B3b. Aims 1 and 2

B3b1. Design. We will use a two-group, 2-week longitudinal, randomized, controlled trial with triads of patients, caregivers, and nurses randomly assigned to either *e-PainSupport* or standard care. With only one nurse for one study patient (intervention or control) in the study, nurses will not be sources of contamination as might occur with patients in both intervention and control groups. Since only newly admitted patients/caregivers will be recruited, control group patients will not have direct contact with nurses already in the intervention. Previously, we followed patient/caregiver dyads for 9 days and saw no changes in caregiver barriers to pain management and self-efficacy.[38] Another hospice study found a 25% mortality rate 2 weeks after enrollment.[31] Thus, we believe using a 2-week follow-up period is feasible and gives patients and caregivers time to complete Education Module designed to reduce barriers to pain management and improve self-efficacy.

B3b2. Setting and sample. Nurses, patients, and their caregivers (132 triads) will be recruited from JourneyCare, the largest not-for-profit hospice agency in Illinois. JourneyCare uses an EHR called NetSmart; one of the most commonly used EHR software in hospice settings; it has over 600,000 users in over 25,000 organizations across the U.S. JourneyCare has a yearly census of 2,500 patients (see letter of support). Approximately 340 patient care nurses have caseloads of 15 patients at any one time. In our previous study, 80% of hospice nurses agreed to participate.[5] Based on these data, we will recruit 132 nurses from a pool of 340 (39%).

Inclusion criteria. Nurses: (a) registered nurse (RN) and(b) provides direct care to patients. Patients:(a) prior enrollment of their hospice nurse; (b) receives analgesics for pain; (c) speaks and reads English; (d) age 18 or older; (e) has primary informal caregiver available for the 2 weeks of study; (f) cognitively intact; (g) expected to survive at least 2 weeks; (h) can verbalize pain. Patients will be recruited upon admission to hospice and will be in study for 2 weeks. It is reasonable to expect patients to survive 2 weeks because hospice patients' average survival in 2017 was 76.1 days, with median survival of 24 days. Patients must achieve nurse-rated score ≥ 30% overall, and ≥ 70% on consciousness item on the Palliative Performance Scale (PPS).[43,44] PPS is routinely administered at admission and thus will not increase burden. It covers 5 domains of functional status: ambulation, activity level, self-care, oral intake, and consciousness level. Each

domain is scored on a scale from 100% = *full function* to 0% = *limited/no function*.[45] A cut-off PPS score of 30% is a commonly used cut-off point for studies similar to ours. An overall PPS cutoff of 30% is associated with a 2-week survival of 42%.[44] Therefore, we expect approximately 42% of patients are expected to survive at least two weeks with a PPS score of 30%. A PPS consciousness score ≥ 70% indicates full consciousness, consistent with full alertness, orientation, and cognitive ability.[43] This prevents generalizing results to patients who are not cognitively intact, but we believe the app should be tested in a cognitively intact sample prior to adaptation to other patients. Diagnosis is not an inclusion criterion; end-of-life pain is not diagnosis specific. Most studies focus on cancer patients, but pain among non-cancer patients is common in hospice.[21] Caregivers: (a) speaks and reads English; (b) age 18 or older; (c) cares for an enrolled patient; and (d) available for the 2 week study.

Recruitment. Nurses: Direct care nurses will be recruited during regular staff team meetings and the study information sessions. Staff meet with interested nurses in person, by phone, or via video conference to explain the study and answer any questions about the study. Refreshments will be served at the in-person meetings. Nurses who attend the information sessions via video conf will receive a $5 gift card. The written consent will be obtained in-person, by phone, or electronically. At that time, they sign an oath of confidentiality, agreeing not to share study information with other nurses for the duration of the study. Nurses may not be enrolled in study if their patients do not participate. Nurses will be informed that, if they have a patient in the *e-PainSupport* condition, they will be invited to a post-intervention interview. Patients and caregivers: During the hospice admission interview, admission nurses will identify patients who appear to meet inclusion criteria and provide recruitment flyers to introduce the study. Nurse case managers will follow up with patients and caregivers by introducing the study if it was not done during the admission process. Nurse case managers will be instructed not to select participants but simply introduce the study to all patients and caregivers who appear to meet inclusion criteria (thus, there will be no selection bias). The flyer includes purpose and contact information (phone and email). Patients also receive a letter saying the hospice medical director supports the study. If interested in learning more, they will give a verbal consent to be contacted by a research staff. If a patient is assigned to a nurse who has agreed to participate, a research staff member will contact patient and caregiver by phone to explain the study (both must agree to participate). The written consent will be obtained in-person, by phone, or electronically. Due to the effects of the COVID-19 pandemic, we have prepared an alternative recruitment strategy to capture patients that may not be introduced to the study by their nurses. To promote timely identification of potential participants and prevent patient loss during the referral process, we would like to recruitment patients by using EHR data. Potential participants will be identified via Electronic Medical Record searches and clinician referrals (outside of RUMC). We will obtain approvals from hospice administrators and healthcare providers to get referrals and contact their patients directly. The participating hospice agencies will query their EHR data to identify patients who receive analgesics for pain and with PPS>30%. Identified patients will be sent or receive a letter from their hospice nurses to introduce the study. The informational letter will include the PI's and Project Director's contact information. Patients and caregivers will be informed that they can call or email the research team for additional information or to opt out of the study. Participants will be able to email or call back expressing interest or preference to decline participation in the study. If study staff does not hear back from potential participants within two business days from mailing or receiving the letter, the research team will call and/or email the patients up to three times to provide them information about the study and ask them if they are interested in participating in the study. If the participant decides to participate, the written consent will be obtained in-person, by phone, or electronically.

We anticipate enrolling about 9 to 10 patients and caregivers per month over 14 months. We will randomly assign them to either control or treatment condition after nurse, caregiver, and patient have signed consent. Randomization will be conducted in blocks of 10 pairs to minimize possible history effects.

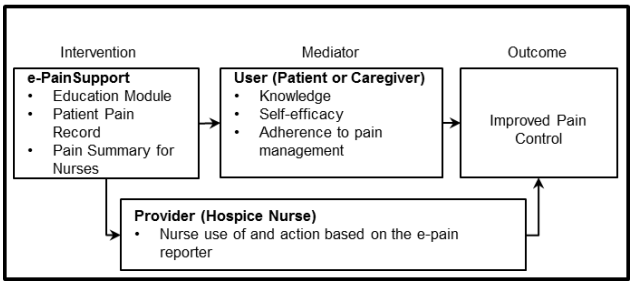
Retention. The following strategies will be used: (1) Data collection at convenient times and dates. (2) Multiple contact methods: Participants will be given the project office number and email, answered by or forwarded to project director's mobile phone. Those in *e-PainSupport* condition will also receive a list of frequently asked questions. (3) Multiple reminders: (a) Project director will call patients and caregivers one day after they receive app to confirm understanding of how to use; (b) if no data are entered for 24 hours during

study period, patient and caregiver will receive automatic text reminder; (c) if no data are entered for 2 days, project director will call and help problem solve; (d) midway during study period (5-7 days), they receive a call, email, or text thanking them for participating and encouraging them to continue; participants receive a mug with study name and phone number; (4) Incentives: Patients and caregivers receive a $10 gift card after baseline data collection and a $30 card after completing study. Nurses receive a $20 card after patients complete study.

B3b3. Standard care condition. Hospice nurses specialize in symptom management and emotional support for grieving or distressed caregivers. Patients receive standard nurse visits 1-2 times/week based on health status. The hospice has routine analgesics (standing orders). Nurses assess patients' pain, select appropriate analgesics, and enter pain score and type of analgesic into the EHR on laptop computer while in the home. Patients or caregivers can call hospice nurse on call 24 hours/day if pain is not controlled. Nurses manage patient and caregiver needs by phone or send a team member (e.g., RN, social worker, grief counselor) to patient's home, if needed. However, *if caregivers fail to call to report uncontrolled pain, the nurse has no way of knowing*. Patients in this condition do not have access to *e-PainSupport* technology.

B3b4. *e-PainSupport* condition. In addition to standard care, this condition includes *e-PainSupport*. The app was guided by our Pain Management in Home Hospice Care Framework (Figure 1). The framework identifies relationships between patient and caregiver factors (knowledge, self-efficacy, and adherence to regimen) and patient-pain intensity. Also, nurses' use of, and actions based on, *e-PainSupport* may influence pain intensity and analgesic use. *e-PainSupport* is a self-administered, digital pain application that can be integrated with any digital device. It has 3 elements: (a) Education Module, (b) Patient Pain Record (Breakthrough Pain Report and Daily Pain Report of worst pain), and (c) Pain Summary for Nurses. Patient Pain Record and Pain Summary for Nurses are directly linked to the EHR using SMART APP Launch Framework. The framework connects third- party applications to EHR and uses oAuth 2.0 for authentication. All data related to analgesic regimen (i.e., name, frequency, route, and dose) for around-the-clock and PRN medications are automatically populated in *e-PainSupport* at enrollment. User information is tracked in real time. Any medication changes are automatically updated from the EHR into the application in real time, and Patient Pain Record is uploaded from application to EHR. On opening, users see introduction with contact information, instructions, and home page, where they select Education Module or Patient Pain Record. Caregivers complete Education Module, and patients may complete it. Caregiver or patient fill out a Breakthrough Pain Report per episode. Only nurses can view Pain Summary for Nurses. A major benefit is nurses are informed in real time of patient's pain level and can respond without delay.

Figure 1. Pain Management in Home Hospice Care Framework



Education Module.

Education Module is adapted from Representation Intervention to Decrease Pain (RIDPAIN), an evidence-based intervention that helps patients and caregivers become knowledgeable about pain reporting and management.[15-17,45] Dr. Ward, developer of RIDPAIN, and Dr. Paice, palliative care pain specialist, will help us adapt RIDPAIN for *e-PainSupport* (see letters of support). TapCloud will build the module. As in pilot study B3a1, we will solicit input on format and content from 3-4 caregivers. The module addresses Ward's 8 pain-management barriers[15-17]. Introduction includes instructions, encouragement to cover all topics, and common terms. Users are prompted to click on each barrier to learn best strategies. A voiceover option accommodates low literacy. Items take about 3½ minutes (total 30 minutes). Users can review any time. American Cancer Society and National Cancer Institute resource links are given.

Patient Pain Record. This includes Breakthrough Pain Report and Daily Pain Report. For both, the user (patient or caregiver) is recorded. Breakthrough Pain Report. Users will complete this report every time the patient experiences moderate to severe pain (greater than 3 on 0-10 scale). Included are location(s) identified on a graphic image of the human body with a touch screen; quality, selected from a list of 21 pain descriptors[47] and intensity, rated on a 0-10 scale depicted on a graphic thermometer image. Caregivers are prompted to ask patients to rate pain intensity, frequency, and duration; thus, all pain reports will be from the patient. If patients are unable to report, the caregiver chooses option of "patient unable to report," and fills it in for the patient. For each report, analgesics and non-pharmacological actions are recorded. If analgesics are given, users select name, time, route, and dosage. If analgesics are not given, dropdown menu includes: (a) gave/took something else, (b) did something else, (c) patient refused, and (d) decided not to take. If they select "gave/took something else," they see menu of alternative medications, or they can type in another medication. If they select "did something else," they see menu of non-pharmacological actions (e.g., cold, heat, massage). Daily Pain Report. Users report worst pain intensity past 24 hours on 0-10 graphic thermometer as well as frequency and average duration of moderate to severe pain (> 3 on 0-10 scale). Caregiver can choose "patient unable to report," and fill it in for patient. Users report how often patients receive analgesics. App has a reminder alarm.

e-PainSupport is a secure system ensuring privacy and integrity of all information. It is configured with a local internet service provider (ISP). A secure ISP connection transfers data. The connection is encrypted and protected by Secure Sockets Layer technology for confidential transmission. Timestamps for entries in Education Module and Patient Pain Record are stored in the same secure database.

Pain Summary for Nurses. This is an automatically generated graphic summary of patients' Breakthrough Pain Reports and Daily Pain Reports over time. It allows nurses to monitor pain and medication and identify patients with worsening pain. Nurses can also communicate with patients via secure text or e-mail. Pain Summary for Nurses is integrated into the EHR and available prior to each visit. Nurses can access it by phone, tablet, or laptop via secure internet connection. It also sends text alert if Daily Pain Report is ≥ 7 on 0-10 scale. This is consistent with American Pain Society Clinical Guidelines[48] that severe pain should trigger reassessment with possible medication adjustment. Nurses are encouraged to check the Pain Summary daily.

B3b6. Measures. Measures are presented in Table 1.

Table 1. Study measures for patients (PT), caregivers (CG), and nurses (RN)

Variable	PT	CG	RN	Description and reliability/validity
Pain intensity (primary outcome; baseline/2wks)	X			PROMIS Pain Intensity-Short Form (PPI-SF) 3a v1.0: 3 items: worst pain and average pain in past 7 days, and current pain, scored from 1 = *no pain*, 2= *mild*, 3 = *moderate*, 4= *severe*, 5 = *very severe pain,* summed for a range of 3 to 15. Interitem correlation (0.33-0.93), convergent validity with PROMIS global pain (0.68), and PROMIS global physical health (0.61).[51] There is strong agreement (.6-.8) between patients' and caregivers' reports of patient-pain intensity; the bias is usually caregivers' rating patient pain higher than patient does.[52] According to 2008 Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials Committee, a 10% change (1.5 points for the PPI-SF) in pain intensity indicates minimally important clinical improvement.[11]
Knowledge (mediator; baseline/2wks)	X	X		Barriers Questionnaire II (BQ-II): Measures 8 knowledge barriers about reporting pain and using analgesics, with four subscales (physiological effects, 12 items; fatalism, 3 items; communication, 6 items; and harmful effects, 6 items (total 27 items), 6-point scale (0 = *don't agree*, 5 = *agree very much*), items averaged (range 0 to 5), α = .89, patients with adequate analgesics had lower scores than patients with inadequate analgesics.[39]

Self-efficacy (mediator; baseline/2wks)	X	X		Chronic Pain Self-Efficacy Scale: Self-efficacy for pain management subscale, measures confidence in managing pain, 5 items on 100-point scales: 10 = *very uncertain*, 100 = *very certain*. Internal consistency (0.80).[9] Caregivers are asked to rate how confident they are that they can help the patient control pain using extra analgesics (e.g., How certain are you that you can decrease the patient's pain quite a bit?). Construct validity: demonstrated in cancer patients at the end of life. Concurrent validity: high self-efficacy was associated with lower strain, decreased negative mood, and increased positive mood.[9] These questions are slightly modified for patients.
Adherence to pain management (mediator; baseline/2wks)	X	X		Morisky Medication Adherence Scale (MMAS): Measures medication adherence, 4 items: Patients answer yes or no to questions (e.g., Do you sometimes forget to take your pain medication?). These questions are slightly modified for caregivers (e.g., Do you sometimes forget to give the patient his or her pain medicine?) Each "yes" answer is scored as 1. Items are summed, with range of 0 to 4. Lower score indicates better adherence.[53]
Background (baseline)	X	X	X	Demographics from NINR common data elements (age, sex, education, and patient diagnosis).
Diffusion of intervention (fidelity; 2wks)			X	Significant Diffusion Effects Measure: Measures possible diffusion of the intervention with social interactions specific to the intervention (4-items) at the worksite. The measure has a Content Validity Index[50] of .94.

We propose adding PROMIS pain interference scale short form 8a and health literacy scale to the study measures. The PROMIS pain interference scale measures the extent to which pain interferes with physical, mental, and social activities. The PROMIS pain interference scale has been tested in diverse patient populations and it is recommended as a measurement of a core outcome in clinical trials of pain treatments. The usefulness of the PROMIS-IF in clinical trials and patient care has been demonstrated in three randomized clinical trials. To assess caregiver health literacy, we will use the rapid assessment of adult literacy (REALM).[2] The REALM is a quick, easily-administered tool that measures one's health literacy based on accuracy of reading 66 medically-relevant words.[2] Scores are calculated based on the number of words read correctly, which are then categorized into one of four reading levels (0-18 third grade or below, 19-44 fourth to sixth grade, 45-60 seventh to eighth grade, and 61-66 ninth grade or above).[3] The REALM has been previously used in caregivers of adult care recipients. [4] The REALM was highly correlated with the short test of functional health literacy in adults (S-TOFHLA), with correlation coefficients ranging from 0.80 to 0.90.[2,5] Cronbach's alpha was .96 when evaluated in a population of adults at primary clinics in Pennsylvania.[6]

B3b7. Procedures. Project director holds one-day staff training for data collectors. Baseline data collectors make home visits for consent and baseline measures, and then open sealed envelope with patient's randomly assigned condition. During the COVID-19 pandemic, we will follow the national and state guidelines. If indicated, the study team members will complete a COVID-19 symptom screener before entering the patient homes. This includes a touchless temperature check and questions about how they are feeling, where they have traveled, and whether they have been in contact with anyone who has been diagnosed with COVID-19. Study team members will be wearing a mask, face shield and gloves throughout the visit. Anytime study team members go to a patient home, they will provide masks to patients and caregivers also. If patients or caregivers are experiencing a fever, cough, runny nose, new rash, chills, muscle pain, sore throat, or new loss of taste or smell, then they will be instructed to contact the study team. If patients and caregivers have been in close contact with a person who has been diagnosed with COVID-19, they will be instructed to contact the study team. *e-PainSupport condition:* Caregiver or patient downloads app onto one device, or receives tablet with wireless capability (returned after the study). As staff enter patient's name in *e-PainSupport*, current prescribed analgesics automatically populate the app. Participants receive intervention training and give return demonstration. They also receive hardcopy of *e-PainSupport* manual and troubleshooting guide. Staff inform patient's nurse of patient's enrollment and arrange 30-minute *e-PainSupport* training. Nurses monitor patient pain using Pain Summary for Nurses. They receive alerts when pain is ≥ 7. Technical support information (email/telephone number) is provided in app and on paper. Nurses complete satisfaction survey at the end of study. Standard care condition: Participants are informed that they will receive care from hospice nurses and should contact them with pain management issues. Both conditions: Patients and caregivers schedule 2-week data collection. Two days prior to data collection, staff confirm the visit. At 2-week visit, participants complete questionnaires. Data collectors at the 2-week visits differ from those who collected baseline data to maintain blinding to condition, and staff collecting project tablets at study completion will differ from data collectors.

B3c. Aim 3. Identify hospice nurses' perceptions of their use of and actions based on *e-PainSupport.*

B3c1. Design. Project director will conduct post-intervention, semi-structured interviews of nurses with patients in *e-PainSupport* condition. We will explore facilitators, barriers, and perceived benefits for their practice. Findings will inform future modifications, testing, and dissemination of *e-PainSupport.*

B3c2. Sample. Nurses in *e-PainSupport* condition will be invited by e-mail to contact office if interested. Approximately 3 weeks after final data collection, we will enroll the first 15 interested nurses.[58]

B3c3. Interview Guide. Semi-structured interviews include (1) ease of use of *e-PainSupport* and problems integrating it into clinical workflow, (2) changes in practice (e.g., frequency of communication with patients, caregivers) after access to pain assessment/management data via *e-PainSupport*, (3) impact of *e-PainSupport* on facilitating adherence to pain/management regimens, and (4) suggestions for future use (Appendix D).

B3c4. Procedures and Data Collection. One week before interviews, we send confirmation e-mail. Study and confidentiality are discussed, and written consent is signed. Interviews take approximately 30 minutes, are audio recorded and held in a private room at agency or other site. Nurses receive $20 for participation.