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WestGem study: WESTphalian study on a medication therapy management and home care based intervention under Gender specific aspects in Elderly Multimorbid patients

Submission date
18/09/2013

Recruitment status
No longer recruiting

Registration date
25/10/2013

Overall study status
Completed

Last Edited
03/06/2016

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Research shows that older patients in particular are affected by multiple diseases and side effects due to intake of multiple medicines. By networking amongst general practitioners, pharmacists and the Care and Housing counseling service, the medication therapy is thought to be managed well.

Who can participate?
The study will recruit men and women over 65 years with three or more long-lasting conditions affecting at least two different organ systems whereas one of the medical conditions must have been present for 4 months in the past year. Patients have to suffer from at least one cardiovascular disease. They had to attend their doctor at least once in each of the last three quarters and take five or more systemic medications as long-term prescriptions.

What does the study involve?
Participating GP surgeries are randomly allocated to one of three groups. Patients attending the first group of surgeries receive the medication therapy management immediately after being enrolled into the study. Patients attending the second and the third group of surgeries receive this management 3 and 6 months after enrollment, respectively. The attending general practitioner conveys the patient's address, diagnoses and medication data to the Care and Housing counseling service. The Care and Housing counseling service visits the patient at home and collects supplementary data about self-medication, the risk of falling as well as the home and social environment. The information is then forwarded to the team of specialized pharmacists, who review the patient´s data and medications as well as the social and environmental aspects and suggest an evidence-based modification of the treatment if necessary. The Care and Housing counseling service passes all suggestions to the general practitioner, who remains responsible for the therapy and verifies the suggestions.

What are the possible benefits and risks of participation?
The total number of prescribed drugs and their side effects could be reduced. The burden of the treatment is likely to be reduced and quality of life might be improved. There will not be considerable risks compared to regular treatment.

Where is the study run from?
There are 14 participating study sites, seven sites per study region. Study sites are general practitioners' surgeries located in the district of Steinfurt and in the city of Ahlen in the northern part of North Rhine-Westphalia, Germany.

When is the study starting and how long is it expected to run for?
July 2013 to December 2014

Who is funding the study?
The Ministry of Health, Equalities, Care and Ageing of the State of North Rhine-Westphalia (Germany) and the European Union

Who is the main contact?
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Study website
http://www.westgem.de

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

005-GW02-76A-H

Study information

Scientific Title
Prospective, cluster-randomized, controlled trial of effectiveness and costs of a cross-professional and cross-organisational medication therapy management in multimorbid patients with polypharmacy (Prospektive, cluster-randomisierte, kontrollierte Studie zur Untersuchung des Wirksamkeit und der Kosten eines professions- und organisationsübergreifenden Medikationsmanagements bei multimorbiden Patienten mit Polypharmazie)

Acronym
WestGem

Study objectives
It is hypothesised that a inter-professional Medication Therapy Management leads to a more appropriate prescription of medication and a more cost-effective and safer treatment of multimorbid patients with polypharmacy compared to standard care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethics Committee of the Medical Association of Westphalia-Lippe, 05/08/2013, ref: 2013-292-f-S
2. The University of Wuppertal Ethics Committee, 15/04/2013

Study design
Pragmatic cluster-randomized controlled prospective multicentric trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Treatment

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

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

Interventions

Randomisation is performed in a stepped wedge design. Participating study sites (general practitioners' offices) are randomized in three groups. The first group starts the inter-professional Medication Therapy Management (MTM) right after the patient enrollment (t1), the second group three months after the patient enrollment (t2) and the third group six months after the patient enrollment (t3).

In the intervention group the attending general practitioner conveys the patient's address, diagnoses and medication data to the Care and Housing counseling service. The Care and Housing counseling service visits the patient at home and collects supplementary data about self-medication, the risk of falling as well as the home and social environment. All of this information is forwarded pseudonymised to the team of specialized pharmacists. The Pharmacists review the patient´s data and medication regimen as well as the social and environmental aspects and suggest an evidence-based modification of the pharmacotherapy if necessary by creating a MTM. The Care and Housing counseling service complements the MTM with nursing aspects and passes all suggestions to the general practitioner, who remains responsible for the therapy and verifies the MTM and nursing suggestions.

Control arm (participants waiting to receive the intervention): Treatment as usual

In the end, all participants will receive the intervention. As the visits of the Care and Housing counseling service are going to be handled by only a few employees, it is not possible to assign all 240 patients to the intervention group at the same time. About 80 participants will receive the Intervention in January 2014, another 80 participants in April 2014 and another 80 patients in July 2014.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Change in the Medication Appropriateness Index (MAI) Scores measured every three months

Secondary outcome measures
1. Quality of life (QoL) measured at baseline and after that every three months
2. Incremental cost-effectiveness ratio
3. Incremental cost-utility ratio
4. Complexity of the pharmacological therapy (Medication Regimen Complexity Index (MRCI), number of pharmaceuticals, daily defined doses) measured every three months
5. Reported patient adherence measured every three months
6. Burden of therapy measured every three months
7. Number of reported (potential) adverse side effects measured every three months
8. Functional status measured every three months
9. Risk of falling measured at baseline and after that every six months
10. Self-reported health measured at baseline and after that every three months
11. Cost of medication therapy measured at baseline and after that every three months
12. Days spent in hospital measured at baseline and after that every three months
13. Cost of illness form the general practitioner´s perspective measured at baseline and after that every three months
14. Quality of medical care provided to vulnerable patient groups

Overall study start date
01/07/2013

Completion date
31/01/2015

Eligibility

Key inclusion criteria
1. Men and women, aged over 65 years
2. Three or more chronic conditions affecting at least two different organ systems
3. One of the medical conditions must have been existent in three quarters of the last 12 months
4. At least one cardiovascular disease
5. At least one visit to the doctor in each of the last three quarters
6. Five or more long-term medications (> 3 months) with systemic effects
7. Ability to answer questionnaires (with assistance if necessary)
8. Written informed consent

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
240

Key exclusion criteria
1. Estimated life expectancy < 12 months
2. Participation in another clinical trial within the last 30 days

Date of first enrolment
01/07/2013

Date of final enrolment
31/01/2015

Locations

Countries of recruitment
Germany

Study participating centre
Rainer-Gruenter-Straße 21
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Sponsor information

Organisation
University of Wuppertal (Germany)

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Sponsor type
University/education

Website
http://www.uni-wuppertal.de

ROR
https://ror.org/00613ak93

Funder(s)

Funder type
Government

Funder Name
The Ministry of Health, Equalities, Care and Ageing of the State of North Rhine-Westphalia (Germany)

Funder Name
European Union (Belgium)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	22/07/2015		Yes	No
Results article	results	02/06/2016		Yes	No