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GeriMedRisk®, a telemedicine geriatric pharmacology consultation service to address adverse drug events in long-term care

Submission date 17/03/2017	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 27/03/2017	**Overall study status** Completed	
Last Edited 26/03/2019	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Multiple illnesses, the use of multiple drugs and age increase the risk of drug toxicity (adverse reactions) in older people. Following a poisoning, they are about four times more likely to die or to require hospitalization compared to their younger counterparts. In Canada there are few clinicians who have the knowledge to prevent such events and most are found in urban areas, resulting in less access for Canadians living in rural and remote areas. GeriMedRisk® is a new technology-based consultation service that aims to improve a patient's medications to improve cognition (thinking), mobility, function, and mental health. The aim of this study is to find out whether using GeriMedRisk decreases falls and drug-related hospital visits among seniors living in long-term care homes.

Who can participate?
All physicians, pharmacists and nurse practitioners who provide patient care in participating long-term care homes in the Waterloo-Wellington region

What does the study involve?
Participating long-term care homes start using GeriMedRisk® at a randomly allocated time point. Clinicians have access to GeriMedRisk® nurses, pharmacists, and physicians specializing in geriatric medicine, clinical pharmacology, and geriatric psychiatry by telephone or through telemedicine. Clinicians are provided with reports including short user-friendly drug information and at least one follow-up call to assess the effectiveness of the recommendations. When necessary, in-person or videoconference consultations with specialist physicians are available.

What are the possible benefits and risks of participating?
By supporting clinicians as they improve their older patients' medications, GeriMedRisk® may decrease drug-related cognitive impairment, falls, and hospital visits. The benefits of participating in this study include access to geriatric pharmacology expertise in a timely fashion without patient travel to an urban academic health centre. Participants also have the opportunity to provide feedback about GeriMedRisk to help improve the service and its impact on real-world practice. Finally, participants have access to a service that supports their

continuing professional development through learning materials relevant to their patients and quarterly summaries of their learning issues generated from their consults. There is no cost for these services. Although each consultation may take up to 45 minutes on the telephone, this time could be decreased by contacting GeriMedRisk through a secure eConsult platform.

Where is the study run from?
1. University Gates Schlegel Village (Canada)
2. Winston Park Schlegel Village (Canada)
3. Riverside Glen Schlegel Village (Canada)
4. St Joseph's Health Centre Guelph (Canada)

When is the study starting and how long is it expected to run for?
February 2017 to December 2017

Who is funding the study?
1. McMaster University (Canada)
2. Regional Geriatric Program of Hamilton (Canada)
3. Canadian Centre for Aging and Brain Health Innovation (Canada)
4. Canadian Mental Health Association Waterloo Wellington (Canada)
5. St. Joseph's Health Centre Guelph (Canada)
6. Schlegel Research Institute for Aging (Canada)
7. Ontario Telemedicine Network (Canada)

Who is the main contact?
Dr Joanne Ho

Contact information

Type(s)
Scientific

Contact name
Dr Joanne Ho

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
GMR-LTC feasibility v4

Study information

Scientific Title
GeriMedRisk®, a telemedicine geriatric pharmacology consultation service to address adverse drug events in long-term care: a cluster randomized feasibility trial protocol

Study objectives
GeriMedRisk (GMR) will be a feasible intervention that has the potential to decrease falls and drug-related hospital visits among seniors residing in a long term care (LTC) home. The cluster stepped wedge randomized controlled trial is a feasible study design for investigating GMR's efficacy at decreasing falls and drug-related hospital visits among LTC residents.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Hamilton Integrated Research Ethics Board submission - pending approval

Study design
Multicentre stepped wedge cluster randomized controlled trial and qualitative study

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Geriatric adverse drug events

Interventions
This study is a stepped wedge cluster randomized controlled trial (simple randomization with a computer generated sequence). The intervention is access to GeriMedRisk®, a pioneering, interdisciplinary, technology-based geriatric pharmacology consultation service that aims to optimize a patient’s medications to improve cognition, mobility, function, and mental health.

Clinicians with a patient-generated geriatric pharmacotherapy question will be able to contact GeriMedRisk® and access GeriMedRisk®'s nurses, pharmacists, and physicians specializing in geriatric medicine, clinical pharmacology and geriatric psychiatry by telephone or telemedicine during business hours. There are two methods for referral:
1. Telephone: This traditional mode of person-to-person consultation can be real-time, or used as a paging service whereby the referring clinician leaves a call-back number and GeriMedRisk® calls back at a later time.
2. Ontario Telemedicine Network (OTN) e-consult: The referring clinician emails an eConsult request through the secure OTNhub (www.OTNhub.ca) to GeriMedRisk® with the necessary clinical information and within days, GeriMedRisk® team responds through eConsult with a request for additional information or recommendations. Additional support through the phone, OTN videoconference or in-person may be arranged if necessary. The GeriMedRisk® staff will collaborate with the referring clinician to perform a geriatric pharmacology consultation, based on a comprehensive geriatric assessment, which aims to optimize the patient's medications, cognition, comorbidities, mobility, function and mental health. Videoconference telemedicine and in-person consultations with specialist physicians across Southwestern Ontario academic health centres (McMaster University, University of Toronto, University of Western Ontario) would be available if necessary. Password-protected consultation reports and knowledge user-friendly drug information materials will be securely sent to the referring clinician through OTN eConsult. GeriMedRisk® will perform at least 1 follow-up to the referring clinician to assess the effectiveness of the recommendations.

Intervention Type
Other

Primary outcome measure
The primary outcome measures of this feasibility study will scrutinize the logistics of the GeriMedRisk® intervention and study design:
1. Number of clinicians who use GeriMedRisk® (GeriMedRisk® (GMR) database) (Timing: monthly after commencement of access to GeriMedRisk):
1.1. MD
1.2. Pharmacist
1.3. NP
1.4. Through TAPERMD
2. Number of clinicians who decline GeriMedRisk® (Roster of LTC clinicians, GMR database) (Timing: monthly after commencement of access to GeriMedRisk):
2.1. MD
2.2. Pharmacist
2.3. NP
3. Number of patients/Substitute Decision Makers who decline GeriMedRisk®. Patients and their caregivers will have the opportunity to opt out of GeriMedRisk®. These will be individually reported and collected real time. (Timing: monthly after commencement of access to GeriMedRisk)
4. Number of consults (GMR database, OTN) (Timing: monthly after commencement of access to GeriMedRisk):
4.1. Telephone
4.2. Telemedicine: OTN e-consult
4.3. Through TAPERMD
4.3.1. Telephone
4.3.2. Telemedicine: OTN e-consult

5. Wait times: (telephone records, OTN) (Timing: monthly after commencement of access to GeriMedRisk):
5.1. Telephone
5.1.1. Time from the conclusion of the initial automated message to:
5.1.1.1. When GeriMedRisk® team member picks up the phone (telephone records)
5.1.1.2. When Caller hangs up (telephone records)
5.1.1.2.1. To use e-consult (telephone records, OTN)
5.1.1.2.2. To leave a call back number (telephone records)
5.1.1.2.3. No further contact in the next 7 days (dropped call) (telephone records, OTN)
5.2. E-consult: Time from e-consult request received to (OTN):
5.2.1. GeriMedRisk® team member commences consult
5.2.2. GeriMedRisk® team member provides e-consult opinion
6. Length of calls (telephone records, GMR database) (Timing: monthly after commencement of access to GeriMedRisk):
6.1. Initial consult with pharmacist/RN
6.2. Initial consult with physician
6.3. Follow up with pharmacist/RN
6.4. Follow up with physician
6.4.1. Geriatrician/clinical pharmacologist
6.4.2. Geriatric psychiatrist
6.5. Stratify above for TAPERMD referrals.
7. Time to follow-up call (GMR database, OTN) (Timing: monthly after commencement of access to GeriMedRisk):
7.1. Defined as time interval from date of initial consult to date of follow up
7.1.1. Measure discrepancies between scheduled followup dates and date of actual followup.
7.2. Number lost to follow up
8. Satisfaction (GMR database, OTN) (Timing: monthly after commencement of access to GeriMedRisk):
8.1. Adherence to recommendations (satisfaction) defined as the percentage of GeriMedRisk® recommendations which were executed by the referring clinician. (GMR database, collected during follow up call). 60% adherence is defined as a positive outcome:
8.1.1. Stratify according to referring clinician clinical background (MD, Pharmacist or NP)
8.1.2. 2 days, 7 days and 14 days post consultation
8.2. Number of times referring clinician uses service (i.e., repeat use may indicate satisfaction)
9. Number of consults requiring physician support (GMR database and OTN) (Timing: monthly after commencement of access to GeriMedRisk):
9.1. Geriatric medicine
9.2. Clinical pharmacology
9.3. Geriatric psychiatry
10. Case complexity (composite of number of consults requiring physician support, number of consults with polypharmacy defined as ≥4 medications, # of consults requiring geriatric psychiatry and ≥ 3 follow up) (Timing: monthly after commencement of access to GeriMedRisk):
10.1. For entire participating LTC site
10.2. For each consult
11. Case resolution: defined as patient discharged from GeriMedRisk® (GMR database, OTN) (Timing: monthly after commencement of access to GeriMedRisk):
11.1. Time required: Time of consult to case resolution
11.2. Number of steps required
11.3. Type of steps required
12. Number of GeriMedRisk® MDs (GMR database, OTN) (Timing: monthly after commencement of access to GeriMedRisk):
12.1. Specialty training:

12.1.1. Geriatric medicine
12.1.2. Clinical pharmacology
12.1.3. Geriatric psychiatry
13. Compensation/Cost-effectiveness (OTN, GeriMedRisk® budget) (Timing: monthly after commencement of access to GeriMedRisk):
13.1. MD: Fee-for-service billing
13.2. MD: e-consult hourly billing
13.3. Pharmacist/Nurse: Salary

Secondary outcome measures
Secondary outcomes include falls, hospital visits and medications. Completeness of secondary outcome data (RAI-MDS LTC electronic medical record). This data is regularly collected with the Minimum Data Set, as mandated by the Ministry of Health and Long-Term Care (Timing: 1 year lookback period defined as -365 to date of intervention, and following the commencement of access to GeriMedRisk, monthly)
1. Falls:
1.1. Monthly rate for entire LTC home
1.2. % of injurious falls (defined as requiring physician services, Emergency Department visit or hospitalization)
2. Emergency Hospital visits (exclude hospitalization recommended for supervised deprescription, or elective procedures):
2.1. For patients with a GeriMedRisk® consultation: Time to ED visit (defined as hours from pt consult to ED visit) (GMR database)
3. Medications:
3.1. Prevalence of potentially inappropriate medications
3.1.1. Dose reduction:
3.1.1.1. GeriMedRisk® patients (defined through TAPERMD; captured by GeriMedRisk® clinical database, pharmacy records)
3.1.1.2. All patients in the LTC site (RAI MDS 2.0, pharmacy records)
3.2. Prevalence of psychotropics per LTC site (defined as an sedative hypnotic, antidepressant, antianxiolytic, antipsychotic, Lithium) or antiseizure medication (without a diagnosed seizure disorder) (RAI MDS 2.0, LTC pharmacy records)
3.3. Prevalence of patients receiving opioids (LTC pharmacy records)

Overall study start date
01/02/2017

Completion date
31/12/2017

Eligibility

Key inclusion criteria
All physicians, pharmacists and nurse practitioners who provide patient care in a participating LTC site (a convenience sample of LTC homes in the Waterloo-Wellington region)

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants
4 clusters, ~15 participants

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/04/2017

Date of final enrolment
30/09/2017

Locations

Countries of recruitment
Canada

Study participating centre
University Gates Schlegel Village
Canada
N2J 0E2

Study participating centre
Winston Park Schlegel Village
Canada
N2E 3K1

Study participating centre
Riverside Glen Schlegel Village
Canada
N1H 8M8

Study participating centre
St. Joseph's Health Centre Guelph
Canada
N1H 5H8

Sponsor information

Organisation
McMaster University

Sponsor details
1280 Main St. W.
Hamilton
Canada
L8S 4L8

Sponsor type
University/education

ROR
https://ror.org/02fa3aq29

Funder(s)

Funder type
University/education

Funder Name
McMaster University Labarge Optimal Aging Opportunities Grant

Alternative Name(s)
McMaster, Mac, McMaster Univ., McMaster-Carr

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Canada

Funder Name
Regional Geriatric Program of Hamilton

Funder Name

Canadian Centre for Aging and Brain Health Innovation

Funder Name
Canadian Mental Health Association

Alternative Name(s)
Association Canadienne pour la Santé Mentale, CMHA, ACSM

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
Canada

Funder Name
St Joseph's Health Centre Guelph

Funder Name
Schlegel Research Institute for Aging

Funder Name
Ontario Telemedicine Network

Results and Publications

Publication and dissemination plan
The trialists plan to disseminate the results of this study in a high-impact peer reviewed journal within 1 year after the overall trial end date.

Intention to publish date
30/06/2019

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	20/06/2018		Yes	No