

Determining the effectiveness and feasibility of a virtual hospital model of care for low back pain: protocol for a hybrid effectiveness-implementation type-I pilot study

Alla Melman, Min Jiat Teng, Danielle M Coombs, Qiang Li, Laurent Billot, Thomas Lung, Eileen Rogan, Mona Marabani, Owen Hutchings, Chris G Maher, Gustavo C Machado

Submitted to: JMIR Research Protocols
on: June 20, 2023

Disclaimer: © The authors. All rights reserved. This is a privileged document currently under peer-review/community review. Authors have provided JMIR Publications with an exclusive license to publish this preprint on its website for review purposes only. While the final peer-reviewed paper may be licensed under a CC BY license on publication, at this stage authors and publisher expressly prohibit redistribution of this draft paper other than for review purposes.

Table of Contents

Original Manuscript..... 5

Supplementary Files..... 23

 Figures 24

 Figure 1..... 25

 Figure 2..... 26

Determining the effectiveness and feasibility of a virtual hospital model of care for low back pain: protocol for a hybrid effectiveness-implementation type-I pilot study

Alla Melman^{1*} MSc, BSc; Min Jiat Teng^{1, 2}; Danielle M Coombs^{1*}; Qiang Li^{3*}; Laurent Billot^{3*}; Thomas Lung^{3, 4*}; Eileen Rogan^{5*}; Mona Marabani^{5*}; Owen Hutchings^{2*}; Chris G Maher^{1*}; Gustavo C Machado^{1*}

¹Sydney Musculoskeletal Health The University of Sydney and Sydney Local Health District Camperdown AU

²RPA Virtual Hospital Sydney Local Health District Sydney AU

³The George Institute for Global Health UNSW Sydney AU

⁴School of Public Health Faculty of Medicine and Health The University of Sydney Sydney AU

⁵Department of Medicine Canterbury Hospital Sydney Local Health District Sydney AU

*these authors contributed equally

Corresponding Author:

Alla Melman MSc, BSc

Sydney Musculoskeletal Health

The University of Sydney and Sydney Local Health District

Level 10N, King George V Building, Royal Prince Alfred Hospital

Missenden Road

Camperdown

AU

Abstract

Background: Low back pain (LBP) was the 5th most common reason for an Emergency Department (ED) visit in 2020–21 in Australia, with >145,000 presentations; 1/3 of these patients were subsequently admitted to hospital. Admitted patient care accounts for half of the total healthcare expenditure on low back pain in Australia.

Objective: The primary aim of the Back@Home study is to assess the effectiveness of a virtual hospital model of care to reduce length of admission in people presenting to ED with musculoskeletal LBP. A secondary aim is to evaluate the acceptability and feasibility of the virtual hospital and our implementation strategy. We will also investigate rates of traditional hospital admission from the ED, re-presentations and readmissions to the traditional hospital, demonstrate non-inferiority of patient-reported outcomes, and assess cost-effectiveness of the new model.

Methods: This is a hybrid effectiveness-implementation type-I feasibility study. To evaluate effectiveness, we plan to conduct an interrupted time series study at three metropolitan hospitals in Sydney, New South Wales, Australia. Eligible patients will include those aged ≥16 years with a primary diagnosis of musculoskeletal low back pain presenting to the ED. The implementation strategy includes clinician education using multimedia resources, staff champions, and an 'audit and feedback' process.

Implementation of 'Back@Home' will be evaluated over 12-months, and compared to a 48-month pre-implementation period, using monthly time-series trends in average length of hospital stay as the primary outcome. We will construct a plot of the observed and expected lines of trend based on the pre-implementation period. Linear segmented regression will identify changes in level and slope of fitted lines, indicating immediate effects of the intervention, as well as effect over time. Ethics approval has been granted for protocol X21-0278 & 2021/ETH10967. Data will be fully anonymised, with informed consent collected for patient-reported outcomes.

Results: As of 24th June 2023, thirty-two patients have been cared for through Back@Home. Five patients have completed semi-structured interviews regarding their experience of virtual hospital care for non-serious back pain. All outcomes will be evaluated at 6-months (Aug 2023) and 12-months post implementation (Feb 2024).

Conclusions: This study will serve to inform ongoing care delivery and implementation strategy of a novel model of care. If found to be effective, it may be adopted by other health districts, adapting the model to their unique local contexts.

(JMIR Preprints 20/06/2023:50146)

DOI: <https://doi.org/10.2196/preprints.50146>

Preprint Settings

1) Would you like to publish your submitted manuscript as preprint?

✓ **Please make my preprint PDF available to anyone at any time (recommended).**

Please make my preprint PDF available only to logged-in users; I understand that my title and abstract will remain visible to all users.
Only make the preprint title and abstract visible.

No, I do not wish to publish my submitted manuscript as a preprint.

2) If accepted for publication in a JMIR journal, would you like the PDF to be visible to the public?

✓ **Yes, please make my accepted manuscript PDF available to anyone at any time (Recommended).**

Yes, but please make my accepted manuscript PDF available only to logged-in users; I understand that the title and abstract will remain visible to all users.

Yes, but only make the title and abstract visible (see Important note, above). I understand that if I later pay to participate in <http://www.jmir.org>, I will be able to access the full manuscript.

Original Manuscript

Determining the effectiveness and feasibility of a virtual hospital model of care for low back pain: protocol for a hybrid effectiveness-implementation type-I pilot study

Alla Melman¹, Min Jiat Teng^{1,6}, Danielle M Coombs^{1, 2}, Qiang Li³, Laurent Billot³, Thomas Lung^{3,4}, Eileen Rogan⁵, Mona Marabani⁵, Owen Hutchings⁶, Chris G Maher¹, Gustavo C Machado¹ for the Back@Home Investigators.

Author affiliations:

¹ Sydney Musculoskeletal Health, The University of Sydney and Sydney Local Health District, Gadigal Country, Sydney, NSW, Australia

² Department of Physiotherapy, Royal Prince Alfred Hospital, Sydney Local Health District, Gadigal Country, Sydney, NSW, Australia

³ The George Institute for Global Health, UNSW, Sydney, NSW, Australia

⁴ School of Public Health, Faculty of Medicine and Health, The University of Sydney, Gadigal Country, Sydney, NSW, Australia

⁵ Department of Medicine, Canterbury Hospital, Sydney Local Health District, Sydney, NSW, Australia

⁶ RPA Virtual Hospital, Sydney Local Health District, Gadigal Country, Sydney, NSW, Australia

Correspondence to:

alla.melman@sydney.edu.au

Institute for Musculoskeletal Health

Level 10N, King George V Building, Royal Prince Alfred Hospital

PO Box M179, Missenden Road Camperdown, NSW, AUS 2050

Words: 3870

Type: Protocol

Alla Melman: alla.melman@sydney.edu.au
Min Jiat Teng: min.teng@health.nsw.gov.au
Danielle M Coombs: danielle.coombs@health.nsw.gov.au
Qiang Li: qli@georgeinstitute.org
Laurent Billot: lbillot@georgeinstitute.org
Thomas Lung: tom.lung@sydney.edu.au
Eileen Rogan: eileen.rogan@health.nsw.gov.au
Mona Marabani: mona.marabani@health.nsw.gov.au
Owen Hutchings: owen.hutchings@health.nsw.gov.au
Chris G Maher: christopher.maher@sydney.edu.au
Gustavo C Machado: gustavo.machado@sydney.edu.au

KEYWORDS:

Length of Stay, Back Pain, Musculoskeletal Pain, Telemedicine, Hospital-Based Home Care

ABSTRACT

Objectives: Low back pain (LBP) was the 5th most common reason for an Emergency Department (ED) visit in 2020–21 in Australia, with >145,000 presentations; 1/3 of these patients were subsequently admitted to hospital. Admitted patient care accounts for half of the total healthcare expenditure on low back pain in Australia. The primary aim of the Back@Home study is to assess the effectiveness of a virtual hospital model of care to reduce length of admission in people presenting to ED with musculoskeletal LBP. A secondary aim is to evaluate the acceptability and feasibility of the virtual hospital and our implementation strategy. We will also investigate rates of traditional hospital admission from the ED, re-presentations and readmissions to the traditional hospital, demonstrate non-inferiority of patient-reported outcomes, and assess cost-effectiveness of the new model.

Methods and analysis: This is a hybrid effectiveness-implementation type-I feasibility study. To evaluate effectiveness, we plan to conduct an interrupted time series study at three metropolitan hospitals in Sydney, New South Wales, Australia. Eligible patients will include those aged ≥ 16 years

with a primary diagnosis of musculoskeletal low back pain presenting to the ED. The implementation strategy includes clinician education using multimedia resources, staff champions, and an 'audit and feedback' process.

Implementation of 'Back@Home' will be evaluated over 12-months, and compared to a 48-month pre-implementation period, using monthly time-series trends in average length of hospital stay as the primary outcome. We will construct a plot of the observed and expected lines of trend based on the pre-implementation period. Linear segmented regression will identify changes in level and slope of fitted lines, indicating immediate effects of the intervention, as well as effect over time. Ethics approval has been granted for protocol X21-0278 & 2021/ETH10967. Data will be fully anonymised, with informed consent collected for patient-reported outcomes.

Results: As of 6th Dec 2023, 108 patients have been cared for through Back@Home. Six patients have completed semi-structured interviews regarding their experience of virtual hospital care for non-serious back pain. All outcomes will be evaluated at 6-months (Aug 2023) and 12-months post implementation (Feb 2024).

Conclusions: This study will serve to inform ongoing care delivery and implementation strategy of a novel model of care. If found to be effective, it may be adopted by other health districts, adapting the model to their unique local contexts.

Strengths and limitations of this study

- Time series trends for length of hospital stay and admission rates will be collected over a long time period (>5 years) to account for seasonal fluctuations. Interruptions due to COVID-19 related restrictions will be accounted for in statistical analysis.
- The primary outcome will be extracted from routinely collected hospital data, reducing burden and optimising data completeness.
- A subsample (n = 200) of patients will be used to evaluate patient-reported outcome measures; response rate may limit interpretation.
- Some clinical measures such as use of analgesia and imaging cannot be directly compared between 'traditional' and 'virtual' admissions due to different methods of data collection.

BACKGROUND

Low back pain (LBP) was the 5th most common reason for an Emergency Department (ED) visit in 2020–21 in Australia, with more than 145,000 presentations¹. One third of these patients were subsequently admitted to hospital. Current annual admission rates for spinal conditions are high in Australia, at 465/100,000 population, compared to 219 in the United Kingdom, 197 in the Netherlands, and 142 in Canada². Admission rates following LBP presentations to ED are higher in Australia^{3,4} than have been reported in the USA⁵. Potential contributors to high admission rates are differences in case mix⁶, patient expectations of hospital admission when experiencing high levels of distress⁷, and lack of alternative pathways for prompt pain management. These hospitalisations pose a significant burden on the healthcare system. In Australia, for example, admitted patient care of LBP lasts an average of 9 days and costs \$15,000 per admission⁸.

Most patients admitted to hospital with a primary LBP diagnosis do not have a serious underlying condition and there is evidence that admissions carry risk of harms. Our recent medical record review of 1,982 admissions found that 57% of inpatients with provisionally diagnosed

musculoskeletal LBP in ED were discharged with this same diagnosis⁹. Bed rest, as typically occurs with traditional hospital admission, is not recommended in LBP guidelines¹⁰ as it can delay recovery. A recent study showed that 23% of LBP admissions had opioid-related complications and other serious events such as falls in hospital (4%) and hospital-acquired infections (1.4%)¹¹. These patients could be diverted to more cost-effective and safer alternate clinical pathways.

Virtual hospitals have been proposed as a potential clinical pathway for people with LBP¹², to facilitate early discharge. Interviews with people admitted for acute LBP have identified that returning home as soon as possible is a key patient priority, however patients fear lack of support if discharged home¹³. There is also evidence from other conditions that virtual hospitals are cost-effective. Systematic reviews of 'early supported discharge' have been shown to safely reduce length of hospital stay in adults with a range of medical conditions¹⁴. A recent US trial of virtual hospital admission for mixed acute medical conditions showed 38% lower costs for virtual hospital patients compared to traditional admissions, and reduced use of laboratory tests, imaging and consultations¹⁵. The virtual hospital cohort had higher levels of patient satisfaction and lower rates of adverse events¹⁵.

We currently lack alternatives to traditional hospital admission for patients with musculoskeletal LBP who present to Australian EDs, and require acute clinical care. A virtual hospital has been implemented in Sydney Local Health District, Australia for COVID-19 positive patients and other patient cohorts¹⁶, caring for over 16,000 patients to date¹⁷. In the virtual hospital, clinicians use technologies for remote patient monitoring and management¹². Monitoring via daily clinician contact is designed to reduce representation to the ED, whilst providing clinical support and pain management, until the patient is able to link in with and attend outpatient services. Given the higher rates of potential serious pathology in this cohort (compared to primary care), it is also a form of safety netting, allowing prompt escalation if required. Physical activity monitoring is designed to substitute regular reminders to mobilise as would be delivered on a traditional ward, and encourage patients to slowly upgrade physical activity. A virtual hospital service, however, is yet to be formally evaluated in patients with musculoskeletal LBP.

Alongside the diagnostic challenge of LBP, is the difficulty of discharging patients home when safe mobility is not yet achieved. Some patients may still require short term traditional hospital admission to allow for effective analgesia to facilitate mobility. Hence, in this study, we will evaluate the effectiveness of an early supported discharge virtual hospital model of care, with traditional hospital length of stay as the primary outcome.

AIMS:

The main aims of the Back@Home study are to assess the effectiveness of a virtual hospital model of care for LBP on health service outcomes (e.g. length of admission), patient-reported outcomes (e.g. satisfaction with care) and costs.

Secondary aims are to evaluate the acceptability and appropriateness of the virtual hospital model of care for LBP, as well as the feasibility and fidelity of our multifaceted implementation strategy.

METHODS:

STUDY DESIGN

This is a hybrid effectiveness-implementation type-I feasibility study¹⁸. This study design will allow

us to assess the effectiveness of a new virtual hospital model of care for LBP on health services outcomes, while assessing the feasibility and acceptability of the new model and our multifaceted implementation strategy, as described by Curran et al.¹⁸. We have used the guidance for conducting feasibility and pilot studies for implementation trials by Pearson et al.¹⁹ and Proctor et al.²⁰ to design this study.

SETTING:

This study will be conducted at three public hospitals in Sydney, New South Wales, Australia. The hospitals have a combined 169,000 ED attendances per year, with 650,000 total 'bed days' available annually, averaging 1,530 inpatients per day²¹. One site (The Canterbury Hospital [TCH]) will serve as the intervention site, whilst two others (Concord General Repatriation Hospital [CRGH] and Royal Prince Alfred Hospital [RPAH]) will serve as control sites in a times-series design.

POPULATION:

To identify the study population, SNOMED-CT-AU diagnosis codes will be used to select ED patients aged 16 years and older with a primary discharge diagnosis related to musculoskeletal LBP. Those with an ED diagnosis code of a 'serious' LBP condition (e.g. vertebral fracture, spinal abscess, cauda equina syndrome) will be excluded. We will then use inpatient discharge diagnosis codes (ICD-10 AM) to classify the LBP admissions as 'serious' or 'musculoskeletal' (i.e. non-specific LBP, lumbosacral radicular pain). Only data from admissions where inpatient discharge diagnosis codes are musculoskeletal LBP admissions will be evaluated.

Patients who presented to the ED with a primary diagnosis related to musculoskeletal LBP and were discharged without an admission into a short-stay or inpatient unit will be included in the data analysis to determine rates of hospital admission.

INTERVENTION:

Patients with LBP requiring admission in ED short-stay or inpatient units will be assessed by senior ED staff. Eligible patients will be referred to the 'Back@Home' virtual LBP service by the ED Medical Officer, in consultation with local Rheumatology or General Medicine admitting teams. Eligibility criteria for the virtual hospital are people aged 16 years and older diagnosed with musculoskeletal LBP, with or without radicular pain, requiring a higher level of clinical support above standard discharge home [see Figure 1: Virtual Low Back Pain Service Workflows].

Back@Home, a service run by RPA Virtual Hospital, will provide virtual 'Hospital in the Home' (HITH) care, including home visits, video calls and remote monitoring. Eligible patients already admitted to the inpatient ward will also be referred to 'Back@Home' to facilitate earlier discharge. Patients will be remotely monitored from home, and have 24/7 access to hospital-based clinicians through a 'virtual' care centre. An escalation pathway will be available if a patient's condition deteriorates at home, and traditional admission, or expedited imaging or intervention is deemed necessary.

Medical care will be provided by virtual hospital physicians and nurses, with consultations from rheumatology specialists provided as required. All patients will be virtually assessed and treated by a

physiotherapist, with additional assessments provided by occupational therapists, psychologists and social workers as required.

Videoconferencing calls will be used to collect clinical observations and provide care. If required, patients will receive home visits from a physiotherapist¹⁷. The need for home visits will be decided by the multi-disciplinary team (physician, nurse, physiotherapist) during daily clinical reviews, in response to patient need. If a patient appears to not be coping well at home, and is at risk of emergency department representation, a home visit will be scheduled.

Remote monitoring of physical activity, such as step count, will be enabled via an activity tracker. The wearable device used (Garmin vivovit4®) is a validated method of recording sleep cycles, sedentary and active time in community settings^{22,23}. Patients will be able to report activity measures to their virtual physiotherapist during daily videocalls, assisting in goal setting and behavioural health coaching.

Care will be provided through a variety of technologies as appropriate: Short Message Services (SMS), telephone calls, videoconferencing calls [Zoom® platform], patient information sheets emailed directly to patients, as well as access to the 'Physitrack' smartphone application for provision of health information content and exercise programs.

Traditionally admitted patients will receive usual clinical care, with referral for physiotherapy mobility assessment if required, as per standard ward protocols. They will be eligible for referral to Back@Home to facilitate early supported discharge, if appropriate.

IMPLEMENTATION STRATEGY:

The implementation strategy will focus on a single site (Canterbury Hospital) for three months. The 'Knowledge to Action Framework'²⁴ (see Figure 2) was used to guide a research program to develop and evaluate the implementation of Back@Home. The framework structure includes identifying a clinical problem, and then developing evidence-based potential solutions, whilst adapting these to the local context, then evaluating the solution and monitoring outcomes.

Semi-structured interviews with hospital clinicians regarding perceived barriers and facilitators to implementation have informed the current design of the model of care⁷. Based on clinicians' input, the Back@Home model of care will incorporate the loan of internet-enabled devices, health care interpreters, and written resources translated into community languages to facilitate more equitable access to care for marginalized groups. Feedback was provided by the Director of Aboriginal Health and the Aboriginal Cultural Support Team. Consultation on the model was also provided by ED medical officers, Rheumatology, General Medical, and Allied Health Departments, as well as Nurse Practitioners and Social Workers.

We will explore additional local barriers to implementation, design and implement strategies to address these barriers, and monitor clinical practice and clinician behaviour change. Formal evaluation will determine effectiveness of the model of care, and if found effective, we will develop strategies to sustain healthcare system changes (see Figure 1).

To increase uptake of the Back@Home model of care, we plan to use several implementation strategies that have been previously shown to be effective in changing professional behaviour:

- i. Staff training will be delivered by Back@Home investigators (MJT, ER, MM, OH) at scheduled staff education sessions attended by Physiotherapists, Nurses, Registrars, Trainees and Consultants in ED and General Medicine. Sessions will last 15 minutes and be delivered before implementation, and at 1- and 3-months post-implementation. Training will describe

the process of referral to virtual care, deliver updates on implementation progress, and provide a forum to raise concerns or questions.

- ii. Key local opinion leaders²⁵, in the form of 'staff champions' will be provided with training. These staff will remind all clinical staff about Back@Home as an option for patients with musculoskeletal LBP requiring admission and will be identified by wearing a badge with the Back@Home logo. The ED primary care physiotherapist will play a key role in championing the Back@Home model of care.
- iii. A summary card containing admission criteria and contact details for the virtual hospital will be provided to relevant staff, which can be attached to staff lanyards for easy access (if permitted). This printed material will be used to reinforce content of educational sessions^{26,27}.
- iv. A monthly email update will be sent to ED, General Medicine and Rheumatology staff regarding the length of hospital stay and rates of admission to traditional hospital. Audit and feedback strategies have been shown to be effective in influencing health professionals behaviour²⁸, and in supporting back pain model of care implementation strategies²⁹.

EVALUATION (See Table 1 for overview):

HEALTH SERVICE OUTCOMES:

1. Monthly mean length of hospital stay (ED short stay units and inpatient units) in those admitted as a traditional inpatient following an ED presentation for musculoskeletal LBP (primary outcome).
2. Monthly proportion of ED musculoskeletal LBP presentations that result in traditional hospital admissions (ED short stay or inpatient units).
3. Monthly proportion of admitted patients re-presenting to traditional hospital, including: representations to the ED within 48 hours since discharge; readmissions to an inpatient unit within 28 days.
4. Mean and total hospital healthcare costs per month, for patients admitted to traditional and virtual hospitals.

IMPLEMENTATION OUTCOMES:

Implementation outcomes discussed in clinician and patient interviews will include:

1. Acceptability, appropriateness, and feasibility of the model of care to clinicians and the health service evaluated at 6 months using semi-structured interviews³⁰.
2. Fidelity to planned implementation at 6 months using a logbook of implementation.

PATIENT-REPORTED OUTCOMES

Collected at 2- and 4-weeks post hospital admission, in patients admitted with LBP to traditional and virtual hospital. Outcomes include average pain intensity in the past week (Numeric Rating Scale, range 0–10), PROMIS Short Form—Physical Function 6b (range 6–30), and global rating of satisfaction with care (range 0–10).

PROCESS MEASURES (virtual hospital admissions only):

1. Proportion of virtually admitted patients receiving diagnostic tests, by type: laboratory tests; lumbar imaging tests: [plain radiography (X-ray); computerised tomography (CT) scan; Magnetic Resonance Imaging (MRI)], per month.
2. Proportion of virtually admitted patients prescribed specific medicines, per month. Pain medicines will be classified according to the Anatomical Therapeutic Chemical (ATC) classification systems. Drug dosage regimen will also be collected for the following groups of medicines: simple analgesics (i.e. paracetamol); non-steroidal anti-inflammatory drugs (NSAIDs); weak opioids (e.g. tramadol, codeine); strong opioids (e.g. oxycodone, morphine); muscle relaxants; benzodiazepines; antiepileptics; antidepressants; corticosteroids.
3. Utilisation rates of the Physitrack® application by patients (log-ins, viewing and marked completion of exercise program).
4. Number and frequency of video consultations with virtual hospital clinical staff.
5. Number and frequency of face-to-face consultations (home visits) with staff.
6. Number and frequency of escalations of care (patient transferred to hospital), and adverse events.
7. Patient-reported experience measures as routinely collected by the virtual hospital, with additional questions relevant to Back@Home patients (26-item survey).

DATA COLLECTION:

HEALTH SERVICE OUTCOMES:

We will extract primary and secondary healthcare use data from electronic medical records. Data extracted will include patient demographics (e.g. age, gender, postcode), ED presentation and inpatient admission/discharge date, length of ED and admission stay, discharge primary and secondary SNOMED/ICD-10 codes, diagnostic tests used (e.g. laboratory tests, imaging), pain medicines received, specialist and allied health consultations, and healthcare costs. Hospital-acquired complications or adverse events will be identified via Classification of Hospital Acquired Diagnoses (CHADx) codes present in ICD-10 AM data³⁰. Patient Medical Record Number, encounter or visit identifier will be replaced by Study ID as part of the data extraction process, resulting in deidentified data.

IMPLEMENTATION OUTCOMES:

Semi-structured interviews will be conducted with key clinical staff and hospital managers at the implementation site, as well as those involved in delivering virtual care. Purposeful sampling will

aim for input from physiotherapists, nurses, ED medical officers and rheumatologists. Patients who have experienced Back@Home virtual care will also be asked to participate (approved by Sydney Local Health District X21-0094 & 2021/ETH00591).

Fidelity of training related implementation delivery will be assessed via a logbook of staff training, noting the number of sessions delivered, session delivery mode, and number of attendees.

PATIENT-REPORTED OUTCOMES:

Patients with musculoskeletal LBP as the primary reason for admission (to traditional or virtual hospital) will be eligible to complete the patient-reported outcome survey.

Pre-implementation, we will use electronic medical records to identify a cohort that would have likely been eligible for virtual admission if it were available. This will include traditionally admitted patients with a Waterlow Mobility Score of 0–3 (not bed-bound) on admission, with a diagnosis of musculoskeletal LBP. All virtually admitted LBP patients will be eligible. Automated text message invitations will be sent to eligible patients (via REDCap and Twilio) containing a link to an online survey, at two- and four-weeks following ED presentation. One reminder message will be sent to non-responders, and patients that do not respond to the text message will be followed up with a telephone call and offered the opportunity to ask any questions regarding participation, or complete the survey by telephone. This process will be used to maximise response rate of the surveys, and has been proven to be feasible³¹.

STATISTICAL ANALYSIS PLAN:

HEALTH SERVICE OUTCOMES:

Time-series trends during a retrospective 48-month period before implementation of the new model of care will be compared with trends during a 12-month post-implementation period. Preliminary analysis will be conducted at 6-months post-implementation. We will display length of admissions as monthly averages and construct a plot of the observed and expected lines of trend based on the pre-implementation period. Linear segmented regression will identify changes in level and slope of fitted lines. The standard interrupted time series model that will be used is:

$$Y_t = \beta_0 + \beta_1 T_t + \beta_2 X_t + \beta_3 X_t T_t$$

In this equation Y_t is the outcome variable (e.g. length of admission) measured at each equally spaced time point t (monthly). β_0 represents the intercept or starting level of the outcome variable and β_1 , the slope or trajectory of the outcome variable until the introduction of the intervention. T_t represents the month of the initial ED presentation with T_0 representing the first month (Jan 2017). β_2 represents the change in the level of the outcome that occurs in the period immediately following the introduction of the intervention (compared with what would have happened in the absence of the intervention). β_3 represents the difference between preintervention and postintervention slopes of the outcome. Thus, we look for significant differences in β_2 to indicate an immediate treatment effect, and in β_3 to indicate a treatment effect over time.

Data will be analysed using SAS V.9.4 software. Descriptive statistics will be used for patient demographics and clinical characteristics. Categorical variables will be described with frequencies (%), and continuous variables will be described with means and standard deviations.

To account for fluctuations in pre-implementation hospital admissions due to COVID-19 related restrictions, time series analysis will account for these time periods. Restricted periods will be considered as 01/02/2020 – 30/06/2020, 01/06/2021 – 01/12/2021, and 01/01/2022 – 01/05/2022.

PATIENT-REPORTED OUTCOMES:

Patient reported secondary outcomes will include pain, physical function, and satisfaction with care at 2- and 4-weeks following admission. Group sample sizes of 100 eligible patients admitted to traditional hospital wards and 100 patients admitted to RPA Virtual Hospital, will be required to achieve 80% power to detect a non-inferiority 1 point difference in patient reported outcome for satisfaction with care (0–10 continuous scale) between groups using a one-sided, two-sample equal-variance t-test. The margin of non-inferiority will be -1. The actual difference between the means will be assumed to be 0. The significance level (alpha) of the test will be set at 0.025. The data will be drawn from populations with a standard deviation of 2.5 in both groups.

ETHICAL CONSIDERATIONS:

This investigation will be conducted in full compliance with the Declaration of Helsinki. Ethics approval has been granted for Protocol X21-0278 & 2021/ETH10967. A waiver of consent has been approved for routinely collected data sourced from electronic medical records. Study data will be fully de-identified, to protect patient and clinician privacy and confidentiality. Informed consent will be collected for all patient reported outcomes. No compensation will be offered for participation.

PATIENT AND PUBLIC INVOLVEMENT:

The virtual hospital model of care was developed with the assistance of semi-structured interviews with clinicians from several disciplines across three metropolitan hospitals. Clinicians from the departments of Physiotherapy, Rheumatology and Emergency Medicine participated in a co-design process with researchers and administrators at RPA Virtual Hospital at Sydney Local Health District.

ECONOMIC EVALUATION PLAN

An economic evaluation will be undertaken from the health system perspective.

Costs associated with implementing Back@Home virtual care and patients' health service use will be measured, using a combination of electronic medical records and financial trial records. Intervention related costs include: the development of training materials and salaried time of staff attending training workshops; changes in workload for staff delivering virtual care; and costs related to information technology support and maintenance of the virtual network. Health service costs will be measured using: Independent Health and Aged Care Pricing Authority (IHACPA) national weighted activity (NWAU) units for admitted inpatient hospital and ED presentations; prescription and over the counter medications using the Pharmaceutical Benefits Scheme and online pharmacy prices. All costs will be reported in Australian dollars. Where necessary, costs will be converted to 2023 prices using the health consumer price index published by the Australian Bureau of Statistics. Costs and effects will be discounted where appropriate.

We plan to conduct a cost-effectiveness analysis alongside this time series analysis with data from the intervention site. Similar to the time series model for health service outcomes, a generalised linear model with a gamma distribution and logarithmic link function will be used for the segmented regression analysis of healthcare costs. An incremental cost effectiveness ratio will be calculated for the health services outcomes: length of stay and hospital admissions. This will be presented as incremental costs per bed day avoided and incremental cost per hospital admission avoided. Non-parametric bootstrapping with 5000 replications will be used to estimate the 95% confidence

intervals around the incremental cost and effect pairs for both health services outcomes. These will be presented on an incremental cost-effectiveness plane. We also plan to explore the cost-effectiveness using the patient outcomes from this study. If the patient outcomes analysis shows non-inferiority as hypothesised, we will perform a cost minimisation analysis by comparing the cost between the control and intervention phases.

RESULTS:

We will collect data from 1 January 2017 to 30 September 2024, and a 60-month period within this timeframe will be used in the analysis, determined by implementation schedule for the new model of care. Back@Home participant data will be collected from February 2023, following roll-out of the service. For primary and secondary health service outcomes, we expect to collect data from approximately 12,500 patients with musculoskeletal LBP attending the three study EDs over a 5-year period, via the electronic medical record system. Interim process evaluation and implementation outcomes are expected to be published in early 2024, and the final study results are expected to be published in 2025. As of 6th Dec 2023, 108 patients have been cared for through Back@Home. Six patients have completed semi-structured interviews regarding their experience of virtual hospital care for non-serious back pain. All outcomes will be evaluated at 6-months (Aug 2023) and 12-months post implementation (Feb 2024).

DISCUSSION:

This study will investigate the implementation of a novel model of care for non-serious back pain, delivered through a virtual hospital. Process evaluation will be used to inform further iterations of the service, guided by the Knowledge To Action framework²⁴. We anticipate that the feasibility of implementing Back@Home will be demonstrated, along with acceptability of the model of care to clinicians and patients, and cost-effectiveness. Additionally, we hypothesize that patient reported outcomes (pain, satisfaction with care) will be non-inferior to traditional hospital admission. Interpretation of Patient Reported Outcomes may be limited by response rate, and strategies have been planned to optimise response rate.

The interrupted time-series design has been commonly used to evaluate the impact of new patient pathways on admission rates, length of stay and ED representation³²⁻³⁴ for a variety of health conditions. We hypothesize that following introduction of Back@Home, hospital length of stay and admission rates for low back pain will be reduced, compared to pre-implementation. If proven to be safe, acceptable, effective, and cost-effective, virtual care for non-serious back pain could be expanded to other health districts in New South Wales, and potentially other states. Implementation in other jurisdictions would depend on staffing and technological resources to deliver virtual care.

CONTRIBUTORS AM, CGM, and GCM conceived the research evaluation. AM drafted the protocol with guidance from GCM, KM, DMC and CGM. MJT, DMC, OH, MM, ER, BR, AA, MD, DC, CD, IH, RB, CN, JE, NG, MS and RD are involved in developing and implementing the model of care. QL and LB contributed to the statistical analysis plan. All authors revised and reviewed the final protocol manuscript.

BACK@HOME INVESTIGATORS:

Alla Melman, Danielle M Coombs, Qiang Li, Laurent Billot, Bethan Richards, Eileen Rogan, Ananthila Anandacoomarasamy, Owen Hutchings, Min Jiat Teng, Kirsten McCaffery, Mona Marabani, Miranda Shaw, Cassandra Dearing, Ian Harris, Rachelle Buchbinder, Chris Needs, James Edwards, Narcyz Ghinea, Michael Dinh, Dane Chalkley, Rachael Dodd, Chris G Maher, Gustavo C Machado.

CONFLICT OF INTEREST DISCLOSURE: None of the authors report a conflict of interest.

AVAILABILITY OF DATA: Requests for data can be made by contacting the corresponding author. Release of data will be governed by Human Research Ethics Approval.

FUNDING: This study has received an HCF Research Grant: Optimising outcomes for patients with back pain by preventing hospital admission. (AU\$315,000) *HCF Health Services Research Grant, HCF Research Foundation*. Grant number: N/A.

PROVENANCE AND PEER REVIEW: Not commissioned; peer reviewed for ethical and funding approval prior to submission.

Table 1: Evaluation plan

Outcome dimension	Outcome	Outcome definition	Data Source	Data collection and analysis period
Service	1. Length of hospital stay 2. Inpatient admission 3. Re-representations 4. Readmissions to inpatient units	1. Monthly mean length of hospital stay (ED short stay units and inpatient units) in those admitted as a traditional inpatient following an ED presentation for musculoskeletal LBP. 2. Monthly proportion of ED musculoskeletal LBP presentations that result in traditional hospital admissions (ED short stay or inpatient units). 3. Monthly proportion of admitted patients re-presenting to traditional hospital, including representations to the ED within 48 hours since discharge. 4. Monthly proportion of admitted patients that are readmissions to an inpatient unit within 28 days.	1–5: eMR	Baseline: Jan-2016 to Feb-2023 T1: Aug-2023 T2: Feb-2024
Implementation	1. Acceptability 2. Appropriateness 3. Feasibility 4. Fidelity	1–3. Acceptability, Appropriateness and Feasibility of Back@Home ‘Model of Care’ and implementation strategies (posters, staff training, videos, newsletter) 4. Fidelity of delivery of implementation strategies as planned.	1–3. Semi-structured interviews with clinicians and patients 4. Logbook of implementation delivery.	T1: Aug-2023
Patient	1. Pain intensity 2. Physical function 3. Satisfaction with care 4. Adverse events	1. Numeric rating pain scale (0–10) 2. PROMIS Physical Function-6a 3. a) 0-10 global satisfaction with care for traditional and virtual admissions b) Patient-reported experience measures as	1–3. Patient online survey 4. eMR	Collected at 2- and 4-weeks post ED presentation or during admission

		routinely collected by the virtual hospital (26-item survey). 4. Proportion of patients experiencing any AE; frequency of AEs for virtual admissions		(adverse events), analysed at T1 and T2
Process	1. Diagnostic tests ordered 2. Pain medicines used 3. Video and phone calls 4. Home visits received 5. Physitrack® application use 6. Physitrack® and Activity tracker usefulness	1. Proportion of virtually admitted patients receiving diagnostic tests. 2. Proportion of virtually admitted patients prescribed specific medicines. 3. Number and frequency of video consultations with virtual hospital clinical staff. 4. Number and frequency of clinician home visits. 5. Utilisation rates of the Physitrack® application by patients (logins, viewing and marked completion of exercise program). 6. Patient-reported experience measures Q7 and Q9 (5 point scale).	1–4. eMR 5. Physitrack® application	Collected during virtual admission, analysed at T1 and T2
Health economic	Hospital admission costs	Cost of delivering virtual care compared to inpatient care for non-serious low back pain	eMR and finance reporting systems	Collected during admission, analysed at T1 and T2

eMR: electronic medical record, ED: Emergency Department, T1: 6 months post-implementation, T2: 12 months post-implementation

REFERENCES

1. AIHW [Australian Institute for Health and Welfare]. Australian Institute of Health and Welfare 2021. Emergency department care. [<https://www.aihw.gov.au/reports-data/myhospitals/sectors/emergency-department-care>]. 2021.
2. Organisation for Economic Co-operation and Development. Health Care Utilisation: Hospital discharges by diagnostic categories. 2018; <https://stats.oecd.org/index.aspx?queryid=30165#>.
3. Buchbinder R, Underwood M, Hartvigsen J, Maher CG. The Lancet Series call to action to reduce low value care for low back pain: an update. *Pain*. 2020;161:S57-S64.
4. Buchbinder R, van Tulder M, Öberg B, et al. Low back pain: a call for action. *Lancet (London, England)*. 2018;391(10137):2384-2388.
5. Waterman BR, Belmont PJ, Schoenfeld AJ. Low back pain in the United States: incidence and risk factors for presentation in the emergency setting. *The Spine Journal*. 2012;12(1):63-70.
6. Melman A, Lord HJ, Coombs D, Zadro J, Maher CG, Machado GC. Global prevalence of hospital admissions for low back pain: a systematic review with meta-analysis. *BMJ Open*. 2023;13(4):e069517.
7. Melman A, Vella SP, Dodd RH, et al. Clinicians' Perspective on Implementing Virtual Hospital Care for Low Back Pain: Qualitative Study. *JMIR Rehabil Assist Technol*. 2023;10:e47227.
8. Coombs D, Machado GC, Richards B, et al. Healthcare costs due to low back pain in the emergency department and inpatient setting in Sydney, Australia. *The Lancet Regional Health - Western Pacific*. 2021;7(100089).
9. Melman A, Maher CG, Needs C, Machado GC. Many people admitted to hospital with a provisional diagnosis of nonserious back pain are subsequently found to have serious pathology as the underlying cause. *Clinical Rheumatology*. 2022; 41:1867-1871.
10. Oliveira CB, Maher CG, Pinto RZ, et al. Clinical practice guidelines for the management of non-specific low back pain in primary care: an updated overview. *European Spine Journal*. 2018;27(11):2791-2803.
11. Kyi L, Kandane-Rathnayake R, Morand E, Roberts LJ. Outcomes of patients admitted to hospital medical units with back pain. *Internal medicine journal*. 2019;49(3):316-322.
12. Melman A, Maher CG, Machado GC. Virtual hospitals: why we need them, how they work and what might come next. *Journal of physiotherapy*. 2021;67(3):156-157.
13. El-Haddad C, Damodaran A, Patrick McNeil H, Hu W. The experience of patients admitted to hospital with acute low back pain: a qualitative study. *International journal of rheumatic diseases*. 2018;21(4):796-803.
14. Gonçalves-Bradley DC, Iliffe S, Doll HA, et al. Early discharge hospital at home. *Cochrane Database of Systematic Reviews*. 2017;6(6):CD000356.
15. Levine DM, Ouchi K, Blanchfield B, et al. Hospital-Level Care at Home for Acutely Ill Adults: A Randomized Controlled Trial. *Annals of internal medicine*. 2020;172(2):77-85.
16. Hutchings OR, Dearing C, Jagers D, et al. Virtual Health Care for Community Management of Patients With COVID-19 in Australia: Observational Cohort Study.

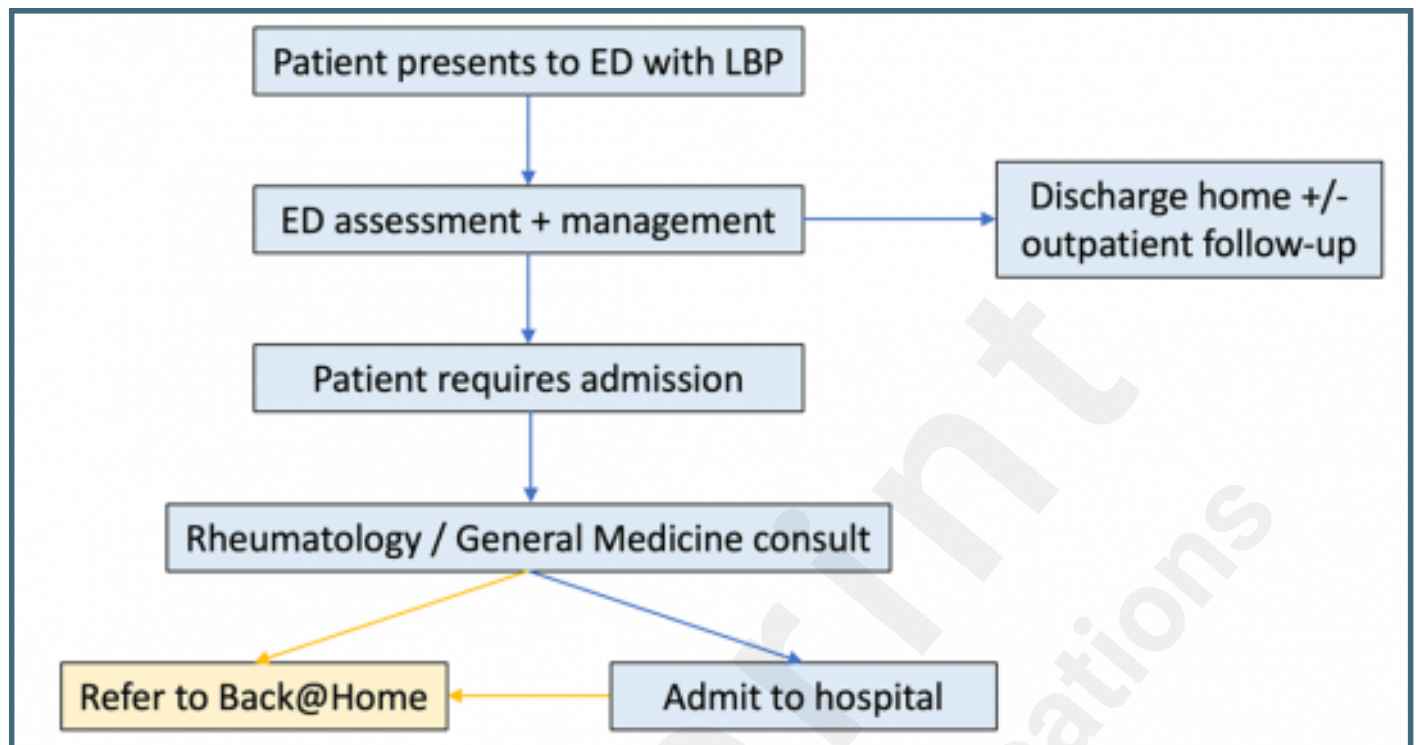
- Journal of medical Internet research*. 2021;23(3):e21064.
17. Hutchings O DC, Jagers D, Shaw M, Raffan F, Jones A, Taggart R, Sinclair T, Anderson T, Ritchie AG. Virtual health care for community management of patients with COVID-19. *medRxiv*. 2020.
 18. Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Medical care*. 2012;50(3):217-226.
 19. Pearson N, Naylor PJ, Ashe MC, Fernandez M, Yoong SL, Wolfenden L. Guidance for conducting feasibility and pilot studies for implementation trials. *Pilot and feasibility studies*. 2020;6(1):167.
 20. Proctor E, Silmere H, Raghavan R, et al. Outcomes for Implementation Research: Conceptual Distinctions, Measurement Challenges, and Research Agenda. *Administration and Policy in Mental Health and Mental Health Services Research*. 2011;38(2):65-76.
 21. Sydney Local Health District. Year In Review 2019–20. 2020; https://www.slhd.nsw.gov.au/pdfs/YIR_19-20.pdf.
 22. Simunek A, Dygryn J, Gaba A, Jakubec L, Stelzer J, Chmelik F. Validity of Garmin Vivofit and Polar Loop for measuring daily step counts in free-living conditions in adults. *Acta Gymnica*. 2016;46(3):129-135.
 23. Kamišalić A, Fister JI, Turkanović M, Karakatič S. Sensors and Functionalities of Non-Invasive Wrist-Wearable Devices: A Review. *Sensors (Basel, Switzerland)*. 2018;18(6):1714.
 24. Graham ID, Logan J, Harrison MB, et al. Lost in knowledge translation: time for a map? *The Journal of continuing education in the health professions*. 2006;26(1):13-24.
 25. Flodgren G, O'Brien MA, Parmelli E, Grimshaw JM. Local opinion leaders: effects on professional practice and healthcare outcomes. *The Cochrane database of systematic reviews*. 2019;6(6):Cd000125.
 26. Giguère A, Zomahoun HTV, Carmichael PH, et al. Printed educational materials: effects on professional practice and healthcare outcomes. *The Cochrane database of systematic reviews*. 2020;8(8):Cd004398.
 27. Forsetlund L, Bjørndal A, Rashidian A, et al. Continuing education meetings and workshops: effects on professional practice and health care outcomes. *The Cochrane database of systematic reviews*. 2009;2009(2):Cd003030.
 28. Ivers N, Jamtvedt G, Flottorp S, et al. Audit and feedback: effects on professional practice and healthcare outcomes. *The Cochrane database of systematic reviews*. 2012(6):Cd000259.
 29. Coombs D, Machado G, Richards B, et al. Effectiveness of a multifaceted intervention to improve emergency department care of low back pain: a stepped-wedge, cluster-randomised trial. *BMJ Quality & Safety*. 2021:bmjqs-2020.
 30. Jackson TJ, Michel JL, Roberts RF, Jorm CM, Wakefield JG. A classification of hospital-acquired diagnoses for use with routine hospital data. *The Medical journal of Australia*. 2009;191(10):544-548.
 31. Amorim AB, Coombs D, Richards B, Maher CG, Machado GC. Text Messaging and Web-Based Survey System to Recruit Patients With Low Back Pain and Collect Outcomes in the Emergency Department: Observational Study. *JMIR mHealth and uHealth*. 2021;9(3):e22732.

32. Elwenspoek MM, Jones T, Dodd JW. Effects of an integrated respiratory service on Chronic Obstructive Pulmonary Disease hospital admissions in England: An interrupted time series analysis. *Journal of health services research & policy*. 2021;26(4):242-250.
33. Wammes JD, Bakx P, Wouterse B, Buurman BM, Murphy TE, MacNeil Vroomen JL. Acute hospital use in older adults following the 2015 Dutch reform of long-term care: an interrupted time series analysis. *The lancet Healthy longevity*. 2023;4(6):e257-e264.
34. Grimley RS, Collyer T, Dewey HM, Andrew N, Cadilhac DA. Stroke and emergency department re-presentation after outpatient TIA management: An interrupted time series study. *Journal of stroke and cerebrovascular diseases : the official journal of National Stroke Association*. 2023;32(1):106900.

Supplementary Files

Figures

Virtual low back pain service workflows.



Knowledge to action framework.

