"Get Ready and Empowered About Treatment" (GREAT) Study: a Pragmatic Randomized Controlled Trial of Activation in Persons Living with HIV

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BACKGROUND: Little is known about strategies to improve patient activation, particularly among persons living with HIV (PLWH).
OBJECTIVE: To assess the impact of a group intervention and individual coaching on patient activation for PLWH.
DESIGN: Pragmatic randomized controlled trial.
SITES: Eight practices in New York and two in New Jersey serving PLWH.
PARTICIPANTS: Three hundred sixty PLWH who received care at participating practices and had at least limited English proficiency and basic literacy.
INTERVENTION: Six 90-min group training sessions covering use of an ePersonal Health Record loaded onto a handheld mobile device and a single 20–30 min individual pre-visit coaching session.
MAIN MEASURES: The primary outcome was change in Patient Activation Measure (PAM). Secondary outcomes were changes in eHealth literacy (eHEALS), Decision Self-efficacy (DSES), Perceived Involvement in Care Scale (PICS), health (SF-12), receipt of HIV-related care, and change in HIV viral load (VL).
KEY RESULTS: The intervention group showed significantly greater improvement than the control group in the primary outcome, the PAM (difference 2.82: 95% confidence interval [CI] 0.32–5.32). Effects were largest among participants with lowest quartile PAM at baseline ($p < 0.05$). The intervention doubled the odds of improving one level on the PAM (odds ratio 1.96; 95% CI 1.16–3.31). The intervention group also had significantly greater improvement in eHEALS (difference 2.67: 95% CI 1.38–3.9) and PICS (1.27: 95% CI 0.41–2.13) than the control group. Intervention effects were similar by race/ethnicity and low education with the exception of eHealth literacy where effects were stronger for minority participants. No statistically significant effects were observed for decision self-efficacy, health status, adherence, receipt of HIV relevant care, or HIV viral load.
CONCLUSIONS: The patient activation intervention modestly improved several domains related to patient empowerment; effects on patient activation were largest among those with the lowest levels of baseline patient activation.
TRIAL REGISTRATION: This study is registered at Clinical Trials.Gov (NCT02165735).

KEY WORDS: patient participation; self-care; HIV; computer literacy; health literacy.

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BACKGROUND

Patient activation is critical to improving patient self-management and reducing avoidable emergency department visits and hospitalizations. Less recognized, however, is that social disadvantage (e.g., poverty, minority race, born outside USA, non-English speaking) contributes to disparities in health care through lower patient activation.[1] HIV is a prime example where low patient activation among socially disadvantaged persons living with HIV (PLWH) contributes to disparities in adherence,[2, 3] viral suppression,[4, 5] and ultimately, to disparities in HIV treatment outcomes,[6–8] such as hospitalizations and mortality.[9, 10] Compared to non-Latino white and/or more affluent PLWH, poor and minority PLWH miss more office visits,[11] ask fewer questions during their visits,[12] report less confidence in self-management and more frequently miss doses,[13] or stop taking their antiretroviral therapy.[14] Death from HIV-related causes represents a top ten leading cause of death among Blacks and Latinos ages 20–54 years.[15] Among Blacks ages 35–44 years, HIV ranks in the top five causes of death.[15] Therefore, improvements in patient

activation may be an important approach to close disparities gaps in health care for PLWH.

Relatively little is known about how to improve patient activation among PLWH.[16, 17] Patient activation requires access to reliable health information, including from online sources and access to one's own personal health information, which is increasingly available through patient portals that are part of most electronic health records (EHR) systems. However, availability of patient portals to EHRs or even use of handheld electronic Personal Health Records (ePHRs) are unlikely to be sufficient to improve self-management, without specific support to enhance knowledge and skills.[18, 19]

This program was developed through community-based participatory research involving PLWH, HIV clinicians, and HIV community-based organizations. The program incorporated principles from the Stanford Chronic Disease Self-Management Program and the Positive Self-Management Program for PLWH, i.e., small groups, staff and peer facilitation, and problem solving and self-management skill development.[20, 21] Our intervention is unique in its training in the use of self-management health technology, particularly an ePHR that prompts PLWH to initiate conversations with their clinician regarding evidence-based care or patient-determined concerns.

The primary objective of this study was to evaluate the effect of a multimodal self-management program, consisting of access to an ePHR, combined with a targeted, peer-led, and group-based intervention on patient activation for PLWH. Secondary objectives were to examine the impact of the intervention on related domains of empowerment, including improvement in eHealth literacy, decision-making, adherence, receipt of HIV preventive services, health status, and HIV viral load, including examining differences in effectiveness across disparity groups.

METHODS

A full description of the methods and protocol has been published.[22] The study was approved by the Institutional Review Boards (IRBs) at University of Rochester, Clinical Directors Network, Inc. (CDN) and the Family Health Centers at NYU Langone. This trial is registered at Clinical Trials.Gov (NCT02165735).

This study, named "Get Ready and Empowered About Treatment" (GREAT), used a pragmatic randomized controlled trial (RCT) design. GREAT was grounded in the principles of Community-Based Participatory Research (CBPR), where patients and stakeholders were active partners throughout.[23, 24] The conceptual model was based on the Capability, Opportunity, Motivation and Behavior (COM-B) model for behavior change.[25] GREAT's intervention consisted of (1) a customized ePHR for PLWH using a smart device (Apple iPod®) which was provided as an incentive to all participants in order to ensure they had access to the internet; (2) six 90-min, group-based, and peer-led training sessions on use of the iPod, ePHR, and web-searching for health information; and (3) a pre-visit coaching session conducted by a peer trainer. To ensure the principal of justice for the study, participants randomized to the intervention group received an iPod prior to training before follow-up measures were obtained; participants randomized to the control group received an iPod after all follow-up measures were obtained.

Setting

Eight primary care practices in New York (Rochester and the Greater New York Metropolitan Area) participated in the study. Three practices had a focus on HIV care, and five were Federally Qualified Health Centers (FQHCs) with large HIV populations. Clinicians at each site received a 1-h, CME-accredited training session. The purpose of this training was to provide an overview of the study, prepare clinicians for activated patients, and demonstrate communication skills that are more engaging for patients.

Participants

Inclusion criteria were confirmed HIV diagnosis, age ≥ 18 years, and receipt of HIV/primary care at a participating site. Exclusion criteria included, prior participation in the pilot, the inability to provide informed consent or limited English proficiency. We recruited participants directly via onsite, face-to-face discussions at the time of patient visits and/or practice outreach. A research assistant contacted patients expressing interest, to describe the study procedures, explain the risks and benefits, answer questions, and obtain written, informed consent.

Randomization and Allocation Procedures

The study statistician generated sequential identification numbers (IDs) using computer-generated random numbers stratified by location of site (Rochester or Greater New York Metropolitan Area). Three hundred and sixty sequentially numbered, opaque, and sealed envelopes were created prior to participant enrollment. A research assistant opened the envelopes sequentially, after the participant had consented and completed the baseline (T0) assessment. Due to the nature of the study, neither patients nor study staff with direct contact with patients were blinded to group assignment. The investigators were blinded to participant randomization assignments.

Intervention Group

A full description of the intervention and the protocol has been published. Appendix 1 online also provides additional details. Briefly, the intervention group received a smart device (the Apple iPod Touch®) and a customized ePHR developed for PLWH named *URHealth* that we pre-loaded on each device. Key features included (1) drop down menus for common HIV medications with accompanying pill pictures; (2) common lab

tests with brief, understandable explanations; (3) ability to set reminders for appointments, as well as for taking and refilling medications; and (4) personalized "prompt list" of potential questions for the patient to ask their clinician.

The intervention consisted of six 90-min training sessions, in groups of mean participant size $N = 11$ (range 7–15), co-facilitated by staff coaches and trained peer educators. The sessions focused on basic HIV literacy, development of basic eHealth competency, use of the ePHR, and how to ask questions. Co-facilitators encouraged participants to assist each other in learning and to celebrate successes. Groups were not assigned based on clinician, although there was likely some natural geographic clustering based on locations of training.

After completing the group training sessions, each patient received one 20–30 min individual coaching session. A staff coach met with each patient before the patient's next HIV office visit to reinforce skills learned during the group training and to prepare participants to be engaged at their office visit including identifying questions/concerns they wished to address during the visit.

We developed a training and fidelity assessment manual for professional staff and peers to conduct the group training and individual coaching sessions. We assessed fidelity using an observation checklist based on the content that was expected to be covered during each of the six training sessions. Trained observers assessed the quality and delivery of the content elements. Fidelity ranged from 0 to 1, with 1 being perfect fidelity. The mean fidelity scores for delivery and quality across each of the groups were 0.95 and 0.91, respectively.

Control Group

The control group was not assigned to an intervention group and received usual care according to their practice's guidelines and resources. Most practices had case managers on staff to assist patients with barriers and to promote adherence. All control group participants also received the iPod device after their follow-up evaluation was completed.

Outcomes

Three hundred and sixty patient participants were enrolled. The primary outcome was change in patient activation at 12 months using the 13-item Patient Activation Measure which is re-scaled (0–100). Secondary measures (Table 1) included other empowerment domains, adherence, health status, viral suppression, and uptake of recommended HIV-related preventive intervention.

Participants were assessed at baseline/time of randomization (T0), 6–8 weeks post-randomization (T1) and at 12 months post-randomization (T2). The measures were collected through survey administration (T0–T2) and chart abstraction by study research assistants (RAs) after participants completed their T2 assessments (T3). There were no changes to trial outcomes after the trial commenced.

Table 1 Baseline Characteristics of Study Participants

Characteristic	Intervention ($n = 180$)	Control ($n = 179$)	p value
Age, mean (SD)	51.7 (10.7)	51.2 (11.3)	0.69
Sex (%)			0.15
Male	62.2	56.4	
Female	37.8	41.9	
Transgender	0	1.7	
Race (%)			0.11
American Indian/Alaska Native	0.6	0	
Asian	0	0	
White	23.9	20.7	
Black or African American	54.4	49.7	
Native Hawaiian or Other Pacific Islander	0	0	
More than one race	10.0	6.7	
Other	8.9	16.7	
Unknown or not reported	2.2	6.7	
Latino ethnicity (%)	20.0	26.3	0.16
Insurance type (%)			0.70
Private	7.2	8.4	
Medicare	28.3	24.0	
Medicaid	77.8	77.1	
ADAP	11.1	13.4	
Other	7.2	6.7	
None	3.3	1.1	
Monthly income (%)			0.88
$0 to $999	70.0	67.6	
$1000 to $1999	21.1	23.5	
$2000 and over	8.9	8.9	
Education (%)			0.66
Less than high school	28.9	31.3	
High school diploma/GED or equivalent	31.1	28.5	
Some college (no degree) or technical school	20.6	24.0	
Associate degree	10.6	6.7	
Bachelor's degree or higher	8.9	9.5	
Frequency of computer use (%)			0.79
Missing	0	1	
Never	25.1	25.1	
Frequency of Internet use (%)			0.23
Number missing	0	2	
Never	17.3	23.0	
Familiarity with an iPod, an iPad, or an iPhone			0.89
Number missing	0	2	
Never heard of it	1.1	1.7	
I've heard of but have not used one	53.6	48.9	
I've used one a few times	18.4	18.5	
I previously owned one	12.3	14	
I currently own one	14.5	16.9	
No. of visits/year	5.6 (3.5)	5.4 (3.4)	0.66
Undetectable viral load (%)	76.7	75.4	0.78
Baseline outcome measures, mean (SD)			
Patient Activation Measure[26]	72.15 (16.70)	70.78 (15.57)	0.21
eHealth Literacy Scale[27]	28.53 (7.75)	27.27 (8.52)	0.14
Decision Self-Efficacy Scale[28]	91.05 (12.63)	90.76 (12.03)	0.41
Perceived Involvement in Care Scale[29]	30.58 (5.89)	30.17 (5.59)	0.25
Instrument on Doctor Patient Communication Skills[30]	85.07 (13.50)	82.63 (17.00)	0.07
HIV Adherence Self-Efficacy Scale[31]	101.27 (18.49)	100.84 (19.54)	0.58
SF-12 (mental)[32]	45.93 (11.15)	45.99 (11.04)	0.52
SF-12 (physical)_ENREF_54[54]	43.15 (12.76)	44.80 (12.17)	0.89

Sample Size

We aimed to detect a medium (0.5) effect size with 80% power at two-tailed significance level of 0.05 using the method described by Donner and Klar.[33] The intracluster correlation (ICC = 0.0207) was estimated from our pilot data and is consistent with other studies.[34] Based on these assumptions, including intracluster correlation (ICC = 0.02) from our pilot and an estimated 15% drop-out rate, we estimated we needed to enroll 360 participants.

Statistical Analysis

We compared changes in patient outcomes using generalized estimating equation (GEE) models that controlled for clustering by site and within cohort. All models were adjusted for any potential confounders. We entered the intervention effect (three time points) as an interaction term (months). We imputed missing values (< 1%) using multiple imputation.[35, 36] To assess the potential impact of extreme values, we conducted sensitivity analyses in which we excluded participants who consistently reported extreme values for a particular scale. For secondary outcomes, we used Bonferroni correction for multiple comparisons.

We used mixed effects models to control for site effects and patient characteristics. Undetectable viral loads were used as binary outputs in GEE models controlling for covariates, site, and cohort. To measure the effect of evidence-based preventive care between intervention and control groups, a structured algorithm was used to generate a count as an outcome variable using 11 preventive care measures: HPV, influenza, tetanus, hepatitis A, B, C testing, hepatitis A and B vaccinations, cervical cancer screening (PAP), mammography, and any colon cancer screening.

To assess for differences within subgroups, we entered interaction terms for randomized group × relevant subgroup into the models. Specifically, interaction terms were entered for race/ethnicity, education, and cut points for lowest quartile for PAM and eHealth literacy. When the interaction term was significant ($p < 0.05$), we conducted stratified analyses to assess the impact of the intervention on these subgroups. All statistical analyses were conducted using SAS (Cary, NC) version 9.4.

RESULTS

Study Participants

Participant enrollment began in July 2014 and the trial ended in March 2017. Figure 1 shows the participant flow through the study. A total of 694 participants were screened for eligibility, 471 met eligibility criteria, and 360 were randomized. Primary reasons for ineligibility were being HIV negative and prior participation in the pilot (Fig. 1). The participants enrolled were predominantly female (40%), African American (52%), Latino/a (23%), uninsured (2%), or had Medicaid (77%). Thirty percent of participants did not graduate from high school or hold a GED. Ninety-one percent had incomes of less than $2000/month. One in four participants had never used a computer. The intervention and usual care groups were well-matched (Table 1).

Adherence to the Intervention

Eighty-four percent of the intervention group attended at least one of the group training sessions. The mean number of sessions attended was four (out of a possible six). Thirty-six percent required extra help, or missed a session and met individually with a trainer. Three of four participants (76%) attended the pre-visit, individual coaching sessions.

We assessed use of the *URHealth* app by identifying IDs of app use during the training sessions among those assigned to the intervention and assessing frequency of login and screen use. One hundred thirty-three participants (74% of those in the intervention group) used the app at least once. One hundred nine participants (61% of the intervention group) used the app at least once in the 6 months after their training (control participants did not have access to the app during the study). Of the 109 participants who used the app post training, 61% used it for a mean of 18 times and had a mean usage time of 131 min. In order of frequency, the most commonly opened screens were tests, events, and to-do list (which included the question prompts).

Outcomes

Table 2 shows the unadjusted changes in mean PAM scores among participants by baseline PAM level and time. Participants with baseline PAM levels of 2–4 performed significantly better in the intervention than the control condition. Level 4 participants in both groups showed declines in PAM scores from baseline, presumably due to regression to the mean.

In mixed models that controlled for patient characteristics and clustering of patients by cohort and by site, the intervention yielded statistically significant effects corresponding to a 2.83-unit improvement in patient activation (Table 3). Specifically, patient activation improved at 12 months to 73.35 ± 1.13 and 70.53 ± 1.14 in the intervention and usual care groups, respectively ($p = 0.0271$). Moreover, the intervention was found to have a moderating effect on PAM level. The interaction between the intervention and PAM level was statistically significant among those in the lowest PAM quartile at baseline ($p < 0.05$). In sensitivity analyses, results remained significant when extreme values were omitted. Notably, the intervention was associated with double the odds of improving one PAM level compared with control (odds ratio 1.96; 95% CI 1.16–3.31).

Results were not statistically significant for decision self-efficacy, patient perception of clinician communication, adherence self-efficacy or adherence, viral

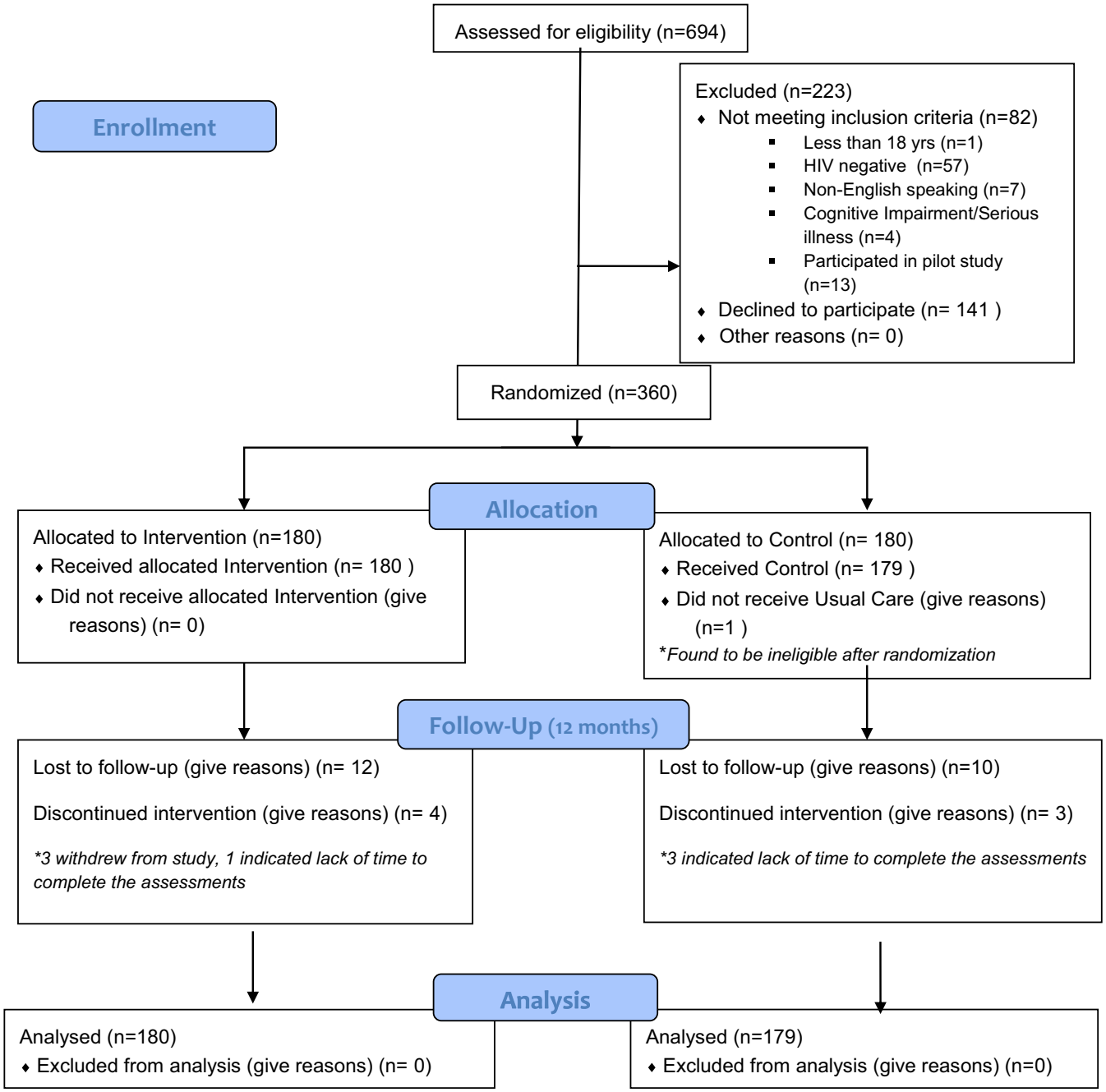

Fig. 1 The GREAT study participant flow diagram.

suppression, receipt of HIV preventive services, or change in physical or mental health status (Table 3). However, the intervention improved eHealth literacy and patient perceptions of involvement in care.

There were no statistically significant interactions by race/ethnicity or education for the intervention's effects on the PAM. We observed a statistically significant interaction in eHealth literacy for minority patients. Stratified analysis by minority race showed that minority patients had statistically significant greater improvement in eHealth literacy than non-minority patients.

DISCUSSION

We found that a multimodal patient self-management group eHealth intervention, co-facilitated by peer trainers for PLWH, modestly improved patient activation and other measures of patient empowerment. Effects were seen across race/ethnicity and education. This improvement in PAM level is clinically relevant. Patients in the lowest level are significantly more likely to develop a new chronic disease in the 3 years of observation with odds ratios ranging from 1.21 to 1.31 compared to those with the highest level.[37] Improvements in PAM levels are associated with lower odds of having an emergency

Table 2 Unadjusted Changes in PAM Score by Baseline Level and Time

PAM levels at T0		Control (C)			Intervention (I)			Difference between T0 vs T2 by arms
		T0	T1	T2	T0	T1	T2	*p* value
Level 1* (*n* = 20, C = 12, I = 8)	Mean (SD)	43.6 (1.8)	56.7 (16.5)	54.6 (11.8)	43.1 (2.5)	55.8 (11.2)	57.8 (6.6)	0.33
Level 2† (*n* = 41, C = 16, I = 25)	Mean (SD)	50.6 (2.5)	60.0 (9.7)	59.3 (8.3)	50.0 (2.4)	65.4 (13.1)	66.3 (9.8)	**0.0008**
Level 3‡ (*n* = 114, C = 61, I = 53)	Mean (SD)	63.1 (4.9)	67.4 (15.1)	66.8 (14.8)	63.2 (5.3)	66.5 (14.9)	69.9 (14.1)	0.05
Level 4§ (*n* = 184, C = 90, I = 94)	Mean (SD)	83.2 (9.9)	77.9 (14.3)	79.0 (14.8)	85.6 (9.3)	81.0 (14.1)	82.8 (13.6)	**0.01**

Bolded numbers refer to statistically significant values, i.e. p <0.05
SD unadjusted standard deviation
**Level 1 (0–47): lack of confidence to play an active role in their health*
†Level 2 (47.1–55.1): building knowledge and confidence, but still struggling with adherence
‡Level 3 (55.2–72.4): taking action to become a more active patient
§Level 4 (72.5–100): maintaining activation and confidence, although still struggling at times

department visit[38] and lower health care costs among high-cost patients.[39] These findings suggest greater cost-effectiveness when targeting patients at increased risk for high costs. Moreover, the intervention was successful in engaging patients in use of the ePHR with a variety of educational levels and variable rates of prior electronic technology use. However, during the 12-month follow-up period, the intervention did not show statistically significant improvement in adherence to ART, viral suppression, receipt of HIV preventive care, or health status.

To our knowledge, this is the first randomized controlled trial of an intervention that was explicitly designed to improve patient activation using eHealth technology among predominantly low-income PLWH. The intervention was designed to provide PLWH not only with knowledge and confidence in managing their health and health care but also with the skills

Table 3 Effect of the GREAT Intervention on 12-Month Outcomes

Outcomes	Intervention		Control		Coefficient estimates	95% CI lower upper		*p* value
	Mean	SD	Mean	SD				
Measures								
Primary outcome								
Patient Activation Measure (PAM)†	73.35	1.13	70.53	1.14	2.82	0.32	5.32	**0.0271**
Secondary empowerment outcomes								
eHealth Literacy Scale†	29.81	1.45	27.67	1.42	2.67	1.38	3.95	**<0.0001**
Decision Self-Efficacy Scale†	91.89	0.86	90.81	0.87	1.09	−0.82	3.00	0.2631
Perceived Involvement in Care Scale†	33.74	0.94	32.47	0.90	1.27	0.41	2.13	**0.0038**
Perceived Clinician Communication (IDPCS)§	85.06	1.24	83.49	1.25	3.18	0.01	6.35	**0.0490**
HIV adherence and viral suppression								
HIV Adherence Self-Efficacy Scale	102.80	1.08	103.13	1.07	−0.33	−3.26	2.60	0.8251
Self-reported adherence	89.33	1.09	89.90	1.09	−0.56	−3.44	2.32	0.7014
Undetectable viral load*	87%	3.1%	86%	3.1%	0.00	−0.06	0.07	0.9113
Receipt of HIV-related care and preventive services								
Index	0.35	0.01	0.35	0.02	−0.01	−0.05	0.05	0.9937
Health status								
SF-12 (mental)	46.38	0.73	46.99	0.73	−0.61	−2.29	1.08	0.4787
SF-12 (physical)	44.83	0.71	45.13	0.72	−0.30	−2.29	1.66	0.7625
Interactions								
PAM: low PAM × arm								**0.0175**
PAM: minority race × arm§								0.9998
PAM: low education × arm								0.1504
PAM: IDPCS × arm								0.5389
eHEALS: minority race × arm§								**0.0275**
eHEALS: low education × arm								0.5509

Bolded numbers refer to statistically significant values, i.e. p <0.05
IDPCS Instrument on Doctor Patient Communication Skills, SF-12 Short Form Health Survey: Physical and Mental Health
**Percent of patients with testing whose viral load was undetectable*
†Significance between arms at α = 0.05 (all remained significant after Bonferroni correction for secondary measures (p < 0.0047) except IDPCS which was no longer statistically significant)
‡For mixed model calculation, arms, cohort, timeline, race, ethnicity, gender, age, computer use, education, familiarity with an iPod, an iPad or iPhone, income, internet use, and marital status have been considered
§minority race = non-white (vs white/non-Hispanic), low education = < high school (vs > high school), low PAM = bottom quartile (vs remainder), low eHEALS = bottom quartile (vs remainder)

and tools, i.e., a mobile device with an online personal eHealth record, to facilitate self-management. Our intervention builds on previous chronic self-management programs through its integration of training and use of handheld EHR and by training patients to ask their clinicians relevant questions, showing improvements in eHealth literacy in addition to patient activation.

Other trials have assessed patient activation interventions for patients with other conditions, e.g., diabetes, heart failure, prevention, and hypertension.[40–49] Participants in GREAT had high mean baseline PAM scores, and their PAM scores were higher than those reported in several other studies.[50–52]

Because our study population had relatively high levels of baseline PAM scores and high ART adherence and viral load suppression, there may have been limited room for improvement ("ceiling effect"). High PAM scores are associated with improved health outcomes, quality of life and healthy lifestyle behaviors. Additionally, we recruited patients from practices with established, relatively robust clinical and care management/support services available for PLWH, which could have attenuated the effect of the intervention. Therefore, it may have been difficult to observe changes in quality of life, viral load outcomes, and other preventive care measures in this intervention during the 12 month follow-up; these changes may require a longer follow-up interval to discern. These findings point to the need to tailor activation interventions to increase skills and confidence for different self-management tasks for those with varying levels of activation. However, our findings also suggest that patient activation training alone, even when provided in groups and accompanied by eHealth tools, may not be sufficiently potent to improve adherence for patients with detectable viral loads. Additional ART adherence training may be needed for the small minority of patients whose HIV viral loads are not suppressed.[53, 54]

Future research should explore use of patient EHR portals that provide personally tailored prompts to patients regarding topics for discussion with their clinician. Research is also needed to replicate our findings among non-HIV+ low-income patients with low eHealth technology use and to assess the cost-effectiveness of this multimodal approach to patient activation.

Limitations

This study had a relatively short duration of the intervention for the outcomes studied. Also, outcome assessments were not blinded introducing possible bias particularly for self-report measures. The sample was limited to English fluent persons with PLWH who received care in participating sites in Rochester, NY, and the NYC area, potentially limiting generalizability to other chronic conditions or groups served in other geographic locations. By design, there was limited involvement of clinicians and practices. Future studies should consider enhancing clinician engagement. Cross contamination by clinicians (all of whom received the 60-min training) may have biased results towards the null. While participants were coached before a visit with their HIV clinician, a single visit may not have been sufficient to address the combination of prompted questions from the ePHR and the patient's own primary concerns.

In summary, this patient activation intervention modestly improved several domains related to patient empowerment. No effects were observed for health status, adherence, receipt of HIV relevant care, or HIV viral load.

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Compliance with Ethical Standards:

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