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Caring Near and Far: Investigating the use of home-based remote monitoring technology with chronic care older adults to see if the technology helps people to remain safely at home and put off admission to hospital or long term care

Submission date
06/10/2016

Recruitment status
No longer recruiting

Registration date
18/10/2016

Overall study status
Completed

Last Edited
25/03/2025

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims

The Canadian healthcare system needs to find creative and effective ways to meet the needs of an aging population, high levels of long-term disease, a strained healthcare work force, competing economic priorities, and the need to develop different ways of delivering care. These challenges create opportunities to reimagine how Canadians can be provided with the right care, at the right time, in the right place. Despite their health challenges, older adults want to remain at home even if their health condition(s) challenges their ability to live independently. Evidence indicates that well-managed home care improves seniors' health and reduces hospital and long term care costs. Family member/friend caregivers are increasingly recognized for the role they play in the care of older adults within the home setting. As the care needs of older adults increases the average number of hours of care provided by these caregivers increases significantly in contrast to the limited publically funded home care service provision. There is growing recognition that the majority of older adults would not be able to stay in their homes without the support from family member/friend caregivers. Active and passive remote monitoring (RM) technologies can support older adults to remain in their homes. Active monitoring applications require individual participation, such as pushing a button, whereas passive RM technologies (e.g. sensors) do not require any action by the individual for the system to work. Remote monitoring is especially helpful in tracking behaviours of older adults with cognitive decline (e.g. forgetting to take medications) and to intervene quickly. These technologies can also benefit home-based older adults and their family caregivers in the short-term by increasing communication and collaboration between and among all stakeholders, and in the long-term RM technologies enable 'big data' analytics that can contribute to improved

healthcare delivery practices. The aim of this study is to investigate the effectiveness and cost effectiveness of RM as a means of supporting older adults to safely remain in their home and to avoid or delay higher levels of care.

Who can participate?
Patients aged 65 years and over who need home health care and are at risk for higher levels of care as determined by the home care provider who makes these decisions, a family member /friend who is caring for them, and the patient's healthcare provider.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive usual home care services provided by the provincial regional home care agency for the four years of the study. Those in the second group have remote monitor sensors placed in their homes in addition to receiving usual home care services. Possible remote monitor sensors could include those that monitor eating, sleeping, movement, and taking medications, depending on individual patient needs. The patient, family member/friend caregiver, and a technical specialist from the remote monitoring company then select the preferred remote monitoring sensors for home monitoring. Together the family member/friend, patient, and the technical specialists determine when the family member/friend caregiver would be notified based on the patient's typical activities. These sensor notifications are set up to notify or alert the family member/friend only when the patient's normal routine or daily activity is out of the ordinary, for example, if the patient has forgotten to take their medication. The family member/friend caregiver is notified of any changes in the patient's normal daily routine by a message sent to their land line, cell phone, or by a text message or an email. At the start of the study and then again after six and twelve months, participants in both groups complete a range of assessments to assess the patient and caregiver's wellbeing and the health care provider's opinion of the care given. In addition, at the end of the study the costs of healthcare are assessed for each group.

What are the possible benefits and risks of participating?
These technologies may benefit home-based older adults and their family / friend caregivers in the short-term by increasing communication and collaboration between the patient and the family member/friend caregiver. The patient and caregiver may experience reduced levels of anxiety and worry about the patient living alone and the caregiver's ability to provide care; it may reduce concerns for the patient's physical health (e.g., falling while alone). Information gathered may provide benefits to society as a whole which include information that may be beneficial to family member/friend caregivers and older adults requiring home care who are at risk for admission to higher levels of care, but who wish to remain at home. Information from the surveys and interviews will be shared with people who make decisions about home care service delivery and will be used to develop other studies of home care service delivery. The information provided may assist those decision-makers to enhance home care services for others. There are no known or anticipated risks associated with participating in this study. However, discussion of personal patient experiences may bring up uncomfortable feelings and the patient may experience the loss of individual and household privacy dependent on the selection of remote sensors in the home.

Where is the study run from?
1. Western University (Canada)
2. University of New Brunswick (Canada)
3. Dalhousie University (Canada)

When is the study starting and how long is it expected to run for?
October 2015 to March 2023

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

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CIHR 348264

Study information

Scientific Title
Caring near and far: A multi-province investigation of remote monitoring technologies connecting community-based older adults and their care team

Study objectives
The primary aim of this study is to examine the use of remote monitoring (RM) technologies in the home as a means of supporting older adults to safely remain in their home and avoid or delay higher levels of care (e.g., long term care).

The objectives of this study are to test:
1. Whether remote monitoring along with usual home care (the intervention) versus usual home care alone (control) support older adults with complex care needs to remain in their home longer and delay or avoid admission to higher levels of care (e.g. hospitalization and long term care)
2. Whether the intervention is cost-effective
3. Whether the intervention will improve the quality of life and functional health status of patients, maintain or minimize family / friend caregiver health status and caregiver burden, and assess healthcare providers perception of RM tools within home care

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Pragmatic multi-centre randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Prevention

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Caring

Interventions
Participants are randomised after consent is obtained and baseline data collection to one of two groups using an internet randomization service for clinical trials.

Control group: Patients will receive usual home care services provided by the provincial regional home care agency including but not limited to, home visits by assistive personnel for activities of daily living, nursing care, and other supports deemed necessary by case coordinator or case manager in the study site.

Intervention group: Patients will receive RM in addition to usual home care services. The intervention group will receive RM sensors tailored to their home care needs that may include sensors to detect medication administration, opening refrigerator/cupboards, use of exit doors, and movement detection and for observation (cameras). Randomization: We will use the services of a randomization program to assign patients to receive either usual home care or remote monitoring with usual home care. Allocation of patients will be communicated to the research staff and patient/ family caregiver by the lead researcher (centralized randomization) by telephone and email. Assessors/care coordinators will be blind to the allocation when identifying potential participants for the study to reduce bias. Patients/caregivers will be blind to the allocation when providing consent to participate but will not be blind to intervention /control arms once randomization occurs. Participants (older adult and their family / friend caregivers) once randomized into the intervention group will have a home visit by the technology partner Care Link Advantage(CLA). They will receive written and verbal overview of the various RM options. Based on the assessment by the CLA technology partner along with patient and family / friend caregiver preferences, RM options will be identified and implemented. The intervention will be offered to the patient for up to 12 months at which time the patient will be transitioned to usual care (which could eventually incorporate the RM intervention as deemed appropriate by the home care agency). Notifications of atypical events (e.g., missed medication, atypical length of time in bed) will be sent to the family / friend caregiver. Action, based on the notification, may include a telephone call to prompt the patient or check on the patient's safety, or emergency action (e.g., ambulance). Notification patterns and trends will be collected by the research team and analyzed over time.

Follow up for all participants involves baseline data being collected at the time of consent. Patient and caregiver will be interviewed separately if possible. Data will be collected either in person (preferred at baseline) or by telephone. A semi-structured interview guide containing open and closed questions will be administered at baseline prior to randomization, then at 6 months and 12 months post randomization. Participants (patient / caregiver) will be informed of follow up processes (e.g. 6 month assessment, reminder calls) and provided with contact information for the if they have any questions.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Remote monitor sensors

Primary outcome measure
Patient's Delay/Avoidance of higher levels of care as measured by number of days at home at baseline, 6 and 12 months.

Secondary outcome measures
1. Patient's Functional Status as measured by HARP (Hospital Admission Risk Profile) at baseline, 6 and 12 months
2. Patient's Quality of Life as measured by Older People's Quality of Life Questionnaire at baseline, 6 and 12 months
3. Patient Satisfaction with Care as measured by researcher developed tool at baseline, 6 and 12 months
4. Patient Satisfaction with Technology as measured by researcher developed tool at baseline, 6 and 12 months
5. Patient Perception of Safety as measured by researcher developed tool at baseline, 6 and 12 months
6. Caregiver Functional Health Status, Caregiver Stress, Caregiver Information Needs, effect of Caregiver burden on Caregiver's work as measured by California Caregiver Resource Centers Uniform Assessment tools and Stanford Presenteeism Scale at baseline, 6 and 12 months
7. Caregiver Positive Aspects of Care as measured by Positive Aspects of Caring at baseline, 6 and 12 months
8. Caregiver Satisfaction with Care as measured by researcher developed tool at baseline, 6 and 12 months
9. Caregiver Satisfaction with Technology as measured by researcher developed tool at baseline, 6 and 12 months
10. Caregiver Perception of Patient Safety as measured by researcher developed tool at baseline, 6 and 12 months
11. Healthcare costs will be measured by undertaking an economic analysis using administrative databases, provincial and regional health authority databases at 12 months

Overall study start date
30/10/2015

Completion date
31/03/2023

Eligibility

Key inclusion criteria
Family Member/Friend Caregiver (FMFC):
1. Aged 18 years of age or older
2. A self-reported caregiver to an adult who is 65 years old or older, who requires home care services, and who is assessed by home care service providers to be at risk for higher levels of care. A caregiver can be a spouse, partner, child, sibling, other family relation or friend who helps care for the patient at home.

3. Willing and able to receive the remote monitoring sensor notifications using a cell phone, or a regular phone (i.e., land line)
4. Able to read and write in either English or French.

Patient:
1. Aged 65 years old or older
2. Requires home care
3. At risk for higher levels of care as determined by the home care provider who makes these decisions
4. Have a family member/friend who is willing and able to receive the remote monitoring sensor notifications using a cell phone, or a regular phone (i.e., land line)
5. Able to read and write in English
6. Have the decisional capacity to consent or have a substitute decision-maker consent on his /her behalf to participate in the study

Health Care Provider:
1. Aged 18 years old or older
2. Caring for a home care patient who has consented to be part of this study
3. Able to read and write in English
4. Have the decisional capacity to consent to participate in the study

Participant type(s)
Mixed

Age group
Senior

Lower age limit
18 Years

Sex
Both

Target number of participants
Intervention group:180 patients, 180 family member/friend caregivers. Control group: 360 patients , 360 family member/friend caregivers.

Total final enrolment
700

Key exclusion criteria
Family member/friend:
1. Individuals who are not caregivers to an adult 65 years old or older who requires home care and is at risk for higher levels of care as determined by home care service providers
2. Unable to read and write in English or French

Patient:
1. Under the age of 65
2. Do not require home care
3. Do not have a family member/friend who is willing and able to receive remote monitoring notification

4. Not at risk for higher levels of care
5. Unable to read and write in English

Health Care Provider:
1. Under the age of 18
2. Not caring for a patient who has consented to participate in this study
3. Unable to read and write in English

Date of first enrolment
01/11/2016

Date of final enrolment
15/01/2020

Locations

Countries of recruitment
Canada

Study participating centre
Western University
1151 Richmond St
London, Ontario
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Study participating centre
University of New Brunswick
3 Bailey Drive
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Study participating centre
Dalhousie University
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Sponsor information

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Sponsor type
University/education

Website
http://www.uwo.ca/research/services/ethics/index.html

ROR
https://ror.org/02grkyz14

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
Planned publication in a high-impact peer reviewed journal is expected approximately one year after the overall trial end date.

Intention to publish date
31/03/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository (Western University's secured network)

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	10/01/2020	13/01/2020	Yes	No
Results article	Qualitative results	14/07/2021	07/03/2022	Yes	No
Results article	Primary outcome in each province	19/03/2025	25/03/2025	Yes	No