HT Helper Study: a Phone Application + Patient Navigation to Improve Medication Adherence among Latina Breast Cancer Patients Experiencing Social Determinants of Health

Patricia Chalela, DrPH,[1] Vivian Cortez, MS,[1] Sandra Sivak, BS,[1] Armida Flores, BA,[1] Martha De La Mora, BS,[1] Zully Garcia, BS,[1] Byeong Choi, PhD, [1] Edgar Muñoz, MS,[1] Qurathul Ahmed, BS, [1] Audrey Cordova, BS, [1] Maria Sung-Cuadrado,[1]
Asra Aslam, PhD,[1] Mauren Duran, BS,[1] Shayannie Sierra,[1] Chastity Garay, [1] Cliff Despres, BJ,[1] Alyssa Gonzales, BA,[1] Virginia Kaklamani, MD,[2] Kate Lathrop, MD,[2] Marcela Mazo Canola, MD,[2] Devasena Inupakutika, PhD,[3] David Akopian, PhD,[3] Amelie G. Ramirez, DrPH[1]
[1]Institute for Health Promotion Research, UT Health SA; [2]Mays Cancer Center, UT Health SA; [3]University of Texas at San Antonio

INTRODUCTION

Hormone therapy (HT) is highly effective for nearly all breast cancer patients with hormone receptor-positive tumors, which represent about 83% of all breast cancer diagnoses.[1,2,3] Long-term use of HT reduces recurrence rates and cuts the risk of breast cancer mortality nearly in half during the second decade after diagnosis. Despite the proven benefits, 33% of women who are prescribed HT do not take it as prescribed by their doctor (<80% take their daily dosage). Latina patients are disproportionately affected by Social Determinants of Health (SDoH) that keep them from adhering to HT and are at higher risk of breast cancer recurrence and mortality.[4,5]

AIM

The goal of this 4-year randomized controlled study is to assess the effectiveness of the existing bilingual, culturally tailored, interactive HT Helper App, in combination with patient navigation (PN), on improving adherence to HT among Latina breast cancer patients experiencing SDoH barriers, i.e., income, health insurance, education, health literacy, and language, that impacts their medication adherence. This theory-based intervention will increase patient education, enhance self-efficacy, facilitate communication with the medical team and coordination of resources to address SDoH barriers and help patients develop self-care skills for optimal adherence to HT, ensuring patients the most equitable treatment outcomes possible, including improvement in quality of life, survival, and life expectancy.

Aim 1: Conduct a parallel 3-group randomized controlled trial to assess the effectiveness of HT Helper App + PN (Group 1) vs. PN alone (Group 2) vs. usual care (Group 3) on HT adherence among Latina patients.

Aim 2: Assess the effect of the HT Helper App + PN (Group 1) vs. PN alone (Group 2) vs. usual care (Group 3) on patients' self-efficacy to identify side effects, use self-care skills to manage side effects, and communicate with the medical team.

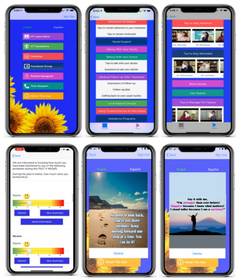
MATERIALS AND METHODS

This parallel 3-group randomized controlled trial with 5-time assessments (baseline, 3, 6, 12, and 18 months) and will enroll 159 breast cancer patients (53/group) who are prescribed HT and are attending the Breast Clinic at the Mays Cancer Center.

Random Assignment of eligible breast cancer patients (R):						
(R) HT Helper + patient navigation	O1	X1	O2	O3	O4	05
(R) Patient navigation alone	O1	X2	O2	O3	O4	05
(R) Usual care	O1	X3	O2	O3	O4	05
X1= HT Helper + patient navigation	O1= Pre-intervention survey					
X2= Patient navigation alone	O2= 3-mo follow-up		O3= 6-mo follow-up			
X3= Usual care	O4= 12-mo follow-up		O5= 18-mo follow-up			

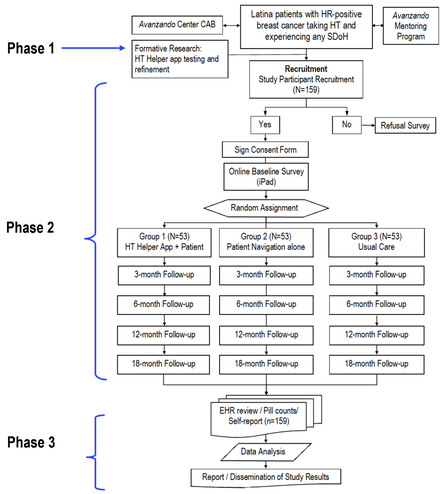
Inclusion Criteria. English/Spanish-speaking Latina patients aged 18 and older who: a) are diagnosed with hormone receptor-positive breast cancer and prescribed HT; b) within 1 to 12 months of starting HT; c) are experiencing any SDoH (*Avanzando Center* SDoH Screener); d) own a smartphone, e) are able to send and receive text messages and access the internet; and f) are able to provide informed consent to participate in the study. (✓)

Phase 1: Formative Research. Betatesting of the HT Helper App with 12 breast cancer patients experiencing SDoH, who will assess the content, educational videos, and general features of the current app and the app's User Guide.



Screenshots of the HT Helper App

MATERIALS AND METHODS *cont.*



Study Flowchart

Outcome Evaluation. Outcome evaluation will include data derived from pill counts, self-report surveys, and medical records review. Validated questionnaires will be used to assess the study's primary and secondary outcomes.

Primary outcome: Adherence to HT (≥80%). We will use pill counts at every visit to calculate an adherence index across the 18-month intervention ((quantity dispensed - remaining)/(quantity prescribed per day*days since last refill))*100.

We will also collect self-report data through the validated Adherence to Refills and Medications Scale (ARMS).

Other primary outcomes of interest are self-efficacy for medication adherence (Self-Efficacy for Appropriate Medication Use Scale - SEAM) and social support (Multidimensional Scale of Perceived Social Support).

Secondary Outcomes: Medication side effects (BCPT Symptoms Scale), patient's quality of life (Functional Assessment of Cancer Therapy-General – FACT-G), depression (Patient Health Questionnaire – PHQ-8), anxiety (Generalized Anxiety Disorder – GAD-7), and usability and satisfaction with the personalized bilingual mobile application.

EXPECTED OUTCOMES

- Promote health equity by creating a more level playing field that gives underserved Latina breast cancer patients an equitable opportunity to receive the benefits of HT, improve overall survival and life expectancy, enhance quality of life, and decrease cancer healthcare costs.
- If proven effective, this study will advance our knowledge about the use of mobile technology and patient navigation as an evidence-based strategy to improve medication adherence among breast cancer patients experiencing SDoH and promote equitable cancer outcomes.
- The intervention can be adapted and tailored to patients' characteristics and promote health equity among future medically underserved breast cancer patients receiving hormone therapy, regardless of race and ethnicity.

CONCLUSION

This proposed multi-level intervention involving a unique combination of mHealth technology + PN has the potential to improve adherence to HT by addressing SDoH and promote equitable breast cancer outcomes, including reduced recurrence and improved quality of life, overall survival and life expectancy among underserved Latina patients. The anticipated outcome is a scalable, evidence-based, and easily disseminated intervention with potentially broad use to patients using oral anticancer medications.

ACKNOWLEDGEMENTS

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