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Improving the safety and continuity of medicines management at care transitions

Submission date
12/03/2018

Recruitment status
No longer recruiting

Registration date
11/04/2018

Overall study status
Completed

Last Edited
27/02/2025

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
When a patient moves (e.g. from hospital to home), medicine problems are common and planned changes are not always followed through. Patients particularly at risk are those with long-term illnesses taking several medicines – especially when medicines have been started or changed in hospital. This study is the final stage in a programme of four work packages, which has been developed to help the way patients are supported with their medicines, and also aims to improve the way medical professionals work together to offer good standards of care to patients when they transition from hospital to home. The study will involve patients with heart failure – chosen because they need a number of medicines. Also, some of these medicines need careful monitoring.

Who can participate?
Patients aged 18 years and over with heart failure

What does the study involve?
Participating NHS centres are randomly allocated to either receive the Medicines at Transition Intervention (MaTI) or continue with treatment as usual. The MaTI includes online training about discharge management, patient held information, enhanced communication between hospital and the patients' community pharmacists, and increased engagement of community pharmacists with patient care after discharge. Data is collected using patient-completed questionnaires (at four timepoints over 12 months), and from routine data providers (this includes NHS Digital, GP records, Office for National Statistics, and the National Heart Failure Audit). All-cause mortality (death) and heart failure rehospitalisation are measured after 12 months.

What are the possible benefits and risks of participating?
This research is an opportunity to enhance patient care through providing additional information and support about medicines. Patients who participate may benefit in the long term through the improvement of medicines management systems that supplies and helps them use their medicines. They will also have the opportunity to share their experiences of their healthcare. There will be few risks for participants in this research project owing to the study aims and design.

Where is the study run from?
University of Leeds (UK)

When is the study starting and how long is it expected to run for?
January 2017 to March 2021

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Mrs Florence Day
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 37060

Study information

Scientific Title
Improving the safety and continuity of medicines management at care transitions

Acronym

ISCOMAT

Study objectives
When a patient moves (e.g. from hospital to home), medicine problems are common and planned changes are not always followed through. Patients particularly at risk are those with long-term illnesses taking several medicines – especially when medicines have been started or changed in hospital.

This cluster randomised controlled trial is the final stage in a programme of four work packages, which has been developed to help the way patients are supported with their medicines, and also aims to improve the way medical professionals work together to offer good standards of care to patients when they transition from hospital to home. The study will involve patients with heart failure – chosen because they need a number of medicines. Also, some of these medicines need careful monitoring.

Ethics approval required
Old ethics approval format

Ethics approval(s)
HRA REC - Yorkshire and the Humber – Bradford Leeds, 01/03/2018, ref: 18/YH/0017

Study design
Randomized; Interventional; Design type: Prevention, Process of Care, Education or Self-Management, Complex Intervention

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Heart failure

Interventions
The aim is to recruit 2100 participants across 42 ‘clusters’, who will be randomised using an automated randomisation service on a 1:1 allocation to either implement the Medicines at Transition Intervention (MaTI), or continue with treatment as usual (TAU).

The MATI consists of the following inputs:
1. Online training to secondary care cardiology, Community Pharmacy and primary care staff about discharge management
2. Patient held information
3. Enhanced communication between hospital and the patients’ community pharmacists
4. Increased engagement of community pharmacists with patient care after discharge

Since this is a cluster randomised controlled trial, consent to deliver the intervention is given by the NHS Trust, and patients will be asked for their consent for data collection purposes only. Data collection will be in the form of patient-completed questionnaires (at four timepoints over 12-months post-registration), and data collection from routine data providers (this includes NHS Digital, GP records, Office for National Statistics, and the National Heart Failure Audit).

Intervention Type
Other

Primary outcome(s)
All-cause mortality and heart failure rehospitalisation; Timepoint(s): 12 months from discharge

Key secondary outcome(s))
Key secondary endpoint:
Still being prescribed at least one of the medications in each of the following three groups at 12 months:
1. ACE Inhibitor (ACEI); Angiotensin II Receptor Blocker (ARB); Salcubitril/Valsartan
2. Beta blocker; Ivabradine
3. Mineralocorticoid Receptor Antagonist (MRA)
*For patients with contraindications to any of the three groups, the endpoint will be derived with respect to the groups that are indicated (e.g. a patient prescribed an ACEI and a beta blocker, but not an MRA, at 12 months will have achieved the endpoint if MRAs are contraindicated).

Other secondary endpoints:
1. The individual components of the primary endpoint, regarded as time-to-event endpoints, namely:
1.1. Time to all-cause mortality
1.2. Time to heart-failure-related rehospitalisation
2. Length of time on guideline recommended (and indicated as above*) cardiovascular medications
3. Patient understanding of their medicines, measured by a 10-point Likert scale in the Patient Experience Survey at 2 and 6 weeks and 12 months post-registration
4. Patient satisfaction with medicines related care, measured by a 10-point Likert scale in the Patient Experience Survey at 2 and 6 weeks and 12 months post-registration
5. Quality-adjusted life years, measured by the EQ-5D-3L at baseline, 3 months and 12 months
6. Days alive and out of hospital, defined as the number of days in the year (365 days) beginning the day after registration that the patient spends alive and not in hospital
7. Time to all-cause hospitalisation and time to CV-related hospitalisation in the 12 months from registration
8. Cause-specific deaths

Completion date
19/03/2021

Eligibility

Key inclusion criteria
1. Admitted or transferred to a ward participating in the ISCOMAT trial
2. Heart failure with evidence of at least moderate left ventricular systolic dysfunction confirmed (via echocardiogram) within the last 5 years
3. Aged 18 years or over at time of admission to hospital
4. Planned discharged from recruiting hospital to their home (defined by usual place of residence) or a care home

5. Planned discharge to within geographical area of that cluster
6. Capacity to provide Informed Consent
7. Provide informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
1641

Key exclusion criteria
NHS Trusts meeting any of the following exclusion criteria will not be eligible for inclusion:
1. Already providing medicines management deemed to be sufficiently similar to the MaTI intervention

Patients meeting any of the following exclusion criteria will not be eligible for inclusion:
1. Patients in a terminal phase of illness / end of life care pathway who are not expected to survive beyond 6 weeks from date of discharge
2. Patients who are already participating in the ISCOMAT study (for example, patients who have been re-admitted)

Date of first enrolment
01/05/2018

Date of final enrolment
28/07/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Leeds
Leeds

United Kingdom
LS2 9JT

Sponsor information

Organisation
Bradford Teaching Hospitals NHS Foundation Trust

ROR
https://ror.org/05gekvn04

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: RP-PG-0514-20009

Results and Publications

Individual participant data (IPD) sharing plan
The researchers are committed to ensuring that publically-funded research data are made available for further legitimate compatible purposes. In order to apply email ctru-dataaccess@leeds.ac.uk.
Organisations are able to apply for permission to access clinical trial or research project datasets for secondary purposes from the Clinical Trials Research Unit (CTRU), University of Leeds. The data requester must be an employee, contractor or agent of the organisation responsible for data use and security.
Data will only be shared if fully justified and robust security measures to protect the data and minimise the risk of unauthorised disclosure are in place. Anonymised data may be released on the basis of valid participant consent
For approved applications, data will be provided as a SAS dataset (unless otherwise agreed) with an accompanying data pack detailing derivations of composite endpoints as specified in the Statistical Analysis Plan and a description of each field name with relevant coding.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		29/04/2022	12/08/2022	Yes	No

HRA research summary			28/06/2023	No	No
Other publications	Process evaluation	09/10/2024	10/10/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes