Study Protocol — Pilot Randomised Controlled Trial

Project title: Randomised controlled trial of the effectiveness of a co-created information leaflet on heart attack, using universal design principles, versus an existing information leaflet.

Lead researcher: Fatma El-Komy (Fatma.Elkomy@umail.ucc.ie), PhD candidate, School of Pharmacy, University College Cork

Supervisors:

Dr Margaret Bermingham (margaret.bermingham@ucc.ie)

Prof. Laura J Sahm (L.Sahm@ucc.ie)

Prof. Stephen Byrne (Stephen.Byrne@ucc.ie)

Dr Michelle O'Driscoll (michelle.odriscoll@ucc.ie)

1. Plain-language summary (≤250 words)

Cardiovascular disease is a leading cause of death in Ireland. Clear patient information after a heart attack (myocardial infarction, MI) helps people understand their condition and treatment, but many leaflets use complex language and are difficult for people with limited health literacy.

This study compares two patient information leaflets:

- **Leaflet A:** a publicly available leaflet currently used in Ireland.
- **Leaflet B:** a leaflet co-created by the research team with public and patient involvement (PPI) and health literacy advocate, designed using universal design principles.

We will run a randomised controlled trial in which members of the public (aged ≥18, non-healthcare professionals) are randomly assigned to read either leaflet A or B, then

complete a short anonymous online survey measuring readability, clarity, actionability, and knowledge about MI and treatments.

Approximately 100 participants will be recruited via community groups, social media, public spaces, and university mailing lists. Results will compare how well each leaflet communicates key messages and how much knowledge participants gain. Findings will inform the design of clearer educational materials to support understanding and self-management after MI.

2. Objectives & research questions

Primary objective:
To pilot a randomised comparison of two MI information leaflets to estimate effect sizes for leaflet comprehension and actionability and to test feasibility of recruitment, randomisation, and data collection procedures.

Research questions:

1. How effectively do Leaflet A and Leaflet B explain MI and its treatments?
2. Do the leaflets differ in the amount of knowledge readers gain?
3. How do members of the public rate each leaflet's clarity, accessibility, and usefulness?
4. What are the strengths and limitations of each leaflet for patient education?

Broad research focus / key themes:
Evaluation of readability, clarity, and educational impact of patient information materials, exploring how design and content influence understanding, with the aim of informing the development of clearer, more effective resources.

3. Study design

Parallel-group, two-arm pilot randomised controlled trial (1:1 allocation). Single-exposure design: participants see **only one leaflet** and complete an immediate post-exposure survey via Qualtrics.

4. Participants

Eligibility

- **Inclusion:** Adults ≥18 years, members of the public, able to provide informed consent.
- **Exclusion:** Healthcare professionals or those with medical/healthcare qualifications; unable to provide consent.

Sample size (pilot)
A target sample of approximately **100 participants** (around **50 per group**) has been chosen on a pragmatic basis and informed by previous work by this research group. As this is a pilot study, formal power calculation is not required.

Recruitment sources

- Community groups, shopping centres, public facilities (permission obtained).
- Social media (Twitter/X, Facebook, LinkedIn, WhatsApp).
- University mailing lists (e.g., UCC staff).
- Recruitment materials include invitation emails, social media adverts, QR codes linking to survey, Participant Information Sheet (PIS), and Consent statement.

5. Materials & intervention

- **Leaflet A:** publicly available MI leaflet.
- **Leaflet B:** co-created leaflet with PPI input and universal design principles.

Survey instrument (Qualtrics):

- Eligibility checks (age ≥18; not a healthcare professional).
- Participant Information Sheet + electronic consent tick box.
- Demographics: age, gender, region.
- Post-leaflet outcomes:
    - Knowledge test (multiple-choice items).
    - Ratings of readability, clarity, and actionability (Likert scales).
    - Optional free-text comments.

Full survey included in Appendix 5.

6. Outcomes

Primary (pilot):

- Knowledge test scores after reading the leaflet.
- Participant ratings of clarity and actionability.

Secondary / feasibility:

- Recruitment and survey completion rates.
- Time to complete survey.
- Proportion of participants rating leaflet as clear/very clear.
- Qualitative themes from free-text comments.

Safety outcomes:

- Any participant-reported distress; signposting provided.

7. Randomisation & allocation concealment

Randomisation occurs via Qualtrics randomiser (1:1), immediately after consent. Participants are blinded to alternative leaflet. Researchers remain blinded during initial data export; group IDs will be coded during analysis.

8. Data collection procedures

- Survey administered via GDPR-compliant Qualtrics.
- No identifiable information collected; IP tracking disabled.
- Debriefing provided at survey end, with signposting to GP and HSE supports.

9. Data management & storage

- Data downloaded within 14 days and removed from Qualtrics.
- Stored on UCC OneDrive/SharePoint in password-protected folders.
- Anonymised, coded dataset retained for 10 years, then securely deleted.
- Only named research team has access.

10. Statistical analysis

- **Descriptive:** demographics, completion rates.
- **Comparative:** t-test or Mann–Whitney for knowledge scores; Likert ratings analysed with appropriate non-parametric tests.
- **Qualitative:** thematic analysis of free-text comments.

No formal hypothesis testing; results will estimate effect sizes and inform future definitive trial.

11. Public & Patient Involvement (PPI)

Patient with lived MI experience and literacy ambassador co-created Leaflet B, reviewed study materials, and will review dissemination outputs.

12. Ethical considerations & risk mitigation

- Low-risk anonymous online survey.
- Informed consent via PIS + tick box.
- Withdrawal possible prior to submission; responses anonymous thereafter.
- Debrief signposting provided.
- GDPR compliance ensured; no identifiable data collected.

13. Dissemination

Findings reported in aggregate in thesis, conferences, and publications. Anonymised datasets may be shared only under controlled, approved conditions.

14. Timeline

- Oct 2025: Materials finalisation, ethical approval.
- Oct–Dec 2025: Recruitment & survey.
- Jan–Mar 2026: Data cleaning & analysis.

15. Appendices

1. Leaflet B (co-created leaflet)
2. Recruitment materials (emails, adverts, posters)
3. Participant Information Sheet (PIS)
4. Consent statement and full survey

Randomised controlled trial of the effectiveness of a co-created information leaflet on heart attack, using universal design principles, versus an existing information leaflet

Appendix 1.

Letter/Email of Invitation to Participate in Survey

Thank you for considering taking part in this research study. My name is Fatma Elkomy, and I am a PhD researcher in the School of Pharmacy, University College Cork. I am contacting you as part of the University College Cork research team working on a project exploring how members of the public understand and use patient information leaflets (PILs) to support knowledge about heart attack and the medicines used. The purpose of this project is to better understand how clear, useful, and accessible the leaflets are. We wish to identify opportunities to improve how health information is communicated to the public. Each participant will randomly receive one of the leaflets.

We are inviting you to share your views and experiences by completing a one-time online survey. The survey should take approximately 10–15 minutes to complete and can be done at a time and place that suits you. Your responses will remain completely anonymous.

To take part, please read the Participant Information Leaflet here (link) and attached. If you are happy to participate, you can provide your consent electronically before beginning the survey. You must be 18 years of age or older to participate and have no experience of studying or working in healthcare. We would like to thank you for considering participating in this research. If you have any further questions, please contact me, Fatma El-Komy (Fatma.Elkomy@ucc.ie), or my supervisor, Dr Margaret Bermingham (margaret.bermingham@ucc.ie)

Kind regards,
Fatma El-Komy

Appendix 2: Flyer for Recruitment:



UCC
Coláiste na hOllscoile Corcaigh
University College Cork, Ireland

Randomised controlled trial of the effectiveness of a co-created information leaflet on heart attack, using universal design principles, versus an existing information leaflet .

Appendix 3. Participant Information Leaflet

Thank you for considering participating in this research project. The purpose of this document is to explain to you what the work is about and what your participation would involve, to enable you to make an informed choice.

The purpose of this study is to assess the effectiveness of different patient information leaflets about heart attack in supporting knowledge and understanding of this condition and the medication used to treat it among members of the public. Should you choose to participate, you will be asked to complete a questionnaire, which will include items on your comprehension of health information, your opinions on the clarity and usefulness of the leaflet, and some basic information about yourself (e.g., your age, gender, education level).

Participation in this study is completely voluntary. There is no obligation to participate, and should you choose to do so you can refuse to answer specific questions or decide to withdraw from the study prior to completing the survey. All information you provide will be confidential and your anonymity will be protected throughout the study.

You maintain the right to withdraw from the study at any stage up to the point of data submission. At this point, your data will be collated with that of other participants and can no longer be retracted.

The anonymous data will be stored on a University College Cork-supported cloud storage platform (OneDrive). The data will be stored for a minimum of ten years, in accordance with the University College Cork Research Records Retention Schedule (series RRS1.2.20) and the UCC Code of Research Conduct.

The information you provide may contribute to research publications and/or conference presentations. The data will also form part of a doctoral thesis.

We do not anticipate any negative outcomes from participating in this study. However, some of the topics broached in the survey may be of a personal nature. Should you wish to do so, you can choose not to answer questions, or to withdraw from the survey. Should you experience distress arising from participating in the research, the contact details for support services provided below may be of assistance: your GP or the HSE support services webpage https://www2.hse.ie/mental-health/services-support/supports-services/.

This study has obtained ethical approval from the University College Cork Social Research Ethics Committee.

If you have any queries about this research, you can contact me Fatma.Elkomy@umail.ucc.ie , or my Supervisor, Dr Margaret Bermingham (Margaret.bermingham@ucc.ie). If you agree to take part in this study, please complete the consent form below.

Randomised controlled trial of the effectiveness of a co-created information leaflet on heart attack, using universal design principles, versus an existing information leaflet Appendix 4

Block 1: Eligibility

Q1. Are you aged 18 years or older?

- Yes
- No → End of Survey

Q2. Do you work in the healthcare field? (e.g., doctor, nurse, pharmacist)

- YES (IF YES End of Survey)
- NO

End of survey message:

Thank you for considering taking part in this survey. As you do not meet the study inclusion criteria, the survey will end now.

Block 2: Consent

Q3. Do you consent to take part in this study?

- Yes, I agree to participate
- No, I do not wish to participate → End of Survey

End of survey message:

Thank you for considering taking part in this survey. As you did not consent to take part in the study, the survey will end now.

Block 3: Demographics

Q4. Do any of the following apply to you

- I have experienced a heart attack
- I support/care for someone who has had a heart attack
- None of the above

Q5. What is your age group?

- 18–29
- 30–39
- 40–49
- 50–59
- 60–69
- 70+

Q6. What is your gender?

- Male
- Female
- Non-binary / Other
- Prefer not to say

Q7. Where do you currently live?

- Ireland (Republic of Ireland)
- Northern Ireland
- Elsewhere in Europe (There is a free text if you would like to give the country)
- Outside Europe (There is a free text if you would like to give the country)

Block 4: Health Literacy (SILS)

Q8. How often do you need help reading hospital materials, leaflets, or other written health information?

- Never
- Rarely
- Sometimes
- Often
- Always

Block 5: Pre-test Knowledge

Before showing you an information leaflet about a heart attack, please answer the following questions, to the best of your knowledge.

Q9a. After a heart attack, is it important to take medicines every day even if you feel well?

- Yes
- No
- Don't know

Q9b. Why do doctors prescribe medicines after a heart attack (Please choose one answer only)?

- To reduce the chance of another heart attack
- To cure heart disease completely
- To replace the need for healthy lifestyle changes
- Don't know

Q9c. If a dose of a heart attack medicine is missed, what should you do?

- Double the next dose
- Skip the missed dose and take the next one as usual
- Stop the medication altogether
- Don't know

Q9d. After a heart attack, medicines should usually be taken for:

- A few weeks

- A few months
- Long term / for life
- Don’t know

Block 6: Leaflet Exposure (Randomiser)

Please take a few minutes to read this leaflet carefully. Afterwards, we'd appreciate your feedback and your answers to a few short questions about it.

Participants will be randomly shown one leaflet:

- Condition A: Publicly available online leaflet (embedded PDF/link)
- Condition B: Co-produced leaflet (embedded PDF/link)

Block 7: Leaflet Evaluation (Quantitative)

Q10. How clear was the information in the leaflet?

- Very clear → Very unclear (5-point Likert)
- **Very clear** → The information was easy to understand straight away, with no confusion at all.
- **Clear** → The information was understandable overall but required a little effort or rereading.
- **Neither clear nor unclear** → Neutral; the information was partly understandable but also had some confusing parts.
- **Unclear** → The information was difficult to follow, caused confusion, or wasn't explained well.
- **Very unclear** → The information was very hard to follow or almost impossible to understand.

Q11. How useful was the leaflet for understanding medicines?

- Very useful → Not at all useful (5-point Likert)
- **Very useful** → The leaflet was extremely helpful for understanding medicines.
- **Useful** → The leaflet was generally helpful overall.
- **Neither useful nor not useful** → Neutral; it was somewhat helpful but also lacking in parts.
- **Not useful** → The leaflet was not very helpful for understanding medicines.
- **Not at all useful** → The leaflet was completely unhelpful for understanding medicines

Q12. How confident would you feel about managing medicines after reading the leaflet?

- Very confident → Not at all confident (5-point Likert)
- **Very confident** → I feel completely sure of myself; I have no doubts about managing the medicines.
- **Confident** → I feel mostly sure, with only minor doubts about managing the medicines.
- **Neither confident nor unconfident** → I feel somewhere in between; neither certain nor doubtful.
- **A little confident** → I feel somewhat unsure or hesitant about managing the medicines.
- **Not at all confident** → I feel no confidence at all in managing the medicines.

Q13. How long did you spend reading the leaflet?

- Less than 1 minute
- 1–3 minutes
- 4–6 minutes
- More than 6 minutes

Block 8: Leaflet Feedback

Q14. What did you find most clear or helpful in the leaflet? (Text Entry)

Q15. What if anything, was unclear or confusing in the leaflet? (Text Entry)

Q16. What do you think about the amount of information in the leaflet?

Very little information → Too much information (5-point Likert)

- **Very little information** → I feel I didn't get enough information; I'm missing details.
- **Little information** → I got some information, but still not enough to feel well-informed.
- **About the right amount of information** → I got the right balance of information; not too little, not too much.
- **Somewhat too much information** → I received more information than I really needed.
- **Too much information** → I feel overloaded with information; it's difficult to manage or make sense of it.

Q17. What do you think about the look and layout of the leaflet (e.g., text size, images, organisation)? (Text Entry)

Q18. What could be improved in the leaflet? (Text Entry)

Q19. Any other comments? (Text Entry)

Block 9: Post-test Knowledge

Q9a–d. Repeat same questions as Q9a–d.

Final Block: Closing

Closing message

Descriptive Text

Thank you for taking part in this study. Your responses are anonymous and confidential.

This research aims to compare two different patient information leaflets to assess understanding of heart attack and its treatment. You have given feedback on one leaflet, while other participants will review the second, so that we can compare the two.

If you have any questions about the study, please contact:

- Fatma El-Komy (Fatma.Elkomy@umail.ucc.ie)

Supervisor: Dr Margaret Bermingham (margaret.bermingham@ucc.ie)