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

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
21/10/2021		Protocol		
Registration date	Overall study status Completed  Condition category Other	Statistical analysis plan		
03/11/2021		<ul><li>Results</li><li>Individual participant data</li></ul>		
Last Edited				
07/07/2025		[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
Ashley.Agus@nictu.hscni.net

# Contact information

#### Type(s)

Public

#### Contact name

Dr Naomi Dickson

#### Contact details

Northern Ireland Clinical Trials Unit (NICTU)
7 Lennoxvale
Belfast
United Kingdom
BT9 5BY
+44 (0)28961 51447
MARCH@nictu.hscni.net

#### Type(s)

Scientific

#### Contact name

Dr Ashley Agus

#### **ORCID ID**

https://orcid.org/0000-0001-9839-6282

#### Contact details

Northern Ireland Clinical Trials Unit (NICTU)
7 Lennoxvale

Belfast United Kingdom BT9 5BY +44 (0)28961 51447 Ashley.Agus@nictu.hscni.net

# Additional identifiers

#### Clinical Trials Information System (CTIS)

Nil known

#### Integrated Research Application System (IRAS)

293630

#### ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

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

#### Study type(s)

Other

#### 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(s)

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.

# Key secondary outcome(s))

- 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)

#### 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** 

#### Healthy volunteers allowed

No

#### Age group

Other

#### Sex

All

#### 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

**United Kingdom** 

England

Northern Ireland

Scotland

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 EH13EG

# 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 United Kingdom NW1 2PG

#### Study participating centre Bedford Hospital

Kempston Road Bedford United Kingdom MK42 9DJ

## Study participating centre Aberdeen Royal Infirmary

Foresterhill Road Aberdeen United Kingdom AB25 2ZN

## Study participating centre Glan Clywd Hospital Rhuddlan Rd

Bodelwyddan

Rhyl United Kingdom LL18 5UJ

# Study participating centre Wrexham Maelor Hospital

Croesnewydd Road Wrexham Technology Park Wrexham United Kingdom LL13 7TD

## Study participating centre Royal Hallamshire Hospital

Glossop Road Sheffield United Kingdom 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 Bury St Edmund United Kingdom 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 United Kingdom 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

#### **ROR**

https://ror.org/02tdmfk69

# 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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes