FULL/LONG TITLE OF THE TRIAL

Adapting ENGAGE-PD: Adapting the ENGAGE-PD physical activity coaching intervention for individuals newly diagnosed with Parkinson’s to be delivered by physiotherapists in NHS rehabilitation settings: perspectives of healthcare professionals using the Nominal Group Technique consensus method.

SHORT TRIAL TITLE / ACRONYM

Adapting ENGAGE-PD physical activity coaching for individuals newly diagnosed with Parkinson’s: perspectives of healthcare professionals using Nominal Group Technique consensus.

This protocol has regard for the HRA guidance and order of content

Version 1.1 09/01/2026

RESEARCH REFERENCE NUMBERS

PEOS 6896, IRAS 366180

TRIAL REGISTRY NUMBER AND DATE

ISRCTN Number: ISCRCTN50241156 02/12/2025

PROTOCOL VERSION NUMBER AND DATE

1.1 09/01/2026

OTHER RESEARCH REFERENCE NUMBERS

NIHR305241; Award Manager AM1001946

SPONSOR / CO-SPONSORS / JOINT-SPONSORS

University of Plymouth

FULL/LONG TITLE OF THE TRIAL

Adapting ENGAGE-PD: Adapting the ENGAGE-PD physical activity coaching intervention for individuals newly diagnosed with Parkinson's to be delivered by physiotherapists in NHS rehabilitation settings: perspectives of healthcare professionals using the Nominal Group Technique consensus method.

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Version 1.1 09/01/2026

RESEARCH REFERENCE NUMBERS

IRAS Number:	366180
ISRCTN Number:	ISCRCTN50241156
SPONSORS Number:	6896
FUNDERS Number:	NIHR305241 AM1001946

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol and will adhere to the principles outlined in the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031), amended regulations (SI 2006/1928) and any subsequent amendments of the clinical trial regulations, GCP guidelines, the Sponsor's (and any other relevant) SOPs, and other regulatory requirements as amended.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the trial publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the trial will be given; and that any discrepancies and serious breaches of GCP from the trial as planned in this protocol will be explained.

For and on behalf of the Trial Sponsor:

Signature: Date:

..../....../......

Name (please print):

....

Position:

....

Chief Investigator:

Signature: Date:

..../....../......

Name: (please print):

....

(Optional)

Statistician:

Signature:

....

Name: (please print):

....

Position:

....

KEY TRIAL CONTACTS

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Funder(s)	**National Institute of Health and Care Research (NIHR)** NIHR Academy 21 Queen Street Leeds LS1 2TW Tel: 0113 532 8444 Email: academy-awards@nihr.ac.uk

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Committees Trial Steering Committee – Independent Members Independent Chair	**Professor Helen Dawes.** Professor Clinical Rehabilitation Co-Director Rehabilitation and Aging NIHR Exeter HRC and BRC Medical school, University of Exeter www.exeter.ac.uk Room F.03, Medical School Building, St Lukes Campus, Heavitree Road, Exeter, EX12LU Tel: 01392661000 Email: H.Dawes@exeter.ac.uk
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ii. LIST OF ABBREVIATIONS

Define all unusual or 'technical' terms related to the trial. Add or delete as appropriate to your trial. Maintain alphabetical order for ease of reference.

AE	Adverse Event
AR	Adverse Reaction
CA	Competent Authority
CI	Chief Investigator
CRF	Case Report Form
CRO	Contract Research Organisation
CTA	Clinical Trial Authorisation
CTU	Clinical Trials Unit
C&C	Confirmation of Capacity and Capability
DMC	Data Monitoring Committee
DSUR	Development Safety Update Report
EC	European Commission
EU	European Union
EUCTD	European Clinical Trials Directive
EudraCT	European Clinical Trials Database
GCP	Good Clinical Practice
ICF	Informed Consent Form
ISF	Investigator Site File (This forms part of the TMF)
NGT	Nominal Group Technique
NHS	National Health Service
NHS R&D	National Health Service Research & Development
OID	Organisation Information Document
PI	Principal Investigator
PIC	Participant Identification Centre
PIS	Participant Information Sheet

PwP	People with Parkinson’s
QA	Quality Assurance
QC	Quality Control
QP	Qualified Person
RCT	Randomised Control Trial
RDN	Research Delivery Network
REC	Research Ethics Committee
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SDV	Source Data Verification
SOP	Standard Operating Procedure
SSI	Site Specific Information
SUSAR	Suspected Unexpected Serious Adverse Reaction
TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee

iii. TRIAL SUMMARY

Trial Title	Adapting ENGAGE-PD: Adapting the ENGAGE-PD physical activity coaching intervention for individuals newly diagnosed with Parkinson's to be delivered by physiotherapists in NHS rehabilitation settings: perspectives of healthcare professionals using the Nominal Group Technique consensus method.	
Internal ref. no. (or short title)	Adapting ENGAGE-PD physical activity coaching for individuals newly diagnosed with Parkinson's: perspectives of healthcare professionals using Nominal Group Technique consensus.	
Trial Design	Nominal Group Technique consensus	
Trial Participants	UK National Health Service Parkinson's rehabilitation service leads, managers and physiotherapy healthcare professionals	
Planned Sample Size	6-8 NHS provider organisation. 6-8 participants at each organisation	
Duration	90-120 minute meeting at each NHS provider organisation	
Follow up duration	Immediate result dissemination with opportunity for further clarification/feedback within one week of meeting	
Planned Trial Period	8 months	
	Objectives	Outcome Measures
Primary	NHS healthcare professional perspectives on the relative importance of the items in version one of the UK version of ENGAGE-PD	Nominal Group Technique consensus method meetings
Secondary	Feasibility: Perceived fit of the ENGAGE-PD intervention in the practice setting.	Nominal Group Technique consensus method meetings
Tertiary	Information on provider organisation usual care Participant demographics	Participation Identification Centre (PIC) feasibility questionnaire Pre-meeting participant questionnaire

iv. FUNDING AND SUPPORT IN KIND

FUNDER(S)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
(Names and contact details of ALL organisations providing funding and/or support in kind for this trial)	
National Institute of Health and Care Research (NIHR) NIHR Academy 21 Queen Street Leeds LS1 2TW Tel: 0113 532 8444 Email: academy-awards@nihr.ac.uk	**£ 477648 (for Training fellowship including 3 study work packages – this protocol relates to work package 2)**

v. ROLE OF TRIAL SPONSOR AND FUNDER

The sponsor for this study, University of Plymouth (UoP), assumes overall responsibility for the initiation and management of the trial.

This study is funded by the National Institute of Health and Care Research as part of a Doctoral Clinical Academic Fellowship for Jonathan Gilby ref. NIHR305241

The sponsor and funder will not have direct involvement in trial design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results.

vi. ROLES AND RESPONSIBILITIES OF TRIAL MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

The Trial Steering Committee (TSC) has an independent chair (Helen Dawes). It has an independent clinician and statistician and two patient representatives. The TSC will meet at least every 6 months to review the progress of the trial and any serious adverse events and will report to the sponsor. The detailed role and remit of the TSC is described in a separate TSC Charter.

The Trial Management Group (TMG) is chaired by the Chief Investigator (CI) and includes representatives from the sponsor and PenCTU (Dr Wendy Ingram, Paigan Aspinal, Abbey Tuft) as well as the trial statistician (Joanne Hosking) and patient representative (Mr Graham Brown). It also has representation from the CI's supervisory team (Professor Jonathan Marsden, Dr Chris Lovegrove, Dr Tom Thompson).

The TMG will meet monthly to review trial progress and to ensure appropriate management of the trial.

A Data Monitoring and Ethics Committee will not be convened for this trial which is considered low risk of harm to participants.

vii. Protocol contributors

The following have contributed to the protocol

Mr Jonathan Gilby Research Fellow (School of Health Professions, Faculty of Health and Human Sciences) University of Plymouth. Mr Gilby is a physiotherapist with expertise in the rehabilitation of people with Parkinsons.

Professor Jonathan Marsden, Professorship and chair of rehabilitation (School of Health Professions, Faculty of Health and Human Sciences) University of Plymouth. Prof Marsden has an expertise in observational trials, neurophysiology and biomechanics in the area of neurological rehabilitation.

Dr Tom Thompson, Senior research fellow (Peninsula Medical School, University of Plymouth). He has expertise in research design and was an advisor for the NIHR Research Design Service.

Dr Chris Lovegrove , Clinical research fellow (Patient Safety Research Collaboration School of Pharmacy, Newcastle University). He is a consultant occupational therapist and previous NIHR clinical doctorate fellow. He has expertise in qualitative research and rehabilitation of Parkinson's Disease.

Dr Wendy Ingram, Senior Clinical Trials Manager, Peninsula Clinical Trials Unit, University of Plymouth. She has expertise in trial design and management

Dr Joanne Hosking, Senior Research Fellow- Medical Statistics, Peninsula Medical School, University of Plymouth. She has expertise in medical statistics.

Mr Graham Brown, Patient representative with Parkinson's. Mr Brown has co-developed the project and assessed all public facing documentation.

viii. KEY WORDS: People with Parkinson's (PwP), Physical Activity (PA), Physiotherapists, Nominal Group Technique (NGT)

ix. TRIAL FLOW CHART

PIC Feasibility

- Study team network links with Research Delivery Network support to identify potential PICs
- Preliminary information gathering via site feasibility questionnaire

Enrolment

- Ethical approvals prior to:
- Sponsor to NHS provider Participant Identification Centre Agreement
- Virtual PIC Initiation Visits including Participant Information Pack provision

Recruitment

- Identification and recruitment of eligible participants at each centre
- Formal informed consent
- Version 1 of UK version of ENGAGE-PD share
- Pre-meeting survey

Nominal Group Technique Meetings (1 per site)

- Introduction and explanation
- Silent generation of ideas
- Sharing ideas
- Group discussion
- Voting and Ranking

Dissemination and co-design

- Results shared to check outcomes of meeting
- Co-design of version 2 of ENGAGE-PD with study team and PAG

1 BACKGROUND

Parkinson's is a progressive neurological condition that causes motor and non-motor symptoms. The cause is believed to involve environmental and genetic factors, occurring more commonly in men than women and those over the age of 60. (1,2) Prevalence is rising more rapidly than in other neurological disorders with 166,000 people estimated to have Parkinson's in the UK in 2025. (3)

Common impairments in Parkinson's are slow movement, balance problems, sleep behaviour disorder, apathy, low mood and memory problems. These can lead to activity and participation limitations and affect quality of life. (4–6) It is thought that these combined impairments contribute to people with Parkinson's (PwP) leading more sedentary lives than age-matched controls. (7,8)

Parkinson's severely affects quality of life with the impact increasing with disease progression. (5,9) This also extends to caregivers. (10) There is a strong relationship between quality of life, severity of Parkinson's and economic costs-of-illness. (11)

The economic impact of Parkinson's Disease is enormous; the estimated annual cost across Europe is €13.9 billion, with annual costs per PwP from €5000 (early stages) to over €17,000 (later stages). (5,12,13) Recent UK research estimates a household where someone has Parkinson's is on average £16,582 per year worse- off (14) with high indirect costs arising from productivity loss and caregiver burden. (13) Parkinson's imposes a significant economic burden on health systems, driven mainly by hospitalisations and medication use. (15,16) Evidence suggests self-management support can positively impact clinical outcomes. (17)

Physical Activity (PA) is any bodily movement produced by skeletal muscle that requires energy expenditure. Exercise is a subset of PA that is planned, structured and repetitive with the primary purpose of improving or maintaining components of physical fitness. (18) Increased PA in older adults is associated with healthier body composition, lower rates of chronic disease, greater levels of independence, lower falls risk and better cognitive functioning. (19) Additional to these benefits, there is high-quality evidence that aerobic exercise improves physical fitness and attenuates motor symptoms for PwP. (20–22) Further, there are indications from animal and human models that it may have preventative and disease-modifying effects on the brain. (23–27) PwP have, however, been shown to do less PA than age-matched controls and in relation to PA guidelines. (7,8)

Therapy, in particular physiotherapy, has been proposed to aid the promotion of healthy PA and exercise to prevent functional decline. (28) Physiotherapists help people affected by illness, injury or disability through approaches including movement and exercise, manual therapy, education and advice. (29) Physiotherapists have additional skills to exercise professionals, to guide people with

long-term conditions in engaging in PA. Physiotherapist-led PA interventions are efficacious at increasing PA levels. (30)

Clinical practice guidelines for Parkinson's recommend physiotherapy soon after diagnosis for education, individualised interventions and PA support. (5,31,32) However, physiotherapy referral for newly diagnosed PwP remains low with only 11.6-percent of cases referred to physiotherapy within one year of diagnosis and 'usual' physiotherapy care varying considerably around the UK. (33,34) This presents a challenge for testing interventions against usual care but is considered a research priority. The UK National Institute for Health and Care Excellence (NICE) Parkinson's Guidelines, recommend physiotherapy referral for people who are in the early stages of Parkinson's (for assessment, education and advice including information about PA) and the following research question: 'Does physiotherapy started early in the course of Parkinson's Disease, as opposed to after motor symptom onset, confer benefits in terms of delaying symptom onset and/or reducing severity?' (31)

A recent scoping review by the study authors demonstrated there is little research into interventions to support physical activity in identifiable cohorts of people within five years of Parkinson's diagnosis. (35)

PwP stated that they wanted a personal, tailored approach to help them become more active and described the relationship with physiotherapists as often key to initiating PA. (36)

One therapy model identified to support people newly diagnosed with Parkinson's is ENGAGE-PD, a pathway of 'Consultative Proactive Rehabilitation', (37,38) delivered by therapists over 14-weeks of input.

ENGAGE-PD tenets:

1. PA Coaching to promote autonomy, competence and relatedness with motivational interviewing strategies.
2. Participant workbook, to identify activity levels, barriers and challenges to exercise, and promote safety during exercise.
3. PA Monitoring, to develop a PA plan of action, record PA and progress, with individualised goals and targets. (38)

The tenets of ENGAGE-PD fit with unmet needs and research priorities in Parkinson's rehabilitation in the UK. The intellectual property for the ENGAGE approach is UK based, and informed the logic modelling and programme theory for the US-based ENGAGE-PD. Early versions in the U.S, in single-arm cohort feasibility and implementation studies, suggest feasibility and acceptability with improvements in exercise levels, self-efficacy, motivation and planned PA, lending support to the intervention logic model (http://alturl.com/up8vz). (39–41)

ENGAGE-PD research recommendations were to explore hybrid models of face-to-face/telehealth delivery and examine situational and social determinants of the intervention to assess how it may be incorporated in other contexts, settings and cultures. (39)(41)

Previous research conducted by the study team represented the first stage of investigating the potential of ENGAGE-PD in the context of NHS Parkinson's rehabilitation for people newly diagnosed with Parkinson's. Group Concept Mapping (GCM) investigated views of people with lived experience of Parkinson's in the UK on specific things to support people newly diagnosed with Parkinson's with PA. Key themes identified were to share information relating to (a) physical activity and wellbeing options, (b) motivational tools, (c) Parkinson's specific activities, (d) active lifestyle support and (e) education and advice.

Analysis of the GCM results by the study team (including Project Advisory Group (PAG) lay members with lived experience of Parkinson's) will lead to the co-design of first iteration of the UK version of ENGAGE-PD to be presented to participants in this research.

The aim of the present study is to investigate the feasibility and acceptability of version one of ENGAGE-PD to healthcare professionals to inform further design of an adapted UK version. Version one of the UK ENGAGE-PD intervention will include a participant workbook and an intervention therapist manual. These will be presented to NHS Parkinson's rehabilitation service providers including service leads, managers and therapists. Nominal Group Technique (NGT) meetings will be held to capture their stakeholder perspectives and inform a second iteration of the UK version. The meetings will be 90-120mins long with six to eight participants in each meeting. Separate meetings will be held at six to eight NHS provider organisation.

2 RATIONALE

PA promotion has characteristics specified by the Medical Research Council (MRC) of complex interventions, considering the components involved, behaviours targeted, expertise and skills required

in delivering and receiving the intervention, and level of intervention flexibility. For intervention research to be most useful to decision-makers, it needs to consider complexity arising from its interaction with the implementation context. (42)

Implementation research is proposed to promote the systematic uptake of research findings into routine practice to improve quality and effectiveness of health services and care. (43)(44) Implementation studies are proposed as a means of improving local delivery of Parkinson's rehabilitation, considering patient and clinician perspectives (37). Complex intervention research needs to go beyond asking whether an intervention works to ask questions such as:

How the intervention interacts with its context?

What is the underpinning programme theory?

How can diverse stakeholder perspectives be included in the research?

How the intervention can be refined? (42)

This study aims to develop a UK version of ENGAGE-PD to be used by physiotherapists in the context of NHS rehabilitation for people newly diagnosed with Parkinson's [within five years of diagnosis]. Diverse stakeholder perspectives will be taken into consideration in co-designing the intervention workbooks with the Project Advisory Group. This study will consult the views of NHS Parkinson's rehabilitation service leads, managers and physiotherapists.

Nominal Group Technique has the benefit of reducing the effects if power dynamics within a group. (45) It can also be completed in one 90-120min session – a key consideration for reducing participant burden and in the context of busy NHS provider services.

2.1 Assessment and management of risk

The study does not involve any intervention or patient interaction. The study is therefore categorised as Type A = No higher than the risk of standard medical care. The main risk to participants is the burden of time for preparation and participation in the Nominal Group Technique meetings. The study team have attempted to minimise this burden by ensuring that meetings will be no more than 2hours duration.

Immediate dissemination of results will be available to participants with the opportunity for further clarification/feedback within one week of meeting.

A data management plan and risk assessment has been completed (See accompanying documents) to safeguard the data collected in the trial and maintain anonymity of participants.

3 OBJECTIVES AND OUTCOME MEASURES/ENDPOINTS

The long-term aim is to undertake a multi-centre, assessor-blinded cluster RCT asking the research question "What is the feasibility, acceptability, and what are the outcomes of an adapted ENGAGE-PD physical activity coaching programme for individuals with newly diagnosed Parkinson's delivered by physiotherapists in NHS rehabilitation settings? Before the RCT, co-design of a UK version of ENGAGE-PD needs to be supported with the following objectives.

3.1 Primary objective

Explore the perspectives of six to eight UK NHS Parkinson's physiotherapy service providers on the relative importance of the contents of a version of the ENGAGE-PD physical activity coaching intervention for people with newly diagnosed Parkinson's. The study is summarised using the SPIDER framework:

S Sample: Six to eight UK NHS Parkinson's physiotherapy service providers with a minimum of three and a maximum of eight service leads, managers and therapists from each service provider contributing.

PI Phenomenon of Interest: Perspectives on a physical activity coaching intervention for people with newly diagnosed Parkinson's

D Design: Nominal Group Technique consensus method meetings (One meeting per service provider)

E Evaluation: Sharing ideas, group discussion, voting and ranking

R Research Type: Qualitative and survey-based research

3.2 Secondary objectives

Explore the perspectives of UK NHS Parkinson's physiotherapy rehabilitation providers on the feasibility and perceived fit in clinical practice of a version of the ENGAGE-PD physical activity coaching intervention for people with newly diagnosed Parkinson's.

Establish characteristics of usual care at each NHS provider organisation.

3.3 Outcome measures/endpoints

Importance of the items in version one of the UK version of ENGAGE-PD.

Feasibility: Perceived fit of the ENGAGE-PD intervention in the practice setting.

NHS provider organisation characteristics relating to usual care for PwP.

Endpoint: Following a nominal group meeting at each of six to eight NHS provider organisation.

3.4 Primary endpoint/outcome

Perceived importance of the items in version one of the UK version of ENGAGE-PD. Rating of importance on a 0-5 Likert scale by each participant taking part in a nominal group session (See Appendix 1 – session structure and questions)

Endpoint: Following six to eight nominal group meetings

3.5 Secondary endpoints/outcomes

Feasibility: Perceived fit of version one of the UK version of ENGAGE-PD intervention in the practice setting. Rating of feasibility of on a 0-5 Likert scale by each participant taking part in a nominal group session (See Appendix 1)

Endpoint: Following six to eight nominal group meetings

3.6 Exploratory endpoints/outcomes

Participant demographics including role, job banding, number of years' experience working in NHS services providing rehabilitation for PwP.

NHS provider organisation characteristics relating to usual care for PwP e.g.,

Organisation size

Size and demographics of population served

Parkinson's specialists (number and role)

Referral pathway to rehabilitation

Average waiting times for rehabilitation

Average duration of rehabilitation (per session, session number and period of rehabilitation).

(See Appendix 2. Pre-meeting Survey)

3.7 Table of endpoints/outcomes

Objectives	Outcome Measures	Timepoint(s) of evaluation of this outcome measure (if applicable)
Primary Objective Importance of the items in version one of the UK version of ENGAGE-PD.	Rating of importance on a 0-5 Likert scale by each participant taking part in a nominal group session	During nominal group meeting
Secondary Objectives Feasibility: Perceived fit of the ENGAGE-PD intervention in the practice setting.	Rating of feasibility on a 0-5 Likert scale by each participant taking part in a nominal group session	During nominal group meeting
Tertiary Objectives Participant demographics	Including: role, job banding, number of years' experience working in NHS services providing rehabilitation for PwP.	Pre-meeting participant questionnaire

NHS provider organisation characteristics relating to usual care for PwP.	Description of NHS provider organisation characteristics in terms of: Organisation size Size and demographics of population served Parkinson's specialists (number and role) Referral pathway to rehabilitation Average waiting times for rehabilitation Average duration of rehabilitation (per session, session number and period of rehabilitation) Typical components of a rehabilitation package Additional advice and education provided (e.g. by nurse specialists). Frequency of medical follow up in first 5 years post diagnosis.	From PIC Feasibility Questionnaire and PIC Initiation Visit prior to nominal group meeting

4 TRIAL DESIGN

The project involves gaining participant consensus on the most important and feasible aspects of a co-designed, UK version of ENGAGE-PD, from the perspectives of Parkinson's healthcare professionals, service leads/managers. This will be gained using Nominal Group Technique in virtual meetings at six to eight NHS provider organisations that provide rehabilitation for people newly diagnosed with Parkinson's. The CI will run these meetings supported by a second researcher from the core study team to support transcription and collating of meeting information.

These meetings will be conducted online using an adapted Nominal Group Technique template with collaborative software available via the University of Plymouth Microsoft 365© package (Also widely used within NHS provider organisations):

1. Idea Generation

Microsoft Forms to collect ideas anonymously or collaboratively.

2. Discussion

A password linked Microsoft Teams meeting with breakout rooms and use of Microsoft Whiteboard for visual discussion (the session will be recorded and the transcript function enabled to allow researchers to return to the raw data, if required, at a later stage).

3. Clarification & Grouping

Microsoft Whiteboard to group similar ideas.

4. Voting & Prioritization

Use Microsoft Forms for ranking or rating linked to Microsoft Excel to tally votes.

5. Final Decision

Present results via a Microsoft PowerPoint summary.

5 TRIAL SETTING

The trial will be conducted online via using Microsoft Teams teleconferencing software.

6 PARTICIPANT ELIGIBILITY CRITERIA

Rehabilitation services will be linked to Neurology and/or Healthcare of the Elderly Services that are able to identify participants within five years of Parkinson's diagnosis and provide NHS physiotherapy rehabilitation services for PwP.

6.1 Inclusion criteria

- Service leads with overall responsibility for NHS Parkinson's rehabilitation services/rehabilitation services that provide therapy for Parkinson's patients
- Managers with delegated responsibility for the day-to-day running of NHS Parkinson's rehabilitation services//rehabilitation services that provide therapy for Parkinson's patients

- Physiotherapists with experience of providing NHS Parkinson’s rehabilitation
- Parkinson’s Nurse Specialists/Parkinson’s Specialist Practitioners who provide a coordination role for multidisciplinary care of Parkinson’s patients at the NHS provider organisation.

6.2 Exclusion criteria

- Staff from services that do not provide, or do not work directly with services that provide Parkinson’s rehabilitation

7 TRIAL PROCEDURES

Trial Period				
	PIC Feasibility	PIC Enrolment	PIC Participation	Dissemination
Timepoint	-t to 0	0 to Month 1	Month 2	Month 3
PIC feasibility questionnaire sent (includes details on Parkinson's rehabilitation provided) e.g. - Organisation size - Size and demographics of population served - Parkinson's specialists (number and role) - Referral pathway to rehabilitation - Average waiting times for rehabilitation - Average duration of rehabilitation (per session, session number and period of rehabilitation) - Typical components of a rehabilitation package	X			
Participant Identification Centre (PIC) Agreement	X			
Confirmation of PIC Capacity and Capability	X			
Online PIC Initiation Visits including clarification of		X →		

usual care details from PIC feasibility questionnaire PICs sent version 1 of UK ENGAGE-PD participant and therapist workbooks for review and pre-meeting questionnaire				
Nominal Group Technique Meetings (x1 90-120min meeting at each PIC)			X →	→
Based on feedback version 2 of UK ENGAGE-PD workbooks co-designed with Project Advisory Group				X →
4 sites chosen to participate in Assessor-blind Cluster Randomised Controlled Trial testing the adapted intervention against usual care (2 sites intervention 2 sites usual care)				X

7.1 Recruitment

NHS provider organisation will be recruited via study team and/or NIHR Research Delivery Network (RDN) contacts. We will aim to have a range of NHS provider organisation from different regions of the UK and different demographic patient profiles e.g., patient ethnic diversity, size of population served, urban, rural, semi-rural, coastal locations.

7.1.1 Participant identification

Initial discussions with service leads, managers and Parkinson's Nurse Specialists at potential NHS provider organisation will help to identify the relevant clinicians who need to be involved in the NGT meetings. RDN support may also be required to facilitate this.

7.1.2 Screening

Potential NHS provider organisation will be screened in relation to the above inclusion/exclusion criteria by the CI with support from the supervisory team and Trial Management Group. RDN support may also be required to facilitate this. In this instance, PIC Feasibility Questionnaires will help provide the background information to the services to assist the above screening.

7.1.3 Payment

Costs are available to provide a £75 voucher for each contributor recognising an estimated 3hour commitment of time (including pre-reading and NGT meeting duration) commensurate with their typical hourly rate (based on NHS pay rates for a typical band 7 clinician).

There are also some minor Research Costs and Excess Treatment Costs accounted for in a Schedule of Events Costs Attributable Tool (SoECAT). These account for Research Delivery Network and service manager support in setting up the study and PIC Initiation Visits at

NHS provider organisations.

7.2 Consent

The CI will retain responsibility for the taking of informed consent for participants at each NHS provider organisation. The CI is fully trained and competent to participate in the informed consent process in accordance with the ethically approved protocol, principles of Good Clinical Practice (GCP) and Declaration of Helsinki.

Informed consent will be obtained prior to the NGT processes of the trial. The right of participants to refuse participation without giving reasons will be respected. An ethically approved Participation Information Sheet (See supporting documents – Participant Information Sheet v1) will be provided prior to the formal consent process to allow consideration of participation in the trial and provide an

opportunity for potential participants to ask questions about the trial both before and during the consent process.

Collection of identifiable participant data will be completed in accordance with the ethically approved protocol and data management plan (See supporting documents – Data Management Plan DMP Online v1)

7.3 Baseline data

Participant demographics including role, job banding, number of years' experience working in NHS services providing rehabilitation for PwP. This will help to establish if the NGT meetings at each NHS provider organisation have similar baseline characteristics.

In addition to NGT outcomes, PIC Feasibility Questionnaires, and PIC Initiation Visits will also inform NHS provider organisation characteristics relating to usual care for PwP e.g.,

Organisation size

Size and demographics of population served

Parkinson’s specialists (number and role)

Referral pathway to rehabilitation

Average waiting times for rehabilitation

Average duration of rehabilitation (per session, session number and period of rehabilitation).

7.4 Trial assessments

This is not a clinical trial so no clinical assessments will be taking place.

A pre-meeting questionnaire will be sent including participant demographic details and details relating to the physiotherapy service provision for people with Parkinson’s at their NHS provider organisation (See Appendix 2) Participant demographic details will be recorded including:

Role

Job banding,

Number of years' experience working in NHS services providing rehabilitation for PwP.

During the maximum 2-hour NGT meeting, participants will be using a 5-point Likert scale to score their views on relative importance and feasibility of version one of the UK version of ENGAGE-PD. They will have a randomly generated participant code so that their contributions are kept anonymous.

7.5. Qualitative assessments

Meetings will be transcribed with a second researcher from the core study team supporting transcription and collating of meeting information. These notes will help to identify key themes from the NGT process, but no formal qualitative methodology will be applied. Combined with information from the NGT outcomes, this will support the understanding of key considerations for the potential introduction of a complex intervention i.e.,

How might the intervention interact with its context?

How can diverse stakeholder perspectives be included in the research?

Also, if there are any NHS provider organisation specific adaptations to a UK version of ENGAGE-PD e.g., translation of resources:

7.6 Withdrawal criteria

Participants will be free to withdraw at any part of this process without giving reason. If they are willing to give a reason, then it will be recorded and documented. Participants who drop out before the NGT meeting will only be replaced if the number of participants at the NGT meeting is likely to be below N=5.

7.7 End of trial

The study will end after data collection at the NGT meetings has been analysed and presented back to the participants.

8. STATISTICS AND DATA ANALYSIS

8.1 Statistical analysis plan

8.1.1 Summary of baseline data and participants

NHS provider organisation and participant characteristics will be presented descriptively.

8.1.2 Primary and secondary outcome analysis

Each feature of version one of the UK version of ENGAGE-PD will be scored 1-5 for relative importance and relative feasibility. The median score and deviation from the median score will be calculated from each statement. (46)

The absolute mean deviation from the median will be calculated at the voting and ranking stage to measure overall level of consensus. 0.42 high , 0.42-0.81 moderate and over 0.81 low consensus. (47) This will also be calculated for level of consensus between NHS provider organisation.

Relative scores for importance and feasibility, levels of consensus, and qualitative feedback will influence the development of a second UK version of ENGAGE-PD co-designed with the Project Advisory Group.

9 DATA MANAGEMENT

Data management activities are summarised in this section. Detailed data management activities are described in a separate Data Management Plan (DMP).

9.1 Data collection tools and source document identification

Source Data

Pre-meeting survey data will be collected via the JISC online survey tool. The Nominal Group Technique meetings will be conducted online using an adapted Nominal Group Technique template with collaborative software available via the University of Plymouth Microsoft 365 package (Also widely used within NHS provider organisations):

1. Idea Generation

Microsoft Forms to collect ideas anonymously.

2. Discussion

A password linked Microsoft Teams meeting with breakout rooms and use of Microsoft Whiteboard for visual discussion (the session will be recorded and the transcript function enabled to allow researchers to return to the raw data, if required, at a later stage).

3. Clarification & Grouping

Microsoft Whiteboard to group similar ideas.

4. Voting & Prioritization

Use Microsoft Forms for ranking or rating linked to Microsoft Excel to tally votes (Participants will have a randomly generated participant code so that their contributions in this stage are kept anonymous).

5. Final Decision

Present results via a Microsoft PowerPoint summary.

The meeting will be recorded to allow clarification of any points raised. Meeting notes, taken by a study supervisory team member, along with meeting chat, digital whiteboard notes and Microsoft Forms responses and linked Microsoft Excel documents will be stored on a secure University of Plymouth Sharepoint site for the duration of the study.

Source Documents

All information recorded in the study will be kept and stored securely.

All documentation for the study will conform to the following standards:

Accurate

Legible

Contemporaneous

Original

Attributable

Complete

Consistent

Enduring

Available when needed

Supervisory team notes - these will be signed, dated, scanned and uploaded to the secure University of Plymouth Sharepoint site.

9.2 Data handling and record keeping

See Data Management Plan (Supporting information DMP Online v1).

9.3 Access to Data

Direct access will be granted to authorised representatives from the Sponsor, host institution and the regulatory authorities to permit trial-related monitoring, audits and inspections- in line with participant consent.

9.4 Archiving

Data will be securely stored for ten years after the completion of the trial. J. Gilby will be responsible for archiving all trial data. Archiving will be authorised by the Sponsor following submission of the end of study report. No paper-based data will be generated from the study and the electronic data from this project will then be stored on SharePoint for 10 years at the University of Plymouth according to their information governance policies.

10 MONITORING, AUDIT & INSPECTION

A trial monitoring plan will be developed and agreed by the Trial Management Group (TMG) and Trial Steering Committee (TSC). The TMG will meet monthly. The TSC will meet three times over the duration of the project, with the first meeting taking place prior to the start of study recruitment.

The TSC will include member's independent from the trial and include an independent chair and statistician (see above for details).

11 ETHICAL AND REGULATORY CONSIDERATIONS

11.1 Research Ethics Committee (REC) review & reports

The trial will not be initiated before the protocol, informed consent forms, participant information sheets and other relevant documents have received approval from the University Faculty Research Ethics Committee (REC) and the Health Research Authority (HRA). The Investigator will ensure that this study is conducted in full conformity with relevant regulations and with the UK Policy Framework for Health and Social Care Research (2025) , which have their basis in the Declaration of Helsinki

Substantial amendments that require review by REC will not be implemented until the REC and HRA grants a favourable opinion for the trial (Amendments may also need to be reviewed and accepted by the NHS R&D departments before they can be implemented in practice at Participant Identification Centres)

All correspondence with the REC and HRA will be retained in the Trial Master File/Investigator Site File

The Chief Investigator will notify the REC and HRA of the end of the trial.

If the trial is ended prematurely, the Chief Investigator will notify the REC and HRA, including the reasons for the premature termination

Within one year after the end of the trial, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

11.1 Peer review

This study was funded by the NIHR Doctoral Clinical Academic Fellowship scheme (NIHR 305241)

through submission and review of the proposed study undergoing 2 rounds of review prior to awarding of funding.

11.2 Public and Patient Involvement

Patient and Public Involvement (PPI) input has been provided by lay members in the development of this study proposal and submission to the NIHR.

A PAG of four members with lived experience of Parkinson's, in addition to two PwP on the TSC, have been involved in the development and review of this protocol and materials used in the study. The PAG will have been involved in the co-design of version one of the UK version of ENGAGE-PD. The feedback from healthcare professionals will also inform co-design with the PAG of version two of the UK version of ENGAGE-PD.

11.3 Regulatory Compliance

The trial will not commence until a favourable REC opinion and HRA approval has been obtained.

Before any NHS provider organisation can enrol participants into the study, the CI will ensure that appropriate

approvals from participating organisations are in place.

For any amendment to the study, the CI, in agreement with the sponsor, will submit information to the

appropriate body for them to issue approval for the amendment. The CI will work with R&D

departments at NHS provider organisations so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

11.4 Protocol compliance

Planned protocol deviations, non-compliances, or breaches which are departures from the approved protocol are not allowed under the UK regulations on Clinical Trials and will not be used e.g. subjects will only be enrolled if they meet the eligibility criteria.

Accidental protocol deviations will be documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately.

11.5 Notification of Serious Breaches to GCP and/or the protocol

A “serious breach” is a breach which is likely to effect to a significant degree –

the safety or physical or mental integrity of the participants of the trial; or

the scientific value of the trial

The sponsor will be notified immediately of any case where the above definition applies during the trial conduct phase. The sponsor of a clinical trial will notify the licensing authority in writing of any serious breach of the conditions and principles of GCP in connection with that trial; or

the protocol relating to that trial, as amended from time to time, within 7 days of becoming aware of that breach

11.6 Data protection and patient confidentiality

All investigators and NHS provider organisation staff will comply with the requirements of the General Data Protection Regulations (2018) with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles.

- The participant's identifying information will be coded using an unrelated sequence of characters for all data analysis.
- The participant's personal data and the linking code will be stored in separate locations using encrypted digital files within password protected folders. This will be stored for the duration of the study to allow contact with the participants (e.g. to clarify missing data and/or send study summaries). After this personal data will be destroyed.
- The number of individuals necessary for quality control, audit, and analysis will be kept to a minimum.
- The confidentiality of data will be preserved when the data are transmitted to sponsors and co-investigators
- Jonathan Gilby is the data custodian for the duration of the study. Once the study is completed the CI (Gilby) is responsible for the long-term storage of data in collaboration with University of Plymouth regulations.

11.7 Financial and other competing interests for the chief investigator, PIs at each site and committee members for the overall trial management

There are no financial or competing interests for the CI or study team and no requirements for PIs at each NHS provider organisation.

11.8 Indemnity

University of Plymouth indemnity scheme will meet the potential legal liability of the sponsor(s):

· For harm to participants arising from the management of the research

· For harm to participants arising from the design of the research

· Arising from harm to participants in the conduct of the research

This is a University of Plymouth research study. If an individual suffers negligent harm as a result of participating in the study, the University of Plymouth indemnity scheme covers University employees.

The University has in force a Public Liability Policy and the activities here are included within that coverage. https://www.plymouth.ac.uk/about-us/universitystructure/service-areas/procurement/insurance-certificates

11.9 Amendments

The sponsor may make a non-substantial amendment at any time during a trial. If the sponsor wishes to make a substantial amendment to the REC application or the supporting documents, the sponsor must submit a valid notice of amendment to the REC for consideration. It is the sponsor’s responsibility to decide whether an amendment is substantial or non-substantial for the purposes of submission to the REC.

Amended documents will be allocated a new sequential version number. Once approved by REC, this version will supersede any previous versions.

11.10 Post trial care

This study does not involve treatment.

11.11 Access to the final trial dataset

Data generated from this trial will be available for inspection on request by the study team, University of Plymouth representatives, the REC, local R&D Departments and regulatory authorities.

12 DISSEMINATION POLICY

12.1 Dissemination policy

- The data arising from the trial will be owned by the University of Plymouth research team
- On completion of the trial, the data will be analysed and tabulated and a Final Trial Report prepared
- Study findings will be published in peer reviewed academic journals and presented at National and International conferences.
- NIHR funding will be acknowledged within the publications
- Participants will be notified of the outcome of the trial, either by provision of the publication, or via social media, as relevant to the participant.
- If a participant specifically requests results from the CI this information would be provided after the results had been published
- It is hoped that the anonymised participant level data set will be made available 1 year after the end of the trial via the Rehabilitation Research Group (University of Plymouth) website.

12.2 Authorship eligibility guidelines and any intended use of professional writers

- The CI and trial management group will have authorship on the final trial report

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14. APPENDICES

14.1 Appendix 1- Nominal Group Technique Structure and Questions

1. **What are the core aspects of physiotherapy usual care for people with Parkinson's that are referred to your service?**

   Take forward to:
   Ideas shared
   Group discussion
   Voting and Ranking

2. **With Question 1 in mind, is there anything missing from version 1 of the ENGAGE PD Participant Workbook?**

   Take forward to:
   Ideas shared
   Group discussion
   Voting and Ranking

3. **Are there any local contextual factors that would help/hinder providing the ENGAGE-PD intervention e.g., time available for appointments/clinic space/language considerations?**
   Take forward to:
   Ideas shared
   Group discussion
   Voting and Ranking

Further Voting and Ranking items:
(*Sections and titles to be confirmed after co-design stage 1)

1. PATIENT/PARTICIPANT WORKBOOK					
Section	**Please rate the sections of version 1 of the ENGAGE-PD workbook for Importance and Feasibility.**				
Introduction	**Relatively Unimportant**				**Very Important**
	1	**2**	**3**	**4**	**5**
	Relatively Unfeasible			**Very Feasible**	
	1	**2**	**3**	**4**	**5**
	Comments:				
Mover Profile*	**Relatively Unimportant**				**Very Important**
	1	**2**	**3**	**4**	**5**
	Relatively Unfeasible				**Very Feasible**
	1	**2**	**3**	**4**	**5**
	Comments:				
Physical Activity Pyramid*	**Relatively Unimportant**				**Very Important**
	1	**2**	**3**	**4**	**5**
	Relatively Unfeasible				**Very Feasible**
	1	**2**	**3**	**4**	**5**
	Comments:				
Exploring Different Exercise	**Relatively Unimportant**				**Very Important**
	1	**2**	**3**	**4**	**5**

Ideas*	Relatively Unfeasible				Very Feasible
	1	2	3	4	5
	Comments:				
Tracking*	Relatively Unimportant				Very Important
	1	2	3	4	5
	Relatively Unfeasible				Very Feasible
	1	2	3	4	5
	Comments:				
Planning*	Relatively Unimportant				Very Important
	1	2	3	4	5
	Relatively Unfeasible				Very Feasible
	1	2	3	4	5
	Comments:				
Goal Setting*	Relatively Unimportant				Very Important
	1	2	3	4	5
	1	2	3	4	5
	Comments:				
Resources*	Relatively Unimportant				
	1	2	3	4	5

	Relatively Unfeasible Very Feasible				
	1	**2**	**3**	**4**	**5**
	Comments:				
Overall Impression of Workbook	**Relatively Unimportant Very Important**				
	1	**2**	**3**	**4**	**5**
	Relatively Unfeasible Very Feasible				
	1	**2**	**3**	**4**	**5**
	Comments:				
2. THERAPIST MANUAL					
Section	**Please rate the sections of version 1 of the ENGAGE-PD therapist manual for Importance and Feasibility.**				
Introduction	**Relatively Unimportant Very Important**				
	1	**2**	**3**	**4**	**5**
	Relatively Unfeasible Very Feasible				
	1	**2**	**3**	**4**	**5**
	Comments:				
Purpose of Manual*	**Relatively Unimportant Very Important**				
	1	**2**	**3**	**4**	**5**
	Relatively Unfeasible Very Feasible				
	1	**2**	**3**	**4**	**5**

	Comments:				
Program Overview*	Relatively Unimportant				Very Important
	1	2	3	4	5
	Relatively Unfeasible				Very Feasible
	1	2	3	4	5
	Comments:				
Theoretical Framework*	Relatively Unimportant				Very Important
	1	2	3	4	5
	Relatively Unfeasible				Very Feasible
	1	2	3	4	5
	Comments:				
Session Planning*	Relatively Unimportant				Very Important
	1	2	3	4	5
	Relatively Unfeasible				Very Feasible
	1	2	3	4	5
	Comments:				
FAQs*	Relatively Unimportant				Very Important
	1	2	3	4	5
	Relatively Unfeasible				Very Feasible
	1	2	3	4	5

	Comments:				
Resources	**Relatively Unimportant**				**Very Important**
	1	**2**	**3**	**4**	**5**
	1	**2**	**3**	**4**	**5**
	Comments:				
Overall Impression of Version 1 of Therapist Manual	**Relatively Unimportant**				**Very Important**
	1	**2**	**3**	**4**	**5**
	Relatively Unfeasible				**Very Feasible**
	1	**2**	**3**	**4**	**5**
	Comments:				

14.2 Appendix 2 – Pre-Nominal Group Technique Survey

Adapting ENGAGE-PD Pre-meeting survey.

Participant Identification Number:

IRAS study number:

Study Title: **Adapting ENGAGE-PD: Adapting the ENGAGE-PD physical activity coaching intervention for individuals newly diagnosed with Parkinson's to be delivered by physiotherapists in NHS rehabilitation settings: perspectives of healthcare professionals using the Nominal Group Technique consensus method.**

Please read the Participant Information Sheet and sign the consent form before taking part in this survey.

This survey will take about 10 minutes to complete. Your responses will be anonymous and will be collated with those from other participants in advance of the Nominal Group Technique consensus meeting.

About you

1. What is your job role?

2. **If** you are a physiotherapist would you describe yourself as a Parkinson's Specialist Physiotherapist? If you are not a physiotherapist, please go on to answer questions 3-12.

   Yes
   No
   Not sure

3. How many years' experience do you have providing or coordinating the provision of rehabilitation for people with Parkinson's?

About your service

4. What is the typical referral source for Parkinson's patients requiring physiotherapy?

   Elderly Care Consultant
   Neurologist
   GP
   Parkinson' s Specialist
   Allied Health Professional Colleague
   Social Care Worker
   Self-referral/relative
   Unable to say
   Other (please specify)

5. Are you able to indicate the typical referral to treatment time (in weeks) for people with Parkinson's to receive physiotherapy rehabilitation (If so, please state below)?

6. Are you able to indicate the typical length (in minutes) of physiotherapy sessions (If so, please state below)?

7. Are you able to indicate the typical number of physiotherapy sessions in an episode of care (If so, please state below)?

8. What would the format and location be (Tick all that apply)?

   Face to Face - Hospital

   Face to Face - Community Setting (excluding patient home)

Face to Face – Patient home

Telehealth

Hybrid

1:1

Group

9. Would physical activity/exercise advice be typically offered to Parkinson's patients within their physiotherapy appointments

   Yes

   No (Please go on to question 12)

   Unable to say (Please go on to question 12)

10. Would any recognised behaviour change approaches be used to support the patient with physical activity/exercise engagement?

    Yes

    No (Please go on to question 12)

    Unable to say (Please go on to question 12)

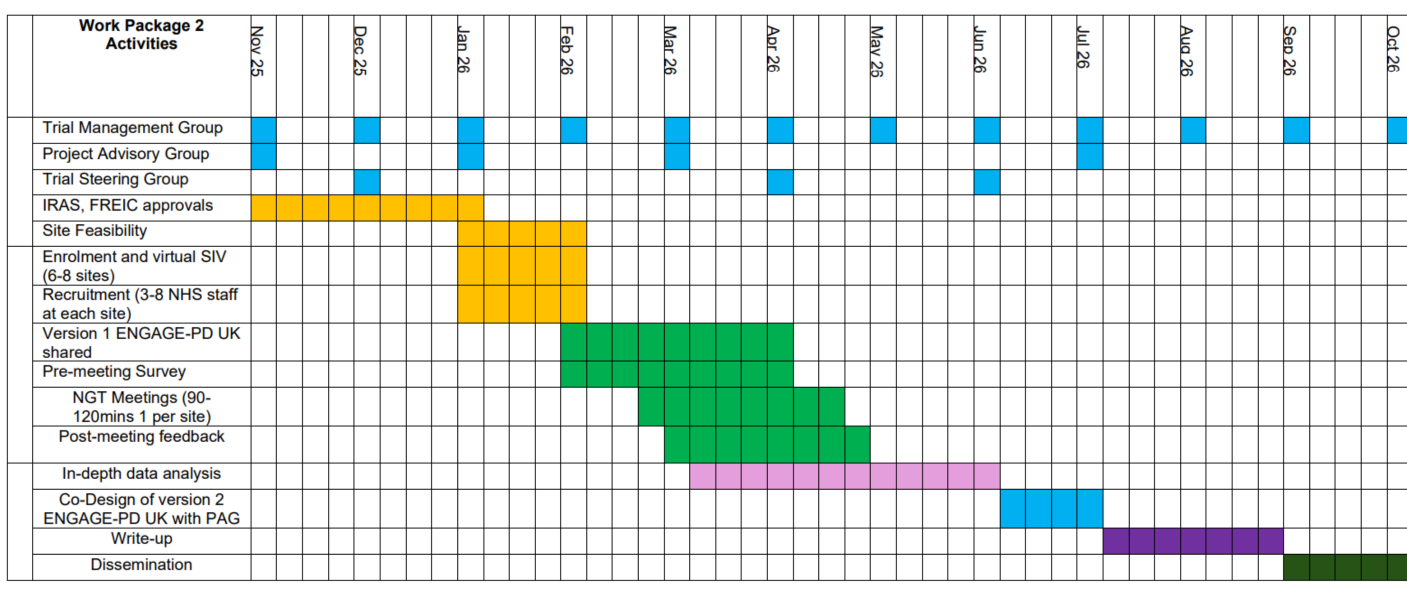
11. Which behaviour change approach(es) would you typically use?

12. What method would you use for setting goals with the patient (please indicate all that apply)?

    COPM
    GAS
    SMART
    Other
    None
    Unable to say

13. Do you have any additional comments or suggestions about usual physiotherapy care for people with Parkinson's?

14.3 Appendix 3 – Project Gantt



14.4 Appendix 4 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made