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Promoting group identity to improve questionnaire return rates in a multicentre randomised controlled trial

Submission date	**Recruitment status**	[X] Prospectively registered
21/10/2021	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/11/2021	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
07/07/2025	Other	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

When participants stay involved in a clinical trial after their treatment has finished, it allows researchers to collect important follow-up information about the study treatments. Unfortunately, participants often drop out of the study before the end, and the reasons for this are poorly understood. High levels of patient dropout is a particular problem in clinical trials that involve patients in critical care. This may be because participants are recruited when they are unconscious and lack capacity. Participants may not understand how important it is to collect information about people's health several months after they are discharged from ICU. Researchers want to see if they can improve the collection of follow-up information in the MARCH trial by running a small study at the same time, called a Study Within a Trial (or SWAT). SWATs help researchers find out the best way to run studies. The researchers want to know whether communication aimed at making people feel part of the MARCH study improves the return rate of follow-up questionnaires. After their discharge from hospital, the researchers will send some study participants a thank you card, personalised letters, and a promotional item (e.g. reusable coffee cup) to encourage the feeling of being part of a group. They will then work out if people feel they belong to the study group, and whether belonging to the study group increases the number of patients who complete and return two health-related questionnaires which will be sent 6 months after they first joined the study.

Who can participate?

In order to take part in the SWAT, patients enrolled in the main MARCH trial must have:
1. Regained consciousness and be able to make decisions for themselves
2. Given consent to continue participation in the main trial
3. Been discharged from hospital

What does the study involve?

Participants will be assigned to one of three groups, called 'S1', 'S2' and 'S3', at random (or by chance). This ensures that the groups are compared fairly. The S3 group will receive the letters that would normally be used to contact patients in a clinical trial. This group is known as the control group. Patients in the other two groups (S1 and S2) will both receive a thank you card

and specially adapted letters. The S2 group will also receive a promotional item. Participants will not be aware that they are taking part in the SWAT.

What are the possible benefits and risks of participating?
This SWAT will provide useful information for researchers to improve patient communication to increase the return of follow-up questionnaires for clinical studies in the future. The researchers do not anticipate any risks associated with being part of this study.

Where is the study run from?
Northern Ireland Clinical Trials Unit (NICTU) (UK)

When is the study starting and how long is it expected to run for?
May 2021 to October 2025

Who is funding the study?
National Institute for Health Research and Care Research Health Technology Assessment (NIHR HTA) Programme (HTA - NIHR130454) (UK)

Who is the main contact?
Dr Ashley Agus
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Study website
https://www.qub.ac.uk/sites/TheNorthernIrelandNetworkforTrialsMethodologyResearch/FileStore/Filetoupload,1219649,en.pdf

Contact information

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
293630

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
SWAT 51, IRAS 293630, HTA - NIHR130454

Study information

Scientific Title
A theory-based intervention for promoting group identity to improve questionnaire return rates in the MARCH multicentre randomised controlled trial: a Study Within a Trial (SWAT)

Acronym
MARCH: SWAT

Study objectives
A Self-Categorisation Theory-based intervention to actively promote group identity in trial participants will improve 6-month questionnaire return rates.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/10/2021, Yorkshire & The Humber - Leeds East Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)207 104 8105, +44 (0)207 104 8103, +44 (0)207 104 8018; leedseast.rec@hra.nhs.uk), REC ref: 21/YH/0234

Study design
Multicentre parallel randomized controlled trial embedded within a randomized controlled trial

Primary study design

Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Trial follow up/retention

Interventions
Participants will be randomised (1:1:1, using mixed block sizes) to one of three arms comprising two SWAT group identity intervention arms (S1 and S2) and one control arm (S3). The randomisation process will be separate from the main trial randomisation. The MARCH trial statistician will generate the randomisation sequence using NQuery Advisor.

S1 and S2 will receive the same correspondence (thank you card, letter and questionnaire incorporating theory-informed wording and adapted trial logo), but S2 will also receive a promotional item (e.g. reusable coffee cup or water bottle).
Patients allocated to the SWAT control arm (S3) will receive the standard trial follow-up correspondence (letter and questionnaire incorporating standard trial follow-up wording and standard trial logo, no thank you card).
The wording of the SWAT correspondence has been designed in consultation with the MARCH Patient and Family Advisory Group, consisting of former critical care patients and family members.

Intervention Type
Other

Primary outcome measure
The return rate for questionnaires sent to participants at 6 months. The researchers will compare the combination of S1 and S2 versus S3 to assess the impact of increasing the salience of the MARCH trial as a “group” on the return rate. They will also compare S1 versus S2 to assess the additional impact of sending a promotional item on the return rate.

Secondary outcome measures
1. Group identification at 6 months post-randomisation, measured using the single-item social identification instrument and a study-specific group membership Likert scale question. The researchers will compare the combination of S1 and S2 versus S3 to assess the impact of increasing the salience of the MARCH trial as a “group” on group identification. They will also compare S1 versus S2 to assess the additional impact of sending a promotional item on group identification
2. Total costs associated with embedding the SWAT in the MARCH trial; a spreadsheet of the

trial resources and related costs (e.g. trial team time input, consumables) associated with the SWAT will be maintained prospectively over the study period by the trial team to allow total costs to be calculated at the end of the study (51-month study duration)
3. Cost per additional questionnaire returned; this will be calculated as the incremental cost of embedding the SWAT divided by the incremental number of questionnaires returned at the end of the study (51-month study duration)

Overall study start date
01/05/2021

Completion date
31/10/2025

Eligibility

Key inclusion criteria
1. MARCH trial participants who have regained capacity
2. Given consent to continue participation in the main trial
3. Who have been discharged from hospital

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
1172

Total final enrolment
1956

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
17/02/2022

Date of final enrolment
30/04/2025

Locations

Countries of recruitment
England

Northern Ireland

Scotland

United Kingdom

Wales

Study participating centre
Royal Liverpool University Hospital
Liverpool University Hospital NHS Foundation Trust
Liverpool
United Kingdom
L7 8XP

Study participating centre
Altnagelvin Hospital
Western Health and Social Care Trust
Derry/Londonderry
United Kingdom
BT47 6SB

Study participating centre
Antrim Area Hospital
Northern Health and Social Care Trust
Ballymena
United Kingdom
BT43 6DA

Study participating centre
Barnsley Hospital
Barnsley Hospital NHS Foundation Trust
Barnsley
United Kingdom
S75 2EP

Study participating centre
Queen Elizabeth Hospital
University Hospitals Birmingham NHS Foundation Trust
Birmingham
United Kingdom
B15 2GW

Study participating centre
Bristol Royal Infirmary
University Hospitals Bristol and Weston NHS Foundation Trust
Bristol
United Kingdom
BS1 3NU

Study participating centre
Royal Infirmary Edinburgh
NHS Lothian
Edinburgh
United Kingdom
EH1 3EG

Study participating centre
Freeman Hospital
Newcastle upon Tyne Hospitals NHS Foundation Trust
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre
Glasgow Royal Infirmary
NHS Greater Glasgow and Clyde
Glasgow
United Kingdom
G12 0XH

Study participating centre
Gloucester Royal Hospital
Gloucestershire Hospitals NHS Foundation Trust
Cheltenham
United Kingdom
GL53 7AN

Study participating centre
St Thomas' Hospital
Guy's and St Thomas' NHS Foundation Trust
London

United Kingdom
SE1 7EH

Study participating centre
Hull Royal Infirmary
Hull University Teaching Hospitals NHS Trust
Hull
United Kingdom
HU3 2JZ

Study participating centre
James Cook University Hospital
South Tees Hospitals NHS Foundation Trust
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
King's College Hospital
King's College Hospital NHS Foundation Trust
London
United Kingdom
SE5 9RS

Study participating centre
Leicester Royal Infirmary
University Hospitals of Leicester NHS Trust
Leicester
United Kingdom
LE1 5WW

Study participating centre
Medway Maritime Hospital
Medway NHS Foundation Trust
Gillingham
United Kingdom
ME7 5NY

Study participating centre

Morriston Hospital
Swansea Bay University Health Board
West Glamorgan
United Kingdom
SA12 7BR

Study participating centre
Musgrove Park Hospital
Somerset NHS Foundation Trust
Taunton
United Kingdom
TA1 5DA

Study participating centre
Queen's Medical Centre
Nottingham University Hospital NHS Trust
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Pinderfields Hospital
The Mid Yorkshire Hospitals NHS Trust
Wakefield
United Kingdom
WF1 4DG

Study participating centre
Poole Hospital
University Hospitals Dorset NHS Foundation Trust
Poole
United Kingdom
BH15 2JB

Study participating centre
University Hospital Lewisham
Lewisham and Greenwich NHS Trust
London
United Kingdom
SE13 6LH

Study participating centre
Rotherham District General Hospital
The Rotherham NHS Foundation Trust
Rotherham
United Kingdom
S60 2UD

Study participating centre
Royal Berkshire Hospital
Royal Berkshire NHS Foundation Trust
Reading
United Kingdom
RG1 5AN

Study participating centre
Royal Bournemouth Hospital
University Hospitals Dorset NHS Foundation Trust
Poole
United Kingdom
BH15 2JB

Study participating centre
Royal Cornwall Hospital
Royal Cornwall Hospitals NHS Trust
Truro
United Kingdom
TR1 3LJ

Study participating centre
Royal Liverpool University Hospital
Liverpool University Hospital NHS Foundation Trust
Liverpool
United Kingdom
L7 8XP

Study participating centre
The Royal Oldham Hospital
The Pennine Acute Hospitals NHS Trust
Manchester

United Kingdom
M8 5RB

Study participating centre
Royal Stoke University Hospital
University Hospitals of North Midlands NHS Trust
Stoke-on-Trent
United Kingdom
ST4 6QG

Study participating centre
Royal United Hospital Bath
Royal United Hospitals Bath NHS Foundation Trust
Bath
United Kingdom
BA1 3NG

Study participating centre
Royal Victoria Hospital
Belfast Health and Social Care Trust
Belfast
United Kingdom
BT12 6BA

Study participating centre
Salford Royal Hospital
Salford Royal NHS Foundation Trust
Manchester
United Kingdom
M6 8HD

Study participating centre
Southmead Hospital
North Bristol NHS Trust
Bristol
United Kingdom
BS10 5NB

Study participating centre

Sunderland Royal Hospital
South Tyneside and Sunderland NHS Foundation Trust
Sunderland
United Kingdom
SR4 7TP

Study participating centre
Watford General Hospital
West Hertfordshire Hospitals NHS Trust
Watford
United Kingdom
WD18 0HB

Study participating centre
Manchester Royal Infirmary
Manchester University Hospitals NHS Foundation Trust
Manchester
United Kingdom
M13 9WL

Study participating centre
York Hospital
York and Scarborough Teaching Hospitals NHS Foundation Trust
York
United Kingdom
YO31 8HE

Study participating centre
Basingstoke and North Hampshire Hospital
Hampshire Hospitals NHS Foundation Trust
Basingstoke
United Kingdom
RG24 9NA

Study participating centre
Ipswich Hospital
East Suffolk and North Essex NHS Foundation Trust
Colchester
United Kingdom
CO4 5JL

Study participating centre
Royal Preston Hospital
Lancashire Teaching Hospitals NHS Foundation Trust
Preston
United Kingdom
PR2 9HT

Study participating centre
Golden Jubilee National Hospital
National Waiting Time Centre Board
Clydebank
United Kingdom
G81 4DY

Study participating centre
University Hospital Coventry
University Hospitals Coventry and Warwickshire NHS Trust
Coventry
United Kingdom
CV2 2DX

Study participating centre
Grange University Hospital
Aneurin Bevan University Health Board
Gwent
United Kingdom
NP18 3XQ

Study participating centre
Queen Alexandra Hospital
Portsmouth Hospitals NHS Trust
Portsmouth
United Kingdom
PO6 3LY

Study participating centre
Royal Victoria Infirmary
Newcastle upon Tyne Hospitals NHS Foundation Trust
Newcastle upon Tyne

United Kingdom
NE1 4LP

Study participating centre
Wythenshawe Hospital
Manchester University NHS Foundation Trust
Manchester
United Kingdom
M23 9LT

Study participating centre
North Manchester General Hospital
Manchester University NHS Foundation Trust
Manchester
United Kingdom
M8 5RB

Study participating centre
Belfast City Hospital
Belfast Health and Social Care Trust
Belfast
United Kingdom
BT9 7AB

Study participating centre
Sandwell General Hospital
Sandwell and West Birmingham Hospitals NHS Trust
West Bromwich
United Kingdom
B71 4HJ

Study participating centre
Queen Elizabeth Hospital
Lewisham and Greenwich NHS Trust
London
United Kingdom
SE18 4QH

Study participating centre

Guy's Hospital
Guy's and St Thomas' NHS Foundation Trust
London
United Kingdom
SE1 9RT

Study participating centre
Addenbrookes
Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Heartlands Hospital
Bordesley Green East
Bordesley Green
Birmingham
United Kingdom
B9 5SS

Study participating centre
Chesterfield Royal Hospital
Chesterfield Road
Calow
Chesterfield
United Kingdom
S44 5BL

Study participating centre
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
Victoria Hospital
Hayfield Road

Kirkcaldy
United Kingdom
KY2 5AH

Study participating centre
Warrington Hospital
Lovely Lane
Warrington
United Kingdom
WA5 1QG

Study participating centre
Royal Free Hospital
Pond Street
London
United Kingdom
NW3 2QG

Study participating centre
Torbay Hospital
Newton Road
Torquay
United Kingdom
TQ2 7AA

Study participating centre
University College London Hospital
250 Euston Road
London
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NW1 2PG

Study participating centre
Bedford Hospital
Kempston Road
Bedford
United Kingdom
MK42 9DJ

Study participating centre
Aberdeen Royal Infirmary
Foresterhill Road
Aberdeen
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AB25 2ZN

Study participating centre
Glan Clywd Hospital
Rhuddlan Rd
Bodelwyddan
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LL18 5UJ

Study participating centre
Wrexham Maelor Hospital
Croesnewydd Road
Wrexham Technology Park
Wrexham
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LL13 7TD

Study participating centre
Royal Hallamshire Hospital
Glossop Road
Sheffield
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S10 2JF

Study participating centre
Northern General Hospital
Northern General Hospital NHS Trust
C Floor, Huntsmnan Building
Herries Road
Sheffield
United Kingdom
S5 7AU

Study participating centre

West Suffolk Hospita
Hardwick Ln
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IP33 2QZ

Study participating centre
University Hospital Monklands
Monkscourt Ave
Airdrie
United Kingdom
ML6 0JS

Study participating centre
Yeovil District Hospital
Orthopaedic Triage Service
Higher Kingston
Yeovil
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BA21 4AT

Study participating centre
William Harvey Hospital
Kennington Road
Willesborough
Ashford
United Kingdom
TN24 0LZ

Study participating centre
Derriford Hospital
Derriford Road
Derriford
Plymouth
United Kingdom
PL6 8DH

Study participating centre
Queen Elizabeth University Hospital
1345 Govan Road
Glasgow

United Kingdom
G51 4TF

Study participating centre
Lincoln County Hospital
Greetwell Road
Lincoln
United Kingdom
LN2 5QY

Study participating centre
Royal Devon and Exeter Hospital
Royal Devon & Exeter Hospital
Barrack Road
Exeter
United Kingdom
EX2 5DW

Study participating centre
North Devon District Hospital
Raleigh Park
Barnstaple
United Kingdom
EX31 4JB

Study participating centre
Royal Hampshire County Hospital
Romsey Road
Winchester
United Kingdom
SO22 5DG

Sponsor information

Organisation
Belfast Health and Social Care Trust

Sponsor details

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Grosvenor Road
Belfast
Northern Ireland
United Kingdom
BT12 6BA
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Alison.Murphy@belfasttrust.hscni.net

Sponsor type
Hospital/treatment centre

Website
http://www.belfasttrust.hscni.net/

ROR
https://ror.org/02tdmfk69

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact open access peer-reviewed journal. The MARCH protocol will be published in a peer-reviewed scientific journal.

Intention to publish date
30/11/2026

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study (MARCH: SWAT) will be available upon request following the publication of the primary and secondary outcomes. Formal requests for data should be made in writing to Prof. Danny McAuley (Chief Investigator) or Dr Bronwen Connolly (Co-Chief Investigator) via the Northern Ireland Clinical Trials Unit (NICTU) and will be reviewed on a case by case basis in collaboration with the Sponsor.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No