

# Enhanced participant information sheet for the recruitment of caregivers to a multicentre randomised trial

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<b>Registration date</b> 23/09/2021	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 06/01/2026	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Recruiting people to a trial, that is people being invited and agreeing to take part in the research study, can sometimes be difficult or slower than expected. In some cases, trials are stopped early before enough people have been recruited. Ending a trial early can reduce the value of the trial results when trying to improve healthcare practices into the future. In an effort to make sure enough people are recruited to a trial so that the trial results have meaning for healthcare practice, researchers often put in place measures that they think could help with this. For example, the lead researcher may visit the study site more often to talk about the trial and recruitment, or the researchers may offer incentives (small gifts such as a voucher) to people for taking part. It is not always clear though if these measures work or not because they are not always formally studied.

When a person is being invited to take part in a trial, the researcher will give the person a participant information sheet (PIS). The PIS contains all of the information about the trial to help a person decide if they would like to take part, or not, as the case may be. The amount of detail in the PIS, the length of the PIS and how easy the PIS is to read can all affect a person's understanding of the trial, and their decision to take part. To study this we aim to compare two types of PIS which will be given to people invited to take part in a randomised trial.

### Who can participate?

Carers of people with heart failure who are being invited, along with the person who has heart failure, to take part in the REACH-HFpEF trial.

### What does the study involve?

The REACH-HFpEF trial is studying the effect of a home-based rehabilitation intervention for patients with heart failure. The intervention PIS for use in the REACH-HFpEF trial will be enhanced with information that carers have described as motivating as well as challenging for them when deciding to take part in a trial. The control PIS will be the usual PIS that was originally designed for use in the REACH-HFpEF trial. Twenty hospitals are taking part in the REACH-HFpEF trial, so half of these will use the enhanced PIS when inviting carers to take part, and the other half will use the usual PIS.

What are the possible benefits and risks of participating?

There are no known risks or benefits to carers by taking part in this embedded study, but it will help us find out if using an enhanced PIS, compared to using a usual PIS, is helpful when we are recruiting carers to a trial. Knowing this information will help other researchers when designing their PIS for carers in future trials.

Where is the study run from and who is funding the study?

The main REACH-HFpEF trial is funded by the UK Government through the National Institute for Health Research. This embedded PIS study has not received extra funding as it will be done as part of the main REACH-HFpEF trial.

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

September 2021 to December 2025

Who is the main contact?

Prof Valerie Smith, [valerie.smith@ucd.ie](mailto:valerie.smith@ucd.ie)

## Contact information

### Type(s)

Scientific

### Contact name

Prof Valerie Smith

### ORCID ID

<https://orcid.org/0000-0003-2249-6038>

### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

298247

### Protocol serial number

NIHR130487, IRAS 298247, CPMS 50258

## Study information

## Scientific Title

Evidence-based enhanced participant information sheet for recruiting caregivers to the REACH-HFpEF multicentre randomised trial: A Study Within a Trial (SWAT)

## Study objectives

To determine if an evidence-based enhanced participant information sheet (PIS) impacts on recruitment and retention of caregivers to the REACH-HFpEF multi-center randomised trial (REACH-HFpEF trial registry number: ISRCTN47894539)

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 27/10/2021, West of Scotland Research Ethics Committee (West of Scotland Research Ethics Service, Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, UK; +44 (0)141 3140213; WoSREC3@ggc.scot.nhs.uk), ref: 21/NS/0085

## Study design

Cluster randomized trial

## Primary study design

Interventional

## Study type(s)

Other

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

Trial recruitment using an enhanced participant information sheet

## Interventions

Part of the REACH-HFpEF multi-center trial (ISRCTN47894539) to assess the effect of using the enhanced compared to the standard participant information.

REACH-HFpEF trial sites will be randomised on a 1:1 ratio to use the intervention enhanced PIS or the control PIS. Sites will be blinded to which PIS they have been allocated.

## Intervention Type

Behavioural

## Primary outcome(s)

1. Proportion of caregivers who are approached and agree to participate in the REACH-HFpEF trial measured using the numbers of caregivers who have consented and are enrolled in the trial
2. Proportion of caregivers allocated in each intervention and control group who provide REACH-HFpEF trial outcomes measured using the numbers of participants who return outcome questionnaires at 4- and 12-months follow-up

## Key secondary outcome(s)

1. Caregiver's level of satisfaction with the PIS (measured on a Likert scale of 1 not at all satisfied to 5 extremely satisfied) in both the intervention PIS and control PIS groups measured at baseline following randomisation to the trial, and at 4-months follow-up

2. Caregivers' priority motivators and barriers for participating in the REACH-HFpEF trial measured a validated questionnaire (Likert scale options from 1 very unimportant to 5 very important) at entry to the trial and at 4 months after enrolling in the trial

**Completion date**

31/05/2026

## Eligibility

**Key inclusion criteria**

Carers/support persons, who are aged 18 years and older and who are being invited to take part in the REACH-HFpEF host trial with their care recipient.

**Participant type(s)**

Carer

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

18 years

**Upper age limit**

110 years

**Sex**

All

**Total final enrolment**

94

**Key exclusion criteria**

Carers/support persons who decline to take part in the REACH-HFpEF host trial.

**Date of first enrolment**

01/11/2021

**Date of final enrolment**

31/05/2025

## Locations

**Countries of recruitment**

United Kingdom

England

Scotland

**Study participating centre**

**Ninewells Hospital and Medical School**

NHS Tayside

Department of Cardiology

Dundee

Scotland

DD1 9SY

**Study participating centre**

**Glasgow Royal Infirmary**

NHS Greater Glasgow and Clyde

84 Castle Street

Glasgow

Scotland

G4 0SF

**Study participating centre**

**Lister Centre**

NHS Ayrshire and Arran

University Hospital Crosshouse

Kilmarnock

Scotland

KA2 0BE

**Study participating centre**

**Aintree University Hospital**

Liverpool University Hospitals NHS Foundation Trust

Lower Lane

Liverpool

England

L9 7AL

**Study participating centre**

**Darlington Memorial Hospital**

County Durham and Darlington NHS Foundation Trust

Hollyhurst Road

Darlington

England

DL3 6HX

**Study participating centre**

**St Thomas' Hospital**

Guy's and St Thomas' NHS Foundation Trust  
Westminster Bridge Road  
London  
England  
SE1 7EH

**Study participating centre**

**Kings College Hospital NHS Foundation Trust**

Denmark Hill  
London  
England  
SE5 9RS

**Study participating centre**

**Glenfield Hospital**

Leicestershire Partnership NHS Trust  
Grobby Road  
Leicester  
England  
LE39 9QP

**Study participating centre**

**Manchester Royal Infirmary**

Manchester Heart Centre  
Manchester University NHS Foundation Trust  
Oxford Road  
Manchester  
England  
M13 9WL

**Study participating centre**

**University Hospital of North Tees**

North Tees and Hartlepool NHS Foundation Trust  
Hardwick Road  
Stockton on Tees  
England  
TS19 8PE

**Study participating centre**

**City Hospital**

Nottingham University Hospitals NHS Trust

Trent Cardiac Centre

Hucknall Road

Nottingham

England

NG5 1PB

**Study participating centre**

**Queen Alexandra Hospital**

Department of Cardiology

Portsmouth Hospitals University NHS Trust

Southwick Hill Road

Portsmouth

England

PO6 3LY

**Study participating centre**

**Royal Devon and Exeter Hospital**

Cardiology Department

Royal Devon and Exeter NHS Foundation Trust

Barrack Road

Exeter

England

EX2 5DW

**Study participating centre**

**The Royal Wolverhampton NHS Trust**

Cardiothoracic Directorate

The Heart and Lung Centre

Wolverhampton

England

WV10 0QP

**Study participating centre**

**Russell's Hall Hospital**

The Dudley Group NHS Foundation Trust

Pensnett Road

Dudley

England

DY1 2HQ

**Study participating centre**

**West Suffolk Hospital**

The Cardiac Centre  
West Suffolk NHS Foundation Trust  
Hardwick Lane  
Bury Saint Edmunds  
England  
IP33 2QZ

**Study participating centre**

**St Catherine's Health Centre**

Wirral Community Health and Care NHS Foundation Trust  
Derby Road  
Tranmere, Wirral  
Merseyside  
England  
CH42 7HA

**Study participating centre**

**Wycombe Hospital**

Cardiology Research  
Ward 3B  
Buckinghamshire Healthcare NHS Trust  
Wycombe  
England  
HP11 2TT

**Study participating centre**

**York Hospital**

York Teaching Hospital NHS Foundation Trust  
Wigginton Road  
York  
England  
YO31 8HE

## **Sponsor information**

**Organisation**

NHS Greater Glasgow and Clyde

ROR

<https://ror.org/05kdz4d87>

## Funder(s)

### Funder type

Government

### Funder Name

Health Technology Assessment Programme

### Alternative Name(s)

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication. The dataset containing the priority motivators and barriers for participating in the REACH-HFpEF trial is an anonymous dataset and will be made available on the open access platform 'Open Science Framework' once data collection is complete, with a link to the dataset provided in the Journal publication reporting the results of the trial.

### IPD sharing plan summary

Other

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>		13/05/2025	06/01/2026	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No