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Effects of remote patient monitoring on chronic disease management

Submission date 05/08/2016	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 09/08/2016	**Overall study status** Completed	
Last Edited 20/12/2021	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Remote patient monitoring can be used to manage chronic (long-term) conditions by providing measurements to support clinical decisions, alert clinicians when there are problems, and help patient to manage their condition. The aim of this study is to test a remote monitoring system called Medly for patients with complex chronic conditions such as heart failure, COPD, chronic kidney disease, and uncontrolled hypertension. Heart failure is a condition where the heart is unable to pump blood around the body properly. Chronic obstructive pulmonary disease (COPD) is a collection of lung diseases that cause breathing difficulties. Chronic kidney disease is a condition where the kidneys do not work effectively. Uncontrolled hypertension (high blood pressure) increases the risk of heart attacks and strokes.

Who can participate?
Patients aged 18 or over with heart failure, COPD, chronic kidney disease, and/or uncontrolled hypertension

What does the study involve?
Participants are randomly allocated into two groups: control or telemonitoring. The control group receive the current standard of care. Participants in the telemonitoring group are provided with a mobile phone and commercial home medical devices, such as a blood pressure monitor and weight scale. The measurements from the medical devices are automatically sent to the mobile phone, and from there to a data server at the hospital for analysis and storage. Both clinicians and participants are able to access these data, and are sent alerts by the system if the measurements are outside of the normal range. The system is tested through interviews and comparing outcomes (e.g., health, cost of healthcare) between the intervention and control groups over 6 months.

What are the possible benefits and risks of participating?
By participating in this study, patients have the opportunity to experience using a new application that is not yet available on the market and is part of a new approach to improving chronic illness management. The application may or may not improve their health. There are no medical risks to the patients from participating in this study. They may experience slight discomfort with sharing their opinion with the study coordinator. However, they are free to

withdraw from the study at any time, and their participation in this study has no effect on the level of care provided to them.

Where is the study run from?
1. University Health Network (Canada)
2. Mount Sinai Hospital (Canada)

When is the study starting and how long is it expected to run for?
August 2015 to November 2020

Who is funding the study?
Canadian Institutes of Health Research (Canada)

Who is the main contact?
Dr Emily Seto

Contact information

Type(s)
Scientific

Contact name
Dr Emily Seto

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
15-9995-BE

Study information

Scientific Title

Randomized controlled trial of a mobile phone-based telemonitoring application for self-management and clinical decision support for patients with complex chronic conditions

Study objectives
The objective of the randomized controlled trial (RCT) is to evaluate a mobile phone-based telemonitoring system for management of a variety of chronic conditions, including heart failure, complex obstructive pulmonary disease, chronic kidney disease and uncontrolled hypertension in specialty clinic settings. The central research question is: What is the impact of a telemonitoring system for patients with complex chronic illnesses on health status, cost, self-management, clinical management, health outcomes, and health service utilization?

Ethics approval required
Old ethics approval format

Ethics approval(s)
University Health Network, 21/03/2016, ref: 15-9995-BE

Study design
Multicentre randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Heart failure (HF), chronic obstructive pulmonary disease (COPD), chronic kidney disease (CKD), uncontrolled hypertension, diabetes

Interventions
Patients will be randomized 1:1 into control and telemonitoring groups (73 in each group). The participants will be block randomized (blocks of 4) and stratified into groups according to their primary condition (HF, COPD, hypertension, and CKD). The HF group will further be stratified based on NYHA classification (NYHA class 2-3, NYHA class 4), and the hypertensive patients will be stratified to those with and those without diabetes.

To perform the randomization, the online computer generated randomization tool, Research Randomizer, will be used (www.randomizer.org). The study coordinator performing the recruitment will be blinded until the patient has consented to participate.

The telemonitoring technology will enable patients with complex chronic illnesses, including multiple chronic conditions, to take clinically relevant physiological measurements with wireless home medical devices and to answer symptom questions on the mobile phone. The measurements will be automatically and wirelessly transmitted to the mobile phone and then to a data server. Specifically, patients with HF will monitor daily weight and blood pressure/heart rate, CKD patients will monitor blood pressure, and HF, COPD, and CKD patients will monitor symptoms. Hypertension patients will monitor their blood pressure. Automated self-care instructions/messages that have been carefully developed with healthcare specialists will be sent to the patient based on the readings and reported symptoms. If there are signs of their status deteriorating, an alert will be sent to a clinician that is responsible for the particular chronic condition of concern (i.e., in the specific specialty clinic). The clinicians will have all the relevant patient data sent to them and will be able to access (through a secure web portal) to view historical and trending data for their patients. Additional app features will also be available, such as educational videos for proper inhaler use for COPD patients.

The control will not receive any interventions. They will receive current standard of care.

Intervention Type
Device

Primary outcome measure
1. Health status: The SF-36 questionnaire will be administered at baseline, 1 month and 6 months
2. Cost of healthcare assessed at 6 months: The cost of the intervention will be tracked, including for equipment costs and human resources for clinical support, technical support, and program management. Standard cost values for a day in-hospital, ED visit, etc. will be used to estimate net cost savings or expenditures

Secondary outcome measures
All the following data (unless otherwise stated) will be collected through patient self-administered questionnaire and through the hospital EMR and a manual chart review of all participants' clinical records. Timepoints for data collection are in parentheses.

All participants:
1. Combined hospitalization: Number of hospitalizations, days in hospital, number of ED and clinic visits, and medications will be determined through the hospital EMR and a manual chart review of all participants' clinical records (baseline, 1 month, 6 months)
2. General quality of life: EQ-5D questionnaire (baseline, 6 months)
3. Mortality: assessed at 6 months

Condition-specific outcomes:

Heart failure:
1. Left ventricular ejection fraction (baseline, 6 months)
2. Brain natriuretic peptide (baseline, 6 months)
3. Self-care: Self-Care of Heart Failure Index (baseline, 1 month, 6 months)
4. Heart-failure specific quality of life as measured: Minnesota Living with Heart Failure Questionnaire (baseline, 1 month, 6 months)
5. Dyspnea: visual analogue scale (baseline, 6 months)
6. Blood work: creatinine, sodium, potassium, hemoglobin, urate (baseline, 6 months)
7. Prognosis: Seattle Health Failure Model (baseline, 6 months)

COPD:
1. Forced expiratory volume in one second (baseline, 6 months)
2. COPD-specific quality of life: COPD Assessment Test score (baseline, 6 months)
3. COPD-specific knowledge: Bristol COPD Knowledge Questionnaire (baseline, 6 months)
4. Self-efficacy at 6 months as measured by the COPD Self-Efficacy Scale (baseline, 6 months)
5. COPD severity: BODE Index (baseline, 6 months)

Chronic kidney disease
1. Estimated glomerular filtration rate (baseline, 6 months)
2. Blood pressure: automatic blood pressure monitor (baseline, 6 months)

Hypertension
1. Blood pressure: automatic blood pressure monitor (baseline, 6 months)

Diabetes
1. HgbA1c (baseline, 6 months)

Overall study start date
10/08/2015

Completion date
01/11/2020

Eligibility

Key inclusion criteria
All participants:
1. Adults (age 18 years or older)
2. Diagnosed with HF, COPD, CKD, and/or uncontrolled hypertension (individuals with diabetes who require blood glucose monitoring will be included as a co-morbidity only if patients have at least one of the above four chronic illnesses, and will be in the form of self-care support only)
3. Patient or their caregiver speaks and reads English adequately to provide informed consent and understand the text prompts in the application
4. Ability to comply with using the telemonitoring system (e.g, able to stand on the weight scale, able to answer symptom questions, etc)

Primary chronic disease-specific criteria:
1. Patients with HF as the primary chronic disease: with reduced ejection fraction (EF<0.40)
2. Patients with COPD as the primary chronic disease: spirometrically confirmed diagnosis of COPD of GOLD Stage II or higher (defined as post-bronchodilator FEV1 < 80% predicted and FEV1/FVC ratio < 70%); smoking history of ≥ 20 pack-years or homozygous alpha-1 antitrypsin deficiency; and prescribed an action plan for the early self-treatment of acute exacerbations
3. Patients with CKD as the primary chronic disease: Grade 3-5 (eGFR < 60mL/1.73 m2)
4. Patients with uncontrolled hypertension as the primary chronic disease: For non-diabetics: blood pressure >=140/90 mmHg auscultatory (manual measurement) or >=135/85 mmHg oscillometric (automated measurement). For diabetics: blood pressure >=130/80 mmHg

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
146

Total final enrolment
96

Key exclusion criteria
1. Patients on mechanical circulatory support
2. Patients on the heart transplant list
3. Terminal diagnosis with life expectancy < 1 year
4. Dementia or uncontrolled psychiatric illness
5. Resident of a long-term care facility

Date of first enrolment
10/08/2016

Date of final enrolment
13/12/2019

Locations

Countries of recruitment
Canada

Study participating centre
University Health Network
Toronto
Canada
M5G 2C4

Study participating centre
Mount Sinai Hospital
Toronto
Canada
M5G 1X5

Sponsor information

Organisation
University Health Network

Sponsor details
R. Fraser Elliott Building, 1st Floor
190 Elizabeth St.
Toronto
Canada
M5G 2C4

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/042xt5161

Funder(s)

Funder type
Government

Funder Name
Canadian Institutes of Health Research

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Publication and dissemination plan
We anticipate to disseminate the results of the trial in high-impact peer reviewed journals and through conference presentations.

Intention to publish date
01/06/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Emily Seto, PhD, University of Toronto at emily.seto@utoronto.ca

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	21/11/2017		Yes	No
Preprint results	results in preprint	07/07/2021	20/12/2021	No	No