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An intervention to reduce sedentary behaviour and improve outcomes after stroke (Get Set Go): A study protocol for the process evaluation of a pilot cluster randomised controlled trial (RECREATE)

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ABSTRACT:

Introduction: Stroke survivors spend long periods of time engaging in sedentary behaviour even when their functional recovery is good. In the RECREATE programme, an intervention aimed at reducing sedentary behaviour ('Get Set Go') will be implemented and evaluated in a pragmatic external pilot cluster randomised controlled trial (cRCT) with embedded process and economic evaluations. We report the protocol for the process evaluation which will address the following objectives: 1) Describe and clarify causal assumptions about the intervention, and its mechanisms of impact; 2) Assess implementation fidelity; 3) Explore views, perceptions and acceptability of the intervention to staff, stroke survivors and their

carers; 4) Establish the contextual factors that influence implementation, intervention mechanisms, and outcomes.

Methods and analysis: This pilot trial will be conducted in 15 UK based National Health Service (NHS) stroke services. This process evaluation study, underpinned by the Medical Research Council (MRC) guidance will be undertaken in six of the randomised services (four intervention, two control). Data collection will include: observations of staff training sessions, non- participant observations in inpatient and community settings, semi-structured interviews with staff, patients and carers, and documentary analysis of key intervention components to assess completion. Additional quantitative data relating to intervention implementation will be collected in all sites. Training observations and documentary analysis data will be summarised, with other observational and interview data analysed using Thematic Analysis. Relevant theories will be used to interpret the findings, including: the Theoretical Domains Framework, Normalisation Process Theory and the Theoretical Framework of Acceptability. Anticipated outputs include: recommendations for intervention refinements (both content and implementation); a revised implementation plan, and a refined logic model (and supporting written intervention description).

Ethics and dissemination: The study was approved by Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (REC reference:19/YH/0403). Findings will be disseminated via peer review publications, and national and international conference presentations.

Trial registration number: ISRCTN82280581

STRENGTHS AND LIMITATIONS OF THE STUDY:

- The process evaluation is underpinned by the Medical Research Council (MRC) guidance for process evaluations and addresses all key functions outlined in the guidance including implementation, mechanisms of impact and context.
- Theory based, comprehensive process evaluation involving staff, patients and family, friends and carers in intervention and control services.
- The process evaluation will be conducted longitudinally, providing information about changes over time.

- The in-depth process evaluation will be conducted in a proportion of trial services, however the implementation team will meet regularly with services not included in the process evaluation to provide an insight into implementation activity. We will also report quantitative implementation data collected across all sites.

INTRODUCTION

Sedentary behaviour (SB) is defined as any waking behaviour characterised by low energy expenditure (≤1.5 Metabolic Equivalent of Task (METs)) while in a sitting, lying or reclining posture (1). In this study, we use the common approach of interpreting sedentary behaviour as sitting/lying down during waking hours without being otherwise active (2). SB is the focus of considerable clinical, policy and research interest, as the evidence supporting its detrimental effects on health and well-being increases (1, 3-6). Higher levels of moderate-vigorous physical activity (MVPA) may reduce risk associated with more daily sedentary time (5). However, achieving recommended levels of MVPA to offset potential harms of high levels of SB (i.e. >300 min/week of MVPA) is likely to be challenging (5), particularly for stroke survivors. Evidence suggests this population group are more sedentary and engage in longer unbroken bouts of sedentary behaviour than other population groups (7-9). Thus, reducing SB has been suggested as a new target for therapeutic intervention after stroke (10).

In 2016, an international group of stroke recovery and rehabilitation experts reported that inadequate theoretical intervention development may explain the lack of efficacy of many existing interventions targeting people after stroke (11). The Medical Research Council (MRC) guidelines advocate the importance of using theory and evidence in developing complex interventions (12). It has also been suggested that taking a partnership approach (e.g. co-production) can facilitate the development of feasible and context-sensitive interventions and may increase the likelihood of developing an intervention that is efficacious, due to the active involvement of all relevant stakeholders (13).

RECREATE Programme

Our National Institute for Health and Care Research (NIHR) funded seven year research programme (RECREATE) seeks to develop and evaluate strategies for reducing SB after stroke to improve outcomes.

The Get Set Go intervention was developed using a structured process, guided by the Behaviour Change Wheel (BCW) which incorporates the Theoretical Domains Framework (TDF) (14) in combination with a co-production approach (15) and tested as part of a feasibility study. Get Set Go aims to decrease SB after stroke by increasing the frequency and duration of standing and moving. The intervention is a whole service intervention, commencing in the inpatient stroke unit and continuing once the stroke survivor is discharged home for at least 12 weeks. The intervention focuses on training inpatient and community staff to support and encourage stroke survivors to stand and move more in everyday stroke care (as part of routine practice). It also focuses on encouraging stroke survivors to monitor their own standing and moving more, with assistance where appropriate.

The RECREATE multicentre cluster randomised controlled trial (cRCT) aimed to evaluate the clinical and cost effectiveness of the Get Set Go intervention. NHS stroke services randomised to the intervention group will be trained to deliver the intervention, whilst those randomised to the control group will continue usual practice. All patients in the stroke services randomised to the intervention will be exposed to Get Set Go. The trial originally aimed to recruit 1,156 stroke survivors in 34 NHS stroke services; however due to issues associated with the worldwide COVID pandemic, a decision was made in agreement with the funder (NIHR) to reduce the trial in size and scope to become an external pilot trial. Accordingly, the recruitment target was revised to 300-400 participants from 15 NHS stroke services, and the objectives were amended as given a definitive evaluation of effectiveness was no longer be possible (protocol for the external pilot cRCT is reported separately). In view of this a decision was also made to reduce the number of process evaluation services from 10 to six. The primary outcome is extended activities of daily living 12 months following recruitment (Nottingham Extended Activities of Daily Living (NEADL)). Secondary outcomes include SB at 12 months, cost-effectiveness, disability, quality of life, and reduction of cardiovascular risk factors

Process evaluation

Complex interventions consist of multiple interacting components, and generate changes within complex systems including the interactions between individuals and teams (e.g. providers and recipients) (16). As Get Set Go includes multiple components and targets the behaviour of health professionals, stroke

survivors, and their carers/family/friends (hereafter all referred to as carers in this paper) in inpatient and community settings, it is important to understand how the complexities of human behaviour and implementation across these different contexts impacts outcomes. Process evaluations are integral to understanding factors which may have contributed to the trial outcomes, and to help understand and evaluate the theoretical assumptions underpinning an intervention (17).

The MRC guidance (12, 17) recommends providing a clear description of the intervention and its causal assumptions and Moore et al. (17) state that the interpretation of intervention outcomes should be informed by an investigation of three key functions: (1) implementation, 2) mechanisms of impact and 3) context) (17). In our process evaluation, the MRC guidance ensured we developed a detailed programme theory represented in a logic model and supported with a written description of how the intervention is intended to work. We also aligned our objectives with the three key functions and selected appropriate methods, according to examples provided by Moore et al. (13).

This paper describes the protocol for the pre-planned mixed-methods process evaluation embedded in the RECREATE pilot cRCT.

Aims and objectives

The process evaluation aims to explore and understand the implementation of Get Set Go and how it is experienced and understood by providers and recipients by addressing the following objectives:

1) Describe and clarify causal assumptions about the intervention, and its mechanisms of impact
2) Describe intervention delivery and assess intervention fidelity
3) Explore views, perceptions and acceptability of the intervention to staff, stroke survivors and their carers
4) Establish the contextual factors that may influence implementation, intervention mechanisms, and outcomes

METHODS AND ANALYSIS

A mixed- methods process evaluation underpinned by the MRC guidance for process evaluations will be conducted by two researchers (JFJ and RS). This approach will combine non-participant observations of staff training sessions, non-participant observations in both inpatient and community settings; semi-structured interviews with stroke survivors, carers and staff, and documentary analysis of key intervention documents.

Study setting

The RECREATE project will be conducted in UK stroke services comprising inpatient and community settings. The process evaluation will be undertaken in six services (four intervention, two control) that will be included in a staggered nature due to the nature of the trial set-up. We will seek to include services that vary according to geographical location and stroke service pathways. For example, some services will include a hyper-acute, acute and rehabilitation service in one location, whereas others will be across different locations. In terms of community service provision, some will have shorter Early Supported Discharge (ESD) services whereas others will have services that are not time limited. Data collection will begin in August 2021 and is expected to be complete in May 2023 (Figure 1).

[Insert Figure 1: Process Evaluation Flowchart]

Theoretical approach

The MRC guidance for process evaluations (17) guided this process evaluation to facilitate a comprehensive understanding of factors that influence whether an intervention is effective or ineffective. The guidance also provides flexibility to select relevant theories. Figure 2 shows how objectives and data collection methods fit with the MRC guidance (17).

[Insert Figure 2: Process evaluation objectives and methods mapped to the MRC guidance (Moore et al., 2015)]

The Get Set Go intervention is designed to target the behaviours of staff, patients and carers, and will be implemented in complex settings; therefore the process evaluation focuses on individual-level behaviour change, and implementation processes. During intervention development, the TDF (Cane et al., 2012) was used whilst working through the BCW, to identify determinants of behaviour that need to be addressed with the intervention (e.g. skills, knowledge, and beliefs). Behaviour Change Techniques (BCTs) were then selected to address behaviours for the different individuals e.g. staff, patients and carers (15). The determinants are presented in the logic model as part of representing the intervention's intended mechanisms of impact; one of the key functions according to Moore et al. (17).

To address the other two key functions (implementation and context), an implementation plan was developed based on the findings from the feasibility study. This expands the information in the logic model to outline in detail the processes that staff would ideally engage in to implement the intervention. Normalisation Process Theory (NPT) was used to formulate the implementation plan, based on four constructs: coherence, cognitive participation, collective action, and reflexive monitoring (18).

The theoretical framework of acceptability (19) is another important framework in this process evaluation as part of addressing objective 3. It comprises seven constructs: affective attitude, burden, ethicality, intervention coherence, opportunity costs, perceived effectiveness and self-efficacy. This framework, along with the TDF and NPT, will all be used to inform the data collection and the interpretation and analysis of findings.

Study participants

Participants (staff, patients and in some cases carers) included in the study will be recruited from intervention and control services. They will be invited to take part in observations and interviews. See Table 1 for the eligibility criteria.

Table 1: Eligibility criteria

	Inclusion criteria	Exclusion criteria
Stroke patient	• Aged ≥16 years at time of stroke • Clinical diagnosis of new or recurrent ischaemic or haemorrhagic (excluding subarachnoid haemorrhage) stroke • Require manual contact of no more than one person to stand to prevent falling (continuous or intermittent light touch to assist balance or co-ordination, i.e., not to support body weight) • Plan to live in the community post-discharge • For individual focused observations (non-participant) of care and treatment or individual activity related to intervention provision: are able and willing to provide written informed consent or for whom a consultee declaration (England) is provided • For interviews: willing to provide consent to follow-up contact for interview, prior to the point of discharge from the stroke service and are able to provide informed consent	• Receiving palliative care • Due to be discharged outside the defined geographical area of the associated community service(s) participating in the trial

	• English-speaking	
Carer	• Aged ≥16 years • Family member or friend regularly engaging with a stroke survivor participant (>once per fortnight) • Able to provide informed consent • Stroke patient agrees for carer to be present in interview or observation • English-speaking	• Stroke patient does not consent to participate
Staff	• A registered physiotherapist, occupational therapist, nurse, doctor; or rehabilitation/ therapy assistant, Stroke Care Coordinator or other multidisciplinary team member working in a participating stroke service for a significant amount of time each week • Are able and willing to provide written/verbal informed consent for observations of care and treatment related to the Get Set Go intervention provided as part of the stroke service (either in hospital or in the community)	

We aim to recruit staff for interviews across inpatient and community settings; 10 in intervention services (including two in a managerial position), and 6 in control services (one in a managerial position). We aim to recruit five patients in each of the intervention and control services. Patients will be asked if they would like a carer to be present in the interview.

Participants will provide either verbal or written consent (depending on the circumstances) to take part in focused non-participant observations and semi-structured interviews. Participants are free to withdraw at any time without affecting their treatment. Participants will be made aware that if they withdraw, data collected up to that point will be included in analysis unless they request otherwise. Data will be removed on request provided it is still feasible to do so depending on the stage of write up.

Data collection methods

Qualitative data will contribute to understanding intervention mechanisms and their impacts, intervention fidelity, perceptions of the intervention and the extent to which it is acceptable and the contextual factors that may influence implementation, intervention mechanisms and outcomes. Quantitative data (documentary analysis and data relating to implementation) will provide additional insights into intervention fidelity. Table 2 provides an overview of all data to be collected.

Table 2: An overview of data collection methods for the process evaluation

	Data collection	Setting (COVID adaptation)	Timing	Quantities	Aims (Objectives)	Data collection informed by	Analysis method
Observations	Training at intervention services	Inpatient and community (Observe via video call)	As training is delivered	Inpatient and community combined: ~1 hour each session, 2-3 sessions per service	Intervention delivery and engagement (Objectives 2, 3, 4)	Observational framework listing intervention components and behaviours expected if delivered with fidelity.	Descriptive summaries, using MRC framework
	Baseline at intervention and control services	Inpatient and community (Staff telephone conversations)	Before intervention delivery	**Inpatient:** ~5 visits (20 hours) including ~3 therapy sessions, per service. **Community:** ~3 therapy sessions per service	Understand usual practice at the service, including how staff support standing and moving (Objectives 2, 4)	Researcher fieldnotes, informed by Spradley's descriptive question matrix (20)	Thematic analysis
	Time points 1, 2 & 3 at intervention services	Inpatient and community (Staff telephone conversations)	1-2 months, 4-5 months & 8-9 months after starting trial recruitment	**Inpatient:** ~8 visits (32 hours) including ~3 therapy sessions, per service. **Community:** ~3 therapy sessions per service	Fidelity of intervention delivery, and influencing factors (Objectives 1, 2, 3, 4)	Observational framework listing behaviours and intervention use expected if delivered with fidelity. Researcher fieldnotes, informed by Spradley's descriptive question matrix (20).	Thematic analysis
	Time points 1 & 2 at control services	Inpatient and community (Staff telephone conversations)	2-3 months & 6-7 months after starting trial recruitment	**Inpatient:** ~5 visits (20 hours) including ~3 therapy sessions, per service **Community:** ~3 therapy sessions per	Understand usual practice at the service, including how staff support standing and moving, and differences/similarities with intervention services	Researcher fieldnotes, informed by Spradley's descriptive question matrix (20).	Thematic analysis

				service	(Objective 4)		
	Documentary analysis intervention services (Time points 1, 2 and 3)	Inpatient and community (In patients home if unable to attend wards)	Alongside intervention service observations	Complete documentary analysis form observation time points 1, 2 & 3	Capture use and delivery (adherence & compliance) of intervention components (e.g. stroke patient use of intervention components) (Objective 2)	Documentary analysis form informed by fidelity expectations	Descriptive summaries
Semi structured interviews	Stroke patients (and carers) at intervention services	Patients' own home (Telephone or video call)	~4-6 months after service started the intervention	Inpatient and community combined: n= 5 per service	Explore stroke patient and carer experiences and views of standing and moving after stroke. Explore intervention use, acceptability, impact and barriers/facilitators. (Objectives 1, 2, 3, 4)	Topic guide informed by normalisation process theory (18) and the intervention acceptability framework (19).	Framework analysis
	Staff at intervention services	Inpatient and community setting (Telephone or video call)	Shortly after service stops using the intervention	Inpatient and community combined: n=10 per service (including 2 senior)	Explore views on supporting standing and moving after stroke. Explore staff views of the intervention and barriers/ facilitators for embedding and sustaining the intervention (Objectives 1, 2, 3, 4)	Topic guide informed by normalisation process theory (18) and the intervention acceptability framework (19).	Framework analysis
	Stroke patients (and carers) at control services	Community (Telephone or video call)	~6 months after trial recruitment starts	Inpatient and community combined: n=5 per service	Explore stroke patient and carer experiences and views of standing and moving after stroke (Objective 4).	Topic guide informed by , normalisation process theory (18) and the intervention acceptability framework (19).	Framework analysis
	Staff at control	Inpatient and community	~9-12 months after	Inpatient and community	Explore staff views on supporting standing and	Topic guide informed by normalisation process theory	Framework analysis

	services	(Telephone or video call)	starting trial recruitment	combined: n=6 per service (including 1 senior)	moving after stroke (Objective 4)	(18) and the intervention acceptability framework (19).	

Qualitative data

Non-participant observations in intervention and control services – general and focused

Training observations will only be conducted in intervention services (Table 2). These will focus on the fidelity of training delivery i.e. they will establish whether the training is being delivered by the implementation team as intended. They will also focus on engagement and interactions between the implementers and the staff receiving the training. We have developed an observational framework to assist the researchers in conducting these observations.

In both intervention and control services, baseline observations followed by a series of general and focused observations at different time points (three further time points in intervention services and two in control services) will be conducted (figure 1). General observations will be conducted in ward areas or community settings to gain an overall understanding of care provided and how staff members interact with each other and with patients in these general spaces. Researchers will introduce themselves to staff and patients to explain why they are undertaking the observations. No formal consent will be required for general observations but staff and patients will have the opportunity to object to being observed. For focused observations of 1:1 therapy sessions, researchers will obtain consent from both the staff members and stroke patients engaging in the therapy session. We intend to include stroke patients with aphasia and those who lack capacity in these focused observations where they are willing. Conversations with staff will help to identify whether patients may need the accessible information sheets and consent forms; and there is also an option for consultees to provide consent on behalf of the patient in circumstances where they lack capacity (consultee declaration).

In both intervention and control services, the baseline observations will be conducted to establish a baseline understanding of the organisations and how stroke care is provided. Observations at two further time points at control services will have a similar focus to the initial baseline observations with some additional exploration of staff and patients' views on standing and moving after stroke. In intervention services, the observations at the three time points after baseline will be undertaken to explore the fidelity of intervention delivery and the factors that influence this, including: contextual factors, competence of staff

delivering the intervention; and the engagement of staff, stroke survivors and carers with the intervention materials.

During general observations, researchers will look for evidence of the intervention being used/ adopted in inpatient and community environments. It will be an opportunity to identify changes to daily practice (from baseline) and whether there is evidence that the intervention is integrated into conversations and impacting on behavioural changes during day to day care. The focused observations will provide an opportunity to see if there are any specific changes to therapy and whether intervention language is used. In both cases researchers would expect to see staff using or talking through intervention materials. If there are circumstances where this is not the case it would be an opportunity for the researchers to understand what factors are impacting upon implementation in the context of daily practice.

In all cases, the researchers will write detailed notes during their observations and use Spradley's descriptive question matrix (20) as a guide for what to document. Researchers will interact with staff in instances where it feels appropriate to clarify what they have observed. However, they will not seek to get involved in conversations that interfere with the care being provided. Contextual features relevant to the stroke services, including relationships with social care, voluntary, or community agencies will also be considered.

Semi- structured interviews

Semi-structured interviews will be undertaken with a sample of staff, stroke survivors and their carers from the participating services (Table 2). Broadly, these interviews will be conducted in addition to the observations to provide further insights into different perceptions of the intervention, its acceptability and the factors that influence whether it can be implemented. Table 1 outlines the inclusion and exclusion criteria for all participants.

Stroke survivor (and carers where appropriate)

A proportion of participants will be invited to take part in a semi-structured interview if they have already consented to the trial and / or completed a 'consent to contact form' which indicates they are willing to be approached about participating in an interview. At the time of signing the initial consent for the trial it will be made clear that not all participants will be contacted regarding an interview and separate consent would be obtained if participants take part in interviews. Their details will be held securely at the CTRU and will be provided to the process evaluation researchers via a Secure File Transfer system.

The interviews will take place approximately four - six months after commencement of the Get Set Go intervention for each stroke patient, with some flexibility. Sampling for the participants across the services (intervention n = 20 across 4 services, control n = 10 across 2 services) will consider severity of stroke, gender, communication difficulties, occupational status and living arrangements (alone/with a carer). Following initial contact via phone, email or post, interested participants will be provided with an information sheet via post or email. Once they have had sufficient time to consider whether they would like to take part in an interview, potential participants will have the opportunity to ask any questions and if they are happy, an interview will be arranged. Stroke patients can express if they would like a carer to be present. Interviews will take place in the participants own home or via telephone/ video call if appropriate. Consent from stroke patients and where relevant, their carer will be sought prior to interview (process evaluation consent is separate from trial consent). Table 2 provides an overview of the focus of these interviews. During interviews, stroke patients will be asked to share intervention materials they received, to facilitate the documentary analysis.

We have also gained ethical approval to approach participants who have not consented to the trial and ask if they would like to take part in an interview. This increases our interviewee pool where needed and provides opportunity for participants to share their experiences of the intervention and the extent to which they think it is acceptable. To facilitate this, the individuals will be approached by a process evaluation researcher and provided with an information sheet and a 'consent to contact' form. Their carer (if available) will also be approached for consent to contact. They will subsequently be approached by the researcher to arrange consent and interview. All data will be held at Academic Unit of Ageing and Stroke Research (AUASR).

Staff

A sample of staff from across the services (intervention n = 40 across 4 services, control n = 12 across 2 services) will be approached face to face at their work-place providing there are no COVID-19 restrictions in place. If COVID-19 restrictions interfere with recruitment, the researcher will liaise with a key member of staff to identify which staff may be interested in taking part in an interview. The aim is to interview a range of staff from across inpatient and community settings in different disciplines and levels of seniority. Following the initial approach, similar procedures to those outlined above for stroke survivors will be undertaken to ensure that staff are provided with an information sheet and given time to consider participation and ask questions. Staff interviews will take place as the intervention ceases at each service (approximately 9 months into intervention delivery). Table 2 outlines the focus of the interviews and how they differ between the intervention and control services. Fully informed consent will be obtained prior to the interview which will take place in a location of staffs' choosing or via telephone/video call.

Data collection materials:

Documents have been created and will be used to facilitate the data collection process during the observations (Table 2). These include observational frameworks, topic guides and a documentary analysis form. The researchers will also use the existing descriptive question matrix (20) to guide the focus of observations.

Training observation framework

The training observation framework was created to capture fidelity, competence and engagement in relation to training sessions delivered by the implementation team to intervention services. The framework will be used to guide the observations and score them (scale 1-5): whether the content for each slide was delivered as intended (fidelity), how well content was delivered (competence), and how engaged the facilitators and participants were during the session. Researchers will also take notes on environmental factors that might be influential, the extent to which there is staff buy-in to the intervention and any additional reflections or aspects to follow up.

Fidelity framework (aligned with the logic model)

We have created fidelity frameworks (one for inpatient, one for community settings) to be completed during observations in the inpatient and community setting. These list all intervention components and expected behaviour if the intervention is implemented with fidelity. As with the training framework, it captures competence and engagement. The competencies are aligned with TDF Framework components, included in the logic model.

Implementation framework

In addition to the frameworks, we will collect detailed information about the implementation of the intervention at each of the intervention services included in the process evaluation using the implementation plan described in the earlier theoretical approach section. We will write notes in each section of the plan and indicate what has been implemented as planned, and any additional unexpected implementation strategies. We will also highlight which constructs of NPT are being addressed and note cases where they are not being addressed as planned. This process will enhance our understandings of the implementation processes needed to successfully implement the intervention.

Topic guides

Topic guides for each of the different interviews (see table 2) were developed based on feasibility study findings, and have also been informed by NPT (18),the theoretical framework of acceptability (19), and the TDF (14). In line with NPT, questions focus on how staff make sense of the intervention (coherence); how they work together to build a community of practice which facilitates implementation (cognitive participation); the operational practices involved in enacting the practices (collective action) and the appraisal work to understand ways that the new practices affect those around them (reflexive monitoring). Questions to address acceptability have been included to address the seven constructs within the framework by Sekhon et al. (19). Questions focused on the TDF domains in the logic model have also been included to understand more about for example skills, knowledge, beliefs around reducing SB from the perspectives of staff, patients and where relevant their families, friends, carers.

Interviews will be adapted to be inclusive of stroke patients, for instance by using accessible information sheets, adapting the topic guide / using appropriate images and writing down key words for people with aphasia. Interviews will be audio recorded and a summary of contextual factors written by the interviewer.

Quantitative data

Documentary analysis form

A documentary analysis form will be used during observations and interviews, conducted on patient-held intervention components and staff-completed records. This form will document how many documents have been checked, how many are complete up to date, and the week in which completion stopped (if incomplete). These capture the recording of delivery of intervention components and provide evidence of fidelity.

Data analysis

All data collected will be analysed to address the relevant objectives (Table 2). Training observations will be summarised with a focus on fidelity, acceptability and engagement and contextual factors that may have influenced how the training was delivered or received. Relevant headings based on the MRC framework (e.g. fidelity, contextual factors) will be used to organise the data.

Both observational and interview data will be subject to thematic analysis (21). Data will be analysed by a minimum of two researchers (JFJ and RS). Observational data will be coded into a thematic framework, and then related codes will be grouped together under thematic headings which convincingly capture and explain the relationship between coded elements of text. The interviews will be transcribed verbatim and anonymised. Data will be entered into NVivo 12 software (QSR International, 2018). Interview data will separately be analysed using a thematic approach (21). To produce the thematic frameworks, a proportion of the data will be coded independently (JFJ and RS) and key themes and subthemes will be identified to form the frameworks. The same theories used to inform the topic guides (NPT (18) and the theoretical framework of acceptability (19)) will be used to inform the thematic frameworks and themes that are

produced during the analysis of the observations and interviews. The logic model, including the domains outlined in the TDF will also be considered when developing the frameworks and throughout the analysis process.

The training summaries, fidelity frameworks that will be completed during observations, and the implementation plan that will be populated based on meetings with the implementation team, and observational and interview data will be used to support the interpretation of findings and will allow for comparisons to be made between services with regards to implementation fidelity, competency and engagement. Data from documentary analysis will be anonymised and summarised descriptively and will similarly be used to aid the interpretation of findings.

Standard approaches to demonstrating trustworthiness and quality in qualitative research will be used, including: the clear documentation of the research process (methods, analysis and any problems encountered and solutions found); transparency of the development of the observational framework and interview topic guides in-light of on-going analysis; documentation of the contextual features in which the research was carried out; discussions of emerging findings among the research team; and researchers will keep a reflexive diary (22).

The anticipated outputs of this evaluation include: recommendations for intervention refinements (both content and implementation); a revised implementation plan, and a refined logic model (and supporting written intervention description).

ETHICAL APPROVAL AND DISSEMINATION

The study has National Health Service (NHS) permission and was approved by Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (REC reference: 19/YH/0403). In light of the COVID pandemic, an ethical amendment approved remote data collection where needed e.g., observations of staff training and audio recorded interviews via zoom. Findings will be disseminated via peer review publications, and national and international conference presentations.

DISCUSSION

Process evaluations are considered an essential part of designing and testing complex interventions (17). They allow us to understand in detail the myriad of complex factors, and complex processes that contribute to whether an intervention has an impact on outcomes. We intend to add to knowledge about: intervention theory and how interventions contribute to change; how interventions interact with their context, wider system dynamics and impacts on implementation; and how individuals experience interventions (patients, staff, and carers. We also anticipate that the findings will be informative and transferable to other similar research focused on evaluating complex interventions in complex settings.

AUTHORS' CONTRIBUTIONS: AF is lead grant holder and Chief Investigator, and will oversee the design and implementation of the trial. JFJ leads the embedded process evaluation and is responsible for planning, undertaking the research and reporting findings alongside RS. SO and LM, assisted by JA, are responsible for managing the delivery of the trial. JA also leads on the ActivPAL and is responsible for the implementation of the intervention alongside SO and AF.RM contributed to the planning of this process evaluation. AFa, GM, CE, CF and DJC are co-investigators who were all involved in the design of the trial and process evaluation, and attend regular programme meetings where advice is provided where needed. All co-investigators and researchers contributed to the development of the protocol. JFJ drafted the manuscript which is written on behalf of the RECREATE Programme Management Group. All authors read and approved the final manuscript.

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SPONSOR: The trial sponsor is Bradford Teaching Hospitals NHS Foundation Trust, Research Management & Support Office, Bradford Institute for Health Research, Bradford, BD9 6RJ, United Kingdom. Tel: +44 (0)1274 38 2575; e-mail: jane.dennison@bthft.nhs.uk. The Sponsor will maintain oversight of trial processes, but is not involved in trial design or delivery processes. The Sponsor will not participate in data analysis or trial reporting processes.

Data sharing statement: The data generated from this process evaluation will be maintained by the Academic Unit of Ageing and Stroke Research. Any requests for data should be sent to corresponding author Dr Johansson and would be subject to review with the CI Professor Forster. All data-sharing activities would require a data-sharing agreement.

COMPETING INTERESTS STATEMENT:

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CE has received grant funding from the Netherlands Organisation for Scientific Research (NOW) Taskforce for Applied Research (SIA RAAK) for work in a similar area (i.e. sitting less and moving more after stroke) and is a Non-executive Director representing interests of Research and Chair of Research Advisory Committee for the Stroke Foundation of Australia (unpaid).

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JFJ, LM, RS, RM, JA, SO and DJC report no competing interests related to the manuscript.

PATIENT AND PUBLIC INVOLVEMENT: Patients and/or the public are integral to the conduct of the research outlined. Please refer to the methods section for further details.

Twitter: @RECREATE_stroke

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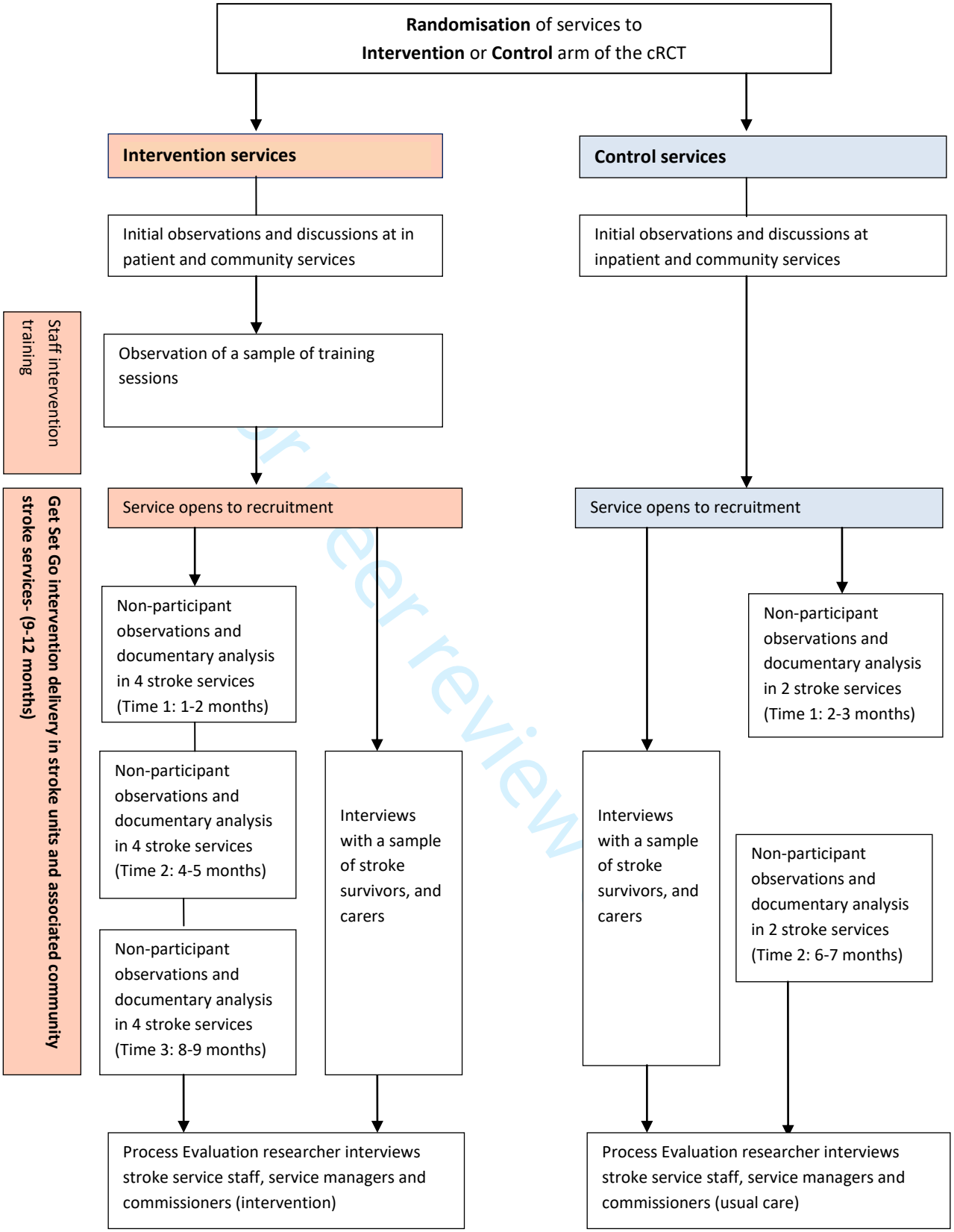
Figure 1: Process Evaluation Flowchart



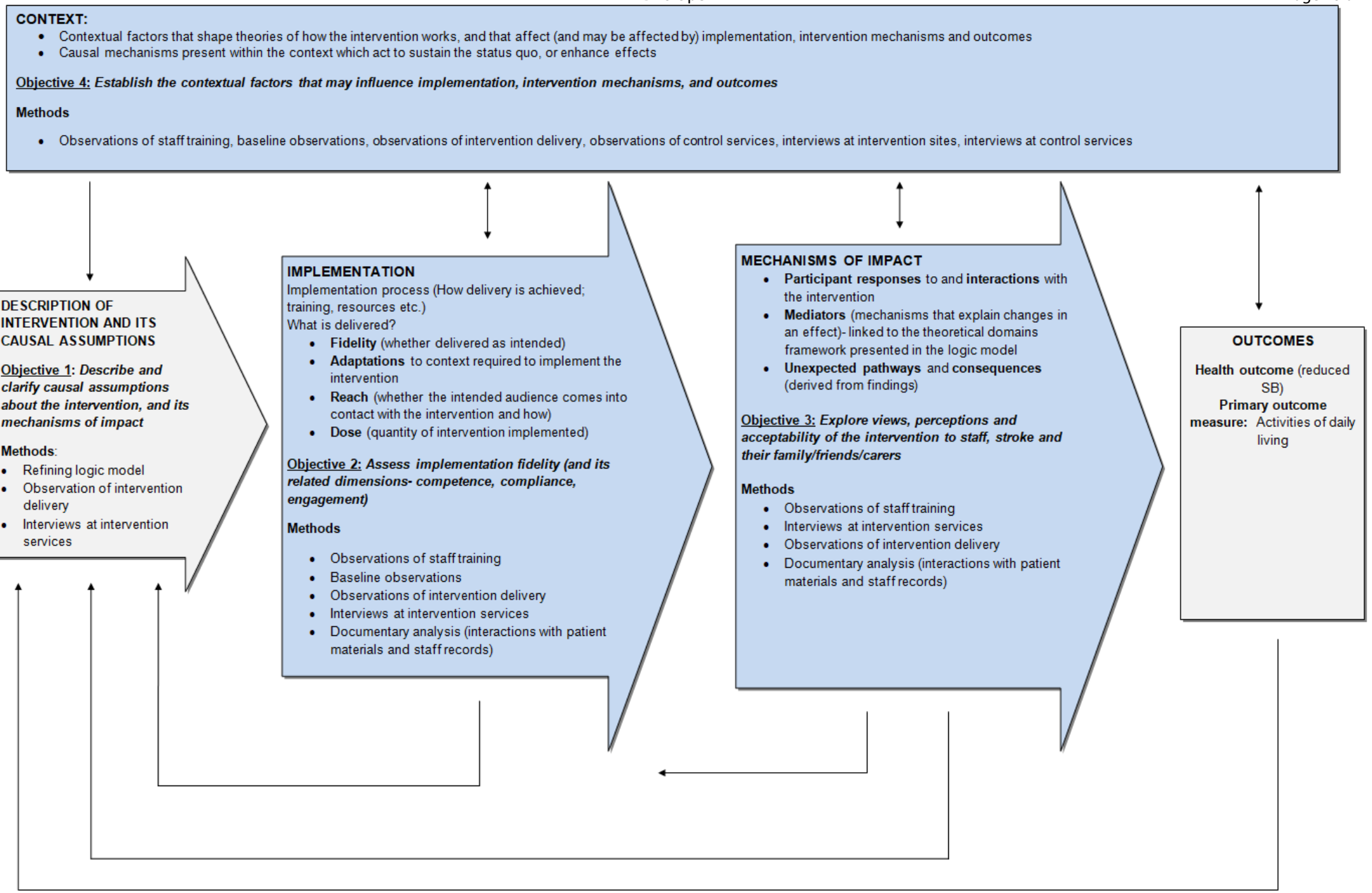


Figure 2: Process evaluation objectives and methods mapped to the MRC guidance by Moore et al., 2015

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An intervention to reduce sedentary behaviour and improve outcomes after stroke (Get Set Go): A study protocol for the process evaluation of a pilot cluster randomised controlled trial (RECREATE)

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An intervention to reduce sedentary behaviour and improve outcomes after stroke (Get Set Go): A study protocol for the process evaluation of a pilot cluster randomised controlled trial (RECREATE)

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ABSTRACT:

Introduction: Stroke survivors spend long periods of time engaging in sedentary behaviour even when their functional recovery is good. In the RECREATE programme, an intervention aimed at reducing sedentary behaviour ('Get Set Go') will be implemented and evaluated in a pragmatic external pilot cluster randomised controlled trial (cRCT) with embedded process and economic evaluations. We report the protocol for the process evaluation which will address the following objectives: 1) Describe and clarify causal assumptions about the intervention, and its mechanisms of impact; 2) Assess implementation fidelity; 3) Explore views,

perceptions and acceptability of the intervention to staff, stroke survivors and their carers; 4) Establish the contextual factors that influence implementation, intervention mechanisms, and outcomes.

Methods and analysis: This pilot trial will be conducted in 15 UK based National Health Service (NHS) stroke services. This process evaluation study, underpinned by the Medical Research Council (MRC) guidance will be undertaken in six of the randomised services (four intervention, two control). Data collection includes: observations of staff training sessions, non- participant observations in inpatient and community settings, semi-structured interviews with staff, patients and carers, and documentary analysis of key intervention components. Additional quantitative implementation data will be collected in all sites. Training observations and documentary analysis data will be summarised, with other observational and interview data analysed using Thematic Analysis. Relevant theories will be used to interpret the findings, including: the Theoretical Domains Framework, Normalisation Process Theory and the Theoretical Framework of Acceptability. Anticipated outputs include: recommendations for intervention refinements (both content and implementation); a revised implementation plan, and a refined logic model.

Ethics and dissemination: The study was approved by Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (REC reference:19/YH/0403). Findings will be disseminated via peer review publications, and national and international conference presentations.

Trial registration number: ISRCTN82280581

STRENGTHS AND LIMITATIONS OF THE STUDY:

- The process evaluation is underpinned by the Medical Research Council (MRC) guidance for process evaluations and addresses all key functions outlined in the guidance including implementation, mechanisms of impact and context.
- Theory based, comprehensive process evaluation involving staff, patients and family, friends and carers in intervention and control services.
- The process evaluation will be conducted longitudinally, providing information about changes over time.
- The in-depth process evaluation will be conducted in a proportion of trial services, however the implementation team will meet regularly with services not included in the process evaluation to

provide an insight into implementation activity. We will also report quantitative implementation data collected across all sites.

INTRODUCTION

Sedentary behaviour (SB) is defined as any waking behaviour characterised by low energy expenditure (≤1.5 Metabolic Equivalent of Task (METs)) while in a sitting, lying or reclining posture (1). In this study, we use the common approach of interpreting sedentary behaviour as sitting/lying down during waking hours without being otherwise active (2). SB is the focus of considerable clinical, policy and research interest, as the evidence supporting its detrimental effects on health and well-being increases (1, 3-6). Higher levels of moderate-vigorous physical activity (MVPA) may reduce risk associated with more daily sedentary time (5). However, achieving recommended levels of MVPA to offset potential harms of high levels of SB (i.e. >300 min/week of MVPA) is likely to be challenging (5), particularly for stroke survivors. Evidence suggests this population group are more sedentary and engage in longer unbroken bouts of sedentary behaviour than other population groups (7-9) and this appears to be independent of the level of functional recovery (10-12) At six months after stroke physical ability only has a small influence on time spent sitting among those living at home (10). Epidemiological studies indicate that stroke survivors are in the highest quartile for cardiovascular risk and increased sedentary behaviour adds to this rising risk. Thus, reducing SB has been suggested as a new target for therapeutic intervention after stroke (13).

In 2016, an international group of stroke recovery and rehabilitation experts reported that inadequate theoretical intervention development may explain the lack of efficacy of many existing interventions targeting people after stroke (14). The Medical Research Council (MRC) guidelines advocate the importance of using theory and evidence in developing complex interventions (15). It has also been suggested that taking a partnership approach (e.g. co-production) can facilitate the development of feasible and context-sensitive interventions and may increase the likelihood of developing an intervention that is efficacious, due to the active involvement of all relevant stakeholders (16).

RECREATE Programme

Our National Institute for Health and Care Research (NIHR) funded seven year research programme (RECREATE) seeks to develop and evaluate strategies for reducing SB after stroke to improve outcomes. The Get Set Go intervention was developed using a structured process, guided by the Behaviour Change Wheel (BCW) which incorporates the Theoretical Domains Framework (TDF) (17) in combination with a co-production approach (18) and tested as part of a feasibility study. Get Set Go aims to decrease SB after stroke by increasing the frequency and duration of standing and moving. The intervention is a whole service intervention, designed to be implemented and embedded in routine practice. Delivery commences in the inpatient stroke unit and continues once the stroke survivor is discharged home for at least 12 weeks.

The intervention includes multiple components and focuses on:

a) Educating staff and stroke survivors (and their family/ friends/ carers where appropriate) about the importance of standing and moving after stroke;

b) Preparing and enabling staff to support and encourage stroke survivors to stand and move more in everyday stroke care (as part of routine practice);

c) Encouraging stroke survivors to monitor their own standing and moving, with assistance from family/ friends/ carers where appropriate.

As GSG is delivered at a service level, all clinical staff in services randomised to deliver the intervention will be invited to attend a training session (~one hour). This will outline the intervention rationale and will provide an overview of key intervention components to prepare staff for delivering GSG. Staff will participate in practical tasks aimed at ensuring they feel confident to support and encourage stroke survivors who are capable of standing independently or with the assistance of one to stand and move more as part of routine stroke care. Staff will be asked to make recommendations for how much standing and moving individuals should be doing based on their usual assessment techniques and clinical judgement. They will be asked to regularly review these recommendations and modify these in line with stroke survivors' capabilities and circumstances.

Staff will be provided with a range of documents to record this activity. Stroke survivors will be encouraged to form habits around standing and moving as part of their day by recording and monitoring this in an

information based guide. Staff will be encouraged to include families in the intervention so they can undertake a supportive role in encouraging standing and moving in the inpatient setting and when the stroke survivor returns home. A Template for Intervention Description and Replication (TIDieR) checklist (19) will be published with trial findings.

The RECREATE multicentre cluster randomised controlled trial (cRCT) aimed to evaluate the clinical and cost effectiveness of the Get Set Go intervention. NHS stroke services randomised to the intervention group will be trained to deliver the intervention, whilst those randomised to the control group will continue usual practice. All patients in the stroke services randomised to the intervention will be exposed to Get Set Go. The trial originally aimed to recruit 1,156 stroke survivors in 34 NHS stroke services; however due to issues associated with the worldwide COVID pandemic, a decision was made in agreement with the funder (NIHR) to reduce the trial in size and scope to become an external pilot trial. Accordingly, the recruitment target was revised to 300-400 participants from 15 NHS stroke services, and the objectives were amended as given a definitive evaluation of effectiveness was no longer be possible (protocol for the external pilot cRCT is reported separately). In view of this a decision was also made to reduce the number of process evaluation services from 10 to six. The primary outcome is extended activities of daily living 12 months following recruitment (Nottingham Extended Activities of Daily Living (NEADL)). Secondary outcomes include SB at 12 months, cost-effectiveness, disability, quality of life, and reduction of cardiovascular risk factors

Process evaluation

Complex interventions consist of multiple interacting components, and generate changes within complex systems including the interactions between individuals and teams (e.g. providers and recipients) (20). As Get Set Go includes multiple components and targets the behaviour of health professionals, stroke survivors, and their carers/family/friends (hereafter all referred to as carers in this paper) in inpatient and community settings, it is important to understand how the complexities of human behaviour and implementation across these different contexts impacts outcomes. Process evaluations are integral to understanding factors which may have contributed to the trial outcomes, and to help understand and evaluate the theoretical assumptions underpinning an intervention (21).

The MRC guidance (15, 21) recommends providing a clear description of the intervention and its causal assumptions and Moore et al. (21) state that the interpretation of intervention outcomes should be informed by an investigation of three key functions: (1) implementation, 2) mechanisms of impact and 3) context) (21). In our process evaluation, the MRC guidance ensured we developed a detailed programme theory represented in a logic model and supported with a written description of how the intervention is intended to work. We also aligned our objectives with the three key functions and selected appropriate methods, according to examples provided by Moore et al. (13).

This paper describes the protocol for the pre-planned mixed-methods process evaluation embedded in the RECREATE pilot cRCT.

Aims and objectives

The process evaluation aims to explore and understand the implementation of Get Set Go and how it is experienced and understood by providers and recipients by addressing the following objectives:

1) Describe and clarify causal assumptions about the intervention, and its mechanisms of impact
2) Describe intervention delivery and assess intervention fidelity
3) Explore views, perceptions and acceptability of the intervention to staff, stroke survivors and their carers
4) Establish the contextual factors that may influence implementation, intervention mechanisms, and outcomes

METHODS AND ANALYSIS

A mixed- methods process evaluation underpinned by the MRC guidance for process evaluations will be conducted by two researchers (JFJ and RS). JFJ is a Senior Research Fellow leading the process evaluation and RS is a Research fellow working on the process evaluation. Both are experienced qualitative researchers, and each have 15 years of experience in conducting a range of qualitative methods analytical approaches. This approach will combine non-participant observations of staff training sessions, non-participant observations in both inpatient and community settings; semi-structured interviews with stroke survivors, carers and staff, and documentary analysis of key intervention documents.

PATIENT AND PUBLIC INVOLVEMENT: Patients and/or the public are integral to the conduct of the research outlined.

Study setting

The RECREATE project will be conducted in UK stroke services comprising inpatient and community settings. The process evaluation will be undertaken in six services (four intervention, two control) that will be included in a staggered nature due to the nature of the trial set-up. We will seek to include services that vary according to geographical location and stroke service pathways. For example, some services will include a hyper-acute, acute and rehabilitation service in one location, whereas others will be across different locations. In terms of community service provision, some will have shorter Early Supported Discharge (ESD) services whereas others will have services that are not time limited. Data collection will begin in August 2021 and is expected to be complete in May 2023 (Figure 1). Data collection activity will be shared by JFJ and RS. Each researcher will undertake activity at three of the six sites each. Where needed to manage the workload, there may be instances where JFJ or RS share activity within their allocated sites.

[Insert Figure 1: Process Evaluation Flowchart]

Theoretical approach

The MRC guidance for process evaluations (21) guided this process evaluation to facilitate a comprehensive understanding of factors that influence whether an intervention is effective or ineffective. The guidance also provides flexibility to select relevant theories. Figure 2 shows how objectives and data collection methods fit with the MRC guidance (21).

[Insert Figure 2: Process evaluation objectives and methods mapped to the MRC guidance (Moore et al., 2015)]

The Get Set Go intervention is designed to target the behaviours of staff, patients and carers, and will be implemented in complex settings; therefore the process evaluation focuses on individual-level behaviour change, and implementation processes. During intervention development, the TDF (Cane et al., 2012) was used whilst working through the BCW, to identify determinants of behaviour that need to be addressed with the intervention (e.g. skills, knowledge, and beliefs). Behaviour Change Techniques (BCTs) were then selected to address behaviours for the different individuals e.g. staff, patients and carers (18). The determinants are presented in the logic model as part of representing the intervention's intended mechanisms of impact; one of the key functions according to Moore et al. (21).

To address the other two key functions (implementation and context), an implementation plan was developed based on the findings from the feasibility study. This expands the information in the logic model to outline in detail the processes that staff would ideally engage in to implement the intervention. Normalisation Process Theory (NPT) was used to formulate the implementation plan, based on four constructs: coherence, cognitive participation, collective action, and reflexive monitoring (22).

The theoretical framework of acceptability (23) is another important framework in this process evaluation as part of addressing objective 3. It comprises seven constructs: affective attitude, burden, ethicality, intervention coherence, opportunity costs, perceived effectiveness and self-efficacy. This framework, along with the TDF and NPT, will all be used to inform the data collection and the interpretation and analysis of findings.

Study participants

Participants (staff, patients and in some cases carers) included in the study will be recruited from intervention and control services. They will be invited to take part in observations and interviews. See Table 1 for the eligibility criteria.

Table 1: Eligibility criteria

	Inclusion criteria	Exclusion criteria
Stroke patient	• Aged ≥16 years at time of stroke • Clinical diagnosis of new or recurrent ischaemic or haemorrhagic (excluding subarachnoid haemorrhage) stroke • Require manual contact of no more than one person to stand to prevent falling (continuous or intermittent light touch to assist balance or co-ordination, i.e., not to support body weight) • Plan to live in the community post-discharge • For individual focused observations (non-participant) of care and treatment or individual activity related to intervention provision: are able and willing to provide written informed consent or for whom a consultee declaration (England) is provided • For interviews: willing to provide consent to follow-up contact for interview, prior to the point of discharge from the stroke service and are able to provide informed consent • English-speaking	• Receiving palliative care • Due to be discharged outside the defined geographical area of the associated community service(s) participating in the trial

Carer	• Aged ≥16 years • Family member or friend regularly engaging with a stroke survivor participant (>once per fortnight) • Able to provide informed consent • Stroke patient agrees for carer to be present in interview or observation • English-speaking	• Stroke patient does not consent to participate
Staff	• A registered physiotherapist, occupational therapist, nurse, doctor; or rehabilitation/ therapy assistant, Stroke Care Coordinator or other multidisciplinary team member working in a participating stroke service for a significant amount of time each week (e.g. 20 hours per week) • Are able and willing to provide written/verbal informed consent for observations of care and treatment related to the Get Set Go intervention provided as part of the stroke service (either in hospital or in the community)	

We aim to recruit staff for interviews across inpatient and community settings; 10 in intervention services (including two in a managerial position), and 6 in control services (one in a managerial position). We aim to recruit five patients in each of the intervention and control services. Patients will be asked if they would like a carer to be present in the interview.

Participants will provide either verbal or written consent (depending on the circumstances) to take part in focused non-participant observations and semi-structured interviews. Participants are free to withdraw at any time without affecting their treatment. Participants will be made aware that if they withdraw, data collected up to that point will be included in analysis unless they request otherwise. Data will be removed on request provided it is still feasible to do so depending on the stage of write up.

Data collection methods

Qualitative data will contribute to understanding intervention mechanisms and their impacts, intervention fidelity, perceptions of the intervention and the extent to which it is acceptable and the contextual factors that may influence implementation, intervention mechanisms and outcomes. Quantitative data (documentary analysis and data relating to implementation) will provide additional insights into intervention fidelity. Table 2 provides an overview of all data to be collected.

Table 2: An overview of data collection methods for the process evaluation

	Data collection	Setting (COVID adaptation)	Timing	Quantities	Aims (Objectives)	Data collection informed by	Analysis method
Observations	Training at intervention services	Inpatient and community (Observe via video call)	As training is delivered	Inpatient and community combined: ~1 hour each session, 2-3 sessions per service	Intervention delivery and engagement (Objectives 2, 3, 4)	Observational framework listing intervention components and behaviours expected if delivered with fidelity.	Descriptive summaries, using MRC framework
	Baseline at intervention and control services	Inpatient and community (Staff telephone conversations)	Before intervention delivery	**Inpatient:** ~5 visits (20 hours) including ~3 therapy sessions, per service. **Community:** ~3 therapy sessions per service	Understand usual practice at the service, including how staff support standing and moving (Objectives 2, 4)	Researcher fieldnotes, informed by Spradley's descriptive question matrix (24)	Thematic analysis
	Time points 1, 2 & 3 at intervention services	Inpatient and community (Staff telephone conversations)	1-2 months, 4-5 months & 8-9 months after starting trial recruitment	**Inpatient:** ~8 visits (32 hours) including ~3 therapy sessions, per service. **Community:** ~3 therapy sessions per service	Fidelity of intervention delivery, and influencing factors (Objectives 1, 2, 3, 4)	Observational framework listing behaviours and intervention use expected if delivered with fidelity. Researcher fieldnotes, informed by Spradley's descriptive question matrix (24).	Thematic analysis
	Time points 1 & 2 at control services	Inpatient and community (Staff telephone conversations)	2-3 months & 6-7 months after starting trial recruitment	**Inpatient:** ~5 visits (20 hours) including ~3 therapy sessions, per service **Community:** ~3 therapy sessions per service	Understand usual practice at the service, including how staff support standing and moving, and differences/similarities with intervention services (Objective 4)	Researcher fieldnotes, informed by Spradley's descriptive question matrix (24).	Thematic analysis
	Documentary analysis	Inpatient and community (In	Alongside intervention	Complete documentary	Capture use and delivery (adherence & compliance) of	Documentary analysis form informed by fidelity	Descriptive summaries

	intervention services (Time points 1, 2 and 3)	patients home if unable to attend wards)	service observations	analysis form observation time points 1, 2 & 3	intervention components (e.g. stroke patient use of intervention components) (Objective 2)	expectations	
Semi structured interviews	Stroke patients (and carers) at intervention services	Patients' own home (Telephone or video call)	~4-6 months after service started the intervention	Inpatient and community combined: n= 5 per service	Explore stroke patient and carer experiences and views of standing and moving after stroke. Explore intervention use, acceptability, impact and barriers/facilitators. (Objectives 1, 2, 3, 4)	Topic guide informed by normalisation process theory (22) and the intervention acceptability framework (23).	Framework analysis
	Staff at intervention services	Inpatient and community setting (Telephone or video call)	Shortly after service stops using the intervention	Inpatient and community combined: n=10 per service (including 2 senior)	Explore views on supporting standing and moving after stroke. Explore staff views of the intervention and barriers/ facilitators for embedding and sustaining the intervention (Objectives 1, 2, 3, 4)	Topic guide informed by normalisation process theory (22) and the intervention acceptability framework (23).	Framework analysis
	Stroke patients (and carers) at control services	Community (Telephone or video call)	~6 months after trial recruitment starts	Inpatient and community combined: n=5 per service	Explore stroke patient and carer experiences and views of standing and moving after stroke (Objective 4).	Topic guide informed by , normalisation process theory (22) and the intervention acceptability framework (23).	Framework analysis
	Staff at control services	Inpatient and community (Telephone or video call)	~9-12 months after starting trial recruitment	Inpatient and community combined: n=6 per service (including 1 senior)	Explore staff views on supporting standing and moving after stroke (Objective 4)	Topic guide informed by normalisation process theory (22) and the intervention acceptability framework (23).	Framework analysis

Qualitative data

Non-participant observations in intervention and control services – general and focused

Training observations will only be conducted in intervention services (Table 2). These will focus on the fidelity of training delivery i.e. they will establish whether the training is being delivered by the implementation team as intended. They will also focus on engagement and interactions between the implementers and the staff receiving the training. We have developed an observational framework to assist the researchers in conducting these observations.

In both intervention and control services, baseline observations followed by a series of general and focused observations at different time points (three further time points in intervention services and two in control services) will be conducted (figure 1). General observations will be conducted in ward areas or community settings to gain an overall understanding of care provided and how staff members interact with each other and with patients in these general spaces. Researchers will introduce themselves to staff and patients to explain why they are undertaking the observations. No formal consent will be required for general observations but staff and patients will have the opportunity to object to being observed. For focused observations of 1:1 therapy sessions, researchers will obtain consent from both the staff members and stroke patients engaging in the therapy session. We intend to include stroke patients with aphasia and those who lack capacity in these focused observations where they are willing. Conversations with staff will help to identify whether patients may need the accessible information sheets and consent forms; and there is also an option for consultees to provide consent on behalf of the patient in circumstances where they lack capacity (consultee declaration).

In both intervention and control services, the baseline observations will be conducted to establish a baseline understanding of the organisations and how stroke care is provided. Observations at two further time points at control services will have a similar focus to the initial baseline observations with some additional exploration of staff and patients' views on standing and moving after stroke. In intervention services, the observations at the three time points after baseline will be undertaken to explore the fidelity of intervention delivery (e.g. whether intervention documents were evident in the inpatient and community settings, whether staff are

encouraging standing and moving as part of their practice or talking to stroke survivors about GSG) and the factors that influence this, including: contextual factors (e.g. where intervention materials are stored, how the stroke service is configured, how daily routines are managed), competence of staff delivering the intervention; and the engagement of staff, stroke survivors and carers with the intervention materials (e.g. completion of documents)

During general observations, researchers will look for evidence of the intervention being used/ adopted in inpatient and community environments. It will be an opportunity to identify changes to daily practice (from baseline) and whether there is evidence that the intervention is integrated into conversations and impacting on behavioural changes during day to day care. The focused observations will provide an opportunity to see if there are any specific changes to therapy and whether intervention language is used. For example instances of staff encouraging stroke survivors to stand and move in the time aside from therapy sessions. In both cases researchers would expect to see staff using or talking through intervention materials. If there are circumstances where this is not the case it would be an opportunity for the researchers to understand what factors are impacting upon implementation in the context of daily practice.

In all cases, the researchers will write detailed notes during their observations and use Spradley's descriptive question matrix (24) as a guide for what to document. Researchers will interact with staff in instances where it feels appropriate to clarify what they have observed. However, they will not seek to get involved in conversations that interfere with the care being provided. Contextual features relevant to the stroke services, including relationships with social care, voluntary, or community agencies will also be considered.

Semi- structured interviews

Semi-structured interviews will be undertaken with a sample of staff, stroke survivors and their carers from the participating services (Table 2). Broadly, these interviews will be conducted in addition to the observations to provide further insights into different perceptions of the intervention, its acceptability and the factors that

influence whether it can be implemented. Table 1 outlines the inclusion and exclusion criteria for all participants.

Stroke survivor (and carers where appropriate)

A proportion of participants will be invited to take part in a semi-structured interview if they have already consented to the trial and / or completed a 'consent to contact form' which indicates they are willing to be approached about participating in an interview. At the time of signing the initial consent for the trial it will be made clear that not all participants will be contacted regarding an interview and separate consent would be obtained if participants take part in interviews. Their details will be held securely at the CTRU and will be provided to the process evaluation researchers via a Secure File Transfer system.

The interviews will take place approximately four - six months after commencement of the Get Set Go intervention for each stroke patient, with some flexibility. Sampling for the participants across the services (intervention n = 20 across 4 services, control n = 10 across 2 services) will consider severity of stroke, gender, communication difficulties, occupational status and living arrangements (alone/with a carer). Following initial contact via phone, email or post, interested participants will be provided with an information sheet via post or email. At this point JFJ and RS will check if an accessible information sheet is required.

Once they have had sufficient time to consider whether they would like to take part in an interview, potential participants will have the opportunity to ask any questions and if they are happy, an interview will be arranged. Stroke patients can express if they would like a carer to be present. Interviews will take place in the participants own home or via telephone/ video call if appropriate. Consent from stroke patients and where relevant, their carer will be sought prior to interview (process evaluation consent is separate from trial consent). The research teams recruiting the participants for the trial will have already established capacity. JFJ and RS are experienced researchers in this population and will be able to make judgements about capacity if there are any changes in circumstances at the point of the interview. Being able to provide consent is an inclusion criteria for the interviews, however there is an option for someone to provide consent as a witness in cases where stroke survivors have capacity but are unable to physically consent due to physical impairments post stroke (e.g. difficulty writing). Table 2 provides an overview of the focus of

these interviews. During interviews, stroke patients will be asked to share intervention materials they received, to facilitate the documentary analysis.

We have also gained ethical approval to approach patients who have not consented to the trial and ask if they would like to take part in an interview. This increases our interviewee pool where needed and provides opportunity for participants to share their experiences of the intervention and the extent to which they think it is acceptable. To facilitate this, the individuals will be approached by a process evaluation researcher and provided with an information sheet and a 'consent to contact' form. Their carer (if available) will also be approached for consent to contact. They will subsequently be approached by the researcher to arrange consent and interview. All data will be held at Academic Unit of Ageing and Stroke Research (AUASR).

Staff

A sample of staff from across the services (intervention n = 40 across 4 services, control n = 12 across 2 services) will be approached face to face at their work-place providing there are no COVID-19 restrictions in place. If COVID-19 restrictions interfere with recruitment, the researcher will liaise with a key member of staff to identify which staff may be interested in taking part in an interview. The aim is to interview a range of staff from across inpatient and community settings in different disciplines and levels of seniority. Following the initial approach, similar procedures to those outlined above for stroke survivors will be undertaken to ensure that staff are provided with an information sheet and given time to consider participation and ask questions. Staff interviews will take place as the intervention ceases at each service (approximately 9 months into intervention delivery). Table 2 outlines the focus of the interviews and how they differ between the intervention and control services. Fully informed consent will be obtained prior to the interview which will take place in a location of staffs' choosing or via telephone/video call.

Data collection materials:

Documents have been created and will be used to facilitate the data collection process during the observations (Table 2). These include observational frameworks, topic guides and a documentary analysis

form. The researchers will also use the existing descriptive question matrix (24) to guide the focus of observations.

Training observation framework

The training observation framework was created to capture fidelity, competence and engagement in relation to training sessions delivered by the implementation team to intervention services. The framework will be used to guide the observations and score them (scale 1-5): whether the content for each slide was delivered as intended (fidelity), how well content was delivered (competence), and how engaged the facilitators and participants were during the session. Researchers will also take notes on environmental factors that might be influential, the extent to which there is staff buy-in to the intervention and any additional reflections or aspects to follow up.

Fidelity framework (aligned with the logic model)

We have created fidelity frameworks (one for inpatient, one for community settings) to be completed during observations in the inpatient and community setting. These list all intervention components and expected behaviour if the intervention is implemented with fidelity. As with the training framework, it captures competence and engagement. The competencies are aligned with TDF Framework components, included in the logic model.

Implementation framework

In addition to the frameworks, we will collect detailed information about the implementation of the intervention at each of the intervention services included in the process evaluation using the implementation plan described in the earlier theoretical approach section. We will write notes in each section of the plan and indicate what has been implemented as planned, and any additional unexpected implementation strategies. We will also highlight which constructs of NPT are being addressed and note cases where they are not being addressed as planned. This process will enhance our understandings of the implementation processes needed to successfully implement the intervention.

Topic guides

Topic guides for each of the different interviews (see table 2) were developed based on feasibility study findings, and have also been informed by NPT (22),the theoretical framework of acceptability (23), and the TDF (17). In line with NPT, questions focus on how staff make sense of the intervention (coherence); how they work together to build a community of practice which facilitates implementation (cognitive participation); the operational practices involved in enacting the practices (collective action) and the appraisal work to understand ways that the new practices affect those around them (reflexive monitoring). Questions to address acceptability have been included to address the seven constructs within the framework by Sekhon et al. (23). Questions focused on the TDF domains in the logic model have also been included to understand more about for example skills, knowledge, beliefs around reducing SB from the perspectives of staff, patients and where relevant their families, friends, carers. See supplementary file 1.

Interviews will be adapted to be inclusive of stroke patients, for instance by using accessible information sheets, adapting the topic guide / using appropriate images and writing down key words for people with aphasia. Interviews will be audio recorded and a summary of contextual factors written by the interviewer.

Quantitative data

Documentary analysis form

A documentary analysis form will be used during observations and interviews, conducted on patient-held intervention components (e.g. information guide used to record standing and moving) and staff-completed records. This form will document how many documents have been checked, how many are complete up to date, and the week in which completion stopped (if incomplete). These capture the recording of delivery of intervention components and provide evidence of fidelity.

Data analysis

All data collected will be analysed to address the relevant objectives (Table 2). Training observations will be summarised with a focus on fidelity, acceptability and engagement and contextual factors that may have

influenced how the training was delivered or received. Relevant headings based on the MRC framework (e.g. fidelity, contextual factors) will be used to organise the data.

Both observational and interview data will be subject to thematic analysis (25). Data will be analysed by a minimum of two researchers (JFJ and RS). Observational data will be coded into a thematic framework, and then related codes will be grouped together under thematic headings which convincingly capture and explain the relationship between coded elements of text. The interviews will be transcribed verbatim and anonymised. Data will be entered into NVivo 12 software (QSR International, 2018). Interview data will separately be analysed using a thematic approach (25). To produce the thematic frameworks, a proportion of the data will be coded independently (JFJ and RS) and key themes and subthemes will be identified to form the frameworks. The same theories used to inform the topic guides (NPT (22) and the theoretical framework of acceptability (23)) will be used to inform the thematic frameworks and themes that are produced during the analysis of the observations and interviews. The logic model, including the domains outlined in the TDF will also be considered when developing the frameworks and throughout the analysis process.

The training summaries, fidelity frameworks that will be completed during observations, and the implementation plan that will be populated based on meetings with the implementation team, and observational and interview data will be used to support the interpretation of findings and will allow for comparisons to be made between services with regards to implementation fidelity, competency and engagement. Data from documentary analysis will be anonymised and summarised descriptively and will similarly be used to aid the interpretation of findings.

Standard approaches to demonstrating trustworthiness and quality in qualitative research will be used, including: the clear documentation of the research process (methods, analysis and any problems encountered and solutions found); transparency of the development of the observational framework and interview topic guides in-light of on-going analysis; documentation of the contextual features in which the research was carried out; discussions of emerging findings among the research team; and researchers will keep a reflexive diary (26).

The anticipated outputs of this evaluation include: recommendations for intervention refinements (both content and implementation); a revised implementation plan, and a refined logic model (and supporting written intervention description).

ETHICAL APPROVAL AND DISSEMINATION

The study has National Health Service (NHS) permission and was approved by Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (REC reference: 19/YH/0403). In light of the COVID pandemic, an ethical amendment approved remote data collection where needed e.g., observations of staff training and audio recorded interviews via zoom. Findings will be disseminated via peer review publications, and national and international conference presentations.

DISCUSSION

Process evaluations are considered an essential part of designing and testing complex interventions (21). They allow us to understand in detail the myriad of complex factors, and complex processes that contribute to whether an intervention has an impact on outcomes. We intend to add to knowledge about: intervention theory and how interventions contribute to change; how interventions interact with their context, wider system dynamics and impacts on implementation; and how individuals experience interventions (patients, staff, and carers. We also anticipate that the findings will be informative and transferable to other similar research focused on evaluating complex interventions in complex settings.

AUTHORS' CONTRIBUTIONS: AF is lead grant holder and Chief Investigator, and will oversee the design and implementation of the trial. JFJ leads the embedded process evaluation and is responsible for planning, undertaking the research and reporting findings alongside RS. SO and LM, assisted by JA, are responsible for managing the delivery of the trial. JA also leads on the ActivPAL and is responsible for the implementation of the intervention alongside SO and AF.RM contributed to the planning of this process evaluation. AFa, GM, CE, CF and DJC are co-investigators who were all involved in the design of the trial and process evaluation, and attend regular programme meetings where advice is provided where needed.

All co-investigators and researchers contributed to the development of the protocol. JFJ drafted the manuscript which is written on behalf of the RECREATE Programme Management Group. All authors read and approved the final manuscript.

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SPONSOR: The trial sponsor is Bradford Teaching Hospitals NHS Foundation Trust, Research Management & Support Office, Bradford Institute for Health Research, Bradford, BD9 6RJ, United Kingdom. Tel: +44 (0)1274 38 2575; e-mail: jane.dennison@bthft.nhs.uk. The Sponsor will maintain oversight of trial processes, but is not involved in trial design or delivery processes. The Sponsor will not participate in data analysis or trial reporting processes.

Data sharing statement: The data generated from this process evaluation will be maintained by the Academic Unit of Ageing and Stroke Research. Any requests for data should be sent to corresponding author Dr Johansson and would be subject to review with the CI Professor Forster. All data-sharing activities would require a data-sharing agreement.

COMPETING INTERESTS STATEMENT:

AF, AFa, CE, CF, GM and DJC are coinvestigators on the grant funding this work therefore are partially supported by the National Institute for Health and Social Care Research (NIHR) (grant number RP-PG-0615-20019).

AF has received additional research grant support from NIHR through the following funding streams: Senior Investigator award, Health Technology Assessment (HTA) and Health and Social Care Delivery Research (HS&DR). AF has previously received support from the Stroke Association to attend the UK stroke forum and received payment from the National Institute for Health (USA) for panel membership (2021, 2022). AF is currently the chair / a member of programme steering committees for NIHR research programmes (Grant reference numbers: NIHR 202339, NIHR 202020) and has served on the following panels: NIHR Doctoral Fellowships, NIHR senior investigators committee (2019/20), NIHR HS&DR committee (2016-2018) and Stroke Association Funding.

CE has received grant funding from the Netherlands Organisation for Scientific Research (NOW) Taskforce for Applied Research (SIA RAAK) for work in a similar area (i.e. sitting less and moving more after stroke) and is a Non-executive Director representing interests of Research and Chair of Research Advisory Committee for the Stroke Foundation of Australia (unpaid).

CF is a coinvestigator / collaborator on other grants on the topic of sedentary behaviour / physical activity and is therefore partially supported by grant funding received from the University of Edinburgh and the Irish Health Board. CE has previously been supported to conduct work in a similar area by grant funding received from the Chief Scientist Office of the Scottish Government, Medical Research Council (MRC) Public Health Intervention Development (PHIND) award and the University of Edinburgh.

JFJ, LM, RS, RM, JA, SO and DJC report no competing interests related to the manuscript.

Twitter: @RECREATE_stroke

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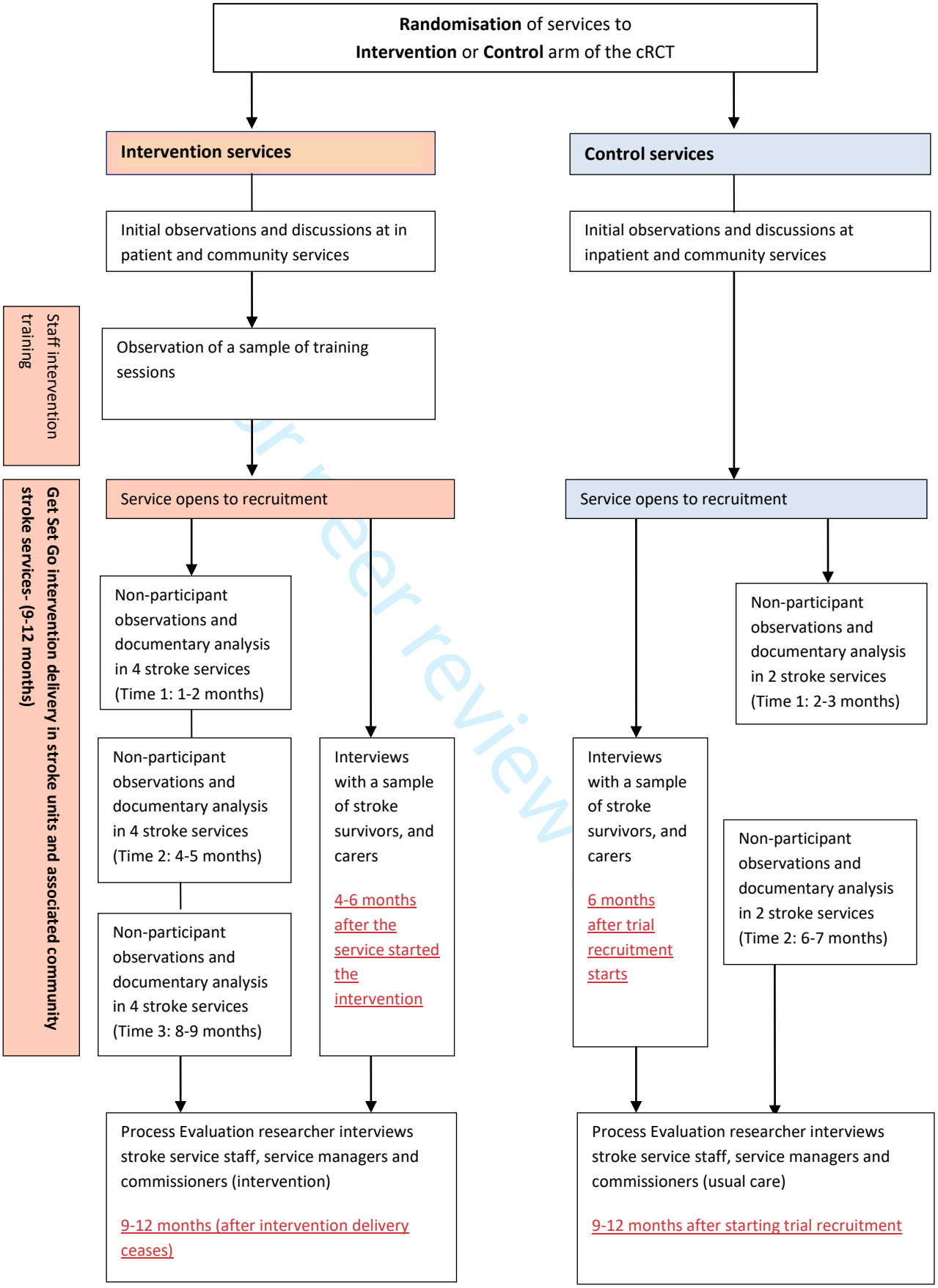
Figure 1: Process Evaluation Flowchart



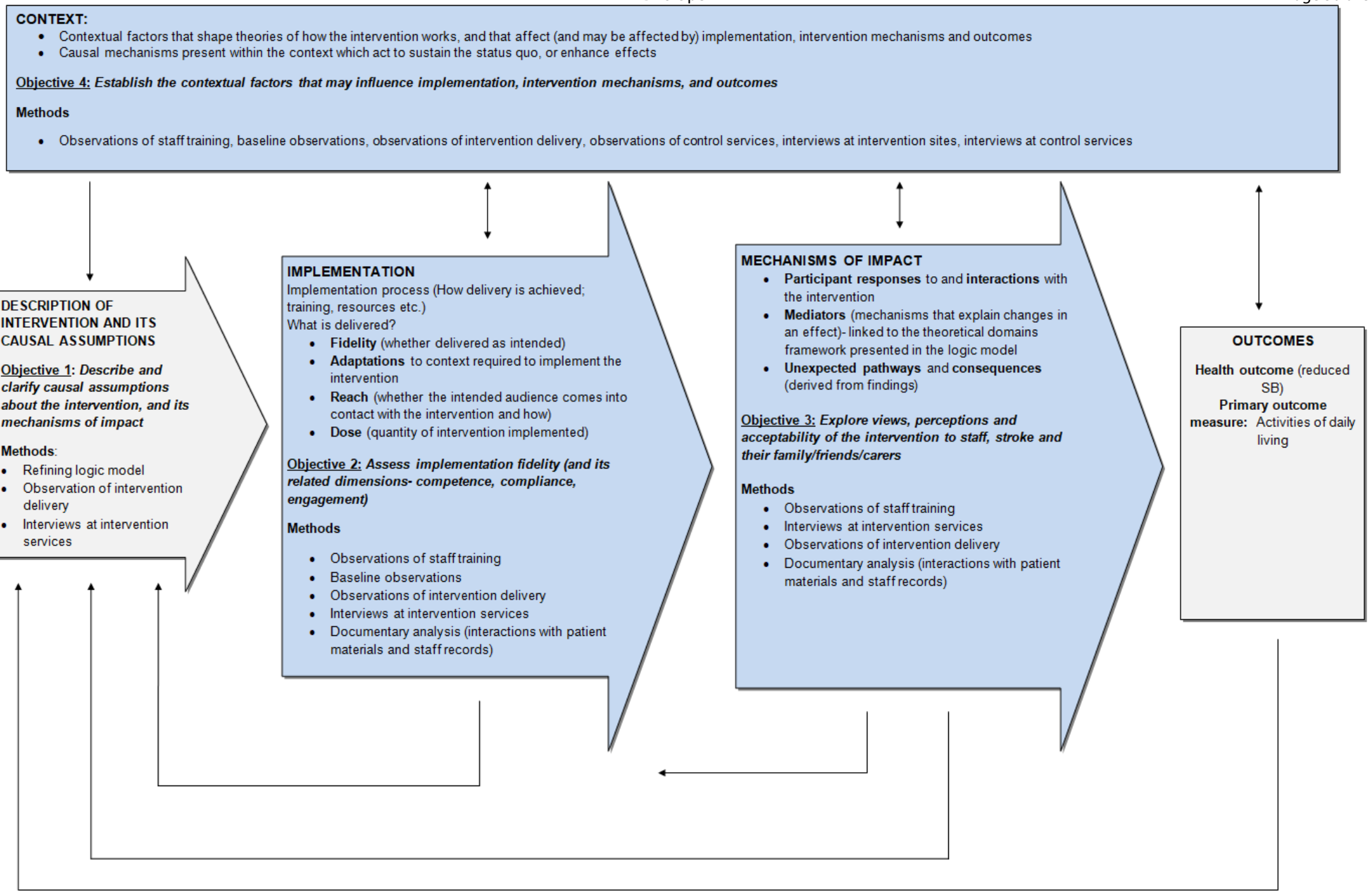


Figure 2: Process evaluation objectives and methods mapped to the MRC guidance by Moore et al., 2015

Supplementary file 1: Topic guides (staff and patients) for intervention and control sites

1. Topic guide for staff - intervention

The purpose of this interview is to hear about your experiences with Get Set Go.

	NPT/TDF/ Sekhon
1. What is your usual role?	
○ Tell me briefly about your role in the stroke service? ○ How long have you been working in stroke care? ○ Does Get Set Go fit with your usual role?	n/a: contextual information
2. Tell me about how you got involved in Get Set Go?	
○ How did your involvement in Get Set Go begin? Attend training or discuss with colleagues? ○ How was the training? What do you remember about it? ○ Was the format OK (in person/ online)? ○ Was it applicable to you and your role? Did it change anything for you? ○ What do you understand about the purpose of Get Set Go? ○ How does Get Set Go differ from the usual care you provide? ○ Was it clear from the training what you needed to do yourself and as a team? ○ Did you have any questions/concerns in the beginning? Did you feel ready/confident to deliver the intervention? ○ Did anything help you make sense of Get Set Go before delivering it?	**Sekhon:** Affective attitude, ethicality, intervention coherence, self-efficacy **NPT:** Differentiation, individual specification
3. How was Get Set Go used on your ward?	
○ Did your team deliver all the intervention components? (go through each). ○ Do you feel your team have a good understand of Get Set Go and their roles? ○ What did you do as a team to ensure a shared understanding of what you want to achieve? ○ Overall, which parts worked well / not so well? ○ To what extent do you feel your team value Get Set Go? ○ Who is responsible for leading/driving Get Set Go forward? Who else was involved?	**Sekhon:** Intervention coherence **NPT:** Communal specification , initiation, enrolment, legitimation
4. Tell me about your experience of using Get Set Go?	
○ What was your role or involvement with Get Set Go? ○ Tell me about your experiences of using each of the intervention components. ○ What parts were the easiest or hardest to use? ○ Did you feel able to help patients understand the purpose and what they needed to do? ○ Were you aware of/ did you use the website? <u>Champions:</u> Can you describe your experiences of being a lead for Get Set Go?	**Sekhon:** Affective attitude, self-efficacy

(Was your role clear? Did you have enough support? What was difficult or negative? What went well or was enjoyable? Did you feel suggestions were acted upon?) Trainers: Can you describe your experiences of delivering the training? How was it received? What were the challenges? Did you feel prepared?	
5. Has Get Set Go helped patients? (has it increased standing and moving)	
○ What are your views on encouraging patients to stand and move more (e.g. benefits, values placed on this) ○ Have patients/ family benefited from Get Set Go? Did it change anything for them? (e.g. prompting standing & moving, health, skills, confidence, mood, motivation, empowerment) ○ What do patients/families think of the recommendations about how much they should stand and move? ○ How do patients respond to the information guide? Where do you think they use it most? (hospital or home) ○ Do they understand the purpose? Are they willing to engage? ○ Is there anything they particularly like or dislike?	**Sekhon:** Perceived effectiveness **NPT:** Internalization
6. Has Get Set Go changed anything for staff/service?	
○ Overall, what have been the positives of using Get Set Go? (what went well) ○ Overall, what have been the negatives of using Get Set Go? (what went not so well) ○ Has it changed the way staff work? Has increased standing and moving become habit? ○ Has it changed the way staff think about sedentary behaviour/standing and moving? (e.g. knowledge, skills confidence, role, routines, risk) ○ Have there been any environmental changes? (e.g. posters, decluttering, influences on standing and moving) ○ Did anyone introduce new ideas? How were these received? Did you share ideas/learning?	**Sekhon:** Affective attitude, perceived effectiveness
7. What were the challenges or things that helped?	
○ What made it difficult/easier to use Get Set Go or to amend practice? ○ Was the delivery sustained over time? (what factors influenced this) (e.g. priorities, workload, cost, space, training, resource, patient ability/willingness, risk, skills/confidence, perceived patient benefit, clear understanding) ○ How was Get Set Go received by the team/service? ○ Was there sufficient time / staff availability? ○ Was there sufficient senior / wider team support? ○ Was there sufficient communication between services? ○ Were there any unplanned events which affected Get Set Go? (e.g. infection, staffing, crises) ○ Would greater involvement of different staff groups have helped? ○ Did everyone know who was responsible for doing what? How did you allocate roles? ○ Did Get Set Go fit into usual routines / roles, or was it too separate? ○ How did you prepare practically for delivering Get Set Go? (managing resources etc)	**Sekhon:** Burden, opportunity costs **NPT:** Activation, interactional workability, relational integration, skill set workability, contextual integration
8. What could we have done better?	
○ Do you have any other feedback or suggested changes? ○ Most and least valued parts?	**Sekhon:**

○ What could we have done to help you use GSG? What would you do differently next time? ○ Does Get Set Go meet its purpose to help stroke survivors recover?	Affective attitude, perceived effectiveness
9. The impacts of the COVID pandemic	
○ Has the COVID pandemic influenced your engagement with the Get Set Go intervention? ○ Has the COVID pandemic had an influence on how much you have been able to support/encourage standing and moving?	
10. Is there anything else you would like to ask or mention?	

2. Topic guide for staff control

This topic guide is to gain insights into staff's perceptions and views related to the provision of usual care to stroke survivors- related to standing and moving/mobilising after stroke.

	NPT/TDF/ Sekhon
1. What is your role?	
- Tell me briefly about your role in the stroke service? - How long have you been working in stroke care?	n/a contextual information
2. Perceptions/ thoughts about standing and moving?	
- What do you think about encouraging patients to stand and move more? (including benefits, how much this is valued) - What sort of time in their care pathway do you think it is most important? (Throughout/inpatient/community). - What do you think it is beneficial for patients to know about standing and moving?	**Sekhon:** Affective attitude, ethicality, perceived effectiveness
3. Experiences of supporting standing and moving more? (Individual and as a team)	
- To what extent does your role involve supporting patients to stand and move? - Tell me about your experiences of supporting standing and moving? (as an individual/team- how this is managed at a ward/community service level) - Is this something that is routinely encouraged? - Which staff are most commonly responsible for encouraging/supporting standing and moving? - Are you/ your team aware of any specific initiatives/ tools to support practices related to standing and moving? - To what extent do you feel adequately equipped to support patients to stand and move?	**Sekhon:** Self-efficacy
4. Challenges or things that help supporting standing and moving?	
- What is your view on your team's willingness/ability/capability to support standing and moving? - What is your view on the patient/carer's willingness/ability to practice standing and moving? - What responses have you had from patients and their carers? - Are there any factors that influence whether you would encourage patients to stand and move more? (e.g. priorities, staffing, workload, cost, space, training, resource specific processes, leadership patient ability/willingness, risk, skills/confidence, perceived patient benefit, clear understanding, environment)? - Any other particular things that work particularly well or not so well that might affect standing and moving	**Sekhon:** Burden, opportunity costs

5. Could anything be better?	
○ Could you or your team do anything more to support/encourage patients to stand or move more? ○ How could current practice be further developed?	
6. The impacts of the COVID pandemic	
- Has the COVID pandemic had an influence on how much you have been able to support/encourage standing and moving?	
7. Is there anything else that you would like to ask or mention?	

3. Topic guide for stroke survivors and carers – intervention

**All questions are for stroke survivor and/or carer, except where "(C)" marks them as for carer only.*

	NPT/TDF/ Sekhon
1. You & your stroke	
- Could you tell me a bit about you? (Hobbies, interests pre and post stroke?) - What were the impacts of your stroke? (symptoms, usual activities, changes over time) - How long has it been since you had your stroke? - How long did you spend in hospital? - Could you describe your experiences of your hospital stroke care? (positives/negatives) - Could you describe your experiences of the stroke care you received since coming home? (positives/negatives, waiting, still receiving, how long) - Have you experienced any other difficulties alongside your stroke that required additional care?	n/a contextual information
2. What are you experiences and thoughts about standing and moving more?	
- How much standing and moving do you do at the moment? Tell me about your daily routines? (types of activities where might be standing and moving, times of day when more likely) - **(C)** Do you play a role in supporting standing and moving? (if yes, explore how) **-** What do you think about trying to/encouraging stand and move more after stroke? (benefits, fears, in hospital, at home, is this valued) - Do you feel confident/capable to stand and move/encourage standing and moving? - At what time after stroke do you think it's most important? (throughout/inpatient/community) - Have you received any support or tools for standing and moving? (e.g. groups, therapy)	**Sekhon:** Affective attitude, ethicality, perceived effectiveness, self-efficacy **NPT:** n/a
3. What are your experiences of Get Set Go? (show examples of the intervention components)	
- Did **staff talk to you** about/ prompting standing and moving more (in hospital or at home)? • Who was it? Were family/friends involved? • How did you feel about it? • Did it make sense? Did you have any questions? Did they give examples of what to do/ when? - In hospital, did you receive an information guide or see anything about GSG on the ward? - What do you think about this? Was it appropriate for you? - Did staff regularly update the recommendations about standing and moving? - Did you record your standing and moving? (reasons why not if not) Will you keep recording? - What did you think of the GSG materials? Were they useful? *[this section includes a breakdown of all intervention components not listed for publication purposes]* - How could the above materials be improved? (format, content, ease of use, social acceptability) - Have you received any follow up contact since returning home?	**Sekhon:** Intervention coherence, Affective attitude, Perceived effectiveness, Self- efficacy, Ethicality **NPT:** Interactional workability
4. Has Get Set Go helped you? (has it increased standing and moving)	

- What did you think about GSG overall? - Which parts worked well / not so well? Is there anything you particularly like or dislike? - Did it make you want to stand and move more? Did you? • Did you benefit in any other way? • Has it helped or hindered your recovery from stroke? Or influenced your life more broadly? • Did it make you do anything differently or change anything? (e.g. Did it affect your: motivation, goals, mood, remembering to stand and move, confidence, activities, health, conversations) • Was your time spent using the guide beneficial? • Have you incorporated new activity into your daily life? Do you feel you will maintain it? - Have your family and friends used the guide and benefitted, or changed anything as a result? - Has engaging with the Get Set Go intervention been worthwhile? - Do you think Get Set Go can help other people? - Does it help recovery after stroke?	**Sekhon:** Burden, Self-efficacy, Opportunity costs, Affective attitudes, Perceived effectiveness **NPT:** n/a
5. What were the challenges or things that helped?	
- Did anything make it difficult to use Get Set Go / to stand and move? (fears, impact of stroke, motivation, unexpected events, confidence, opportunities, environment, forgetting, mood, other responsibilities/ lack of time, not knowing what to do, seeing the benefit, equipment) • Is there anything you struggle with/ have concerns/ uncertainties about in terms of Get Set Go/standing and moving? • Did you feel confident you could ask for help? • Did staff talk to you about GSG (or did it feel like something to do on your own)? - Did anything make it easier to use Get Set Go / to stand and move? (staff, family, confidence, opportunities, environment, motivation, mood, timing after stroke, knowing what to do, seeing the benefit, equipment) • Did you make any changes to your surroundings to make it easier for you to move around (in hospital or at home)? Was it easy or difficult to make these changes? • Is there anything else that could be better to help you use Get Set Go/stand and move more? - Has anything else influenced your behaviour/affected your standing and moving alongside the programme?	**Sekhon:** Burden, Opportunity costs, Affective attitude, Self-efficacy **NPT:** Interactional workability
6. Could anything be better?	
- Is there anything else you would like to say about your experience / other feedback? - What might you do differently next time?	**Sekhon:** Affective attitude **NPT:** n/a
7. The impacts of the COVID pandemic	
- What impact has the COVID pandemic and the associated restrictions had on your day-to-day life? (health, physical, social, emotional) - Could you describe any changes in your activities as a result of the COVID pandemic? (e.g. physical, social, day-to-day- explore if doing any activities less or more) - Has the COVID pandemic influenced your standing and moving? - Has the COVID pandemic influenced your engagement with the Get Set Go intervention? - (C) Has the COVID pandemic had an influence on how much you have been able to support/encourage standing and moving?	
8. Is there anything else you would like to ask or mention?	

4. Topic guide for stroke survivors and carers – control

**All questions are for stroke survivor and/or carer, except where "(C)" marks them as for carer only.*

	NPT/TDF/ Sekhon
1. About you (stroke survivor)	
- Could you tell me a bit about you? (Hobbies, interests pre and post stroke?	n/a contextual information
2. Your stroke (stroke survivor)	
- How long has it been since you had your stroke? - What were the impacts of your stroke? (symptoms and how they may have changed over time) - How long did you spend in hospital? - Could you describe your experiences of the stroke care you received? (inpatient/community care/any additional support/positives/negatives) - Have you experienced any other difficulties alongside your stroke that have required additional care?	n/a contextual information
3. Perceptions/ thoughts about standing and moving? (stroke survivor and carer)	
- **(SS)** What do you thinking about trying to stand and move more after stroke? (benefits, fears) - **(SS and C)** To what extent do you feel confident/capable to stand and move/encourage standing and moving? **- (C)** What do you think about encouraging people who have had a stroke to stand and move more? (including benefits, how much this is valued) -**(SS and C)** What sort of time in their care pathway do you think it is most important? (Throughout/inpatient/community). - **(SS and C)** Do you feel as though you could benefit from learning more about standing and moving after stroke? (what could be helpful?)	**Sekhon:** Affective attitude, ethicality, perceived effectiveness, self-efficacy
3. Standing and moving more- your experiences	
- (SS) Could you tell me a little about your day-to-day routines? - **(SS)** How much standing and moving would you tend to do each day? (discuss types of activities where might be standing and moving, or times of day when more likely) - **(C)** Do you play a role in supporting standing and moving? (is yes, explore how they provide support) - **(SS and C)** What do you remember about being encouraged to stand and move in hospital/by community teams? **(SS and C)** Have you received any support about standing and moving (e.g. from therapists, groups). - **(SS and C)** Are you aware of any specific initiatives/ tools to support standing and moving?	
4. Challenges or things that help supporting standing and moving?	
- **(SS)** Tell me about any challenges you may face in standing and moving? (physical, cognitive, fears of falls, confidence, opportunities, environmental factors, motivation) - **(C)** Tell me about any challenges you may face in supporting standing and moving? (same prompts as above) - **(SS and C)** Any other particular things that work particularly well or not so well that might affect standing and moving?	**Sekhon:** Burden, opportunity costs
5. Could anything be better?	
- **(SS and C)** Is there anything that could facilitate standing and moving more? **(SS)** Could you benefit from more support to encourage you to stand and move more?	

6. The impacts of the COVID pandemic	
- What impact has COVID and the associated restrictions had on your day-to-day life? (health, physical, social, emotional) - Could you describe any changes in your activities as a result of the COVID pandemic? (e.g. physical, social, day-to-day- explore if doing any activities less or more) - Has the COVID pandemic influenced your standing and moving? - (C) Has the COVID pandemic had an influence on how much you have been able to support/encourage standing and moving?	
7. Is there anything else that you would like to ask or mention?	

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An intervention to reduce sedentary behaviour and improve outcomes after stroke (Get Set Go): A study protocol for the process evaluation of a pilot cluster randomised controlled trial (RECREATE)

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An intervention to reduce sedentary behaviour and improve outcomes after stroke (Get Set Go): A study protocol for the process evaluation of a pilot cluster randomised controlled trial (RECREATE)

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ABSTRACT:

Introduction: Stroke survivors spend long periods of time engaging in sedentary behaviour even when their functional recovery is good. In the RECREATE programme, an intervention aimed at reducing sedentary behaviour ('Get Set Go') will be implemented and evaluated in a pragmatic external pilot cluster randomised controlled trial (cRCT) with embedded process and economic evaluations. We report the protocol for the process evaluation which will address the following objectives: 1) Describe and clarify causal assumptions about the intervention, and its mechanisms of impact; 2) Assess implementation fidelity; 3) Explore views,

perceptions and acceptability of the intervention to staff, stroke survivors and their carers; 4) Establish the contextual factors that influence implementation, intervention mechanisms, and outcomes.

Methods and analysis: This pilot trial will be conducted in 15 UK based National Health Service (NHS) stroke services. This process evaluation study, underpinned by the Medical Research Council (MRC) guidance will be undertaken in six of the randomised services (four intervention, two control). Data collection includes: observations of staff training sessions, non- participant observations in inpatient and community settings, semi-structured interviews with staff, patients and carers, and documentary analysis of key intervention components. Additional quantitative implementation data will be collected in all sites. Training observations and documentary analysis data will be summarised, with other observational and interview data analysed using Thematic Analysis. Relevant theories will be used to interpret the findings, including: the Theoretical Domains Framework, Normalisation Process Theory and the Theoretical Framework of Acceptability. Anticipated outputs include: recommendations for intervention refinements (both content and implementation); a revised implementation plan, and a refined logic model.

Ethics and dissemination: The study was approved by Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (REC reference:19/YH/0403). Findings will be disseminated via peer review publications, and national and international conference presentations.

Trial registration number: ISRCTN82280581

STRENGTHS AND LIMITATIONS OF THE STUDY:

- The process evaluation is underpinned by the Medical Research Council (MRC) guidance for process evaluations and addresses all key functions outlined in the guidance including implementation, mechanisms of impact and context.
- Theory based, comprehensive process evaluation involving staff, patients and family, friends and carers in intervention and control services.
- The process evaluation will be conducted longitudinally, providing information about changes over time.
- The in-depth process evaluation will be conducted in a proportion of trial services, however the implementation team will meet regularly with services not included in the process evaluation to

provide an insight into implementation activity. We will also report quantitative implementation data collected across all sites.

INTRODUCTION

Sedentary behaviour (SB) is defined as any waking behaviour characterised by low energy expenditure (≤1.5 Metabolic Equivalent of Task (METs)) while in a sitting, lying or reclining posture (1). In this study, we use the common approach of interpreting sedentary behaviour as sitting/lying down during waking hours without being otherwise active (2). SB is the focus of considerable clinical, policy and research interest, as the evidence supporting its detrimental effects on health and well-being increases (1, 3-6). Higher levels of moderate-vigorous physical activity (MVPA) may reduce risk associated with more daily sedentary time (5). However, achieving recommended levels of MVPA to offset potential harms of high levels of SB (i.e. >300 min/week of MVPA) is likely to be challenging (5), particularly for stroke survivors. Evidence suggests this population group are more sedentary and engage in longer unbroken bouts of sedentary behaviour than other population groups (7-9) and this appears to be independent of the level of functional recovery (10-12) At six months after stroke physical ability only has a small influence on time spent sitting among those living at home (10). Epidemiological studies indicate that stroke survivors are in the highest quartile for cardiovascular risk and increased sedentary behaviour adds to this rising risk (13). Thus, reducing SB has been suggested as a new target for therapeutic intervention after stroke (14).

In 2016, an international group of stroke recovery and rehabilitation experts reported that inadequate theoretical intervention development may explain the lack of efficacy of many existing interventions targeting people after stroke (15). The Medical Research Council (MRC) guidelines advocate the importance of using theory and evidence in developing complex interventions (16). It has also been suggested that taking a partnership approach (e.g. co-production) can facilitate the development of feasible and context-sensitive interventions and may increase the likelihood of developing an intervention that is efficacious, due to the active involvement of all relevant stakeholders (17).

RECREATE Programme

Our National Institute for Health and Care Research (NIHR) funded seven year research programme (RECREATE) seeks to develop and evaluate strategies for reducing SB after stroke to improve outcomes. The Get Set Go intervention was developed using a structured process, guided by the Behaviour Change Wheel (BCW) which incorporates the Theoretical Domains Framework (TDF) (18) in combination with a co-production approach (19) and tested as part of a feasibility study. Get Set Go aims to decrease SB after stroke by increasing the frequency and duration of standing and moving. The intervention is a whole service intervention, designed to be implemented and embedded in routine practice. Delivery commences in the inpatient stroke unit and continues once the stroke survivor is discharged home for at least 12 weeks.

The intervention includes multiple components and focuses on:

a) Educating staff and stroke survivors (and their family/ friends/ carers where appropriate) about the importance of standing and moving after stroke;

b) Preparing and enabling staff to support and encourage stroke survivors to stand and move more in everyday stroke care (as part of routine practice);

c) Encouraging stroke survivors to monitor their own standing and moving, with assistance from family/ friends/ carers where appropriate.

As GSG is delivered at a service level, all clinical staff in services randomised to deliver the intervention will be invited to attend a training session (~one hour). This will outline the intervention rationale and will provide an overview of key intervention components to prepare staff for delivering GSG. Staff will participate in practical tasks aimed at ensuring they feel confident to support and encourage stroke survivors who are capable of standing independently or with the assistance of one to stand and move more as part of routine stroke care. Staff will be asked to make recommendations for how much standing and moving individuals should be doing based on their usual assessment techniques and clinical judgement. They will be asked to regularly review these recommendations and modify these in line with stroke survivors' capabilities and circumstances.

Staff will be provided with a range of documents to record this activity. Stroke survivors will be encouraged to form habits around standing and moving as part of their day by recording and monitoring this in an

information based guide. Staff will be encouraged to include families in the intervention so they can undertake a supportive role in encouraging standing and moving in the inpatient setting and when the stroke survivor returns home. A Template for Intervention Description and Replication (TIDieR) checklist (20) will be published with trial findings.

The RECREATE multicentre cluster randomised controlled trial (cRCT) aimed to evaluate the clinical and cost effectiveness of the Get Set Go intervention. NHS stroke services randomised to the intervention group will be trained to deliver the intervention, whilst those randomised to the control group will continue usual practice. All patients in the stroke services randomised to the intervention will be exposed to Get Set Go. The trial originally aimed to recruit 1,156 stroke survivors in 34 NHS stroke services; however due to issues associated with the worldwide COVID pandemic, a decision was made in agreement with the funder (NIHR) to reduce the trial in size and scope to become an external pilot trial. Accordingly, the recruitment target was revised to 300-400 participants from 15 NHS stroke services, and the objectives were amended as given a definitive evaluation of effectiveness was no longer be possible (protocol for the external pilot cRCT is reported separately). In view of this a decision was also made to reduce the number of process evaluation services from 10 to six. The primary outcome is extended activities of daily living 12 months following recruitment (Nottingham Extended Activities of Daily Living (NEADL)). Secondary outcomes include SB at 12 months, cost-effectiveness, disability, quality of life, and reduction of cardiovascular risk factors

Process evaluation

Complex interventions consist of multiple interacting components, and generate changes within complex systems including the interactions between individuals and teams (e.g. providers and recipients) (21). As Get Set Go includes multiple components and targets the behaviour of health professionals, stroke survivors, and their carers/family/friends (hereafter all referred to as carers in this paper) in inpatient and community settings, it is important to understand how the complexities of human behaviour and implementation across these different contexts impacts outcomes. Process evaluations are integral to understanding factors which may have contributed to the trial outcomes, and to help understand and evaluate the theoretical assumptions underpinning an intervention (22).

The MRC guidance (16, 22) recommends providing a clear description of the intervention and its causal assumptions and Moore et al. (22) state that the interpretation of intervention outcomes should be informed by an investigation of three key functions: (1) implementation, 2) mechanisms of impact and 3) context) (22). In our process evaluation, the MRC guidance ensured we developed a detailed programme theory represented in a logic model and supported with a written description of how the intervention is intended to work. We also aligned our objectives with the three key functions and selected appropriate methods, according to examples provided by Moore et al. (13).

This paper describes the protocol for the pre-planned mixed-methods process evaluation embedded in the RECREATE pilot cRCT.

Aims and objectives

The process evaluation aims to explore and understand the implementation of Get Set Go and how it is experienced and understood by providers and recipients by addressing the following objectives:

1) Describe and clarify causal assumptions about the intervention, and its mechanisms of impact
2) Describe intervention delivery and assess intervention fidelity
3) Explore views, perceptions and acceptability of the intervention to staff, stroke survivors and their carers
4) Establish the contextual factors that may influence implementation, intervention mechanisms, and outcomes

METHODS AND ANALYSIS

A mixed- methods process evaluation underpinned by the MRC guidance for process evaluations will be conducted by two researchers (JFJ and RS). JFJ is a Senior Research Fellow leading the process evaluation and RS is a Research fellow working on the process evaluation. Both are experienced qualitative researchers, and each have 15 years of experience in conducting a range of qualitative methods analytical approaches. This approach will combine non-participant observations of staff training sessions, non-participant observations in both inpatient and community settings; semi-structured interviews with stroke survivors, carers and staff, and documentary analysis of key intervention documents.

PATIENT AND PUBLIC INVOLVEMENT: Patients and/or the public are integral to the conduct of the research outlined.

Study setting

The RECREATE project will be conducted in UK stroke services comprising inpatient and community settings. The process evaluation will be undertaken in six services (four intervention, two control) that will be included in a staggered nature due to the nature of the trial set-up. We will seek to include services that vary according to geographical location and stroke service pathways. For example, some services will include a hyper-acute, acute and rehabilitation service in one location, whereas others will be across different locations. In terms of community service provision, some will have shorter Early Supported Discharge (ESD) services whereas others will have services that are not time limited. Data collection will begin in August 2021 and is expected to be complete in May 2023 (Figure 1). Data collection activity will be shared by JFJ and RS. Each researcher will undertake activity at three of the six sites each. Where needed to manage the workload, there may be instances where JFJ or RS share activity within their allocated sites.

[Insert Figure 1: Process Evaluation Flowchart]

Theoretical approach

The MRC guidance for process evaluations (22) guided this process evaluation to facilitate a comprehensive understanding of factors that influence whether an intervention is effective or ineffective. The guidance also provides flexibility to select relevant theories. Figure 2 shows how objectives and data collection methods fit with the MRC guidance (22).

[Insert Figure 2: Process evaluation objectives and methods mapped to the MRC guidance (Moore et al., 2015)]

The Get Set Go intervention is designed to target the behaviours of staff, patients and carers, and will be implemented in complex settings; therefore the process evaluation focuses on individual-level behaviour change, and implementation processes. During intervention development, the TDF (Cane et al., 2012) was used whilst working through the BCW, to identify determinants of behaviour that need to be addressed with the intervention (e.g. skills, knowledge, and beliefs). Behaviour Change Techniques (BCTs) were then selected to address behaviours for the different individuals e.g. staff, patients and carers (19). The determinants are presented in the logic model as part of representing the intervention's intended mechanisms of impact; one of the key functions according to Moore et al. (22).

To address the other two key functions (implementation and context), an implementation plan was developed based on the findings from the feasibility study. This expands the information in the logic model to outline in detail the processes that staff would ideally engage in to implement the intervention. Normalisation Process Theory (NPT) was used to formulate the implementation plan, based on four constructs: coherence, cognitive participation, collective action, and reflexive monitoring (23).

The theoretical framework of acceptability (24) is another important framework in this process evaluation as part of addressing objective 3. It comprises seven constructs: affective attitude, burden, ethicality, intervention coherence, opportunity costs, perceived effectiveness and self-efficacy. This framework, along with the TDF and NPT, will all be used to inform the data collection and the interpretation and analysis of findings.

Study participants

Participants (staff, patients and in some cases carers) included in the study will be recruited from intervention and control services. They will be invited to take part in observations and interviews. See Table 1 for the eligibility criteria.

Table 1: Eligibility criteria

	Inclusion criteria	Exclusion criteria
Stroke patient	• Aged ≥16 years at time of stroke • Clinical diagnosis of new or recurrent ischaemic or haemorrhagic (excluding subarachnoid haemorrhage) stroke • Require manual contact of no more than one person to stand to prevent falling (continuous or intermittent light touch to assist balance or co-ordination, i.e., not to support body weight) • Plan to live in the community post-discharge • For individual focused observations (non-participant) of care and treatment or individual activity related to intervention provision: are able and willing to provide written informed consent or for whom a consultee declaration (England) is provided • For interviews: willing to provide consent to follow-up contact for interview, prior to the point of discharge from the stroke service and are able to provide informed consent • English-speaking	• Receiving palliative care • Due to be discharged outside the defined geographical area of the associated community service(s) participating in the trial

Carer	• Aged ≥16 years • Family member or friend regularly engaging with a stroke survivor participant (>once per fortnight) • Able to provide informed consent • Stroke patient agrees for carer to be present in interview or observation • English-speaking	• Stroke patient does not consent to participate
Staff	• A registered physiotherapist, occupational therapist, nurse, doctor; or rehabilitation/ therapy assistant, Stroke Care Coordinator or other multidisciplinary team member working in a participating stroke service for a significant amount of time each week (e.g. 20 hours per week) • Are able and willing to provide written/verbal informed consent for observations of care and treatment related to the Get Set Go intervention provided as part of the stroke service (either in hospital or in the community)	

We aim to recruit staff for interviews across inpatient and community settings; 10 in intervention services (including two in a managerial position), and 6 in control services (one in a managerial position). We aim to recruit five patients in each of the intervention and control services. Patients will be asked if they would like a carer to be present in the interview.

Participants will provide either verbal or written consent (depending on the circumstances) to take part in focused non-participant observations and semi-structured interviews. Participants are free to withdraw at any time without affecting their treatment. Participants will be made aware that if they withdraw, data collected up to that point will be included in analysis unless they request otherwise. Data will be removed on request provided it is still feasible to do so depending on the stage of write up.

Data collection methods

Qualitative data will contribute to understanding intervention mechanisms and their impacts, intervention fidelity, perceptions of the intervention and the extent to which it is acceptable and the contextual factors that may influence implementation, intervention mechanisms and outcomes. Quantitative data (documentary analysis and data relating to implementation) will provide additional insights into intervention fidelity. Table 2 provides an overview of all data to be collected.

Table 2: An overview of data collection methods for the process evaluation

	Data collection	Setting (COVID adaptation)	Timing	Quantities	Aims (Objectives)	Data collection informed by	Analysis method
Observations	Training at intervention services	Inpatient and community (Observe via video call)	As training is delivered	Inpatient and community combined: ~1 hour each session, 2-3 sessions per service	Intervention delivery and engagement (Objectives 2, 3, 4)	Observational framework listing intervention components and behaviours expected if delivered with fidelity.	Descriptive summaries, using MRC framework
	Baseline at intervention and control services	Inpatient and community (Staff telephone conversations)	Before intervention delivery	**Inpatient:** ~5 visits (20 hours) including ~3 therapy sessions, per service. **Community:** ~3 therapy sessions per service	Understand usual practice at the service, including how staff support standing and moving (Objectives 2, 4)	Researcher fieldnotes, informed by Spradley's descriptive question matrix (25)	Thematic analysis
	Time points 1, 2 & 3 at intervention services	Inpatient and community (Staff telephone conversations)	1-2 months, 4-5 months & 8-9 months after starting trial recruitment	**Inpatient:** ~8 visits (32 hours) including ~3 therapy sessions, per service. **Community:** ~3 therapy sessions per service	Fidelity of intervention delivery, and influencing factors (Objectives 1, 2, 3, 4)	Observational framework listing behaviours and intervention use expected if delivered with fidelity. Researcher fieldnotes, informed by Spradley's descriptive question matrix (25).	Thematic analysis
	Time points 1 & 2 at control services	Inpatient and community (Staff telephone conversations)	2-3 months & 6-7 months after starting trial recruitment	**Inpatient:** ~5 visits (20 hours) including ~3 therapy sessions, per service **Community:** ~3 therapy sessions per service	Understand usual practice at the service, including how staff support standing and moving, and differences/similarities with intervention services (Objective 4)	Researcher fieldnotes, informed by Spradley's descriptive question matrix (25).	Thematic analysis
	Documentary analysis	Inpatient and community (In	Alongside intervention	Complete documentary	Capture use and delivery (adherence & compliance) of	Documentary analysis form informed by fidelity	Descriptive summaries

	intervention services (Time points 1, 2 and 3)	patients home if unable to attend wards)	service observations	analysis form observation time points 1, 2 & 3	intervention components (e.g. stroke patient use of intervention components) (Objective 2)	expectations	
Semi structured interviews	Stroke patients (and carers) at intervention services	Patients' own home (Telephone or video call)	~4-6 months after service started the intervention	Inpatient and community combined: n= 5 per service	Explore stroke patient and carer experiences and views of standing and moving after stroke. Explore intervention use, acceptability, impact and barriers/facilitators. (Objectives 1, 2, 3, 4)	Topic guide informed by normalisation process theory (23) and the intervention acceptability framework (24).	Framework analysis
	Staff at intervention services	Inpatient and community setting (Telephone or video call)	Shortly after service stops using the intervention	Inpatient and community combined: n=10 per service (including 2 senior)	Explore views on supporting standing and moving after stroke. Explore staff views of the intervention and barriers/ facilitators for embedding and sustaining the intervention (Objectives 1, 2, 3, 4)	Topic guide informed by normalisation process theory (23) and the intervention acceptability framework (24).	Framework analysis
	Stroke patients (and carers) at control services	Community (Telephone or video call)	~6 months after trial recruitment starts	Inpatient and community combined: n=5 per service	Explore stroke patient and carer experiences and views of standing and moving after stroke (Objective 4).	Topic guide informed by , normalisation process theory (23) and the intervention acceptability framework (24).	Framework analysis
	Staff at control services	Inpatient and community (Telephone or video call)	~9-12 months after starting trial recruitment	Inpatient and community combined: n=6 per service (including 1 senior)	Explore staff views on supporting standing and moving after stroke (Objective 4)	Topic guide informed by normalisation process theory (23) and the intervention acceptability framework (24).	Framework analysis

Qualitative data

Non-participant observations in intervention and control services – general and focused

Training observations will only be conducted in intervention services (Table 2). These will focus on the fidelity of training delivery i.e. they will establish whether the training is being delivered by the implementation team as intended. They will also focus on engagement and interactions between the implementers and the staff receiving the training. We have developed an observational framework to assist the researchers in conducting these observations.

In both intervention and control services, baseline observations followed by a series of general and focused observations at different time points (three further time points in intervention services and two in control services) will be conducted (figure 1). General observations will be conducted in ward areas or community settings to gain an overall understanding of care provided and how staff members interact with each other and with patients in these general spaces. Researchers will introduce themselves to staff and patients to explain why they are undertaking the observations. No formal consent will be required for general observations but staff and patients will have the opportunity to object to being observed. For focused observations of 1:1 therapy sessions, researchers will obtain consent from both the staff members and stroke patients engaging in the therapy session. We intend to include stroke patients with aphasia and those who lack capacity in these focused observations where they are willing. Conversations with staff will help to identify whether patients may need the accessible information sheets and consent forms; and there is also an option for consultees to provide consent on behalf of the patient in circumstances where they lack capacity (consultee declaration).

In both intervention and control services, the baseline observations will be conducted to establish a baseline understanding of the organisations and how stroke care is provided. Observations at two further time points at control services will have a similar focus to the initial baseline observations with some additional exploration of staff and patients' views on standing and moving after stroke. In intervention services, the observations at the three time points after baseline will be undertaken to explore the fidelity of intervention delivery (e.g. whether intervention documents were evident in the inpatient and community settings, whether staff are

encouraging standing and moving as part of their practice or talking to stroke survivors about GSG) and the factors that influence this, including: contextual factors (e.g. where intervention materials are stored, how the stroke service is configured, how daily routines are managed), competence of staff delivering the intervention; and the engagement of staff, stroke survivors and carers with the intervention materials (e.g. completion of documents)

During general observations, researchers will look for evidence of the intervention being used/ adopted in inpatient and community environments. It will be an opportunity to identify changes to daily practice (from baseline) and whether there is evidence that the intervention is integrated into conversations and impacting on behavioural changes during day to day care. The focused observations will provide an opportunity to see if there are any specific changes to therapy and whether intervention language is used. For example instances of staff encouraging stroke survivors to stand and move in the time aside from therapy sessions. In both cases researchers would expect to see staff using or talking through intervention materials. If there are circumstances where this is not the case it would be an opportunity for the researchers to understand what factors are impacting upon implementation in the context of daily practice.

In all cases, the researchers will write detailed notes during their observations and use Spradley's descriptive question matrix (25) as a guide for what to document. Researchers will interact with staff in instances where it feels appropriate to clarify what they have observed. However, they will not seek to get involved in conversations that interfere with the care being provided. Contextual features relevant to the stroke services, including relationships with social care, voluntary, or community agencies will also be considered.

Semi- structured interviews

Semi-structured interviews will be undertaken with a sample of staff, stroke survivors and their carers from the participating services (Table 2). Broadly, these interviews will be conducted in addition to the observations to provide further insights into different perceptions of the intervention, its acceptability and the factors that

influence whether it can be implemented. Table 1 outlines the inclusion and exclusion criteria for all participants.

Stroke survivor (and carers where appropriate)

A proportion of participants will be invited to take part in a semi-structured interview if they have already consented to the trial and / or completed a 'consent to contact form' which indicates they are willing to be approached about participating in an interview. At the time of signing the initial consent for the trial it will be made clear that not all participants will be contacted regarding an interview and separate consent would be obtained if participants take part in interviews. Their details will be held securely at the CTRU and will be provided to the process evaluation researchers via a Secure File Transfer system.

The interviews will take place approximately four - six months after commencement of the Get Set Go intervention for each stroke patient, with some flexibility. Sampling for the participants across the services (intervention n = 20 across 4 services, control n = 10 across 2 services) will consider severity of stroke, gender, communication difficulties, occupational status and living arrangements (alone/with a carer). Following initial contact via phone, email or post, interested participants will be provided with an information sheet via post or email. At this point JFJ and RS will check if an accessible information sheet is required.

Once they have had sufficient time to consider whether they would like to take part in an interview, potential participants will have the opportunity to ask any questions and if they are happy, an interview will be arranged. Stroke patients can express if they would like a carer to be present. Interviews will take place in the participants own home or via telephone/ video call if appropriate. Consent from stroke patients and where relevant, their carer will be sought prior to interview (process evaluation consent is separate from trial consent). The research teams recruiting the participants for the trial will have already established capacity. JFJ and RS are experienced researchers in this population and will be able to make judgements about capacity if there are any changes in circumstances at the point of the interview. Being able to provide consent is an inclusion criteria for the interviews, however there is an option for someone to provide consent as a witness in cases where stroke survivors have capacity but are unable to physically consent due to physical impairments post stroke (e.g. difficulty writing). Table 2 provides an overview of the focus of

these interviews. During interviews, stroke patients will be asked to share intervention materials they received, to facilitate the documentary analysis.

We have also gained ethical approval to approach patients who have not consented to the trial and ask if they would like to take part in an interview. This increases our interviewee pool where needed and provides opportunity for participants to share their experiences of the intervention and the extent to which they think it is acceptable. To facilitate this, the individuals will be approached by a process evaluation researcher and provided with an information sheet and a 'consent to contact' form. Their carer (if available) will also be approached for consent to contact. They will subsequently be approached by the researcher to arrange consent and interview. All data will be held at Academic Unit of Ageing and Stroke Research (AUASR).

Staff

A sample of staff from across the services (intervention n = 40 across 4 services, control n = 12 across 2 services) will be approached face to face at their work-place providing there are no COVID-19 restrictions in place. If COVID-19 restrictions interfere with recruitment, the researcher will liaise with a key member of staff to identify which staff may be interested in taking part in an interview. The aim is to interview a range of staff from across inpatient and community settings in different disciplines and levels of seniority. Following the initial approach, similar procedures to those outlined above for stroke survivors will be undertaken to ensure that staff are provided with an information sheet and given time to consider participation and ask questions. Staff interviews will take place as the intervention ceases at each service (approximately 9 months into intervention delivery). Table 2 outlines the focus of the interviews and how they differ between the intervention and control services. Fully informed consent will be obtained prior to the interview which will take place in a location of staffs' choosing or via telephone/video call.

Data collection materials:

Documents have been created and will be used to facilitate the data collection process during the observations (Table 2). These include observational frameworks, topic guides and a documentary analysis

form. The researchers will also use the existing descriptive question matrix (25) to guide the focus of observations.

Training observation framework

The training observation framework was created to capture fidelity, competence and engagement in relation to training sessions delivered by the implementation team to intervention services. The framework will be used to guide the observations and score them (scale 1-5): whether the content for each slide was delivered as intended (fidelity), how well content was delivered (competence), and how engaged the facilitators and participants were during the session. Researchers will also take notes on environmental factors that might be influential, the extent to which there is staff buy-in to the intervention and any additional reflections or aspects to follow up.

Fidelity framework (aligned with the logic model)

We have created fidelity frameworks (one for inpatient, one for community settings) to be completed during observations in the inpatient and community setting. These list all intervention components and expected behaviour if the intervention is implemented with fidelity. As with the training framework, it captures competence and engagement. The competencies are aligned with TDF Framework components, included in the logic model.

Implementation framework

In addition to the frameworks, we will collect detailed information about the implementation of the intervention at each of the intervention services included in the process evaluation using the implementation plan described in the earlier theoretical approach section. We will write notes in each section of the plan and indicate what has been implemented as planned, and any additional unexpected implementation strategies. We will also highlight which constructs of NPT are being addressed and note cases where they are not being addressed as planned. This process will enhance our understandings of the implementation processes needed to successfully implement the intervention.

Topic guides

Topic guides for each of the different interviews (see table 2) were developed based on feasibility study findings, and have also been informed by NPT (23),the theoretical framework of acceptability (24), and the TDF (18). In line with NPT, questions focus on how staff make sense of the intervention (coherence); how they work together to build a community of practice which facilitates implementation (cognitive participation); the operational practices involved in enacting the practices (collective action) and the appraisal work to understand ways that the new practices affect those around them (reflexive monitoring). Questions to address acceptability have been included to address the seven constructs within the framework by Sekhon et al. (24). Questions focused on the TDF domains in the logic model have also been included to understand more about for example skills, knowledge, beliefs around reducing SB from the perspectives of staff, patients and where relevant their families, friends, carers. See supplementary file 1.

Interviews will be adapted to be inclusive of stroke patients, for instance by using accessible information sheets, adapting the topic guide / using appropriate images and writing down key words for people with aphasia. Interviews will be audio recorded and a summary of contextual factors written by the interviewer.

Quantitative data

Documentary analysis form

A documentary analysis form will be used during observations and interviews, conducted on patient-held intervention components (e.g. information guide used to record standing and moving) and staff-completed records. This form will document how many documents have been checked, how many are complete up to date, and the week in which completion stopped (if incomplete). These capture the recording of delivery of intervention components and provide evidence of fidelity.

Data analysis

All data collected will be analysed to address the relevant objectives (Table 2). Training observations will be summarised with a focus on fidelity, acceptability and engagement and contextual factors that may have

influenced how the training was delivered or received. Relevant headings based on the MRC framework (e.g. fidelity, contextual factors) will be used to organise the data.

Both observational and interview data will be subject to thematic analysis (26). Data will be analysed by a minimum of two researchers (JFJ and RS). Observational data will be coded into a thematic framework, and then related codes will be grouped together under thematic headings which convincingly capture and explain the relationship between coded elements of text. The interviews will be transcribed verbatim and anonymised. Data will be entered into NVivo 12 software (QSR International, 2018). Interview data will separately be analysed using a thematic approach (26). To produce the thematic frameworks, a proportion of the data will be coded independently (JFJ and RS) and key themes and subthemes will be identified to form the frameworks. The same theories used to inform the topic guides (NPT (23) and the theoretical framework of acceptability (24)) will be used to inform the thematic frameworks and themes that are produced during the analysis of the observations and interviews. The logic model, including the domains outlined in the TDF will also be considered when developing the frameworks and throughout the analysis process.

The training summaries, fidelity frameworks that will be completed during observations, and the implementation plan that will be populated based on meetings with the implementation team, and observational and interview data will be used to support the interpretation of findings and will allow for comparisons to be made between services with regards to implementation fidelity, competency and engagement. Data from documentary analysis will be anonymised and summarised descriptively and will similarly be used to aid the interpretation of findings.

Standard approaches to demonstrating trustworthiness and quality in qualitative research will be used, including: the clear documentation of the research process (methods, analysis and any problems encountered and solutions found); transparency of the development of the observational framework and interview topic guides in-light of on-going analysis; documentation of the contextual features in which the research was carried out; discussions of emerging findings among the research team; and researchers will keep a reflexive diary (27).

The anticipated outputs of this evaluation include: recommendations for intervention refinements (both content and implementation); a revised implementation plan, and a refined logic model (and supporting written intervention description).

ETHICAL APPROVAL AND DISSEMINATION

The study has National Health Service (NHS) permission and was approved by Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (REC reference: 19/YH/0403). In light of the COVID pandemic, an ethical amendment approved remote data collection where needed e.g., observations of staff training and audio recorded interviews via zoom. Findings will be disseminated via peer review publications, and national and international conference presentations.

DISCUSSION

Process evaluations are considered an essential part of designing and testing complex interventions (22). They allow us to understand in detail the myriad of complex factors, and complex processes that contribute to whether an intervention has an impact on outcomes. We intend to add to knowledge about: intervention theory and how interventions contribute to change; how interventions interact with their context, wider system dynamics and impacts on implementation; and how individuals experience interventions (patients, staff, and carers. We also anticipate that the findings will be informative and transferable to other similar research focused on evaluating complex interventions in complex settings.

AUTHORS' CONTRIBUTIONS: AF is lead grant holder and Chief Investigator, and will oversee the design and implementation of the trial. JFJ leads the embedded process evaluation and is responsible for planning, undertaking the research and reporting findings alongside RS. SO and LM, assisted by JA, are responsible for managing the delivery of the trial. JA also leads on the ActivPAL and is responsible for the implementation of the intervention alongside SO and AF.RM contributed to the planning of this process evaluation. AFa, GM, CE, CF and DJC are co-investigators who were all involved in the design of the trial and process evaluation, and attend regular programme meetings where advice is provided where needed.

All co-investigators and researchers contributed to the development of the protocol. JFJ drafted the manuscript which is written on behalf of the RECREATE Programme Management Group. All authors read and approved the final manuscript.

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SPONSOR: The trial sponsor is Bradford Teaching Hospitals NHS Foundation Trust, Research Management & Support Office, Bradford Institute for Health Research, Bradford, BD9 6RJ, United Kingdom. Tel: +44 (0)1274 38 2575; e-mail: jane.dennison@bthft.nhs.uk. The Sponsor will maintain oversight of trial processes, but is not involved in trial design or delivery processes. The Sponsor will not participate in data analysis or trial reporting processes.

Data sharing statement: The data generated from this process evaluation will be maintained by the Academic Unit of Ageing and Stroke Research. Any requests for data should be sent to corresponding author Dr Johansson and would be subject to review with the CI Professor Forster. All data-sharing activities would require a data-sharing agreement.

COMPETING INTERESTS STATEMENT:

AF, AFa, CE, CF, GM and DJC are coinvestigators on the grant funding this work therefore are partially supported by the National Institute for Health and Social Care Research (NIHR) (grant number RP-PG-0615-20019).

AF has received additional research grant support from NIHR through the following funding streams: Senior Investigator award, Health Technology Assessment (HTA) and Health and Social Care Delivery Research (HS&DR). AF has previously received support from the Stroke Association to attend the UK stroke forum and received payment from the National Institute for Health (USA) for panel membership (2021, 2022). AF is currently the chair / a member of programme steering committees for NIHR research programmes (Grant reference numbers: NIHR 202339, NIHR 202020) and has served on the following panels: NIHR Doctoral Fellowships, NIHR senior investigators committee (2019/20), NIHR HS&DR committee (2016-2018) and Stroke Association Funding.

CE has received grant funding from the Netherlands Organisation for Scientific Research (NOW) Taskforce for Applied Research (SIA RAAK) for work in a similar area (i.e. sitting less and moving more after stroke) and is a Non-executive Director representing interests of Research and Chair of Research Advisory Committee for the Stroke Foundation of Australia (unpaid).

CF is a coinvestigator / collaborator on other grants on the topic of sedentary behaviour / physical activity and is therefore partially supported by grant funding received from the University of Edinburgh and the Irish Health Board. CE has previously been supported to conduct work in a similar area by grant funding received from the Chief Scientist Office of the Scottish Government, Medical Research Council (MRC) Public Health Intervention Development (PHIND) award and the University of Edinburgh.

JFJ, LM, RS, RM, JA, SO and DJC report no competing interests related to the manuscript.

Twitter: @RECREATE_stroke

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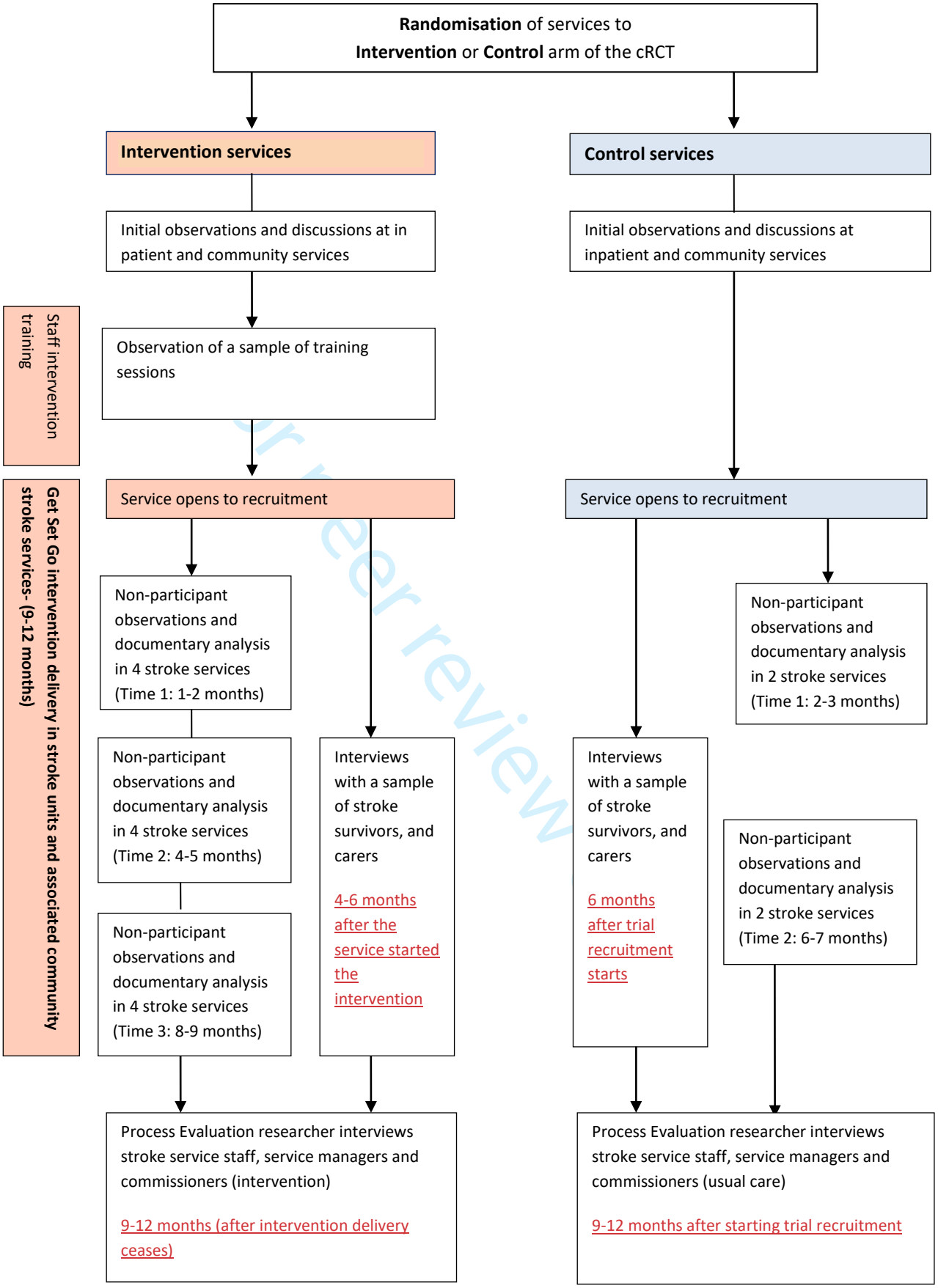
Figure 1: Process Evaluation Flowchart



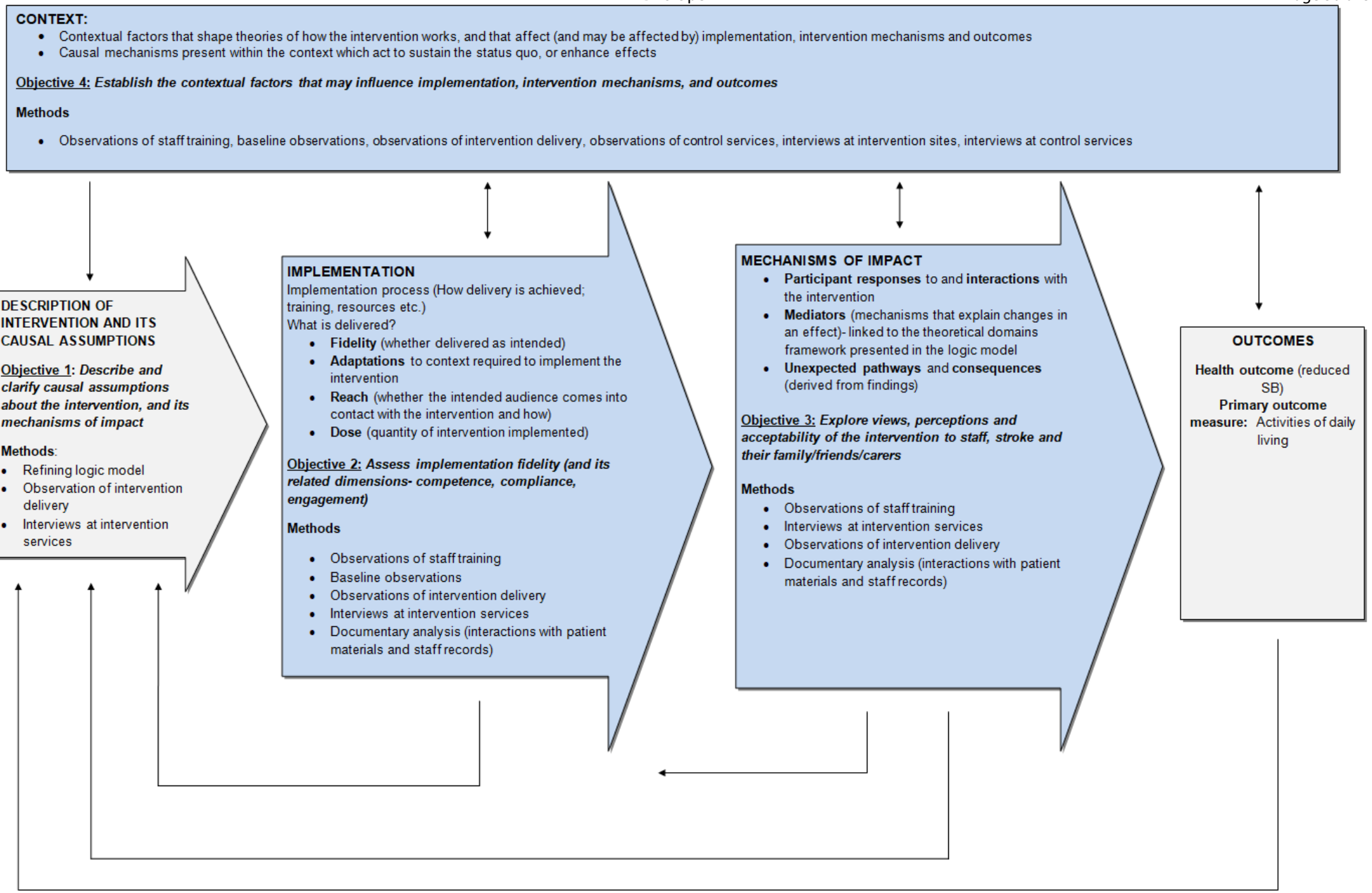


Figure 2: Process evaluation objectives and methods mapped to the MRC guidance by Moore et al., 2015

Supplementary file 1: Topic guides (staff and patients) for intervention and control sites

1. Topic guide for staff - intervention

The purpose of this interview is to hear about your experiences with Get Set Go.

	NPT/TDF/ Sekhon
1. What is your usual role?	
○ Tell me briefly about your role in the stroke service? ○ How long have you been working in stroke care? ○ Does Get Set Go fit with your usual role?	n/a: contextual information
2. Tell me about how you got involved in Get Set Go?	
○ How did your involvement in Get Set Go begin? Attend training or discuss with colleagues? ○ How was the training? What do you remember about it? ○ Was the format OK (in person/ online)? ○ Was it applicable to you and your role? Did it change anything for you? ○ What do you understand about the purpose of Get Set Go? ○ How does Get Set Go differ from the usual care you provide? ○ Was it clear from the training what you needed to do yourself and as a team? ○ Did you have any questions/concerns in the beginning? Did you feel ready/confident to deliver the intervention? ○ Did anything help you make sense of Get Set Go before delivering it?	**Sekhon:** Affective attitude, ethicality, intervention coherence, self-efficacy **NPT:** Differentiation, individual specification
3. How was Get Set Go used on your ward?	
○ Did your team deliver all the intervention components? (go through each). ○ Do you feel your team have a good understand of Get Set Go and their roles? ○ What did you do as a team to ensure a shared understanding of what you want to achieve? ○ Overall, which parts worked well / not so well? ○ To what extent do you feel your team value Get Set Go? ○ Who is responsible for leading/driving Get Set Go forward? Who else was involved?	**Sekhon:** Intervention coherence **NPT:** Communal specification , initiation, enrolment, legitimation
4. Tell me about your experience of using Get Set Go?	
○ What was your role or involvement with Get Set Go? ○ Tell me about your experiences of using each of the intervention components. ○ What parts were the easiest or hardest to use? ○ Did you feel able to help patients understand the purpose and what they needed to do? ○ Were you aware of/ did you use the website? <u>Champions:</u> Can you describe your experiences of being a lead for Get Set Go?	**Sekhon:** Affective attitude, self-efficacy

(Was your role clear? Did you have enough support? What was difficult or negative? What went well or was enjoyable? Did you feel suggestions were acted upon?) Trainers: Can you describe your experiences of delivering the training? How was it received? What were the challenges? Did you feel prepared?	
5. Has Get Set Go helped patients? (has it increased standing and moving)	
○ What are your views on encouraging patients to stand and move more (e.g. benefits, values placed on this) ○ Have patients/ family benefited from Get Set Go? Did it change anything for them? (e.g. prompting standing & moving, health, skills, confidence, mood, motivation, empowerment) ○ What do patients/families think of the recommendations about how much they should stand and move? ○ How do patients respond to the information guide? Where do you think they use it most? (hospital or home) ○ Do they understand the purpose? Are they willing to engage? ○ Is there anything they particularly like or dislike?	**Sekhon:** Perceived effectiveness **NPT:** Internalization
6. Has Get Set Go changed anything for staff/service?	
○ Overall, what have been the positives of using Get Set Go? (what went well) ○ Overall, what have been the negatives of using Get Set Go? (what went not so well) ○ Has it changed the way staff work? Has increased standing and moving become habit? ○ Has it changed the way staff think about sedentary behaviour/standing and moving? (e.g. knowledge, skills confidence, role, routines, risk) ○ Have there been any environmental changes? (e.g. posters, decluttering, influences on standing and moving) ○ Did anyone introduce new ideas? How were these received? Did you share ideas/learning?	**Sekhon:** Affective attitude, perceived effectiveness
7. What were the challenges or things that helped?	
○ What made it difficult/easier to use Get Set Go or to amend practice? ○ Was the delivery sustained over time? (what factors influenced this) (e.g. priorities, workload, cost, space, training, resource, patient ability/willingness, risk, skills/confidence, perceived patient benefit, clear understanding) ○ How was Get Set Go received by the team/service? ○ Was there sufficient time / staff availability? ○ Was there sufficient senior / wider team support? ○ Was there sufficient communication between services? ○ Were there any unplanned events which affected Get Set Go? (e.g. infection, staffing, crises) ○ Would greater involvement of different staff groups have helped? ○ Did everyone know who was responsible for doing what? How did you allocate roles? ○ Did Get Set Go fit into usual routines / roles, or was it too separate? ○ How did you prepare practically for delivering Get Set Go? (managing resources etc)	**Sekhon:** Burden, opportunity costs **NPT:** Activation, interactional workability, relational integration, skill set workability, contextual integration
8. What could we have done better?	
○ Do you have any other feedback or suggested changes? ○ Most and least valued parts?	**Sekhon:**

○ What could we have done to help you use GSG? What would you do differently next time? ○ Does Get Set Go meet its purpose to help stroke survivors recover?	Affective attitude, perceived effectiveness
9. The impacts of the COVID pandemic	
○ Has the COVID pandemic influenced your engagement with the Get Set Go intervention? ○ Has the COVID pandemic had an influence on how much you have been able to support/encourage standing and moving?	
10. Is there anything else you would like to ask or mention?	

2. Topic guide for staff control

This topic guide is to gain insights into staff's perceptions and views related to the provision of usual care to stroke survivors- related to standing and moving/mobilising after stroke.

	NPT/TDF/ Sekhon
1. What is your role?	
- Tell me briefly about your role in the stroke service? - How long have you been working in stroke care?	n/a contextual information
2. Perceptions/ thoughts about standing and moving?	
- What do you think about encouraging patients to stand and move more? (including benefits, how much this is valued) - What sort of time in their care pathway do you think it is most important? (Throughout/inpatient/community). - What do you think it is beneficial for patients to know about standing and moving?	**Sekhon:** Affective attitude, ethicality, perceived effectiveness
3. Experiences of supporting standing and moving more? (Individual and as a team)	
- To what extent does your role involve supporting patients to stand and move? - Tell me about your experiences of supporting standing and moving? (as an individual/team- how this is managed at a ward/community service level) - Is this something that is routinely encouraged? - Which staff are most commonly responsible for encouraging/supporting standing and moving? - Are you/ your team aware of any specific initiatives/ tools to support practices related to standing and moving? - To what extent do you feel adequately equipped to support patients to stand and move?	**Sekhon:** Self-efficacy
4. Challenges or things that help supporting standing and moving?	
- What is your view on your team's willingness/ability/capability to support standing and moving? - What is your view on the patient/carer's willingness/ability to practice standing and moving? - What responses have you had from patients and their carers? - Are there any factors that influence whether you would encourage patients to stand and move more? (e.g. priorities, staffing, workload, cost, space, training, resource specific processes, leadership patient ability/willingness, risk, skills/confidence, perceived patient benefit, clear understanding, environment)? - Any other particular things that work particularly well or not so well that might affect standing and moving	**Sekhon:** Burden, opportunity costs

5. Could anything be better?	
○ Could you or your team do anything more to support/encourage patients to stand or move more? ○ How could current practice be further developed?	
6. The impacts of the COVID pandemic	
- Has the COVID pandemic had an influence on how much you have been able to support/encourage standing and moving?	
7. Is there anything else that you would like to ask or mention?	

3. Topic guide for stroke survivors and carers – intervention

**All questions are for stroke survivor and/or carer, except where "(C)" marks them as for carer only.*

	NPT/TDF/ Sekhon
1. You & your stroke	
- Could you tell me a bit about you? (Hobbies, interests pre and post stroke?) - What were the impacts of your stroke? (symptoms, usual activities, changes over time) - How long has it been since you had your stroke? - How long did you spend in hospital? - Could you describe your experiences of your hospital stroke care? (positives/negatives) - Could you describe your experiences of the stroke care you received since coming home? (positives/negatives, waiting, still receiving, how long) - Have you experienced any other difficulties alongside your stroke that required additional care?	n/a contextual information
2. What are you experiences and thoughts about standing and moving more?	
- How much standing and moving do you do at the moment? Tell me about your daily routines? (types of activities where might be standing and moving, times of day when more likely) - **(C)** Do you play a role in supporting standing and moving? (if yes, explore how) **-** What do you think about trying to/encouraging stand and move more after stroke? (benefits, fears, in hospital, at home, is this valued) - Do you feel confident/capable to stand and move/encourage standing and moving? - At what time after stroke do you think it's most important? (throughout/inpatient/community) - Have you received any support or tools for standing and moving? (e.g. groups, therapy)	**Sekhon:** Affective attitude, ethicality, perceived effectiveness, self-efficacy **NPT:** n/a
3. What are your experiences of Get Set Go? (show examples of the intervention components)	
- Did **staff talk to you** about/ prompting standing and moving more (in hospital or at home)? • Who was it? Were family/friends involved? • How did you feel about it? • Did it make sense? Did you have any questions? Did they give examples of what to do/ when? - In hospital, did you receive an information guide or see anything about GSG on the ward? - What do you think about this? Was it appropriate for you? - Did staff regularly update the recommendations about standing and moving? - Did you record your standing and moving? (reasons why not if not) Will you keep recording? - What did you think of the GSG materials? Were they useful? *[this section includes a breakdown of all intervention components not listed for publication purposes]* - How could the above materials be improved? (format, content, ease of use, social acceptability) - Have you received any follow up contact since returning home?	**Sekhon:** Intervention coherence, Affective attitude, Perceived effectiveness, Self- efficacy, Ethicality **NPT:** Interactional workability
4. Has Get Set Go helped you? (has it increased standing and moving)	

- What did you think about GSG overall? - Which parts worked well / not so well? Is there anything you particularly like or dislike? - Did it make you want to stand and move more? Did you? • Did you benefit in any other way? • Has it helped or hindered your recovery from stroke? Or influenced your life more broadly? • Did it make you do anything differently or change anything? (e.g. Did it affect your: motivation, goals, mood, remembering to stand and move, confidence, activities, health, conversations) • Was your time spent using the guide beneficial? • Have you incorporated new activity into your daily life? Do you feel you will maintain it? - Have your family and friends used the guide and benefitted, or changed anything as a result? - Has engaging with the Get Set Go intervention been worthwhile? - Do you think Get Set Go can help other people? - Does it help recovery after stroke?	**Sekhon:** Burden, Self-efficacy, Opportunity costs, Affective attitudes, Perceived effectiveness **NPT:** n/a
5. What were the challenges or things that helped?	
- Did anything make it difficult to use Get Set Go / to stand and move? (fears, impact of stroke, motivation, unexpected events, confidence, opportunities, environment, forgetting, mood, other responsibilities/ lack of time, not knowing what to do, seeing the benefit, equipment) • Is there anything you struggle with/ have concerns/ uncertainties about in terms of Get Set Go/standing and moving? • Did you feel confident you could ask for help? • Did staff talk to you about GSG (or did it feel like something to do on your own)? - Did anything make it easier to use Get Set Go / to stand and move? (staff, family, confidence, opportunities, environment, motivation, mood, timing after stroke, knowing what to do, seeing the benefit, equipment) • Did you make any changes to your surroundings to make it easier for you to move around (in hospital or at home)? Was it easy or difficult to make these changes? • Is there anything else that could be better to help you use Get Set Go/stand and move more? - Has anything else influenced your behaviour/affected your standing and moving alongside the programme?	**Sekhon:** Burden, Opportunity costs, Affective attitude, Self-efficacy **NPT:** Interactional workability
6. Could anything be better?	
- Is there anything else you would like to say about your experience / other feedback? - What might you do differently next time?	**Sekhon:** Affective attitude **NPT:** n/a
7. The impacts of the COVID pandemic	
- What impact has the COVID pandemic and the associated restrictions had on your day-to-day life? (health, physical, social, emotional) - Could you describe any changes in your activities as a result of the COVID pandemic? (e.g. physical, social, day-to-day- explore if doing any activities less or more) - Has the COVID pandemic influenced your standing and moving? - Has the COVID pandemic influenced your engagement with the Get Set Go intervention? - (C) Has the COVID pandemic had an influence on how much you have been able to support/encourage standing and moving?	
8. Is there anything else you would like to ask or mention?	

4. Topic guide for stroke survivors and carers – control

**All questions are for stroke survivor and/or carer, except where "(C)" marks them as for carer only.*

	NPT/TDF/ Sekhon
1. About you (stroke survivor)	
- Could you tell me a bit about you? (Hobbies, interests pre and post stroke?	n/a contextual information
2. Your stroke (stroke survivor)	
- How long has it been since you had your stroke? - What were the impacts of your stroke? (symptoms and how they may have changed over time) - How long did you spend in hospital? - Could you describe your experiences of the stroke care you received? (inpatient/community care/any additional support/positives/negatives) - Have you experienced any other difficulties alongside your stroke that have required additional care?	n/a contextual information
3. Perceptions/ thoughts about standing and moving? (stroke survivor and carer)	
- **(SS)** What do you thinking about trying to stand and move more after stroke? (benefits, fears) - **(SS and C)** To what extent do you feel confident/capable to stand and move/encourage standing and moving? **- (C)** What do you think about encouraging people who have had a stroke to stand and move more? (including benefits, how much this is valued) -**(SS and C)** What sort of time in their care pathway do you think it is most important? (Throughout/inpatient/community). - **(SS and C)** Do you feel as though you could benefit from learning more about standing and moving after stroke? (what could be helpful?)	**Sekhon:** Affective attitude, ethicality, perceived effectiveness, self-efficacy
3. Standing and moving more- your experiences	
- (SS) Could you tell me a little about your day-to-day routines? - **(SS)** How much standing and moving would you tend to do each day? (discuss types of activities where might be standing and moving, or times of day when more likely) - **(C)** Do you play a role in supporting standing and moving? (is yes, explore how they provide support) - **(SS and C)** What do you remember about being encouraged to stand and move in hospital/by community teams? **(SS and C)** Have you received any support about standing and moving (e.g. from therapists, groups). - **(SS and C)** Are you aware of any specific initiatives/ tools to support standing and moving?	
4. Challenges or things that help supporting standing and moving?	
- **(SS)** Tell me about any challenges you may face in standing and moving? (physical, cognitive, fears of falls, confidence, opportunities, environmental factors, motivation) - **(C)** Tell me about any challenges you may face in supporting standing and moving? (same prompts as above) - **(SS and C)** Any other particular things that work particularly well or not so well that might affect standing and moving?	**Sekhon:** Burden, opportunity costs
5. Could anything be better?	
- **(SS and C)** Is there anything that could facilitate standing and moving more? **(SS)** Could you benefit from more support to encourage you to stand and move more?	

6. The impacts of the COVID pandemic	
- What impact has COVID and the associated restrictions had on your day-to-day life? (health, physical, social, emotional) - Could you describe any changes in your activities as a result of the COVID pandemic? (e.g. physical, social, day-to-day- explore if doing any activities less or more) - Has the COVID pandemic influenced your standing and moving? - (C) Has the COVID pandemic had an influence on how much you have been able to support/encourage standing and moving?	
7. Is there anything else that you would like to ask or mention?	