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A pilot study comparing a co-designed patient information leaflet with a standard leaflet for care after a heart attack

Submission date 24/06/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 08/07/2026	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 15/07/2026	**Condition category** Circulatory System	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
People who have had a heart attack (also called a myocardial infarction) are often prescribed several medicines to help prevent future heart problems. However, many people find it difficult to understand information about their condition and treatment. This can make it harder to manage their health and medicines with confidence.

This study compared two information leaflets about heart attack care. One leaflet was an existing publicly available leaflet. The other was a new leaflet developed by researchers together with patients and members of the public to improve clarity and understanding. The study aimed to find out whether it would be practical to run a larger trial in the future and to explore which leaflet people found easier to understand and more useful. The researchers also looked at whether the leaflets improved participants' knowledge about heart attacks and their treatment.

Who can participate?
Adults aged 18 years or older who were willing and able to provide informed consent could take part. Healthy volunteers were allowed to participate. People employed in the healthcare sector, those aged under 18 years, and those who did not give informed consent were not eligible to take part.

What does the study involve?
Participants first completed a questionnaire. They were then randomly assigned to receive one of two information leaflets about heart attacks and their treatment. After reading their allocated leaflet, participants completed additional questions.
The questionnaires assessed participants' knowledge and understanding of heart attacks before and after reading the leaflet. Participants were also asked about the leaflet's clarity, relevance, usefulness, and overall acceptability.

What are the possible benefits and risks of participating?
Participants may benefit from learning more about heart attacks and the medicines used to

treat them. Their feedback could also help researchers improve patient information materials and support the development of a larger future study.
As the study involves reading information leaflets and completing questionnaires, any risks would be expected to be minimal.

Where is the study run from?
The study is run from the School of Pharmacy, University College Cork, in Cork, Ireland. Participants were recruited in Ireland.

When is the study starting and how long is it expected to run for?
January 2026 to February 2026

Who is funding the study?
The study is investigator initiated and funded.

Who is the main contact?
1. Ms Fatma El-Komy, Fatma.elkomy@umail.ucc.ie
2. Dr Margaret Bermingham, margaret.bermingham@ucc.ie
3. Prof. Laura J. Sahm, L.Sahm@ucc.ie
4. Dr Michelle O'Driscoll, michelle.odriscoll@ucc.ie
5. Prof. Stephen Byrne, Stephen.Byrne@ucc.ie

Contact information

Type(s)
Public, Scientific

Contact name
Ms Fatma El-Komy

ORCID ID
https://orcid.org/0009-0006-2630-9980

Contact details
School of Pharmacy, University College Cork
Cork
Ireland
T12 YN60
+353 833765226
Fatma.elkomy@umail.ucc.ie

Type(s)
Principal investigator

Contact name
Dr Margaret Bermingham

Contact details
School of Pharmacy, University College Cork
Cork
Ireland

T12 YN60
-
margaret.bermingham@ucc.ie

Type(s)
Scientific

Contact name
Prof Laura J. Sahm

ORCID ID
https://orcid.org/0000-0002-7496-9477

Contact details
School of Pharmacy, University College Cork
Cork
Ireland
T12 YN60
+353 (0)21 490 1662
L.Sahm@ucc.ie

Type(s)
Scientific

Contact name
Dr Michelle O'Driscoll

ORCID ID
https://orcid.org/0000-0001-5466-4214

Contact details
School of Pharmacy, University College Cork
Cork
Ireland
T12 YN60
+353 (0)21 490 1662
michelle.odriscoll@ucc.ie

Type(s)
Scientific

Contact name
Prof Stephen Byrne

ORCID ID
https://orcid.org/0000-0003-3141-7004

Contact details
School of Pharmacy, University College Cork
Cork
Ireland

T12 YN60
+353 (0)21 490 1662
Stephen.Byrne@ucc.ie

Additional identifiers

Study information

Scientific Title
A pilot randomised controlled trial evaluating the effectiveness of a co-designed information leaflet about post-myocardial infarction care, versus an existing information leaflet

Study objectives
1. To assess the feasibility of conducting a pilot RCT comparing two patient information leaflets about myocardial infarction and its management
2. To evaluate the acceptability and usability of Leaflet A and Leaflet B among participants
3. To compare participants' knowledge and understanding of MI following exposure to Leaflet A or Leaflet B
4. To assess participants' perceptions of the clarity, readability, relevance, and accessibility of each leaflet
5. To generate data to inform the design, outcome selection, and sample size considerations for a future definitive trial

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 05/11/2025, University College Cork Social Research Ethics Committee (College Road, Cork, T12 K8AF, Ireland; -; srec@ucc.ie), ref: 2025-252

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Dose comparison

Assignment
Single

Purpose
Health services research, Supportive care

Study type(s)

Health condition(s) or problem(s) studied
Post-myocardial infarction care

Interventions
Randomisation:
Participants were randomly allocated in a 1:1 ratio to either the intervention (Leaflet B) or comparator (Leaflet A) group using the randomisation function within Qualtrics® survey software. The Qualtrics randomisation feature automatically assigned participants to one of the two study arms using an equal allocation ratio. Allocation was concealed through the platform's built-in blinding/randomisation functionality, ensuring that participants were not exposed to the alternative leaflet and that allocation occurred automatically without investigator involvement.

Intervention arm (Leaflet B):
Participants allocated to the intervention arm received Leaflet B, a theory-informed, patient-centred information leaflet about myocardial infarction (MI) and its treatments. Leaflet B was developed through a multi-phase research process informed by a systematic review, qualitative interviews with healthcare professionals involved in MI care, patients, and an informal caregiver, behavioural science frameworks (Theoretical Domains Framework, Capability Opportunity Motivation-Behaviour model, and Behaviour Change Wheel), Patient and Public Involvement (PPI), Universal Design for Learning (UDL), and health literacy principles. Participants were asked to read the leaflet and then complete a questionnaire before and after leaflet exposure, assessing the feasibility of study procedures, the acceptability of the leaflet, and participants' knowledge and understanding of MI and its treatments.

Comparator arm (Leaflet A):
Participants allocated to the comparator arm received Leaflet A, an existing publicly available patient information leaflet for people who have experienced an MI. Participants were asked to read the leaflet and complete the same questionnaire as the intervention group.

Duration of intervention and follow-up:
The intervention consisted of a single exposure to the allocated leaflet during one online survey. Before leaflet exposure, 4 questions were asked, and immediately after reviewing the leaflet, participants completed the same 4 questions, along with additional questions regarding the design and clarity of the allocated leaflet. There was no follow-up period.

Intervention Type
Other

Primary outcome(s)
1. Recruitment rate measured using recruitment rate, calculated as the proportion of eligible participants recruited during the pilot trial at the end of the study

2. Retention rate measured using retention rate, calculated as the proportion of recruited participants retained during the pilot trial at the end of the study

3. Completion rate measured using completion rate, calculated as the proportion of recruited participants completing study assessments during the pilot trial at the end of the study

Key secondary outcome(s)
1. Participants’ general knowledge and understanding of myocardial infarction measured using structured questionnaire at before and after leaflet exposure

2. Participants’ perceptions of clarity, relevance and acceptability of Leaflet A or Leaflet B measured using 5-point Likert scale and open-ended questions at immediately following review of the allocated leaflet

Completion date
23/02/2026

Eligibility

Key inclusion criteria
1. Adults aged 18 years or older
2. Willing and able to provide informed consent

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
122

Key exclusion criteria
1. Individuals employed in the healthcare sector
2. Individuals who were <18 years old
3. Individuals who did not provide informed consent

Date of first enrolment
22/01/2026

Date of final enrolment
23/02/2026

Locations

Countries of recruitment
Ireland

Sponsor information

Organisation
University College Cork

ROR
https://ror.org/03265fv13

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		01/11/2025	25/06/2026	No	No