

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

Submission date 12/09/2021	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 23/09/2021	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/01/2026	Condition category 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

Contact information

Type(s)

Scientific

Contact name

Prof Valerie Smith

ORCID ID

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

Contact details

School of Nursing, Midwifery and Health Systems,
University College Dublin

Dublin

Ireland

D04

+353-1-8964031

valerie.smith@ucd.ie

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

298247

ClinicalTrials.gov (NCT)

Nil known

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?
Protocol article		13/05/2025	06/01/2026	Yes	No

