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

Submission date
12/09/2021

Recruitment status
Recruiting

Registration date
23/09/2021

Overall study status
Ongoing

Last Edited
19/08/2024

Condition category
Other

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

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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
31/12/2025

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
Adult

Lower age limit
18 years

Sex
All

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
31/12/2025

Locations

Countries of recruitment
United Kingdom

England

Scotland

Study participating centre
Ninewells Hospital and Medical School
NHS Tayside
Department of Cardiology
Dundee
United Kingdom
DD1 9SY

Study participating centre
Glasgow Royal Infirmary
NHS Greater Glasgow and Clyde
84 Castle Street
Glasgow
United Kingdom
G4 0SF

Study participating centre
Lister Centre
NHS Ayrshire and Arran
University Hospital Crosshouse
Kilmarnock
United Kingdom
KA2 0BE

Study participating centre
Aintree University Hospital
Liverpool University Hospitals NHS Foundation Trust
Lower Lane
Liverpool
United Kingdom
L9 7AL

Study participating centre
Darlington Memorial Hospital
County Durham and Darlington NHS Foundation Trust
Hollyhurst Road
Darlington
United Kingdom
DL3 6HX

Study participating centre

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

Study participating centre
Kings College Hospital NHS Foundation Trust
Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre
Glenfield Hospital
Leicestershire Partnership NHS Trust
Groby Road
Leicester
United Kingdom
LE39 9QP

Study participating centre
Manchester Royal Infirmary
Manchester Heart Centre
Manchester University NHS Foundation Trust
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
University Hospital of North Tees
North Tees and Hartlepool NHS Foundation Trust
Hardwick Road
Stockton on Tees
United Kingdom
TS19 8PE

Study participating centre

City Hospital
Nottingham University Hospitals NHS Trust
Trent Cardiac Centre
Hucknall Road
Nottingham
United Kingdom
NG5 1PB

Study participating centre
Queen Alexandra Hospital
Department of Cardiology
Portsmouth Hospitals University NHS Trust
Southwick Hill Road
Porstmouth
United Kingdom
PO6 3LY

Study participating centre
Royal Devon and Exeter Hospital
Cardiology Department
Royal Devon and Exeter NHS Foundation Trust
Barrack Road
Exeter
United Kingdom
EX2 5DW

Study participating centre
The Royal Wolverhampton NHS Trust
Cardiothoracic Directorate
The Heart and Lung Centre
Wolverhampton
United Kingdom
WV10 0QP

Study participating centre
Russell's Hall Hospital
The Dudley Group NHS Foundation Trust
Pensnett Road
Dudley
United Kingdom
DY1 2HQ

Study participating centre
West Suffolk Hospital
The Cardiac Centre
West Suffolk NHS Foundation Trust
Hardwick Lane
Bury Saint Edmunds
United Kingdom
IP33 2QZ

Study participating centre
St Catherine's Health Centre
Wirral Community Health and Care NHS Foundation Trust
Derby Road
Tranmere, Wirral
Merseyside
United Kingdom
CH42 7HA

Study participating centre
Wycombe Hospital
Cardiology Research
Ward 3B
Buckinghamshire Healthcare NHS Trust
Wycombe
United Kingdom
HP11 2TT

Study participating centre
York Hospital
York Teaching Hospital NHS Foundation Trust
Wigginton Road
York
United Kingdom
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?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes