Impact of a Tailored Patient Support Mobile App on Viral Suppression and HIV Care Engagement

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BACKGROUND

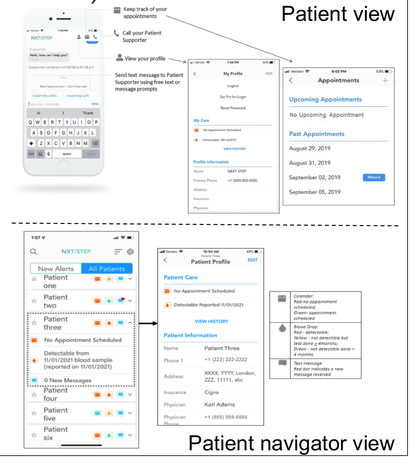
- We hypothesized that an mHealth-enhanced linkage, adherence, and retention (mLAR) app could be successfully implemented and would improve HIV virologic suppression and care engagement among people living with HIV (PLWH) in Baltimore, Maryland when compared to existing clinic linkage, retention, and adherence protocols (LAR).

METHODS

- Individual-level, hybrid effectiveness-implementation randomized-controlled trial (RCT) completed in Baltimore, Maryland between February 2020 and December 2022 with 12-month follow-up.
- Effectiveness Evaluations:
  - Primary Outcome: virologic suppression
  - Secondary Outcomes: out of care (no clinic appointment or HIV viral load) and all-cause mortality.
- Implementation Evaluations:
  - Client Satisfaction Questionnaire (CSQ-8)
  - In-depth interviews with study participants (n=23; 17 mLAR, 6 LAR) and patient navigators (n=20; 14 pre-intervention, 6 post-intervention).
- Extensive pre-, during-, and post-study consultations were held with a Community Advisory Board consisting of PLWH, HIV providers, patient navigators, and public health officials.

NextStep App (mLAR Intervention)

Two mobile apps, one for patients and one for clinic-based patient support navigators were designed to display HIV lab data (uploaded directly from health department), send appointment reminders, facilitate communication with clinic staff, and streamline patient-initiated requests.



This study assessed an **mHealth-enhanced linkage, adherence, and retention intervention** compared to standard clinic protocols using an **effectiveness-implementation RCT**.

Though **acceptability appeared high** based upon user satisfaction and interviews, the intervention showed **no impact on HIV virologic suppression, engagement in care, and all-cause mortality.**

RESULTS

Participant Demographics and Enrollment

Patient Characteristic		LAR		mLAR	
Count per Study Arm (n)		225		223	
Continuous Variables		Mean	(min, max)	Mean	(min, max)
Patient Age in Years		45.0	(20,78)	45.1	(21,70)
Categorical Variables		n	%	n	%
Baseline Viral Load	Undetectable (<200, c/ml)	128	56.9%	112	50.2%
	Detectable (≥200, c/ml)	82	36.4%	93	41.7%
	No VL record	15	6.7%	18	8.1%
Care History	Newly diagnosed	7	3.1%	16	7.2%
	Re-engaged	42	18.7%	42	18.8%
	Currently in care	176	78.2%	165	74.0%
Gender	Female	77	34.2%	89	39.9%
	Male	148	65.8%	134	60.1%
Racial Identity	Black / African American	177	78.7%	179	80.3%
	White	18	8.0%	22	9.9%
	Other	36	16.0%	29	13.0%
Ethnicity	Hispanic / Latino	22	9.8%	28	12.6%

Table. Baseline characteristics of study participants.

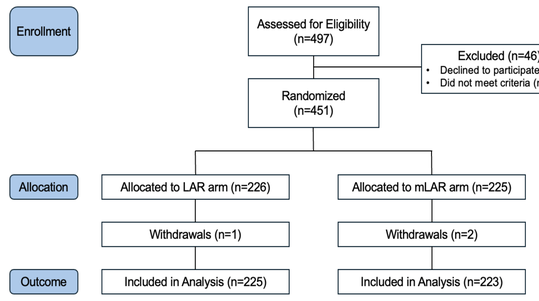


Figure 1. Flow diagram of study participation.

Effectiveness Evaluation

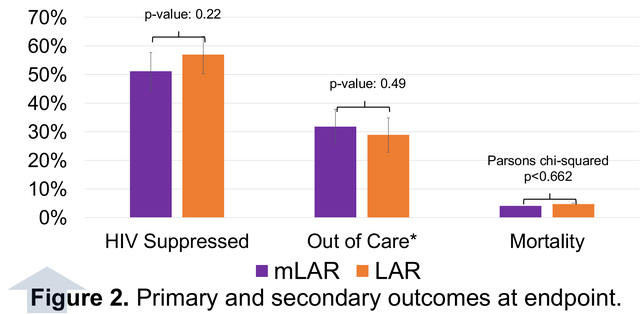


Figure 2. Primary and secondary outcomes at endpoint.

Viral Suppression

- 53.6% had a suppressed HIV viral load at enrollment and 54.0% at 12 months with no significant difference across study arms. There was no time by study arm interaction.

* Over half of participants without an endpoint viral load in both arms filled HIV medications (i.e. may have been suppressed but did not have lab monitoring data for confirmation.)

Implementation Evaluation

- 91.4% satisfaction score in mLAR vs. 92.1% in the LAR arm, Pearson chi-squared of p<0.650.
- Participants: Felt supported/in control and facilitated attending clinic appointments.
  - Challenges: interfacing with the technology and redundancy with the electronic medical record.
- Patient navigators: Streamlined professional tasks and facilitated real-time communication.
  - Challenges: lack of synergy/redundancy with electronic medical record and blurred boundaries between work and personal time.

CONCLUSIONS

An mLAR app showed no differences in HIV virologic suppression, care engagement, and mortality among PLWH in Baltimore, Maryland when compared against existing clinic LAR protocols.

- Reach was high (participants assessed for eligibility excluded from the study (9.3%, 46/497) and all participants randomized to mLAR were able to login at least once and send a test message.
- Adoption was suboptimal with one-third of participants using the app for one week or less.

There were contextual factors that likely affected negative study results, including COVID-19 pandemic, increased mHealth accessibility, and evolving clinic protocols.

- Fragmentation of information through multiple mHealth platforms including electronic health records accelerated rapidly during COVID likely impacted participant and provider app use.
- Major interruptions and HIV funding shortfalls in Baltimore City Health Department programs led to delays and recruitment challenges.

For populations with complex socio-structural determinants of health, additional strategies beyond an mHealth app are needed to improve HIV care outcomes.

ADDITIONAL KEY INFORMATION

Ethical Approvals and Registration:

- Johns Hopkins School of Medicine (IRB00195120)
- Baltimore City Health Department (BCHD)
- ClinicalTrials.gov (NCT03934437)

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PLAIN LANGUAGE SUMMARY

A mobile phone app designed to facilitate communication between patients living with HIV and a clinic-based patient support staff member had no impact on HIV health outcomes or engaging in clinical care (going to appointments, getting labs, etc.)