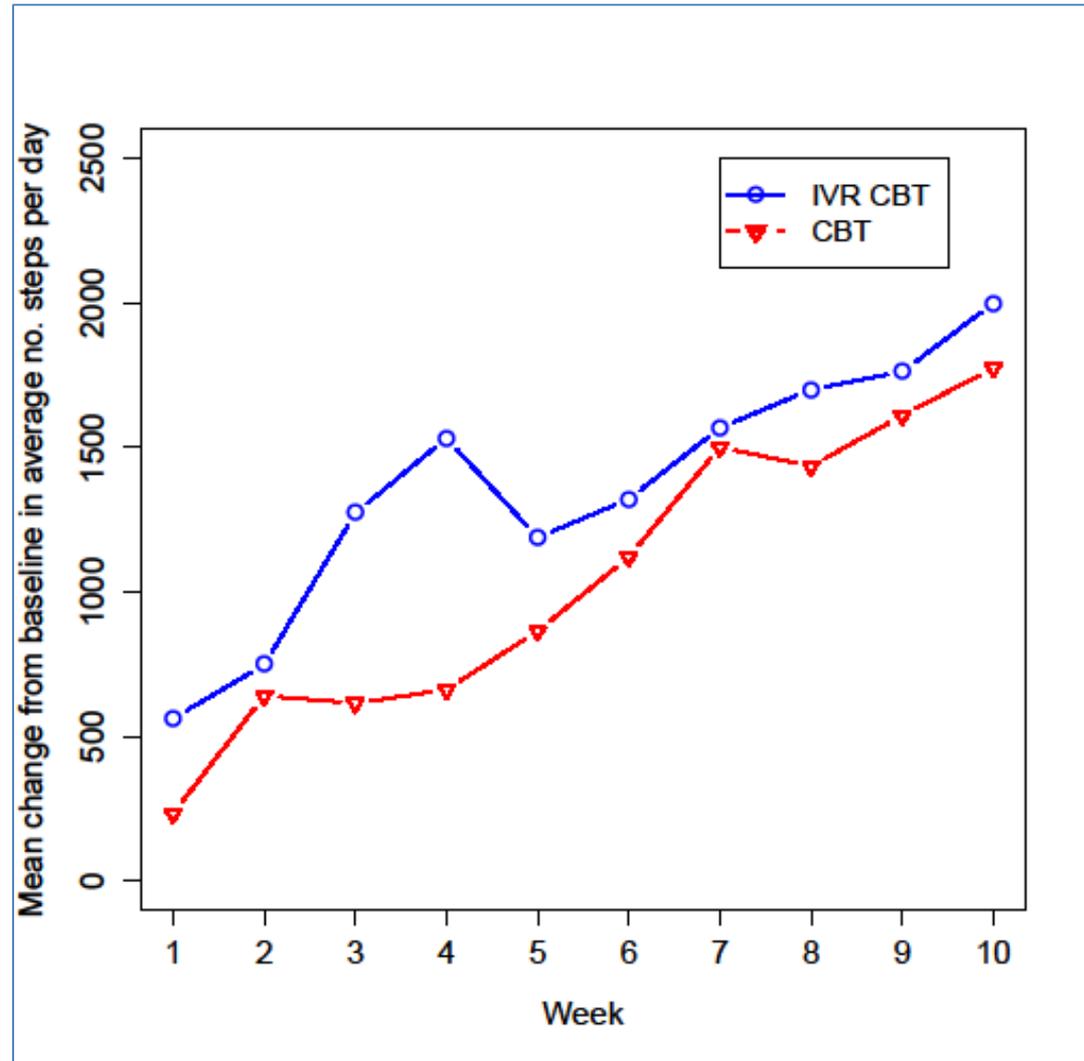
IVR-reported pain intensity

“What is your level of pain today, with 0 meaning no pain and 10 meaning the worst pain imaginable?”

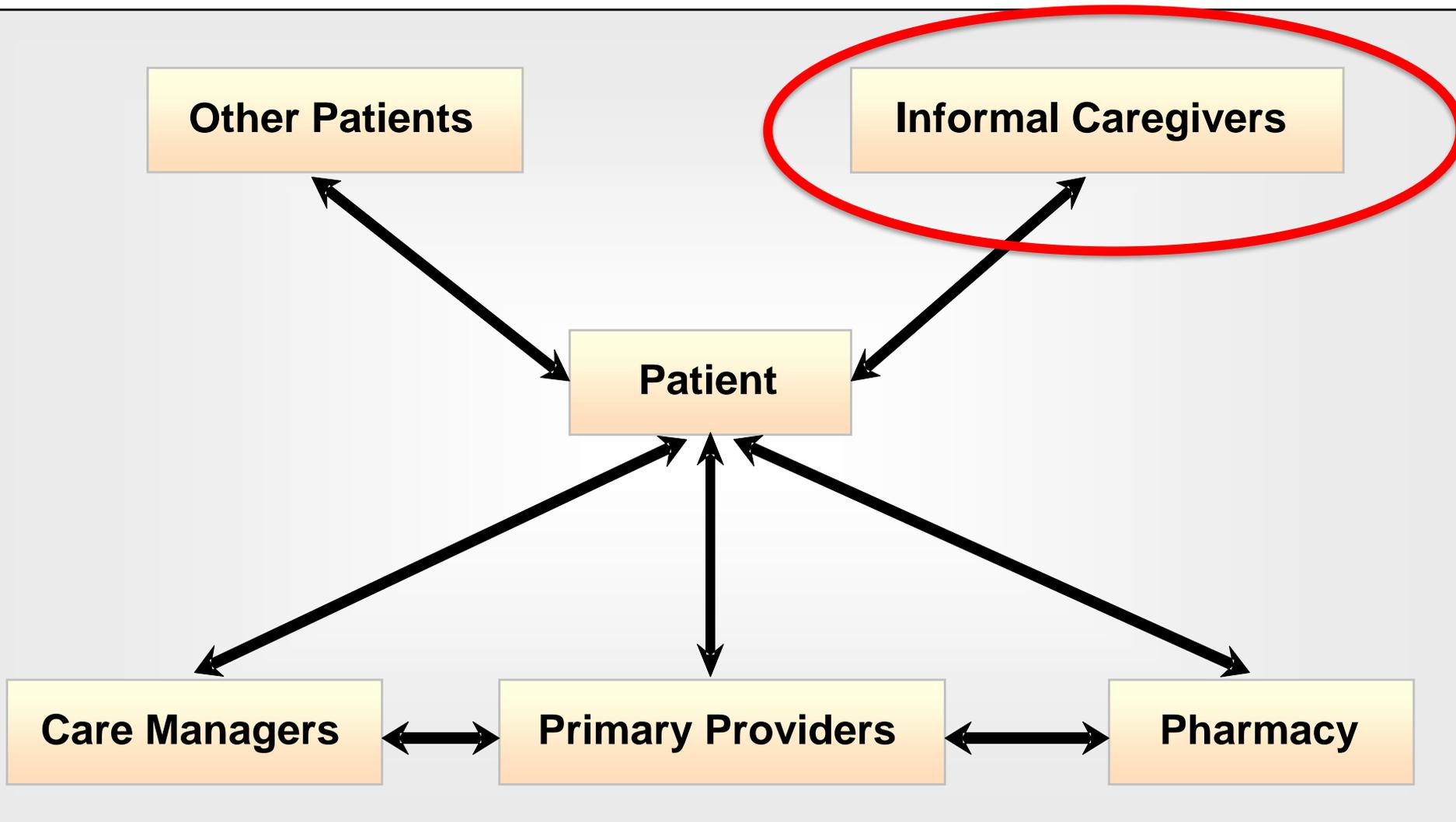
At week 10, patients in IVR-CBT showed a 0.98 point greater decrease in pain compared to F:F



Pedometer step counts



Our targets for improving Veterans' chronic illness care







The CarePartner Program

The CarePartner Program



1 Patient receives a call from the system and reports information regarding their health. Based on the responses, the patient receives information to improve their self-care.



2 Clinic receives alerts about the patients' worrisome signs and symptoms.



3 Family member or friend receives an email, IVR call, or SMS with updates on the patient's status.

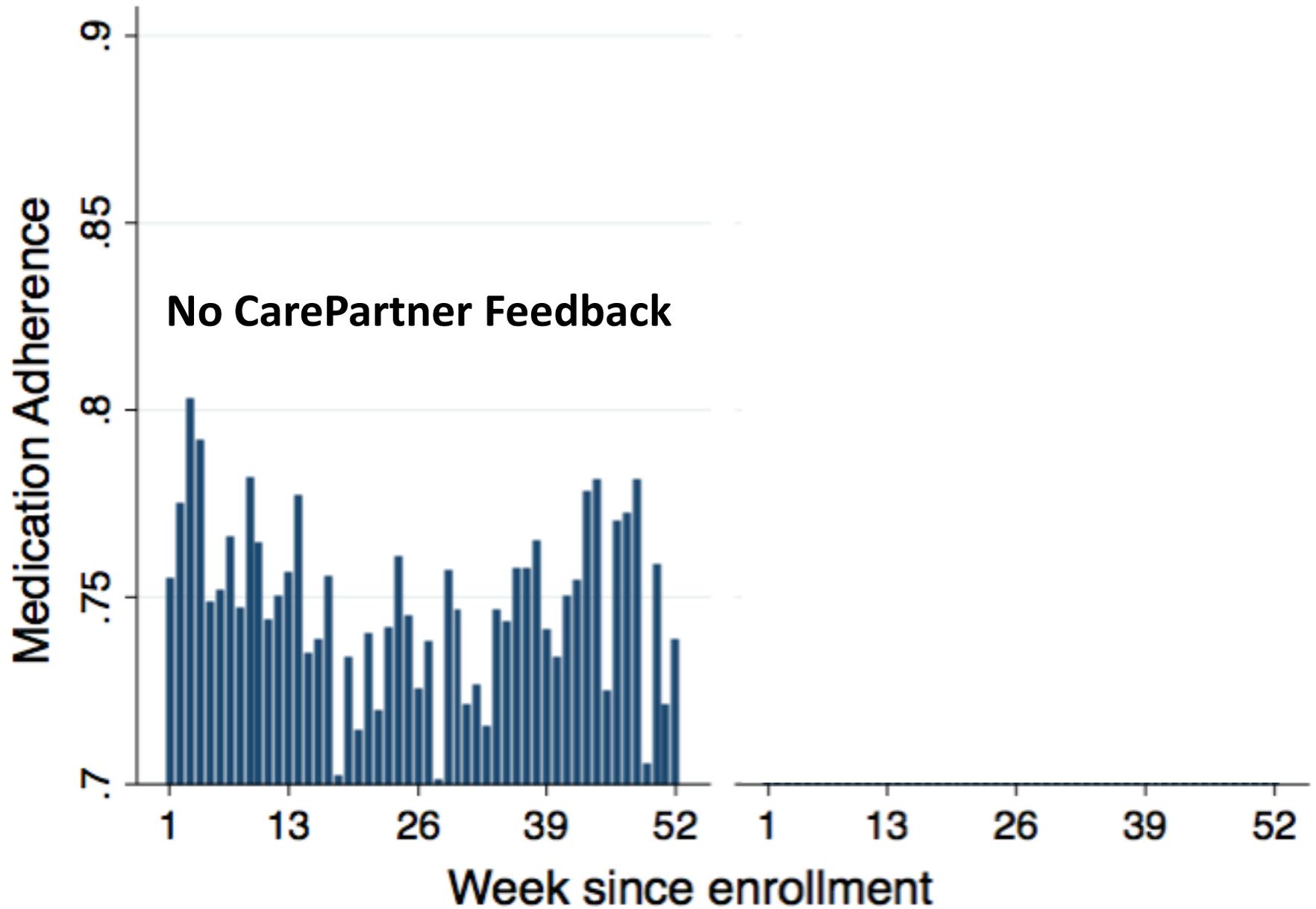




CHF CarePartners:

A Randomized Comparative Effectiveness Trial

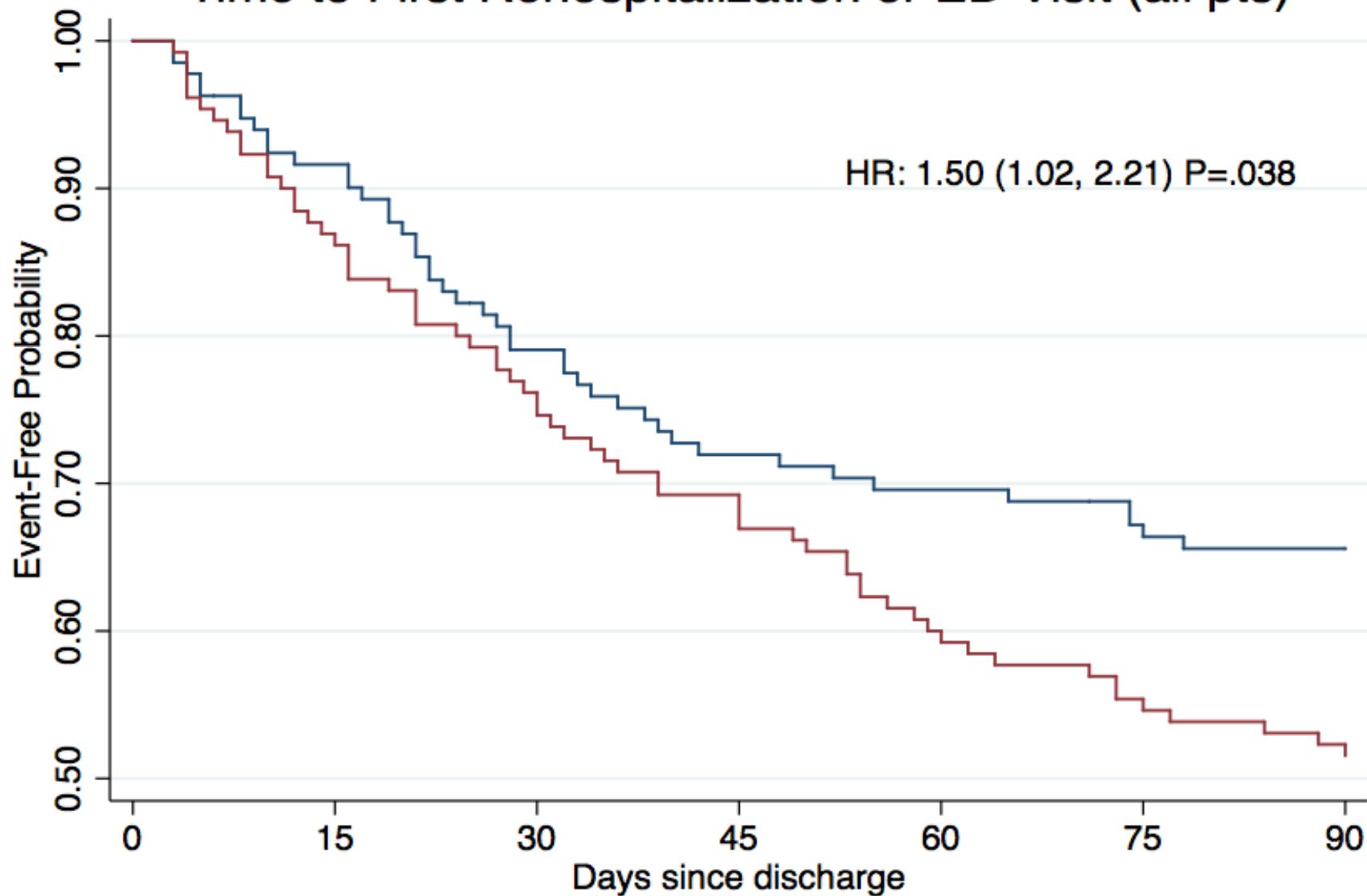
Changes in IVR-Reported Medication Adherence





Improving Post-Discharge Outcomes

Time to First Rehospitalization or ED Visit (all pts)



Medication Questions? Get Answers Online with MiDrugChat

The UHS Pharmacy now offers online chat through MiDrugChat, in collaboration with the U-M College of Pharmacy.



With MiDrugChat:

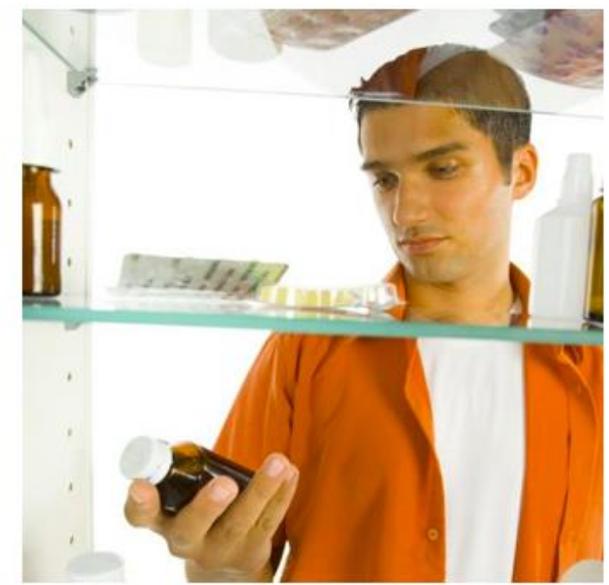
- You can get answers about medications including dosing, side effects and warnings
- Your privacy will be protected because no identifying information is collected
- You may find it a convenient way to connect with a UHS pharmacist during [open hours](#)

[Start MiDrugChat Now](#)

Alternatively, you may call the UHS Pharmacy at 734-764-7387 for answers.

In case of emergency:

- Call 911 or
- Call Poison Control at 800-222-1222



Using artificial intelligence to optimize counseling to reduce opioid misuse.

Misuse or non-adherence behaviors common among those prescribed opioids for chronic pain

-As much as 78% in some samples (Morasco & Dobscha, 2008)

Less Risk

Risk of Opioid Use

More Risk

“Saving” a pill for later

Taking more than prescribed for breakthrough pain

Borrowing someone else’s to take more

Taking other drugs or alcohol with opioids

Crushing and snorting to get high

Crushing and injecting to get high

Investigators need a source for compliant mHealth programs

- Developing VA-compliant services is technically specialized
 - HSR&D investigators spend valuable time identifying, understanding, and comparing compliant vendor options
 - Once a system is developed, investigators struggle to keep abreast of changes in VA data security rules and the IT environment over the course of a study
- Non-VA vendors (if available) are prohibitively expensive
 - Costs in excess of \$250K for a single build are common
- Functional limitations
 - The few vendors that do exist often lack key functionality that investigators need. Not all IVR programs are created equal
- Once a grant ends, re-using a vendor's program is difficult
 - Boutique development using small-scale telephony software is not replicable or sustainable for large-scale entities like the VA

SOLUTION:

QUICCCNextGen: a VA-compliant version of our team's mobile health development platform that can be deployed for VA projects



QUICCCNextGen meets all VA security requirements

VA security requirements are twofold:

- (1) TRM review and approval of software
- (2) FedRAMP Authorized-“High” for VA-data hosted on non-VA servers

All software within this proposal are TRM-approved

Hosting options are FedRAMP Authorized as “High”

Software packages include: CXP for building IVR and SMS programs, Prophecy for telephony deployment, and Microsoft Dynamics for program management.

VA TRM-approved software

Customer Experience Platform (Aspect’s CXP, version 18)

<https://www.oit.va.gov/Services/TRM/ToolPage.aspx?tid=8435>

Aspect Prophecy

<https://www.oit.va.gov/Services/TRM/ToolPage.aspx?tid=7916>

Microsoft Dynamics 365

<https://www.oit.va.gov/Services/TRM/ToolPage.aspx?tid=6271>

We will use only FedRAMP approved servers

- Software, databases, and telephony resources will be hosted in a VA-compliant cloud-based infrastructure
- FedRAMP Authorized-High options include:
 - Amazon AWS GovCloud
 - Microsoft Azure Government (Note that Dynamics 365 is pending review for high designation)
- Compliant environments have provisional Authority to Operate (P-ATO) in place
 - Full ATO is granted when the environment + software meet all VA requirements or “controls”

The system will have multi-channel capabilities

- Inbound/outbound automated (IVR) telephone calls
- Inbound/outbound text (SMS) messages
- Live Chat features
- Artificial Intelligence integration
- Outbound emails to clinicians and/or informal caregivers
- Agile assessment scheduling tailored to varying contact frequencies
- Tailored content provision (e.g. tailored thresholds for clinical notifications)

Our team has engaged all relevant stakeholders



Locally – Ann Arbor
(Investigators, ISOs, Contracting)

Regionally
(VISN 10, Investigators, ISOs)

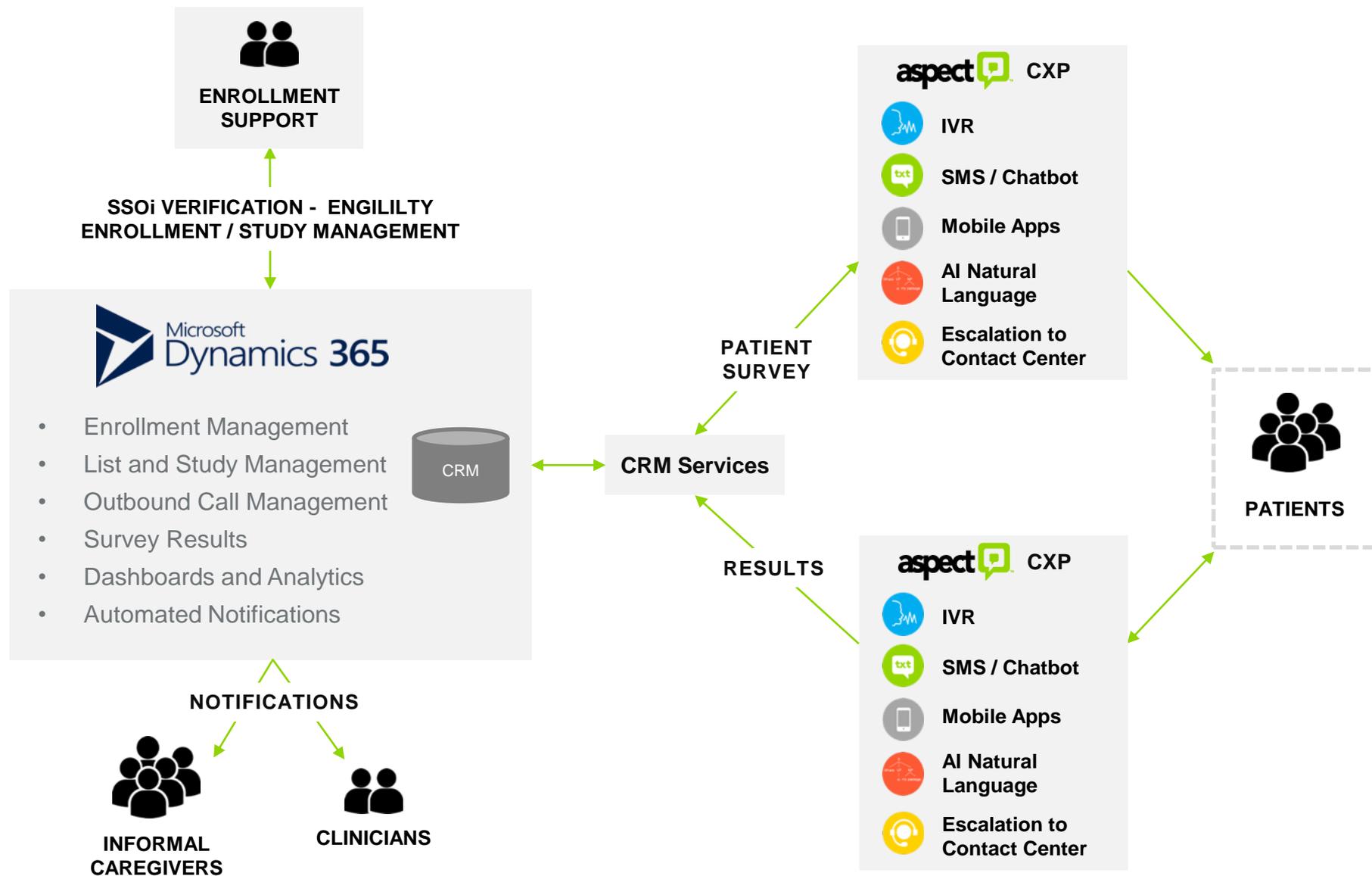
Nationally

- Director Connected/Telehealth
- Software/hosting vendors: Microsoft, Aspect, Amazon
- Compliance & SSOi Integration: Engility

Microsoft Azure



Seamlessly link patients to interactive monitoring options



Next steps for establishing the QUICCCNextGen platform

1. Acquire server space

Procure lab, production, and backup servers in FedRAMP Authorized-High space



2. Install and configure software and telephony resources

Install and configure CXP Pro, Prophecy, and Dynamics 365 on lab/production/backup servers



3. Test and finalize the platform

Develop IVR and SMS programs to test the system and configuration. Finalize the platform and sign off on development.



4. LAUNCH * MAINTENANCE * SUPPORT

1. Acquire server space

Establish a robust server environment that is configured for high availability

- Lab servers (development, or pre-production) allow staff to develop programs and perform beta-testing prior to introduction on production servers
- Production servers host live patient programs and databases
- Backup servers are configured as a warm environment, ready to take over if hot production servers were to go down/offline, decreasing the chance of any lapse in data collection

2. Install and 3. Test

- QUICCCNextGen staff will facilitate the vendor (Aspect) in the installation of CXP, Prophecy, and Dynamics 365 on the acquired servers
- Software tailoring and configuration will be completed with QUICCCNextGen staff and Aspect
- Telephony resources (SIP trunk, local telephone number acquisition, SMS resources) will be acquired on a per-project basis with connections advised by Aspect
- Confirmation of software functionality and basic telephony resource connections will be completed prior to finalizing the platform

4. Launch, maintenance, and support

- Product support will be provided by Aspect
 - Product specialists will be available to update software and troubleshoot issues
 - Product specialists will be available to assist with telephony setup (IVR, SMS)
 - Aspect has completed the VA 6500.6 checklist, approval pending
 - Aspect is exploring SSOi integration with Engility
- Program support will be provided by QUICCCNextGen
 - Software and computer science specialists will be available to develop program infrastructure, deploy programs into production, and monitor live systems
 - QUICCCNextGen staff will be available to collaborate with the hosting vendor, the software vendor, and VA information security to ensure adherence to VA regulations

THANK YOU! QUESTIONS?
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